MICROBIOLOGY OF THERMALLY PROCESSED COMMERCIALLY STERILE AND SHELF-STABLE MEAT AND POULTRY PRODUCTS

To understand the microbiology of thermally processed commercially sterile and shelf-stable meat and poultry products you must first be familiar with the microbiology of meat and poultry, as well as some basics of processed food microbiology in general. In this section you will learn about microorganisms of significance in thermally processed commercially sterile and shelf-stable products, the sources of these microorganisms, the conditions affecting their growth and inactivation, and the specific microbiology of acidified and low-acid “canned” (commercially sterile) foods. You will learn more about the specific microbiology of other shelf-stable meat and poultry products such as dry and acidified/fermented products in the section on the Microbiology of Shelf-Stable Dried Meats.

The objectives of this section are for you to be able to:

1. Recognize pathogens of concern for thermally processed commercially sterile and shelf-stable products and distinguish them from spoilage organisms.
2. Identify conditions affecting microbial growth and related control methods.
3. Identify causes of canned food spoilage.

Introduction to the Microbiology of Food Processing

All raw foods normally contain microorganisms that will eventually cause spoilage unless they are controlled or destroyed. Food preservation is a competition between the human species and microorganisms – we attempt to preserve the food, the microorganisms attempt to destroy it (by breaking down the food for its own consumption) in order to survive. Many of the thousands of microorganisms that have been discovered and identified perform some useful function. Without microorganisms, we would not have some of the tasty foods we enjoy, such as breads, cheese, wine, beer, sauerkraut and other fermented foods, including many sausages. Vanilla, olives, tea and chocolate are other products that include a microbial fermentation step. In addition, these microorganisms are needed to make products useful to industry and medicine, such as enzymes, antibiotics, glycerol and other alcohols. Still other types of microorganisms have the ability to break down organic matter and return it to the earth in a recycling process to form food for plants, which in turn provide food for animals. Without such microorganisms, the earth would accumulate dead animals, leaves and other non-decayed matter – all of which would have eliminated life on earth long ago.

However, it is also true that most diseases of humans, animals or plants are caused by specific microorganisms. The microorganisms that can cause illness are known as pathogens. The pathogen, or the substances it produces, must invade the human, animal or plant body to cause illness. Fortunately, comparatively few of the tens of thousands of known microorganisms are harmful to humans. While many diseases can be transmitted from person to person or from animals to humans, only a few can be transmitted through foods. Although it is becoming recognized that the vast majority of cases of food borne illnesses are caused by viruses such as hepatitis A and noroviruses (67% of all cases of food borne illness, according to one analysis), bacterial agents, such as *Salmonella* and *Campylobacter,* are most frequently identified as the cause of illness because we have a much greater understanding of how to isolate and identify them.

Significant Microorganisms in Food Processing

There are many different ways to classify and group microorganisms, including groupings based on microscopic appearance, the materials they can use as foods, the byproducts resulting from the breakdown of these foods, their tolerance to oxygen, their growth temperatures, and their resistance to such destructive agents as heat and chemicals. The microorganisms of primary concern to the food processor are generally molds, yeasts and bacteria, because they can grow in the food and cause spoilage. Processors are also concerned about viruses and parasites in foods, although they are not capable of growing in the food and do not cause spoilage. Bacteria, viruses and parasites are of particular concern because a number of them cause illness. A brief review of the significant groups of microorganisms in food processing follows.

►Molds

Molds exhibit some of the characteristics of the higher plants. They are multiple cell organisms forming tubular filaments. Molds demonstrate branching and reproduce by means of fruiting bodies, called spores, which are borne in or on aerial structures. Their mycelia, or intertwined filaments, may resemble roots. They are many times larger than bacteria and somewhat longer than yeasts.

Molds are widely distributed in nature, both in the soil and in the dust carried by air. Under suitable conditions of moisture, air and temperature, molds will grow on almost any food. The black or green discoloration that appears on moldy bread is familiar evidence of such growth. Molds are also able to survive on a wide variety of substances not normally thought suitable for the support of life. These include concentrated solutions of some acids and water containing minute quantities of certain salts, as well as on building structures. Molds grow readily on the walls and ceilings of buildings where there is high humidity and considerable moisture condensation. Mold growth can even occur in refrigerators, because molds are much more tolerant to cold than to heat. Molds can grow at reduced water activities (a_w) and can be a problem in improperly processed dry and semi-dry fermented products, as discussed later.

Molds are capable of consuming acids, thereby raising the pH of products. Their growth in foods has, on very rare occasions (and never in meat or poultry products), removed the acid conditions that inhibit growth of *Clostridium botulinum,* a food borne pathogen discussed later in this section.

Most molds have little heat resistance and cannot survive the thermal processes for low-acid canned foods. Some molds produce a type of spore (ascospore) that is more resistant to heat, but these spores are much less resistant than the spores that are the target of processes for low-acid and acidified canned foods; these heat-resistant molds have not caused problems in meat and poultry products. Therefore, molds are present in canned meat and poultry products only as a result of gross under-processing or as a post-processing contaminant. Since molds must have oxygen to grow, only slight growth can occur unless the food container has an opening to the outside environment.

Mold growth in thermally processed commercially sterile and shelf-stable foods has to date not been shown to present a public health problem. In fact, mold is used in the ripening process of some sausages, as will be discussed in other sections.

►Yeasts

Another microorganism of importance to food preservation/spoilage is yeast. Yeasts are single cell, microscopic living bodies, usually egg-shaped. They are smaller than molds, but larger than bacteria. Their greatest thickness is about 1/2,000 of an inch. Yeasts reproduce mainly by budding. A small bud forms on the parent yeast cell and gradually enlarges and breaks off into another yeast cell. A few varieties reproduce by forming spores within a special cell; later these spores may form new yeast cells.

Yeasts are widely found in nature and are particularly associated with liquid foods containing sugars and acids. They are quite adaptive to adverse conditions such as acidity and dehydration. Like molds, yeasts are more tolerant to cold than to heat. Compared to bacterial spores, yeasts and their spores possess little resistance to heat. Most yeast forms are destroyed on heating to 170ºF (77ºC). Spoilage may result from the presence of yeast in canned food, but if this happens, gross under-processing or leakage must be suspected. Usually the growth of yeasts results in the production of alcohol and large amounts of carbon dioxide gas, which swells the container.

Yeast growth in processed foods does not present a public health problem.

►Viruses

Virus particles are so small they cannot be seen by the standard light microscopes used in laboratories – a special electron microscope is needed to see these microorganisms. A virus particle is composed of either RNA or DNA enclosed in a coat of protein, sometimes with an outer envelope containing lipids (fats). (Deoxyribonucleic acid (DNA) is a nucleic acid which carries genetic instructions for the biological development of all cellular forms of life and many viruses. Ribonucleic acid (RNA) transmits genetic information from DNA to proteins, and carries the genetic instructions for many viruses.) Viruses lack the enzymes and other components needed to replicate. Thus, viruses cannot multiply in food – they can only replicate themselves in suitable living host cells. Viruses transmitted by food are produced in the human body and shed in the feces. Of particular concern for foods are the hepatitis viruses and noroviruses. These latter viruses have been mentioned in many news stories in recent years for causing large outbreaks of vomiting illnesses at large gatherings and on cruise ships. Viruses get into food through contaminated water and infected food handlers with poor hygienic practices.

Viruses are not heat resistant, with most having resistance similar to non-spore forming bacteria (see below). Hepatitis A virus is somewhat more resistant, but is still inactivated at 185°F (85°C). Avian influenza virus, which can infect chickens, turkeys, pheasants, quail, ducks, geese, and guinea fowl, as well as a wide variety of other birds, has been known to infect humans, but it is not transmitted through foods, nor is exotic Newcastle disease virus, which also causes a highly contagious poultry disease. Heating to at least to 161.6°F (72°C) internal temperature is considered adequate to inactivate both these viruses.

The Human Immunodeficiency Virus (HIV) which causes the disease AIDS (Acquired Immune Deficiency Syndrome) is a severe public health problem. AIDS has never been shown to be transmitted by food or drink. Individuals who are known to be infected with the virus can handle food safely if they observe basic sanitation precautions for food handling and take care to avoid injury when preparing food. As with any food handler, should an injury occur, food contaminated with blood should be discarded for aesthetic as well as safety reasons. Employees should be restricted from handling food if they have evidence of infection or illness that would otherwise require that they not handle food.

Viruses are not a concern in thermally processed commercially sterile and shelf-stable meat and poultry products.

►Parasites

The parasites of concern in the production of meat and poultry products include worms and protozoa. Some of them are large enough to be seen with the naked eye, whereas others are microscopic. Parasites cannot multiply in food, only in a host cell, and they are not heat resistant.

Parasitic worms of public health importance are the beef and pork tapeworms (*Taenia saginata* and *Taenia solium*, respectively) and the roundworm that causes trichinosis (*Trichinella spiralis*, also referred to as trichinae) found in pork.

These small cysticerci (refered to as *Cysticercus cellulosae*) are approximately 6-18mm wide by 4 - 6mm in length when found in the muscles or subcutaneous tissues (the normal sites for the larvae of this parasite). The cysticerci may however be found in other tissues, such as those of the central nervous system, where they may grow much larger up to several cm in diameter.

Muscle and organs of animals with severe tapeworm infection are usually visually detected by government inspection personnel or by plant employees through evidence of the immature stages (larval stage in a cyst known as a cysticercus) of tapeworms, which are 6- 18 mm wide by 4 – 6 mm in length when found in the muscles. Such product cannot be further processed for human consumption. When the cysts are less severe or evident, infected meat may enter the human food chain, however illness will not occur if meat is properly cooked. Humans consuming undercooked meat infected with these tapeworms become ill with taeniasis generally after the mature stages of the tapeworms, which develop from the cysticercus, invade the intestinal tract. Most cases of infection with adult worms are without symptoms. Some persons may experience abdominal pain, weight loss, digestive disturbances, and possible intestinal obstruction. Taeniasis may last many years without medical treatment. However, people can get a more serious illness called cysticercosis by consuming food or water contaminated with the eggs of *T. solium* (pork tapeworm). Worm eggs hatch and the larvae then migrate to various parts of the body and form cysts (cysticerci). This can be a serious or fatal disease if it involves organs such as the central nervous system, heart, or eyes. Symptoms may vary depending on the organ or organ system involved. For example, an individual with cysticercocis involving the central nervous system (neurocysticercosis) may exhibit neurological symptoms such as psychiatric problems or epileptic seizures. Death is common.

Trichinella spiralis is an intestinal worm that produces larvae that migrate to and encyst in muscles of a number of animals, particularly swine. Humans consuming infected pork that is undercooked get ill from the cysts, which then live in the muscles of the human hosts. The first symptoms are nausea, diarrhea, vomiting, fever, and abdominal pain, followed by headaches, eye swelling, aching joints and muscles, weakness, and itchy skin. In severe infections, persons may experience difficulty with coordination and have heart and breathing problems. Death may occur in severe cases.

Parasitic protozoa of concern in meat processing include *Cryptosporidium parvum* and *Toxoplasma gondii*. *Cryptosporidium* is typically transmitted to humans from fecal material of animals, primarily cattle, via contaminated water or occasionally, food. The organism is destroyed by boiling water. *Toxoplasma gondii* is carried by cats but can infect many warm-blooded animals. A form known as the oocyst is shed and can sporulate and survive in soil and other environments for extended times; the sporulated oocyst is infectious to all warm-blooded hosts. When ingested, the sporulated oocysts go through several forms, eventually forming cysts in tissue such as muscle. These cysts are infective if ingested. *Toxoplasma* can cross the placenta and affect the fetus, resulting in blindness and more serious effects in the brain.

Parasites are readily destroyed at cooking temperature and are not a major concern in thermally processed commercially sterile meat and poultry products since they are subjected to temperatures well in excess of what is needed to destroy parasites. Parasites are a concern with respect to shelf-stable products that are not cooked. For example, trichinae are a concern with respect to shelf-stable products, such as dried sausages, containing pork. We'll discuss this further in the module for the microbiology of shelf-stable dried meats.

►Bacteria

Bacteria are the most important and troublesome of all the microorganisms for the food processor. Bacteria are single-celled living bodies so small that individually they can be seen only with the aid of a microscope. They are among the smallest living creatures known. The cells of bacteria vary in length from 1/25,000 to 1/1,000 of an inch. The number of these tiny microorganisms that could be placed on the head of a pin would equal the population of New York City! Viewed with a microscope, bacteria appear in several shapes or forms, but are primarily either round in shape (called "cocci") or rod-shaped (called "rods").

Reproduction of bacterial cells

Bacteria reproduce by division, which microbiologists call fission. When a bacterial cell is ready to divide, the cell material gradually increases until its volume is almost doubled. The cocci shapes become oval while rod shapes stretch to nearly twice their length. The cell then constricts in the middle. This constriction deepens until the cell contents are held in two distinct compartments separated by a wall. These two compartments finally separate to form two new cells, which are duplicates of the former cell and each other. Since the reproduction of bacteria increases the numbers, it is often referred to as “growth.”

Experiments conducted to determine the growth rate of bacteria under favorable conditions have found that each cell divides, on the average, about every 20 or 30 minutes. At this rate of cell division, each single cell will produce four cells at the end of the first hour. At the end of two hours, each cell will have produced 16 new cells. After 15 hours, each parent cell will have produced 1,000,000,000 (one billion) cells identical to the original. For example, if there were 75,000 bacteria per square inch on a conveyor belt, by the end of one hour there could be 300,000 bacteria per square inch of that belt. At the end of a three-hour shift, the bacteria count per square inch of belt surface could be 4,800,000.

Bacterial growth becomes limited without a constant supply of available fresh food. Also, large numbers of bacteria result in an accumulation of substances that are byproducts of bacterial growth and that also inhibit growth. With cessation of growth due to pollution of their environment, the cells may die. However, if the microorganism is a type that forms resistant but dormant spores, these cells can remain alive under conditions that kill other cells.

Sporeforming and non-sporeforming bacteria

Bacteria can be divided into two groups based on their ability or inability to form spores. Practically all of the round-shaped bacteria (cocci) and many of the rod-shaped bacteria cannot form spores; thus they are classified as non-sporeformers. However, a number of the rod-shaped bacteria have the ability to produce a spore within the cell (endospore). Spores are a dormant stage in the normal growth cycle of these organisms. They have the ability to survive a wide range of unfavorable conditions. The primary function of most spores is to ensure the survival of the organism through periods of environmental stress. Spores have been compared to plant seeds because they will germinate and grow when conditions are suitable. The major sporeforming bacteria are species of *Clostridium* and *Bacillus*. Cells of non-sporeformers and the cells of sporeformers that have not formed spores are referred to as “vegetative cells.” These cells generally have little resistance to heat, drying and other unfavorable conditions.

When formed in yeasts and molds, spores represent reproductive bodies, but bacterial spores are a resting stage in the growth cycle of these organisms. When a bacterial spore germinates, it is simply the same organism continuing its growth process.

Resistance of spores to the environment

In general, bacterial spores are extremely resistant to heat, cold and chemical agents. Some bacterial spores can survive in boiling water – 212ºF (100ºC) – for more than 16 hours. The same organisms in the vegetative state and the non-sporeforming bacteria will not survive heating in boiling water.

As a general rule, spores that successfully resist heat are also highly resistant to destruction by chemicals. There are bacterial spores that can survive more than three hours in sanitizing solutions normally used in a food processing plant. On the other hand, vegetative cells (non-sporeforming bacteria and the vegetative cell form of sporeformers) are readily destroyed by these sanitizing agents. The purpose of sanitizing is not to sterilize surfaces (to remove all bacteria), so the survival of spores under appropriate sanitation practices is not a concern – they will be present in low numbers and will be inactivated or controlled in the final product.

Bacterial hazards of concern in meat and poultry

Of the microbiological hazards of concern in meat and poultry, the most important are bacteria. Illness from meat and poultry is primarily caused by bacterial pathogens. The pathogens that are most likely to be found in livestock (cattle, sheep, and swine) and poultry (chicken and turkey) include *Salmonella*, *Campylobacter*, and *Listeria monocytogenes*. *Listeria monocytogenes* also is widespread in the environment. *Escherichia coli* is also found in livestock and poultry, but most strains are not pathogenic; the pathogenic *E. coli* of primary concern is known as *E. coli* O157:H7 and is found in beef. (Although the organism has occasionally been found in chickens and pigs, it has not been known to cause illness from those animals.) *Yersinia enterocolitica* is a pathogen most commonly associated with pork; only certain serotypes (strains) are pathogenic. *Clostridium perfringens* can also be found in meat and poultry; the spores may survive cooking and grow to high numbers in foods due to temperature abuse. *Clostridium botulinum* is rare in meats. When present, it is there in very low numbers (estimates are 0.1 spore to 7 spores per kg meat). *Bacillus cereus* is another sporeformer of concern in meat and poultry products, especially those containing spices, which is a common source of the spores.

All of these pathogens have been implicated in food borne disease outbreaks associated with the consumption of meat and poultry products in which these hazards were not properly controlled. Proper cooking or thermal processing, fermentation, cooling, and storage of food can destroy and/or prevent growth of these bacteria.

Sources of Microorganisms

Raw materials and ingredients are the primary sources of microorganisms that must be addressed in the production of thermally processed commercially sterile and shelf-stable products. Although muscle tissue is generally considered to be sterile, raw meat and poultry become contaminated during slaughter and further processing. The ultimate source for pathogens in raw meat and poultry is apparently-healthy animals that may shed these bacteria in their feces. While dressing the carcasses during the slaughter process, these bacteria may be transferred from the hide, skin, feathers, gastrointestinal tract and other offal to the carcass, causing contamination. This is also a major source of spoilage microorganisms.

Soil or water can be a common source of food borne microorganisms and spores. Vegetables become contaminated during production, with those that grow close to or through the soil usually having high numbers of bacteria and bacterial spores, including spores of *C. botulinum*. Contaminated water used for irrigation has also been a source of pathogens on vegetables. Dried herbs and spices can be a primary source of sporeformers, since the spores will survive for extended times in the dehydrated product. Soy and milk protein ingredients can also be sources of spores.

Contamination can also come from the processing environment. Utensils such as knives used in slaughter and fabrication, workers hands and gloves, equipment, and occasionally aerosols with dust and other particles carrying microorganisms can all contribute to the microbial load of products. Contaminants may be present on containers and other packaging materials, although this is generally not a likely source of pathogens. Proper sanitation of the environment and protecting containers from environmental contamination can prevent these from being major sources of contamination such that they will negatively impact thermally processed commercially sterile and shelf-stable products.

Conditions Affecting Microbial Growth

The following information focuses on bacteria, since we are most concerned with bacterial pathogens; however, much of it is applicable to yeasts and molds as well. It is not applicable to parasites and viruses, since they do not grow in food.

►Nutrient Requirements

A suitable food supply is the most important condition affecting growth of bacteria. Every living cell requires certain nutrients to multiply. These include solutions of sugars or other carbohydrates, proteins and small amounts of other materials such as phosphates, chlorides and calcium. If the food supply is removed, bacteria will not multiply.

►Moisture Requirements

The concentration of moisture and its availability in a food (referred to as water activity, or a_w) are important factors to prevent microbial growth. The bacterial cell has no mouth, and therefore its food must be in a soluble form to enter the cell through the cell wall. Without sufficient available moisture, the inflow of food and the outflow of food residues and cell body fluids would be impossible. Later we will discuss how bacterial growth can be prevented by controlling the amount of moisture available to the bacteria.

►Oxygen Requirements

Some bacteria – called aerobes – require free oxygen in order to survive. For others, called anaerobes, the reverse is the case – the smallest quantity of free oxygen prevents their growth. The majority of bacteria – called facultative anaerobes – are neither strict aerobes nor strict anaerobes, but can tolerate to some degree either the presence or absence of oxygen.

►pH Requirements

The term pH designates the acidity or alkalinity of an aqueous solution. Scientifically, pH is the negative logarithm of the hydrogen ion concentration. The pH scale ranges from 0 to 14, with pH 7 being neutral. Numbers smaller than 7 indicate an increase in hydrogen ion (more acid) and numbers greater than 7 indicate a decrease in hydrogen ion concentration (more basic, or alkaline). All bacteria have an optimum (most favorable) pH range for growth (generally around neutral pH), as well as a minimum below which the organism will not grow (and where the organism may die) and a maximum above which it cannot grow. The pH of foods can be adjusted to help control microbial growth, as will be described later.

►Temperature Requirements

As with pH, all bacteria have an optimum temperature range for growth. Temperatures below and above the optimum for each group adversely affect the growth of the organism; all bacteria have a minimum and a maximum temperature below or above which the organism cannot grow. Bacterial groups bear names that indicate their relationships to temperature – psychrophile, psychrotroph, mesophile, thermophile.

The psychrophilic and psychrotrophic group

The terms psychrophile and psychrotroph are sometimes used interchangeably, but the groups are distinguished by their optimum growth temperatures and temperature ranges. Both psychrophiles and psychrotrophs grow over the temperature range of subzero to 68°F (20°C). True psychrophilic bacteria (“psychro” for “cold,” “phile” for “loving”) have an optimum temperature of 59°F (15°C) and cannot grow above 77°F (25°C). Psychrotrophic bacteria generally grow best at around 77°F (25ºC), or even mesophilic temperatures (see below), but can grow slowly in or on food at refrigerator temperatures (around 40ºF (4ºC)). These organisms are primarily responsible for spoilage of refrigerated foods. *L. monocytogenes* and some strains of *C. botulinum* (*C. botulinum* type E and non-proteolytic strains of type B and F) are considered to be psychrotrophs. None of these bacteria – except perhaps the strains of *C. botulinum* – is of concern to low-acid or acidified canned foods.

The mesophilic group

Mesophilic bacteria grow best at temperatures of 86ºF to 104°F (30ºC to 40°C) (the normal range of warehouse temperatures, depending on geographic locations), although some mesophiles grow well at higher temperatures such as 116ºF (46.7ºC). All of the bacteria that affect food safety grow within this mesophilic temperature range, although some may be considered psychrotrophic as well. The sporeforming organism *C. botulinum* is a member of this group, although some strains are considered psychrotrophs (see above).

The thermophilic group

Thermophiles (“thermo” for heat, “phile” for loving) are bacteria that grow at high temperatures. Thermophilic bacteria are found in soil, manure, compost piles, and even hot springs. Many are sporeforming bacteria and are divided into two groups based on the temperature at which the spores will germinate and grow. If the spores will not germinate and grow below 122ºF (50ºC), the bacteria are called obligate thermophiles, i.e., the high growth temperature is an absolute requirement. If growth occurs at thermophilic temperatures of 122º to 150ºF (50ºC to 66ºC) and at lower temperatures – e.g., about 100ºF (38ºC) – the bacteria are called facultative thermophiles, meaning they have the ability to grow at both temperature ranges.

Some of the obligate thermophiles can grow at temperatures up to 170ºF (77ºC). Laboratory tests have indicated that the spores of these bacteria are so heat-resistant that they can survive for more than 60 minutes at temperatures of 250ºF (121ºC). Thermophilic bacteria are not pathogenic and do not produce toxins during spoilage of foods; therefore, they do not affect food safety.

►Interaction of Factors

The level of a single growth-limiting factor to inhibit a microorganism is usually determined under conditions under which other factors that could influence growth are optimal. When other factors are not optimal, the organism will not be able to grow at the minimum or maximum level of another factor. For example, when the water activity is lower, the pH range at which an organism can grow is more limited. When the pH is lower, the water activity that limits growth will be higher. The presence of preservatives can affect the pH at which an organism grows; growth may take longer at lower temperatures when preservatives are present. With that in mind, let’s look at some of the control methods for microorganisms in foods.

Control Methods for Microorganisms

►Control of Bacteria by Temperature

Bacterial growth can be controlled by keeping food at temperatures below the minimum or above the maximum for the organism to grow. Thus, refrigeration, freezing and hot holding can be used to control growth. However, the most effective use of temperature to control microorganisms is to kill them with heat. The amount of heat needed to inactivate the microorganisms of concern will be dependent on the specific microorganism (the species and whether or not it is in the spore form), the number of microorganisms to be inactivated, and the food product in which the microorganism is heated (and factors of the food such as its pH, a_w, the presence of preservatives such as nitrite).

The thermal resistance of microorganisms is generally expressed using D- and z-values. The D-value is the time in minutes at a constant temperature to destroy 90% (or 1 log) of the organism present; the z-value is the number of degrees between a 10-fold change (1 log cycle) in an organism’s resistance. For example, if an organism has a D-value of 5 minutes at 140°F and a z-value of 10°F, then the D-value at 130°F will be 50 minutes and the D-value at 150°F will be 0.5 minutes. If there are <100,000 microorganisms present in a sample, then a process that delivered a 5-D reduction (also called a 5-log reduction) to the sample would result in <1 microorganism remaining. We will refer to this log-reduction concept again in the section on thermal processing of commercially sterile products and in the section on the microbiology of shelf-stable dried meats.

In general, low-acid commercially sterile products will require high temperatures that are achieved by processing under pressure to inactivate the organisms of concern. Acidified meat and poultry products can be processed at lower temperatures, since only vegetative cells must be inactivated; the pH prevents germination and outgrowth of the spores. In canned cured products, the presence of nitrite and salt reduces the amount of heat needed to achieve commercial sterility (heat kills the vegetative cells of pathogens; salt and nitrite prevent germination and outgrowth of spores). In most canned products it is not the pathogen of concern that determines the amount of heat needed but rather the spoilage microorganisms, which are more heat resistant than the pathogens. If these organisms are not inactivated, the product will not be shelf-stable. In most instances, this provides a wide margin of safety with respect to survival of pathogens in the product.

►Control of Bacteria by pH

As noted above, microorganisms can be controlled by reducing the pH below the minimum for growth of the organism. An “acidified low acid product” is defined by FSIS as a canned product which has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower within 24 hours after the completion of the thermal process unless data are available from the establishment’s processing authority demonstrating that a longer time period is safe. Proper acidification is necessary to prevent the growth of *C. botulinum*. Unlike processes for low-acid foods that destroy *C. botulinum* spores, processes for acidified foods depend upon the pH of the food to prevent this organism from growing. The final equilibrium pH of an acidified food must be 4.6 or lower to prevent growth of *C. botulinum* However, since some microorganisms can cause illness at very low levels (e.g., *Escherichia coli* O157:H7), preventing growth alone will not provide a safe product. Reduced pH can be combined with other factors to control the pathogens of concern. For example, a reduced pH, combined with a mild heat treatment, is used to achieve commercial sterility in acidified meat and poultry products such as pasta sauces containing meat. The role of pH in conjunction with other factors in the production of acidified/fermented meat and poultry products will be covered in the sections on Principles of Preservation of Shelf-Stable Dried Meat Products and the

Microbiology of Shelf-Stable Dried Meats. The pH values for representative canned meat and poultry products are shown in Table 1.

Table 1 – pH values of representative canned meat and poultry products

Food	pH
Beans with wieners	5.7
Beef chili	5.6
Beef stew	5.4-5.9
Chicken and dumplings	6.4
Chorizos	5.2
Corned beef	6.2
Corned beef hash	5.0-5.7
Ham	6.0-6.5
Spaghetti and meatballs	5.0
Spaghetti sauce with beef	4.2
Sloppy Joe	4.4
Vienna sausage	6.2-6.5

Acidification procedures

To produce products with a pH of 4.6 or less, acidification must be properly carried out. While there are several methods to obtain properly acidified foods, one commonly used with meat products is direct batch acidification. Ingredients are mixed in a kettle, and acid or, more commonly an acid food, is added directly to the batch. (An elevated temperature may improve the rate of acid penetration into solid particles.) The pH of the batch is checked before the material is sent from the batch kettle to the filler. If the particle size is small enough, the product pH will be below 4.6 at this point. With larger particles, the product may not reach the desired pH until later; however a pH taken at this point can be used to determine that the acidification process is under control. Another method that is used for acidification of meat products is the addition of acidified brine, such as with pickled pigs' feet. Other methods will be discussed in the section on Principles of Thermal Processing.

Determination of pH

The most important factor in the production of acidified foods is the timely attainment and maintenance of a pH level that will inhibit the growth of *C. botulinum* spores. To achieve this goal, it is necessary to measure pH.

Although pH can be measured using colorimetric methods (dye solutions and pH paper) or by titratable acidity, the recommended method for determining pH is the electrometric method using a pH meter. The pH meter measures the electrical potential developed between a glass and a reference electrode when they are immersed in a solution. USDA currently requires the electrometric method to be used any time pH is specified as a critical factor for a scheduled process.

The sensing elements used with pH meters are called electrodes. Combination electrodes contain both a glass and reference electrode in a single probe. They come in a number of different sizes and conformations, which increases the applications of this type of electrode. For example, flat-surface electrodes are useful for measuring the surface pH of a solid sample; long, thin electrodes may be inserted in tubes for measuring pH of small sample volumes or inserted into the process stream for continuous monitoring of pH. Unbreakable electrodes should be used in food processing plants to minimize the chances of contaminating food. For best results, pH meters should be operated in accordance with manufacturer's instructions; the manufacturer’s recommendations should be followed for care and maintenance of all pH electrodes.

Once the unit has been turned on and allowed to warm up, the meter should be properly standardized (calibrated) using two buffers to cover the pH range of interest, such as one at pH 4.0 and the other at pH 7.0. The meter should be standardized (1) before any food pH measurements are taken and (2) at least once an hour following that. More frequent standardization and cleaning may be necessary with some products that contain oil, grease or fats.

The sample to be tested must be properly prepared, which is dependent on the type of product to be evaluated. Homogeneous products, such as sauces, require little preparation. Products that consist of solid and liquid components should have the solid components tested separately to determine if they have been properly acidified. One means of sample preparation is to transfer a portion of the solid component to a screen, rinse it with a small volume of distilled water (10-20 ml), and thoroughly blend before taking a pH. Sufficient tests must be made to ensure that the finished equilibrium pH of the product is not higher than 4.6. These tests indicate whether the acidification process is sufficient to bring the product to the appropriate pH.

Electrodes should be rinsed between samples and after use. The purpose of rinsing is to prevent cross-contamination between samples that could result in errors in pH values for products. Rinsing with distilled water is recommended. However, if enough sample is available, rinsing with a portion of the next sample to be measured and throwing away the rinse solution is the best way to prevent cross-contamination. If distilled water is used, the water should be blotted – not wiped – off the electrodes. If the electrode is rinsed with the next sample, this step is not necessary. Electrodes should not be wiped, because wiping could implant a charge on the electrode causing it to drift. Oil and grease from samples may coat or clog elements; therefore, electrodes should be cleaned with ethyl ether or acetone in accordance with the manufacturer's instructions, and the instrument should be re-standardized frequently. If the primary use is to test high fat/oil products, special electrodes are available.

►Control of Bacteria by Water Activity (a_w)

For thousands of years people have dried fruits, meats and vegetables as a method of preservation. It was also discovered that the addition of sugar would allow preservation of foods such as in the production of candies and jellies. Salt preservation of meat and fish has been extensively practiced over the ages.

As late as 1940, food microbiologists thought that the percentage of water in a food product controlled microbial growth, but gradually they learned that it is the availability of the water that is the most important factor influencing growth. The measure of the availability of water in a food is made by determining the water activity. Water activity is usually designated with the symbol "$a_{w.}$"

When substances are dissolved, there is substantial reaction between the substance and the water. A number of the molecules of the water are bound by the molecules of the substances dissolved. All of the substances dissolved in the water reduce the number of unattached water molecules and, in this way, reduce the amount of water available for microbial growth. The extent to which the water activity is lowered depends primarily on the total concentration of all dissolved substances. Thus, if some ingredient – such as sugar, salt, etc. – is added to food, it competes with the bacteria for available water. The water-binding capacity of a particular dissolved ingredient influences the amount of water left for the growth of bacteria.

Meat or poultry containing products with a water activity of 0.85 or less are not covered by the USDA canning regulations (9 CFR 318 Subpart G (meat) and 381 Subpart X (poultry)) even if they are in hermetically sealed containers.

The a_w is the ratio of the vapor pressure of a substance to the vapor pressure of pure water, and is equal to the equilibrium relative humidity divided by 100. Thus, a_w is a fraction between 0 and 1.00, with the a_w of pure water being 1.00.

A measurement of a_w on a food provides information as to which types of microorganisms are most likely to cause spoilage and how close the a_w is to the safety limits. Most bacteria, yeasts and molds will grow above a water activity of 0.95 (See Table 2), and most foods have a water activity above this level.

Spores of *C. botulinum* are generally inhibited at an a_w of about 0.93 or less. (For more information on the effect of a_w on *C. botulinum*, see the section on salt under Control by Chemicals below.) Therefore if the amount of water available to spores is decreased to a point where they are inhibited and mild heat treatment is applied to destroy the vegetative cells, we have a method of preservation for products whose quality is sensitive to high heat.

Table 2 – Minimum a_w requirements for microorganism growth

Microorganism	Minimum a_w For Growth
Most molds (e.g., *Aspergillus*)	0.75[1]
Most yeasts	0.88[2]
C. botulinum[3]	0.93
Staphylococcus aureus[4]	0.85
Salmonella	0.94
Listeria monocytogenes	0.92

[1] some strains – 0.61
[2] some strains – 0.62
[3] Proteolytic strains, 10% NaCl
[4] Minimum for toxin production is higher.

Examples of foods preserved with mild heat and reduced a_w are some cheese spreads, peanut butter, syrups, jams and jellies, and many meat products. The water activity of some common foods is shown in Table 3.

Table 3 – Water activity of some common foods

Food	a_w
Perishable and canned foods (including meats, vegetables, fish and milk)	0.95-1.00
Liverwurst	0.96
Some cheese spreads	0.95
Some cheeses and cured meats	0.91-0.95
Chorizos	0.92
Many fermented sausages	0.87-0.91
Semi-moist pet food	0.83
Salami	0.82
Chocolate syrups	0.75-0.83
Jams	0.75-0.80
Peanut butter – 15% total moisture	0.70
Jerky	$\leq$0.80

It is apparent that as far as *C. botulinum* is concerned, a water activity of 0.85 provides a large margin of safety. Studies with this organism show that an accurate water activity of 0.93 plus pasteurization will give commercial sterility. However, some questions exist about the precision or accuracy of the instruments and methods used to determine water activity and about some factors that control water activity. Therefore, if water activity between 0.90 and 0.93 plus pasteurization is used to control commercial sterility, data must be obtained and records kept showing that the process yields commercial sterility.

Methods for determining a_w

Several methods exist for determining the water activity of a food. One commonly used method is an electric hygrometer with a sensor to measure equilibrium relative humidity (ERH). As noted above, the equilibrium relative humidity above the food in a closed container divided by 100 is a measure of the available moisture – the water activity. The instrument was actually devised by weathermen, and the sensors are the same as those used to measure relative humidity in air. A dew point instrument is also commonly used to measure a_w. This instrument measures the temperature at which condensation occurs on a cooled mirror in the headspace of the sample chamber. The a_w is computed by converting sample and mirror temperatures to vapor pressures and calculating the ratio, which is the a_w.

In determining the a_w using an electric hygrometer, 30-90 minutes may be required for the water vapor (relative humidity) to reach equilibrium in the headspace above the food in the closed container. A dew point instrument is usually much faster – generally only 5 minutes. Generally the formulation of the product to give the required a_w is predetermined and very accurately controlled at the time of processing. For products that have a reduced a_w due to reduction in moisture (e.g., through a drying process), following proper procedures can be critical. Determination of a_w in a laboratory is often used to verify that the formulation and other steps that reduced product moisture were correctly carried out and the appropriate a_w was achieved. Samples of the final product should be checked as frequently as necessary to ensure that the appropriate water activity is being achieved.

►Control of Bacteria by Chemicals

Chemicals (often called preservatives, antimicrobial compounds, or antimicrobials) may be added to foods to inhibit microbial growth or to kill microorganisms. However, at normal levels of use (which must be approved by regulatory agencies such as FDA and FSIS), most chemicals cause inhibition rather than inactivation. Acids and their salts (e.g., lactic acid, sodium lactate), nitrites, some phosphates, and sodium chloride (salt) are common chemicals added to meat and poultry. In order to produce a commercially sterile or shelf-stable product, chemicals are usually combined with other factors such as heat or reduced a_w.

Salt

For example, salt has been used to preserve meat products (i.e., salt-cured meats). Salt, which lowers the a_w, is often supplemented with other ingredients, such as nitrites, that aid in spoilage prevention. In all cases the salt is necessary to inhibit the growth of sporeforming bacteria, such as *C. botulinum*, and only enough heat is applied to kill the non-heat resistant vegetative cells. Strains of *C. botulinum* that grow in a suitable food containing 7 percent salt are known. For example, toxin was produced in experimentally produced turkey frankfurters with an a_w of 0.956 (7% NaCl) in 12 days at 27°C (81°F). The growth of these strains, however, is inhibited at a concentration of 10 percent, which is equivalent to a water activity of 0.935, when all other conditions are optimum. If conditions are not optimum for growth (e.g., low pH or temperature) then less NaCl is required to inhibit growth. For example, growth of *C. botulinum* may occur at an a_w of 0.96 (6.5% NaCl) at pH 7.0, but if the pH is reduced to 5.3, growth will be inhibited at an a_w of 0.97 (5% NaCl). The actual salt content of a meat product is not as important in inhibiting *C. botulinum* as the brine concentration (percent of salt in the aqueous portion of the meat). Toxin production is inhibited at a brine level exceeding 9.0%.

Nitrite

When direct addition of nitrite was approved for meats in 1925, it was believed that the sole function was for color development. However, within a few years scientific studies began to demonstrate the antimicrobial effects of this compound. Numerous studies now document the efficacy of nitrite in inhibiting growth and toxin production by *C. botulinum* in meat systems. However, studies also determined that there was little or no effect of nitrite on bacterial growth at or above neutral pH. In spite of large amounts of research, there is still not a complete understanding of how nitrite controls *C. botulinum* in meat products. Nevertheless, it is now recognized that nitrite inhibition is due to a combination of factors, not nitrite alone.

►Control of Bacteria by Combinations of Factors

As has been noted above for chemicals, combinations of inhibitory factors that individually are insufficient to control microorganisms can often be effective. This has sometimes been referred to as the hurdles concept – if enough hurdles or barriers are included, bacteria will not be able to overcome the hurdles and grow. Commercially sterile, canned cured meats are preserved by thermal destruction of vegetative cells of microorganisms, partial destruction of microbial spores and inhibition of the surviving spores by the effects of salt, nitrite, and possibly other additives such as ascorbate/isoascorbate.

The hurdle approach is used for many fermented meat products – curing chemicals such as nitrite and salt, reduced a_w due to drying, reduced pH due to fermentation, and, in some cases, mild heat processes result in a safe and shelf-stable product. This will be covered in much more depth in the sections on shelf-stable products.

Workshop: Microbiology of Commercially Sterile and Shelf-Stable Products

The following questions are multiple-choice questions. Circle the answer(s) you believe to be correct; some questions have more than one answer.

1. Microorganisms that can grow in food and cause spoilage include _____ .

   a. viruses
   b. bacteria
   c. molds
   d. yeasts
   e. parasites

2. A psychrotrophic non-sporeforming pathogen that can grow at refrigerator temperatures is ___.

   a. *Clostridium botulinum*
   b. *Bacillus cerus*
   c. *Clostridium perfringens*
   d. *Listeria monocytogenes*

3. Controlling microorganisms in foods can be achieved by _______ .

   a. temperature
   b. pH
   c. acidification
   d. water activity

4. The pH established to provide safety with respect to *C. botulinum* is ____ .

   a. 4.6
   b. 4.7
   c. 4.8
   d. 4.9

5. Spores of *C. botulinum* are generally inhibited at an a_w of about ___or less.

   a. 0.98
   b. 0.85
   c. 0.93

6. Reducing the water activity of a food product to 0.85 would have the best potential for inhibiting ________ .

   a. bacteria
   b. mold
   c. yeast

7. Bacteria that can survive adverse conditions caused by heat, cold and chemical agents are __________ .

   a. psychrotrophic bacteria
   b. facultative bacteria
   c. sporeforming bacteria

8. Acidified low-acid foods are products with a pH less than or equal to ____.

   a. 4.6
   b. 4.2
   c. 3.8

9. When low water activity is used to preserve a food, the most important factor controlling microbial growth is

   a. the amount of available water in the product.
   b. the total water content.
   c. a scheduled process approved by a processing authority with supporting data.

10. Thermophiles are bacteria that grow best

   a. at temperatures of about 80˚F to 98˚F (27˚C to 37˚C).
   b. at temperatures of about 122˚F to 150˚F (50˚C to 66˚C).
   c. in acid media.

The Microbiology of Low-Acid Canned Foods

►*Clostridium botulinum*

The pathogen of primary concern for low-acid foods in hermetically sealed containers is not among those typically associated with illness from other meat and poultry products, such as *Salmonella* – it is the sporeforming bacterium *Clostridium botulinum*. The term "*clostridium*" indicates an organism that is able to grow in the absence of air or oxygen and is a sporeformer. The term "*botulinum*" comes from the Latin word "botulus," meaning sausage, because the organism was first isolated from a sausage that had produced the illness now called "botulism."

Clostridium botulinum (*C. botulinum*) is of great concern to home and commercial canners because (1) when it grows it can produce a potent toxin, (2) it can be isolated from soil or water practically everywhere in the world, (3) it is the pathogen with the greatest heat resistance due to its ability to produce heat resistant spores, and (4) canning foods provides an anaerobic environment favorable to growth of the organism if it has not been destroyed by the process. As noted before, the ability to form spores enables *C. botulinum* to survive a wide range of unfavorable conditions, such as heat and chemicals. The spores survive many heat processes that kill other pathogens of concern in meat and poultry. In fact, certain types of *C. botulinum* spores are able to survive five to 10 hours in boiling water. (As you will learn later, processes to kill *C. botulinum* are on the order of 250°F for 3 minutes, compared to, for example, 157°F for 15 seconds to kill *Salmonella* in certain cooked meat and poultry products.) Oxygen is excluded from sealed containers, thus providing the anaerobic environment for spores to germinate, become vegetative cells, multiply and produce toxin when the foods are stored at temperatures that allow growth. It is important to recognize that it is not the spore that produces the toxin, but the vegetative cell. If spores are present but prevented from forming vegetative cells, as in acidified foods, toxin will not be produced.

Certain strains of *C. botulinum* are called putrefactive because this term describes the odor produced during their growth. These strains require proteins to grow (they are proteolytic) and they grow best at temperatures between 86ºF (30ºC) and 98ºF (37ºC), although growth can occur at any temperature between 50ºF (10ºC) and 104ºF (40ºC). Other strains, which are non-proteolytic, are more dependent on carbohydrates, such as sugars and starch, for growth and do not produce putrefactive odors. Some of these strains are associated with marine environments; they grow best at 64-77°F (18-25°C) and have a minimum growth temperature of 38ºF (3.3ºC). Their spores will not withstand heating to 212ºF (100ºC).

Because *C. botulinum* spores are found everywhere, any raw food may be contaminated with them (although, as was noted before, the organism is rare in meats, and at low levels – 0.1 to 7 spores/kg – when present in meats). However, it is only when the vegetative form of the organism grows in a food that the toxin or poison is produced. Although the spores are heat resistant, the toxin is not. The toxin can be inactivated by boiling temperatures – 212ºF (100ºC).

Heat processes for low-acid canned meat and poultry are designed, at a minimum, to produce a product that is safe with respect to *C. botulinum*. Microbial inhibitors and pH can impact the processes needed to inactivate *C. botulinum*. Inclusion of sodium nitrite and sodium chloride in meat and poultry products (e.g., commercially-sterile, canned cured meats) can lower the thermal process required to produce a commercially sterile product that is stable at room temperature. For example, processes equivalent to 0.4-0.6 minutes at 250°F (121°C) are common for commercially sterile, cured luncheon meats containing ~ 150 ppm ingoing nitrite and 5.0-5.5% brine strength. These processes may range from 0.1 to 1.5 minutes depending on nitrite, brine strength and other factors (compared to processes of 3.0 minutes for uncured products). (It should be noted that there are both perishable and commercially sterile cured meat and poultry products packed in hermetically sealed containers. If the products are not commercially sterile, they are not subject to the canning regulations.) Reducing the pH can also lower the process required, even when the product is not acidified to a pH that produces an acidified food (see below).

►Other Microorganisms Important in Low-Acid Canned Foods

Although heat processes for thermally processed commercially sterile foods are designed to destroy any microorganisms of public health significance, we are also concerned about other microorganisms that could grow in the product under normal storage conditions and result in adulterated product. As will be discussed when we get to the principles of thermal processing, processes designed to ensure commercial sterility of low-acid canned foods usually target *Clostridium sporogenes* or similar organisms (putrefactive anaerobes). Because spores of *C. sporogenes* have higher heat resistance than those of *C. botulinum*, processes targeted to destroy spores of *C. sporogenes* will also destroy *C. botulinum* spores.

Note that commercial sterility is not the same as absolute sterility – there may be viable microorganisms present in commercially sterile products. Spores of thermophilic bacteria such as *Bacillus stearothermophilus* or *Clostridium thermosaccharolyticum*, if present, can survive processes that achieve commercial sterility. However, these organisms, which are not harmful to humans, cannot grow under normal conditions of storage. If product is properly cooled and stored, generally the spores are not exposed to the high temperatures they require for germination and growth. Although canned foods are not generally processed to inactivate thermophiles, one exception to this is hot-vended products. Products that will be held hot in vending machines will be exposed to temperatures at which thermophiles can grow and will receive higher processes to ensure thermophilic spoilage does not occur.

The Microbiology of Acidified Canned Foods

Meat and poultry products to which acids or acid products have been added to reduce the pH to 4.6 or below are called acidified foods. Spores of *C. botulinum* do not germinate and grow out in foods that have a pH below 4.8; a pH of 4.6 is set for acidified foods to provide a margin of safety. Heat processes for acidified foods target organisms other than *C. botulinum*, since the pH prevents its growth. The safety of acidified meat and poultry products is achieved by controlling the pH to 4.6 or less and applying a mild heat treatment to inactivate the vegetative cells of pathogens (e.g., *Salmonella*, *E. coli* O157:H7 and *C. botulinum*). However, achieving commercial sterility of these products requires treatments that inactivate yeast, mold and bacteria, including some sporeformers, that could grow in the product. The type of organism to be destroyed by the process will depend on the pH of the product. If the pH is below 4.2, only vegetative cells need be considered; however, if the pH is 4.2-4.6, processes may need to take into account sporeforming organisms such as *Bacillus coagulans* and the butyric acid anaerobes (e.g., *Clostridium pasteurianum* and *Clostridium butyricum*). For more information on these organisms see the later section on Spoilage by Acid-Tolerant Sporeformers.

The Microbiology of Shelf-Stable, Canned, Cured Meats

The safety and stability of shelf-stable, canned, cured meat products (e.g., canned hams and luncheon meats) are related primarily to the concentrations of salt (sodium chloride, NaCl) and nitrite and the thermal process acting synergistically. These products only receive mild heat treatments, relying on NaCl and nitrite to inhibit surviving sporeformers, in particular *C. botulinum*. The inherent low levels of spores in these products also contribute to ensuring safety and shelf stability.

Canned Food Spoilage

►Indications of Microbial Spoilage

Most bacteria produce gas when allowed to grow in a canned food. This gas causes the containers to swell. Exceptions are the flat-sour sporeforming organisms, which produce acid and sour the food without producing gas, leaving the container ends flat. These organisms are an economic but not a public health problem.

The most obvious indicator of spoilage in processed food is a swollen container – bulging at one or both ends. This implies that the food has possibly undergone spoilage by the action of gas-forming bacteria. Consumers are advised by public health officials, food trade associations and regulatory agencies not to use any container with a bulged end or ends, even though the swelling may be of non-microbial origin.

The appearance and odor of the container contents may also indicate spoilage. If the product is broken down and mushy, or if a normally clear brine or syrup is cloudy, spoilage may be suspected. In jars, a white deposit may sometimes be seen on the bottom or on pieces of food. This is not always a sign of spoilage, as starch sometimes precipitates from certain foods.

Bacterial decomposition of thermally processed product may result from one of six causes:

1. Incipient spoilage – growth of bacteria before processing;
2. Contamination after processing – leakage of bacteria into the container;
3. Inadequate heat processing;
4. Growth of thermophilic bacteria in the processed food;
5. Spoilage by acid-tolerant sporeforming bacteria; and
6. Spoilage due to improper curing.

The last two causes of spoilage are specific to products with reduced pH and to cured products, respectively. In addition, there can be non-microbial causes of spoilage.

►Incipient Spoilage (Spoilage Before Processing)

Processed food is sometimes held too long between filling or closing the containers and thermal processing. Such delays may result in growth of bacteria normally present in the food and the initiation of spoilage before the retorting process. This type of spoilage is referred to as “incipient spoilage.” The microorganisms that grow will be killed by the process; with sufficient time, sporeformers may germinate and form vegetative cells that will be killed. Typically incipient spoilage manifests itself as low or no vacuum in the container and a slight change in pH of the product. Generally no viable microorganisms are recovered in subculture media. Although the product presents no risk to public health, if there is sufficient growth, the product may be considered to be adulterated (e.g., if the product characteristics are changed). The degree of spoilage depends on the specific product and the time and temperature conditions during the delay. For example, if the product has been heat treated (e.g., cooked) prior to container filling, there may be low levels of bacteria present such that holding product for several hours may result in bacterial increases that are not significant. Products that contain inhibitors, those that are held at lower temperatures (e.g., below 70°F) or those that are filled hot (above microbial growth temperatures) may also demonstrate only limited bacterial growth for several hours.

The loss of vacuum that can result from growth of microorganisms in sealed containers held too long prior to retorting may lead to extensive internal pressures in the containers during retorting. The build-up of internal pressure strains the container seams or seals and increases the potential of leaker spoilage. Some containers may actually buckle or rupture, rendering them unusable. Steps should be taken to avoid such a delay before retorting the containers.

►Contamination After Processing (Leakage)

Leaker spoilage – or post-processing contamination with microorganisms – usually shows up rapidly as swollen containers. It may take several weeks until all spoilage has ceased. If many swells are present, a small percentage of flat, spoiled containers (flat-sours) may be expected, and normal appearing cans should be examined with this potential in mind. Leakage is generally due to inadequately formed seams, container damage or cooling water contaminated with large numbers of microorganisms.

While theoretically leakage could result in post-processing contamination with pathogens, this is unlikely in plants operating under good manufacturing practices. Incidents of typhoid fever resulted from consumption of meat products (imported into the UK from Argentina in the 1950s and 1960s) that were contaminated when cans were cooled using river water contaminated with sewage. Recontamination with *C. botulinum* has occurred with seafood, but not meat products. Based on existing reports of food borne disease for which package defects are alleged or proven to have contributed to the problem, the probability of post-process contamination with organisms of public health significance is extremely low. In fact, it was estimated in 1984 that the probability of botulism from container leakage is about one chance in every 260 billion cans of food consumed (or one potential botulism incident about every 9 years). The report concluded that this probability compares well to the risk associated with the minimum acceptable thermal process for low-acid canned foods.

►Inadequate Heat Processing

The term “inadequate heat processing” (also referred to as under-processing) is almost self-explanatory. Heat processes for thermally processed food are designed to destroy any microorganisms of public health, as well as non-health, significance that could grow in the product under normal storage conditions. In many instances, the product receives sufficient heat to inactivate pathogenic sporeformers such as *C. botulinum*, with the more heat resistant spoilage organisms surviving and spoiling the product. However, if the heat process is inadequate to destroy *C. botulinum*, the situation can be very hazardous, since botulinum toxin could be produced and, if the product is consumed, cause botulism in the consumer.

Botulism is the disease caused by ingestion of the toxin produced when *C. botulinum* grows in a food. Symptoms include, dry mouth, dizziness, and weakness, generally within 12-48 hours after consumption of the toxin. Nausea and vomiting may also occur. Neurologic symptoms follow, including blurred or double vision, inability to swallow, difficulty in speech, descending weakness of skeletal muscles and, ultimately, respiratory paralysis. Untreated, this can lead to death.

A heat process may be inadequate for a variety of reasons, including but not limited to the following:

1. If the time and/or temperature (or its equivalent) specified in the scheduled heat process for the particular product in the particular size of container is not used.
2. If the scheduled heat process was not established properly.
3. If the scheduled heat process is not properly applied because of some mechanical or personnel failure.
4. If one or more of the scheduled process critical factors is not met.
5. If the formulation is changed such that the critical factors change.

►Thermophilic Spoilage

Generally, the higher the temperature at which a sporeforming organism can grow, the greater the heat resistance of its spores will be. Thus, the spores of thermophilic bacteria usually have a greater heat resistance than the spores of mesophilic bacteria. The spores of thermophilic bacteria are so resistant to heat that heat processes designed to kill the mesophilic bacteria may not be adequate to destroy thermophilic bacteria. In order to prevent thermophilic spoilage, the product must be properly cooled, preferably below 105ºF (41ºC), after thermal processing and held below 95ºF (35ºC). Thermophiles may grow in equipment that contacts food if the temperature is within their growth range. Consequently, product should always be held at 170ºF (77ºC) or above or at room temperature or below to prevent the growth of thermophiles.

For meat and poultry products containing ingredients known to be a source of thermophiles (e.g., such as sugar, starch and/or spices) where thermophilic spoilage may be a problem, prudent processors will use ingredients that the supplier guarantees are free of thermophilic bacteria or that meet specifications for thermophiles for canning processes. This is particularly important if the product is to be hot-vended. This is the responsibility of the establishment, as it is a quality issue, not one of safety.

►Spoilage by Acid-Tolerant Sporeformers

As noted above, acidified foods (those products with a pH 4.6 or below) do not require a severe thermal process to assure product safety. Therefore a variety of acid-tolerant sporeformers may survive the process. A thermal process scheduled for acidified foods is designed to inactivate a certain level of these sporeformers. Their survival is typically a result of excessive pre-processing contamination. Sometimes underprocessing, either due to inadequate processing or process deviations, may also result in survival of these acid-tolerant sporeformers. The organisms of spoilage significance are butyric-acid producing anaerobes and aciduric flat sour sporeformers.

The butyric-acid producing anaerobes, such as *Clostridium butyricum* and *Clostridium pasteurianum*, are mesophilic sporeformers that produce butyric acid as well as carbon dioxide and hydrogen. The spores are capable of germination and growth at pH values as low as 4.2-4.4 and consequently are of spoilage significance in acidified foods, particularly if the pH is above 4.2. In products where the pH is not low enough, spoilage by butyric acid anaerobes may be controlled by either further acidification of the product or by increasing the thermal process. Growth of these organisms in foods is characterized by a butyric odor and the production of large quantities of gas. Occasionally strains will be encountered that can grow at a pH lower than 4.2. If these strains are present in high numbers, the heat process may be inadequate and spoilage may occur.

Aciduric “flat sours” are facultative anaerobic sporeformers that seldom produce gas in spoiled products. The ends of spoiled cans remain flat; hence the term “flat sour.” Spoiled products have an off flavor that has been described as “medicinal” or “phenolic.” These organisms have caused spoilage in acid foods such as tomato products (by *Bacillus coagulans*) and could cause problems in meat products with tomato sauces if the sauces are prepared from fresh tomatoes. (The problem is unlikely if the tomato ingredients are previously processed to inactivate these organisms, as with commercially sterile products). It may be necessary to ensure that the thermal process is adequate to inactivate an expected number of spores, which can be determined through bacteriological surveys. Pinpointing the ingredient that is contributing the most to the total spore load may prove beneficial in process control. For example, proper handling of vegetables prior to use, such as washing and culling, may help to reduce spore loads.

Most food processing operations do not provide anaerobic conditions; therefore, heavy build-up of acid-tolerant anaerobic sporeformers seldom occurs. This is one reason why “dead ends” (“dead legs”) must be avoided in processing lines. However, when this does occur, under-sterilization spoilage can result because of the heavy load of spores in the product. The spoilage pattern within the affected lots is often spotty and scattered, more typical of post-processing spoilage that is due to container leakage, than of the pattern expected from sporeformers that survive a thermal process. Thermal processing records and other processing parameters usually give no indication of any irregularities. In most cases, the problem can be identified only by investigation at the factory, which includes a bacteriological survey, plus the absence of demonstrable leakage and package defects in the spoiled containers.

►Spoilage Due to Improper Curing

As was noted before, canned cured meat and poultry products are made commercially sterile by the interrelationship of salt, nitrite, heat and low levels of spores. Spoilage due to underprocessing in canned cured meats is rare, and is usually the result of improper curing rather than inadequate heating. The heat processes for canned cured meat and poultry products are not designed to inactivate mesophilic sporeformers, as their outgrowth will be inhibited by salt and nitrite. Reduced levels of salt or nitrite can result in spoilage, as the heat treatment may be inadequate for product containing these lower levels.

►Non-microbial Spoilage

Spoilage in canned foods can sometimes occur as the result of container deterioration; this may at times result from chemical interactions of the food and the container. To avoid this type of spoilage, the packer must be aware of the impact of container, processing, and product chemistry variables on the corrosion shelf life of the container. Container deterioration may result in swollen containers resulting from the production of hydrogen (“hydrogen swells”) or in leaking containers due to pinholes or cracks.

Non-microbial spoilage rarely results in a health hazard. However, in high acid products where detinning of containers has occurred, there have been instances of illness due to high levels of tin (>200 ppm), which can cause acute toxicity (nausea, vomiting, cramps and diarrhea). This has not been a problem in meat and poultry products.

There are four main types of corrosion inside plain tinplate containers: normal corrosion, rapid detinning, pitting corrosion and cosmetic corrosion. The normal corrosion process is slow, even detinning of the tinplate surface. The canned product will have a minimum shelf life of about 2 years. Rapid detinning involves rapid tin dissolution of the tinned surface and pitting corrosion involves rapid dissolution of iron, with or without tin dissolving. These two forms of corrosion lead to either hydrogen swells or perforations. Cosmetic corrosion problems, such as sulfide staining, are not of public health significance, but consumers may reject the pack for aesthetic reasons.

Meat and poultry products are usually packed in enameled cans rather than plain tinplate. Corrosion inside enameled cans is localized at fractures in the coating where the plate is exposed to the product. There are five main manifestations of corrosion in coated cans – 1) normal corrosion, 2) pitting corrosion, 3) under-enamel corrosion and enamel flaking, 4)stress corrosion cracking and 5) sulfide black corrosion. The normal corrosion process involves iron dissolution from small pores, and the corrosion shelf life will exceed 18-24 months. Pitting corrosion involves rapid iron dissolution from the container walls at coating defects. Under-enamel corrosion is detinning or staining through the coating at areas where the coating has lost adhesion. Stress corrosion cracking involves a reaction between the container and stress inducing components in the product. Cracks through the container have been observed in as little as 4 months. Sulfide black corrosion involved rapid iron dissolution through the coating with black deposits forming about 24 hours after processing. Sulfide black discoloration is a type of cosmetic corrosion that is objectionable to the consumer.

External corrosion involves rusting, detinning or staining of the outside walls of the container. It rarely leads to perforations from the outside in. Filiform corrosion involves tunneling through the walls of the can. It occurs at the scratch defects in the coating on the outside of cans. It sometimes leads to pinholes in the container.

►Determining the Cause of Spoilage

Analysis of spoilage of commercially sterile canned food products requires expertise to conduct the analysis and to appropriately interpret the results. The isolation of microorganisms from spoiled product does not necessarily mean they are the cause of spoilage. For example, if acidified foods are cultured in neutral laboratory media, microorganisms that are present in the product but are inhibited by the pH may grow out. These are of no significance since they cannot grow in the product due to its pH. Likewise, if other inhibitors are present in product, culturing in laboratory media may dilute the inhibitors such that microorganisms which are viable in the product but prevented from growing can grow in the media. Again, it is unlikely that these organisms are significant with respect to spoilage of the product. Thus, microbiological examination of products intended to be commercially sterile requires a trained analyst following accepted procedures such as those outlined in the USDA/FSIS Microbiology Laboratory Guidebook for examination of heat processed, hermetically sealed (canned) meat and poultry products or the equivalent.

Workshop: Microbiology of Canned Products

The following questions are multiple-choice questions. Circle the answer(s) you believe to be correct; some questions have more than one answer.

1. Commercial sterility refers to applying a heat treatment to a low-acid canned food designed to destroy pathogens and spoilage organisms capable of growing in the product at normal storage conditions. What is the pathogen of greatest concern in a low-acid canned food?

   a. *Clostridium botulinum*
   b. *E. coli* O157:H7
   c. *Clostridium perfringens*
   d. *Listeria monocytogenes*

2. Certain types of *Clostridium botulinum* spores

   a. produce a potent toxin.
   b. are able to survive for 5 to 10 hours in boiling water.
   c. produce toxin that cannot be inactivated by boiling at 212˚F (100˚C).

3. *Clostridium botulinum* is

   a. an anaerobic, sporeforming bacterium.
   b. a mesophilic acid-tolerant microorganism.
   c. a thermophilic microbe.

4. Botulism is an illness that can be caused by

   a. eating spores of *Clostridium botulinum* or other food spoilage organisms.
   b. eating vegetative cells of *Clostridium botulinum* which may be found in raw meat and spices.
   c. eating food in which vegetative cells of *Clostridium botulinum* have grown and produced toxin.

5. Incipient spoilage in canned foods is caused by

   a. holding closed containers too long before retorting.
   b. under processing.
   c. post-process contamination, especially from dirty cooling water.

6. Thermophilic bacterial spores

   a. are less heat resistant than mesophilic bacterial spores.
   b. are never present in low-acid canned foods.
   c. may not be destroyed during the heat process for low-acid foods.

Workshop: Spoilage of Canned Foods Case Study

(**Note**: This is a simplified training example only.)

While walking through the warehouse of Uncle Sam's Canned Goods Company, you and the warehouse supervisor notice several cases of canned beef stew that look wet. The QA manager is called to the warehouse to inspect the problem. Upon opening the cases he finds **several cans that are swollen or leaking.** He pulls out the swollen and leaking cans, along with several of the normal-looking flat cans. He then sends some of the sample cans to Microtesting, Inc., a microbiology laboratory that specializes in analyses of canned food products. You send the remaining samples to the FSIS laboratory in Athens, Georgia. The lot of product is placed on hold pending the laboratory results.

Upon receipt of the samples on Friday afternoon at 4:45pm, the diligent laboratory technician at Microtesting, Inc., begins analysis of the samples. The laboratory sends back preliminary results to the QA manager the following week.

The laboratory results listed below are four possible "what-if" scenarios. Please read the possible scenarios then answer the following questions.

	Microbiological Results	**Container Evaluation**
Scenario #1	Thermophilic microorganisms were identified.	No container defects were detected.
Scenario #2	Mixed culture of rods and cocci were identified. No sporeformers or heat resistant microorganisms were recovered.	Can exam revealed false seam on packer's end.
Scenario #3	Mesophilic organisms with spores were identified.	No container defects were detected.
Scenario #4	No viable bacteria (sporeformers or non-sporeformers) were recovered.	Hydrogen gas was detected.

►Questions

1. Which of these scenarios, if any, suggests microbiological problems due to potential under-processing? Why?

2. Which of these scenarios, if any, suggest post-process contamination? Why?

3. Which of the scenarios, if any, is indicative of microbial spoilage that has the potential for an adverse public health consequence?
Why?

4. Which of the scenarios, if any, is indicative of detinning of the can interior? Why?

5. After receiving the results indicated in Scenario #1, Uncle Sam's decides to sort and remove the swollen and leaking cans from the lot and release the normal cans.

   The lot of cans are incubated in an unair-conditioned trailer held at 110-120˚F and checked weekly. After 6 weeks there are no additional swollen containers. Since the cause of spoilage was the growth of thermophilic microorganisms, the plant manager believes that it is acceptable to release the flat containers. The plant microbiologist wants to conduct a simple test to determine the pH of random samples before making the decision to release. Why?

6. Is every swollen can an indication of an adverse public health consequence? Why or why not?

PRINCIPLES OF THERMAL PROCESSING

The “canning” of foods has been practiced for almost 200 years, but the science supporting the canning process has been understood for only about half of that time. In this section we will discuss the theory and science that forms the basis for the development and application of thermal processes to low-acid and acidified foods packaged in hermetically sealed containers. This section will identify and review some of the major factors affecting thermal processing of canned food products.

The objectives of this section are for you to be able to:

1. define commercial sterility;
2. identify who can establish a thermal process;
3. identify the components in establishing a thermal process;
4. identify factors that impact the thermal process; and
5. recognize a process deviation.

The Scheduled Process

As mentioned in the Introduction Section, “canned” products are treated with heat to make them commercially sterile. The condition of commercial sterility (or shelf-stability as it is characterized in the FSIS Canning Regulations -9 CFR 318.300 and 9 CFR 381.300) is recognized as follows:

> **Commercial Sterility** – The condition achieved by application of heat, sufficient alone or in combination with other ingredients and/or treatments, to render the product free of microorganism capable of growing in the product at nonrefrigerated condition (over 50°F or 10°C) at which the product is intended to be held during distribution and storage.

A condition of commercial sterility will result in products that are safe to eat because the pathogens of concern are destroyed or inactivated. The product will remain shelf-stable as long as the container is intact because any spoilage organism that favors the environmental conditions within the container (i.e., anaerobic) and normal storage temperatures (i.e., mesophilic bacteria) are also destroyed with the thermal process. The current FSIS Canning Regulations (9 CFR 318.300 and 9 CFR 381.300) refer to this condition as shelf-stability, but in this course we will refer to “canned” products as being commercially sterile to avoid confusion with the dry and semi-dry meat and poultry products that are also shelf-stable.

The application of heat to make a product commercially sterile is conducted in a controlled manner; this has been traditionally called the scheduled process or process schedule. The FSIS Canning Regulations (9 CFR 318.300 and 9 CFR 381.300) require that scheduled processes be established by a processing authority. A ***processing authority*** is a person or organization having expert knowledge of thermal processing requirements for foods packed in hermetically sealed containers and having adequate facilities to make these process determinations.

The scheduled process, as designed by a processing authority, if properly executed, will produce a commercially sterile product. The scheduled process, includes thermal processing parameters such as initial temperature of the product, the process temperature and the process time, plus any other critical factors that may affect the attainment of commercial sterility. Critical factors may include any characteristic, condition or aspect of a product, including formulation, container, preparation procedures, or processing system that affect the scheduled process. We will discuss critical factors again later in this section.

Processing authorities use their knowledge of food microbiology (specifically, thermobacteriology), heating characteristics of food, and processing systems as the basis for process schedule establishment. Contrary to other cooked meat and poultry products, the cook process for commercially sterile products is controlled by monitoring the process parameters (such as process temperature and time) rather than monitoring a temperature of the product. Temperature and time are easily controlled and monitored to ensure delivery of a proper thermal process.

For low-acid canned foods (those with a pH greater than 4.6), the thermal process focuses on the destruction of the spores of certain sporeforming bacteria. (These have been discussed in the previous section). The target pathogen for low-acid canned foods is *Clostridium botulinum* (specifically the spores of the organism.) Failure to destroy these spores, followed by germination and growth, can lead to the production of the deadly botulinum toxin, an extremely potent neurotoxin. Low-acid canned food processes that assure the destruction of *C. botulinum* spores are adequate to protect human health; however, as noted previously, a more substantial process, or a commercial sterility process, is required to destroy spores of other microorganisms that could germinate and grow under normal storage and handling conditions and cause economic spoilage. The target for commercial sterility is typically *C. sporogenes*, an organism very similar to *C. botulinum* but with a higher heat resistance.

Thermal processes for acidified foods are targeted toward vegetative cells of microorganisms and are generally significantly milder than those applied to low-acid foods. This is primarily because spores of microorganisms such as *C. botulinum* will not germinate due to the acid nature in the product. Keeping the spores from germinating will prevent the growth of the vegetative cells of *C. botulinum* and subsequent toxin production. In distinguishing between acidified and low-acid foods, the standard used is a pH of 4.6 (greater than 4.6 is low-acid and less than or equal to 4.6 is acid or acidified). Typical thermal processes for acidified foods will maintain the commercial sterility of a product as long as good sanitation and GMPs are followed. Lack of pH control for an acidified food can lead to problems if the pH is high enough to allow surviving spores of *C. botulinum* to germinate and produce toxin.

Determining the scheduled process with the proper temperature and process time needed to produce commercially sterile products has been the subject of years and years of study in the canning industry. Sound process determinations depend upon good knowledge of the :

1. nature of the product and how it heats;
2. container in which the product is packed;
3. details of the thermal processing procedures used; and
4. characteristics of the target microorganisms such as growth, survival, and thermal resistance.

These four factors are related to the thermal resistance of the microorganisms and the heating characteristics of the product. Utilizing all this information, the processing authority will establish a thermal process that will specify the amount of time at a specific temperature necessary to ensure the destruction of *C. botulinum* and spoilage organisms that may be present.

Establishing a Thermal Process

As mentioned previously, the processing authority will base the establishment of a thermal process for a particular food product on two separate factors: 1) the thermal (also known as heat) resistance of the microorganism of choice in that food and 2) the heating characteristics of the product. In simplified terms, the processing authority needs to know 1) how much heat and for how long is necessary to destroy microorganisms in the food product and 2) how fast does the product heat (in the case of conventional canning) or how does the product flow (in the case of aseptic processing). The combination of these two factors is used to establish the thermal process.

The establishment of the thermal process will also depend upon the method of processing: conventional canning or aseptic processing. As noted in the Introduction section, in conventional canning, the product is filled into the container, the container is hermetically sealed, and the container and product are thermally processed at a specified time and temperature to achieve commercial sterility. For aseptic processing, packages or packaging material and the food product are sterilized in separate systems. Product sterilization involves heating a pumpable product to a sterilizing temperature and holding it at that temperature for sufficient time to sterilize the product. The packaging materials are sterilized with heat, chemicals, radiation or a combination. The sterile package is then filled with sterile product, closed and hermetically sealed in a sterile chamber.

Once a process has been established for a particular food, it is specific for that particular set of parameters regarding formulation, preparation, thermal processing system, container, etc. Since a seemingly insignificant change in any of these parameters could result in under-processing, it is important that processes not be altered without consultation with a processing authority.

Thermal Resistance of Microorganisms

The thermal resistance of microorganisms (vegetative cells or spores) is dependent upon a number of factors: 1) the growth characteristics of the microorganisms, 2) the nature of the food in which the microorganisms are heated, and 3) the kind of food in which the heated microorganisms are allowed to grow. Because of the variability of any biological entity, thermobacteriology is a highly complex science, and variations in any of these factors can affect the heat resistance of microorganisms.

►Thermal Death Time (TDT) Tests

The amount of heat required to destroy microorganisms in a product can be determined through thermal death time (TDT) tests. TDT tests are conducted by thermobacteriologists in a laboratory. Very few food processing establishments have the facilities to conduct TDT tests on-site. The instrumentation and equipment used for TDT tests include TDT retorts, tubes, and/or cans; three-neck flask, oil baths, sealed plastic pouches, and/or capillary tubes. The equipment and instrumentation used will depend on the type of product being tested – whether it is low-acid, acidified, thick puree, solid or a liquid.

TDT tests involve heating a known amount of microorganisms in a buffer solution or food at several temperatures and for several time intervals at each temperature. The results from the TDT tests are used to calculate D- and z-values. These values are used to define the heat resistance of the microorganisms of concern.

►Determination of D- and z-values

In conducting TDT tests, the thermal characteristics (D- and z-values) of the microorganisms will be determined. The D-value is defined as the time at a particular temperature required to reduce a known number of microorganisms by 90% or to result in a 1-log reduction. This is also termed the decimal reduction time because exposure for this length of time decreases the population by 90%, thus shifting the decimal point in the number of microorganisms remaining one place to the left. For example, if you had 100,000 spores and if exposing them to a temperature of 240°F for 3 minutes reduced the count to 10,000 spores, the $D_{240°F}$ would be 3 minutes.
The D-value decreases as the temperature increases, since it takes less time to destroy the microorganisms at the higher temperature. By determining the D-values at various temperatures, a z-value can be determined from the slope of the line that results from plotting the log of D-values versus temperature. The z-value, indicative of the change in the death rate based on temperature, is the number of degrees between a 10-fold change (1 log cycle) in an organism’s resistance. As an example, suppose that z = 18°F and the $D_{232°F}$ = 3 minutes. The $D_{250°F}$ would be 0.3 minutes. (Because 232°F + 18°F = 250°F and 3 minutes / 10 = 0.3 minutes.) Both D- and z-values are indirectly used to establish thermal

processes.

►"Minimum Health" and Commercial Sterility Processes

Traditionally, a 12D process for spores of *C. botulinum* has been used to assure public health protection for low-acid canned foods. This has been based on historical data indicating that a heavy load of *C. botulinum* spores in a canned food product would be 10^{12} spores; therefore, a 12D reduction would provide a one-in-a-billion chance that a spore would survive in a canned food. For all practical purposes the 12D process is very conservative, as it is highly unlikely that spore loads of *C. botulinum* would approach these levels, especially in meat and poultry products. (Remember, *Clostridium botulinum* is rare in meats, and when present is there in very low numbers - 0.1 spore to 7 spores per kg meat.) A typical D-value for *C. botulinum* spore destruction in many foods is ~0.2 minutes at 250°F; therefore, a 12D destruction would be ~2.4 (=12 x 0.2) minutes at 250°F. (A value of 3 minutes is sometimes used to incorporate a margin of safety.) However in some products, the components of a food (or ingredients in a formulated food) can have adverse or beneficial effects on the thermal destruction of spores and will impact the D-values. For example, if 3 minutes at 250°F is needed to ensure public health at pH of 6.0, 2.0 minutes may be sufficient if the food is acidified to pH 5.3. (See discussion of F_o values on the next page.) Processing authorities refer to the times and temperatures needed to inactivate *C. botulinum* as "minimum health" processes because this is what is necessary for public health protection.

In order to attain commercial sterility, a thermal process more strenuous than that required for public health protection must be provided. Commercial sterility means the condition achieved in a product by the application of heat to render the product free of microorganisms capable of reproducing in the food at normal non-refrigerated conditions of storage and distribution. A commercial sterility process will destroy other spores in addition those of *C. botulinum*. These spores, if not destroyed, have the potential to grow under normal storage and handling conditions and cause economic spoilage, even though they pose no public health risk. A 5D destruction of *C. sporogenes* spores (such as PA3679) is the target for commercial sterility. This 5D process for *C. sporogenes* spores is more lethal than a 12D process for *C. botulinum* spores due to the fact that spores of *C. sporogenes* are more heat resistant than spores of *C botulinum*.

In order to compare thermal processes calculated for different temperatures, a standard F_o value is assigned for each product. This F_o value is the time in minutes (at a reference temperature of 250°F and with a z = 18°F) to provide the appropriate spore destruction (minimum health protection or commercial sterility). As previously noted, using D- and z-values, this reference value at 250°F can be converted to other temperatures. Due to a variety of factors (e.g., influence of the food on the destruction of spores) different foods will have different F_o values. For example, if an F_o of 6 minutes is needed to ensure commercial sterility at pH of 6.0, an F_o of 4 minutes may be sufficient if the food is acidified to pH 5.3. In cured meat products containing 150 ppm nitrite and 3-4% brine (% NaCl X 100/ % NaCl + % water), an F_o of 0.3–1.5 minutes may be sufficient to render the product commercially sterile.

F_o values are already established for many food products. However, there are times, such as for novel formulas of food products, when TDT work may be needed to determine D- and z-values and appropriate F_o values for spores of *C. botulinum* and *C. sporogenes* for a specific product. In the absence of TDT data on a specific formulation, a processing authority will apply a conservative F_o that is known to result in a safe product.

Product Heating Data Determinations

Processing authorities determine product heating characteristics through the use of heat penetration tests. The rate at which a product heats can be measured using devices to monitor the rate of change in temperature of the food as it is being heated within the container (heat penetration studies). These determinations are made with a temperature sensor or thermocouple located in the product at the slowest heating region of the container. The slowest heating region will depend on the type of product, container size, processing method and the heat transfer mechanism. Typical heat transfer mechanisms in canned foods are convection (heat current flowing within the container as experienced in canned broths), conduction (molecule to molecule as experienced in corned beef hash), and combinations (for example, convection then conduction due to thickening of the product as maybe experienced in formulated products such as chicken and dumplings). The number of containers per run and the number of runs necessary to ensure the data are adequate depends on the variability of the product and the processing system. When either demonstrates significant variability, additional containers/runs may be required to ensure confidence in the process.

The need to simulate the worst case scenario likely to occur when producing product cannot be overstated, because the thermal process is controlled by monitoring and controlling the process parameters rather than with the actual temperature of the product. The processing authority will review variables in product preparation such as changing a starch or protein in the formulation, filling procedures, rehydration procedures, etc., to determine the impact on the heating rate of the product. More viscous product, higher fill weights, or improperly rehydrated product can all affect the heating rate of the product. If the heat penetration tests do not account for this effect or if the establishment can not control for these variations, the result could be under-processed product.

The heating characteristics of the product aseptically processed are also important. For aseptic processing, the heated product flows at a constant rate through tubing of a specified length; it is the flow characteristics of the product that determine whether certain particles in the fluid stream move through the tubing faster than others. The speed of the fastest moving particles (which remain at the elevated temperature for the shortest time) and the temperature of the flowing product determine the heat (lethality) attained by the product.

Process Schedule Calculations

For conventionally canned products, the process authority will calculate a process using the product heating data and the thermal resistance data for the significant spoilage organisms or organisms of public health consequence expected to be present in the product. These mathematical procedures combine the F_o value that provides commercial sterility with the factors that define the product heating rate. There are several acceptable methods for calculating thermal processes. Some of the more common methods are the General Method, the Ball Formula Method, and the NumeriCAL™ Method.

For aseptically processed products, the process authority will calculate a process using the flow characteristics of the product and the thermal resistance data for the significant spoilage organisms or organisms of public health consequence expected to be present in the product. The resulting process schedule will indicate a specific sterilization time or residence time at a specific temperature. The residence time is directly related to the rate of flow of the fastest moving particle/fluid stream through the system.

Although the method of characterizing the product heating rate is different for conventionally canned and aseptically processed products, the F_o value for a particular food is the same in either processing method.

ACIDIFIED FOODS

Products that are high acid (have a low pH) or are acidified to a pH of 4.6 or less do not require a high temperature process. The foods may be processed at the temperature of boiling water – 212°F (100°C) – or lower. The thermal process is designed to destroy vegetative cells and some spores of low heat resistance. The product's low pH (4.6 or less) will prevent the remaining spores from growing out.

To produce products with a pH of 4.6 or less, acidification must be properly carried out. Here are some methods to obtain properly acidified foods.

1. **Blanch the food ingredients in an acidified aqueous solution.** To acidify large food particulates, the particulates could be blanched in a hot acid bath. The ability to obtain a properly acidified product is dependent upon blanch time and temperature, as well as the type of and concentration of acid.

2. **Immerse the blanched foods in an acid solution.** That is, blanch the product in the normal steam or water blancher. Then, dip it into an acid solution, remove it from the acid solution and place it into containers. Proper acidification depends upon how well the product is blanched, the concentration of the acid and the contact time.

3. **Direct batch acidification.** This is normally the best way to acidify fluid material. Ingredients are mixed in a kettle, and acid is added directly to the batch. (An elevated temperature may improve the rate of acid penetration into solid particles.) The pH of the batch is checked before the material is sent from the batch kettle to the filler.

4. **Add acid foods to low-acid foods in controlled portions**. Essentially, this is how a formulated product such as pasta sauce is made. Components in the sauce, such as meat or onions, are low-acid foods, while the tomato sauce is an acid food. The acid food is mixed with the low-acid food to get an acidified food product. The formulation, including the proportion of tomato sauce to low-acid components, is critical to obtain uniform and accurate control of pH of the finished product.

5. **Directly add a predetermined amount of acid to individual containers**

during production. This involves addition of acid pellets, known volumes of acid solution, or some other means for direct acidification of each container. This is probably the most inaccurate and least consistent method of acidification, because acid addition to a given container may be overlooked. Although this is a permissible way to acidify, it is not recommended and it is not used for meat and poultry products.

Processes for acidified foods may involve a hot-fill-hold process or the conventional canning process. Hot-fill-hold processing involves filling the product hot, sealing the container, then holding filled containers for a period of time at or above a certain temperature before cooling. Acidified products may also be processed in a pasteurizer, atmospheric cooker or retort for a given period of time to destroy the target microorganisms. The processing authority will calculate a process using pH, fill temperature, and the thermal resistance data for the significant spoilage organisms.

INOCULATED TEST PACK

It is possible and sometimes desirable (e.g., with new products or new processing systems) to confirm the calculated process by means of inoculated test packs. In this procedure, the test product is prepared under commercial plant operating conditions. Appropriate test microorganisms of known heat resistance are added to the product. (It is undesirable to use *C. botulinum* spores in processing plants processing low-acid canned foods due to the risk associated with the potential toxin production.) The product is inoculated with a known number of microorganisms and is then subjected to various processing times at one or a number of different processing temperatures. The product is then incubated at an appropriate temperature for growth of the test organism. Product that received a process inadequate to destroy the added microorganisms will show evidence of spoilage. A satisfactory process is demonstrated by the absence of spoilage. Substantial agreement between calculated processes and those determined by inoculated packs furnishes the strongest possible assurance of the adequacy and safety of a particular process.

Occasionally, due to peculiarities of the thermal processing systems or the product, reliable heating data cannot be obtained. Under these circumstances, consideration may be given to using an inoculated pack alone to establish a safe thermal process.

Process Deviations

A deviation in processing (or a process deviation) occurs whenever an actual thermal process is less than the scheduled process (or process schedule) or when any critical factor does not comply with the requirements for that factor as specified in the process schedule. Common causes of process deviations for traditional canning operations include failure to meet initial temperature, process time, or retort temperature requirements or failure to meet any other specified critical factor. For aseptic processing and packaging systems, deviations can result from improper hold tube temperature, flow rate, or package sterilization; breach of the aseptic zone; etc. According to FSIS regulations (9 CFR 318.308 and 381.308) deviations involving meat and poultry products may be handled in accordance with a HACCP plan for canned product that addresses hazards associated with microbial contamination or alternative documented procedures that will ensure that only safe and stable product is shipped in commerce. Otherwise, deviations must be handled in accord with procedures specified in paragraph (d) of the regulations.

Product involved in deviations identified during processing may be immediately reprocessed using the full scheduled process, may be given an appropriate alternate process established in accordance with FSIS regulations, or may be held for later evaluation by a processing authority to determine its safety and stability. It should be kept in mind that, in some cases, the original process may change the heating characteristics of the processed product (e.g., thickening due to starch). For this reason it is a good idea to consult with the processing authority to assure that the reprocess is adequate for the product and conditions of use.

Upon completion of the evaluation of the process deviation, the establishment maintains a complete description of the deviation along with all necessary supporting documentation; a copy of the evaluation report; and a description of any product disposition actions, either taken or proposed. Product handled in accordance with paragraph (d) of the regulations shall not be shipped from the establishment until the inspection personnel have reviewed all of the information submitted and the product disposition actions.

If an alternate process schedule is used that is not on file with the inspector or if an alternate process schedule is immediately calculated and used, the product shall be set aside for further evaluation as noted above.

Product involved in process deviations that are identified through review of processing and production records shall be held and the deviations evaluated by a processing authority in accord with the requirements noted above. If product involved in a deviation is destroyed, destruction shall be conducted in accordance with FSIS regulations.

FSIS regulations also require the maintenance of a process deviation file. The establishment shall maintain full records regarding the handling of each deviation, regardless of the seriousness of the deviation. Such records shall include, at a minimum, the appropriate processing and production records, a full description of the corrective actions taken, the evaluation procedures and results, and the disposition of the affected product. Such records shall be maintained in a separate file or in a log that contains the appropriate information. The file or log shall be retained for no less than one year at the establishment, and for an additional 2 years at a suitable location. The file or log shall be made available to inspection personnel upon request.

Workshop: Process Letter Review

Note: This is a simplified example prepared for instructional purposes only.

Review the following process letter and answer the questions.

1/24/2005

Dr. John Smith
Food Safety Manager
Uncle Sam's Canned Goods Company
1234 E. Canning Plant Rd
Somewhere, ST 12345-1234

Dear John,

Based on the heat penetration data that you provided to us, we would recommend the following thermal processes for your **Chili No Beans** in 300X407 metal cans.

Processing Conditions

Product:	**Chili No Beans**
Processing System:	Water Immersion with Container Rotation
Container Size:	300x407 metal cans
Least Sterilizing Value (F_o)	5.3
Critical Factors:	
Fill weight of fully soaked beans:	**10.0 ounces**
Container orientation:	**Vertical**
RPM:	**18-20**
Headspace (inches):	**10/16**
Product:	**Preparation method and Formulation**
Minimum come up time (minutes):	**13**

Process Time in Minutes

	Process Time (minutes at Retort Temperature (°F))		
Initial Temp. (°F)	**250**	**251**	**252**
90	**40**	**39**	**38**
100	**39**	**38**	**37**
110	**38**	**37**	**36**
120	**38**	**37**	**36**

These processes are designed to produce a commercially sterile product provided that all processing and packaging operations are completed satisfactorily. Please give us a call if you have any further questions.

Sincerely yours,

Kelly White
Senior Scientist, TPA, Inc.

Questions:

1. What are the critical parameters that will need to be controlled by Uncle Sam's Canned Goods Company when processing this product?

2. There are several errors on the process letter. Please identify the errors or information that needs to be clarified.

3. What would be the impact if the headspace requirement was not met?

4. What would be the impact if the beans were not soaked?

5. What process time would Uncle Sam's Canned Goods Company use if the product initial temperature was 115°F and the retort was operated at 252°F?

Uncle Sam's Canned Goods Company has set the following as the operating process for this product:

Minimum IT = 100ºF
Minimum Retort Temperature = 252ºF
Minimum Process Time = 40 minutes

6. Would the operating process result in a higher or lower Fo than the scheduled process? Why would the firm use an operating process rather than a schedule process?

7. Which of the following situations is a processing deviation?

IT = 90ºF RT = 250ºF Process Time = 40 minutes	IT = 100ºF RT = 251ºF Process Time = 42 minutes	IT = 112ºF RT = 249ºF Process Time = 42 minutes

IFTPS

Institute For Thermal Processing Specialists

NOMENCLATURE FOR STUDIES IN THERMAL PROCESSING

Various symbols have been employed to represent measured and derived variables in the applications of thermal processing science. The overall objective of these guidelines is to recommend a standard system of nomenclature for thermal processing applications. **The following recommendations are to be considered voluntary guidelines.** While this does not preclude the use of other symbols, these guidelines have been developed by consensus of the Institute for Thermal Processing Specialists and should be given serious consideration for adoption by individuals involved in thermal processing studies

a_w - Water activity defined as the ratio of the partial pressure of water above a food to the water vapor pressure of pure water above a food (p) to the water vapor pressure of pure water (p_o) at a given temperature ($a_w = p/p_o$)

A - Frequency factor in the Arrhenius equation, $K = A \exp(-E_a/RT)$ where T is expressed in Kelvin

c - Cook rate, $c = 10^{(T - T_x)/z}$

C - Concentration of a nutrient or chemical component

C_T^z - Cook value used to relate a high temperature thermal process to an equivalent process at stove top temperatures, generally applied with T=100°C (212°F) and a z-value related to quality attributes

D_T - Decimal reduction time equal to the time at a given temperature, T, for a survivor curve to traverse one log cycle or equivalently, to reduce a microbial population by 90%, $t = D_T(\log N_o - \log N)$

E_a - Activation energy in the Arrhenius equation, $K = A \exp(-E_a/RT)$, $E_a = 1.8*2.303*R*T_x*T/z$ where T_x and T are expressed in Kelvin

f - Temperature response parameter equal to the time for the linear section of a heating or cooling curve plotted on semi-log coordinates to traverse one log cycle

f_2 - Temperature response parameter of the second straight line segment of a broken heating curve

f_c - Temperature response parameter derived from the cooling curve

f_h - Temperature response parameter derived from the heating curve

F - Time intercept from a thermal death time curve (log t_{gm}vs T) at $T = T_x$

F_T^z - Accumulated lethality to reflect the total lethal effect of heat applied; expressed as equivalent minutes at a specific reference temperature for a specific z-value, $F_T^z = D_T(\log N_o - \log N_f) = D_T Y_N$; may also be referred to as F-biological

F_c - Accumulated lethality in the cooling phase

F_h - Accumulated lethality in the heating phase

F_i - Factor relating the lethality at the retort temperature to lethality at the reference temperature, $F_i = 10(T_x - T_r)/z$

F_o - Accumulated lethality when T_x = 121.1°C (250°F) and z = 10 C° (18 F°)

F_s - Integrated lethal or degradative capacity of heat received by all points in a container during a process

F_λ - Accumulated lethality at an iso-j surface

g - Unaccomplished temperature difference, $g = T_r - T_c$

g_c - Unaccomplished temperature difference at the end of the heating period, $g_c = T_r - T_{ic}$

g_{bh} - Unaccomplished temperature difference at the intersection of f_h and f_2 for a broken heating curve

g_{ih} - Initial unaccomplished temperature difference, $g_{ih} = T_r - T_{ih}$

g_{λ} - Unaccomplished temperature difference at an iso-j surface

I_r - Ratio of the log of the straight line survivor curve zero intercept to the initial spore count (N_o)

j_c - Cooling lag factor, $j_c = (T_w - T_{pic})/(T_w - T_{ic})$

j_{cl} - Cooling lag factor associated with an iso-j surface

j_h - Heating lag factor, $j_h = (T_r - T_{pih})/(T_r - T_{ih})$

k - Reaction rate constant for base 10 logarithms

K - Reaction rate constant for base e (natural) logarithms; death rate constant in the Arrhenius model, K = 2.303/D

L - Lethal rate expressed as minutes at the reference temperature per minute at the product temperature, $L = 10(T - T_x)/z$

m - Unaccomplished temperature difference during cooling, $m = T_c - T_w$

m_{ic} - Value of m at the beginning of the cooling cycle, $m_{ic} = T_{ic} - T_w$

n - Number of samples

N - Number of surviving microorganisms

N_o - Initial number of viable spores or vegetative cells before heat is applied, initial bioburden

N_f - Final number of surviving spores or vegetative cells after heat is applied

N_{mp} - Most probable number of survivors in a thermal resistance experiment

N_s - Number of microbial cells remaining after a preservation treatment to a specified probability of finding a non-sterile unit; end point process specification

pH - The degree of acidity or alkalinity of a water solution

- Pasteurizing value used in place of F-value for pasteurizing processes

P - Pasteurizing value defined as the accumulated lethality when T_x= 60°C (140°F) and z = 10 C°(18 F°)

R - Number of negative responses in a thermal resistance experiment

R - Universal gas constant, 1.987 cal/mol×K, 8.314 J/mol×K where K refers to Kelvin temperature units

t **- Time**

t_B - Ball's process time, $t_B = t_p + 0.42\ t_c$ simple heating, $t_B = f_h(\log j_h g_{ih} - \log g_c)$ broken heating, $t_B = f_h \log j_h g_{ih} + (f_2 - f_h)\log g_{bh} - f_2 \log g_c$

t_c - Come-up time is the time between the start of heating and the time when the retort reaches processing temperature

t_D - Time when the first sample exhibiting no growth is observed in a thermal death time (TDT) experiment

t_p - Process time is the time from the end of the come-up period to the end of heating, defined as $t_p = t_B - 0.42\ t_c$ in the Ball Formula Method

t_S - Time when the last sample exhibiting growth is observed in a thermal death time (TDT) experiment

t_{bh} - Time measured from $t_B = 0$ to the intersection of f_h and f_2 for a broken heating curve

t_{gm} - Geometric mean time, square root of (t_S * t_D)

T - Temperature

T_c - Container center or coldspot temperature

T_{ic} - Product temperature at the start of the cooling cycle

T_{ih} - Initial product temperature measured before heating

T_{pic} - Pseudo-initial cooling temperature determined by extrapolating the linear portion of a cooling curve to the start of cooling

T_{pih} - Pseudo-initial heating temperature determined by extrapolating the linear portion of a heating curve to time, $t_B = 0$

T_r - Retort temperature

T_s - Mass average temperature

T_w - Cooling water temperature

T_x - Reference temperature

U - Sterilizing value in terms of minutes at the heating medium temperature, $U = F_oF_i = F_o/L$

Uc - Sterilizing value for the cooling phase

Uh - Sterilizing value for the heating phase

Y_N - Spore-log reduction, $Y_N = \log N_o - \log N_f$

Y_s - Spore-log reduction to reach a specified probability of finding a non-sterile unit, $Y_s = \log N_o - \log N_s$

z - Number of degrees of temperature required for the thermal death time curve (log F vs. T) or thermal resistance curve (log D_T vs T) to traverse one log cycle, $z = (T_x - T)/(\log F_T - \log F_{Tx})$ or $z = (T_x - T)/(\log D_T - \log D_{Tx})$

a - Thermal diffusivity, a =thermal conductivity/(specific heat * density), is inversely proportional to f_h where the proportionality constant is related to the container geometry

r - Fraction of total lethality delivered during heating, $r = U_h/(U_h + U_c)$ or $r = F_h/(F_h + F_c)$

- The Institute for Thermal Processing Specialists is a non-profit organization established exclusively for the purpose of fostering education and training for those persons interested in procedures, techniques and regulatory requirements for thermal processing of all types of food or other materials, and for the communication of information among its members and other organizations.

- Part of the mandate of the IFTPS Committees is to develop protocols to be used as guides for carrying out the work of thermal processing specialists. This is the first such protocol prepared by the Committee on Temperature Distribution and reviewed extensively by members of the Institute. The protocol has been approved by the Board of Directors. **This document may be photocopied in its entirety for use.**

- Single copies of the protocol, as well as information on membership in IFTPS may be obtained from: Institute for Thermal Processing Specialists, 304 Stone Rd. W. Ste. 301, Guelph, ON N1G 4W4 Phone: (519) 824 6774 Fax: (519) 824 6642, E-Mail: info@iftps.org

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FOOD SCIENCE 4075
LAB_____
THERMAL PROCESS CALCULATION

WARNING: This lab contains at least 28 pages - you may not want to print the entire thing - just what you need.

PURPOSE: Demonstrate the techniques involved in determining the processing time and temperature for canned food products.

MATERIALS: Two food products; one heavy, semisolid and one more liquid, cans, thermocouples, multipoint recorder, retort, sealer

PROCEDURE: In order to determine the processing time for a certain size container with a 'specific' product; two things must be known: (1)the lethality of the microorganisms which may cause spoilage; and (2)the manner of heat penetration in the canned product. For non-acid foods the organism in question is *Clostridium botulinum* and the thermal lethality of this organism is well documented. For acid foods any number of other organisms become more important, some of which are even more resistant than *C. botulinum*. All that remains is to determine the manner of heat penetration into the product in the specific size container.

1. Install copper-constantan thermocouples into the sides of the can. The thermocouples must be placed at the coldest point in the can. For heavy thick products, the coldest point is the geometric center of the can. For very dilute water-like products, because of convection heating the cold point is below the geometric center of the can and is determined by experimentation. As a general rule, with smaller cans (eg. 303 x 406) the cold point is about 0.75 inch above the bottom, assuming the can is standing upright. For large containers (like a No. 10) the cold point is about 1.5 inches above the bottom.

2. Fill two cans with each product, exhaust and seal in a closing machine. Place cans upright into the retort and attach the thermocouple extension wires. Connect the other ends of the wires to a data logger or multipoint recorder for temperature recording.

3. Set temperature controls on retort and begin the process. <u>Note when steam was turned on</u> (mark on the chart paper or circle data logger time). Also note time when venting is finished and when retort operating temperature RT is achieved, as measured by the mercury-in-glass thermometer. <u>[It is convenient to also use a stopwatch here to measure the time between steam on and time when operating temperature is reached on the glass therrmometer.</u> This will be used later for determining adjusted 0.] Rapid heating products should be scanned rapidly (every minute or so) while slower heating products can be scanned at longer intervals. Continue heating until the can temperatures are within about 2 degrees of the retort temperature. Turn off steam (noting the time) and begin cooling

cycle. When cans are about 100-120°F, open retort and remove.

4. Prepare a table of "time after steam on" versus can temperature in convenient time units. For example, for conduction heated foods you might use 2, 4 or 8 minute increments. For convection heated foods, you might use 0.5 or 1 minute increments. If there are two samples of each product, just average the temperatures of the two samples at each time reading. To determine the process timing points, you can use the times printed on the data logger tape or, if using a multipoint recorder, you must determine the times using the chart speed and the gage lines on the paper. For instance, if the chart speed was 15 inches per hour and the chart gradations are 0.5 inch, then each gradation represents 2 minutes. **Time=0 is the point at which steam was turned on**. The time at which the retort reaches the operating temperature as indicated on the mercury-in-glass thermometer is the "come-up time".

5. There are two ways of calculating the process time for a product: the graphical method; and the formula method (SEE ATTACHMENT - for complete descriptions, and then some!). We will use the formula method. The heat penetration data is plotted on 3 or 4 log cycle semi-log graph paper - 3 cycle paper is included as the last page of the attachments or you may purchase semi-log paper at the book store - eg. National Brand Engineering Form 12-183. Temperature (IN DEGREES F) is plotted on the log scale and time (IN MINUTES) on the linear scale. Note: For plotting this data, the paper is inverted (i.e. turned upside down) compared to the normal way semi-log paper is used. Start numbering the log cycles on the Y-axis (on the left side) with the temperatures beginning at the top line and continuing downward. See example listed as Fig. 1 in the attached sheets. The very top line should be 1°F lower than the retort temperature. For example if the RT=245˚F then the first line would be 244˚F. Proceed with temperatures downward --- remember this is log paper so there will be a step change every 10 lines.
The lower linear time scale (X-axis) should begin in the lower left corner with time 0. On the right hand side (Y2-axis), if not already printed for you[but upside down], number the typical log values starting with 1.0 on the top line which represents 1°F below RT. Proceed downward to 1000 for 3 log cycle paper. This axis represents **degrees below retort temperature**. If the axes are labeled correctly then values on the left scale should be equal to the retort temperature minus the values on the right scale directly across.
Plot the points from your table on the chart paper. Try to draw a line through the maze of dots so that it is within 1 degree or so of all points. Hopefully the plot will be mostly a straight line except for an initial lag in the first 5 minutes or so and a tail which trails off upward or sideward near the end (you can disregard these points). You will need at least 6 to 10 points to get a reasonable estimate of the regression line. Some products exhibit a broken curve heating in which two intersecting lines must be drawn through the points (see Fig. 2 in attached sheets). Pray that this does not happen for your product.
We need to get two data points from this plot: j, the lag factor; and f_h, the slope.

6. First determine "corrected 0 time". To do this you must find the total time it took for the

retort to “come up” to the operating temperature from “time on”. Find the time on the X axis which represents 0.60 of the total come-up time in the retort after steam-on (or conversely 0.40 of the come-up time before steam-up). Draw a vertical line upward from this point until it intersects the straight line you drew in step 5. The temperature at the point of intersection can be read from the temperature scale at the left and this value is subtracted from the retort operating temperature RT to get jI. Alternatively, jI **can be read directly** from the scale on the right which is degrees below RT. The initial temperature of the product in the can before retorting is IT. First calculate I = RT-IT, then calculate j = jI/I from the jI of the graph and I from the previous calculation. The value j must be corrected if cans are small and the product is a **conduction heated** type. To do this, multiply the calculated value by the appropriate "Correction factors for j" found in the attached handout = $j_{corrected}$.

7. To determine f_h count the minutes required for the drawn regression line to pass through one log cycle (change by a factor of 10 eg. from 10 to 100 or 5 to 50) of temperature on the left scale. Remember this is 3 log cycle paper.

8. To calculate the processing time we will assume *C. botulinum* is the problem organism and we will want a desired value F_{250} or F_o=2.45 min. Find F_i for the actual operation temperature [if not 250°F] used from table 4 in handout. Then calculate

$$(f_h/U) = \quad f_h/(F_o \times F_i)$$

with this value of (f_h/U) go to table 3 and find the value of log g corresponding to the f_h/U.

9. The processing time (B_B) in minutes is found by

$$B_B = f_h\ [\log (j_{corrected} \times I) - \log g]$$

SOME CAUSES OF UNRELIABLE HEAT PENETRATION DATA

The following is a partial list of some factors that have been associated with unreliable heat penetration data.

1. Thermocouple readings not continued for a sufficient length of time to adequately define heating rate or rates.
2. Heat penetration test conducted in a retort load of commercial production and stopped at the end of the scheduled process for quality determinations, rather than continued long enough to obtain sufficient data.
3. Frequency of readings not sufficient to obtain accurate heating rate or rates.
4. Erroneous temperatures received as a result of inadequate electrical grounding of potentiometer.
5. No initial temperatures taken on the test cans.
6. No notation of retort come-up time, or a come-up time significantly different from

that used in commercial practice.

7. Multiple thermocouples in small cans of product.
8. No coldspot study, or insufficient number of replicates at the coldspot thermocouple location.
9. No time notation on temperature recorder.
10. No notation of "steam on" for test.
11. No free lead reference.
12. No mercury thermometer readings.
13. Erratic processing temperature control during test.
14. Critical factors associated with product and processing system not recorded and controlled.
15. Large temperature disagreement between thermocouple free lead and mercury thermometer.
16. Initial temperature of test cans significantly different from that used in commercial production.
17. In agitating retorts, rotation speed incompatible with commercial production.
18. No complete can-position study in rotating-cage retorts.
19. Excessive delay in running test after containers are sealed.
20. Product for tests not prepared according to procedures used commercially for raw product preparation or condition.
21. Large difference in processing temperatures between heat penetration tests and commercial practice.
22. One unexplained abnormally-slow-heating can within a group of cans.
23. Erratic and illogical thermocouple readings.
24. No readings taken until processing temperature is reached.

DISCUSSION QUESTIONS:

1. What are some factors which influence thermal resistance of micro-organisms?
2. What are some factors which influence heat penetration into a canned product?
3. How is thermal resistance determined?

ATTACHMENT

Plotting Heat Penetration Curve

Heat penetration data are usually plotted on three cycle semilogarithmic paper. Temperature is represented on the logarithmic scale and time on the linear scale. If the graph paper is inverted, the temperatures can be plotted directly as shown in Figure 1 for a straight line heating curve and in Figure 2 for a broken heating curve.

The temperatures should be numbered from the top down starting with 1° be low the retort temperature. The time divisions should be numbered from left to right starting with 0 and ending with the time at which the test was ended.

Plot the temperatures for the corresponding time. Inspect the data plotted. Simple heating curves consist of a lower portion which rises slowly in temperaturetime. This is the lag when the container outside is heating rapidly but the product in the cold zone is not receiving heat. When the product in the cold zone begins to receive heat, the temperature rises logarithmically. For straight convection or conduction heating products, a single straight line can be drawn to the data points. This fine is known as the heat penetration curve.

PROCESS CALCULATIONS

The symbols used here are consistent with those used in the industry for many years. it is assumed that time and temperature data have been obtained by heat penetration tests or that heat penetration factors for the product involved are available. Values for the parameters m+g and z have been taken as 180°F and 18°F, respectively. All tables and graphs are based on these values. See definition of terms and symbols at end of this chapter.

Methods of Analyzing Data

After time and temperature data for a given product in a given can size have been obtained by heat penetration studies, these data may be analyzed by either of two methods:

(1)The "general" or "graphical" method.

(2)The "formula" method.

The two methods of determining process times or levels are based on identical principles but the mechanics or procedures used are different. Each method has its own advantages. The choice of methods may be governed by the following conditions:

The graphical method is used when it is desired to measure the exact sterilizing value of a process, when such conditions as come-up time, cooling water temperature, or the holding time after processing but before water cooling are different from normal retorting procedures. This method is also adapted to conditions when the heat penetration curve cannot be represented by one or two straight lines within the lethal temperature range on semi-logarithmic paper. It is not readily adapted to the calculation of processes when the retort temperature and/or initial temperature are different from those under which the heating data were obtained. Time and temperature data during the cooling cycle as well as the heating cycle must be recorded in order to use the graphical method. The graphical method is not applicable to air cooled products.

The formula method is used when the heat penetration curve can be represented by not more than two straight lines on semi-logarithmic paper. The formula permits evaluating processes for retort and initial temperature conditions differing from those under which the heating data were obtained. In the case of heating curves represented by one line only on semi-log paper, the heat penetration factors can be converted to different can sizes. The various methods of calculating processes win be described in detail.

Standards

It is first necessary to set up a standard sterilizing value. The greatest interest in processing canned foods is with low-acid products. With such foods, 250°F has been generally established as the reference temperature and the lethal heat expressed in terms of minutes at 250°F. This reference temperature will be used here.

The Graphical or General Method

As mentioned above, the lethal heat of a process is expressed in minutes at 250 degrees F. One minute at 250 degrees F or an equivalent amount of heat is defined as one unit of sterilizing value. The symbol for sterilizing value is Fo.

Temperatures other than 250°F have lethal heat. Under conditions used here. one minute at 250°F is equivalent to 10 minutes at 232°F or 100 minutes at 214°F. In other words. for each 18° drop in temperature the time necessary to obtain the equivalent bacterial destruction increases ten times.

The lethal ratio (Fo/t) or the sterilizing value effective in one minute at other temperatures (T) can be expressed mathematically as:

$$F_0 = \frac{1}{\log^{-1} \dfrac{(250 - T)}{(18)}}$$

Lethal rate values in the range 200°F to 260°F are shown in Table 1.

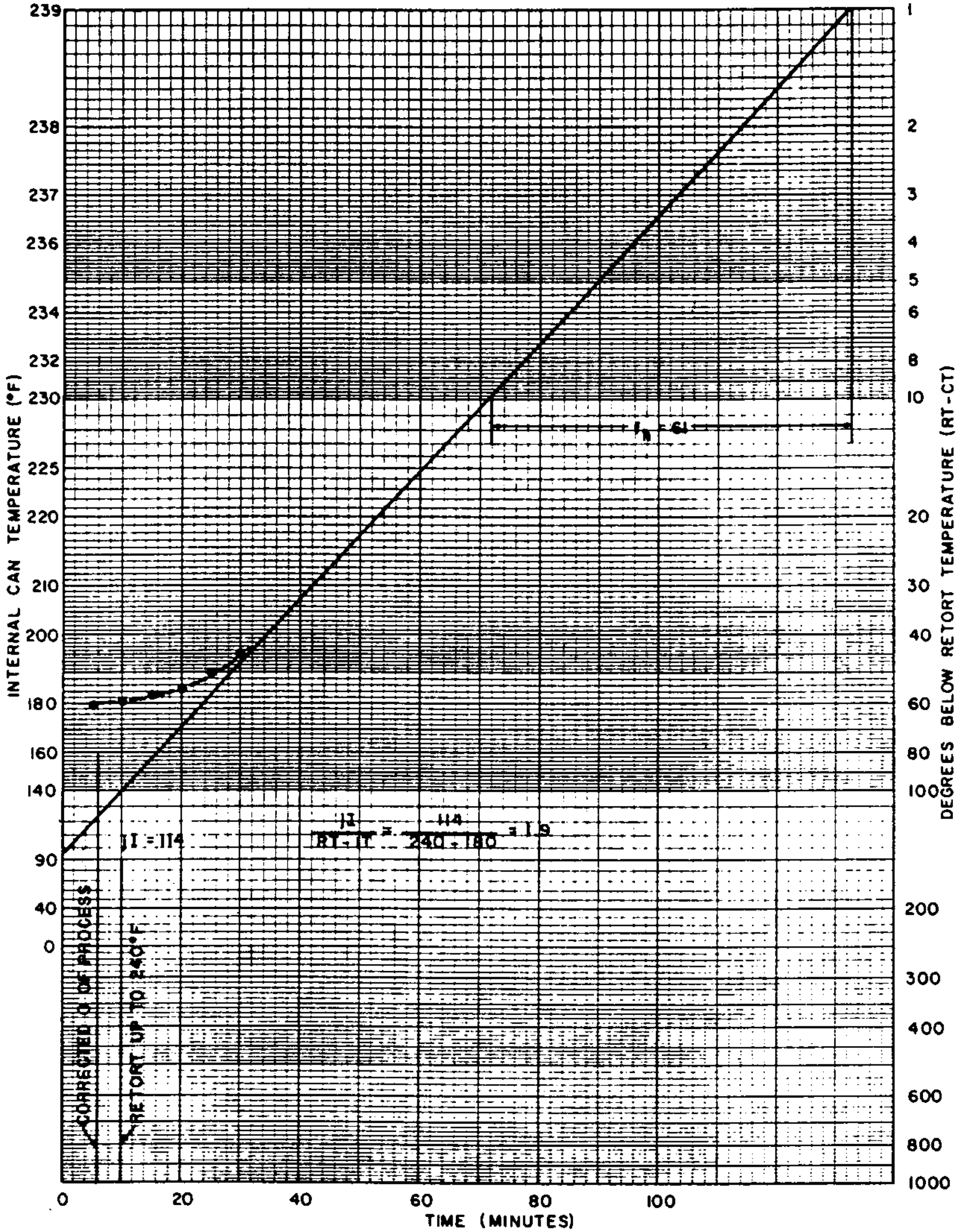


Fig. 1
Plot of a simple heating curve.

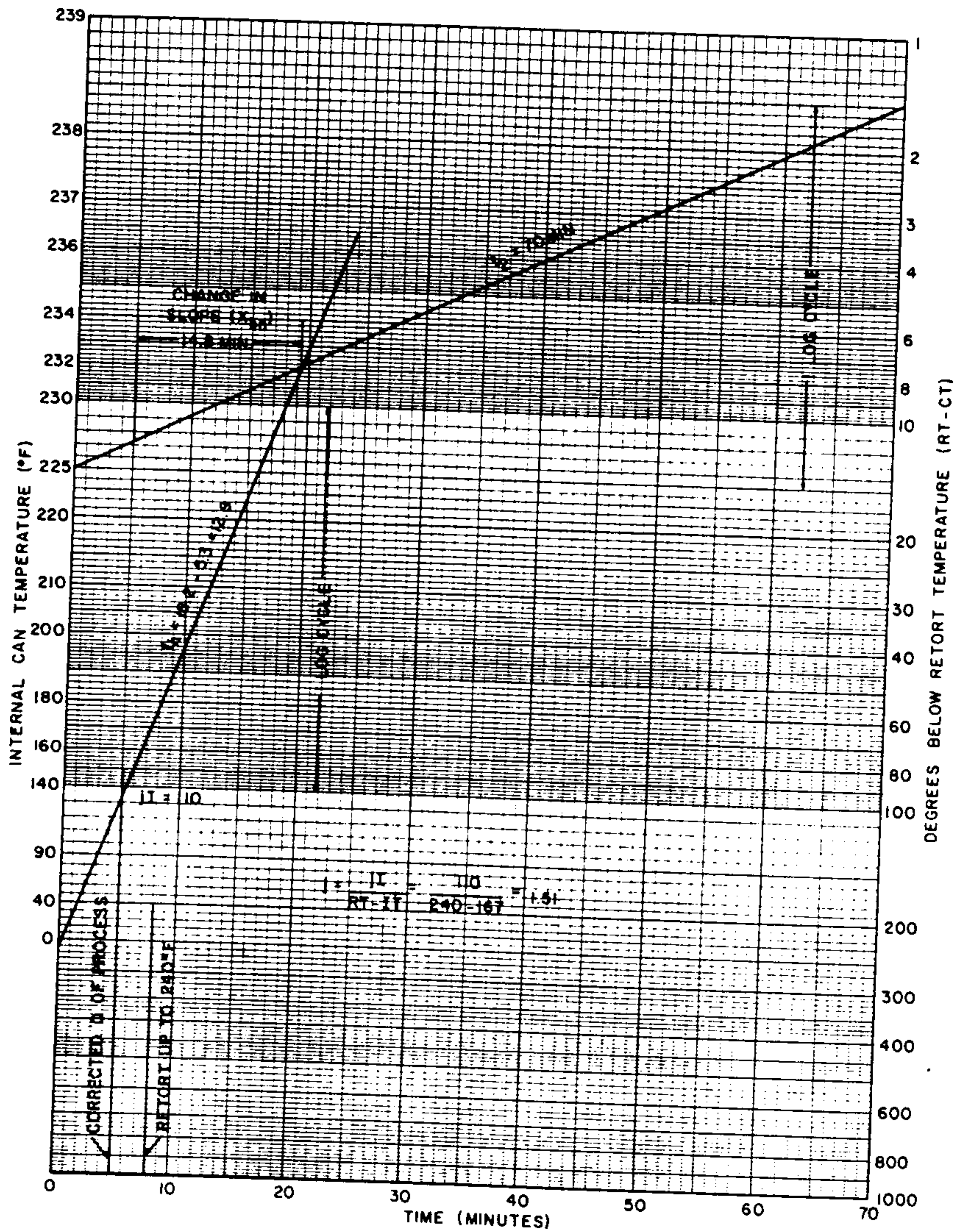


Fig. 2
Plot of a broken heating curve.

Table 1
LETHAL RATES
(For z equals 18)

TEMP °F.	(tenths of degrees F) 0.0	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9
190	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.001	0.001
191	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
192	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
193	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
194	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
195	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
196	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
197	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
198	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
199	0.001	0.001	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002
200	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002
201	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002
202	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002
203	0.002	0.002	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
204	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
205	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.004	0.004
206	0.004	0.004	0.004	0.004	0.004	0.004	0.004	0.004	0.004	0.004
207	0.004	0.004	0.004	0.004	0.004	0.004	0.004	0.004	0.005	0.005
208	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005
209	0.005	0.005	0.005	0.005	0.006	0.006	0.006	0.006	0.006	0.006
210	0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.007	0.007	0.007
211	0.007	0.007	0.007	0.007	0.007	0.007	0.007	0.007	0.008	0.008
212	0.008	0.008	0.008	0.008	0.008	0.008	0.008	0.008	0.009	0.009
213	0.009	0.009	0.009	0.009	0.009	0.009	0.010	0.010	0.010	0.010
214	0.010	0.010	0.010	0.010	0.011	0.011	0.011	0.011	0.011	0.011
215	0.011	0.012	0.012	0.012	0.012	0.012	0.012	0.012	0.013	0.013
216	0.013	0.013	0.013	0.013	0.014	0.014	0.014	0.014	0.014	0.014
217	0.015	0.015	0.015	0.015	0.015	0.016	0.016	0.016	0.016	0.016
218	0.017	0.017	0.017	0.017	0.018	0.018	0.018	0.018	0.018	0.019
219	0.019	0.019	0.019	0.020	0.020	0.020	0.020	0.021	0.021	0.021
220	0.022	0.022	0.022	0.022	0.023	0.023	0.023	0.024	0.024	0.024
221	0.024	0.025	0.025	0.025	0.026	0.026	0.026	0.027	0.027	0.027
222	0.028	0.028	0.029	0.029	0.029	0.030	0.030	0.030	0.031	0.031
223	0.032	0.032	0.032	0.033	0.033	0.034	0.034	0.035	0.035	0.035
224	0.036	0.036	0.037	0.037	0.038	0.038	0.039	0.039	0.040	0.040
225	0.041	0.041	0.042	0.042	0.043	0.044	0.044	0.045	0.045	0.046
226	0.046	0.047	0.048	0.048	0.049	0.049	0.050	0.051	0.051	0.052
227	0.053	0.053	0.054	0.055	0.056	0.056	0.057	0.058	0.058	0.059
228	0.060	0.061	0.062	0.062	0.063	0.064	0.065	0.066	0.066	0.067
229	0.068	0.069	0.070	0.071	0.072	0.073	0.074	0.075	0.075	0.076
230	0.077	0.078	0.079	0.080	0.081	0.083	0.084	0.085	0.086	0.087
231	0.088	0.089	0.090	0.091	0.093	0.094	0.095	0.096	0.097	0.099
232	0.100	0.101	0.103	0.104	0.105	0.107	0.108	0.109	0.111	0.112
233	0.114	0.115	0.117	0.118	0.120	0.121	0.123	0.124	0.126	0.128

234	0.129	0.131	0.133	0.134	0.136	0.138	0.139	0.141	0.143	0.145
235	0.147	0.149	0.151	0.153	0.154	0.156	0.158	0.161	0.163	0.165
236	0.167	0.169	0.171	0.173	0.176	0.178	0.180	0.182	0.185	0.187
237	0.190	0.192	0.194	0.197	0.200	0.202	0.205	0.207	0.210	0.213
238	0.215	0.218	0.221	0.224	0.227	0.230	0.233	0.236	0.239	0.242
239	0.245	0.248	0.251	0.254	0.258	0.261	0.264	0.268	0.271	0.275
240	0.278	0.282	0.285	0.289	0.293	0.297	0.300	0.304	0.308	0.312
241	0.316	0.320	0.324	0.329	0.333	0.337	0.341	0.346	0.350	0.355
242	0.359	0.364	0.369	0.373	0.378	0.383	0.388	0.393	0.398	0.403
243	0.408	0.414	0.419	0.424	0.430	0.435	0.441	0.447	0.452	0.458
244	0.464	0.470	0.476	0.482	0.489	0.495	0.501	0.508	0.514	0.521
245	0.527	0.534	0.541	0.548	0.555	0.562	0.570	0.577	0.584	0.592
246	0.599	0.607	0.615	0.623	0.631	0.639	0.647	0.656	0.664	0.673
247	0.681	0.690	0.699	0.708	0.717	0.726	0.736	0.745	0.755	0.764
248	0.774	0.784	0.794	0.805	0.815	0.825	0.836	0.847	0.858	0.869
249	0.880	0.891	0.903	0.914	0.926	0.938	0.950	0.962	0.975	0.987
250	1.000	1.013	1.026	1.039	1.053	1.066	1.080	1.094	1.108	1.122
251	1.136	1.151	1.166	1.181	1.196	1.212	1.227	1.243	1.259	1.275
252	1.292	1.308	1.325	1.342	1.359	1.377	1.395	1.413	1.431	1.449
253	1.468	1.487	1.506	1.525	1.545	1.565	1.585	1.605	1.626	1.647
254	1.658	1.690	1.711	1.733	1.756	1.778	1.801	1.824	1.848	1.872
255	1.896	1.920	1.945	1.970	1.995	2.021	2.047	2.073	2.100	2.127
256	2.154	2.182	2.210	2.239	2.268	2.297	2.326	2.356	2.387	2.417
257	2.448	2.480	2.512	2.544	2.577	2.610	2.644	2.678	2.712	2.747
258	2.783	2.818	2.855	2.891	2.929	2.966	3.005	3.043	3.082	3.122
259	3.162	3.203	3.244	3.286	3.328	3.371	3.415	3.459	3.503	3.548
260	3.594	3.640	3.687	3.734	3.782	3.831	3.881	3.930	3.981	4.032
261	4.084	4.137	4.190	4.244	4.299	4.354	4.410	4.467	4.524	4.583
262	4.642	4.701	4.762	4.823	4.885	4.948	5.012	5.076	5.142	5.208
263	5.275	5.343	5.412	5.481	5.552	5.623	5.696	5.769	5.843	5.919
264	5.995	6.072	6.150	6.229	6.310	6.391	6.473	6.556	6.641	6.726
265	6.813	6.901	6.989	7.079	7.171	7.263	7.356	7.451	7.547	7.644
266	7.743	7.842	7.943	8.046	8.149	8.254	8.360	8.468	8.577	8.687
267	8.799	8.913	9.027	9.143	9.261	9.380	9.501	9.624	9.747	9.873
268	10.000	10.129	10.259	10.391	10.525	10.661	10.798	10.937	11.078	11.220
269	11.365	11.511	11.659	11.809	11.961	12.115	12.271	12.429	12.589	12.751
270	12.915	13.082	13.250	13.421	13.594	13.769	13.946	14.125	14.307	14.491

At the slowest heating point within the container. there is a gradual rise in the temperature. the rate being dependent on the physical characteristics of the product. There will be some lethal effect during each minute of the process; the amount during this interval is dependent upon the temperature at that time. These values are obtained from Table 1 and they can be added to obtain the total effective lethal heat of the process.

Heat penetration time and temperature data are usually recorded at some convenient time interval and can be set up in four columns as shown in Table 2. In the third column is added the sterilizing value effective in one minute (lethal rate) at the temperature indicated. The sum of Fo values in the third column will be the sterilizing value of the process if the temperature observation had been made of each minute of the process. When temperature observations are not made each minute of the process. lethal rate values must be extrapolated from the known Fo per minute values. as shown in the fourth column.

TABLE 2 HEAT PENETRATION DATA
CONDUCTION HEATING - 211 x 304 CAN

Come-Up Time: 10 minutes				Retort Temperature: 240°F			
Heating time	Temperature	Lethal Rate	$\sum F_0$/min	Cooling time	Temperature	Lethal Rate	$\sum F_0$/min
IT	160	0		71	237.8	0.21	0.21
6	164	0		72	235.9	0.165	0.165
12	174	0		73	232.7	0.109	0.109
18	195	0.001	0.003	74	228.7	0.066	0.066
21	201	0.002	0.006	75	223.8	0.035	0.035
24	208	0.005	0.015	76	218	0.017	0.017
27	214	0.01	0.03	77	212	0.008	0.008
30	218.5	0.017	0.058	78	206	0.004	0.004
33	222.5	0.028	0.084	79	199	0.001	0.001
36	225.5	0.041	0.123	80	192	0.001	0.001
39	228	0.06	0.18	85	157	0	0
42	230	0.077	0.231	90	132	0	0
45	232	0.1	0.3	95	115	0	0
48	233.5	0.121	0.363	100	102	0	0
51	234.6	0.138	0.414	105	94	0	0
54	235.3	0.153	0.459				0.616
57	236.4	0.176	0.528				
60	237	0.19	0.57				
63	237.6	0.205	0.615	Heating time F_0 =		5.089	
66	238	0.215	0.645	Cooling time F_0 =		0.616	
69	238.4	0.227	0.227	Process F_0 =		5.705	
70	238.5	0.23	0.23				
70	steam off		5.089				

The lethal rate figures can be plotted against time on coordinate paper to obtain a lethal rate curve as shown in Figure 3. Since the vertical distance on this curve at each minute represents the F_0 effective in that minute. it follows In other words. the sterilizing value is proportional to the area under the curve. that the total sterilizing value is equal to the sum of all the vertical distances for every minute of the process. It is necessary to measure the area under the curve in order to determine process sterilizing value. This can be done by Simpson's rule. or with method of counting the small squares or with an instrument called a planimeter. The area in square inches must be multiplied by a factor to be converted to F_o units. This factor is found by determining the area of a unit sterilization area such as ABCD shown in Figure 3.

The product of the height and width of this area in terms of F_0 per minute and time is unity. The factor to be multiplied by the square inch area under the lethal rate curve is the reciprocal of the square inch area of the unit sterilization rectangle. This means that if the area under the curve is 6.5 square inches. Fo equals 6.5 divided by 0.5 equals 13.

The procedure for determining the length of a process for a known sterilizing value is quite similar except that instead of measuring area for a known length of process. the process is found to yield a known area under the curve. For example. suppose a process is wanted having a sterilizing value of 10. previous experience having shown that this value gives satisfactory results. It is necessary then to find the time that would yield an area of 5 square inches under the lethality curve. Inspection of the curve would lead us to believe that this time would not be far from 65 minutes. We will. therefore. estimate the cooling curve from 65 minutes which we can do fairly accurately by drawing it parallel to the actual cooling curve from 78 minutes. Now. we will measure the area under this 65 minute curve by one of the methods previously described. and we find it to be 4.56 square inches. Since this process fails to give us 5 square inches. or 10 F_o units under the curve. we know that 65 minutes is not quite enough. Actually. we need not go further than this as it is almost a certainty that the next higher practical process. i.e.. 70 minutes. would yield at least 5 square inches. We check these though. and find

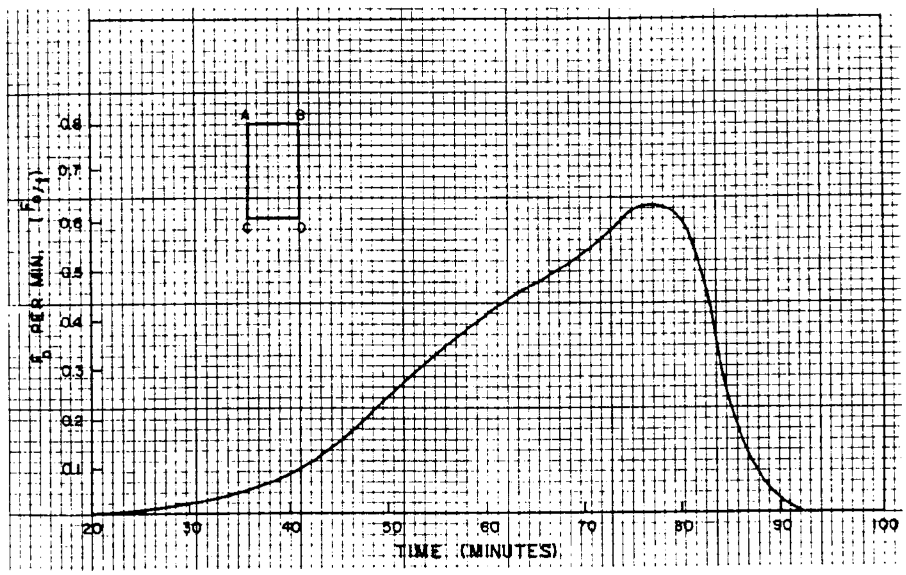


Fig. 3 Lethal rate curve.

the area under the 70 minute curve to be 5.85 square inches or 11.7 F_o units. We could of course. interpolate between 65 and 70 minutes to get a more exact time. but for practical purposes we will select 70 minutes.

It should be emphasized again that the results obtained by this method are valid only when the initial and retort temperature conditions are the same as those of the heat penetration tests. If the heat penetration curve can be represented by one or two straight lines on semi-log paper. it is possible to make corrections for these factors. but in this case. the graphical method is not the recommended one. Either the formula method or the nomogram method is better suited for such a calculation.

Effect of 3 Degrees F Errors in Retort Temperature on
F_o Value of Heating Phase of Typical Processes
for 303 x 406 Cans

Product	Initial Temp. (°F)	Process Time (min)	Retort Temp. (°F)	F_o (min)
Green beans in brine	120	20	237	2.0
			240	3.0
			243	4.7
Cream-style corn	140	95	237	3.2
			240	4.4
			243	6.2

The Formula Method

The first step in calculating processes by the formula method is to plot the time-temperature data on semi-log paper. time being plotted as abscissae and temperature as the logarithmic ordinate. Zero time is the time at steam on. The time at which the retort reaches processing temperature is noted as come-up time. Three cycle semi-log paper generally provides a convenient range for plotting the data.

Actually. the temperatures plotted are the retort temperature minus the can temperature. Instead of making these subtractions it is more practical to turn the semi-log paper upside down and plot can temperatures directly. The temperature on the top line is one degree below retort temperature. At the bottom of the first log cycle the temperature is 10 degrees below retort temperature and at the bottom of the second log cycle. 100 degrees below.

Either one straight line (simple heating curve) or not more than two straight lines (broken heating curve) are drawn through the points in the lethal temperature range (above 210°F). An attempt should be made to pass the straight lines within 1 degree of all the points rather than fit them by any geometric mean method.

Having drawn the lines on the graph paper. factors must be determined that will describe the positions. Simple and broken heating curves will be discussed separately.

Simple Heating Curve

A plot of a simple heating curve is shown in Figure 1. From this plot we obtain two factors used in calculating processes. These factors are j (lag factor) and fh (slope).

In making a heat penetration test. some time is required in bringing retort to processing temperature. It will be obvious that the come-up time does not have the heating value of the processing or holding temperature but that its heating value would be more than 0 minutes. Conventionally. the heating value of the come-up me is taken as 0.42 of the come-up time. This means the corrected beginning of process is not when the retort reaches process temperature but 0.4 of the come-up time before steam-up or 0.6 of the come-up time after steam-on. With a 10 minute come-up. the corrected 0 is at 6 minutes on the time scale. It is necessary make this correction because retort come-up times will vary over comparatively wide limits and. unless means are provided for correcting these to the come-up time will always have to be specified with the heat penetration curve. If because of the long come-up time it is necessary to make allowance for come-up 0.4 of the come-up can be subtracted from the calculated process or the sterilizing value is the sought unknown 0.4 of the come-up time is added to process time.

Having determined the corrected zero time. a vertical line is drawn at this value on the time scale and crossing the extended straight line drawn through the time-temperature plotted. The point where these two lines cross will be a certain number of degrees below the retort temperature and this value is called "jI". A temperature value can be read on the left side temperature scale corresponding to the point the lines cross and this value subtracted from the retort temperature. If a degree-below-retort-teperature scale is marked on the right hand side of the graph paper, the value of "jI" can be read from this scale directly.

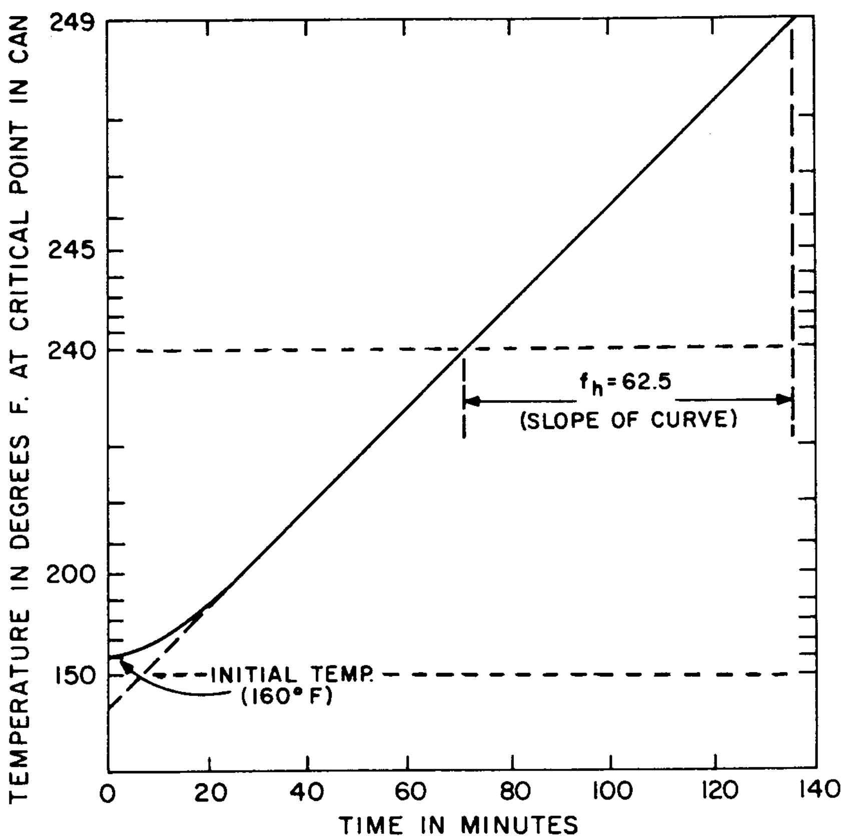
(1) I = RT-IT

The retort temperature (RT) is the retort temperature obtained during the heat penetration test. and the initial temperature (IT) is the center temperature of a particular can for which the time_temperature data are plotted.

Then:

(2) j = jI/I

Thiss value of j remains constant for the given product; it does not change when converting the heating data to another can size. With smaller cans of conduction heating products. a correction to the j value is advisable to compensate for heat conducted into the product by the thermocouple wires and fittings. These corrections are discussed by Ecklund in his article. "Correction Factors for Heat Penetration Thermocouples". (Food Technol. 10:43-44. 1956). The following table gives correction factors for j.



HEAT PENETRATION CURVE
(Retort Temperature Equals 250 degrees F)

Correction factors for "j"

Can Size	Use on conduction heating products only Multiply "j" factor by:
202 x 214	1.36
211 x 400	1.16
300 x 407	1.10
307 x 409	1.06

The second heat penetration factor obtained from the graph of a simple heating curve is f_h. This factor is the time in minutes for the straight line drawn through the time-temperature plots to pass through one logarithmic cycle. A log cycle is the distance between any two points on the logarithmic ordinate in which the number of degrees below retort temperature increases ten times. For example. the distance can be from 1 to 10. 3 to 30. 10 to 100 or 20 to 200 as read on the right hand side of the graph sheet.

With the values of j and f_h obtained from the graph of the heating data. the sterilizing value (F_o) of a process can be determined or the process time in minutes (B_B) can be calculated for a desired F_o value.

To calculate F_o we use the following equations:

(3) $$\log g = \log jI - \frac{B_B}{f_h}$$

(4) $$F_o = \frac{f_h}{(f_h / U)F_i}$$

In equation (3) the values of j and f_h have already been determined. B_B (process time) is known and I = RT-IT. RT is a retort temperature at which the product will be processed and IT is the initial temperature that will be encountered under commercial canning conditions. These values are substituted in equation (3) and the value of "log g" calculated. The value of "g" is the number of degrees below retort temperature at the slowest heating point in the container at the end of the process. In order to simplify calculations. the log g is used in the equations.

For each value of log g there is a corresponding value of the term f_h/U. This relationship is shown in Table 3. The term "F_i" is related to the retort temperature. It can be calculated by the equation:

(5) $$F_i = \log^{-1}\left[\frac{(250 - RT)}{18}\right]$$

Values of F_i for various retort temperatures are listed in Table 4.

The proper value of F_i for the retort temperature is selected and substituted in equation (4) along with f_h/U (found from Table 5 for the corresponding value of log g) and f_h. The F_o value obtained will be the sterilizing value of the process.

To calculate B_B we use the following equations:

(6) $$fh / U = \frac{f_h}{F_o \times F_i}$$

(7) $$B_B = f_h(\log jI - \log g)$$

In equation (6). fh is from the heat penetration curve. F_o is the desired sterilizing value and F_i is obtained from Table 4 for the particular retort temperature involved. With these values. f_h/U is calculated. From the relationship of f_h/U and log g shown in Table 3. the value of log g can be found which corresponds to the value of f_h/U calculated in equation (6).

This value of log g is substituted in equation (7). The values of j and fh are from the heat penetration curve and I again is RT-IT. The value of B_B calculated would be the process time in minutes.

TABLE 3

LOG G GIVEN FH/U

FH/U	LOG G	FH/U	LOG G	FH/U	LOG G	FH/U	LOG G
0.350	-2.147	0.440	-1.563	0.530	-1.177	0.620	-0.907
0.352	-2.131	0.442	-1.552	0.532	-1.170	0.622	-0.903
0.354	-2.115	0.444	-1.542	0.534	-1.163	0.624	-0.898
0.356	-2.099	0.446	-1.532	0.536	-1.156	0.626	-0.894
0.358	-2.083	0.448	-1.522	0.538	-1.149	0.628	-0.890
0.360	-2.068	0.450	-1.512	0.540	-1.142	0.630	-0.886
0.362	-2.052	0.452	-1.502	0.542	-1.135	0.632	-0.881
0.364	-2.037	0.454	-1.493	0.544	-1.128	0.634	-0.877
0.366	-2.022	0.456	-1.483	0.546	-1.122	0.636	-0.873
0.368	-2.007	0.458	-1.473	0.548	-1.115	0.638	-0.868
0.370	-1.993	0.460	-1.464	0.550	-1.108	0.640	-0.864
0.372	-1.978	0.462	-1.455	0.552	-1.102	0.642	-0.860
0.374	-1.964	0.464	-1.445	0.554	-1.095	0.644	-0.856
0.376	-1.950	0.466	-1.436	0.556	-1.089	0.646	-0.851
0.378	-1.936	0.468	-1.427	0.558	-1.082	0.648	-0.847
0.380	-1.922	0.470	-1.418	0.560	-1.076	0.650	-0.843
0.382	-1.908	0.472	-1.409	0.562	-1.069	0.652	-0.838
0.384	-1.894	0.474	-1.400	0.564	-1.063	0.654	-0.834
0.386	-1.881	0.476	-1.391	0.566	-1.057	0.656	-0.830
0.388	-1.867	0.478	-1.382	0.568	-1.051	0.658	-0.825
0.390	-1.854	0.480	-1.373	0.570	-1.044	0.660	-0.821
0.392	-1.841	0.482	-1.365	0.572	-1.038	0.662	-0.817
0.394	-1.828	0.484	-1.356	0.574	-1.032	0.664	-0.812
0.396	-1.815	0.486	-1.348	0.576	-1.026	0.666	-0.808
0.398	-1.803	0.488	-1.339	0.578	-1.020	0.668	-0.804
0.400	-1.790	0.490	-1.331	0.580	-1.014	0.670	-0.800
0.402	-1.778	0.492	-1.323	0.582	-1.008	0.672	-0.795
0.404	-1.765	0.494	-1.314	0.584	-1.002	0.674	-0.791
0.406	-1.753	0.496	-1.306	0.586	-0.996	0.676	-0.787
0.408	-1.741	0.498	-1.298	0.588	-0.991	0.678	-0.782
0.410	-1.729	0.500	-1.290	0.590	-0.985	0.680	-0.778
0.412	-1.717	0.502	-1.282	0.592	-0.979	0.682	-0.774
0.414	-1.705	0.504	-1.274	0.594	-0.974	0.684	-0.770
0.416	-1.694	0.506	-1.266	0.596	-0.968	0.686	-0.765
0.418	-1.682	0.508	-1.259	0.598	-0.962	0.688	-0.761
0.420	-1.671	0.510	-1.251	0.600	-0.949	0.690	-0.757
0.422	-1.660	0.512	-1.243	0.602	-0.945	0.692	-0.753
0.424	-1.648	0.514	-1.236	0.604	-0.940	0.694	-0.748
0.426	-1.637	0.516	-1.228	0.606	-0.936	0.696	-0.744
0.428	-1.626	0.518	-1.221	0.608	-0.932	0.698	-0.740
0.430	-1.616	0.520	-1.213	0.610	-0.928	0.700	-0.736
0.432	-1.605	0.522	-1.206	0.612	-0.924	0.702	-0.732
0.434	-1.594	0.524	-1.198	0.614	-0.919	0.704	-0.727
0.436	-1.584	0.526	-1.191	0.616	-0.915	0.706	-0.723
0.438	-1.573	0.528	-1.184	0.618	-0.911	0.708	-0.719

LOG G GIVEN FH/U

FH/U	LOG G	FH/U	LOG G	FH/U	LOG G	FH/U	LOG G
0.710	-0.715	0.800	-0.544	0.890	-0.406	0.980	-0.293
0.712	-0.711	0.802	-0.541	0.892	-0.403	0.982	-0.291
0.714	-0.707	0.804	-0.537	0.894	-0.400	0.984	-0.289
0.716	-0.703	0.806	-0.534	0.896	-0.397	0.986	-0.287
0.718	-0.699	0.808	-0.530	0.898	-0.395	0.988	-0.285
0.720	-0.694	0.810	-0.527	0.900	-0.392	0.990	-0.282
0.722	-0.690	0.812	-0.524	0.902	-0.389	0.992	-0.280
0.724	-0.686	0.814	-0.520	0.904	-0.387	0.994	-0.278
0.726	-0.682	0.816	-0.517	0.906	-0.384	0.996	-0.276
0.728	-0.678	0.818	-0.514	0.908	-0.381	0.998	-0.274
0.730	-0.674	0.820	-0.511	0.910	-0.379	1.000	-0.271
0.732	-0.670	0.822	-0.507	0.912	-0.376	1.005	-0.266
0.734	-0.666	0.824	-0.504	0.914	-0.373	1.010	-0.261
0.736	-0.662	0.826	-0.501	0.916	-0.371	1.015	-0.255
0.738	-0.658	0.828	-0.498	0.918	-0.368	1.020	-0.250
0.740	-0.654	0.830	-0.494	0.920	-0.366	1.025	-0.245
0.742	-0.651	0.832	-0.491	0.922	-0.363	1.030	-0.240
0.744	-0.647	0.834	-0.488	0.924	-0.361	1.035	-0.235
0.746	-0.643	0.836	-0.485	0.926	-0.358	1.040	-0.230
0.748	-0.639	0.838	-0.482	0.928	-0.355	1.045	-0.225
0.750	-0.635	0.840	-0.479	0.930	-0.353	1.050	-0.220
0.752	-0.631	0.842	-0.476	0.932	-0.350	1.055	-0.215
0.754	-0.627	0.844	-0.473	0.934	-0.348	1.060	-0.210
0.756	-0.624	0.846	-0.469	0.936	-0.345	1.065	-0.205
0.758	-0.620	0.848	-0.466	0.938	-0.343	1.070	-0.201
0.760	-0.616	0.850	-0.463	0.940	-0.341	1.075	-0.196
0.762	-0.612	0.852	-0.460	0.942	-0.338	1.080	-0.191
0.764	-0.609	0.854	-0.457	0.944	-0.336	1.085	-0.187
0.766	-0.605	0.856	-0.454	0.946	-0.333	1.090	-0.182
0.768	-0.601	0.858	-0.451	0.948	-0.331	1.095	-0.177
0.770	-0.597	0.860	-0.448	0.950	-0.328	1.100	-0.173
0.772	-0.594	0.862	-0.445	0.952	-0.326	1.105	-0.168
0.774	-0.590	0.864	-0.443	0.954	-0.324	1.110	-0.164
0.776	-0.586	0.866	-0.440	0.956	-0.321	1.115	-0.160
0.778	-0.583	0.868	-0.437	0.958	-0.319	1.120	-0.155
0.780	-0.579	0.870	-0.434	0.960	-0.317	1.125	-0.151
0.782	-0.576	0.872	-0.431	0.962	-0.314	1.130	-0.147
0.784	-0.572	0.874	-0.428	0.964	-0.312	1.135	-0.142
0.786	-0.568	0.876	-0.425	0.966	-0.309	1.140	-0.138
0.788	-0.565	0.878	-0.422	0.968	-0.307	1.145	-0.134
0.790	-0.561	0.890	-0.420	0.970	-0.305	1.150	-0.130
0.792	-0.558	0.882	-0.417	0.972	-0.303	1.155	-0.126
0.794	-0.554	0.884	-0.414	0.974	-0.300	1.160	-0.122
0.796	-0.551	0.886	-0.411	0.976	-0.298	1.165	-0.118
0.798	-0.548	0.888	-0.408	0.978	-0.296	1.170	-0.114

TABLE 3–Continued

LOG G GIVEN FH/U

FH/U	LOG G	FH/U	LOG G	FH/U	LOG G	FH/U	LOG G
1.175	-0.110	1.400	0.042	1.75	0.210	2.20	0.357
1.180	-0.106	1.405	0.045	1.76	0.214	2.21	0.360
1.185	-0.102	1.410	0.048	1.77	0.218	2.22	0.362
1.190	-0.098	1.415	0.051	1.78	0.221	2.23	0.365
1.195	-0.094	1.420	0.054	1.79	0.225	2.24	0.368
1.200	-0.090	1.425	0.057	1.80	0.229	2.25	0.370
1.205	-0.086	1.430	0.059	1.81	0.233	2.26	0.373
1.210	-0.083	1.435	0.062	1.82	0.237	2.27	0.376
1.215	-0.079	1.440	0.065	1.83	0.240	2.28	0.378
1.220	-0.075	1.445	0.068	1.84	0.244	2.29	0.381
1.225	-0.072	1.450	0.070	1.85	0.248	2.30	0.383
1.230	-0.068	1.455	0.073	1.86	0.251	2.31	0.386
1.235	-0.064	1.460	0.076	1.87	0.255	2.32	0.388
1.240	-0.061	1.465	0.079	1.88	0.258	2.33	0.391
1.245	-0.057	1.470	0.081	1.89	0.262	2.34	0.393
1.250	-0.054	1.475	0.084	1.90	0.265	2.35	0.396
1.255	-0.050	1.480	0.087	1.91	0.269	2.36	0.398
1.260	-0.046	1.485	0.089	1.92	0.272	2.37	0.400
1.265	-0.043	1.490	0.092	1.93	0.275	2.38	0.403
1.270	-0.040	1.495	0.094	1.94	0.279	2.39	0.405
1.275	-0.036	1.50	0.097	1.95	0.282	2.40	0.408
1.280	-0.033	1.51	0.102	1.96	0.285	2.41	0.410
1.285	-0.029	1.52	0.107	1.97	0.289	2.42	0.412
1.290	-0.026	1.53	0.112	1.98	0.292	2.43	0.415
1.295	-0.023	1.54	0.117	1.99	0.295	2.44	0.417
1.300	-0.019	1.55	0.122	2.00	0.298	2.45	0.419
1.305	-0.016	1.56	0.127	2.01	0.302	2.46	0.421
1.310	-0.013	1.57	0.132	2.02	0.305	2.47	0.424
1.315	-0.010	1.58	0.136	2.03	0.308	2.48	0.426
1.320	-0.006	1.59	0.141	2.04	0.311	2.49	0.428
1.325	-0.003	1.60	0.146	2.05	0.314	2.50	0.430
1.330	0.000	1.61	0.150	2.06	0.317	2.51	0.433
1.335	0.003	1.62	0.155	2.07	0.320	2.52	0.435
1.340	0.006	1.63	0.159	2.08	0.323	2.53	0.437
1.345	0.009	1.64	0.164	2.09	0.326	2.54	0.439
1.350	0.013	1.65	0.168	2.10	0.329	2.55	0.441
1.355	0.016	1.66	0.172	2.11	0.332	2.56	0.443
1.360	0.019	1.67	0.177	2.12	0.335	2.57	0.445
1.365	0.022	1.68	0.181	2.13	0.338	2.58	0.448
1.370	0.025	1.69	0.185	2.14	0.340	2.59	0.450
1.375	0.028	1.70	0.189	2.15	0.343	2.60	0.452
1.380	0.031	1.71	0.194	2.16	0.346	2.61	0.454
1.385	0.034	1.72	0.198	2.17	0.349	2.62	0.456
1.390	0.037	1.73	0.202	2.18	0.352	2.63	0.458
1.395	0.040	1.74	0.206	2.19	0.354	2.64	0.460

TABLE 3—Continued

LOG G GIVEN FH/U

FH/U	LOG G	FH/U	LOG G	FH/U	LOG G	FH/U	LOG G
2.65	0.462	3.10	0.541	3.55	0.604	4.00	0.655
2.66	0.464	3.11	0.543	3.56	0.605	4.01	0.656
2.67	0.466	3.12	0.544	3.57	0.606	4.02	0.657
2.68	0.468	3.13	0.546	3.58	0.608	4.03	0.658
2.69	0.470	3.14	0.547	3.59	0.609	4.04	0.659
2.70	0.472	3.15	0.549	3.60	0.610	4.05	0.660
2.71	0.474	3.16	0.550	3.61	0.611	4.06	0.661
2.72	0.476	3.17	0.552	3.62	0.613	4.07	0.662
2.73	0.478	3.18	0.553	3.63	0.614	4.08	0.663
2.74	0.479	3.19	0.555	3.64	0.615	4.09	0.664
2.75	0.481	3.20	0.556	3.65	0.616	4.10	0.665
2.76	0.483	3.21	0.558	3.66	0.617	4.11	0.666
2.77	0.485	3.22	0.559	3.67	0.619	4.12	0.667
2.78	0.487	3.23	0.561	3.68	0.620	4.13	0.668
2.79	0.489	3.24	0.562	3.69	0.621	4.14	0.669
2.80	0.491	3.25	0.564	3.70	0.622	4.15	0.670
2.81	0.492	3.26	0.565	3.71	0.623	4.16	0.671
2.82	0.494	3.27	0.567	3.72	0.624	4.17	0.672
2.83	0.496	3.28	0.568	3.73	0.626	4.18	0.673
2.84	0.498	3.29	0.569	3.74	0.627	4.19	0.674
2.85	0.500	3.30	0.571	3.75	0.628	4.20	0.675
2.86	0.501	3.31	0.572	3.76	0.629	4.21	0.676
2.87	0.503	3.32	0.574	3.77	0.630	4.22	0.677
2.88	0.505	3.33	0.575	3.78	0.631	4.23	0.678
2.89	0.507	3.34	0.576	3.79	0.632	4.24	0.679
2.90	0.508	3.35	0.578	3.80	0.634	4.25	0.680
2.91	0.510	3.36	0.579	3.81	0.635	4.26	0.681
2.92	0.512	3.37	0.580	3.82	0.636	4.27	0.682
2.93	0.514	3.38	0.582	3.83	0.637	4.28	0.683
2.94	0.515	3.39	0.583	3.84	0.638	4.29	0.684
2.95	0.517	3.40	0.585	3.85	0.639	4.30	0.684
2.96	0.519	3.41	0.586	3.86	0.640	4.31	0.685
2.97	0.520	3.42	0.587	3.87	0.641	4.32	0.686
2.98	0.522	3.43	0.589	3.88	0.642	4.33	0.687
2.99	0.524	3.44	0.590	3.89	0.643	4.34	0.688
3.00	0.525	3.45	0.591	3.90	0.645	4.35	0.689
3.01	0.527	3.46	0.592	3.91	0.646	4.36	0.690
3.02	0.529	3.47	0.594	3.92	0.647	4.37	0.691
3.03	0.530	3.48	0.595	3.93	0.648	4.38	0.692
3.04	0.532	3.49	0.596	3.94	0.649	4.39	0.693
3.05	0.533	3.50	0.598	3.95	0.650	4.40	0.694
3.06	0.535	3.51	0.599	3.96	0.651	4.41	0.694
3.07	0.537	3.52	0.600	3.97	0.652	4.42	0.695
3.08	0.538	3.53	0.601	3.98	0.653	4.43	0.696
3.09	0.540	3.54	0.603	3.99	0.654	4.44	0.697

TABLE 3--Continued

LOG G GIVEN FH/U

FH/U	LOG G	FH/U	LOG G	FH/U	LOG G	FH/U	LOG G
4.45	0.698	4.90	0.734	6.75	0.843	9.00	0.927
4.46	0.699	4.91	0.735	6.80	0.845	9.05	0.929
4.47	0.700	4.92	0.736	6.85	0.848	9.10	0.930
4.48	0.701	4.93	0.737	6.90	0.850	9.15	0.931
4.49	0.701	4.94	0.737	6.95	0.852	9.20	0.933
4.50	0.702	4.95	0.738	7.00	0.854	9.25	0.934
4.51	0.703	4.96	0.739	7.05	0.857	9.30	0.936
4.52	0.704	4.97	0.740	7.10	0.859	9.35	0.937
4.53	0.705	4.98	0.740	7.15	0.861	9.40	0.939
4.54	0.706	4.99	0.741	7.20	0.863	9.45	0.940
4.55	0.707	5.00	0.742	7.25	0.865	9.50	0.942
4.56	0.707	5.05	0.745	7.30	0.867	9.55	0.943
4.57	0.708	5.10	0.749	7.35	0.869	9.60	0.944
4.58	0.709	5.15	0.753	7.40	0.871	9.65	0.946
4.59	0.710	5.20	0.756	7.45	0.873	9.70	0.947
4.60	0.711	5.25	0.759	7.50	0.875	9.75	0.948
4.61	0.712	5.30	0.763	7.55	0.877	9.80	0.950
4.62	0.712	5.35	0.766	7.60	0.879	9.85	0.951
4.63	0.713	5.40	0.769	7.65	0.881	9.90	0.952
4.64	0.714	5.45	0.773	7.70	0.883	9.95	0.954
4.65	0.715	5.50	0.776	7.75	0.885	10.0	0.955
4.66	0.716	5.55	0.779	7.80	0.887	10.2	0.960
4.67	0.716	5.60	0.782	7.85	0.889	10.4	0.965
4.68	0.717	5.65	0.785	7.90	0.890	10.6	0.970
4.69	0.718	5.70	0.788	7.95	0.892	10.8	0.975
4.70	0.719	5.75	0.791	8.00	0.894	11.0	0.979
4.71	0.720	5.80	0.794	8.05	0.896	11.2	0.984
4.72	0.720	5.85	0.797	8.10	0.898	11.4	0.988
4.73	0.721	5.90	0.800	8.15	0.899	11.6	0.992
4.74	0.722	5.95	0.802	8.20	0.901	11.8	0.997
4.75	0.723	6.00	0.805	8.25	0.903	12.0	1.001
4.76	0.724	6.05	0.808	8.30	0.905	12.2	1.005
4.77	0.724	6.10	0.811	8.35	0.906	12.4	1.008
4.78	0.725	6.15	0.813	8.40	0.908	12.6	1.012
4.79	0.726	6.20	0.816	8.45	0.910	12.8	1.016
4.80	0.727	6.25	0.819	8.50	0.911	13.0	1.020
4.81	0.728	6.30	0.821	8.55	0.913	13.2	1.023
4.82	0.728	6.35	0.824	8.60	0.914	13.4	1.027
4.83	0.729	6.40	0.826	8.65	0.916	13.6	1.030
4.84	0.730	6.45	0.829	8.70	0.918	13.8	1.033
4.85	0.731	6.50	0.831	8.75	0.919	14.0	1.037
4.86	0.731	6.55	0.834	8.80	0.921	14.2	1.040
4.87	0.732	6.60	0.836	8.85	0.922	14.4	1.043
4.88	0.733	6.65	0.838	8.90	0.924	14.6	1.046
4.89	0.734	6.70	0.841	8.95	0.925	14.8	1.049

TABLE 3–Continued

LOG G GIVEN FH/U

FH/U	LOG G	FH/U	LOG G	FH/U	LOG G	FH/U	LOG G
15.0	1.052	31.	1.193	102.	1.368	192.	1.442
15.2	1.055	32.	1.198	104.	1.370	194.	1.443
15.4	1.058	33.	1.204	106.	1.373	196.	1.445
15.6	1.061	34.	1.209	108.	1.375	198.	1.446
15.8	1.063	35.	1.214	110.	1.377	200.	1.447
16.0	1.066	36.	1.218	112.	1.379		
16.2	1.069	37.	1.223	114.	1.382		
16.4	1.071	38.	1.227	116.	1.384		
16.6	1.074	39.	1.231	118.	1.386		
16.8	1.076	40.	1.235	120.	1.388		
17.0	1.079	41.	1.239	122.	1.390		
17.2	1.081	42.	1.243	124.	1.392		
17.4	1.084	43.	1.247	126.	1.394		
17.6	1.086	44.	1.250	128.	1.396		
17.8	1.089	45.	1.254	130.	1.397		
18.0	1.091	46.	1.257	132.	1.399		
18.2	1.093	47.	1.260	134.	1.401		
18.4	1.095	48.	1.264	136.	1.403		
18.6	1.098	49.	1.267	138.	1.405		
18.8	1.100	50.	1.270	140.	1.406		
19.0	1.102	52.	1.276	142.	1.408		
19.2	1.104	54.	1.281	144.	1.410		
19.4	1.106	56.	1.287	146.	1.411		
19.6	1.108	58.	1.292	148.	1.413		
20.0	1.112	60.	1.296	150.	1.414		
20.5	1.117	62.	1.301	152.	1.416		
21.0	1.122	64.	1.306	154.	1.417		
21.5	1.126	66.	1.310	156.	1.419		
22.0	1.131	68.	1.314	158.	1.420		
22.5	1.135	70.	1.318	160.	1.422		
23.0	1.139	72.	1.322	162.	1.423		
23.5	1.143	74.	1.326	164.	1.425		
24.0	1.147	76.	1.329	166.	1.426		
24.5	1.151	78.	1.333	168.	1.427		
25.0	1.155	80.	1.336	170.	1.429		
25.5	1.158	82.	1.339	172.	1.430		
26.0	1.162	84.	1.343	174.	1.431		
26.5	1.165	86.	1.346	176.	1.433		
27.0	1.169	88.	1.349	178.	1.434		
27.5	1.172	90.	1.352	180.	1.435		
28.0	1.175	92.	1.355	182.	1.436		
28.5	1.178	94.	1.357	184.	1.438		
29.0	1.181	96.	1.360	186.	1.439		
29.5	1.184	98.	1.363	188.	1.440		
30.0	1.187	100.	1.365	190.	1.441		

TABLE 4

F_i VALUES FOR VARIOUS RETORT TEMPERATURES (°F.)

RT	Fi	RT	Fi	R T	Fi
214	100.00	233	8.799	252	0.7743
215	87.99	234	*7.743*	253	0.6 813
216	77.43	235	6.813	254	0.5995
217	68.13	236	5.995	255	0.5275
218	59.92	237	5.275	256	0.4642
219	52.75	238	4.642	257	0.4085
220	46.42	239	4.085	258	0.3594
221	40.85	240	3.594	259	0.3163
222	35.94	241	3.163	260	0.2783
223	31.63	242	2.783	261	0.2449
224	27.83	243	2.449	262	0.2154
225	24.48	244	2.154	261	0.1896
226	21.54	245	1.896	264	0.1668
227	18.96	246	1.668	265	0.1468
228	16.68	247	1.468	266	0.1292
229	14.68	248	1.292	267	0.1136
230	12.92	249	1.136	268	0.1000
231	11.36	250	1.000	269	0.0880
232	10.000	251	0.8799	270	0.0774

TABLE 5

FH/U FOR GIVEN LOG (G)

LOG (G)	.000	.002	.004	.006	.008
-1.990	0.3704	0.3701	0.3698	0.3695	0.3693
-1.980	0.3717	0.3715	0.3712	0.3709	0.3706
-1.970	0.3731	0.3729	0.3726	0.3723	0.3720
-1.960	0.3745	0.3743	0.3740	0.3737	0.3734
-1.950	0.3759	0.3757	0.3754	0.3751	0.3748
-1.940	0.3774	0.3771	0.3768	0.3765	0.3762
-1.930	0.3788	0.3785	0.3782	0.3779	0.3776
-1.920	0.3802	0.3799	0.3797	0.3794	0.3791
-1.910	0.3817	0.3814	0.3811	0.3808	0.3805
-1.900	0.3831	0.3828	0.3826	0.3823	0.3820
-1.890	0.3846	0.3843	0.3840	0.3837	0.3834
-1.880	0.3861	0.3858	0.3855	0.3852	0.3849
-1.870	0.3876	0.3873	0.3870	0.3867	0.3864
-1.860	0.3891	0.3888	0.3885	0.3882	0.3879
-1.850	0.3906	0.3903	0.3900	0.3897	0.3894
-1.840	0.3922	0.3918	0.3915	0.3912	0.3909
-1.830	0.3937	0.3934	0.3931	0.3928	0.3925
-1.820	0.3953	0.3949	0.3946	0.3943	0.3940
-1.810	0.3968	0.3965	0.3962	0.3959	0.3956
-1.800	0.3984	0.3981	0.3978	0.3975	0.3971
-1.790	0.4000	0.3997	0.3994	0.3990	0.3987
-1.780	0.4016	0.4013	0.4010	0.4006	0.4003
-1.770	0.4032	0.4029	0.4026	0.4023	0.4019
-1.760	0.4049	0.4045	0.4042	0.4039	0.4036
-1.750	0.4065	0.4062	0.4058	0.4055	0.4052
-1.740	0.4082	0.4078	0.4075	0.4072	0.4068
-1.730	0.4098	0.4095	0.4092	0.4088	0.4085
-1.720	0.4115	0.4112	0.4108	0.4105	0.4102
-1.710	0.4132	0.4129	0.4125	0.4122	0.4119
-1.700	0.4149	0.4146	0.4143	0.4139	0.4136
-1.690	0.4167	0.4163	0.4160	0.4156	0.4153
-1.680	0.4184	0.4181	0.4177	0.4174	0.4170
-1.670	0.4202	0.4198	0.4195	0.4191	0.4188
-1.660	0.4219	0.4216	0.4212	0.4209	0.4205
-1.650	0.4237	0.4234	0.4230	0.4227	0.4223
-1.640	0.4255	0.4252	0.4248	0.4244	0.4241
-1.630	0.4274	0.4270	0.4266	0.4263	0.4259
-1.620	0.4292	0.4288	0.4284	0.4281	0.4277
-1.610	0.4310	0.4307	0.4303	0.4299	0.4296
-1.600	0.4329	0.4325	0.4322	0.4318	0.4314
-1.590	0.4348	0.4344	0.4340	0.4337	0.4333
-1.580	0.4367	0.4363	0.4359	0.4355	0.4352
-1.570	0.4386	0.4382	0.4378	0.4374	0.4371
-1.560	0.4405	0.4401	0.4398	0.4394	0.4390
-1.550	0.4425	0.4421	0.4417	0.4413	0.4409
-1.540	0.4444	0.4440	0.4437	0.4433	0.4429
-1.530	0.4464	0.4460	0.4456	0.4452	0.4448
-1.520	0.4484	0.4480	0.4476	0.4472	0.4468
-1.510	0.4505	0.4500	0.4496	0.4492	0.4488
-1.500	0.4525	0.4521	0.4517	0.4513	0.4509

TABLE 5—Continued

FH/U FOR GIVEN LOG (G)

LOG (G)	.000	.002	.004	.006	.008
-1.490	0.4545	0.4541	0.4537	0.4533	0.4529
-1.480	0.4566	0.4562	0.4558	0.4554	0.4550
-1.470	0.4587	0.4583	0.4579	0.4575	0.4570
-1.460	0.4608	0.4604	0.4600	0.4596	0.4591
-1.450	0.4630	0.4625	0.4621	0.4617	0.4613
-1.440	0.4651	0.4647	0.4643	0.4638	0.4634
-1.430	0.4673	0.4669	0.4664	0.4660	0.4655
-1.420	0.4695	0.4690	0.4686	0.4682	0.4677
-1.410	0.4717	0.4713	0.4708	0.4704	0.4699
-1.400	0.4739	0.4735	0.4730	0.4726	0.4721
-1.390	0.4762	0.4757	0.4753	0.4748	0.4744
-1.380	0.4785	0.4780	0.4776	0.4771	0.4766
-1.370	0.4808	0.4803	0.4798	0.4794	0.4789
-1.360	0.4831	0.4826	0.4822	0.4817	0.4812
-1.350	0.4854	0.4850	0.4845	0.4840	0.4836
-1.340	0.4878	0.4873	0.4869	0.4864	0.4859
-1.330	0.4902	0.4897	0.4892	0.4888	0.4883
-1.320	0.4926	0.4921	0.4916	0.4912	0.4907
-1.310	0.4950	0.4946	0.4941	0.4936	0.4931
-1.300	0.4975	0.4970	0.4965	0.4960	0.4955
-1.290	0.5000	0.4995	0.4990	0.4985	0.4980
-1.280	0.5025	0.5020	0.5015	0.5010	0.5005
-1.270	0.5051	0.5045	0.5040	0.5035	0.5030
-1.260	0.5076	0.5071	0.5066	0.5061	0.5056
-1.250	0.5102	0.5097	0.5092	0.5086	0.5081
-1.240	0.5128	0.5123	0.5118	0.5112	0.5107
-1.230	0.5155	0.5149	0.5144	0.5139	0.5133
-1.220	0.5181	0.5176	0.5171	0.5165	0.5160
-1.210	0.5208	0.5203	0.5198	0.5192	0.5187
-1.200	0.5236	0.5230	0.5225	0.5219	0.5214
-1.190	0.5263	0.5258	0.5252	0.5247	0.5241
-1.180	0.5291	0.5285	0.5280	0.5274	0.5269
-1.170	0.5319	0.5313	0.5308	0.5302	0.5297
-1.160	0.5348	0.5342	0.5336	0.5330	0.5325
-1.150	0.5376	0.5371	0.5365	0.5359	0.5353
-1.140	0.5405	0.5400	0.5394	0.5388	0.5382
-1.130	0.5435	0.5429	0.5423	0.5417	0.5411
-1.120	0.5464	0.5459	0.5453	0.5447	0.5441
-1.110	0.5495	0.5488	0.5482	0.5476	0.5470
-1.100	0.5525	0.5519	0.5513	0.5507	0.5501
-1.090	0.5556	0.5549	0.5543	0.5537	0.5531
-1.080	0.5587	0.5580	0.5574	0.5568	0.5562
-1.070	0.5618	0.5612	0.5605	0.5599	0.5593
-1.060	0.5650	0.5643	0.5637	0.5631	0.5624
-1.050	0.5682	0.5675	0.5669	0.5663	0.5656
-1.040	0.5714	0.5708	0.5701	0.5695	0.5688
-1.030	0.5747	0.5741	0.5734	0.5727	0.5721
-1.020	0.5780	0.5774	0.5767	0.5760	0.5754
-1.010	0.5814	0.5807	0.5800	0.5794	0.5787
-1.000	0.5848	0.5841	0.5834	0.5828	0.5821

TABLE 5–Continued

FH/U FOR GIVEN LOG (G)

LOG (G)	.000	.002	.004	.006	.008
-0.990	0.5882	0.5875	0.5869	0.5862	0.5855
-0.980	0.5917	0.5910	0.5903	0.5896	0.5889
-0.970	0.5952	0.5945	0.5938	0.5931	0.5924
-0.960	0.5988	0.5981	0.5974	0.5967	0.5959
-0.950	0.5994	0.5984	0.5974	0.6002	0.5995
-0.940	0.6042	0.6032	0.6023	0.6013	0.6003
-0.930	0.6090	0.6080	0.6071	0.6061	0.6051
-0.920	0.6137	0.6128	0.6118	0.6109	0.6099
-0.910	0.6185	0.6175	0.6166	0.6156	0.6147
-0.900	0.6232	0.6223	0.6213	0.6204	0.6194
-0.890	0.6279	0.6270	0.6260	0.6251	0.6241
-0.880	0.6326	0.6316	0.6307	0.6298	0.6288
-0.870	0.6373	0.6363	0.6354	0.6345	0.6335
-0.860	0.6419	0.6410	0.6400	0.6391	0.6382
-0.850	0.6466	0.6456	0.6447	0.6438	0.6428
-0.840	0.6512	0.6503	0.6493	0.6484	0.6475
-0.830	0.6558	0.6549	0.6540	0.6531	0.6521
-0.820	0.6605	0.6596	0.6586	0.6577	0.6568
-0.810	0.6651	0.6642	0.6633	0.6623	0.6614
-0.800	0.6698	0.6689	0.6679	0.6670	0.6661
-0.790	0.6744	0.6735	0.6726	0.6716	0.6707
-0.780	0.6791	0.6782	0.6772	0.6763	0.6754
-0.770	0.6838	0.6829	0.6819	0.6810	0.6801
-0.760	0.6885	0.6876	0.6866	0.6857	0.6847
-0.750	0.6932	0.6923	0.6913	0.6904	0.6895
-0.740	0.6980	0.6970	0.6961	0.6951	0.6942
-0.730	0.7028	0.7018	0.7009	0.6999	0.6989
-0.720	0.7076	0.7066	0.7056	0.7047	0.7037
-0.710	0.7124	0.7114	0.7105	0.7095	0.7085
-0.700	0.7173	0.7163	0.7153	0.7144	0.7134
-0.690	0.7222	0.7212	0.7202	0.7192	0.7183
-0.680	0.7272	0.7262	0.7252	0.7242	0.7232
-0.670	0.7321	0.7311	0.7301	0.7291	0.7281
-0.660	0.7372	0.7362	0.7352	0.7342	0.7332
-0.650	0.7423	0.7413	0.7402	0.7392	0.7382
-0.640	0.7474	0.7464	0.7454	0.7443	0.7433
-0.630	0.7526	0.7516	0.7505	0.7495	0.7485
-0.620	0.7579	0.7568	0.7558	0.7547	0.7537
-0.610	0.7632	0.7621	0.7611	0.7600	0.7589
-0.600	0.7686	0.7675	0.7664	0.7654	0.7643
-0.590	0.7740	0.7729	0.7719	0.7708	0.7697
-0.580	0.7796	0.7784	0.7773	0.7762	0.7751
-0.570	0.7851	0.7840	0.7829	0.7818	0.7807
-0.560	0.7908	0.7897	0.7885	0.7874	0.7863
-0.550	0.7966	0.7954	0.7943	0.7931	0.7920
-0.540	0.8024	0.8012	0.8000	0.7989	0.7977
-0.530	0.8083	0.8071	0.8059	0.8047	0.8036
-0.520	0.8143	0.8131	0.8119	0.8107	0.8095
-0.510	0.8204	0.8191	0.8179	0.8167	0.8155
-0.500	0.8266	0.8253	0.8241	0.8228	0.8216

FH/U FOR GIVEN LOG (G)

LOG (G)	.000	.002	.004	.006	.008
-0.490	0.8328	0.8316	0.8303	0.8290	0.8278
-0.480	0.8392	0.8379	0.8366	0.8354	0.8341
-0.470	0.8457	0.8444	0.8431	0.8418	0.8405
-0.460	0.8522	0.8509	0.8496	0.8483	0.8470
-0.450	0.8589	0.8576	0.8562	0.8549	0.8536
-0.440	0.8657	0.8644	0.8630	0.8616	0.8603
-0.430	0.8726	0.8712	0.8699	0.8685	0.8671
-0.420	0.8797	0.8782	0.8768	0.8754	0.8740
-0.410	0.8868	0.8854	0.8839	0.8825	0.8811
-0.400	0.8941	0.8926	0.8911	0.8897	0.8882
-0.390	0.9015	0.9000	0.8985	0.8970	0.8955
-0.380	0.9090	0.9075	0.9060	0.9045	0.9030
-0.370	0.9166	0.9151	0.9136	0.9120	0.9105
-0.360	0.9244	0.9229	0.9213	0.9197	0.9182
-0.350	0.9324	0.9308	0.9292	0.9276	0.9260
-0.340	0.9404	0.9388	0.9372	0.9356	0.9340
-0.330	0.9487	0.9470	0.9454	0.9437	0.9421
-0.320	0.9570	0.9554	0.9537	0.9520	0.9503
-0.310	0.9656	0.9638	0.9621	0.9604	0.9587
-0.300	0.9742	0.9725	0.9708	0.9690	0.9673
-0.290	0.9831	0.9813	0.9795	0.9778	0.9760
-0.280	0.9921	0.9903	0.9885	0.9867	0.9849
-0.270	1.0013	0.9994	0.9976	0.9957	0.9939
-0.260	1.0106	1.0087	1.0069	1.0050	1.0031
-0.250	1.0201	1.0182	1.0163	1.0144	1.0125
-0.240	1.0299	1.0279	1.0259	1.0240	1.0221
-0.230	1.0397	1.0378	1.0358	1.0338	1.0318
-0.220	1.0498	1.0478	1.0458	1.0438	1.0417
-0.210	1.0601	1.0580	1.0560	1.0539	1.0519
-0.200	1.0706	1.0685	1.0664	1.0643	1.0622
-0.190	1.0813	1.0791	1.0770	1.0748	1.0727
-0.180	1.0921	1.0899	1.0878	1.0856	1.0834
-0.170	1.1032	1.1010	1.0988	1.0966	1.0943
-0.160	1.1146	1.1123	1.1100	1.1077	1.1055
-0.150	1.1261	1.1238	1.1214	1.1191	1.1168
-0.140	1.1379	1.1355	1.1331	1.1308	1.1284
-0.130	1.1499	1.1474	1.1450	1.1426	1.1402
-0.120	1.1621	1.1596	1.1572	1.1547	1.1523
-0.110	1.1746	1.1721	1.1696	1.1671	1.1646
-0.100	1.1873	1.1848	1.1822	1.1796	1.1771
-0.090	1.2003	1.1977	1.1951	1.1925	1.1899
-0.080	1.2136	1.2109	1.2082	1.2056	1.2029
-0.070	1.2271	1.2244	1.2217	1.2190	1.2163
-0.060	1.2409	1.2381	1.2354	1.2326	1.2298
-0.050	1.2550	1.2522	1.2493	1.2465	1.2437
-0.040	1.2694	1.2665	1.2636	1.2607	1.2579
-0.030	1.2841	1.2811	1.2781	1.2752	1.2723
-0.020	1.2990	1.2960	1.2930	1.2900	1.2870
-0.010	1.3143	1.3113	1.3082	1.3051	1.3021
-0.000		1.3268	1.3237	1.3206	1.3174

TABLE 5–Continued

FH/U FOR GIVEN LOG (G)

LOG (G)	.000	.002	.004	.006	.008
0.000	1.3300	1.3331	1.3363	1.3395	1.3427
0.010	1.3459	1.3491	1.3524	1.3557	1.3589
0.020	1.3622	1.3655	1.3688	1.3722	1.3755
0.030	1.3789	1.3822	1.3856	1.3890	1.3924
0.040	1.3958	1.3993	1.4028	1.4062	1.4097
0.050	1.4132	1.4167	1.4203	1.4238	1.4274
0.060	1.4310	1.4346	1.4382	1.4418	1.4454
0.070	1.4491	1.4528	1.4565	1.4602	1.4639
0.080	1.4676	1.4714	1.4752	1.4789	1.4828
0.090	1.4866	1.4904	1.4943	1.4981	1.5020
0.100	1.5059	1.5099	1.5138	1.5178	1.5218
0.110	1.5257	1.5298	1.5338	1.5378	1.5419
0.120	1.5460	1.5501	1.5542	1.5584	1.5625
0.130	1.5667	1.5709	1.5751	1.5794	1.5836
0.140	1.5879	1.5922	1.5965	1.6008	1.6052
0.150	1.6096	1.6140	1.6184	1.6228	1.6273
0.160	1.6317	1.6362	1.6408	1.6453	1.6499
0.170	1.6544	1.6591	1.6637	1.6683	1.6730
0.180	1.6777	1.6824	1.6871	1.6919	1.6967
0.190	1.7015	1.7063	1.7111	1.7160	1.7209
0.200	1.7258	1.7308	1.7357	1.7407	1.7457
0.210	1.7508	1.7558	1.7609	1.7660	1.7712
0.220	1.7763	1.7815	1.7867	1.7920	1.7972
0.230	1.8025	1.8078	1.8132	1.8185	1.8239
0.240	1.8293	1.8348	1.8403	1.8458	1.8513
0.250	1.8568	1.8624	1.8680	1.8737	1.8793
0.260	1.8850	1.8908	1.8965	1.9023	1.9081
0.270	1.9139	1.9198	1.9257	1.9316	1.9376
0.280	1.9436	1.9496	1.9557	1.9617	1.9679
0.290	1.9740	1.9802	1.9864	1.9926	1.9989
0.300	2.0052	2.0116	2.0179	2.0243	2.0308
0.310	2.0373	2.0438	2.0503	2.0569	2.0635
0.320	2.0701	2.0768	2.0835	2.0903	2.0971
0.330	2.1039	2.1108	2.1177	2.1246	2.1316
0.340	2.1386	2.1456	2.1527	2.1599	2.1670
0.350	2.1742	2.1815	2.1888	2.1961	2.2034
0.360	2.2109	2.2183	2.2258	2.2333	2.2409
0.370	2.2485	2.2561	2.2638	2.2716	2.2794
0.380	2.2872	2.2951	2.3030	2.3110	2.3190
0.390	2.3270	2.3351	2.3433	2.3514	2.3597
0.400	2.3680	2.3763	2.3847	2.3931	2.4016
0.410	2.4101	2.4187	2.4273	2.4360	2.4447
0.420	2.4535	2.4623	2.4712	2.4802	2.4891
0.430	2.4982	2.5073	2.5164	2.5256	2.5349
0.440	2.5442	2.5536	2.5630	2.5725	2.5820
0.450	2.5916	2.6013	2.6110	2.6208	2.6306
0.460	2.6405	2.6504	2.6605	2.6705	2.6807
0.470	2.6909	2.7011	2.7115	2.7219	2.7323
0.480	2.7429	2.7534	2.7641	2.7748	2.7856
0.490	2.7965	2.8074	2.8184	2.8295	2.8406

TABLE 5–Continued

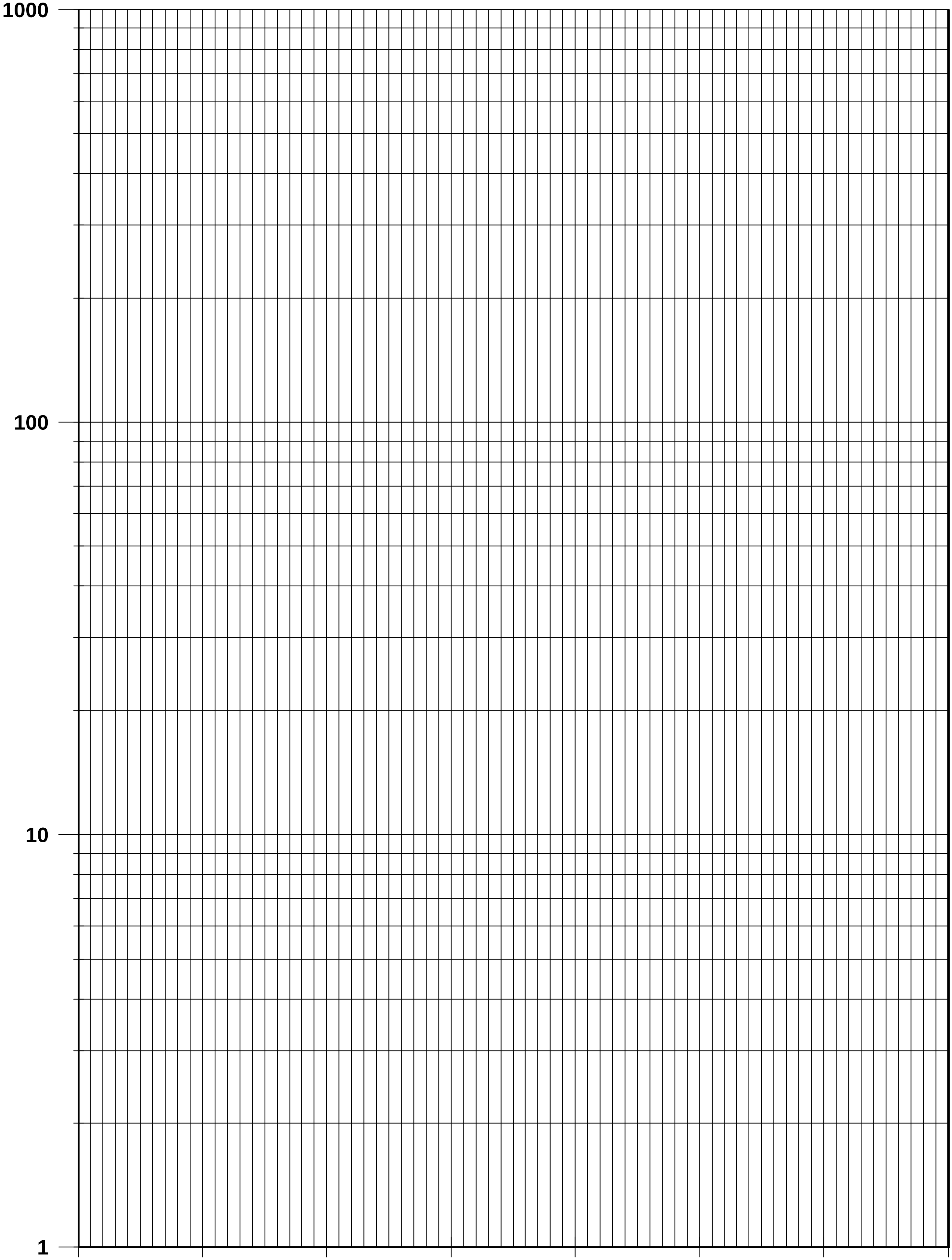
FH/U FOR GIVEN LOG (G)

LOG (G)	.000	.002	.004	.006	.008
0.500	2.8518	2.8631	2.8744	2.8859	2.8974
0.510	2.9089	2.9206	2.9323	2.9441	2.9560
0.520	2.9680	2.9800	2.9921	3.0043	3.0166
0.530	3.0289	3.0414	3.0539	3.0665	3.0792
0.540	3.0919	3.1048	3.1177	3.1308	3.1439
0.550	3.1571	3.1704	3.1838	3.1973	3.2108
0.560	3.2245	3.2382	3.2521	3.2660	3.2801
0.570	3.2942	3.3085	3.3228	3.3372	3.3518
0.580	3.3664	3.3812	3.3960	3.4109	3.4260
0.590	3.4412	3.4564	3.4718	3.4873	3.5029
0.600	3.5186	3.5344	3.5504	3.5664	3.5826
0.610	3.5989	3.6153	3.6318	3.6484	3.6652
0.620	3.6821	3.6991	3.7162	3.7335	3.7509
0.630	3.7684	3.7861	3.8039	3.8218	3.8398
0.640	3.8580	3.8763	3.8948	3.9134	3.9321
0.650	3.9510	3.9700	3.9892	4.0085	4.0280
0.660	4.0476	4.0674	4.0873	4.1074	4.1276
0.670	4.1480	4.1686	4.1893	4.2101	4.2312
0.680	4.2524	4.2737	4.2953	4.3170	4.3389
0.690	4.3609	4.3831	4.4055	4.4281	4.4509
0.700	4.4739	4.4970	4.5203	4.5438	4.5675
0.710	4.5914	4.6155	4.6398	4.6643	4.6890
0.720	4.7139	4.7390	4.7643	4.7899	4.8156
0.730	4.8415	4.8677	4.8941	4.9207	4.9476
0.740	4.9746	5.0019	5.0294	5.0572	5.0852
0.750	5.1134	5.1419	5.1706	5.1996	5.2288
0.760	5.2583	5.2881	5.3180	5.3483	5.3788
0.770	5.4096	5.4407	5.4720	5.5036	5.5355
0.780	5.5677	5.6001	5.6329	5.6659	5.6993
0.790	5.7329	5.7669	5.8011	5.8357	5.8706
0.800	5.9057	5.9413	5.9771	6.0133	6.0498
0.810	6.0866	6.1238	6.1613	6.1992	6.2374
0.820	6.2760	6.3149	6.3543	6.3939	6.4340
0.830	6.4744	6.5152	6.5564	6.5980	6.6400
0.840	6.6824	6.7252	6.7684	6.8121	6.8561
0.850	6.9006	6.9455	6.9909	7.0367	7.0829
0.860	7.1296	7.1768	7.2244	7.2725	7.3211
0.870	7.3701	7.4197	7.4697	7.5202	7.5713
0.880	7.6228	7.6749	7.7275	7.7807	7.8344
0.890	7.8886	7.9434	7.9987	8.0546	8.1111
0.900	8.1682	8.2259	8.2841	8.3430	8.4025
0.910	8.4626	8.5233	8.5847	8.6467	8.7094
0.920	8.7728	8.8368	8.9015	8.9669	9.0329
0.930	9.0997	9.1673	9.2355	9.3045	9.3742
0.940	9.4447	9.5160	9.5880	9.6608	9.7344
0.950	9.809	9.884	9.960	10.037	10.115
0.960	10.194	10.273	10.354	10.435	10.517
0.970	10.600	10.684	10.770	10.856	10.943
0.980	11.031	11.120	11.210	11.301	11.393
0.990	11.486	11.581	11.676	11.772	11.870

TABLE 5—Continued

FH/U FOR GIVEN LOG (G)

LOG (G)	.000	.002	.004	.006	.008
1.000	11.969	12.069	12.170	12.272	12.376
1.010	12.481	12.587	12.694	12.803	12.913
1.020	13.024	13.136	13.250	13.366	13.482
1.030	13.601	13.720	13.841	13.964	14.088
1.040	14.213	14.341	14.469	14.600	14.732
1.050	14.865	15.001	15.138	15.277	15.417
1.060	15.560	15.704	15.850	15.998	16.147
1.070	16.299	16.453	16.608	16.766	16.926
1.080	17.088	17.251	17.418	17.586	17.756
1.090	17.929	18.104	18.281	18.461	18.643
1.100	18.828	19.015	19.205	19.397	19.592
1.110	19.789	19.989	20.192	20.398	20.606
1.120	20.817	21.032	21.249	21.469	21.693
1.130	21.919	22.149	22.382	22.618	22.857
1.140	23.100	23.346	23.596	23.850	24.107
1.150	24.367	24.632	24.900	25.172	25.448
1.160	25.729	26.013	26.301	26.594	26.891
1.170	27.192	27.498	27.808	28.123	28.443
1.180	28.767	29.097	29.431	29.770	30.115
1.190	30.465	30.820	31.180	31.546	31.918
1.200	32.295	32.678	33.067	33.462	33.864
1.210	34.271	34.685	35.105	35.532	35.966
1.220	36.407	36.855	37.309	37.771	38.241
1.230	38.718	39.202	39.695	40.195	40.704
1.240	41.221	41.746	42.280	42.822	43.374
1.250	43.935	44.505	45.084	45.673	46.272
1.260	46.881	47.500	48.130	48.770	49.421
1.270	50.083	50.757	51.442	52.138	52.847
1.280	53.568	54.301	55.047	55.806	56.579
1.290	57.364	58.164	58.977	59.805	60.648
1.300	61.505	62.378	63.266	64.171	65.091
1.310	66.028	66.982	67.953	68.942	69.948
1.320	70.974	72.017	73.080	74.163	75.266
1.330	76.389	77.533	78.698	79.885	81.094
1.340	82.326	83.581	84.859	86.162	87.490
1.350	88.843	90.222	91.627	93.060	94.520
1.360	96.01	97.52	99.07	100.65	102.26
1.370	103.89	105.57	107.27	109.01	110.78
1.380	112.59	114.43	116.31	118.23	120.19
1.390	122.19	124.22	126.30	128.42	130.59
1.400	132.80	135.05	137.35	139.70	142.10
1.410	144.54	147.04	149.59	152.20	154.85
1.420	157.57	160.34	163.17	166.06	169.01
1.430	172.03	175.11	178.26	181.47	184.76
1.440	188.12	191.55	195.05	198.63	202.29
1.450	206.03	209.86	213.77	217.76	221.85
1.460	226.02	230.29	234.66	239.12	243.69
1.470	248.36	253.14	258.02	263.02	268.13
1.480	273.36	278.72	284.19	289.79	295.53
1.490	301.40	307.40	313.55	319.84	326.29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IFTPS

Institute For Thermal Processing Specialists

PROTOCOL FOR CARRYING OUT HEAT PENETRATION STUDIES

Various methods and equipment may be employed in order to collect accurate heat penetration data. The overall objective of these guidelines is to recommend procedures for carrying out heat penetration studies for establishing thermal processes necessary to produce commercially sterile foods packaged in hermetically sealed containers. The following recommendations are to be considered voluntary guidelines. While this does not preclude the application of other methods and equipment for collecting heat penetration data, these guidelines have been developed by consensus of the Institute for Thermal Processing Specialists and should be given serious consideration for adoption as methodology by individuals performing heat penetration studies.

1. NOMENCLATURE

t - Time

tc - Retort come-up time is the time between the start of heating and the time when the retort reaches processing temperature (at times referred to as CUT)

tp - Process time is the time from the end of the come-up period to the end of heating (at times referred to as the operator's process time)

T - Temperature

Tc - Container center or coldspot temperature (at times referred to as CT)

Tr - Retort temperature (at times referred to as RT)

Tw - Cooling water temperature (at times referred to as CW)

2. TERMINOLOGY

2.1 Ballast Containers: Containers may be required to fill the retort during heat penetration studies to simulate production retort conditions. Type, shape and size of containers should be the same as used for the intended process. Material used for filling containers could be the test product, or any suitable material having heating characteristics similar to that of the test product, or in some circumstances, water.

2.2 *Cooling Time:* Time required following the introduction of the cooling medium to decrease the internal temperature of the product to a specified value, commonly 35 to 45o C (95 - 110o F).

2.3 *Critical Factors:* Physical and chemical factors that can influence the thermal response of a product to a thermal process, the variation of which may influence the scheduled process, including: container, product, retort and processing conditions.

2.4 *Fill, Drain and Net Weights:* Fill weight is the weight of solids prior to processing; drain weight, the weight of solids after processing; and net weight, the weight of all product in a container

2.5 *Heat Penetration Curve:* Plot of the logarithmic difference between either retort temperature and product temperature (heating curve) or product temperature and cooling medium temperature (cooling curve) versus time.

2.6 *Mercury-in-Glass Thermometer (MIG):* Generally used as the retort reference temperature device and regulated for that application by government agencies in some countries. Other temperature measuring devices may be calibrated against a MIG retort thermometer which has been calibrated against a traceable temperature standard.

2.7 *Resistance Temperature Detector (RTD):* Thermometry system based on the positive change in resistance of a metal sensing element (commonly platinum) with increasing temperature

2.8 *Temperature Measuring Device (TMD):* Device used for measuring temperature, including: thermometers, thermocouples, RTDs and thermistors.

2.9 *Thermistor:* TMD manufactured from semiconductor materials which exhibits large changes in resistance proportional to small changes in temperature. Thermistors are more sensitive to temperature changes than thermocouples or RTDs and are capable of detecting relatively small changes in temperature.

2.10 *Thermocouple:* TMD composed of two dissimilar metals which are joined together to form two junctions. When one junction is kept at an elevated temperature as compared to the other, a small thermoelectric voltage or electromotive force (emf) is generated which is proportional to the difference in temperature between the two junctions.

3. DESIGN OF A HEAT PENETRATION STUDY

The purpose of a heat penetration study is to determine the heating and cooling behavior of a product/package combination in a specific retort system for the establishment of safe thermal processes and evaluating process deviations. The study must be designed to adequately and accurately examine all critical factors associated with the product, package and process which affect heating rates. Numbers of containers per test run, and number of test runs to account for statistical variability are important and discussed in sections 5.11 and 5.12. Before commencing a heat penetration study, an evaluation of retort temperature and heat transfer uniformity, at times referred to as a heat or temperature distribution study (IFTPS, 1992), should have been completed. A goal in conducting these studies is to identify the worst case temperature response expected to occur in commercial production as influenced by the product, package and process.

4. FACTORS AFFECTING HEATING BEHAVIOR

Several product, process, package and measurement related factors can contribute to variations in the time-temperature data gathered during a heat penetration test. Establishment of a process requires expert judgment and sound experimental data for determining which factors are critical and the effect of changing those factors both within and beyond established critical limits. The list of items addressed in this section is extensive, but should not be assumed to cover all possible factors. Quantitative data on variability should be recorded where appropriate and all pertinent data should be documented to better understand and account for possible variations in heat penetration behavior.

4.1 *Product:*

4.1.1 Product formulation and weight variation of ingredients should be consistent with worst case production values. Changes in formulation may necessitate a new heat penetration study.

4.1.2 Fill weight used for heat penetration studies should not be less than the maximum declared on the process schedule. Excess product may be expressed as percent overfill.

4.1.3 Solids content should be measured for nonhomogeneous products both before and after processing. Solids content deposited in a sieve should be weighed and expressed as a percentage of total weight. Note: Addition of compressed or dehydrated ingredients may result in increased drained weight.

4.1.4 Consistency or viscosity of semi-liquid or liquid components should be measured before and after processing. Flow behavior will change with type and concentration of thickening agent (starch, gums, etc.), temperature and shear rate. Changes may be reversible or irreversible which may be important when reprocessing product.

4.1.5 Size, shape and weight of solid components should be measured before and after processing.

4.1.6 Integrity and size of solid component clusters may change during processing and affect temperature sensor placement in the product and coldspot location.

4.1.7 Methods of product preparation prior to filling should simulate commercial practice. For example, blanching may cause swelling, matting or shrinkage which could influence heat penetration characteristics.

4.1.8 Product matting or clumping may change heat penetration characteristics and influence coldspot location. Also caution should be exercised with sliced products which may stack together during processing.

4.1.9 Rehydration of dried components, either before or during processing, is a critical factor which may influence heat penetration behavior, as well as process efficacy with respect to spore inactivation. Details of rehydration procedures should be recorded during the heat penetration study.

4.1.10 Product may heat by convection, conduction or mixed convection/ conduction depending on its physical properties. Some foods exhibit complex (broken) heating behavior. Product may initially heat by convection, then due to a physical change in the product, change to conduction heating behavior. For example, for products such as soups which contain starch, the change in heating behavior may be due to starch gelatinization at a particular temperature. Small variations in product formulation or ingredients may cause the transition from convection to conduction heating to occur at a different temperature and related time. Special care should be taken to identify and control specific product and process variables related to the heating rates of these products.

4.1.11 Additional product characteristics such as salt content, water activity, pH, specific gravity, concentration of preservatives, and methods of acidification may influence heat transfer or microbiological resistance and should be recorded.

4.2 ***Container:***

4.2.1 Manufacturer and brand name information should be recorded in case information related to filling, sealing or processing is required.

4.2.2 Container type (metal cans, glass jars, retort pouches, semi-rigid containers), size and dimensions should be recorded.

4.2.3 Nesting of low profile containers can influence heating behavior. Heat penetration studies on jumble loaded retorts (no racks or dividers) should include tests conducted on stacks of nested cans as well as single cans.

4.2.4 Container vacuum and headspace should be recorded for rigid containers. For flexible and semi-rigid containers the volume of residual gases in the container should be determined. Entrapped gases may create an insulating layer in the container causing a shift in the coldspot location and a decrease in the heating rate. Controlled overpressures during processing have been found to reduce these effects.

4.2.5 Maximum thickness of flexible packages (pouches) has a direct relationship to the coldspot temperature history with thicker packages heating more slowly. Heat penetration studies should be carried out at the maximum specified package thickness.

4.2.6 Container orientation (vertical or horizontal) within the retort may be a critical factor for some product/package combinations and should be studied where appropriate. Changes in container orientation may also influence vent schedules and come-up time.

4.2.7 Postprocessing examination of test containers for abnormalities should be conducted with special emphasis on the slowest and fastest heating containers. It is strongly recommended that flexible packages be carefully examined following processing to identify the thermocouple junction location. If the intended sensing location has shifted, it is likely that heat penetration data collected are not reliable.

4.3 Method of Fill:

4.3.1 Fill temperature of the product should be controlled. It will affect the initial temperature which may influence some heat penetration parameters (lag factor, retort come-up period). This may constitute a critical control point for a process, particularly for products which exhibit broken heating behavior.

4.3.2 Fill and net weights may influence heating rates both in still and rotary cooks. Information on variability may be found in statistical process control and product quality control records.

4.3.3 In most cases, controlling headspace by determining net weight is not sufficient due to possible variations in the specific gravity of the food product. Care should be taken to avoid incorporation of air which would affect the headspace vacuum. In rotary processes, container headspace is a critical control point since the headspace bubble helps mix the product during agitation.

4.4 *Closing or Sealing:* Closing or sealing equipment should provide a strong, hermetic seal which is maintained during the thermal process. Vacuum in cans and jars for most canned foods is recommended to be between 35-70 kPa (10-20 in-Hg) measured at room temperature. Vacuum is affected by variables such as: headspace, product temperature, entrapped air, and vacuum efficiency of the closing equipment. Some products such as vegetables vacuum packed in cans may have a minimum vacuum as a critical control point. For others packed in flexible or semi-rigid containers, vacuum setting will influence the residual air content in the package, also constituting a critical control point.

4.5 *Retort System:* The type of retort system used may have a significant influence on the heating rates of products processed in the retort. Results from a heat penetration test should be reported with reference to the retort type and conditions existing at the time of testing.

4.5.1 Retort come-up time should be as short as possible consistent with obtaining satisfactory temperature distribution. Laboratory size retorts may be used for development work on heat penetration behavior. Results will be conservative when the smaller retorts have shorter come-up times and cool more quickly than production retorts. After development, the thermal process should, if physically possible, be verified in an appropriate production retort.

4.5.2 Racking systems may be used to separate layers of cans or jars; constrain the expansion of semi-rigid and flexible containers; provide support and circulation channels for thin profile containers; and ensure maximum pouch thickness is not exceeded. Care should be taken to understand the influence of a specific rack design on retort performance and heat transfer to containers.

4.5.3 Still batch retort systems vary in operation based on: type of heating medium(steam, steam/air, water immersion, water spray); orientation of the retort (vertical, horizontal); method of heating medium agitation (fans, pumps, air injection); and other factors which may influence the heating behavior.

4.5.4 Rotational batch retort systems (axial, end-over-end) are designed to rotate (or oscillate) entire baskets of product during processing. Container agitation may provide faster rates of heat penetration to the container coldspot as compared to still cooks. However, while this is true for some containers, it may not be so for all containers within a load and caution must be exercised to identify the slowest heating containers. This may entail a detailed can-position study. It is recommended that during initial testing, data be collected at small time increments (15 s) particularly for viscous fluids where the coldspot may move in relationship to a fixed thermocouple during rotation, producing erroneous results. Slip-ring connectors should be cleaned and thermocouple calibration verified at regular intervals. Critical factors in these retorts include: headspace, product consistency, solids to liquid ratio, initial temperature, container size, rotational speed and radius of rotation.

4.5.5 Continuous retort systems may move containers through the processing vessel along a spiral track located at the outside circumference of a horizontal retort shell or be carried through a hydrostatic retort in chain driven flights. Regardless of the configuration, it becomes difficult or impossible to use thermocouples to collect heat penetration data in these systems. Data may be obtained using self-contained temperature measurement and data storage modules in the commercial vessel or by using process simulators.

5. TEMPERATURE MEASUREMENT AND DATA ACQUISITION

5.1 *Data Acquisition System:* Accuracy and precision of the data acquisition system (datalogger) used for heat penetration studies will affect temperature readings. Dataloggers are typically comprised of a multi-channel temperature measuring and digital data output system. Calibration of a data acquisition system should include verification of the data acquisition rate, since errors in the time base would result in erroneous data.

5.2 *Type of Thermocouple:* The most common TMDs used in thermal processing are duplex Type T (copper/constantan) thermocouples with Teflon insulation. Common configurations are flexible wires (20-, 22- or 24-gauge) and rigid needle types. Details on thermocouples and connecting units are available in Bee and Park (1978) and Pflug (1975).

5.3 *Type of Connectors and Associated Errors:* Connectors used in a thermocouple circuit are fittings attached to a thermocouple within which electrical connections are made. Several types of connectors are available for specific applications and thermocouple type. Caution must be exercised to avoid certain sources of error which may be associated with the use of connectors and extension wires. These include: disparity in thermal emf between thermocouples, connectors and extension wires; temperature differences between two wire junctions; and reversed polarity at the thermocouple-extension wire junction. Thermocouple connectors should be cleaned frequently with metal cleaner to assure good electrical contact and prevent errors in thermocouple readings. Similar concerns should be addressed when using RTDs and thermistors.

5.4 *Thermocouple Calibration:* Thermocouples should be calibrated against a traceable calibration standard (thermometer, RTD, thermistor). Inaccuracies in temperature measurements may result in errors in process evaluation; hence, frequent calibration is essential to provide reliable data. Factors affecting calibration include: worn or dirty slip-rings, improper junctions, metal oxidation, multiple connectors on one lead, and inadequate datalogger cold junction compensation. As a consequence, thermocouples should be calibrated in place as part of the complete data acquisition system. Some precautions when using thermocouple based data acquisition systems include: minimizing multiple connections on the same wire; cleaning all connections; grounding the thermocouples and recording device; slitting thermocouple outer insulation outside the retort to prevent flooding of datalogger or data recording device (see NFPA, 1985, or ASTM, 1988 for illustrations); and using properly insulated thermocouple wires.

5.5 *Positioning of Thermocouple in the Container:* The method of inserting a thermocouple into a container should result in an airtight, watertight seal which should be verified after testing. Thermocouple sensing junctions should be positioned in the slowest heating component of the food product and situated in the slowest heating zone within the container. During insertion of the thermocouple, caution must be taken to avoid physical changes to the product. Also, the method employed for mounting the thermocouple into the container should not affect the container geometry which could influence heat penetration characteristics. Flexible or rigid thermocouples may be inserted into rigid, flexible and semi-rigid containers using compression fittings or packing glands. For flexible containers, NFPA (1985) provides illustrations of thermocouple positioning into a solid particulate and several thermocouple positioning devices to ensure the thermocouple remains in a fixed position within the container. The most appropriate device for a particular application will depend upon the product, racking system, container type and sealing equipment. Leakage may be detected by weighing the container before and after processing to determine changes in gross weight. If there is leakage caused by improperly mounted thermocouples, data collected for that container should be discarded. Note: Ecklund (1956) reported correction factors for heat penetration data to compensate for errors associated with the use of nonprojecting, stainless steel receptacles. While not reported in the literature, this may also be a concern with other fittings.

5.6 *Type and Placement of Containers:* The type and size of container used in the heat penetration study should be the same as that used for the commercial product. The racking and loading of rigid (cans), semi-rigid (trays and cups) and flexible (pouches) containers should simulate commercial practice. Test containers should be placed at the slowest heating location in the retort, as determined by temperature and heat transfer distribution studies.

5.7 *Temperature of the Heating Medium:* TMDs should be positioned so as to prevent direct contact with racks or containers and identified according to their specific location in the retort. A minimum of two thermocouples is recommended for retort temperature measurement: one situated close to the sensing bulb of the retort MIG thermometer, the other located near the test containers. In addition, at least one thermocouple should be placed near the sensor for the temperature controller when that location is remote from the location of the MIG thermometer bulb.

5.8 *Retort Pressure:* Overpressure conditions during processing will influence package expansion by constraining the expansion of headspace gases. This may be beneficial by improving heat transfer to food in flexible and semi-rigid containers or detrimental by restricting the size of the headspace bubble in rotary processes. For steam/air retorts, overpressure conditions are also related to the steam content of the heating medium at a particular processing temperature which may influence heat transfer conditions within the retort. In addition, cooling without overpressure may result in depressurization within a container upon collapse of steam at the end of a process, leading to accelerated decreases in temperature for fluid foods.

5.9 *Coldspot Determination:* The location of the slowest heating or coldspot in a container is critical to establishing a process. For a conduction heating product in a cylindrical can with minimal headspace, the geometric center of the can is considered to be the slowest heating spot. Generally, if a larger headspace is included, the coldspot may shift closer to the top of the can due to the insulating effect of the headspace which may be significant if the height-to-diameter ratio of the can is small. The coldspot location in vertically oriented cylindrical cans containing products which heat by natural convection may be near the bottom of the container. Products which exhibit broken heating behavior may have a coldspot which migrates during heat processing as the physical properties of the product change. The use of containers with different geometries or constructed from different materials may have differing effects on coldspot locations. A coldspot location study should be completed to determine the slowest heating location for a specific product/package/process combination. Usually, the coldspot location will be determined from a series of heat penetration tests employing several containers with thermocouples inserted at different locations. Alternatively, more than one thermocouple per container may be used; however, multiple thermocouples may influence heating behavior, especially for products in smaller containers. In all cases, care should be taken to determine the "worst case" anticipated during production. Careful judgment, based on a number of preliminary experiments, must be exercised to ensure the coldspot location has been identified.

5.10 ***Initial Product Temperature:*** Measurement of initial product temperature should be taken immediately prior to testing.

5.11 ***Number of Containers per Test Run:*** A heat penetration test should evaluate at least 10 working thermocouples from each test run (NFPA, 1985). If the retort cannot accommodate this quantity, the number of replicate test runs should be increased.

5.12 ***Number of Test Runs:*** Replication of heat penetration test runs is important in order to obtain results which account for run-to-run, product, container and process variability. After initial coldspot determination tests are completed and all critical factors have been determined, at least two full replications of each test are recommended. Should results from these tests show variation, a minimum of a third test is recommended. Variation in the results is expected and quite common, especially for products which are non-homogeneous or exhibit complex heating behavior. Variability is generally evaluated based on plots of the heating and cooling curves and/or lethality calculations and should be considered when identifying or predicting the slowest heating behavior of a process.

6.0 SUMMARY OF DOCUMENTATION

The following provides a summary of details which may be incorporated in a checklist and documented in their entirety or partially as deemed appropriate for a specific study. Other factors not listed in this section may also be relevant.

6.1 ***Pre-test Documentation:***

6.1.1 Product Characteristics 6.1.1.1 Product name, form or style, and packing medium

6.1.1.2 Product formulation and weight distribution of components

6.1.1.3 Net weight and volume

6.1.1.4 Consistency or viscosity of the liquid component

6.1.1.5 Size, shape and weight of solid components

6.1.1.6 Size of solid component clusters

6.1.1.7 pH of solid and liquid components

6.1.1.8 Methods of preparation prior to filling (ingredient mixing methods, special equipment)

6.1.1.9 Matting tendency

6.1.1.10 Rehydration of components

6.1.1.11 Acidification procedures

6.1.1.12 Other characteristics (% solids, density, etc.)

6.1.2 Container Description

6.1.2.1 Container material (brand name and manufacturer)

6.1.2.2 Type, size and inside dimensions

6.1.2.3 Container test identification code

6.1.2.4 Maximum thickness (flexible container)

6.1.2.5 Gross weight of container

6.1.2.6 Container nesting characteristics

6.1.2.7 Slowest heating or coldspot location in container

6.1.3 Data Acquisition Equipment and Methodology

6.1.3.1 Identification of datalogging system

6.1.3.2 Thermocouple and connector plugs maintenance

6.1.3.3 Thermocouples and connectors numbered

6.1.3.4 Electrical ground checked

6.1.3.5 Thermocouples placed in heating medium and readings compared with a reference TMD

6.1.3.6 Type, length, manufacturer and identification code of thermocouples and connectors

6.1.3.7 Thermocouple location in container

6.1.3.8 Positioning technique for thermocouple

6.1.3.9 Calibration data for each thermocouple

6.1.4 Fill Method

6.1.4.1 Fill temperature of product

6.1.4.2 Fill weight of product

6.1.4.3 Headspace

6.1.4.4 Filling method (comparison to commercial process)

6.1.5 Sealing Operations

6.1.5.1 Type of sealing equipment

6.1.5.2 Time, temperature, pressure and vacuum settings (if applicable)

6.1.5.3 Gas evacuation method

6.1.5.4 Can vacuum

6.1.5.5 Volume of residual gases in flexible containers

6.1.6 Retort System

6.1.6.1 Retort system: still or rotary (end-over-end, axial, oscillatory)

6.1.6.2 Reel diameter (number of container positions) and rotational speed

6.1.6.3 Can position study data for batch rotary retorts

6.1.6.4 Heating medium (steam, steam/air, water immersion, water spray) and flow rate

6.1.6.5 Circulation method for water or overpressure media

6.1.6.6 Temperature distribution records

6.1.6.7 Retort venting schedule

6.1.6.8 Retort identification number

6.1.7 Loading of Retort

6.1.7.1 Loading or racking system details

6.1.7.2 Location of test containers in retort (slowest heating zone)

6.1.7.3 Container orientation

6.1.7.4 Location of thermocouples for retort temperature

6.1.7.5 Use of ballast containers to ensure fully loaded retort (some retort systems)

6.1.7.6 Selected time interval for data logging system

6.1.8 Additional Information

6.1.8.1 Date

6.1.8.2 Test identification

6.1.8.3 Processor and location

6.1.8.4 Individual(s) performing heat penetration test

6.2 ***Test-Phase Documentation:***

6.2.1 Test run identification

6.2.2 Initial temperature of product at the start of heating

6.2.3 Time heating starts

6.2.4 Time vent closed and temperature, if applicable

6.2 5 Temperature indicated on MIG thermometer

6.2.6 Time retort reaches set point temperature (tc)

6.2.7 Pressure from a calibrated pressure gauge or transducer

6.2.8 Time process begins

6.2.9 Time cooling begins (pressure cooling, if applicable)

6.2.10 Time cooling ends

6.2.11 Rotation speed (if applicable)

6.2.12 Cooling water temperature

6.2.13 Any process irregularities or inconsistencies

6.3 ***Post-Test documentation:***

6.3.1 Container net and gross weight check for leakage

6.3.2 Thickness of container

6.3.3 Location of the thermocouple and whether or not it is impaled in a food particle

6.3.4 Measurement of container vacuum (rigid metal and glass) or residual air content (flexible and semi-rigid containers)

6.3.5 Post-processing product characteristics: syrup strength, appearance, viscosity, headspace, drained weight, pH, consistency, shrinkage, matting, clumping

6.3.6 Container location and orientation (jumble pack)

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- **Prepared by The Committee on Heat Penetration Institute For Thermal Processing Specialists Approved for Publication Nov. 10, 1995**

- The Institute for Thermal Processing Specialists is a non-profit organization established exclusively for the purpose of fostering education and training for those persons interested in procedures, techniques and regulatory requirements for thermal processing of all types of food or other materials, and for the communication of information among its members and other organizations.

- Part of the mandate of the IFTPS Committees is to develop protocols to be used as guides for carrying out the work of thermal processing specialists. This is the first such protocol prepared by the Committee on Temperature Distribution and reviewed extensively by members of the Institute. The protocol has been approved by the Board of Directors. **This document may be photocopied in its entirety for use.**

- Single copies of the protocol, as well as information on membership in IFTPS may be obtained from: Institute for Thermal Processing Specialists, 304 Stone Rd. W. Ste. 301, Guelph, ON N1G 4W4 Phone: (519) 824 6774 Fax: (519) 824 6642, E-Mail: info@iftps.org

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OPERATIONS IN THE THERMAL PROCESSING AREA

OPERATING PROCESSES

9 CFR 431.5(a) requires that a LACF manufacturer post the operating processes and venting procedures to be used for each product and container size being packed in a conspicuous place near the processing equipment, or place the processes where they are readily available to the retort operator and to the Consumer Safety Inspector (CSI). During the CSI’s verification checks, it must remember that the firm’s operating process may be different than the firms scheduled process for the same product. Many firms employ an operating process of one to two degrees above their filed scheduled process temperature and one to two minutes longer then the filed process time to compensate for minor fluctuations in the steam supply and possible improper employee setting or reading of timing devices. This process is called the firm's operating process. If the operating process exceeds the scheduled process, a drop of time or temperature below the operating process is not a process deviation if the drop is not below the scheduled process. The firms scheduled process should be used to evaluate the thermal process for that product.

INITIAL TEMPERATURE

Initial temperature (I.T.) is defined in 431.5(c) as the average temperature of the contents of the coldest container to be processed at the time the thermal processing cycle begins, as determined after thorough stirring or shaking of the filled and sealed container.

The initial temperature of the contents of one container to be processed must be determined with sufficient frequency to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the filed scheduled process. The regulations do not require that the initial temperature of each retort load of product be checked. The closer that a firm operates to the minimum initial temperature in the filed scheduled process the more critical measurement of the initial temperature at frequent intervals becomes.

When initial temperature is measured in those products which incorporate frozen ingredients extra care may need to be taken to insure that the temperature reading is of the (average) temperature of the contents of the container and not just the temperature of the covering liquid. Initial temperature may have a significant effect on the thermal process delivered to the product, and the effect may be determined only through the analysis of process establishment data for that product.

Initial temperature is normally determined using a dial, electronic or other type of hand held thermometer. Glass stem thermometers are normally not used to determine initial temperature because of the potential risk of breakage. Firms have attempted to use pyrometers to measure initial temperature with mixed results. The use of pyrometer's to measure the outside temperature of a container to determine the initial temperature of a process requires adequate studies by the firm to document a correlation between outside container temperature and the actual product initial temperature in the container.

When determining the initial temperature of containers being processed by steam, a container is normally selected from one of the first containers going into the bottom layer of the first retort crate. This container is then set aside where it is not subject to extreme changes in temperature. At the time that the retort lid is closed and the steam is turned on the initial temperature in the container is determined. This same procedure is normally acceptable for all batch type retort systems except as noted. For those retort systems using water to cushion the fall of containers into the retort, or where water is in the retort prior to the addition of the containers, provisions must be made to insure that the temperature of the water does not lower the initial temperature of the containers. In those instances where water comes in contact with the containers prior to beginning the thermal process, the initial temperature of the process may be either the temperature of the contents of the container or the temperature of the water in the retort, whichever is the lowest. In systems that use cushion water, such as the crateless retort system, the initial temperature may be the temperature of one of the last containers to enter the retort, if the cushion water is maintained at a high temperature. For continuous retort systems a container should be obtained just prior to entry into the retort system for initial temperature determination.

Line breakdowns and processing delays may cause the initial temperature in containers to fall below the minimum scheduled initial temperature. During inspections of LACF manufacturers the investigator should determine the firm's procedures for handling product in the event of thermal processing delays. When a product is placed into a retort that has to be cooled to restart the process, or to move the product to a second retort for processing, a new initial temperature may have to be determined.

CRITICAL FACTORS-MEASUREMENT EQUIPMENT

A variety of equipment is used to measure critical factors including: scales, thermometers, gauges, and consistency-meters or devices. The accuracy of the equipment must be documented by the LACF manufacturer. There is no specific requirement in the LACF regulations that equipment used for the measurement of critical factors be checked for accuracy and calibrated as necessary. Good judgment however dictates that equipment used to measure critical factors be accurate. The investigator can determine the accuracy of scales, thermometers and gauges used to determine critical factors by making comparison measurements during the factory inspection. It is suggested that the manufacturing firm also make accuracy checks on their scales and thermometers on a routine basis and that records of these checks be made. If a thermometer used to determine initial temperature or a scale used to determine fill weight is found to be out of calibration, the thermal process for the product for which the device was used may be in question back to the date that the measuring device was last checked for accuracy.

TIMING DEVICES

Devices used to time retort thermal processes must be accurate. Pocket and wrist watches are not considered satisfactory for timing purposes. Even though wrist and pocket watches may be accurate, one problem noted with the use of wrist watches is that several people involved in separate portions of the thermal process may use wrist or pocket watches with different times of the day. When this happens the thermal processing records do not correspond to each other. A large wall clock which can be read from all areas of the thermal processing room is the best method for timing thermal processes. If more than one clock is used in the thermal processing area they both should be set to the same time of day. During the inspection of LACF manufacturers the accuracy of the timing clock should be checked with an accurate stop watch.

431.5(d) states digital clocks may be used if the operating process and the venting schedule have a 1 minute or greater safety factor over the scheduled process and venting schedule. If the digital clock reads out to the second this requirement is not necessary.

When timing clocks are read, the method used must be conservative to insure that the time of vent, come up time, the time of thermal processing, and other operations are carried out for the required time interval. Except in those instances where automatic equipment is used to record times, the operator normally records operations in the thermal processing area in full minutes (e.g., 7:15). If time is not recorded to the second that the operation takes place then the operator must record the time for the beginning of the operation at the next full minute and the time for the end of the operation to the last full minute to insure that the full required time for an operation is achieved (e.g., if the retort vent is turned on at 07:10:15, the operator would record 07:11 and if the retort vent was turned off at 07:10:15, the operator would enter 07:10). Operations in the retort room must be monitored during the inspection to insure that timing of the operations are accurate. Use of a stop watch by the investigator insures that accurate time intervals are measured.

CONTROL OF RETORT TRAFFIC

431.5(b) defines that traffic in the retort room and processing area must be controlled to prevent unprocessed LACF from circumventing the thermal process. The retort area should be designed so that product enters one end of the processing area and leaves the opposite end. This can be done in several ways depending upon the retort system in use. For batch retort systems a routine procedure should be designed by the firm to stage unprocessed product in an area separate from processed product. When multiple vertical retorts are arranged in rows or rings, the product should enter the row or ring at a different location than product exits the ring or row. In systems using continuous conveyors or chains to move the product through the retort system the entry and exit of product should be physically separated if possible to prevent the mixing of processed and unprocessed containers. Containers which are found to be on the floor or off of normal conveying equipment should be destroyed.

Crates and containers of LACF products must be identified in a manner which will readily identify the status of the product. One method of identifying the status of LACF product containers is through the use of thermal indicators. Thermal indicators are placed on the containers, on one container in a retort crate, or on the retort crate itself. Thermal indicators may be impregnated onto a paper tag to be attached to a retort crate, painted onto the surface of a container or crate, incorporated into a tape to be placed onto a container or crate, or incorporated into an ink jet spray which is applied by the can manufacturer or canning firm. Some container manufacturing firms incorporate thermal ink into a container manufacturing code which is placed on each container. Thermal indicators can be purchased to meet the temperature range of the thermal process being used. Thermal indicators do not however indicate that an adequate thermal process has been applied to the LACF product, only that the product has been subjected to a heat source. The thermal indicators should be examined following processing and written records of changes in thermal indicators should be made. In lieu of thermal indicators the firm can use other effective means of visually distinguishing between processed and unprocessed containers.

STEAM SUPPLY

Although other methods of heating LACF are being developed, steam is the predominant heating medium used to process LACFs. The steam may be used to directly or indirectly heat the products or containers. Steam in modern canneries is normally produced in remote steam boilers. Two common types of steam boilers or generators found in canneries are the fire-tube and water-tube. Smaller boilers of the "packaged" boiler type are almost always fire-tube boilers, and in physical appearance are unusually long and relatively low. Such boilers are often referred to as "scotch-marine" or "marine" type boilers. Larger boilers which have been constructed in place are almost always water-tube boilers, and are usually nearly square and quite high, some times 4 or 5 stories high. The fire-tube boiler is operated at pressures normally under 150 psi. One advantage of the fire-tube boiler is the large water storage capacity. Because of this feature, wide and sudden changes in steam demand are met with little change in pressure. Watertube units on the other hand are capable of considerably higher overloads. Boilers may be fired using a variety of fuels including, natural gas, liquid propane gas, fuel oil, coal and wood. The method of firing the boiler may have an impact on the steam pressure supply and recovery time.

Boiler or steam generator capacities are normally listed in terms of horsepower or lbs of steam per hour. The term horsepower is defined as the ability of the unit to change approximately 34 lbs of water at 212° F to 34 lbs of steam at 212° F. If boiler capacity is given in pounds of steam per hour it can be converted to equivalent number of horse power by dividing by 34.5. The rated capacity of a boiler is not an absolute measure of the amount of steam that can be generated. Fire tube boilers may be operated at 135 to 150% of the rated capacity and water tube boilers may be operated at 150 to 200% of capacity. Operation of the boiler depends upon proper maintenance of the boiler. A boiler with heavily encrusted scale in the tubes or one which is not properly fired may not be able to even meet the rated capacity of the boiler. This is usually beyond the ability of the investigator to determine.

Steam pressures in the main steam line (header) may vary depending upon the operation of the boiler(s) and the demand upon the steam supply. Boilers are normally operated by either of two methods, use of modulating burners, or on-off operation of the boiler. Modulating control is normally used in larger installations. Small plants usually operate by on-off operation of one boiler; if additional boilers are used they are normally fired at a fixed rate. The pressure gauge on the main steam line should be watched over a period of time to determine if there are large fluctuations in steam pressure. Modulated systems will normally have only small variations in the steam supply; however the variation in on-off systems can be quite large. A reserve steam capacity is sometimes obtained by operating the boilers at a high pressure (150 psi) and using a reducing valve to reduce the steam pressure to (100 psi) at the retort steam supply header.

Steam header pressure at the retorts of 100 to 125 psi is recommended for best performance. Lower steam pressures can provide for adequate operation of retort systems if the steam supply valve and plumbing of the retorts is carefully selected. Temperature distribution testing in the retort system should be performed on these systems to document adequate operation under the highest plant steam demand. The greatest steam demand for retort systems normally occurs when the maximum number of steam retorts are being vented or during the heating or come-up period of other retort systems. A standard three or four crate vertical still steam retort can require from 2,500 to 6000 lbs of steam per hour (depending upon the size of the steam inlet) during venting. One-fourth to one-half of the total steam demand of the retort is required for venting. The steam demand of the retort rapidly drops to 100 to 150 lbs per hour after the vent is closed and the retort reaches processing temperature. Other retort systems have similar peak demands during the initial heating phases of the retort and product. The steam supply to the retorts must take into consideration the maximum number of retorts to be vented or brought to processing temperature at one time and any other equipment, such as blanchers, steam kettles, steam peelers, and steam exhaust boxes, which may have a steam demand at the same time. The steam demand of the entire plant should be taken into consideration during the establishment of venting and come-up schedules for retort systems. Fluctuations in the header steam pressure should be correlated with fluctuations in retort temperatures, long vent periods and long come-up times in the retort systems.

Most boiler systems require the addition of water treatment chemicals to prevent the buildup of scale on the boiler tubes and to prevent corrosion in the boiler system. When the steam comes into contact with the LACF, through direct injection of the steam into the food; during the exhausting of containers in a steam exhaust box; through injection of steam into the headspace of containers to form a vacuum, or through any other means, the boiler additives must be approved for use as a food additive and labeled for that use as per 21 CFR Part 173.310, Boiler Water Additives.

THERMAL PROCESSING SYSTEMS INSTALLATION AND INSTRUMENTATION

Although retort systems vary from still batch type retorts to more complex continuous retorts, employ different heating mediums during processing, and may use control systems ranging from operator to computer controls; there are still basic equipment requirements specified in the LACF regulations 431.6 that are applicable to all retort systems.

MERCURY-IN-GLASS (MIG) THERMOMETER

Each retort system used for the thermal processing of LACF(s) must be equipped with a MIG thermometer as per 431.6(a)(1)(i). This is emphasized in the LACF regulations by being repeated for each specific retort system covered

431.6(a)(1)(ii) allows other temperature-indicating devices, such as resistance temperature detectors, used in lieu of mercury-in-glass thermometers, provided they meet know, accurate standards for such devices when tested for accuracy.

The MIG thermometer is the reference instrument for all temperature readings, including vent temperatures, come-up temperatures and process temperature during the processing of LACF(s).

The regulations require that the MIG thermometer be graduated in divisions which are easily readable to 1° F (1/2° C) and whose temperature range does not exceed 17° F (8° C) per inch (2.54 cm). The thermometer may be graduated in 2° F (1° C) divisions as it is possible to read a MIG thermometer graduated in this manner to the nearest 1° F (1/2° C). The LACF regulations require that MIG thermometers be tested for accuracy upon installation, and at least once per year after that. It is important that the MIG thermometer be tested/calibrated at the operating temperature of the retort system (i.e. 240° F, 250° F, 260° F etc.) and if possible in the heating medium used in the retort. If the retort is operated at more than one processing temperature or over a wide range of temperatures the MIG thermometer should be checked at all of the temperatures normally used for processing LACF(s). The MIG thermometers should be tested against a thermometer that can be traced back to an NIST (National Institute of Standards and Technology) Standard thermometer. The standard thermometer should also be checked for accuracy on a routine basis. Documentation should be available for the calibration of the standard thermometer used and its last check for accuracy. The accuracy of the standard thermometer should be checked at least once every 3 years depending upon how it is handled and stored.

One way that firms using steam for thermal processing can check their MIG thermometers is to use a cross made of 3/4 inch pipe for holding the thermometers with 1/16 inch holes drilled in the fittings to provide for a flow of steam past the thermometer bulb. The cross is then mounted on a retort or steam manifold with a certified standard thermometer in the center and one MIG retort thermometer to be tested in each of the two outside arms. The thermometers are then allowed to heat to equilibrium for 10 to 15 minutes. If an adjustment is needed the face plate screws are loosened and the face plate is adjusted on the MIG thermometers. After the adjustment another reading is taken to insure that the thermometer is now reading the same as the standard MIG thermometer.

The installation of the standard thermometer in the retort next to the MIG thermometer to be checked and the use of a circulating laboratory oil bath are also acceptable methods used to check MIG thermometers for accuracy.

Records should be kept of the accuracy check of all MIG thermometers which include the date of the last check, the person performing the check, the standard used, the method used, and the amount of correction needed to bring the thermometer back into calibration. The regulations recommend that each thermometer be identified with a tag, seal or through some other means that identifies the date on which the last accuracy test was made. The MIG thermometer must at least be identified in a manner that will allow the thermometer to be matched with the thermometer calibration records.

MIG thermometers that have a divided column, that are broken, or which can not be adjusted must be repaired or replaced immediately.

The MIG thermometer must be installed in a manner that it can be easily read, without the operator having to go to extraordinary measures, such as entering a steam flow, touching hot equipment, or climbing a ladder to make the reading. If it is difficult for the MIG thermometer to be read, the operator will be more likely to use the recording chart or some other method to obtain temperature readings, not the MIG as required by the regulations.

TEMPERATURE RECORDING DEVICE

The LACF regulations in 413.6(a)(2) require that each retort system be equipped with an accurate temperature-recording device. This has been interpreted to mean that the recording device provides a continuous record of the temperature in the retort system during thermal processing. Common systems found use circular or strip charts which are marked with ink pens, electrical sparks, pressure pins, or which are created by graph plotters at the time temperature readings are received.

The regulations require that graduations on the temperature-recording device charts must not exceed 2° F (1° C) within a range of 10° F (5.5° C) of the processing temperature. A working scale of not more than 55° F per inch (12° C per Cm) is required within 20° F (10° C) of the processing temperature. A ruler can be used during the inspection to determine the firm's compliance with this part of the LACF regulations. The object of the chart specifications is to provide a chart which can be easily read by the operator and record reviewer. The regulations require that the temperature recording chart be adjusted as closely as possible to the reference MIG thermometer but to be in no event, higher than the known accurate reference thermometer. The working accuracy of most recording devices is at least 1 F (1-1/2°C). In most instances the recording chart can be adjusted to agree with the MIG thermometer to within 1 F (1-1/2°C).

The temperature recorder should provide a fine temperature recording line which can be easily read to the nearest 1 F (1/2C). A conservative approach should always be taken

when reading a wide line on a temperature recording curve or line. The temperature recorded should always be determined by reading the bottom of the recorded line on the temperature chart.

The pen arm on a circular chart recorder should follow the time curve on the chart. Failure of the pen arm to follow the time curve indicates that the pen is out of adjustment, bent, or that the wrong chart is being used. It is evident that the pen is not following the temperate curve on the circular chart when it is noted that the temperature curve travels back in time as the pen arm moves up or down on the chart. Some of the more common recorders found in use have a mark inside of the chart case for adjusting the arc of the pen. The number of the chart to use with the recorder may also be stamped inside of the recorder case.

Recorders are driven either by electrical or mechanical wind-up clock mechanisms. If driven by a wind up clock the firm must insure that the clocks are wound on a daily basis. The recorder chart should be adjusted at the beginning of the production day to agree with the time of day. The majority of charts in use can be adjusted to agree at least to within 15 minutes of the time of day. The accuracy of the timing mechanism should be determined over a designated time interval through the use of stop watch. If the timing mechanism is not accurate, the recorder will not provide accurate temperature recordings of the thermal process.

A means of preventing unauthorized changes to the temperature recorder must be provided by the firm. This can consist of a locked recorder box, and/or a posted notice from management that only authorized persons are allowed to make changes.

The temperature recorder probe must be installed in the retort in a manner which will provide a true recording of the retort temperature. The recorder sensing probe is normally installed next to or in the same manner as the MIG thermometer. The recorder is then adjusted to the MIG thermometer.

The LACF regulations recommend that each retort system be equipped with a pressure gauge that is graduated in divisions of 2 lbs or less. A pressure gauge is necessary for observing the pressure during pressure cooling, and processing over-pressure in those systems using air or steam to create pressures higher than those created by the system temperature. The pressure gauge is also an extra safety device which lets the operator know if excess retort pressure is being created.

Vents are large pipes, located opposite the steam entry on steam retorts, used to expel the air from the retort prior to beginning the thermal process. Retort systems other than steam retorts sometimes identify a purge valve, used for removing air from the system to allow for the addition of water to a processing drum or for the rapid introduction of steam to a steam-air retort, as a vent valve. The valves on these systems do not serve the same function as the vent valve on a steam retort. The operation of the vent or purge valve may be critical to the thermal process achieved in the retort system. Bleeders are small openings required on steam retorts to remove air from the retort during processing, promote circulation, and remove condensate from specific retort systems. A bleeder is also necessary to ensure adequate steam flow past thermometer bulbs. They should be open at all times during venting, come-up and thermal processing. Bleeders must be installed in a manner that allows the operator to observe that they are functioning during operation of the retort.

Mufflers are mechanical devices placed on bleeders or vents of steam retorts to reduce the noise of the escaping steam. If mufflers are used the LACF manufacturing firm must have information on hand in the form of temperature distribution data or other documentation, such as a letter from the manufacturer, that shows that the mufflers do not impede the flow of steam.

STEAM CONTROLLERS

Automatic steam controllers are required by the LACF regulations 431.6(a)(3) for all retort systems. The automatic steam controller may operate independently of or in conjunction with the temperature recorder. Steam controllers are of two main types: on/off or modulating. With an on/off system the steam valve is either fully open or fully closed. In a system with an on/off steam valve you would expect to find fluctuations in the temperature curve produced by the temperature recorder. Modulating systems control the steam valve to proportionally supply steam to the system as needed.

One method of retort temperature control found prior to the current LACF regulations in some U.S. LACF plants, and still found in LACF plants in foreign countries, is the operator manually controlled steam valve. In these retort systems the operator observes the steam pressure on a retort pressure gauge and/or the retort temperature on a MIG thermometer, or on some other type of thermometer. The steam valve is then opened and closed by the retort operator to maintain the required steam pressure or thermometer readings. In some plants where this type of control has been used, it has been noted that by assigning one operator to each retort, the steam supply to the retort can be controlled to provide for a consistent temperature. The retort temperature control is dependent upon the operator observing the retort steam pressure and/or temperature constantly. This type of steam/temperature control does not meet the requirements of this section of the regulation.

The temperature of saturated steam of high quality bears a fixed relationship to its absolute pressure (psia). In most instance steam is measured as gauge pressure (psig), which has its zero point at 14.7 psia (equivalent to atmospheric pressure at sea level). 15.1 psig (Pounds per Square Inch Gauge Pressure) of steam at sea level is equal to 250F. Attachment 1 is a table which provides the corresponding gauge pressure and process temperatures at various altitudes. Gauge pressures above those listed for the corresponding temperatures may indicate air pockets in a steam retort system.
One of the oldest methods of temperature control in steam retort systems is the use of the relationship between steam pressure and temperature in the retort. In this type of control system a pressure line is connected between the retort and a steam control valve. The diaphragm on the control valve is opposed by a spring which pushes against the valve stem and opens the valve. When the steam is turned on to the retort the steam pressure in the retort is low and the steam control valve is forced open by the spring tension. As the pressure/temperature in the retort rises, steam pressure against the diaphragm forces the steam valve to close, and less steam is supplied to the retort. As

the pressure/temperature in the retort fluctuates the valves opens and closes to modulate the steam supply to the retort. This type of controller may provide for adequate temperature control if it is well maintained. You will normally see fluctuations in the temperature recorder curve as the pressures changes in the retort and steam supply. Firms using this type of controller normally operate several degrees above their filed scheduled process temperature to account for fluctuations in the temperature in the retort.

Control of steam supplies to retorts has been reported using valves which are connected to the steam header. One type of valve is actuated in one direction by a lever arm with adjustable weights, operating against an opposing fixed spring. In another type the valve is set to open a fixed amount by adjusting the compression of a moveable spring, operating against an opposed fixed spring. If the steam header pressure does not fluctuate appreciably, these will perform satisfactorily. If the header pressure does vary, the retort pressure/temperature will vary also; for these valves are essentially steam pressure ratio valves.

For example: Assume that the header pressure is 105 psig when a valve of this type is adjusted to hold 15 psig (250 F) in the retort. If the header pressure drops to 90 psig at any time, the retort pressure will drop to 12.5 psig (245 F).

$$(P1-P2)/P2 = \text{pressure ratio therefore } (105-15)/15 = 6$$
$$\text{and } (90-15)/X = 6, \text{ or } X = (90-15)/6 = 12.5 \text{ psig}$$

For this reason in those systems which use these types of controllers it is important to observe the retorts operate through several cycles to determine if temperature fluctuations are being caused by fluctuations in the steam supply. Using this type of steam controller to supply steam to more than one retort would not meet the requirements of 431.7(a)(3). Fluctuations in temperature control should be documented during the inspection. Records should be reviewed to determine if process deviations have occurred because of fluctuations in steam supply to the retorts.

Self-actuated steam supply/temperature control valves which operate directly off of the pressure generated in a liquid/vapor filled temperature sensing tube are available for temperature control in industrial situations. In this type of control system the vapor generated by the heating of the liquid in the temperature sensing bulb is used to exert pressure on the diaphragm of the steam control valve. The pressure on the diaphragm is opposed by a spring. As the liquid heats up in the sensing tube the gas pushes on the valve diaphragm causing the valve to close. As the temperature drops the spring forces the valve open. Different liquids are used to fill the sensing tube depending on the temperature range to be controlled. The system temperature would be adjusted by adjusting the spring tension on the steam control valve. This type of temperature control is not normally found on retort systems.

One of the most common types of retort temperature control systems found in the U.S.

is the pneumatic (air to open) steam control valve (Attachment 2). This valve is opened by supplying air to a diaphragm which is connected to the valve stem. The valve is closed by spring pressure on the valve stem. The valves are air-to-open for safety reasons. If the power or air supply fails, the loss of air to the system results in the steam valve closing and the retort pressure/temperature falling. These valves are commonly connected to a mechanical recorder/controller which controls the supply of air to the valve (Attachment 2) when using the mechanical recorder/controller a temperature bulb in the retort is connected through a thermal tube to a Bourdon tube located in the control panel. The temperature changes in the retort cause the Bourdon tube to expand and contract.

Expansion/contraction of the Bourdon tube causes the recording arm to move which also controls the amount of air to the control valve. As the temperature in the retort rises, the supply of air to the valve diaphragm would be reduced, the spring would force the valve partly closed and less steam would be supplied to the retort. As the temperature in the retort starts to fall, more air is supplied to the valve diaphragm and the valve is forced open, with more steam being supplied to the retort.

Pneumatic air controlled valves are also common in many advanced computer controlled retort systems. In these systems the air supply to the steam control valve is usually controlled through an electronic solenoid.

With any retort using air for control of the system it is very important that the air supply to the instruments and control valves be kept clean and free of oil, water, rust and other contaminants. It is ideal for the air supply to the instruments to be separate from the air supply to the rest of the plant. This air supply should be equipped with devices for keeping the air clean, such as air filters, condensate traps, water drains and oil traps. Maintenance of the air supply system on a routine basis is essential to the continued accurate operation of pneumatic air controls.

A simple mechanical/electrical control system for an electronic solenoid operated steam control valve may consist of a temperature dial to set the selected retort temperature, a temperature sensing element in the retort which is connected to a Bourdon tube or some other type of expanding gas or liquid sensor, and a steam supply valve which is controlled by air, an electric solenoid or rotary motor. These systems act much the same way that a thermostat in your house would be used to control the temperature. As the set temperature in the retort is reached the expansion of the liquid/gases in the temperature sensing element causes the Bourdon tube to expand, expansion of the tube causes electrical contacts to open or close, depending upon the design of the control mechanism. As the electrical contacts close an electrical source is supplied to an electronic solenoid or motor to operate the valve. This type of system may supply steam in an on/off fashion instead of proportionally.

A similar type system would replace the Bourdon Tube with a solid state electronic temperature controller using a thermocouple or resistance temperature devices (RTD) to sense the temperature in the retort. The solid state electronic circuits would then be set to control the retort at the selected operating temperature through the use of an electronic solenoid, solenoid/air or electric motor operated steam control valve. The solid state circuits may provide for on/off or proportional operation of the steam valve depending upon the control system and manufacturer.

In systems using RTDs or thermocouples a low level electrical signal is sent to a control mechanism. It is important not only for a firm to properly calibrate the RTD/thermocouple but to insure that the electrical signal sent to the sensor is not interfered with. The circuits (wires) used to transmit the signal to the signal convertor or sensor must be designed and installed to prevent electrical interference on the circuit. Electrical interference on the circuit can cause false readings to be received from the RTD/thermocouple. The firm should have in place a system for routine calibration and maintenance of RTD's and thermocouples including the complete control circuit.

MECHANICAL/ELECTRICAL TIMED RETORT CONTROL SYSTEMS

Addition of a manually set electrical/mechanical clock to the pneumatic air/electrically controlled valve systems mentioned above provides for timing of the retort thermal process. An additional mechanical/electrical clock for the timing of the vent cycle on steam retorts further automates the system. These systems are designed so that both a time and temperature must be reached for venting; the process timing does not start before the process temperature is reached, and the process ends after the set process time has been reached. These systems still require the observation and manual recording of MIG thermometer readings and processing times.

In 1948 Taylor Instrument Co. supplied the LACF industry with the first fully automatic controlled retort systems. Other manufacturers have introduced similar systems since that time. These systems use electronic/mechanical clocks, stepping switches electronic relays, pressure switches, solenoid valves and temperature sensors to provide for automatic/pneumatic control of vent valves, bleeder valves, cooking times, over-pressure, cooling water, cooling times, and draining of the retort. The operators function is to set the process time, the thermal process temperature, and the vent times to meet those of the operating thermal process. In order to start the process the operator only has to push a start button. The control of the retort thermal process is then through the controller. The system may be equipped with a series of lights which indicate when the steam is turned on, when the process is up to temperature (start of thermal process) and when the retort is in the cooling phase. The operator is still required to observe and manually record MIG thermometer temperature readings, processing times, vent times and other factors critical to the process. At the end of the process the timing clocks are automatically reset to the preselected times. The system is then ready for the next thermal process.

Because these systems are fully automatic, including the operation of the bleeder valves, maintenance of the system is often neglected. Failure to adequately maintain the system can result in failure of bleeder valves, vent valves and system controls to operate properly. When these types of retort control systems are encountered the investigator must observe the operation of the system through several cycles to insure

that all control valves are operating properly, that bleeder valves are fully open and functional during the venting and thermal processing cycles, and that scheduled process time and temperature parameters are being met.

Cam operated control systems have been used by U.S. and European equipment manufacturers to automatically control retort processing including processing temperature, pressure, processing times and cooling times. In these systems a cam is cut out of plastic, metal or some other durable material. As the cam is turned by an electrical/mechanical clock a cam follower rides upon the cam and operates a series of electrical sensing switches. The electrical switches are used to operate electrical and/or pneumatic control valves which supply steam and air to the retort or serve other functions such as venting of the retort. Care has to be taken to cut the correct profile in the cam to provide the correct thermal process. As the cam wears the profile may change, changing the thermal process.

European manufactures such as LaGarde and Stock have used card readers to control retort temperature, retort pressure and process timing. In these systems a card made of plastic, metal or paper is either cut or punched to a certain profile for each thermal process. The card is then placed in a card reader. In the LaGarde system the card is read by a light source. As the card passes through the reader the light source activates limit switches. In the Stock system the card comes into contact with the limit switches as is passes through the card reader. The limit switches control the signals sent to the control valves which may be either electronically or pneumatically controlled. The profile of the cards are very important. Care has to be taken to punch or cut the correct profile for each thermal process. If the profile is not cut correctly for the process the correct process will not be provided. The cards also become worn or damaged during use and care must be taken to maintain the cards in good working condition.

DIGITAL ELECTRONIC CONTROLLERS

In recent years digital electronic controllers have replaced the relays and sensing switches of mechanical/electrical control systems. Digital control systems may range from the single-loop controller to complex high-end computer systems.

If the process to be controlled consists of numerous sequential (logical) steps, the controlling device can be a first-level computer device called a logic controller. The logic controller may be set up as a single loop controller.

A single loop controller would be responsible for controlling one function such as temperature in the retort. The controller loop would be programmed to control the retort temperature within set temperature parameters. The loop would consist of the microprocessor controller, a sensor, and actuator for the steam valve and a digital/analog signal converter. The simple single loop controller contains Read Only Memory (ROM) which is manufactured into the controller or programmed into the controller by using Programmable Read Only Memory (PROM), Erasable Programmable Read Only Memory (EPROM), or Electronically Erasable Programmable Read Only Memory (EEPROM). PROM is field programmable by the manufacturer or customer one time only by burning out fuses in the PROM microprocessor chips. EPROM is electronically programmed by the manufacturer or user. EPROM microprocessor chips can be reprogrammed by exposing the chip to an ultraviolet light source which resets the original chip configuration. EEPROM microprocessor chips can be reprogrammed by electronically erasing the memory on the chip. ROM is normally used to control processes where the options of the customer or operator do not need to be changed.

Random Access Memory (RAM) using battery backed volatile memory components is another type of memory component. This memory requires a power supply but lends itself to modification and reprogramming. Advanced microprocessor or computer systems would normally use a combination of ROM and RAM to program control of retort functions.

A more advanced system would use a programmable logic controller (PLC) which would allow the operator or firm to alter the control limits of the controller. This type of controller would use algorithms (a programmed procedure for solving a problem) to control the loop. Algorithms are written to provide the microprocessor with a logical sequence of events for solving a problem.

Control of multiple parameters such as temperature, pressure, rotation, etc may be controlled by installation of several loop controllers controlled by one PLC, microprocessor or computer.

With the advancement of technology, defining the differences between microprocessors, minicomputers and mainframe computers has become more difficult. Size is usually the distinguishing factor. The size of the computer needed for control depends upon the number of loops to be controlled and whether the system is set up as an independent (each retort control system is self standing), centralized (one computer controls all retorts), or a distributed system (two or more computers talking to each other).

In the independent system each retort would be controlled by its own PLC or microprocessor. If one of the retort control systems failed the remainder of the systems would continue to operate.

In a centralized system all data would be collected and analyzed by a central computer. This provides for quick capture of all processing information and for control from a central location. Failure of this control system would mean that all processing systems would be down.

In the distributed system a PLC or microprocessor can be used for independent control of each retort system. The retort microprocessor is then used to supply information to a systems computer which captures all retort data for storage and printing. The systems computer in turn is used to store process programs and to program the logic controls of the microprocessor.

Computer controlled retort systems may be marketed with one or more peripherals added to the basic PLC or microprocessor. Peripherals may include: keyboard or key pads for programming and entering information, printers for printing stored and captured in-process information, personnel computers for programming the PLC, CRT (touch screens) for monitoring the process and entering information, and modems which allow for connections to remote computers for programming or trouble shooting.

During inspections of LACF manufacturers using computers to control thermal processes or to control other factors critical to the process the investigator must determine the functions of the computer system.

In many cases LACF manufacturing firms will not have on hand detailed information covering the development and validation of the software and microprocessors used on their retort systems. Many firms buy the microprocessors as black boxes from the equipment vendor. The investigator must then determine the functions of the control system in as much detail as possible. It is important to remember that computer controlled retort systems must function to provide for control of the thermal process, the same as any other type of control system. The mercury-in-glass thermometer is still the reference thermometer as per the LACF regulations. The operator is required to read and record mercury-in-glass thermometer readings the same as for any other control system (these may be entered into a computer record). Each retort system is still required to be equipped with a temperature recorder as per the LACF regulations. This recorder must provide a continuous record of the thermal process; must meet the specifications of the LACF regulations; and must not record a temperature higher than the MIG thermometer reading. It is important to determine that the system is controlling the retort to meet the requirements of the firms filed scheduled processes for time and temperature; that critical factors such as rpm's in agitating retorts and come up time in water immersion retorts are being controlled; and that vent times and temperatures for steam retorts are being adequately controlled. If the firm has a schematic drawing of the control system this should be obtained or the investigator may prepare a simplified schematic drawing, which will be helpful in explaining the system operations. If the firm does not have detailed information on the microprocessor control system the investigator should obtain any limited information that is available. At a minimum this would include the vendor and model numbers of the computer control system and the functions performed by the computer control system. Observation of the system as it operates can be used to determine if critical factors such as RPM, vent times, temperatures, pressures, and thermal process times are being adequately controlled by the microprocessor. This may require observation of the system through several thermal process cycles. The investigator should determine who is responsible for programming the system, how the system is programmed, the name and number of programmable functions, if the programming functions are password or otherwise protected and who is responsible for record review and process verification.

It is also important to determine if the operator has the ability to override any of the computer control functions. If operator override of computer functions are possible, details on how this is done, what overrides are possible, and how this is reflected in the thermal process record should be determined.

The investigator should determine how the system handles process deviations during thermal processing. If the computer system is able to calculate new processes or chose alternate pre-programmed processes the investigator must determine the parameters for computing or selecting the alternate process.

During inspections where microprocessor or computers are being used to control thermal processes in retorts the CSI should determine at a minimum:

1. The equipment specifications for software and hardware.
2. The critical factors that are controlled by the system.
3. How the critical factors are controlled.
4. How does the firm ensure that the microprocessor or computer is indicating the correct information (validation).
5. How, and how often is the equipment calibrated and/or checked for accuracy.

The references "Guide to Inspection of Computerized Systems in Drug Processing" Feb. 1983, U.S. Dept. of Health and Human Services, Food and Drug Administration and "Software Development Activities" July, 1987, U.S. Department of Health and Human Services, Food and Drug Administration, should be used as guides to inspecting firms using complex computer controlled retort systems (these guides are currently undergoing revision). DEIO also has in process 'Guide to Inspection of Computerized Systems in the Food Processing Industry.

An example of a parameter that could be under digital electronic control is pressure in a retort, which is normally controlled by adding or releasing air from the retort. A common method for pressure control is the use of a pressure sensor to transmit a signal to a pressure controller. The pressure controller will then send signals to position the air supply and pressure release valves. Control of pressure through addition and release of air allows for a more uniform pressure control in the retort. The valves used in pressure control may be pneumatic, electric or a combination of these types. Control of other factors critical to the proper operation of the retort system, such as water level in water immersion retorts, water circulation in cascading & spray water systems, and RPM's in agitating retorts may be monitored and controlled by a variety of methods, including mechanical, electrical and combination systems.

It is important to remember that the system used must provide assurance that the retort system is operating in a manner that the scheduled process will be delivered to the LACF product.

RETORT VALVES

A variety of valve types may be used on retort systems including:

PLUG COCK VALVE - This valve consists of a tapered plug with a vertical slot which fits into a tapered valve body. Full flow is obtained when the opening in the tapered plug faces in the direction of flow. When the plug is rotated a quarter of a turn, flow is stopped. Opening and closing the valve is usually accomplished by using a wrench or lever applied to the valve stem. Plug cock valves are noted on retort bleeders and may be used on retort vent lines.

GATE VALVE - Gate valves are full flow valves normally used to start or stop flow. A gate (sliding shut-off wedge) within the valve body is raised and lowered through a set of threads on the valve stem. The valve is operated by turning the valve stem counter clockwise to open the valve and clockwise to close the valve. These valves are usually either fully open or fully closed during service. When fully open the gas or fluid flows through the valve in a straight line with very little resistance to flow. This feature makes the valve ideal for use in the vent lines of steam retorts, where rapid removal of air may be important to proper temperature distribution. A gate valve can normally be recognized by a long stem, by the number of turns of the valve stem that it takes to close the valve (more turns are needed for a gate as compared to a globe valve), and sometimes by the appearance of the outside of the valve body (more square when compared to a rounded globe valve). If the gate valve cannot be identified in this manner the valve stem may have to be removed to identify the type of valve.

GLOBE VALVE - Globe valves are extensively used for the control of flow and where positive shut off is required. A globe valve employs an internal seat within the valve body. Hand operated globe valves are operated by turning the valve stem counter clockwise to open the valve and clockwise to close the valve. Threads on the valve stem cause the seal on the valve stem to mate with or move away from the valve seat. Close control over flow is readily accomplished. As the fluid or gas moves through this type of valve it must change direction. This results in increased resistance to flow. For this reason this type of valve is not ideal for venting of steam retorts. Globe valves are ideal for use on water and air lines where close control over flow is required. Globe valves have a positive shut off feature which can prevent leakage of air and water into retorts during processing.

BALL VALVE - Ball valves are quick opening, full flow valves, needing only a quarter of a turn to be fully open. A ball with a non-restricting port rides in a valve body on plastic non-sticking seats. Ball valves can provide a bubble tight seal. The ball valve can be used for full flow (venting), and control (water and air supply) functions on retorts.

BUTTERFLY VALVE - Butterfly valves are quick opening, full flow valves which employ a metal disk which when rotated on a shaft seals against seats in the valve body. Butterfly valves are normally used as throttling valves to control flow. Butterfly valves may be found on some of the newer retort systems

DIAPHRAGM VALVE - Diaphragm valves contain a moveable diaphragm within the valve body which fits against a valve body seat. When the diaphragm is raised or lowered by the valve stem flow is increased or decreased through the valve. Diaphragm valves may be found on some of the newer retort systems.

Valves may be operated by hand, pneumatically (by air, steam or other gas), electrically (by a solenoid or motor) or by a combination of these methods.

Free flow valves such as the gate or ball valve are normally used on steam retort vent lines. The use of globe or other type valves on steam retort vent lines is not prohibited by the LACF regulations. If these types of valves are used, temperature distribution studies are required to document adequate temperature distribution in the retort prior to the start of the thermal process.

Valves which provide a tight seal, such as the globe or ball valve must be used on air and water lines to prevent leakage into the retort during thermal processing. Valve seats and seals must be maintained to prevent the valves from leaking. During a LACF inspection the retort should be examined for evidence of leaking water and air valves. Some firms may employ the use of double valves on air and water lines to insure that no air or water is leaked into the retort during processing.

TEMPERATURE DISTRIBUTION

Temperature distribution is the work performed to ensure that the retort instrumentation accurately reflects that adequate temperature distribution has been achieved throughout the retort at the time that the sterilization cycle begins. This is accomplished by distributing an adequate number of thermocouples or other temperature measuring devices (TMDs) throughout the load (external to the containers), and making several runs or tests to ensure that temperature differences have been minimized. The number of thermocouples (TMDs) to be used is normally limited by the equipment available. A minimum of 12 thermocouples has been suggested by The Institute for Thermal Processing Specialists. With large retort systems and numerous retort crates a greater number of thermocouples may allow for a more extensive test to be completed. At least one thermocouple is placed next to the MIG thermometer and used as a reference during the study. The worst case situation for temperature distribution normally occurs when heat flow to the product is the greatest. The heat absorption rate of a convection heating (heat currents are formed in the container) is much higher than a conduction heating (heat must penetrate through the material) product. It is normally suggested that a convection heating product in the smallest container processed or a special cold water pack be used to test temperature distribution in still retorts. Other conditions may present the worst case for temperature distribution in a specific retort system or for a specific product or container type. This must be documented in the temperature distribution study. In some retort systems temperature distribution tests must be performed for each container type (e.g. glass, metal, plastic), for each container size, for each container racking system, for each container shape, for each product produced and for each individual retort system.

Acceptable temperature ranges in the retort at the time that the process begins varies with retort systems and products. Normally you would expect to find all thermocouples (TMDs) within 1ºF of the processing temperature at the time the process timing begins for still steam retorts. For water immersion retorts you would normally expect to find all thermocouples (TMDs) at or above the set point temperature and no greater than a 2ºF degree difference between the minimum and maximum TMD. Other conditions may be acceptable to meet the requirements of adequate temperature distribution in a particular retort system. These conditions should be documented in the temperature distribution study. Equipment and procedures which fail to provide adequate temperature distribution in a retort system prior to start of the process must be modified to provide adequate temperature distribution.

There must be documentation on hand at the LACF plant, from the processing authority, which specifies the come-up procedures (e.g. venting, cut-up time) to be employed to ensure adequate temperature distribution is achieved at the time that the thermal process or sterilization cycle begins. The firm must employ the same procedures during production as were used to establish the temperature distribution in the retort.

Among the factors which may affect temperature distribution are:

Initial temperature of the product
Loading configuration (retort crate and retort)
Retort geometry
Steam spreader design
Type of heating media (steam, water immersion, cascading water, water spray, steam air etc.)
Circulation of heating medium
Use of agitation
Size, type and location of vent valve in steam retorts
Steam header pressure

In some foreign countries LACF manufacturers attempt to establish the effectiveness of the retort by performing heat penetration tests in various areas of the retort, or by performing numerous heat penetration tests using a limited number of containers placed in different areas of the retort during several different process cycles. This method of retort temperature validation has not been accepted by FSIS as being a valid method for performing temperature distribution studies. Variations in such things as retort load, retort cycles, product fill, and initial temperatures can cause temperature readings obtained from thermocouples inside of the containers to vary by several degrees.

A good reference for temperature distribution protocol for steam still retorts has been published by the Institute for Thermal Processing Specialists.

Heat penetration, in contrast to temperature distribution, is designed to measure the rate of heating of the food product under consideration. In these tests thermocouples or other temperature measuring devices are inserted into the containers to measure the product heating rate. Not only should the slowest heating container in the test be identified, but also the slowest heating zone within any given container. Thus it may be necessary to do a preliminary "cold-spot" study to identify the slowest-heating zone within the container prior to doing the actual heat penetration test on several containers. In addition, the performance of heat penetration work must be based upon adequate knowledge of the heat resistance of the microorganism(s) of concern in the specific product to be processed. Finally, the heat penetration test must cover all the variables expected to be encountered during the course of commercial operation in the plant.

Among the factors which may affect heat penetration results are:

Container position, geometry and heat transfer characteristics.
Type of heating medium
Product factors (e.g. fill weight, viscosity, particle size, percent solids, method

of preparation)
Equipment factors (e.g. filling method, head space, rotational speed)

The information developed during the heat penetration test is then used along with other information such as the heat resistance of the microorganism(s) in question (this can be effected by the food being tested), and the numbers of microorganisms expected to be present in the product, to calculate a theoretical process.

The theoretical process may be confirmed by using an inoculated pack. In an inoculated pack a known amount of an organism with a known heat resistance is placed into each container. The containers are then processed at various calculated process times and/or temperature(s) and examined for surviving organisms. The objective of the inoculated pack method is to determine the time/temperature combination that will kill all of the spores added to the product. A similar method called the count reduction method uses a procedure which relates the decrease in the numbers of spores from the initial number to some final number with process F^o value. Processes may also be established using other procedures such as chemical indicators to provide F^o values.

The process should be established by qualified persons having expert knowledge of the thermal processing requirements of LACF, and having adequate equipment and facilities to make such determinations. All critical factors, including the establishment of venting or other come-up procedures to ensure adequate temperature distribution, must be investigated by the processing authority. There must be some form of documentation on hand at the factory; at least a letter or other similar transmittal from the processing authority, which details all factors critical to the delivery of the scheduled process.

Should no documentation exist at the plant, every effort should be made to determine whether such documentation exists at any location, before leaving the plant.

Should the documentation for the scheduled thermal process be more extensive than a letter or other similar document, a preliminary review should be made to determine if any of the procedures are questionable (it may not always be possible to accomplish this at foreign plants if the documentation is not in English).

The information from the processing authority should be compared with the operations at the firm and with the information which the firm submitted with their scheduled thermal process.

The LACF regulations require that crates, trays, gondolas etc. for holding containers must be made of strap iron, adequately perforated sheet metal or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1 inch holes on 2 inch centers. If divider plates are used they should be perforated as above.

Other arrangements can be used as long as there is temperature distribution documentation on hand for the equipment in use. It is important for good temperature distribution to use a crate with as much open area as possible. The percent open area of the crate bottom and the divider plate can be calculated by dividing the total open area of the holes by the total area of the bottom or divider plate x 100. A divider plate which meets the specification of the regulations (1 inch holes on 2 inch centers) has approximately 27% open space. Tightly packed small round containers may cover over 90% of the divider plate. The holes in divider plates must be carefully designed to provide for the maximum heating medium flow between the containers. By using closely spaced smaller holes the percent open space can be dramatically increased. The crates and divider plates in use should at least be no more restrictive than those used to establish the retort operating procedures. When a firm changes the type or design of divider plates the effect of the new divider plates must be evaluated by the firms processing authority.

If dividers, racks, trays, or other means are used to position flexible containers in place they must be designed and employed to ensure even circulation of the heating medium around all containers.

Discuss equipment and procedures as they apply to each of the various types of retort systems. In addition to the common types of retort systems discussed there are other less common types which may be encountered.

When inspecting these systems always review the LACF regulations to determine compliance of equipment installation and operation.

RETORT SYSTEMS
FOR THERMAL PROCESSING OF LOW-ACID, CANNED FOOD (LACF)

Equipment and procedures common to all retort systems has been previously discussed. The following section will discuss equipment and procedures as they apply to each of the various types of retort systems. In addition to the common types of retort systems discussed, there are other less common types which may also be encountered.

Always review regulations 9 CFR 431.1-431.12 to determine requirements for equipment installation and operations when inspecting these systems.

STILL STEAM RETORTS

Equipment and procedures for pressure processing in steam in still retorts are covered by 9 CFR 431.6(b)(1) of the LACF regulations.

Still steam retorts (Figures 1 and 6) are identified as vertical, in which the crates are lowered by hand or overhead hoist into the retort; horizontal, in which the crates are pushed or conveyed into the retort; or crateless (Figure 3), in which the containers drop into cushion water in the retort. Vertical retorts vary from small one crate, to retorts holding several crates. Vertical retorts are commonly found to be approximately 42 inches in diameter and to hold 3 or 4 crates of product. Horizontal retorts vary from small one crate, to large retorts holding 12 or more crates of product. Retort size normally depends upon the size of the firm, the amount of product to be processed at one time, the length of the thermal process and the closing capacity of the firm.

Still steam retorts were one of the first types of retort systems used to pressure process LACF. Steam under pressure provides a number of advantages for processing LACF products in metal containers:

- It is an excellent medium for heat transfer
- Its temperature is easily regulated
- The steam pressure required in the retort in order to achieve the required processing temperature serves to counter-balance the pressure built up inside of the container during processing.
- Steam can be easily manufactured and held in reserve for immediate use.
- The stored energy property of steam makes it a superior heating medium as compared to water or steam-air. The stored energy results from the fact that in the manufacture of steam considerable heat (970 B.T.U.'s) is required to change one pound of boiling water to one pound of steam at the same temperature. When the steam condenses on the containers during processing this latent heat is given up to the container. It is important in the operation of still steam retorts to remove air from the retort prior to starting the process. Air in the retort acts as an insulator around the containers which prevents steam from contacting the container. Air in

the presence of high heat may also cause the containers to rust. Small amounts or pockets of air in the retort can cause containers in those areas of the retort to be under processed.

RETORT HOOK-UP AND SPECIFIC OPERATING INSTRUCTIONS

VERTICAL RETORTS – Simple Process Without Pressure Cooling

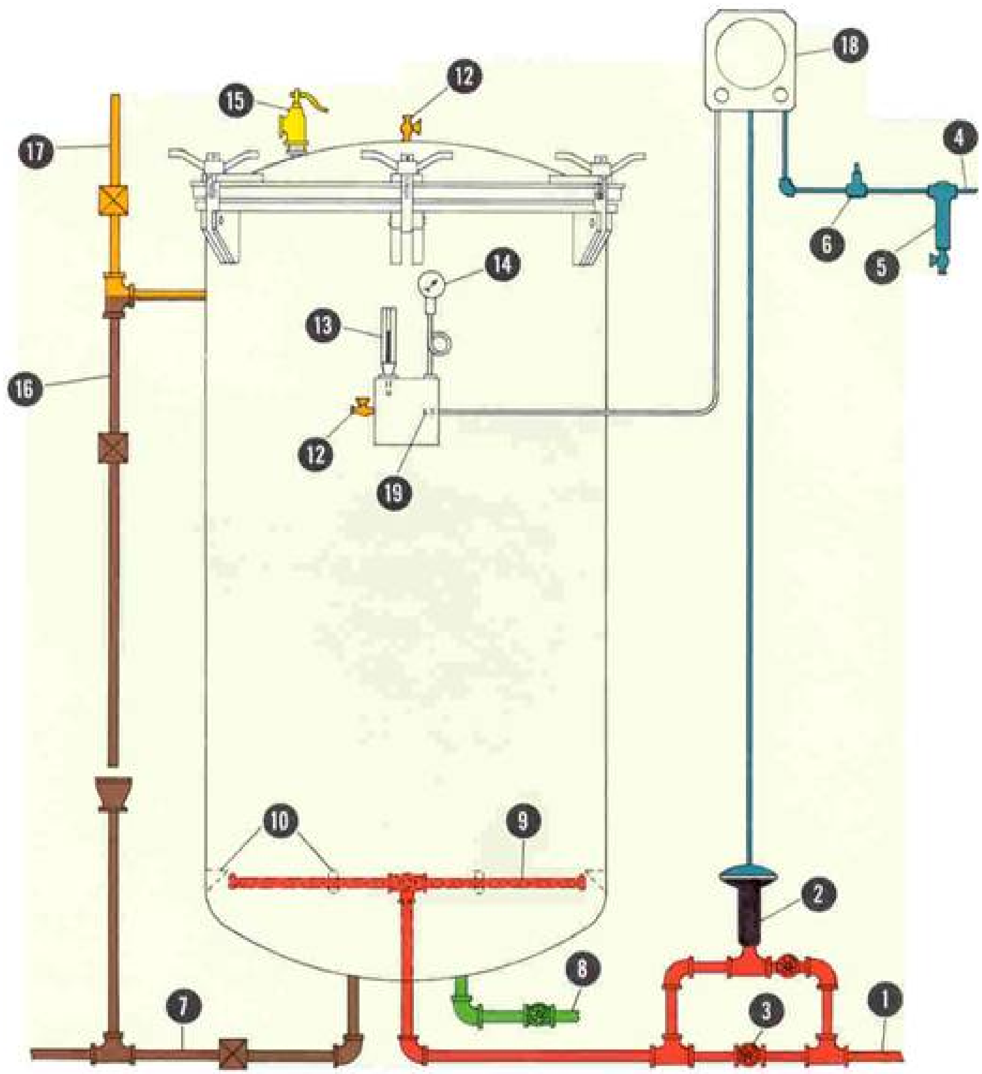

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FIGURE 1

HORIZONTAL RETORTS Pressure Cooling Under Air Pressure—Venting Through Outside Manifold

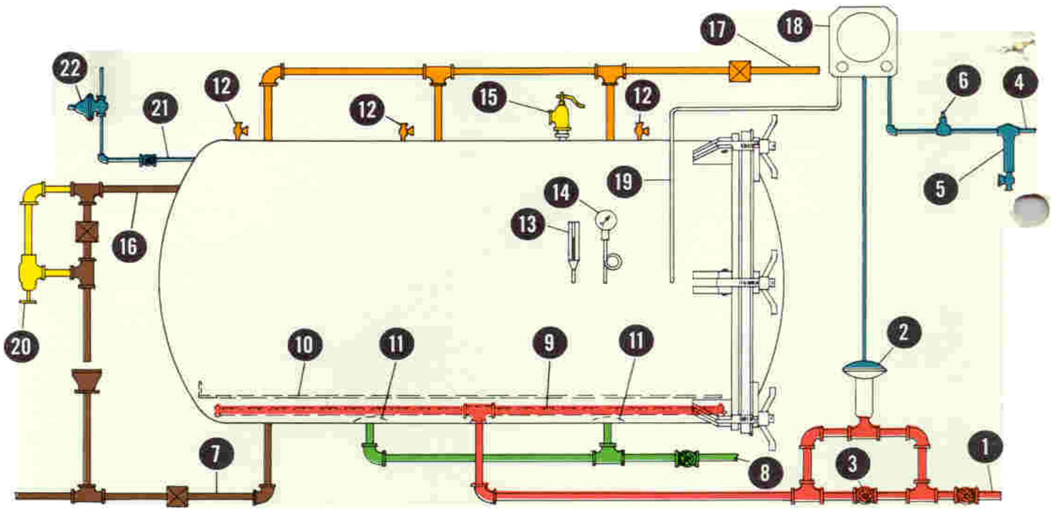

FIGURE 6

Air is removed from the retort prior to processing through the retort vent and bleeders. 9 CFR 431.6(b)(1) describes vent plumbing and operating procedures for various vertical and horizontal still steam retorts. As long as the equipment is installed and operated exactly as per the regulations, the vent times and temperatures given are adequate to meet the requirements of the regulations for containers in jumble stack (containers randomly dropped into the crates) or off-set stack arrangements.

The Grocery Manufacturers Association Bulletin 26L recommends venting schedules similar to those found in the regulations. The recommendations found in Bulletin 26L do not, however, apply to retort systems which utilize divider plates. Bulletin 26L suggests that the venting schedules for still steam retorts using divider plates be obtained from a process authority.

Each retort system must be equipped with a steam inlet large enough to provide sufficient steam for proper operation of the retort. Steam may enter either the bottom or top portion of the retort, but must enter that portion of the retort opposite the vent. This is important to provide for adequate circulation of steam and removal of air during the venting of the retort. It is recommended that the automatic steam control valve be of the same size or larger than the steam inlet. This allows the use of the automatic steam controller during retort venting. If an automatic steam controller valve of a size smaller than the steam inlet line is used, a steam by-pass may be needed during venting and come-up to provide enough steam to the retort to rapidly vent the retort. The steam by-pass may be manually operated by the retort operator or automatically operated through the retort control system. At the time that the retort reaches processing temperature the by-pass valve would be closed. Control of retort temperature during processing would be through the smaller automatic steam control valve. Use of a smaller automatic steam control valve provides for more accurate control of processing temperature with less temperature fluctuation.

Steam spreaders which are continuations of the steam inlet line inside of the retort should not be larger than the steam inlet line. Steam spreaders are required in horizontal retorts. In horizontal retorts, the steam spreader must extend the entire length of the retort. The steam spreader should have perforations along the top 90º (that is within 45º on either side of top dead center of the spreader). Horizontal retorts over 30 feet long should have two steam inlets connecting to the steam spreader. In vertical still steam retorts, a steam spreader is not required, however if one is used it should be operational. When used, the spreader should be in the form of a cross with perforations along the center line of the pipe facing the interior of the retort or along the sides of the pipe. The steam should not flow directly onto the retort bottom (this erodes the metal) or directly onto the containers.

Vertical steam retorts are required to have crate supports to prevent the crate from sitting upon the steam spreader.

The number of perforations in steam spreaders should be such that the total cross sectional area of the perforations is equal to 1.5 to 2 times the cross sectional area of the smallest restriction in the steam inlet. The following table can be used for guidance:

Number of Holes in Steam Spreaders of Steam Inlet Pipe Size

SIZE HOLES* (INCHES)	1" PIPE	1-1/4" PIPE	1-1/2" PIPE	2" PIPE	2-1/2" PIPE
3/16	47-62	81-108	111-148	183-244	260-346
1/4	27-36	45-60	62-84	102-137	147-196
3/8		2 1-28	28-37	45-60	66-88
1/2		11-15	15-20	26-36	36-48

*Inside Diameter

Vents must be installed in such a way that all air is removed from the retort before timing of the process begins. Vents are normally controlled by a gate, plug cock or ball valve, which must be fully open during venting. Vents must be installed so that a back pressure is not created during venting. Vents must not be connected directly to a closed drain system. Vent pipe(s) exits cannot be submerged under water during venting. On those retort systems where more than one retort vent pipe from a single retort connects to a manifold, the manifold must be of a size that the cross sectional area of the manifold is greater than the cross sectional area of all of the connecting vents. The manifold may be controlled by one free flowing valve. Where vents from more than one retort or manifold pipes are connected to a header, the header must have a cross sectional area at least equal to the cross sectional area of the connecting pipes from the maximum number of retorts to be vented at one time. The header must not be controlled by a valve. Vent installations may differ from the above specifications if the firm has evidence in the form of heat distribution data that adequate venting of air is accomplished.

Bleeders are openings in retorts used to remove air entering the retort with the steam, and to promote circulation of the steam in the retort. The LACF regulations require that all retort bleeders, except thermometer well bleeders, have an inside diameter of no less than 1/8 inches when fully opened. Thermometer well bleeders are required to have an inside diameter no less than 1/16 inch when fully opened. Bleeders must be wide open and emit steam continuously during the entire process including the come-up time. The operator must be able to observe the operation of the bleeders during processing. If the retort has the steam entry in the top of the retort, a bleeder of adequate size must be installed in the bottom of the retort to remove the condensate from the retort during processing. The condensate bleeder has to be installed in a manner that allows the operator to observe its function.

Vertical still retorts are required to have at least one bleeder opposite the steam entry. Horizontal retorts are required to have at least one bleeder opening within one foot of the outermost location of containers at each end of the retort, and at intervals of no less than 8 feet along the top of the retort.

As previously noted, each retort system must be equipped with a mercury-in-glass (MIG) thermometer, a temperature-recording device, and an automatic steam controller. The sensing bulbs for the MIG thermometer and the temperature recording device may be installed within the retort shell or in an external well attached to the retort. External wells or pipes must be connected to the retort through at least a 3/4 inch diameter opening, and be equipped with at least a 1/16 inch diameter bleeder to provide for a free flow of steam past the thermometer sensing bulb.

Air may be supplied to the still steam retort to provide overpressure during the water cooling of containers in the retort. Considerable pressure is built up in the container during thermal processing. To prevent buckling (the container ends become permanently distorted) of the container overpressure from air or steam is provided during cooling. Air overpressure is more easily controlled because the steam tends to collapse in the retort headspace. The overpressure must be controlled within limits. Too great a pressure or cooling for too long will panel (permanently distort the side panels) the containers. The air supply line must be equipped with a tight fitting valve (e.g., globe or ball) to prevent air leaking into the retort during thermal processing. Generally pressure cooling is needed when processing container sizes with diameters above 401 (4 1/16 inches) at temperatures greater than 240° F. Smaller containers processed at higher temperatures may also require pressure cooling.

CRATELESS RETORTS

Equipment and procedures for crateless retorts, which are still steam retorts (see above), are covered by 9 CFR 431.6(b)(1)(ix)(d) of the LACF regulations.

Crateless retort systems are manufactured by Malo Inc., by the FMC Corp. and by others. Crateless retort systems are still steam retorts in which the containers are fed directly into the retort from a continuous belt (Figure 3). Crateless systems are normally operated in a series of from 2 to 6 or more retorts depending upon the firms requirements. One operator can normally operate several crateless retorts at one time. Crateless retorts may be up to 8 feet high and 6 feet in diameter. The capacity of the retort is several times that of the normal 3 crate vertical retort (over 10,000 cans for some smaller containers). Container size is not limited by the retort design. Prior to filling the retort with containers, the retort is filled to approximately half full with preheated cushion water at a temperature which will not lower the product temperature below the minimum temperature specified in the process schedule. When used, the automatic conveyor system is set to feed the preset number of containers (depending upon can size) into the retort through the top sliding door. A counter counts the number of containers added to the retort. The product containers fall into the water to limit container damage. The containers are jumble stacked in the retort. When the preset number of containers have entered the retort the containers are automatically diverted to the next retort to be filled. The hydraulic push button operated top sliding door of the retort is then closed. Steam is admitted to the retort through a spreader in the top of the retort, forcing out the cushion water which is normally collected, reheated, and reused. In some plants the cushion water is gravity drained before venting. The drain is left open until all cushion water has been removed from the retort and venting conditions met. Newer models of crateless retorts are normally equipped with a false bottom door at the exit end (bottom) of the retort. The false bottom door is perforated with holes which allow for a flow of steam between the false bottom door and the discharge door. The false bottom door also prevents containers of product from contacting the condensate which may build up in the bottom of the retort. Condensate is removed from the bottom of the retort through a condensate bleeder (normally 3/8" or larger) normally located in the bottom door of the retort. A 1/8" bleeder is recommended between the false bottom door and the condensate bleeder to provide visual assurance to the operator that there is no condensate buildup in the retort during thermal processing. Some older systems may still be encountered which do not use a false bottom and/or employ a second 1/8" bleeder. These systems should be carefully evaluated to determine that the condensate is being removed from the retort during thermal processing.

After the cushion water has been removed from the retort using the steam forced method, the retort is vented for a short period of time (this must be established by a processing authority). The processing of the product normally starts when the retort reaches processing temperature, but not before a free flow of steam is noted from the 1/8 bleeder located between the false bottom door and the discharge door. Failure of condensate bleeders to function properly in these retort systems has caused several instances of improperly processed LACFs. Condensate buildup in the bottom of the retort may contact only a few cans in the bottom of the retort, causing underprocessing of those containers. Such a situation can result in a very few cans of underprocessed product in a large lot of containers. After the product has been processed cooling water is normally brought into the retort to partially cool the product. In some systems, the product is dumped from the bottom of the retort into a cooling canal. The discharge door on some systems is below the level of the water in the cooling canal. This causes a vacuum to be formed in the retort and the cans drift slowly out of the retort into the cooling canal. A chain in the cooling canal then moves the container through the cooling water to the unscrambling station. In some of the older crateless retort systems, containers were dropped into the cooling canal through a vibrating basket on the retort or directly onto a chain conveyor. Excessive container damage was sometimes noted in those systems.

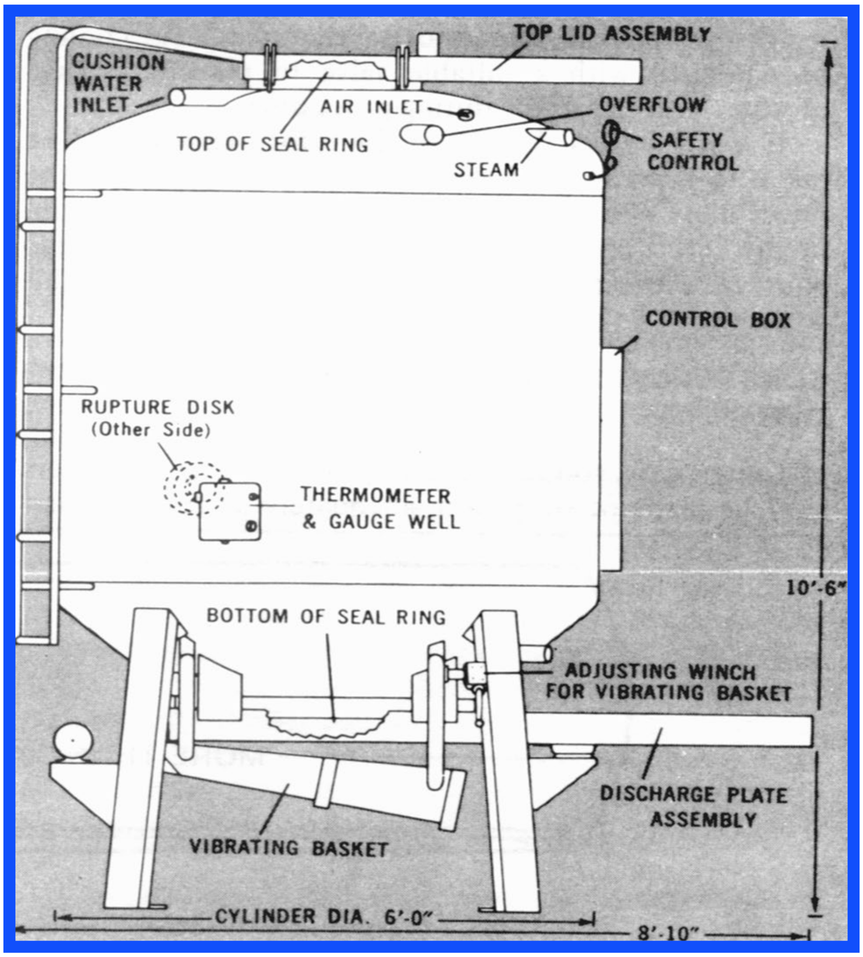

Figure 3

STILL WATER IMMERSION RETORTS

Equipment and procedures for pressure processing in water in still retorts are covered by 9 CFR 431.6(c)(1) of the LACF regulations. The requirements for still water immersion retort systems (Figures 2 and 4) would also apply to those agitating systems used in the still non-agitating mode.

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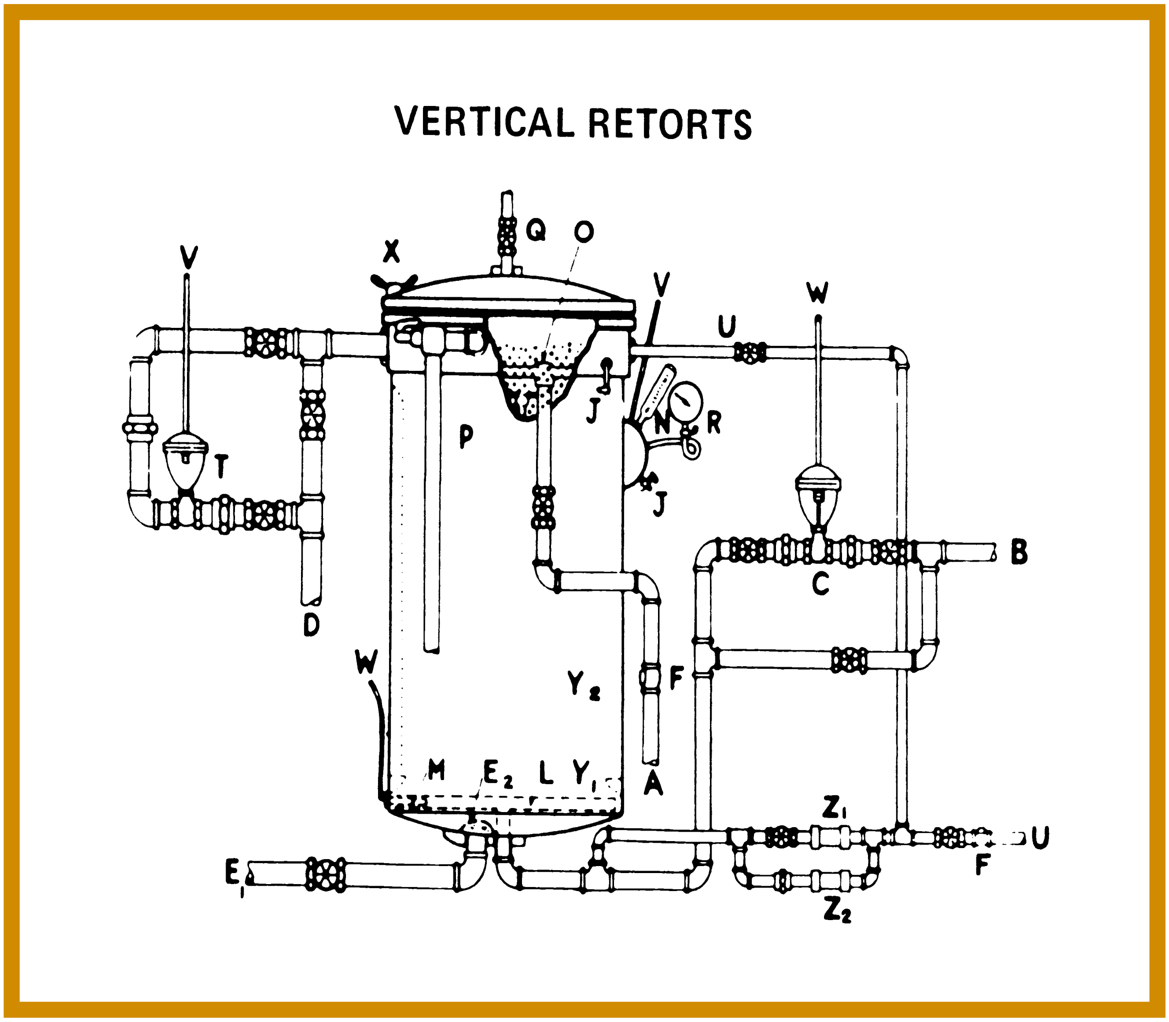

Figure 2

Thermal processing of glass, plastic, laminated pouch, and large profile metal containers require that an overpressure greater than the pressure created by the retort temperature be provided to maintain container integrity. Pressures in the range of 20 to 32 psig are normally used for glass containers. When the product in a container is heated to high temperatures, pressures exceeding those of the retort can be created in the container. This higher pressure is due to the combination of increased vapor pressure and expansion of the contents in the container. In the case of small metal cans, the metal can may be able to withstand these pressures without permanent distortion of the metal in the can. In the case of glass jars and other less durable containers, an overpressure must be used to prevent the container from venting the contents, or becoming permanently distorted or destroyed. The water immersion still retort was first designed for use in processing glass jars. Water immersion still retorts are now used to process a variety of containers requiring an overpressure. In some cases, the water immersion retort may be used to process small metal containers as well. If the water immersion retort is used to process metal containers there is some concern with the rusting of containers caused by the addition of air to the processing water.

Basically there are four principle differences in a still retort equipped for pressure processing in water as compared to a still steam retort:

- Compressed air must be provided to the retort to create the overpressure during processing and cooling.
- A pressure control valve must be added to the retort.
- The temperature of the retort must be controlled independently of the pressure.
- The containers are processed and cooled under water.

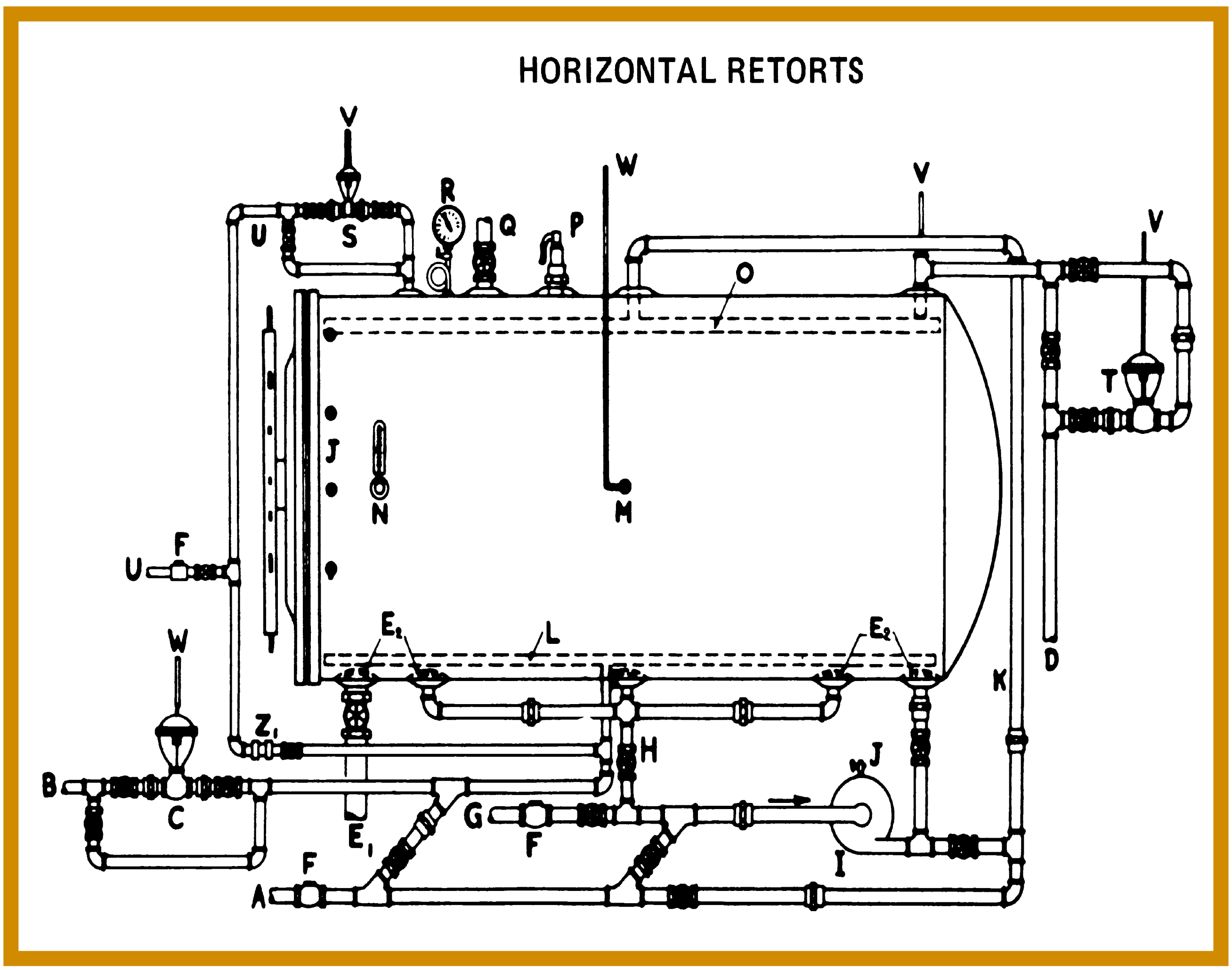

Figure 4

The water level in the retort must be maintained to provide water above the top level of the containers at all times. It is recommended that the containers be covered by at least 6 inches of water. If the water level falls below the level of the top containers those containers exposed to the steam/air mixture in the top of the retort must be identified and set aside for reprocessing or evaluation by a processing authority. A water level indicator is required on all water immersion retorts. This can be in the form of a water glass sight tube, pet cocks, or mechanical indicator. A low-water alarm (visual & audible) is suggested. The operator must observe the water level during processing to insure that the water does not drop below the level of the top containers. At a minimum, observations should be made and recorded at the start of the process and at the end of the thermal process prior to the addition of cooling water to the retort. A non-clogging water tight drain valve is required to prevent leakage of water from the retort during processing. It is suggested that this valve be screened to protect the valve from being clogged with broken glass and other debris.

Heating and circulation of the water to provide for uniform thermal processing temperatures in the retort system is important.

Steam introduction into the bottom of vertical retorts can be accomplished in one of several satisfactory ways. One way is by using a steam spreader equipped with six pipes radiating out from the center with "fish tail" nozzles which direct the flow of steam up along the sides of the vertical retort outside of the crates. A second acceptable method is to use a 4 legged cross steam spreader in which each pipe is perforated with holes directed 15° below horizontal along one side only. The legs are arranged in opposing pairs so that the holes face each other to give alternate live and dead quadrants. This arrangement provides for circulation of the water in the retort. In horizontal retorts, the steam distributor should run the full length of the retort with perforations distributed uniformly along the pipe. Several still water immersion retorts of European design inject steam directly into the water circulation line to maintain the processing temperature. Any of the above, or other methods, are appropriate as long as there is documentation in the form of temperature distribution data or other documentation from a processing authority that supports the method of heating the water.

Circulation of the water is important to provide uniform temperature throughout the retort. Adequate circulation of the processing water by air or pump must be established through procedures recognized by a processing authority.

Air is added to the steam supply line prior to the steam spreader in vertical retorts to aid in the mixing of the water. As the air is added with the steam, it also prevents steam 'knock" or "chatter" (a loud bumping sound) in the retort which happens when live steam is introduced into water. The air and steam mix to form bubbles out of the steam distributor. As the bubble moves up through the water the heat from the steam is lost to the water. The air that remains reaches the top of the vertical retort to provide the air overpressure. Excess pressure is released through the pressure control valve. A large flow of air (15 to 18 cubic feet per minute) is needed during the initial heating and come-up phases of the retort. This may be provided through an air bypass line. When the retort processing temperature is reached the flow of air can normally be reduced to (4 to 5 CFM). Air flow is normally regulated by placing an orifice in the line which provides a certain air flow at a regulated pressure. The air flow to vertical retorts should be documented during establishment of the temperature distribution in the retort. The air flow should be verified by the establishment using a flow meter at intervals sufficient to insure that the retort is operating under the parameters used to establish the temperature distribution in the retort.

For horizontal retorts, a water circulation system is recommended. This system uses a pump to draw water out of the bottom of the retort through several screened openings (suction manifold) and to discharge the water over the entire length of the top of the retort through a water spreader. The pump should be capable of circulating the entire volume of retort water at least every 4 to 5 minutes. A pilot light is normally used to indicate that the pump motor is running. Even though the light indicates that the pump motor is running, it does not insure that the water circulation is adequate. Plugged lines, bent impellers on the pump and other mechanical problems may not be indicated by the pilot light. A flow meter on the circulation line is recommended to provide a true indication of water flow in the circulation line. Air must still be added to the horizontal retort to provide for the overpressure during processing.

Vertical still water immersion retorts are required to have centering guides, which should be installed so as to insure that there is a clearance of approximately 1 1/2" along the side of the retort to provide for circulation of the water during thermal processing and cooling, in addition to crate supports.

Containers are normally added to vertical retorts that contain water at or near the same temperature as the initial temperature of the product. If product in glass jars is subjected to water which is too cold, thermal shock may break the containers. If the water in the retort is more than 15° F above the temperature of the container, the glass container closure may vent product. Water must be added to horizontal retorts after the containers are loaded. A separate warm water supply at or near the initial temperature of the product which can be used to fill the retorts aids in more rapid production of glass containers. If the water added to the retort is below the initial temperature of the containers, measures must be taken to insure that the initial temperature in the container is not lowered, or that the temperature of the water is used as the initial temperature. Several retort systems use hot water storage tanks located above the processing shell. The temperature of the stored water is dependent upon the container to be processed, and may range from several degrees above the thermal processing temperature for metal cans to only a few degrees above the initial temperature of glass containers. Following processing, a portion of the processing water is forced back into the upper storage drum and reheated for processing the next batch.

Cooling water is normally added to the circulation pump line on horizontal retorts or through a cooling ring above the containers in a vertical retort. It is important that glass containers are not subjected to a severe thermal shock to prevent glass breakage.
The overpressure must be maintained in the retort until the pressure in the container falls

to levels which do not cause container failure. Overpressure may be critical to the thermal process for large profile half steam tray metal container and retortable flexible pouches. The overpressure maintains the container profile and holds the container against the product allowing for more efficient heat transfer from the container to the product. When overpressure is listed as a factor critical to the thermal process, a record of the process pressure must be made. The overpressure used during thermal processing should be the same as that used during establishment of the thermal process or as recommended by the firms processing authority.

It is recommended that the temperature probe in water immersion retorts be located next to the MIG thermometer, except in vertical retorts which are equipped with a combination recorder/controller. The controller bulb in these vertical retorts must be located in the bottom of the retort beneath the lowest crate rest in such a position that the steam does not strike it. This should be the coldest spot in the vertical retort. In a horizontal retort the recorder/controller probe should be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity of direct steam impingement on the control bulb.

Some water immersion systems may be set up to process in both steam and water. Those systems must be carefully evaluated to insure that they meet the mandatory provisions of both sections of the LACF regulations.

CONTINUOUS AGITATING STEAM RETORTS

Equipment and procedures for processing in continuous steam retorts are covered by 9 CFR 431.6(b)(3) of the LACF regulations.

These systems provide for continuous container handling with intermittent product agitation. Continuous agitating steam retorts are manufactured by FMC (Sterilmatic) in the U.S. and Europe and by Stork (Steristork) in Europe. The basic design of both systems is similar (Figure 5).

The retort systems are made up of a series of processing vessels called shells. The arrangement and number of shells is dictated by the product, production capacity, and space limitations in the establishment. Common arrangements found include: Two-shell: one pressure cooker and one pressure cooler; three-shell: one pressure cooker shell, one pressure cooler shell and one atmospheric cooler shell; and four-shell: preheater shell, one pressure cooker shell, one pressure cooler shell and one atmospheric cooler shell. Specialized systems may have up to seven shells. The shells can be arranged side by side or offset end to end depending upon the available establishment space.

Containers are fed mechanically through the series of at least one heating and one cooling shell. Within each processing shell is an open, closely fitting rotating reel which runs the length of the vessel. Cans are carried horizontally in channels made up of angles, usually of stainless steel, welded around the perimeter of the reel. A spiral T-track is welded to the inside of the shell spaced at intervals slightly larger than the can length. As the reel turns the containers are forced against the spiral T which causes the cans to move down the length of the retort while being carried by the reel. The containers are fed into the processing shell or preheater through a pocket valve; a rotary transfer valve which is timed to the reel and designed to prevent loss of steam from the retort (Figure 7).

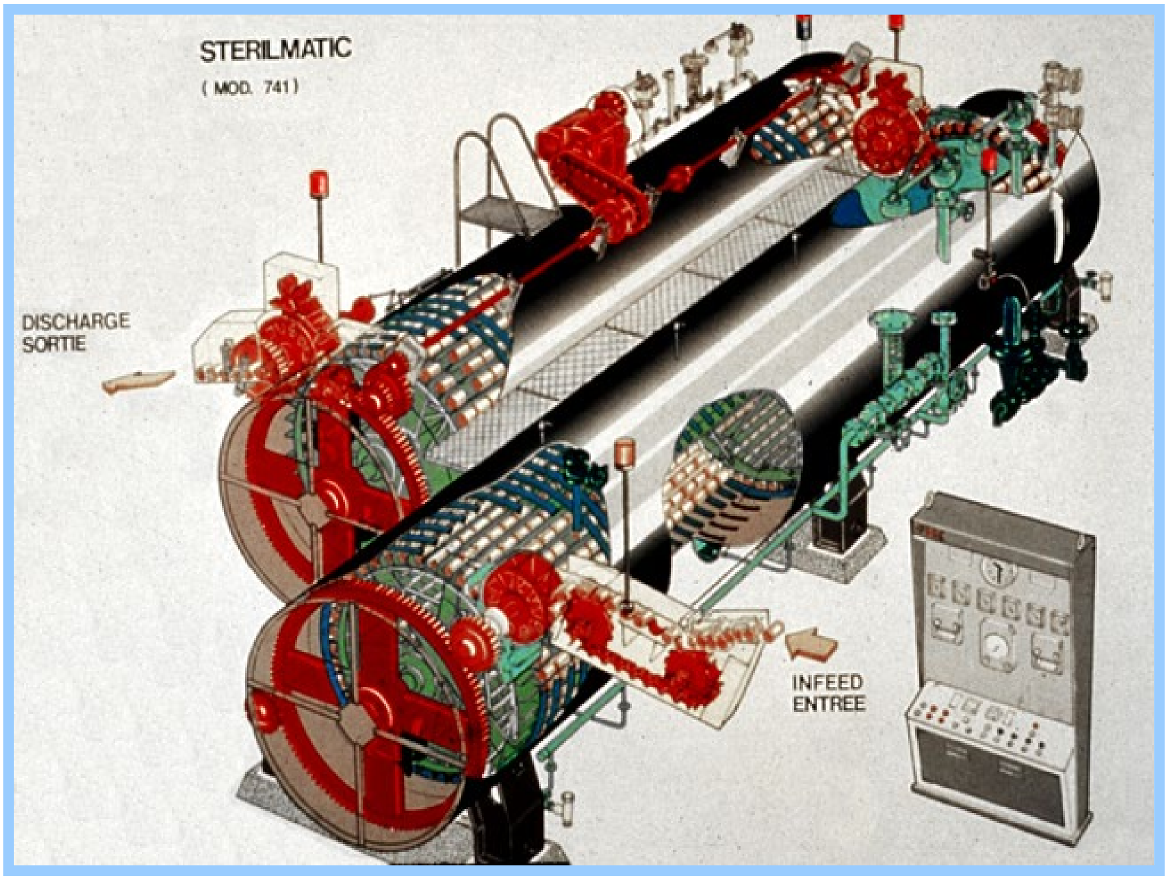

Figure 5

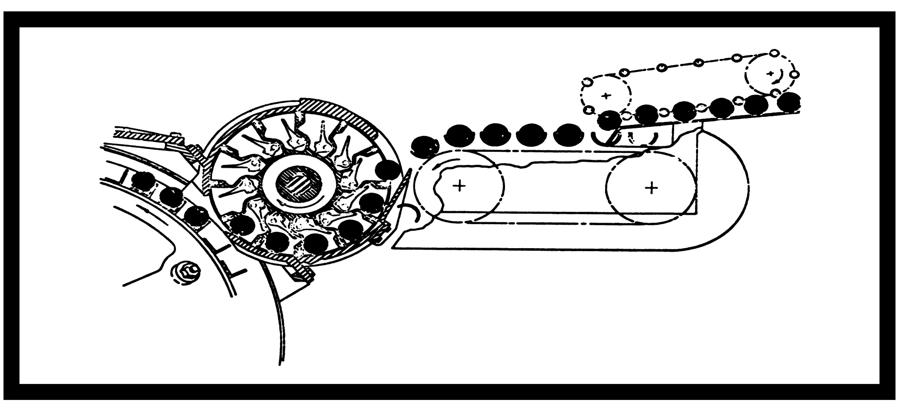

Figure 7

There is a wheel at the exit end of the retort and into a second transfer valve which transfers the cans to the next processing or cooling shell while maintaining processing pressure if needed. All of the shells are driven by one variable speed motor or drive mechanism through a series of interconnecting gears to insure that the reels are timed to each other. The drive mechanism is required to be locked or protected by a sign that states that only authorized persons are to make adjustments.

Because of the physical limitations of the reel and spiral T these retort systems are normally limited to a narrow range of can sizes. The length of the can going into the retort can not be longer than the maximum distance between the spirals in the T. The diameter of the can is limited by the distance between the steps in the reel. The number of steps (number of cans around the diameter of the reel) is determined by the can size and the diameter of the reel. For the FMC systems these steps are standardized for can sizes (unless the system has been altered or custom built). The number of steps can be used along with other information to calculate process time.

STEPS PER TURN OF REEL FOR STERILMATIC CONTINUOUS AGITATING RETORTS

Can Size	Steps per Turn of Reel
211	56
300-303	47
307-401	42
404	36
603	24

The container capacity is normally stamped on the end of the shaft of the processing shell.

The length of the process is controlled by the capacity of the retort and the speed at which the reel is turned. The capacity is determined by the length of the retort shell and the number of steps in the reel.

By knowing the retort capacity, the number of steps in the reel and other processing information the following formulas can be used to determine reel speed or process time:

Seconds for 10 reel revolutions = (10 rvs) x (60 secs) x reel steps x process time/capacity
Example: (10x60x47x10)/4136 = 68.18 seconds for 10 revolutions

Containers per minute = Capacity/Process Time
Example: 4136/10 = 413.6 seconds

Revolutions = Capacity/(reel steps x cook time)
Example: 4136/(47x10) = 8.8 revolutions per minute (RPM)

Seconds for 10 revs = (10 revs x 60 secs x reel steps)/(cans per minute)

or (10 revs x 60 sec)/RPM
Example: (10x60)/8.8 = 68.18

The actual process time is determined by using a stop watch and timing 10 revolutions of the retort reel. One arm on the retort reel is selected and observed to pass a stationary mark on the retort shell for the required number of revolutions. Reel speeds that are too fast will cause the product to move through the retort at a faster rate shortening the process time. A reel speed that is too slow increases the process time but may reduce the agitation of the product and reduce the thermal process given to the product. The process is normally designed with the slowest reel speed (minimum agitation) taken into account.

The rotational speed of the retort shall be specified in the process schedule. The speed shall be adjusted as specified, and recorded by the establishment when the retort is started, and checked and recorded at intervals not to exceed 4 hours to ensure that the correct retort speed is maintained. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. If a recording tachometer is used, the speed shall be manually checked against an accurate stopwatch at least once per shift and the results recorded. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

The standard continuous agitating retort systems are designed to operate over a wide range of temperatures up to 275° F (135° C), with custom designs operated at temperatures of up to 294° F (146° C).

Steam is fed into the bottom of the sterilizer through a steam manifold to a steam trough in the bottom of the retort. The condensate that forms in the bottom of the retort from cold containers continuously entering the retort must be removed to prevent the condensate from building up and touching the containers. This not only cools the containers but may prevent agitation of the product in the containers. Condensate is normally removed during venting by opening the drain valve in the bottom of the retort. After the retort is up to processing temperature, continuous draining of the condensate is through a 3/4 inch drain valve left partly open or through an automatic condensate trap. A 1/8 inch (minimum) bleeder is required in the bottom of the steam trough to provide visual assurance to the operator that there is no condensate buildup in the retort.

Venting of the retort takes place at the beginning of the production period and need not be performed again as long as the retort is not cooled. Venting should be performed as per the retort manufacturers or processing authority's instructions. The FMC continuous retort is normally vented for 7 minutes to 220° F through the two 2-inch vents located in the top portion of the retort shell. If the retort shell has to be cooled for repairs or is stopped and cooled for any other reason, the retort must be vented when it is brought back up to processing temperature.

Air is removed from the retort during processing by the continuous operation of bleeders which are located within one foot of the outermost product at each end of the retort and not more than 8 feet apart along the top of the retort.

Agitation in this system is intermittent axial agitation. The container rotation can be divided into three phases (Attachment 7) consisting of fixed reel, sliding rotation, and free rotation. The headspace bubble, provided by the gases in the headspace, moves through the product to provide agitation and increased rates of heating in the product during periods of rotation. Maintaining the headspace filed as part of the process schedule insures a headspace bubble. In the fixed reel portion of rotation the container is carried by the reel through the top 260° of rotation. During this phase no or little agitation of products occurs. As the container approaches the lower 140° of rotation in the retort shell, it starts to contact the spiral "T" welded to the interior of the retort shell and begins to turn. This sliding rotation transition phase lasts for approximately 20° of rotation and provides some product agitation. As the container enters the lower 100° of rotation (free rotation phase), the container contacts the retort shell and rotates freely. The majority of agitation occurs in this phase. As the container starts up the side of the retort, sliding rotation takes over and changes to the fixed reel phase. Agitation is dependent upon control of factors such as: headspace, consistency, reel speed and fill weight which must be controlled during processing.

Intermittent agitation will increase the heating rate of the product only if the headspace bubble is free to move. Solid pack products will normally not benefit from an agitated process. Some manufactures will still use the continuous retort to process products based on a non-agitating process because of the convenience of the container handling in the continuous system. For products where agitation is not taken into consideration during establishment of the process, headspace may not be critical to the process.

When checking reel speed there are usually two speeds of concern. During process schedule establishment, the minimum reel speed is studied. Then process schedules are recommended to the manufacturer. When the manufacturing firm sets the retort to meet the process schedule, the reel speed may need to be different to meet the process. For example, the RPM for meeting a time of 15 minutes may be 4.2 RPM whereas the minimum RPM is 3.5. The actual RPM should never be less than the minimum RPM and the actual RPM should assure that the process schedule time is achieved.

Following thermal processing in the processing shell, the containers are transferred through a pressure transfer valve to either a pressure cooler or an atmospheric cooler depending upon process temperature and can size. Some containers can be cooled in a Micro-cool valve, where water is sprayed on the containers, to a low enough temperature to allow for atmospheric cooling. The pressure cooler and or Micro-cool valve must be operated at a pressure at least 2 lbs below that in the processing shell to prevent air and water from being forced out of the cooling shell or valve into the thermal processing vessel. The closed cooling shell is approximately 2/3 full of water to provide flood cooling of the containers. Some systems also use an atmospheric open or half-shell cooler where water is sprayed over the containers. The cooling water normally enters the can exit end of the cooling shell and flows to an overflow on the can entry end of the cooling shell. This provides for counter flow cooling of the containers. Additional cold water is added to control the water temperature and to maintain the water level in the cooling shell. The temperature of the cooling water at the can entry end of the cooler is normally at a very high temperature (> 200° F) as the hot cans enter the water.

The heating of the cooling water as it passes over the containers tends to drive off chlorine if it is used to sanitize the cooling water. A measurable level of chlorine may not be found in the cooling water at the water discharge point of the cooler shell. If the quality of the water in the cooling shells is not maintained by good sanitary practices such as; sanitation of the cooling water, routine draining and replacement of the cooling water, and cleaning of the cooling shell, excessive microbiological growth in the cooling shells may cause post processing contamination.

If the retort jams or breaks down during processing operations, necessitating retort repairs, the retort must be operated in a manner that ensures commercial sterility of the product. The retort can be operated as a still retort per 431.9(c)(1)(vi)(A)(1). All containers can be given a still emergency process using a process supplied by the firms processing authority. Any containers in the intake transfer valve and any containers in transfer valves between processing shells have to be removed, given a still process, opened and reprocessed or destroyed. Complete records of the still process must be maintained.

If a temperature drop occurs in the retort the temperature drop should be handled per 431.9(c)(1)(vi)(A)(2). The retort should be equipped with an automatic device to stop the reel when the temperature drops to below the specified process temperature.
If the temperature drop was 10ºF or more the reel must be stopped and all of the containers must be given a still process as above, discharged and reprocessed, repacked and reprocessed or discarded. If the temperature drop was less than 10ºF, an authorized emergency still process may be used prior to restarting the reel, or container entry to the retort can be stopped and authorized emergency agitating process used. Complete records of the handling of temperature drops must be made.

These systems may be installed with modifications which will allow unique processing to take place. Known system modifications include: the addition of dual spiral construction which allows for the processing of two container sizes at the same time using the same processing conditions; the use of metal carriers to hold and transport glass containers through the system; the use of steam air mixtures to thermally process LACF; and the use of the continuous retort system as a water immersion retort with steam over-pressure. When modified continuous cookers are encountered, the inspector must insure that the retort installation and operation meets the requirements of the firm's process schedule and the LACF regulations.

DISCONTINUOUS AGITATING STEAM RETORTS

Equipment and procedures for pressure processing in steam in discontinuous agitating retorts are covered by 9 CFR 431.6(b)(2) of the LACF regulations.

These retort systems are batch systems which provide for either continuous axial agitation of the product or end over end agitation of the product during thermal processing and cooling of the containers. The most common axial agitation batch retort in the United States is the FMC Orbital (Orbitort) Sterilizer. This system was designed to process large institutional size (603 X 703, #10) cans of medium viscosity products such as cream style corn. Other sizes of cans can be processed with modifications to the system.

The orbital sterilizer does its pressure processing and cooling in one shell. The sterilizer consists of a horizontal retort shell which contains an outer reel to which a spiral has been attached, and an inner reel which contains the container channels or steps.

During loading, cans are fed into the retort through a large air-operated gate valve located high on the retort wall. The outer spiral reel is locked to the retort shell. The inner reel is turning during loading causing the containers to move toward the exit end of the sterilizer.

A counter keeps track of the number of containers loaded into the retort. A second counter advances the cans two turns separating processed and unprocessed cans by two spiral turns. This is a safety factor to keep unprocessed and processed cans separate. At the same time that containers are being loaded, processed containers are being unloaded through an air-operated gate valve located low on the exit end of the retort shell. When the retort is full the loading/unloading gates are closed, the outer "spiral" reel is locked to the inner "channel" reel holding the containers in place during thermal processing and cooling.

The retort is vented per the processing authority or equipment manufacturers' recommendations. Documentation that adequate venting is achieved must be kept on file by the processor. At the time that steam is turned on, the drain must be left open for sufficient time to remove the steam condensate from the retort, and provision should be made for continuing drainage of the condensate during the retort operation. It is important to remove the condensate so that the containers do not contact condensate build up in the bottom of the retort which could cool the containers during thermal processing.

During thermal processing any air coming in with the steam is removed from the retort through bleeders located within one foot of the outermost container on each end of the retort and no more than 8 feet apart along the top of the retort or through some other arrangement proven to be satisfactory by temperature distribution studies.

At the conclusion of the thermal processing cycle, cooling water is introduced into the retort while the containers are still being agitated. When the product is cooled the retort is ready for emptying and reloading.

The product agitation in this retort system is produced by forcing the head space bubble through the product at very high (approximately 35 RPM) reel speeds (Figure 8). High speed rotation is possible because the containers are locked in place. The speed of the retort must be adjusted as necessary to agree with the speed of the retort listed in the process schedule. The rotational speed as well as the process time must be recorded for each retort load. A recording tachometer may be used to provide a continuous record of retort rotational speed. The accuracy of the recording tachometer shall be determined and recorded at least once per shift by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

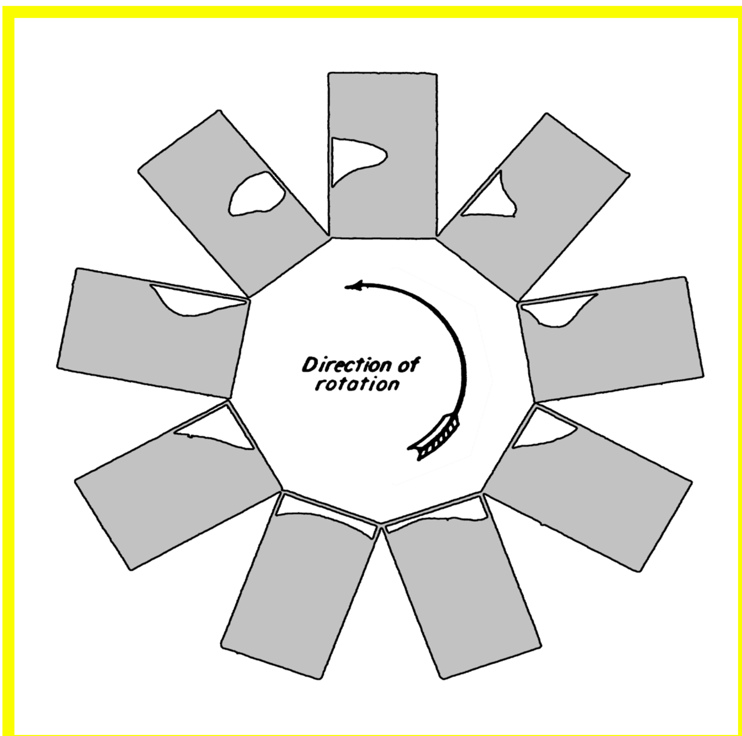

Figure 8

Factors critical to obtaining the induced agitation in these systems include: maintaining the correct headspace, product consistency, minimum machine vacuum in vacuum packed products, maximum fill-in or drained weight, and percent solids as specified in the process schedule.

DISCONTINUOUS AGITATING WATER IMMERSION RETORTS

Equipment and procedures for processing in discontinuous agitating water immersion retorts are covered by 9 CFR 431.6(c)(2) of the LACF regulations.
These are batch retort systems which provide for continuous product agitation by movement of the head space bubble during thermal processing. Agitation in these systems is normally induced through end over end rotation of the container (Figure 8) as opposed to the axial rotation of the container in the FMC continuous and orbital retorts

previously discussed. Because of the rotational axis of various containers in the baskets during processing, the containers against the outside walls of the basket may receive more agitation than those in the center of the basket.

Discontinuous agitating water immersion retorts are manufactured by AlIpax Products Inc. in the United States under an agreement with the Maskinfabrikken Phoenix subsidiary of the Klinge group in Denmark. Known manufacturers of these systems in Europe include: Herman Stock in Germany, Lubeca in Germany, and Phoenix in Denmark. All of these systems are or have been available for installation in the United States through U.S. distributors. The Stock Rotomat is one which has been distributed for a number of years, with numerous installations in the U.S. and world wide.

The majority of these systems operate in a similar manner. These systems can be found with a wide variety of valve types and plumbing arrangements. The valves and plumbing may be changed for custom installation by the manufacturer or installer of the equipment to provide additional functions or for better operation of the system. Many of the early Rotomat retorts were equipped with on/off steam control valves which have been replaced with modulating steam control valves to provide for better control of the retort temperature. Retort systems now entering the U.S. are often modified to meet the U.S. requirements for MIG thermometers and instrumentation, and to replace the control valves on the retort. The configuration of the retort must be carefully reviewed during inspection of these systems.

Discontinuous agitating water immersion retorts can be used for the processing of numerous container types including: metal cans, glass jars, and plastic containers and unusual container shapes such as semi-rigid plastic bottles, flexible pouches and half-steam table trays.

The processing system consists of two pressure shells or drums, one sitting on top of the other. The top drum is used to store and preheat the processing water. The lower drum is the processing drum (Figure 9).

Containers are loaded into crates or specially designed racking systems depending upon the container type. The crates are then loaded into a reel within the lower retort shell and locked into place during processing.

Water in the upper drum is heated by steam prior to processing. The temperature of the stored water is dependent upon the type of container to be processed, and may range from several degrees above the thermal processing temperature for metal cans to only a few degrees above the initial temperature of glass containers. Storage drum temperature may be critical to achieving adequate temperature distribution. To achieve correct temperature distribution in the retort, the firm must meet the minimum temperature requirement.

Figure 9

Processing in the Rotomat retort system is designed to proceed through a series of programmed phases which may consist of several steps within each phase. The steps normally encountered include:

- Heating of the upper storage drum
- Sterilization I - in older models this includes dropping the heating water and heating the water to processing temperature, in later models this involves only dropping the processing water.
- Sterilization II – in earlier models this is the sterilization (hold) phase, in the later models this is the heating phase to process temperature.
- Sterilization III – this is the sterilization phase in later models.
- Pressure cool I – this is the initial cooling phase where the process water is recaptured
- Pressure cool II – this is the final cooling stages.
- Open door – retort is ready for unloading

The phases and steps used may vary with the make of retort system used, the model of the retort used, the control system used, and the product being processed. It is important to determine the retort steps and sequencing during the inspection. This information should be compared to the information in the process schedule.

These retorts may be equipped with a wide range of control systems depending upon the manufacturer, model and customer specifications including: manual controls, semiautomatic electronic relay controls, electronic card readers, electronic pre-programmed logic controls and microprocessor controls.

At the beginning of the sterilizing cycle, water from the pressurized upper drum is dropped into the lower processing drum through a connecting pipe and valve. At that time, the circulation pump begins to circulate the water by drawing the water out of the bottom of the retort through a suction manifold (also called the "circulation channel") and returning the water through a distribution manifold in the top of the lower drum. The returns located in the bottom of the retort shell should be screened to prevent debris from entering the water circulation system. As the water is circulated, it passes through a steam injection chamber where live steam is injected into the water to maintain processing temperatures.

When water enters the lower drum, air must be expelled to make room for the water. This is done through a purge valve (some times called a vent valve by the firm). If the purge valve is not open for a long enough time period, air will remain in the lower drum and the lower drum will take a longer time to fill with water. If the purge valve is open too long, the hot water will flash to steam, and water and steam will be lost out of the purge valve lowering the temperature in the processing vessel. This may cause the come-up period to be extended to reach processing temperature, and has been reported in some cases to affect temperature distribution in the retort system. The length of time that the purge (vent) valve is open is determined by the processing authority and normally programmed into the retort controls as a set time period.

The come-up time (CUT) prior to processing is very important in this type of retort. During the CUT the retort is brought up to processing temperature and the water temperature throughout the retort is stabilized at or above the process schedule temperature. This may require a CUT which extends beyond the time when the processing temperature is first reached, as indicated by the retort instrumentation. Usually both a time and temperature are required to be met to fulfill CUT requirements. If CUT is used in establishing the process schedule, it must be part of the process and controlled as a critical factor. If CUT is only critical based on the temperature(s) and time(s) required to achieve adequate temperature distribution, it is not part of the process but still must be controlled and recorded as part of the processing record. CUT varies by retort model and make, and for different products.

In the sterilization (hold) phase, the product is held for at least the minimum time at the minimum temperature specified in the process schedule.

When the thermal process is complete cold water is introduced into the lower drum through the water distribution system or through a separate pump. This cold water forces a portion of the hot processing water back up into the top storage drum where it is captured and reheated for the next process.

The water circulation pump is the principle device for insuring adequate temperature distribution in the retort. Temperature distribution and heating programs are normally established at the maximum flow rate. If the water distribution system becomes clogged or the pump is damaged or worn, the flow rate may decrease. Severe drops in flow rate may be indicated by temperature drops in the retort. However, this may not be the case for less severe flow rate changes. Most of the systems are equipped with at least a pilot light that indicates that the pump is in operation. Some of the newer systems also incorporate a pressure differential alarm, which measures the difference in pressure from one side of the pump to the other, and alarms if the pressure differential falls outside of preset limits. Neither of the above methods measures the actual water flow in the system. A flow-indicting device is recommended for this purpose.

Rotation in the retort may be fixed at one speed, allow for selection of several speeds, or may be variable over a wide range of speeds. The newer systems may allow for rotation to be in either direction, to provide a rocking motion agitation, and provide for the baskets to be in different positions during come-up and processing. The systems are normally operated between 6 and 46 RPM. For those systems which do not take agitation into consideration when establishing the process, it is still recommended by some authorities that the reel be rotated at a minimum speed to enhance mixing of the processing water and to maintain proper temperature distribution. Temperature distribution must be documented for those systems operated in the still mode. Timing of the rotation is done either through the use of a stopwatch and observation of rotation of the driving mechanism on the rear of the retort, or through the use of a recording tachometer. The accuracy of the recording tachometer shall be determined and recorded at least once per shift by checking the retort or reel speed using an accurate stopwatch. The rotational speed of each retort load must be recorded.

Overpressure during processing (to maintain container integrity) is supplied to the majority of these systems by using compressed air. The majority of the retorts are equipped with both a valve for supplying additional air and a valve for releasing excess pressure (small vent or purge valve). This allows for more uniform control of overpressure processing. The Stock systems normally use steam pressure in the upper drum to provide over-pressure through a connecting valve to the lower drum. Stock systems can also use air for overpressure if requested by the customer. Stock claims that when steam is used in the lower shell to provide an over-pressure that deviations are not normally caused by lower than normal water levels in the processing shell of agitating retorts, as the head space will provide a steam processing medium. There is some question as to whether the head space is pure steam or a mixture of steam/air which may not provide a uniform temperature. When lower than normal water levels are noted, the manufacturer should treat the process as a processing deviation; requiring the reprocessing of the product, the destruction of the product or the review of the thermal process by a processing authority unless there is documentation on hand to support processing with lower than normal water levels.

The majority of the systems noted have been equipped with a water sight glass or mechanical indicator of water level in the retort as well as being equipped with electronic alarms for low-water levels.
Adequate temperature distribution in the batch agitating water immersion retort is

dependent upon such factors as the proper functioning of the centrifugal pump, rotation of the reel, and the number of cages in the retort. A minimum number of cages full of containers (e.g. 3 cages in a 4 cage retort) is required to maintain the water level in the retort. The number of cages also affects the CUT (come-up time) to the processing temperature. If the minimum number of product filled crates are not available the firm may use ballast (e.g. containers filled with water) to fill the additional crates required. In addition, the open area provided by divider plates or spacers, as well as the cages or racks themselves, can have an affect on adequate temperature distribution. Any change to a more restrictive-to-flow design in any of the above must be validated by new temperature distribution studies. Temperature distribution may be affected by container type, container size, racking configurations, number of containers in the retort, product being produced and many other variations in thermal processing. Because of the many variables that can influence temperature distribution in these retorts in some cases each retort, each containers type, each racking system and each container size will have to be evaluated to determine their effect on temperature distribution.

Delivery of the process schedule is also dependent upon the control of critical factors such as: headspace, product consistency, fill-in or drained weights, vacuum in vacuum packed products, minimum net weights, percent solids and other critical factors identified in the process schedule.

HYDROSTATIC RETORTS

Equipment and procedures for pressure processing in steam in hydrostatic retorts are covered by 9 CFR 431.6(b)(4) of the LACF regulations.

Generally the hydrostatic retort can be thought of as a still steam retort operated at a constant temperature through which containers are conveyed by a continuous carrier chain at a constant rate designed to provide the correct process time (Figure 10).

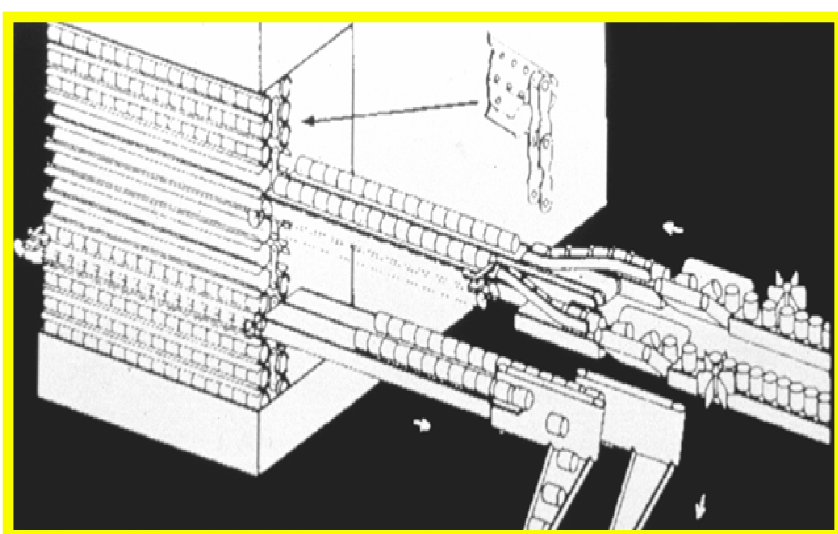

Figure 10

Hydrostatic retorts are manufactured by the FMC Corporation in the U.S. and by Stork and others in Europe. Newer designs now offer end over end or axial agitation of the product; the use of overpressure for the maintenance of container integrity; the ability to process glass and flexible pouches; and water as a heating medium in addition to steam. The systems are used for high volume products which need long cook times such as condensed soups and pet foods.

The name hydrostatic is derived from the fact that the pressure in the steam dome is counter balanced by water in the entry and exit legs of the retort. The higher the water level, the higher the pressure and temperature obtained in the steam dome. For example, the water height in the water legs must be 37 feet high at sea level to counter balance a processing temperature of 250° F (121° C). Operating at temperatures above 250° F will require a higher water level. The retorts can be operated below the maximum temperature as long as the pressure remains high enough to prevent water contact with the containers in the steam dome.

Start up procedures for a hydrostatic retort requires venting of the retort and bringing the water in the feed legs up to temperature. This procedure takes a longer period of time than the venting of still steam retorts. The hydrostatic retort is normally operated for periods of up to several weeks and may be shut down and cooled only when required for maintenance or repairs.

These retort systems are very large and normally extend several stories into the air. Containers are loaded into a horizontal carrier on the continuous chain and conveyed up to the inlet leg of the sterilizer. The inlet leg is filled with water which counter balances the pressure in the steam dome. The temperature of the water increases as the container moves from the top of the inlet leg down toward the steam-water interface at the bottom of the leg. Water temperature in the inlet leg may range from ambient to boiling. The feed leg may contribute to the process lethality by increasing the initial temperature of the product. If process lethality is claimed for the inlet leg of the retort, the water temperature in the inlet leg must be carefully controlled. The container is conveyed through the steam water interface into the steam dome. The number of times that the carrier passes through the steam dome as well as the speed of the carrier determines the process time. Traveling from the top of the steam dome to the bottom, and vice-versa, is referred to as one pass. Hydrostatic retorts with 2, 4, 6, and 8 passes are common. After traveling through the steam dome the containers are conveyed into the exit water leg where the temperature decreases as the container passes up the leg. The cans leaving the steam dome are heated to a high level and give up their heat to the water in the discharge leg. This results in several situations depending upon the design of the retort:

- The water in the discharge leg ranges from 215° F near the steam-water interface to 212° F near the top of the leg, and the water quietly boils and steam is discharged from the top of the leg.

- Cross circulation pumps are used to pump the hot water from the base of the exit leg to the base of the inlet leg and from the top of the inlet leg to the top of the exit leg, stabilizing the temperatures in the legs.

- Water is pumped from the base of the exit leg through a heat exchanger with the cooled water being returned to the top of the exit leg.

Any of the above three methods of operation are acceptable.

As the container exits the leg it is exposed to atmospheric pressure, and it may pass through a series of water spray coolers to further cool the product. The conveyor chain carries the containers back to near the loading station where the processed product is unloaded from the continuous carrier. Because the container inlet and exit are close together, care must be taken to insure that unprocessed containers do not become mixed with processed containers. Containers found on the floor or elsewhere whose status is questionable should be destroyed.

Control of the water levels in the feed and exit legs are important to maintain the hydrostatic pressure in the retort. The water level is normally controlled through a differential pressure controller which adds water when it is needed and dumps excess water from the legs. Water level fluctuation in the feed and exit legs may be caused by fluctuations in the feeding and discharge of containers. As more containers are fed into the container conveyor more water is displaced from the legs, a lack of production results in a lack of containers in the legs and the water level falls.

Hydrostatic retorts have been installed with up to 3 carrier chains operating in the same steam dome. This allows for the production of different can sizes at the same temperature by adjusting the process time through the speed of the conveyor. Carrier chains designed for cans can normally be used to process a number of different diameter cans within limits (e.g., 211 - 303, 404 - 603).

Steam is fed into the steam dome, depending upon the manufacturer, either in the center or top of the steam dome. Standard temperature or pressure controllers are normally used to control the retort temperature. The control of retort temperature through the use of a water level float has been used on some European systems.

9 CFR 431.6(b)(4)(i) requires that the MIG thermometer be installed in the retort steam dome near the steam-water interface. This should be the coldest spot in the retort dome. If the thermal process is based on lethality gained in the feed or exit water legs, a MIG thermometer is required to be installed near the bottom temperature recorder in each water leg (Figure 11).

9 CFR 431.6(b)(4)(i) requires the installation of additional temperature recorders near the top and bottom of each hydrostatic water leg if the process schedule specifies maintenance of particular temperatures in the water legs.

9 CFR 431.6(b)(4)(iv) requires the hydrostatic retort to be equipped with at least one bleeder 1/4 inch or larger at the top of the steam chamber or chambers at the opposite end

of steam entry. In addition, all bleeders must be arranged in such a way that the operator can observe that they are functioning properly.

The carrier conveyor in the hydrostatic retort may be numbered so that the location of the carriers can be determined during processing. Carrier location becomes important if the retort temperature/pressure falls to a level where the containers contact the water. The retort should be equipped with an automatic stop if the temperature drops below the minimum process schedule temperature. If the retort is stopped at that point, the operator can identify those carriers in contact with the water. The containers in the affected carriers can then be set aside for reprocessing, destroyed or held for evaluation by a processing authority.

The carrier speed is controlled for each container conveyor through a variable speed motor. Carrier conveyor speed may be measured by the number of flights per minute using a stop watch or electronically by a sensing probe. Electronic measurement of the conveyor speed should be verified by using a stop watch on a routine basis. The correct container-conveyor chain speed can be determined in the following manner.

1. The desired carriers-per-minute is determined by dividing the desired process time into the number of carriers in steam. Number of carriers in steam = Carriers-per-minute Process time in minutes
2. Calculate the actual carriers-per-minute rate by timing 50 carriers with a stop watch. Divide this time in seconds into 3,000 to get actual carriers per minute. 3,000/Second for 50 carriers = Carriers-per-minute

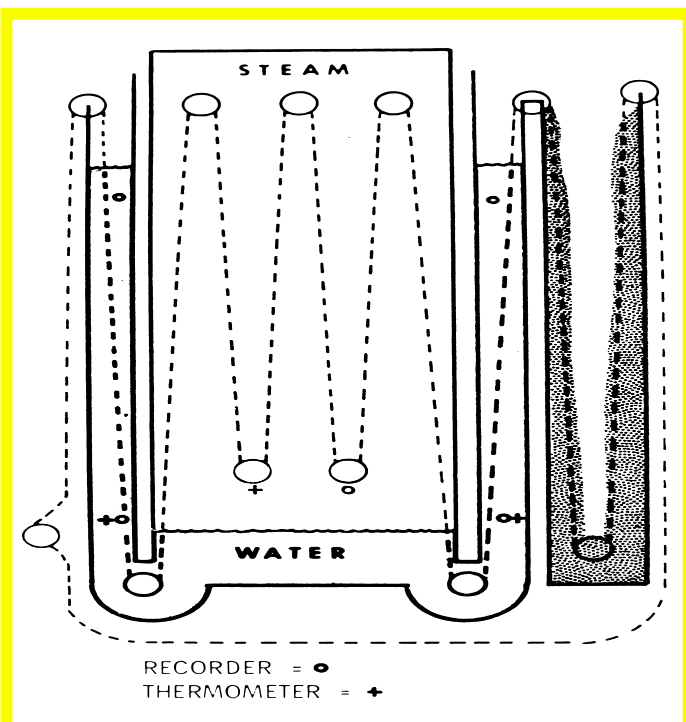

Figure 11

CASCADING WATER RETORTS

Equipment and procedures for processing in cascading water retorts are covered by 9 CFR 431.6(c)(1)(2) of the LACF regulations.

Cascading water retorts are known to be manufactured by the Food Processing Machinery Division of FMC U.S.A. (Universal and Convenience sterilizers), Lubeca in Germany (Lubeca Model LW406 and LW402 G), Herman Stock in Germany (Autovap and Rotovap), Phoenix A/S a division of the Klinge Corporation in Denmark (Phoenix) and by Barriquand in France (Steriflow). Copies of these retort systems may be made in other countries. Custom built cascading water systems may also be encountered.

Figure 12

Cascading water retorts may be either still or end over end agitating batch type retorts. They are normally operated with an air over-pressure and may be used to process a wide variety of container types including glass, metal, plastic, and flexible pouches.

The Barriquand Steriflow has been the cascading water system most often encountered by FSIS.

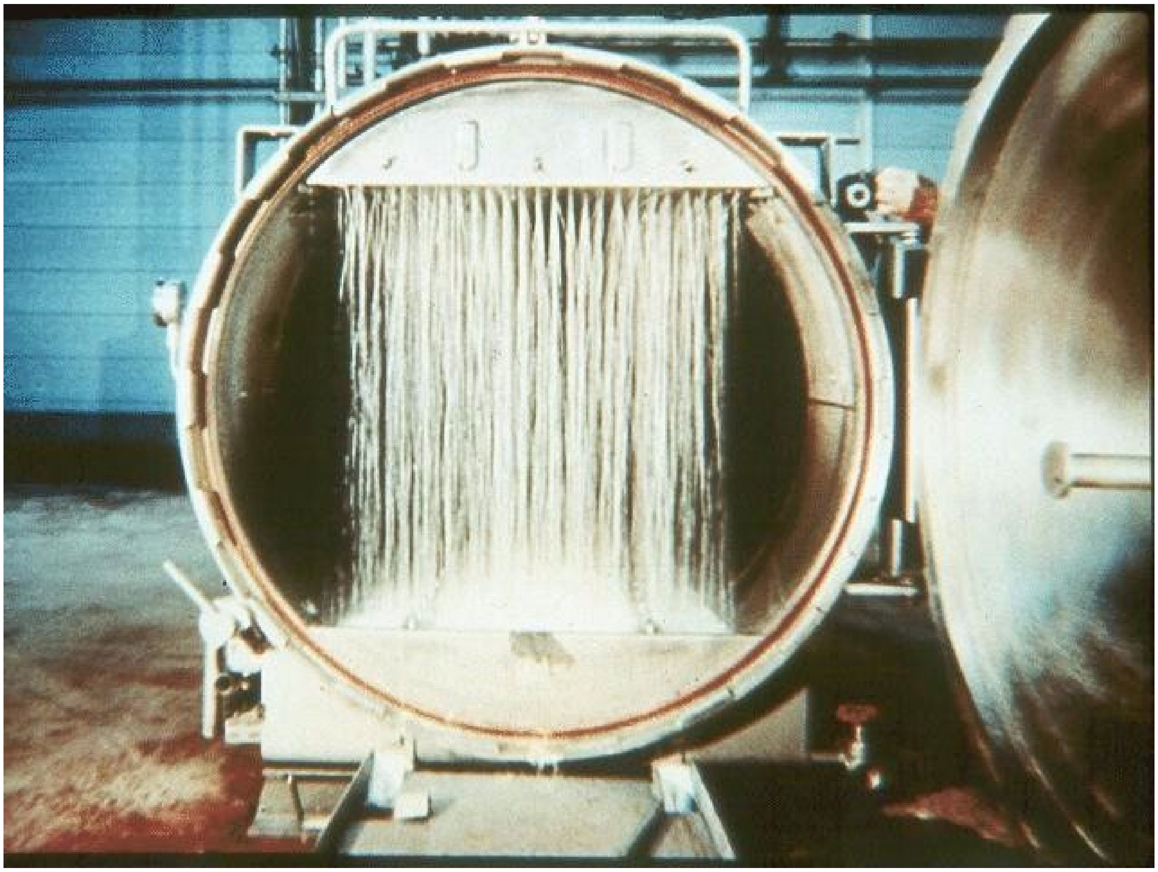

Figure 13

The Steriflow is an over-pressure retort designed to operate at high temperatures, at or above 130ºC (265° F), at pressures of up to 84 psig (5.9 kg/cm2), with very short cook times. The overpressure is supplied by compressed air and controlled separate from the retort temperature. The Steriflow uses less water for processing when compared to a water immersion retort, (e.g., 100 liters per basket in the standard 1300 mm model retort). At the start of processing, the process water is added to the bottom of the retort shell. A gate in the bottom front of the retort shell prevents the loss of processing water when the retort door is opened. During processing, this water is drawn from a trough in the bottom of the retort by a centrifugal pump capable of recirculating the water in the system approximately once every 9 seconds. The processing water passes through an indirect heat exchanger where steam is used to heat the water to processing temperature. The processing water then exits the heat exchanger and enters a water distribution manifold above the crates and containers. The processing water is forced through a series of small holes (e.g., 4 mm (5/16") on 21 mm (13/16") centers) in the manifold and cascades down over the crates and containers. At the conclusion of the thermal process, cold water is introduced into the heat exchanger to cool the processing water. The same water used to process the containers is used to cool the containers. The cooling water in the heat exchanger is never in contact with the containers. This provides for the use of low quality water (such as sea water) in the heat exchanger as the cooling medium.

Water entry into the water distribution manifold has been noted to be at the center or the end of the manifold in different models of the Steriflow. Location of the manifold water entry may be important. Temperature distribution studies have indicated that the cold zone in the retort may be affected by the location of the water entry.

Process water is normally used throughout a production shift prior to being replaced. Small amounts of water may be added prior to each cycle to replace water lost when the door is opened and product is removed.

In the standard 1300 mm retort, solid sided, perforated bottom 33" x 34" x 30" high retort carts are normally used with perforated dividers [19 mm (3/4") on 25 mm (1") centers] between layers. Container orientation is normally vertical. Container orientation, size, shape and loading configuration may have an effect on temperature distribution.

Temperature and pressure may be controlled either by a cam programmer on older systems, by a microprocessor/computer on newer systems, or by manual control. Temperature is normally controlled through a Resistance Temperature Device (RTD) located at the exit end of the heat exchanger. A second RTD located at the entry to the circulation pump is used to drive the temperature recorder. A MIG thermometer should be installed at this location. The entry to the water circulation pump has been selected as the location of the coldest water being circulated in the retort during thermal processing. Pressure is controlled separately through feed back from a pressure transducer and operation of compressed air entry and pressure relief valves.

The production programs for some systems are designed to bring the coldest spot in the retort up to thermal processing temperature through a series of time/temperature steps to insure that the temperature in the retort is at or above the filed thermal processing temperature at the time that the retort thermal process begins. An example of a stepped program is as follows:

- Preheat water to 115° C (2390 F).
- Heat from 115° C (239° F) to 137° C (279° F) 6 minutes (must meet both time and temperature).
- Heat for 136° C (277° F) 1 minute (time and temperature). This over-shoot temperature is used to help achieve adequate temperature distribution in the retort.
- Heat for 135>° C (275° F) 1 minute (time and temperature).
- Heat for 134>° C (273° F) 5 minutes (scheduled operating process temperature).
- Cool

To obtain adequate temperature distribution the system is normally operated with a temperature overshoot of at least 1°C above the process schedule temperature.

The stepped program varies with the retort, product and container. This program should be part of the firm's process schedule. Documentation that the steps in the come up portion of the retort program take place may be difficult. The come-up temperatures sensed by the microprocessor may not be the same temperatures displayed by the MIG thermometer and the temperature recording chart.

There are several areas of concern unique to the water cascade retort systems which should be addressed when inspecting these systems.

- The come-up portion of the process must be designed to provide for adequate temperature distribution (all parts of the retort are at or above retort temperature at the start of the thermal process hold time). The come-up requirements may differ from one product to another in the same retort, and from one container type to another in the same retort. Ideally temperature distribution studies should be performed on each retort model, each product produced, each container type used, and on each individual retort installation to determine the come-up procedures. The firm should have documented by temperature distribution studies that their come-up procedures result in adequate temperature distribution in the retort prior to the start of the timing of the process schedule.

- Care should be taken to determine the location of the control and recording RTD5. The recording RTD has been noted to be installed in the exit end of the heat exchanger. This may provide a recorded temperature higher than the coldest temperature in the retort. At least one manufacturer now recommends that the control RTD be located after the heat exchanger, with a feed-back RTD located at the entry to the circulation pump. The latter RTD also drives the temperature recording instrument. Both RTD5 should read at or above the process schedule temperature prior to beginning the thermal process timing.

- FDA has noted that the Steriflow is not always equipped with a MIG thermometer. When modified for a MIG thermometer, the MIG thermometer should be installed in the inlet line of the circulation pump, next to the recorder RTD, to monitor the temperature of the return cold water, which is the average coldest spot in the retort. MIG thermometer lag will normally be observed during the come-up steps.

- Water flow is not normally controlled as a critical factor. A pressure differential may be measured between the pressure on the entry and exit ends of the water circulation pump. This pressure differential alarms the control system if the set limits are exceeded. The pressure differential is a measurement of the differences in pressure on the two sides of the pump and may not measure a true water flow. The pressure differential will indicate failure of the water pump but may not always indicate a clogged water distribution system. A flow measuring device is recommended to provide a more accurate measurement of actual water flow in the system. Water flow in the system must be the same as that used during temperature distribution studies in the retort.

- The holes in the water distribution manifold may become plugged with product or mineral deposits. There should be a program in place for routine maintenance and cleaning of return ports, the water distribution manifold, and water filter screens if present. During inspection of these systems, the water distribution manifold should be examined to determine if the holes are plugged or have been reduced by mineral scale buildup.

- The processing records maintained by the firm must document that operating steps required to attain uniform temperature distribution in the retort during thermal processing are being met. These steps should be listed as critical factors on the firm's process filing form.

The Phoenix cascading water retort operates in a manner similar to the Steriflow. The Phoenix retort system is offered in the U.S. by AlIpax Products Inc. Mandeville, La. under the name Spray-Pax in still and rotational models.

Cascading water retorts manufactured by Lubeca and Stock in Germany differ from the Steriflow in that they offer heating by direct steam injection into the water, or by plate heat exchanger as a customer option. Cooling is by addition of cooling water to the retort or by indirect cooling through a heat exchanger. A method of recovering process water may be provided if cooling water is added to the retort.

The FMC Universal and Convenience Food sterilizers differ from the other cascading water retorts in that they utilize a weir arrangement (a small dam used to direct water flow) in the container basket to force the heated water to flow over the containers in a uniform manner from top to bottom or from one side to the other depending upon the container type. The water then overflows the basket and falls back into the bottom of the retort where it is picked up by a circulation pump and recirculated through a steam injector to reheat the water.

When any of these systems are encountered, it is important to determine if the retort system is being operated under the same conditions used during temperature distribution testing. The areas of concern for these systems are similar to those for the Steriflow including the control probe location.

SPRAY WATER RETORT SYSTEMS

Equipment and procedures for processing in spray water retorts are covered by 9 CFR 431.6(c)(1)(2) of the LACF regulations.

Spray Water retort systems are known to be manufactured by the Food Processing Machinery Division of FMC U.S.A. (FMC Surdry), Surdry S.L. in Spain (Surdry Convac) and in Japan by Hisaka Works Inc. The Hisaka retort is sold in the U.S. by Advanced Retort Systems, Inc.

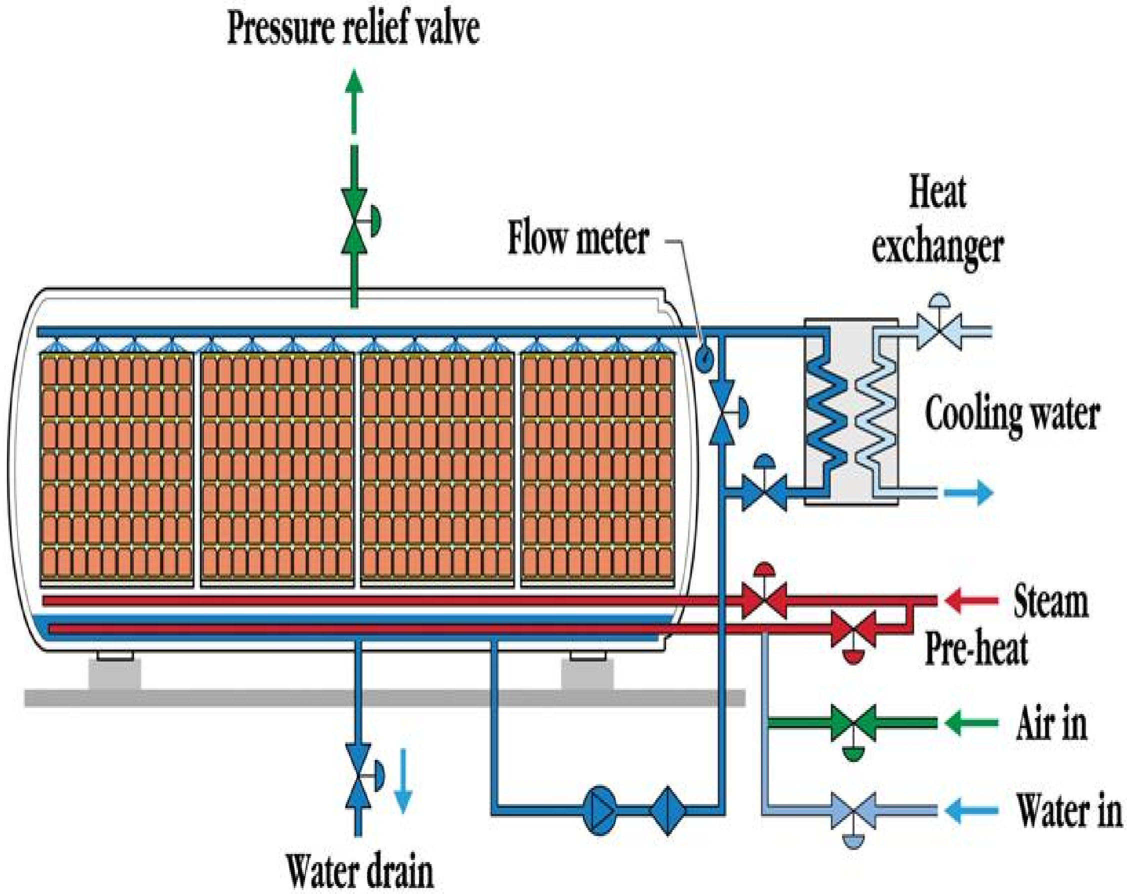

Figure 14

Spray water retort systems may be either static or rotary batch, (end-over-end) systems, depending upon the make or model (Figure 14 and 15). These retorts are designed to process a wide variety of packages including: glass, metal, rigid plastic and flexible pouches. They are normally operated with a compressed air over-pressure to maintain container integrity during thermal processing.

Spray water retorts differ from the cascading water retort (in which the water falls or is sprayed over the top of the containers) in that the water is sprayed over the containers, from several different angles to atomize the air used for over-pressure.

In the Surdry retort the spray nozzles are located on four to six manifolds on the top and along the sides of the retort. A small amount of water in the bottom of the retort is heated by the addition of steam through two steam spreaders located in the bottom of the retort. The water is pumped through the system by a high capacity pump. The water sprays circulate the steam/air mixture in the retort. The containers are cooled after processing by the addition of cooling water to the retort. Instrumentation is normally located in the shell of the retort. The MIG thermometer and the temperature recorder probe are located to sense the temperature of the steam/air/water mixture in the retort.

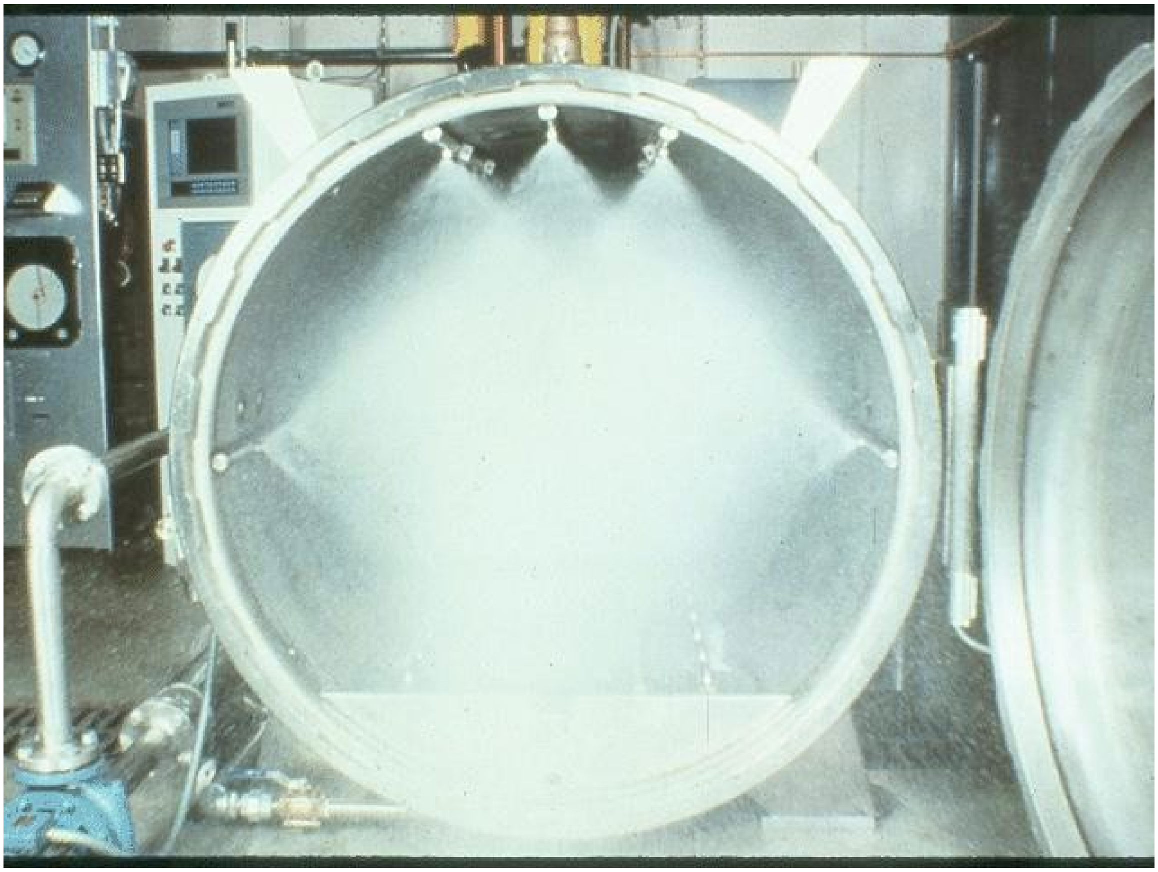

Figure 15

In the Hisaka retort, spray nozzles are located on manifolds along the sides and in the top of the retort. The spray nozzle banks in these retorts can oscillate (back and forward and up and down). The water in the retort is heated by means of a heat exchanger using steam. When the thermal process has been completed the water and condensate in the retort is cooled by the external heat exchanger to cool the product.

The areas of concern with spray water retort systems are similar to those for the water cascade type retort system.

1. The process must be designed to provide for adequate temperature distribution. The cold spot in the retort must be determined. This may vary with container type and arrangement in the retort. Temperature distribution studies should be performed on each retort model, each product produced, each container type used, each crate or racking configuration used and on each individual retort installation.

2. Care should be taken to determine the location of the control and recording instruments. The recording sensing probe must be located where it will provide an accurate record of the thermal process. The MIG thermometer must be installed where it will indicate the true thermal processing temperature in the retort.

3. Water flow may not normally be directly controlled as a critical factor. A water

flow measuring device is recommended to provide a more accurate measurement of actual water flow in the system. Water flow in the system must be the same as that used during temperature distribution studies in the retort.

4. The holes in the water distribution sprays may become plugged through clogging with product, and through the buildup of mineral deposits. There should be a program in place for routine maintenance and cleaning of the water sprays and water filter screens if present. During the inspection of these systems the water distribution sprays should be examined to determine if the holes are plugged or have been reduced by mineral scale buildup.

5. The records maintained by the firm must document that operating steps set-up to provide uniform temperature distribution in the retort during processing are being met.

When spray water retort systems are encountered, it is important to determine if the retort system is being operated under the same conditions used during temperature distribution testing.

STEAM-AIR RETORTS

Equipment and procedures for processing in steam-air retorts are covered by 9 CFR 431.6(d) of the LACF regulations.

Steam-air retorts are normally batch type static or rotary, end-over-end, retorts. Steam-air has been used as the heating medium in the Hydrolock (a horizontal continuous feed water lock retort) manufactured by the Rexham Corporation, and in at least one hydrostatic retort in Japan. These retorts are however the exception and not the rule.

Known manufacturers of batch type steam retorts include: J.L. LaGarde in France (Distributed in the U.S. by Stork Food Machinery), Lubeca in West Germany, Marrodan in Spain, and Barriquand in France (Steristeam). At one time the Container Machinery Corp. built the Truxton Steristar in the U.S. The Steristar steam-air retort is now built by Malo. Custom installations of steam-air retorts have been reported and other manufacturers may exist. An example of the steam-air retort system is the LaGarde steam-air retort (Figure 16).

The steam-air retort uses a mixture of steam and air, which is added to create an over-pressure in the retort. The air overpressure allows thermal processing of a wide variety of containers including: glass, metal cans, rigid plastic, and flexible pouches. Steam-air mixtures, although in a gaseous state similar to 100% steam, when used as a heating medium behave more like water. The heat capacity of the steam-air is very small when compared to pure steam. As the steam condenses and gives off heat, the air remains. Because the retort uses air in the steam mixture, there must be a method of mixing the air and steam to prevent the formation of air pockets in the retort and to provide for the rapid movement of the heating medium over the container surface. Air may provide insulation around the container preventing the heat from reaching the container walls in an efficient manner. A large fan is normally used to rapidly mix the steam-air mixture and to force this mixture to flow through the retort and containers during processing.

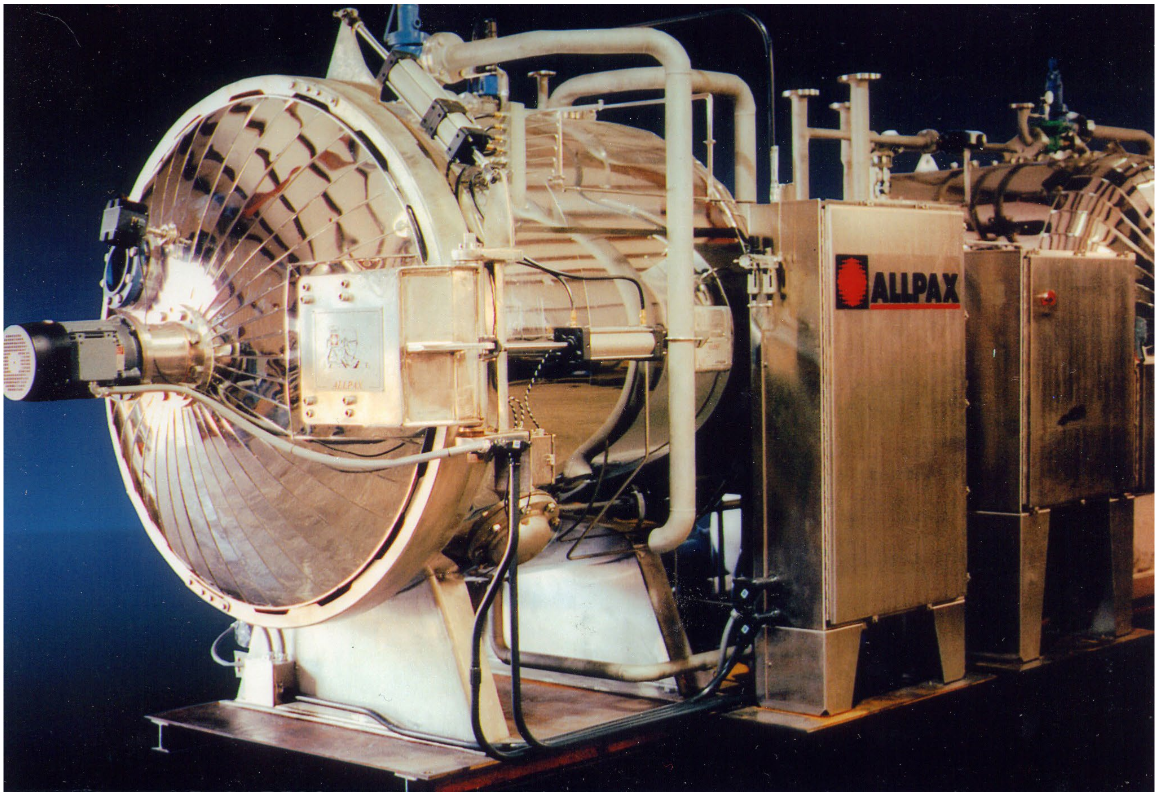

Figure 16

It is very important to maintain the correct steam-air ratio in this type of retort. The steam-air ratio should be the same as that used during studies to determine temperature distribution in the retort.

Steam-air retorts are normally operated at steam-air ratios ranging from 75% steam/25% air to 95% steam/5% air, depending upon the air over-pressure in the retort. The steam-air ratio is normally determined by the processing temperature and the type of package being processed.

The pressure in a steam-air retort must be maintained at the correct pressure to prevent container distortion and to maintain the correct steam-air ratio. If the amount of steam in the steam air ratio drops to too low a level, the energy available to heat the product is reduced. If the temperature is maintained by the steam controller, the partial pressure of the steam remains constant throughout the process. The pressure of the system is controlled by releasing over-pressure through a small purge valve and adding compressed air as needed.

The percent steam can be calculated using the following formula:

Steam pressure PSIA (pounds per square inch actual) = % steam Total system pressure psia

Steam pressure PSIA is determined by determining the amount of steam pressure generated at a certain temperature [e.g. 240° F generates 10 PSIG (pounds per sq. inch gauge)] plus 14.7 PSI (atmospheric pressure at sea level) equals 24.7 PSIA. The total system pressure is determined by taking the gauge reading and adding 14.7 PSI. A steam air system having a total gauge pressure of 15 lbs operating at 240° F would have 83% steam and 17% air mixture.

14.7 PSI atmospheric + 10 PSIG (steam at 240°F) = 24.7 PSIA
15 PSIG + 14.7 PSI atmospheric = 29.7
24.7/29.7=83% steam and 17% air

The LaGarde retort is offered in static or rotational end over end agitation models. The LaGarde is normally operated in the following manner:

- Product is placed into the retort in either standard rectangular baskets or crates for metal, glass and rigid plastic containers. Special racking trays are used for flexible and other containers needing support during processing.

- The retort is purged for 1 to 2 minutes through a large purge (vent) valve, the bottom drain or by vacuum to remove excess air from the retort and to enhance the steam entry into the retort. Steam is introduced into the retort through steam spreaders in the bottom of the retort.

- The fan is turned on to circulate the steam-air mixture. The retort is brought up to temperature during a 3-10 minute come-up period. The maximum amount of steam is injected at this time. The retort may use a steam bypass valve to provide a large flow of steam to the retort.

- A process hold period during which the retort temperature is maintained at the correct temperature by the addition of steam through an automatic steam control valve. This may be a small steam supply valve used to maintain a more uniform temperature. Excess pressure is released through a small purge (vent) valve in the retort shell. Compressed air may be added to the rear of the retort to maintain the retort over-pressure.

- Pre-cool, at the end of the thermal process a small amount of water may be injected into the retort steam-air channels to condense the steam or in some models cold water coils located in the retort are used to condense the steam.

- Cooling is then completed by adding water to the retort through top or bottom water spreaders. In some of the newer systems plate heat exchangers may be used to cool products through indirect cooling.

The steam-air mixture is forced through the LaGarde retort by a fixed speed fan located at one end of the retort. The steam-air mixture is normally drawn through the basket by the fan (an automotive type blade fan in the LaGarde and a squirrel cage type in some other systems) and pushed back up along the sides of the retort through channels created by welding metal sheets to the top and bottom at each side of the retort. The plates are generally referred to as "directional baffles". The space between the plates and the retort shell is sometimes referred to as the steam-air "plenum". The flow rate is fixed at approximately 30 cubic feet per second. LaGarde states that a temperature overshoot, (where the temperature of the retort is operated at several degrees above the required product temperature for the first part of the process and as the internal package temperature begins to achieve the desired temperature the temperature of the retort is reduced) can be used to produce a superior product. This process is reportedly designed to achieve shorter processing times and better heat transfer without stressing the container by causing high pressure within the containers. If the temperature overshoot is used, it must be filed as part of the process schedule.

The Lubeca LW3003 steam-air retort is offered in both static and rotational models. The Lubeca differs from the LaGarde in that in addition to using a large fan to mix the steam-air mixture this system also pumps the condensate from the bottom of the retort and distributes the condensate over the top of the containers. At the beginning of the process, a small amount of water is added to the bottom of the retort. This water is heated by the addition of steam through steam spreaders in the bottom of the retort. A large squirrel type ventilator fan pulls air along the bottom of the retort and pushes the air along the top of the retort and back through the crates of product. Instrumentation is located in the shell of the retort. The temperature of the condensate and water may not be measured or recorded during production. Following the thermal process the containers are cooled by the addition of cooling water to the retort.

The Barriquand Steristeam retort differs from the LaGarde in that each basket has it own circulation fan. The fans are mounted on the side of the retort and circulate the steam-air mixture up over the basket and back through the containers. Cooling of product is normally through an external heat exchanger or by the addition of cooling water to the retort shell at the customer’s option.

The Truxton Steristar is a modified version of the LaGarde. The Steristar may use a squirrel cage or an automatic type fan, heavier components, proportional control valves, preheated compressed air and a number of other modifications to the LaGarde system. Operation of the system is similar to the LaGarde.

Air flow in the steam-air retort system is very important to the maintenance of proper temperature distribution during processing. Changes in the container, crate or loading configuration can change the air flow in the retort. Steam-air retorts are normally operated with a full load of product or with dummy crates of product to fill out the retort during the processing of partial loads. In some systems, a baffle may be used to block off the retort at the last crate and allow for processing with less than a full retort load.

Temperature distribution studies or other documentation should be on hand to demonstrate that adequate temperature distribution is achieved under less than full load conditions and with the container/crate configuration being used.

There should be some method for determining that the fan in a steam-air retort is operating. A visual inspection of the fan operation should be made on a routine basis. Inspection of operation of the fan should be documented.

DURING THE INSPECTION OF ALL THERMAL PROCESSING SYSTEMS, BE CERTAIN TO REFER TO THE APPLICABLE SECTIONS OF THE MEAT AND POULTRY CANNING REGULATIONS.

Institute For Thermal Processing Specialists

GUIDELINES FOR CONDUCTING THERMAL PROCESSING STUDIES

The following recommendations are to be considered voluntary guidelines. These recommendations do not preclude the application of other methods and equipment for conducting thermal processing studies. These guidelines have been developed by consensus of the Institute for Thermal Processing Specialists and should be given serious consideration for adoption as methodology by individuals performing thermal processing studies.

The Institute for Thermal Processing Specialists is a non-profit organization established exclusively for the purpose of fostering education and training for those persons interested in procedures, techniques and regulatory requirements for thermal processing of all types of food or other materials, and for the communication of information among its members and other organizations.

This document is a compilation and re-structuring of previously published IFTPS guidance documents. Prior documents were modified to follow a common format and were also updated to reflect current practices. Common sections amongst previously published documents, such as Retort Survey, were placed into separate chapters. Information was added to Chapters on Temperature Distribution, Heat Transfer Distribution, and Heat Penetration to provide recommendations regarding Data Analyses, Success Criteria, and Risks, Issues and Other Considerations.

Hyperlinks have been embedded throughout the document to assist the reader in navigating between different chapters. Hyperlinks may be identified as underlined, blue text.

Instructions for following hyperlinks in documents

To follow a link to the point being referenced – Press CTRL key + left click on the mouse to move to referenced item. Note that the instruction to CTRL + click will also show when the cursor is placed within a hyperlink.

To return to the place in the document where you were reading – Press ALT key + back arrow(Alt + ←) (note that using the "backspace" key will not work).

This document was approved for publication in March, 2014 by the IFTPS Board of Directors.

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1 DEFINITIONS

This chapter provides definitions commonly used for thermal processing studies.

TERM	DEFINITION
Ballast Containers	These are containers used to fill the retort during thermal processing studies to simulate production conditions. Typically, ballast containers for heat penetration, temperature distribution and heat transfer distribution studies are the same type, shape and size of containers as used for the intended process. In some retort systems, e.g., multi-basket batch retorts, ballast containers may not need to be the same in baskets not containing heat penetration and heat transfer distribution probes. Material used for filling containers may be the test product, or any suitable material having heating characteristics similar to that of the test product, or in some circumstances, water (e.g., temperature distribution).
Broken Heating	Heat transfer characteristic of some foods, particularly those with starches, where the heat transfer rate changes due to a change in the product as a result of product heating. The change in heat transfer rate may represent a change from heating primarily by convection to heating by conduction.
Calibration	To check, adjust, or determine by comparison with a traceable standard the graduations of a quantitative measuring instrument.
Cassettes/Trays/Racks	A means by which filled packages are held/carried in a retort. Cassettes/trays/racks may be loaded into cubes, baskets, or other means to convey filled packages into and out of a retort.
Cold Spot – Heat Penetration	The cold spot for heat penetration studies is determined experimentally and represents the slowest heating location within the container. In the case of non-homogenous foods, the slowest heating food particle in the slowest heating location within the container would be considered to be the cold spot.
Cold Spot – Temperature Distribution	The cold-spot for temperature distribution is generally that area of the retort which is the last area in the retort to reach a minimum processing temperature during come-up.
Cold Spot – Heat Transfer Distribution	The slow/slower to heat location(s) for Heat Transfer Distribution is generally the location(s) in the retort where heat transfer into the product is the slowest. This is indicated by the location with the largest f_h value.
Come-Up Time (CUT)	Come-up time (CUT) is defined as the time requirement for the reference TID to read at or above the minimum process temperature <u>AND</u> all TMDs to read within 1F° (0.5°C) of minimum process temperature within 1 minute of starting the hold time.
Commercial Sterility	Commercial sterility is defined as the condition achieved by application of heat, or other treatments that renders the product free of viable microorganisms having public health significance as well as microorganisms of non-health significance capable of reproducing in food under normal non-refrigerated conditions of storage and distribution.

Computer Control System	Computer used for automation of electromechanical processes. Also referred to as a Programmable Logic Controller (PLC).
Conduction	A type of heat transfer that may be characterized as one where agitation of the package with the food does not impact the heat transfer rate.
Convection	A type of heat transfer that may be characterized as one where agitation of the package with the food does impact (positively) the heat transfer rate.
Crateless Retort	A non-agitating (i.e., still) batch retort wherein cans are sterilized in saturated steam as a “jumble pack”, without baskets, trays or cassettes. Loading is by dropping cans from the retort top into a cushion of water and cans are unloaded by gravity dropping out the bottom into a water canal with a drag chain to drying and packing.
Critical Factors	US-FDA 21CFR Part 113 defines critical factors as – “any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility”. Critical factors may include physical and chemical aspects/parameters associated with the container, the product, the retort and processing conditions.
f_h	The time for the heat penetration curve to traverse one log cycle. Also referred to as the heating rate index.
Fill, Drained, and Net Weights	Fill Weight means the weight of solid product in the container before processing and does not include the weight of the package or cover liquid (if applicable); Drained Weight is the weight of solids after processing; and Net Weight of a product refers to the weight of all product in the container including any cover liquid minus the weight of the container.
Flow Meter	An instrument/device/sensor that measures fluid flow rate.
Heat Penetration	Studies conducted to determine and establish a Scheduled Process. Heat Penetration studies are typically conducted under “worst case” conditions for product, package, location, and retort parameters.
Heat Transfer Distribution	Heat transfer distribution studies are used to establish the ability of a retort process to uniformly mix and distribute the heat transfer medium especially when the heat transfer into product may be rate limiting.
Heat Input Unit(HIU)	Appropriate material such as a polymer, clay, or food product with repeatable/definitive thermo-physical properties, and capable of being used for heat transfer distribution studies.
Heat Penetration Curve	Plot of the logarithmic difference between either retort temperature and product temperature (heating curve) or product temperature and cooling medium temperature (cooling curve) versus time.
Hermetic Seal	The condition which excludes the ingress of microorganisms, filth or other environmental contaminants that could render the product unfit for consumption or which could reduce the quality of the product to a level less than intended.

Initial Temperature	The average temperature of the contents of the coldest container to be processed at the time the sterilization cycle begins.
Low-Acid Canned Food (LACF)	Any food, other than alcoholic beverages, with a pH >4.6 and a water activity (a_w) greater than 0.85 packaged in a hermetically sealed containers that are thermally processed and stored at ambient temperatures.
Loading Pattern/Map	A depiction showing locations of probes and/or probed containers (e.g., temperature distribution, heat penetration, and heat transfer distribution) within a retort load.
Nesting/Shingling	Condition that occurs when more than one container is stacked fully or partially on top of another container. In the case of pouches, this is referred to as shingling. Nesting/shingling may negatively impact heat transfer/heat penetration.
Overpressure	Pressure in excess of that corresponding to saturated steam vapor pressure at a given temperature and when corrected for altitude. Overpressure may be necessary to maintain package integrity during the process.
Packing Gland (Stuffing Box)	Soft rubber or other material that is used to create a tight seal around TMDs/PMDs that assists in providing a means to penetrate the retort shell without allowing process media to leak to atmosphere (if applicable).
pH	A measure of acidity or alkalinity. Chemically, pH is defined as the negative log of the hydrogen ion concentration.
Piping and Instrumentation Diagram (P&ID)	Diagram which shows the piping of the process flow together with the installed equipment and instrumentation.
Plenum/Shroud	In a steam/air retort, the plenum/shroud is the space between the retort shell and the portion of the retort holding the baskets/cassettes. The function of the plenum/shroud, usually in conjunction with a fan, facilitates movement of steam/air through the retort and retort load.
Pocket space	Space within a cassette/rack/tray to hold a package.
Pressure Control Sensing Device	Instrument used to control pressure inside the retort.
Pressure Indicating Device (PID)	Instrument used to monitor pressure inside the retort, e.g., pressure gauge or pressure transmitter with electronic display.
Pressure Measuring Device (PMD)	Pressure sensor placed within (or mounted on) the retort to accurately monitor pressures attained and maintained throughout the applied process.
Process Deviation	A change in any critical factor of the scheduled process that reduces the sterilizing value of the process, or which raises a question regarding the public health safety and/or commercial sterility of the product lot/batch.
Process Establishment	Scientific procedure to determine the adequate process time and temperatures required to produce commercially sterile canned products.
Resistance Temperature Detector(RTD)	Thermometry system based on the positive change in the resistance of a metal sensing element (commonly platinum) with increasing temperature.

Retort	Any closed vessel or other equipment used for thermal processing. May also refer to the act of applying a thermal process to a canned food in a closed pressurized vessel. May also be referred to as a "sterilizer". The terms "retort" and "sterilizer" are often used interchangeably.
Retort – Continuous Rotary/Reel and Spiral Cooker/Cooler Retorts	In Continuous Rotary/Reel and Spiral Cooker Cooler retorts, cans enter and exit the processing vessel through mechanical pressure locks. Once in the vessel, cans move through a spiral track mounted on a reel that is rotating inside a horizontal cylindrical shell. In one revolution of the reel, cans roll by gravity along the bottom part of the arc (approximately 90-120°), which provides most of the product mixing within the can. The cans are essentially static as they pass through the remainder of the arc (approximately 240-270°).
Retort –Hydrostatic	A retort in which total pressure in the sterilization section is determined and maintained by the hydrostatic pressure of inlet and outlet water columns. Packages are continuously conveyed through the machine.
Separator/Divider Sheet	Separator/divider sheets are used to separate layers of packages in a basket/crate. These typically contain perforations/holes to help facilitate free movement of the heat transfer medium. Materials of construction can vary – metal/stainless steel, rubber, plastic, and so forth.
Scheduled Process	The process defined by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility.
Should	Should is used in this document to indicate a recommendation or option for consideration.
Simple Heating	Heat transfer characteristic of some foods where the heat transfer rate is relatively constant during product heating.
Slip Ring	A device that allows for transfer of the thermocouple voltage signal from a rotating environment to a stationary electrical contact outside of a retort.
Steam/Air Flow Indicator	Indicator located in the retort shell to determine the direction and to measure flow (cubic feet per minute - cfm) of process media.
Steam/Air Ratio	The steam/air ratio (for isothermal/isobaric conditions of the cook segment) is calculated by volume by determining the amount of steam pressure at a certain temperature plus the atmospheric pressure at sea level and dividing that value by the total absolute Total Pressure of Steam and Air/Nitrogen as indicated by the retort gauge pressure plus the atmospheric pressure. For example, using the steam tables, at 240°F (115.6°C), the absolute saturated steam pressure at sea level is 24.968 psia/1.722 bar (or 10.272 psig and 0.708 bar gauge). For a process with a gauge pressure of 15psig (1.034 bar gauge), the absolute pressure at sea level is 29.696 psia (2.048 bar). This would equate to a steam/air mixture that is 84% saturated steam (i.e., 24.968/29.696 X 100% or 1.722/2.048 X 100%) and 16% overpressure air (i.e. 29.696-24.968/29.696 X 100%). Note that the altitude of the processing facility should be considered when converting gauge pressure to absolute pressure.
Steam/Air Retort	A **steam/air** retort is a batch retort that uses air/nitrogen to provide overpressure.

Steam/Air Retort – Forced Flow Steam/Air Retort	In a forced-flow retort, a mixing fan induces a forced convection of the process heating media by drawing the steam/air mixture through the product and circulating it through a return plenum. Steam is introduced between baskets while air over-pressure is introduced into the return plenum cavity.
Steam/Air Retort – Air Make-up Steam/Air Retort	In this type of retort, small vent valves on the retort remain open after desired temperature and pressure are achieved and provide continuous venting of the retort during the heating period. Air is re-introduced into the retort as needed to satisfy over-pressure requirements while steam is simultaneously added to maintain temperature.
Steam/Air Retort – Positive Flow Steam/Air Retort	In this type of retort, a continuous flow of steam and air are passed through the vessel to create a homogeneous mixture throughout the retort. This creates an overpressure condition in the retort and results in continuous venting of the steam/air mixture thus creating flow past the containers.
Sterilizer	See definition above for Retort.
Sufficient Sampling Frequency (Data Collection)	As used in this document, sufficient sampling frequency is determined by the processor and should be frequent enough to confirm that the measured parameter is within control.
Temperature Control Sensing Device	Device used for controlling temperature in a retort.
Temperature Indicating Device(TID)	Device used for monitoring temperature, including thermometers, thermocouples, RTDs and thermistors and generally referred to as the “official” or “reference” temperature monitoring device on a retort system. A Mercury-in-Glass (MIG) thermometer is an example of a TID.
Temperature Measuring Device (TMD)	Device used for measuring temperature, including thermometers, thermocouples, RTDs, wireless data-loggers, and thermistors.
Temperature Uniformity and Stability	Verification of temperature across/within the retort load (uniformity) and over time (stability) of the process particularly during Cook/Hold.
Thermistor	TMD manufactured from semiconductor materials which exhibits large changes in resistance proportional to small changes in temperature. Thermistors are more sensitive to temperature changes than thermocouples or RTDs and are capable of detecting relatively small changes in temperature.
Thermocouple	TMD composed of two dissimilar metals which are joined together to form two junctions. When one junction is kept at an elevated temperature as compared to the other, a small thermoelectric voltage or electromotive force (emf) is generated which is proportional to the difference in temperature between the two junctions.

Temperature Distribution	Studies conducted in a sterilizer (retort)using distributed temperature measuring devices (TMD) to establish venting procedures, venting schedules, come-up requirements, and temperature stability and uniformity, which are necessary to establish heating and cooling performance (i.e., temperature uniformity) throughout the retort. Temperature distribution studies are typically performed using actual production retort conditions or parameters.
Tray/Rack	See Cassette/Tray/Rack above
Validation	There are multiple definitions of the word "validation". In the context of this guideline document, validation is assumed to mean at least two successive and successful replicate studies that meet established success/acceptance criteria.
Vent/Venting	A vent is a device/valve through which air is removed from a retort. Venting is the process by which air is removed.
Verification	In the context of this guidance document, verification is assumed to mean replicate studies that are intended to confirm a process. Verification may also be used to indicate confirmation of the calibration status of process measurement devices used to collect thermal process data.
Water Activity (a_w)	Water activity (a_w) is defined as the ratio of the partial pressure of water above a food to the water vapor pressure of pure water at a given temperature (a_w= p/p_o).
Water Cascade Retort	A **water *cascade*** retort is defined as one where a small amount of process water is drawn from the bottom of the retort by a high-capacity pump and distributed through metal plate(s) or manifold(s) in the top of the retort. This process water cascades down over the retort cassettes, cages or racks in a rainwater or "shower" fashion, passing over the product containers on the way back to the bottom of the retort where it is re-circulated through the heating and distribution system. Processing water may be heated using one or more direct or indirect heating methods including heat exchangers, direct steam injection, or via steam distribution pipes or spreaders.
Water Immersion Retort	A **water *immersion*** retort is defined as one where process water is sometimes heated in a separate vessel and once the process water reaches the desired processing temperature, is dropped into the processing vessel. Water is re-circulated during processing. Sufficient water to completely cover the packages may be used. In other cases, packages may only be partially covered with water during processing.
Water Spray Retort	A **water *spray*** retort is defined as one where a controlled amount of process water is drawn from the bottom of the retort by a high capacity pump and distributed through spray nozzles located along the top and sides of the retort. This process water is sprayed over the retort cassettes, cages or racks in a high-pressure "mist" fashion passing over the product containers on the way back to the bottom of the retort where it is re-circulated through the heating and distribution system. Processing water may be heated using one or more direct or indirect heating methods including heat exchangers, direct steam injection, or steam distribution pipes or spreaders.
	A sensor/measuring device that is self-contained (i.e., does not require wires). These

Wireless Data-logger	devices typically require programming prior to use and collected data are then downloaded or transmitted for analyses after use.
%CV	The coefficient of variance is mathematically calculated by dividing the standard deviation of a set of numbers by the average of the same set of numbers and then multiplying that quotient by 100. (%CV = standard deviation/average * 100)

2 TEST EQUIPMENT AND CALIBRATION OF TEST EQUIPMENT

SCOPE

2.1. The guidelines in this chapter apply to equipment used to collect thermal process data in any retort system. The guidelines apply to both internal and external measuring and data collection systems. Test equipment used for collecting thermal process data should be suitable for the purpose of the studies being conducted. Devices to collect temperature distribution, heat transfer distribution, and heat penetration data, in general, should be calibrated relative to the expected test conditions and ranges prior to conducting thermal process studies. Ideally, devices should also be calibrated upon completion of thermal process studies. Process efficacy and success criteria of thermal processing studies may not be met if sensors and measuring devices are inaccurately calibrated.

2.2. Biological indicators are not addressed in this chapter.

OBJECTIVE

2.3. The objective of this document is to provide guidance with regard to calibration of test equipment used to collect thermal process data.

TOOLS, EQUIPMENT, INSTRUMENTATION

2.4. *Data Acquisition System* – The data acquisition system should be calibrated prior to use. It should also be equipped with sufficient channels to accurately monitor and record temperature/pressure within the process delivery system. Manual recording of data may be used if a sufficient sampling frequency can be maintained.

2.5. *Temperature Measuring Device (TMD)* – TMDs may be thermocouples, wireless data-loggers, or other similar devices. All TMDs must be of sufficient accuracy, size, and length, and in sufficient quantity, to adequately and accurately monitor the process environment.

2.6. *Pressure Indicating Devices* – Operational gauges, electronic indicators, and/or wireless data-loggers may be used to monitor pressures associated with the retort operation during a test. These devices should be calibrated prior to the start of data collection. Typical pressure measurements could include: retort vessel pressure, steam line pressure, and other line pressures that may be critical to the process.

2.7. *Reference Temperature Indicating Device (TID)* – This may be a retort Mercury-In-Glass (MIG) thermometer or other valid reference temperature measuring device including a digital thermometer of sufficient accuracy and precision.

2.8. *Packing Gland (Stuffing Box)* – This is needed for entry of lead wires into the retort when wired data collection devices are used. Materials used should be soft enough to provide a tight seal without over-tightening and damaging the TMDs. Examples include Neoprene or other synthetic materials.

2.9. *Slip Ring* – This allows for transfer of thermocouple outputs from a rotating environment to a stationary electrical contact outside of the retort.

2.10. *Flow Meters* – Where applicable, flow meters may be used to measure flow of process water during come-up, heating, and cooling in those systems using circulating pumps. Flow meters may be used to measure volume or velocity of air flow in those systems using air for agitation of heating and cooling media.

2.11. *Stopwatch* – This is needed to verify rotation rate/speed in systems that have agitation and/or continuous container handling.

2.12. *Heat Input Unit (HIU)* – An appropriate material to simulate the product being studied in heat transfer distribution studies. Packaged product may also be used as an HIU.

METHODS FOR TEST EQUIPMENT STANDARDIZATION

2.13. *Retort Temperature Indicating Device (TID)* – The reference temperature measurement device must conform to applicable regulations. For example, US-FDA regulation 21 CFR Part 113 establishes the requirement that temperature indicating devices and reference devices must be tested against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other metrology institute. The reference device is typically calibrated for accuracy against a known certified reference device at least annually. The preference is to have the Retort TID calibrated near to the time data are collected. The last calibration check date should be included in the study documentation.

2.14. *Measurement System(s)* – Measurement systems include as applicable: thermocouples/TMDs (with extension wires as applicable), data acquisition system, pressure measurement devices, and flow meters. The recommendations of the datalogging equipment manufacturer should be followed or an instrument professional should be consulted regarding the correct grounding technique to use.

TMD Standardization/Calibration

2.14.1. Prior to conducting thermal process studies, standardization or calibration of test equipment should be performed. Thermocouples ideally would be calibrated in the test retort(s). All thermocouples, extensions, connections and the specific data logger should be assembled as they will be used under the actual test conditions. Consideration for conducting duplicate calibration studies prior to conducting critical thermal processing studies is recommended.

2.14.2. An acceptable method of calibration is to bundle all TMDs and locate them in close proximity to the known accurate reference TID, taking care not to inhibit flow of the heat transfer medium across the reference TID. The retort is brought up to the same sterilization set-point temperature and pressure as defined for the test and the retort is allowed to equilibrate. Equilibration time may be dependent upon the specific retort and/or retort type. The temperature differences between the reference TID and TMDs are then calculated and documented. These differences may be applied as correction factors for each TMD. A typical range of correction factors for thermocouples is usually not more than 1-2F° (0.6 – 1.2C°). Large correction factors may indicate an issue with the TMD that merits investigation and corrective actions prior to use in thermal processing studies. Non-thermocouple TMDs such as wireless data-loggers should be within manufacturer's specifications at the time of their use provided those specifications are consistent with conditions of intended use of the TMD.

2.14.3. Alternatively, TMDs may be calibrated off-line in an established calibration program within the temperature range to be used during data collection. The difference between the TMDs against the known accurate reference device should be calculated and documented as part of the study data. This difference may be applied as correction factors for each TMD.

2.14.4. Verification of the calibration of all TMDs after completing thermal processing studies is recommended. Off-sets which are substantially different than the pre-study values should be evaluated relative to the data that were collected.

Pressure Measurement Devices – Various methods are available to calibrate pressure measurement devices. Traditional calibrated and traceable dead weight testers (or their electronic analogs) are recommended to be used as the primary reference standard against which pressure gauges, transmitters and data logging devices should be calibrated. Regardless of method used, standardization results should be documented as part of the overall study data package where pressure is part of the process. Accuracy of pressure measurement systems should preferably be ≤1% of the calibrated and traceable pressure reference standards used, in the planned working or operating pressure range of the processes in which they are to be used. In addition, the accuracy should satisfy the applicable following considerations:

2.14.5. For steam/air retort processes, the accuracy of pressure measurements should not result in calculated intrinsic (unsafe) Steam Air Ratios ≥1% (i.e. richer in steam) for the actual process value.

2.14.6. For non-overpressure retort systems (primarily saturated steam), the accuracy of pressure measurements should not result in an overestimate (unsafe) error of the equivalent saturated steam temperature (corrected for sea level) of ≥0.2F° (0.1C°), if process temperatures are planned to be calculated from pressure values for any evaluation or consideration.

Flow Meters – A number of methods may be used to calibrate flow meters. Regardless of method used, standardization results should be documented as part of the overall study data package.

2.14.7. Fluid flow rates are often determined by flow meters or indirectly by revolutions per minutes (RPM) of fans, pumps or motors for known/fixed cross section flow areas.

2.14.8. Flow meters (usually mechanical or electronic), direct contact or non-contact, have become increasingly specialized and complicated and manufacturers have set up specialized flow test benches to provide calibration services for their flow meters.

2.14.9. Periodically (e.g., annually), factory electronic flow sensor output should be verified with volumetric, gravimetric or other approaches (e.g., tachometers, velocity meters, current or voltage draw) and results compared to calibration data. Re-calibration would be needed if the verification results are not consistent with the calibration data.

2.14.10. Based on the way flow is measured or imputed, process fluid flow sensor accuracy should be calibrated for use in production or validation in the operating range of the process and validations should factor in known off-sets, errors and calibration inaccuracies. Process efficacy and success criteria of thermal processing studies may not be met if flow meters are inaccurately calibrated.

Stopwatches – Stopwatches typically are received calibrated with an expiration date from the stopwatch equipment supplier.

Non-product based Heat Input Units (HIU) – Each HIU used in heat transfer distribution studies must have a unique identity.

2.14.11. Using either a pilot scale retort or the test retort, a standardization test for a complete set of HIU (e.g., 12-24 separate units) should be made using expected operating parameters (i.e., temperature and pressure) to establish a baseline for the heating performance as measured by the heating rate index (i.e., f_h) prior to use and periodically during their life expectancy.

2.14.12. All HIUs within a set should be in close proximity to one another during the standardization/calibration study.

2.14.13. All TMDs used in conjunction with HIUs must be calibrated prior to calibrating the HIU.

2.14.14. A reasonable means of determining acceptable standardization for the use of a set of HIUs in heat transfer distribution studies at any time during their life expectancy is to utilize the statistical measure of coefficient of variance of the f_h of the HIUs (%CV = standard deviation/average * 100%). A value of less than or equal to 1% would be acceptable for a set of HIUs to be used to collect heat transfer distribution data.

2.14.15. In addition, each individual non-product based HIU within a set should always be within 1% of its historical performance as measured by f_h for the same standardization/calibration process. Once the %CV exceeds 1% for a given HIU relative to its established baseline, consideration for removing it from service should be made. A rationale for using an HIU that falls outside of this recommendation could be based on its performance in a specific study provided the data collected meet the success criteria established (i.e., f_h %CV ≤5% in a heat transfer distribution study).

Product-based HIU – Product should be representative of the product heating type (e.g., conduction, convection) to be studied during heat transfer distribution tests.

RISKS, ISSUES, AND OTHER CONSIDERATIONS

2.15. To meet the calibration criteria noted above (section 2.14) and to ensure accuracy of test results, consideration should be given to minimizing errors inherent in any component of the temperature measuring system. For example, use of special limits of error (SLE) wire or premium grade thermocouple wire should be used to make thermocouples. The use of 3 or 4 wire high accuracy RTD can help to reduce intrinsic error.

2.16. ***Thermocouple Calibration:*** Thermocouples should be calibrated against a traceable calibration standard (e.g., thermometer, RTD, thermistor). Inaccuracies in temperature measurements may result in errors in thermal process studies; hence, frequent calibration is essential to provide reliable data. Factors affecting calibration include: worn or dirty slip-rings, improper junctions, metal oxidation, multiple connectors on one thermocouple and inadequate data acquisition system cold junction compensation. As a consequence, thermocouples should be calibrated in place as part of the complete data acquisition system. Some precautions when using thermocouple-based data acquisition systems include: minimizing multiple connections on the same wire, cleaning all connections, grounding the thermocouples and recording device, slitting thermocouple outer and inner insulation outside the retort to prevent flooding of data-logger or data recording device (4, 8), and using properly insulated thermocouple wires.

2.17. ***HIU*** **–**The considerations discussed below apply to HIUs other than packaged product.

2.17.1. Inherent variations associated with any HIUs must be considered when selecting the specific type of HIU, e.g., polymer-based solid material, bentonite suspensions, and oils. In addition, the design and geometry of an HIU must also be considered.

2.17.2. The nature of the process environment (temperature and pressure) may dictate the HIU material. The material selected must withstand the operating conditions repeatedly and reliably.

2.17.3. The geometric design of the HIUs should consider the package(s) general shape in all dimensions and placement within the package holding system (e.g., rack, trays, baskets) in order to mimic potential flow restrictions of the process media. Typically, the HIUs should be designed to conform to the shape of containers forming the ballast.

2.17.4. The thermal properties of the HIUs should be verified before and after their last use to ensure that their properties remain unchanged. Since material thermal diffusivity relates indirectly to heating rate index (i.e., f_h), thermal property verification could be in the form of heating rate determination of all HIUs under specific heating conditions before and after a test.

2.17.5. Factors that can influence standardization/calibration of the HIU materials include: machining tolerances, seals, air and water residues in the TMD wells, and heat degradation of the HIU upon repeated use.

2.17.6. HIUs such as bentonite suspensions at different concentrations exhibit different heating characteristics resulting in convection and conduction (simple or broken heating) profiles. Preparation steps should be consistent from batch to batch to minimize inherent errors (13, 14).

2.18. When actual packaged product is being used to collect heat transfer distribution or heat penetration data, a critical assumption is that it is uniform across all test packages. Any intrinsic variability in the product would be built into the data collected during its use in specific thermal processing studies such as heat penetration or heat transfer distribution tests. This intrinsic variability would/could eventually affect Process Establishment or meeting Heat Transfer Distribution Success Criteria.

DOCUMENTATION

Calibration or standardization results should be included in study documentation. A listing of records required by US-FDA regarding calibration records for temperature indicating and reference devices can be found in 21 CFR Part 113.100.

3 DOCUMENTING PROCESSING EQUIPMENT AND TEST CONDITIONS

It is important to establish proper documentation regarding the processing equipment used for thermal processing studies including: temperature distribution, heat transfer distribution, and heat penetration. While processing equipment surveys are not a part of data collection per se, they are important in identifying retorts that are used for thermal processing studies, documenting study test conditions, as well as helping plant management realize that projects outside the retort room may have an effect on processing operations.

Surveys should be periodically performed on all retorts to ensure that they remain consistently and properly installed to previously documented conditions. These may also be an important part of a plant's change control program. Note that USDA requires annual surveys or audits of retort systems.

SCOPE

The guidelines in this chapter are applicable to any retort system. The listed items for a processing room survey should not be considered as being "all inclusive". Some listed items may not be applicable to the particular retort/processing system being documented.

OBJECTIVES

The objectives of conducting a retort/processing survey include:

3.1. Documentation of test retort(s).

3.2. Providing documentation to aid in the identification and sometimes the selection of retorts for temperature distribution, heat transfer distribution, and heat penetration studies.

3.3. Documentation of "as existing" conditions that may then be used as part of an overall change control program.

ITEMS TO INCLUDE IN THE SURVEY

Retort

3.4. Shell – Physical dimensions of the retort and capacity (e.g., number of baskets, cassettes, dividers, etc.). Secure if possible, the retort manufacturer's or factory blueprints of the retort and all attendant piping, as well as, any alterations since the retort was originally installed.

3.5. Controls- Process controls and installation variations from one retort to another (if any) in the selected test retort group

3.6. Location of Instrumentation including instrument wells – Size, shape and location of well(s) used to locate sensors.

3.7. Reference Temperature Indicating Device (TID) – Type, location and calibration status.

- **3.7.1.** Where used, Mercury-in-glass (MIG) thermometer location, temperature range and increments, length of scale, calibration date, and length of insertion, i.e., the length of the sensing bulb that is inside either the retort shell or instrument well.
- **3.7.2.** Electronic TID type (e.g., RTD, thermocouple, thermistor, etc.), range, response time, location, and length of insertion. If applicable, record if the reference TID is located directly in the heat transfer medium.

3.8. Temperature Control Sensing Device– Type and location of the temperature control sensing device. Describe location of control sensor in relation to the TID sensor and to the steam distributor. If applicable, record if the temperature control sensor is located directly in the heat transfer medium.

3.9. Pressure Control Sensing Device – Type and location of the pressure control sensing device.

3.10. Overflow/purge/vents (air removal)

- **3.10.1.** Valve type and size
- **3.10.2.** Pipe size and connections to drain headers or channels
- **3.10.3.** Vents – location and size of pipes, type and size of valves
- **3.10.4.** Vent manifold or manifold headers – location and size of all pipes and connecting pipes
- **3.10.5.** Bleeders, mufflers – location, number, size and construction
- **3.10.6.** Safety valves – size, type and location
- **3.10.7.** Additional piping or equipment such as condensate removal systems, etc.

3.11. Pressure Indicating Device/Sensor – Note type, range and location of pressure sensors and gauges.

3.12. Drains including water level dumps, overflows, condensate removal

- **3.12.1.** Valve type and size
- **3.12.2.** Pipe size and length
- **3.12.3.** Note if check valves are used
- **3.12.4.** Note location of the condensate removal system in relation to critical zones, e.g., relation of condensate drain to the bottom of the cook shell in a continuous rotary/reel and spiral cooker.

3.13. Steam supply to the retorts

- **3.13.1.** Boiler capacity (horsepower, BTU rating), pressure, and method of firing (gas, oil, coal, dual capacity).
- **3.13.2.** Header pressure. This is important to determine that adequate steam pressure and volume is available for the retorting system. This part of the survey should be performed during both peak use and off-load hours.
- **3.13.3.** Pipe size and length, valve size and types, pressure regulators or reducers, pipe fittings including steam by-pass pipes, from the main steam line to the test retort(s)
- **3.13.4.** Size of all connecting steam pipes to the main line, noting all equipment using steam (e.g., blanchers, exhaust boxes, etc.).

3.14. Steam Introduction into the Retort –

3.14.1. Type and specifications for the steam distribution system including configuration (e.g., fishtail, cross, in-line, etc.), steam flow piping, size, number and location of steam injection perforations

3.14.2. Steam injection chamber (if applicable)

3.14.3. Steam injection points – size, type and location

3.14.4. Steam spreader or nozzle – shape, size, location and configuration, number, size and location of holes in pipe, size of "T", or any other pipe fittings.

3.14.5. Describe the heating medium (e.g., steam, hot water) and temperature.

3.14.6. Describe the cooling medium (e.g., re-circulated refrigerated water, ambient well water, evaporative cooling towers or ponds in re-circulating cooling water circuits).

3.15. Air or nitrogen supply to and into the retorts

3.15.1. Compressor type, capacity and operating pressure

3.15.2. Type and size of filter, dryer and tank

3.15.3. Line size, pressure, filters and dryers for instrument air

3.15.4. Process air header line size(s), pressure and pressure regulation, if used

3.15.5. Entry location and inlet size, control valve size and type, pressure setting and flow rate during testing. Availability to supply instruments. Indicate if air is heated or air lines are in close proximity to steam or water lines.

3.15.6. For Overpressure Retorts - Location and size of pipes and valves (type and size) and method of control.

3.16. Water supply to and into the retorts

3.16.1. Process water supply source, quality, temperature, and controls, if applicable

3.16.2. Cooling water supply source, quality (including microbial control methods), temperature, and controls, if applicable

3.16.3. Use of any alternate methods of heating processing water

3.16.4. Describe the method used to heat and cool the processing water including type (e.g., heat exchanger, cooling tower, etc.)

3.16.5. Location and size of pipes, valve size and type, pump and/or spreader size, type and location (if applicable)

3.16.6. Water level indicators – where applicable, type (e.g., sight glass, petcock, electronic, etc.) and location

3.17. Depending upon the retort system, document the following:

3.17.1. Where applicable, water recirculation system including pump type and capacity, location and sizes and filters of inlet/outlet ports, recirculation line size, flow meter type and capacity, output rates at operating conditions (e.g., gpm or L/min), rpm, pipe diameter for pump inlet and outlet and horsepower rating, impeller size

3.17.2. Air flow, orifice size, pressure setting and flow rate, if applicable

3.17.3. Pressure and/or flow switches type, location, and trip point setting, if applicable

3.18. For Steam/Air Retorts

3.18.1. Type and description of circulation and mixing system for steam/air mixing; bleeder(s) size, type and location

- **3.18.2.** **Air Plenum and fan shroud (if applicable)**
- **3.18.3.** Distance (length) from retort shell to plenum material if designed as a “shell in shell”.
- **3.18.4.** Details on fan shroud design and connection to the plenum

3.19. For Water Spray and Water Cascading Retorts

- **3.19.1.** Water spreader(s) size, type and location
- **3.19.2.** Water recirculation system – pump type and capacity, impeller size, motor size, location and sizes and filters of inlet/outlet ports, recirculation line size, type and capacity of flow meter
- **3.19.3.** Steam injection points – size, type and location
- **3.19.4.** Heat exchanger – use, size and type
- **3.19.5.** Water distribution Plate(s) (Water Cascade)
- **3.19.6.** Location of water inlet pipe to manifold (e.g., top/center of retort shell, top/rear of retort shell)
- **3.19.7.** Dimensions of manifold and material of construction
- **3.19.8.** Number, size and location (hole pattern) of holes in water distribution plate; percent open area of the holes in the water distribution plate should be calculated (Water Cascade)
- **3.19.9.** Water distribution pipes (Water Spray Retorts)
- **3.19.10.** Entrance location of entrance of water inlet pipe into retort shell
- **3.19.11.** Location of water distribution pipes in relation to circumference of retort interior
- **3.19.12.** Length of pipes, do they extend the length of the retort?
- **3.19.13.** Number, size and location of holes in pipes
- **3.19.14.** If connected to nozzles, describe the nozzle type. Are nozzles fixed or capable of oscillation? Describe if nozzles restrict diameter of the openings.
- **3.19.15.** Describe water flow rate, e.g., liters per minute, gallon per minute, etc.
- **3.19.16.** Process water retention channel or trough in bottom of retort
- **3.19.17.** Note if and how process water is retained for cooling or re-use
- **3.19.18.** Length, width and depth of water channel or trough
- **3.19.19.** Amount of water (liters or gallons) at start of process and how it is controlled and measured.
- **3.19.20.** If applicable, location of steam distributors or spreaders in relation to channel or trough.

3.20. Rotational Equipment – rotational speed indicator and drive system

3.21. Recording Device – Recorder or recorder/controller type and description including: resolution, parameters recorded, and calibration status.

3.22. Retort Loading Considerations/Loading Equipment

- **3.22.1.** Container information to include material, size and dimensions, orientation for processing (vertical, horizontal, jumbled), and loading configuration (e.g., layered, nested, compartmented, offset, etc.)
- **3.22.2.** Maximum number of containers per layer

3.22.3. Maximum number of cassettes, baskets, or racks per retort

3.22.4. Cassette, basket or rack dimensions, hole size, configuration and spacing in the base plate and sides of cassettes, baskets or racks

3.22.5. Separator sheet dimension, hole size including open area, configuration, and spacing

3.22.6. Partial load arrangement, if permitted

3.22.7. Water displacement requirements (ballast)

3.22.8. Distance between cassettes, baskets or racks, where applicable

3.22.9. Orientation of the cassettes, baskets or racks in the retort during processing

3.22.10. Percent open area of the cassettes, baskets or racks, if used

3.22.11. Describe basket clamping devices, where applicable

3.22.12. Describe top and bottom plates holding baskets, where applicable

3.23. Other Equipment – Other control or functional equipment installed that might affect the thermal process study being conducted. Examples of other types of equipment that should be noted include:

3.23.1. Sampling ports

3.23.2. Water or condensate level dump valves

3.23.3. Initial charge and make-up water systems

3.23.4. Insulation and/or jacketing of retort shell

DOCUMENTATION

Results and observations made should be documented and retained for future reference. The use of digital images may prove useful.

4 CONDUCTING TEMPERATURE DISTRIBUTION TESTS

Temperature distribution studies are conducted in a sterilizer (retort) using distributed temperature measuring devices (TMDs) to establish venting procedures, venting schedules, come-up requirements, temperature stability and uniformity, all of which are necessary to establish reproducible and reliable heating and cooling performance throughout the retort. Temperature distribution studies are typically performed using estimated production retort operating conditions or parameters.

SCOPE

4.1. The guidelines in this chapter are applicable to conducting temperature distribution studies in batch saturated steam, steam/air, water immersion, water spray, and water cascade retorts operating in both still and agitated modes.

4.2. Crateless retorts are excluded from the guidelines provided in this document.

4.3. Continuous Rotary/Reel and Spiral and Hydrostatic retorts are excluded from the guidelines in this document.

OBJECTIVES

4.4. The objectives of conducting temperature distribution studies include:

- **4.4.1.** Establishing venting procedures and schedules (where applicable), come-up requirements, identifying the existence (if any) of slowest to come to process temperature location(s), as well as temperature stability and uniformity during the Cook.
- **4.4.2.** Temperature distribution data may also provide insight into the impact of changes made to processing equipment, utilities, and other identified critical factors (e.g., package size, type, loading configuration, etc.).

INTRODUCTION and BACKGROUND

4.5. Acceptable temperature distribution is a requirement for process establishment.

4.6. New retorts require temperature distribution studies. Similarly, retorts that have undergone extensive repair re-design, or relocation can be expected to require temperature distribution studies.

4.7. Consideration should be given to testing all retorts on a regular basis to confirm they continue to perform as previously tested and documented. The replacement or normal wear of components associated with maintaining acceptable temperature distribution also warrant consideration for performing temperature distribution studies. These components may include, but are not limited to: water circulating pumps, valves and pipes associated with steam/water flow, steam injectors (fishtails), air orifices, overflow/pressure regulating valves, spray nozzles, heat exchangers, water distribution plates, and control system changes.

4.8. Temperature distribution can vary with individual installations of identical equipment at the same location. Consideration should be given to performing temperature distribution in each individual retort to document variation within individual retorts.

4.9. If appropriate, information taken in the processing equipment survey and an understanding of plant change control processes, validation, and operation procedures may be used to develop a reduced testing plan.

4.10. Demonstration of adequate temperature distribution is usually a prerequisite for conducting heat transfer distribution (where applicable).

MATERIALS, TOOLS, EQUIPMENT

4.11. See Chapter 2 – Test Equipment and Standardization of Test Equipment

METHODS

4.12. Test Retort Selection

4.12.1. Consideration should be given to testing all retorts in a system.

4.12.2. When appropriate, a reduced testing plan can be developed based on the information taken in the processing equipment survey (see – Chapter 3, Documenting Processing Equipment and Test Conditions). The reasons for retort selection should be documented in testing records. The retort(s) selected should represent the one(s) identified as having the greatest potential for diminished delivery of the critical process utilities such as steam, air, and water. Factors that may help identify the test retort (s) include: retort position (e.g., at the beginning or end of a line of retorts, furthest from steam header), container configuration, divider sheet style, type of heat transfer medium, and processing partial loads.

4.12.3. The results of the processing equipment survey should be verified for completeness and accuracy prior to the start of tests.

4.13. Test Retort Documentation

4.13.1. Test retort documentation may include photographs, diagrams, and a description of the operation, condition, and calibration status of sensors/measurement devices.

4.14. Location of Temperature Measuring Devices in the retort

TMDs should be placed in the following locations:

4.14.1. Attached or in close proximity to the reference TID probe.

4.14.2. Attached or in close proximity to the temperature control device, unless the reference TID and the controller probe are located together.

4.14.3. Located in at least two containers filled with test medium for the purpose of determining initial product temperatures. These containers should be located in the positions that are representative of the potential worst case locations in the retort load.

4.14.4. The lowest of initial temperatures to be encountered during normal commercial operation should be taken into account in establishing temperature distribution. The initial temperature measured should be considered in the context of retort shell and basket/crate/rack temperatures which may be lower or higher than the product temperatures and could have an effect on the total heat load.

4.14.5. An adequate number of TMDs are needed to ensure that the slowest to come-up to temperature locations are identified. A minimum of five (5) TMDs per basket/crate are typically used. These should be located in different layers or otherwise separated in each basket/crate in the initial phase of the temperature distribution study. The intent is to determine the slowest to come-up to temperature location in each basket/crate. Note that additional studies with a higher concentration of TMDs in a particular area or zone may be required to verify that the slowest come-up to temperature location(s) within the retort load have been identified.

4.14.6. TMDs should be placed so those measuring junctions are not in direct contact with containers or other surfaces. All TMDs must be securely fastened in place to prevent damage and unplanned movement during the process (particularly in agitating systems).

4.14.7. In subsequent studies, where no changes have been made to the equipment and previous studies have indicated consistency of cold spot location(s), a reduced number of TMDs per basket/crate/rack may be sufficient.

4.15. Location of pressure sensor(s)

4.15.1. At least one pressure sensor should be located in the retort shell. If the operational pressure sensor has been recently calibrated, it can be used in place of a test device. Pressure gauges should also be used to monitor line pressures of steam, air, and cooling water during a test.

4.16. Location of flow meter(s)

4.16.1. A calibrated flow meter (or alternate method) should be located in a manner to provide an accurate record of the water circulation flow during the process cycle in systems using circulation pumps.

4.16.2. A calibrated flow meter (or alternate method) should be located in a manner to provide an accurate record of the air flow during the process cycle in systems using air for agitation and mixing of process water.

4.16.3. For steam/air retorts – a calibrated flow meter (or alternative method) may be located in the return air plenum to provide an accurate record of the steam/air mixture during the process cycle. If the circulating fan is equipped with a directional/rotational and rpm sensing ability of the fan shaft, then the details of the fan motor from the retort survey will suffice.

4.17. Record of Monitored Locations (TMD Map)

4.17.1. A schematic drawing to show the placement of all monitoring devices within the retort should become part of the documentation for the temperature distribution tests.

4.18. Preparing Retort with Containers

4.18.1. Container Size – The container size and load density that are likely to be the most difficult to achieve temperature uniformity are typically selected for temperature distribution studies. In many cases this will be the smallest container and/or the densest load in use.

In some cases, multiple container sizes, types, configurations and orientations will need to be tested.

4.18.1.1. Since temperature distribution may vary widely with some systems depending upon container and type, it may be necessary to study each different container/ type and loading condition to develop a different come-up profile for each size/type and loading condition.

4.18.2. Container Contents – Containers may be filled with water, or the fastest heating product, for studying retorts that process convection heating products. For conduction heating products, the containers should be filled with product, starch suspensions, or other material that simulates the product. Regardless of material chosen, caution should be exercised when heating characteristics may change with multiple heating cycles. For water immersion, water spray, or water cascade retorts that use a temperature "overshoot" in the come-up profile to help temperature uniformity, use of conduction heating containers is often the worst case situation, and should be carefully considered. Note that stabilization periods at the end of come-up are not considered to be overshoots.

4.18.2.1. For saturated steam retorts, water may be used for conduction heating products; however the come-up times may be somewhat longer than what will occur with product.

4.18.2.2. Document the reasons for ballast container content selection in test documentation.

4.18.3. Container Placement Considerations – Containers are placed in the basket/crate in a manner that is equivalent to the worst-case situation as seen in the commercial operation. The worst-case may be the maximum number of containers per layer, actual number of layers, maximum load density, loading pattern, maximum fill of pocket space, and other conditions that result in the densest load. Where vertical channelling is possible, this condition should be considered in the temperature distribution test design. These aspects may need to be evaluated through additional testing to ensure that the worst-case has been defined.

4.18.4. Container Organization – This includes aspects related to baskets, divider sheets, trays, racks, and other means of holding or configuring packages in the retort.

4.18.4.1. The separator or divider sheets should be the same as those to be used in production. If more than one type of separator or divider sheet is used in production, then the dividers with the smallest percent open area should be used. If additional dividers are used on either the top or the bottom of the container load, this procedure must be duplicated for the test.

4.18.4.2. For a tray or rack that is used to hold and/or separate containers, the design of the tray or rack that will be used in production must be used for temperature distribution studies.

4.18.4.3. Variations in basket/crate/rack loading configuration and design expected in production may need to be tested to determine which yields the worst-case situation. The smallest anticipated partial load and location of the partial load should be compared to full load conditions noting the uniformity and temperature control and stability throughout the retort.

4.19. Conducting the Test

Data Collection/Monitoring Points – Depending upon the retort system, the following should be monitored and recorded during temperature distribution studies.

All Retorts

4.19.1. Temperature and Pressure Controller set point(s), including if there is an overshoot set point for come-up and a lower set point for processing

4.19.2. Product or Ballast Initial Temperature

4.19.3. Time process cycle starts, Time = 0 (time zero)

4.19.4. Times when the end of come-up, start of thermal processing/cook step has been achieved, as indicated by either the step change in a control program or the achievement of process set-point temperature at both the reference TID and the recorder/controller

4.19.5. Reference TID readings at sufficient intervals during the entire cycle, including the point in time it reaches the process temperature set point.

4.19.6. Monitor rotation or agitation rate at sufficient intervals using an accurate calibrated stopwatch or calibrated device including any points where rotation rate changes during processing or on a continuous chart where rotation or agitation is used.

4.19.7. Time at the end of thermal process, and start of cool.

4.19.8. Actual basket/crate/rack orientation in the retort.

4.19.9. Operating activity of other retorts including the number of retorts entering come-up during the study.

4.19.10. Numbers and descriptions of other equipment using steam (e.g., blanchers) at the time of the study and before, during, and after come-up.

In addition to the above, these items should be monitored and recorded based on the retort being studied:

Steam/Air

4.19.11. Temperature of air supply entering the retort.

4.19.12. Water level in relation to spreaders and lowest level of containers in the retort, if applicable.

4.19.13. Time when the pressure set-point(s) is achieved.

4.19.14. Time and temperature when the drain is closed, if it is open during a portion of the vent if applicable.

4.19.15. Time and temperature taken from the reference TID when the vent closes.

4.19.16. Air flow in scfm or liters per minute, if applicable and available.

4.19.17. Line steam pressure at the time of the test and before, during, and after come-up, if possible.

4.19.18. Retort pressure, throughout the test cycle at sufficient intervals or on continuous chart.

Saturated Steam

4.19.19. Water level in relation to spreaders and lowest level of containers in the retort.

4.19.20. Time and temperature when the drain is closed, if it is open during a portion of the vent.

4.19.21. Time and temperature taken from the reference TID when the vent closes.

4.19.22. Line steam pressure at the time of the test and before, during, and after come-up, if possible.

4.19.23. Time steam bypass valve closes.

Water Spray and Water Cascade

4.19.24. Temperature of initial process water.

4.19.25. Water level in relation to spreaders and lowest level of containers in the retort.

4.19.26. Flow or recirculation rate of water as determined by flow meter or other acceptable means.

4.19.27. Time when the pressure set-point(s) is achieved.

4.19.28. Retort pressure, throughout the test cycle at sufficient intervals or on continuous chart.

Water Immersion

4.19.29. Temperature of initial process water.

4.19.30. Fill time (displacement) in those systems dropping water from a storage drum or tank into the working processing vessel.

4.19.31. Water level in process vessel in relation to the top surface of containers, stated as a minimum or an actual level throughout the process.

4.19.32. Flow or recirculation rate of water as determined by flow meter or other acceptable means.

4.19.33. Time when the pressure set-point(s) is achieved.

4.19.34. Air flow in scfm or liters per minute, if applicable and available.

4.19.35. Line air pressure at the time of the test and before, during, and after come-up, if possible.

4.19.36. Retort pressure, throughout the test cycle at sufficient intervals or on continuous chart.

4.20. Data-logger

4.20.1. The data-logger should record the temperature of each TMD at sufficient sampling frequencies, typically 10-30seconds, throughout the length of the study.

4.20.2. The data-logger should record the temperature from cycle start through completion of cooling.

4.21. Other critical data collection point frequencies

4.21.1. Assumed or potential process-related critical factors should be recorded at intervals of sufficient frequency to describe and verify retort operating parameters during the test. Recordings are part of the permanent test records and should include the temperature recording chart, the pressure readings/chart, flow rate records, reference TID readings, and other data gathered that were identified as critical data collection points.

4.22. Study time duration

4.22.1. The test should extend for at least as long as needed for the retort control system to stabilize, establish a definite temperature profile, and all monitoring and TMDs have reached a steady-state condition.

4.22.2. If desired, retort cooling phase temperatures may be recorded through the entire cooling cycle. This is particularly important if product cooling lethality will be based on actual retort cooling profiles in developing scheduled processes.

4.23. Retort Test Conditions

Operating Procedures – Normal commercial operating procedures testing the extremes of allowable ranges to examine the effects of loading, overpressure, and agitation should be followed.

4.23.1. Temperature distribution studies should be run at the maximum retort temperature to be used for commercial processing. For example, one should **not** run temperature distribution studies at 250°F (121°C) if the product is processed at 266°F (130°C). Generally, temperature distribution studies should not be run any higher or lower than 5F° (~2.5C°) from the temperature at which product will be processed.

4.23.2. Minimum vent temperature and time is a critical factor for steam retorts. The temperature and time at which the vent is closed become the minimum vent schedule for the process.

4.23.3. Partial loading conditions should be studied in addition to the full load where permitted.

4.23.4. Basket rotation should be studied at or below the expected Scheduled Process value.

Where applicable, the following additional conditions may be tested at the standard retort processing temperature used for commercial production:

Steam/Air

4.23.5. High steam to air ratio (Low Overpressure).

4.23.6. Low steam to air ratio (High Overpressure).

Water Spray, Water Cascade, and Water Immersion Retorts

4.23.7. Low flow of the heat transfer medium.

4.24. Replication – To demonstrate reproducibility**,** at a minimum duplicate temperature distribution studies should be performed for each situation (e.g., container size, container type, operating temperature, basket/crate/rack system) with uniform and comparable results obtained from each test.

4.25. Post-test inspection

4.25.1. The condition of the measuring sensors, the test containers, and other attributes of the retort load should be examined after the completion of the entire set of studies to determine if the test results may have been affected by movement or other changes to the desired test setup.

DATA ANALYSES

4.26. Plot or tabulate the minimum and maximum measured temperatures for all TMDs within the retort load at each scan/time interval. The TID, Controller, and Chart temperatures at specific time points should be evaluated relative to the TMD's temperature.

4.27. Evaluate the difference between the minimum measured temperature and the programmed or set-point minimum process temperature at specific time points to establish or confirm temperature off-sets and to establish come-up time.

4.28. Identify the location of the TMD that was the slowest to achieve come-up criteria. Identify the time this TMD achieved come-up criteria.

4.29. Identify the minimum Initial Temperature.

SUCCESS CRITERIA

4.30. Come-Up –

- **4.30.1.** The TID should be at or above minimum process temperature at the end of come-up.
- **4.30.2.** All TMDs should be within 1F° (0.5C°) of minimum process temperature at the end of come-up.
- **4.30.3.** All TMDs should be at or above the minimum process temperature within 1 minute of starting the hold time.

4.31. Cook/Hold –

- **4.31.1.** After the start of Hold, the TID should not fall below the minimum process temperature.
- **4.31.2.** After the first minute of the Hold phase, the uniformity and stability of temperatures is confirmed by having no TMD temperature fall below minimum process temperature once that TMD has reached the minimum process temperature.

4.32. Cooling – If specific cooling profiles are critical to the process delivery, the temperature distribution during cooling must support those profiles.

4.33. Other –

- **4.33.1.** The location of all TMDs must be confirmed at the end of all studies. Any TMD that shifted during data collection should be evaluated for impact on study outcomes.
- **4.33.2.** The integrity of test packages/ballast should be confirmed to be acceptable.
- **4.33.3.** All critical retort operating parameters (e.g., Temperature, Rotation, Pressure, Flow, Water Level, and Fan Speed) were achieved as planned and/or programmed.
- **4.33.4.** Situations or conditions that do not meet these criteria should be critically evaluated.
- **4.33.5.** Identify the minimum Initial Temperature for which the temperature distribution is valid.
- **4.33.6.** Identify all other aspects of the product, package, ballast, loading pattern, and so forth for which the temperature distribution is valid.

DOCUMENTATION

Temperature distribution findings should be summarized in a report. Supporting items that should be included are:

4.34. Reason(s) for retort selection.
4.35. Results from the retort survey and test retort documentation.
4.36. Schematic showing placement of all measuring devices in the retort.
4.37. Reason(s) for product selection.
4.38. Retort charts, operator logs, retort control program, and control system reports.
4.39. Critical point observations to include Initial Temperature.
4.40. Calibration information for all sensors/devices used.
4.41. Data-logger data for both retort and product.
4.42. Graphical depictions of minimum/maximum data.

5 CONDUCTING HEAT TRANSFER DISTRIBUTION TESTS

This Guideline covers the scientific basis and fundamentals for conducting Heat Transfer Distribution Studies with emphasis on critical elements to be considered. This Guideline provides rationale for considerations to be used by an end user in deciding when Heat Transfer Distribution Studies are needed in addition to Temperature Distribution Studies.

SCOPE

5.1. The guidelines in this chapter are applicable to conducting Heat Transfer Distribution Studies in steam/air retorts and may be applied to water spray, water cascade, and water immersion retorts where air overpressure in excess of the saturated steam pressure (corrected for altitude) at process temperature is used. These guidelines are applicable to retorting systems operating in both still and agitated modes.

OBJECTIVES

The objectives of Heat Transfer Distribution Studies include:

5.2. Identification of the slowest to heat location in a retort to the extent that it impacts process delivery within the retort load when using the same process, product, package, and load conditions. Load Conditions include: Partial loading of baskets (e.g., less than a full basket of trays), less than a full retort load (e.g., 4 baskets in a 5-basket retort), tray/racks loading (e.g., not all package locations filled with a package), and density and/or percentage of open volume/void volume.

5.3. Identification of the repeatability of those relatively slower to heat locations across retorts and studies using the same process, product, package, and load conditions.

5.4. Identification of recommended locations to place Heat Penetration containers for Process Establishment.

5.5. Verification of the adequate delivery of the thermal process over time for a given product/package combination and loading condition(s).

INTRODUCTION and BACKGROUND

5.6. Temperature Distribution testing usually focuses on come-up and cook portions of the retort cycle. Temperature uniformity in these portions of the retort cycle may not always correlate to adequate heat transfer into packages throughout the retort, hence the need for Heat Transfer Distribution studies. Acceptable Temperature Distribution is recommended prior to conducting Heat Transfer Distribution Studies.

5.7. Heat Transfer Distribution testing may be recommended when:

- **5.7.1.** A non-condensable gas such as nitrogen or air is introduced into the heat transfer medium to provide overpressure in excess of the saturated steam pressure (corrected for altitude) at the Cook Temperature.
- **5.7.2.** For heating medium delivery systems (including type, flow, rack, package, etc.) whenever it is possible that in certain areas of the retort load the rate of heat energy supplied to the package is not in excess of the rate at which the package can absorb the heat energy.
- **5.7.3.** For new retorts, new retort programs/controls, new product/package/closure combinations including trays/racks/load configurations requiring overpressure air in excess of the saturated steam pressure at Cook Temperature.
- **5.7.4.** As part of an overall Change Control Program.
- **5.7.5.** When partial loads may be processed during manufacturing.
- **5.7.6.** Any time there are concerns that heat transfer delivery may be impacted by the retort's heating medium mixing and distribution system such as the presence of a fan, nozzles, shrouds/plenum, racking/tray design, and so forth.

5.8. Heat Transfer Distribution data may assist in conducting deviation analyses provided data are collected using actual product and package.

5.9. Heat Transfer Distribution data can be used as part of an overall ongoing program to verify retort operations over time.

5.10. The effects of package location along the radius of rotating loads are often not considered in Temperature Distribution testing, nor are effects of fastest to heat packages compared to those that are fastest to cool. Heat Transfer Distribution Studies may provide insight into potential effect of location along the radius of rotating loads as well as effects of faster to heat and cool packages within the retort load. In addition, insight may be gained on retort fan position, heating medium/air inlet design and shroud design, and their influence on the flow and mixing of the heating medium.

5.11. If desired, lethality data collected using actual packaged product (vs. non-product based HIUs) may be separated into that achieved during come-up and cook versus that achieved in cool. This information may be valuable in assessing the effects on nutrients and the product's physical stability throughout the retort load. Modifications to the retort, package, loading configurations, trays/racks, processing cycle, etc. to reduce or minimize the lethality differential throughout the load may be then possible. <u>Note that Heat Transfer Distribution data are not used for Process Establishment</u>.

5.12. As part of an overall Change Control program, Heat Transfer Distribution data collection should be considered whenever:

- **5.12.1.** Changes are made to packaged product loading such as new or modified trays, baskets, etc. are introduced.
- **5.12.2.** Changes are made to load density, flow rate of heat transfer medium, and shroud design.
- **5.12.3.** Changes are made to the primary package (e.g., heavier bottle), change to package fill volume and/or headspace volume, etc.
- **5.12.4.** New formulations are introduced.

5.12.5. Changes are made to utilities or the retort such as those done as part of upgrades to equipment or significant repairs.

5.12.6. The amount of air overpressure in excess of saturated steam pressure (when corrected for altitude) at Cook Temperature is modified.

5.12.7. Partial loads are to be processed.

5.13. Heat Transfer Distribution studies, in contrast to Heat Penetration studies, must always be conducted in the production retort(s). Pilot Plant Retorts or Research Simulators should not be used for studying or extrapolating Heat Transfer Distribution performance.

5.14. Microbiological techniques are not recommended for Heat Transfer Distribution studies.

5.15. Temperature and pressure must be independently controlled and recorded.

MATERIALS, TOOLS, EQUIPMENT

5.16. See IFTPS Guidelines for Conducting Thermal Processing Studies, Chapter 2 – Test Equipment and Calibration of Test Equipment.

5.17. Heat Transfer Distribution measurements may be obtained from instrumented/probed:-

5.17.1. Product-filled packages; or

5.17.2. Non-product based HIUs made from polymer-based materials such as Teflon, clays such as bentonite suspensions, and oils. Please refer to, Section 2.14.11 for criteria regarding use of non-product based HIUs.

5.18. A sufficient number of instrumented/probed samples to ensure that all areas of the retort load are being studied and to support statistically valid analyses must be included in each study.

METHODS

Test Retort Selection

5.19. In general, all of the information taken in the processing equipment survey should be used to select the retort(s) that will be used for Heat Transfer Distribution Studies. The reasons for retort selection should be documented in testing records or all retorts should be studied.

5.20. The retort(s) selected should represent the one(s) identified as having the greatest potential for diminished mixing and delivery of the heat transfer medium.

5.21. Heat Transfer Distribution Studies must be conducted using production retorts under expected production and operating conditions.

Test Retort Documentation

5.22. Information based on data from the processing equipment survey and from Temperature Distribution Studies should be included in study documentation.

5.23. The specific process, product, package, and load conditions being studied must be documented.

Ballast Retort Load

5.24. The ballast used may be product-filled packages of the type and size being evaluated. Alternatively, other materials may be used provided their heating characteristics are consistent with the product being studied.

5.25. Ballast packages should retain their heating and physical characteristics if they are to be re-used. Re-use of ballast packages should be documented in a Test Report.

5.26. Note that water-filled packages generally should not be used as ballast for Heat Transfer Distribution Studies to allow the retort controls to perform representatively for heating media, delivery and its replenishment within the load.

Baskets/Trays and Loading Considerations

5.27. The loading conditions used or expected to be permitted during manufacture of packaged product must be studied. This includes using the baskets, trays/racks, dividers, cassettes, etc. that will hold/carry product-filled packages.

5.28. Load density may have a dramatic impact on Heat Transfer Distribution. This is due to inhibition or retardation of distributing the heat transfer medium throughout the retort load. Therefore, optimization with respect to the specific retort's heat transfer medium mixing and distribution should be considered wherever possible. Optimization factors to consider include the design of:

- **5.28.1.** Trays/racks/baskets,
- **5.28.2.** Package,
- **5.28.3.** Number of packages per layer/rack/basket, and
- **5.28.4.** Retort operating parameters such as temperature and pressure values and ramps, timing of air introduction, any venting at the start of the retort cycle, or pre-heating of the overpressure air.

Locations of Probed Packaged Product/HIU in the retort

5.29. Heat Transfer Distribution test units are placed in suspected or known slower to heat locations within the retort load. Multiple studies may be required to confidently identify the slower to heat locations within the retort load.

- **5.29.1.** TMDs to measure temperatures surrounding the test packages should be located in proximity to those test packages. These TMDs are to be used to accurately calculate f_h values of adjacent test packages.

5.30. TMDs to measure product/HIU temperatures to be used for data analyses should be securely fastened inside the test package so that the measuring junction/tip is held in the test package cold spot.

5.31. At a minimum, five (5) probed product packages/HIUs should be located in separate suspected or known slower to heat areas of each basket. Symmetry and rotation effects should also be considered when determining locations for Heat Transfer Distribution test units.

5.32. All baskets in the retort should contain test units**.**

Location of pressure sensor(s)

5.33. Independent verification of total retort pressure during Heat Transfer Distribution Studies is recommended when possible and practical.

Location of flow meter(s)

5.34. Independent verification of flow rates of the heating medium is recommended when possible and practical.

Record of Monitored Locations (Loading Pattern/Map)

5.35. A schematic drawing to show the placement of all monitoring devices within the retort should become part of the documentation for Heat Transfer Distribution Studies.

Retort Control and Process Conditions

5.36. Heat Transfer Distribution Studies should be conducted using the process parameter conditions such as temperature, pressure, mixing and distributing the heat transfer medium, and rotation set-points used during normal production or manufacture of the packaged food being studied.

5.36.1. Since f_h and the associated %CV are used as the primary measures to assess adequacy of Heat Transfer Distribution, data do not necessarily need to be collected at the highest allowed overpressure permitted for the product/package being evaluated. This is in contrast to Heat Penetration studies where all “worst case” retort conditions and parameters must be used.It is important that the amount of overpressure used during Heat Transfer Distribution Studies be representative of the expected production condition for the product/package being studied.

Conducting the Test

5.37. Data Collection/Monitoring Points – Heat Transfer Distribution test units must be located in suspected or known slower to heat locations within the retort load. Independent verification of parameters such as controlling temperature, pressure, heat transfer medium flow rates, etc. is recommended. Location of independent sensors is at the discretion of the persons responsible for the study design.

5.38. Scan Frequency for Measurement Devices

5.38.1. Where possible, measurement devices should be set to a scan frequency sufficient to accurately determine heating parameters (i.e., f_h).

5.39. Study time duration

5.39.1. Cook durations should be of sufficient length to adequately determine f_h values and to confirm that Temperature Distribution success criteria were satisfied (See Temperature Distribution success criteria).

5.40. Replication

5.40.1. At a minimum, duplicate Heat Transfer Distribution Studies should be performed for each situation (e.g., package size, package type, operating temperature, basket/tray/rack system, etc.) with uniform and comparable results obtained from each test. Success Criteria must be met in all replicate studies.

5.40.2. Replicates should be true replicates in all respects, including Initial Temperature, Retort Temperature, Pressure, rpm, and so forth.

5.41. Pre- and Post-test inspections

5.41.1. See Chapter 2 –Test Equipment and Calibration of Test Equipment.

5.41.2. The fabrication, accuracy, condition of the HIUs, the product-filled test packages, and other attributes of the retort load should be examined before Heat Transfer Distribution are initiated to determine if they are acceptable for use and Heat Transfer Distribution results using them will not be adversely affected by the testing sub-systems.

5.41.3. The condition of the measuring sensors, the HIU/product-filled test packages, and other attributes of the retort load should be examined after the completion of the test to determine if the test results may have been affected by movement of these sensors or other changes to the desired test setup.

5.41.4. Comparison of pre- and post-test fill weights to ensure test packages have not leaked during testing. Consideration should be given to discarding data from leaking packages.

DATA ANALYSES

5.42. Calculate f_h values and the associated % CV

5.43. Identify the slower to heat locations within the retort load, e.g., f_h distribution within the retort.

5.44. Confirm adequate Temperature Distribution including come-up time.

5.45. Confirm that retort control and process conditions were achieved as designed.

5.46. If HIUs/product-filled test packages have also been placed in faster to heat locations, the f_h differential between slow and fast to heat locations may also be compared.

5.47. Determine product slower and faster to heat locations for the HIUs/product-filled test package combination. The slowest to heat location is determined based on the largest f_h value.

5.48. All subsequent process determination studies, i.e. Heat Penetration, should be conducted placing test packages in the known slowest to heat locations determined from Heat Transfer Distribution studies.

5.49. If desired, determine product slowest and fastest to cool locations.

SUCCESS CRITERIA

Heat Transfer Distribution may be considered acceptable when:

5.50. Temperature Distribution success criteria have been met during each Heat Transfer Distribution Study.

5.50.1. Note that demonstration of adequate Temperature Distribution is recommended prior to conducting Heat Transfer Distribution Studies.

5.51. Retort control and process conditions achieved/met as designed.

5.52. f_h % CV ≤ 5% within and across replicate studies. When this condition is met, uniform heat transfer conditions have been confirmed and Heat Penetration probes may be located anywhere in the retort.

5.52.1. In the event the f_h CV is found to be>5%, it should first be confirmed that the sensors used were consistent with accuracy stipulations (see Chapter 2 – HIU). Additional Heat Transfer Distribution studies need to be conducted to ascertain that the slowest to heat locations have been reliably and consistently determined, with appropriate confidence and rigor. Thereafter, all Process Establishment Heat Penetration Studies for the test (i.e. product, package, process, retort and load) combination need to be conducted at the identified slowest to heat locations.

5.52.2. Alternatively, when the %CV is >5%, iterative changes could be made to the retort, retort control, load density, rack design, etc. in an attempt to achieve an f_h % CV ≤ 5%. Once changes have been completed, replicate Heat Transfer Distribution studies should be conducted. Note that temperature distribution studies are a pre-requisite to conducting heat transfer distribution studies. The need to collect temperature distribution data after making changes should be evaluated prior to conducting additional heat transfer distribution studies.

5.53. Verified that the retort is uniform in terms of heat transfer media distribution and delivery and/or the slowest to heat location(s) within the retort load that may be used for Heat Penetration studies for Process Establishment have been identified.

5.54. If product-filled packages are used, product functionality and seal integrity are within accepted parameters.

RISKS, ISSUES, AND OTHER CONSIDERATIONS

5.55. HIU geometry should not interfere with the normal flow pattern and mixing of the heat transfer medium within the retort load.

5.56. Heat Transfer Distribution data are not used for Process Establishment.

5.57. f_h values determined from HIU other than actual the product/package may not be used for deviation evaluations.

5.58. Sufficient quantity of probed packages/HIU to conduct a valid statistical evaluation of the f_h variability within a test is required. Typically this will require that more than 6 values are used to calculate a mean f_h and the associated standard deviation and %CV. In general, a larger number of values will provide more robust values.

5.59. Replicate studies are recommended. The number of replicate studies will depend upon the number of retorts being evaluated and whether you are studying a new retort/process/package/formulation or if this is part of a periodic (e.g., annual) re-verification program. When replicate studies fail to meet Success Criteria for Heat Transfer Distribution, additional studies are needed.

5.60. Since f_h and the associated % CV are used as the primary measures to assess adequacy of Heat Transfer Distribution, data do not necessarily need to be collected at the highest allowed overpressure for the product/package being studied. This is in contrast to Heat Penetration studies where the “worst case” retort conditions as defined by the Scheduled Process must be used. It is important that the amount of overpressure used during Heat Transfer Distribution Studies be representative of the expected production condition for the product/package being studied.

5.61. Non-product based HIUs may be a preferred option to product-filled packages when the food being studied heats primarily by conduction.

DOCUMENTATION

Documentation of heat transfer distribution studies should include:

5.62. Reason(s) for retort selection.

5.63. Results from the retort survey and test retort documentation including digital photos showing the heating media delivery system including fans, pumps, nozzles, spreaders, shrouds, and so forth.

5.64. Schematics and/or digital photos showing placement of all monitoring devices in the retort.

5.65. Reason(s) for use of the specific HIU selected, i.e., packaged product vs. non-product based HIU.

5.66. Reason(s) for use of the specific Ballast selected, i.e., packaged product, packaged water or HIU.

5.67. Schematics and digital photos or packages, HIUs, Racks, Trays and Loads used for testing.

5.68. Retort charts, operator logs, retort control program, and control system reports

5.69. Critical factor records.

5.70. Calibration information for all sensors/devices used.

5.71. Raw data for both Temperature and Heat Transfer Distribution probes and that for any other monitoring devices such as pressure sensors that were used during the study.

5.72. Data and statistical analyses, re-tests, results and discussion as part of a Heat Transfer Distribution Testing Report, documenting testing deviations, findings, success criteria and recommendations for additional/subsequent work.

6 CONDUCTING HEAT PENETRATION STUDIES

SCOPE

The guidelines in this chapter apply to conducting heat penetration studies in any retort system including saturated steam, steam/air, water spray, water cascade, water immersion, and crateless. Batch retorts may be operated in either the still or agitating mode. Considerations for collecting heat penetration data in continuous rotary/reel and spiral and hydrostatic retorts are included. The intent of this document is to provide guidance in regards to the preparation and execution of heat penetration studies. Suggestions regarding data analysis of heat penetration data are also provided.

OBJECTIVES

6.1. The purpose of a heat penetration study is to determine the heating and cooling behavior of a product/package combination in a specific retort system for the establishment of safe thermal processes to deliver commercially sterile products and to assist in evaluating process deviations.

6.2. The study must be designed to adequately and accurately examine all critical factors associated with the product, package and process which affect heating rates.

6.3. Before commencing a heat penetration study, where applicable, an evaluation of retort temperature distribution and heat transfer distribution should have been completed.

6.4. A goal in conducting these studies is to identify the worst case temperature response expected to occur in commercial production as influenced by the product, package and process.

INTRODUCTION and BACKGROUND

Several product, process, package and measurement related factors can contribute to variations in the time-temperature data gathered during a heat penetration test. Establishment of a process requires expert judgment and sound experimental data for determining which factors are critical and the effect of changing those factors both within and beyond established critical limits. The list of items addressed in this section is extensive, but should not be assumed to cover all possible factors. Quantitative data on variability should be recorded where appropriate and all pertinent data should be documented to better understand and account for possible variations in heat penetration behavior.

6.5. Product

6.5.1. Product formulation and weight variation of ingredients should be consistent with worst case production values. Changes in formulation may necessitate a new heat penetration study.

6.5.2. Fill weight used for heat penetration studies should not be less than the maximum declared on the process schedule. Excess product may be expressed as percent overfill.

6.5.3. Solids content should be measured for nonhomogeneous products both before and after processing. Solids content deposited in a sieve should be weighed and expressed as a percentage of total weight. Note: Addition of compressed or dehydrated ingredients may result in increased drained weight.

6.5.4. Note that solids content may be considered a critical factor for homogeneous products and should be measured before processing.

6.5.5. Consistency or viscosity of semi-liquid or liquid components should be measured before and after processing. Flow behavior will change with type and concentration of thickening agents (e.g., starch, gums, etc.), temperature and shear rate. Changes may be reversible or irreversible which may be important when reprocessing product.

6.5.6. Size, shape and weight of solid components should be measured before and after processing, when appropriate. For example, measuring size and shape of cooked rice in product may not be possible or useful.

6.5.7. Integrity and size of solid component clusters may change during processing and affect temperature sensor placement in the product and cold spot location.

6.5.8. Methods of product preparation prior to filling should simulate commercial practice. For example, blanching may cause swelling, matting or shrinkage which could influence heat penetration characteristics.

6.5.9. Product matting or clumping may change heat penetration characteristics and influence cold spot location. Also, caution should be exercised with sliced products which may stack together during processing.

6.5.10. Rehydration of dried components, either before or during processing, is a critical factor which may influence heat penetration behavior, as well as process efficacy with respect to spore inactivation. Details of rehydration procedures should be recorded during the heat penetration study.

6.5.11. Product may heat by convection, conduction or mixed convection/conduction depending on its physical properties. Heating properties may also be influenced by presence/absence of agitation during processing, headspace volume, etc.

6.5.12. Some foods exhibit complex (broken) heating behavior. Product may initially heat by convection, then due to a physical change in the product, change to conduction heating behavior. For example, for products such as soups which contain starch, a change in heating behavior may be due to starch gelatinization at a particular temperature. Small variations in product formulation or ingredients may cause the transition from convection to conduction heating to occur at a different temperature and related time. Special care should be taken to identify and control specific product and process variables related to the heating rates of these products.

6.5.13. Additional product characteristics such as salt content, water activity, pH, specific gravity, concentration of preservatives, and methods of acidification may influence heat transfer or microbiological resistance and should be recorded.

6.6. Container

6.6.1. Manufacturer and brand name information for the container should be recorded in case information related to filling, sealing or processing is required.

6.6.2. Container type (metal cans, glass jars, retort pouches, semi-rigid containers); size and dimensions should be recorded.

6.6.3. Nesting of low profile packages can influence heating behavior. Heat penetration studies where nesting can occur, including jumbled loads, should include tests conducted on stacks of packages as well as non-nested packages.

6.6.4. Container vacuum and headspace should be recorded for rigid containers. For flexible and semi-rigid containers, the volume of residual gases in the container should be determined. Entrapped and dissolved gases may create an insulating layer in the container causing a shift in the cold spot location and a decrease in the heating rate. Controlled overpressure during processing has been found to reduce these effects.

6.6.5. Maximum thickness of flexible packages (pouches) has a direct relationship to the cold spot temperature history with thicker packages heating more slowly. Heat penetration studies should be carried out at the maximum specified and permitted package thickness.

6.6.6. Container orientation (vertical, horizontal, and specific location of top/bottom of the package) within the retort may be a critical factor for some product/package combinations and should be studied, where appropriate. Changes in container orientation may also influence vent schedules and come-up time as well.

6.6.7. Post-processing examination of test containers for abnormalities should be conducted with special emphasis on the slowest and fastest heating containers. It is strongly recommended that flexible packages be carefully examined following processing to identify the thermocouple junction location. If the intended sensing location has shifted, it is likely that heat penetration data collected are not reliable.

6.7. Method of Fill

6.7.1. Fill temperature of the product should be controlled. It will affect the initial temperature which may influence some heat penetration parameters (lag factor, retort come-up period). This may constitute a critical factor for a process, particularly for products which exhibit broken heating behavior.

6.7.2. Fill and net weights may influence heating rates both in still and rotary cooks. Information on variability may be found in statistical process control and product quality control records.

6.7.3. In most cases, controlling headspace by determining net weight is not sufficient due to possible variations in the specific gravity of the food product. Care should be taken to avoid incorporation of air which would affect the headspace vacuum. In rotary processes, container headspace is a critical factor since the headspace bubble helps mix the product during agitation.

6.8. Closing or Sealing

6.8.1. Closing or sealing equipment should provide a strong, hermetic seal which is maintained during the thermal process.

6.8.2. Vacuum is affected by variables such as: headspace, product temperature, entrapped air, and vacuum efficiency of the closing equipment.

6.8.3. Some products such as vegetables vacuum-packed in cans may have a minimum vacuum as a critical factor. For others packed in flexible or semi-rigid containers, vacuum setting will influence the residual air content in the package, also constituting a critical factor.

6.9. Retort System - The type of retort system used may have a significant influence on the heating rates of products processed in the retort. Results from a heat penetration test should be reported with reference to the retort type, heat transfer medium, agitation, and other pre-defined conditions existing at the time of testing.

6.9.1. When testing convection and conduction heating products, retort come-up time should be as short as possible consistent with obtaining satisfactory temperature distribution. Results will be conservative when using laboratory size retorts or simulators as these tend to have shorter come-up times and cool more quickly than production retorts. However, caution should be exercised when processing broken heating products where the length of the come-up period may affect the time at which the product heating characteristics change from convection to conduction. This may also be of concern where come-up times are longer in production than defined by the designed process.

6.9.2. Laboratory size retorts or simulators may be used for development work on heat penetration behavior. After development, the thermal process should, if physically possible, be verified in an appropriate production retort.

6.9.3. Heat transfer distribution studies should be conducted prior to conducting heat penetration studies for overpressure retort systems.

6.9.4. Racking systems may be used to separate layers of cans or jars; constrain the expansion of semi-rigid and flexible containers; provide support and circulation channels for thin profile containers; and ensure maximum pouch thickness is not exceeded. Care should be taken to understand the influence of a specific rack design on retort performance and heat transfer to containers.

6.9.5. Still batch retort systems vary in operation based on: type of heating medium(e.g., steam, steam/air, water); orientation of the retort (vertical, horizontal); method of heating medium agitation (fans, pumps, air injection); and other factors which may influence the heating behavior.

6.9.6. Rotational batch retort systems (e.g., axial, end-over-end) are designed to rotate (or oscillate) entire baskets of product during processing. Container agitation may provide faster rates of heat penetration to the container cold spot as compared to still cooks.

6.9.7. It is recommended that data be collected at small time increments (e.g., 15-seconds or less) particularly for low viscosity fluids where the cold spot may move in relationship to a fixed TMD during rotation, producing erroneous results. Short time intervals are important with low viscosity liquids and broken heating products that change from convection to conduction. Slightly longer time intervals (e.g., 30-seconds) may be acceptable for conduction heating products. 1 minute is adequate for most conduction heating products, and 3 minutes may be adequate for large containers of conduction heating products where the process time is longer. In general, 50 to 100 data points collected over the collection time may be sufficient for many conduction heating products.

6.9.8. Slip-ring connectors should be cleaned and TMD calibration verified at regular intervals. Critical factors for rotational batch retorts may include: headspace, product consistency, solids to liquid ratio, initial temperature, container size, rotational speed and radius of rotation.

6.9.9. Continuous retort systems move containers through the processing vessel along a spiral track located at the outside circumference of a horizontal retort shell or may be carried through a hydrostatic retort in chain driven flights. Regardless of the configuration, it becomes difficult or impossible to use thermocouples to collect heat penetration data in these systems. Data may be obtained using simulators and then confirmed using wireless data-loggers in the commercial vessel.

6.9.10. Heat penetration data, in some cases can be collected using process simulators. An understanding of scaling or other differences between commercial vessels and the process simulator and the impact on heat penetration is needed and should be documented.

MATERIALS, TOOLS, EQUIPMENT

6.10. See Chapter 2 – Test Equipment and Calibration of Test Equipment

METHODS

6.11. *Positioning of Temperature Measuring Devices (TMDs) in the Container*

6.11.1. The method of inserting a TMD into a container should result in an airtight, watertight seal which should be verified after testing. Verification may be accomplished through comparison of container weights recorded pre-and post-testing.

6.11.2. TMD sensing junctions should be positioned in the cold-spot of the package.

6.11.3. During insertion of the TMD, caution must be taken to avoid physical changes to the product components such as creating a conduction pathway to the particulate center. Care should also be taken to address potential agitation created by the probe, which can occur in rotation processes if the probe acts as a stirrer.

6.11.4. The method employed for mounting the TMD into the container should not affect the container geometry which could influence heat penetration characteristics.

6.11.5. Flexible or rigid TMDs may be inserted into rigid, flexible or semi-rigid containers using compression fittings or packing glands. For flexible containers, NFPA (4) provides illustrations of thermocouple positioning into a solid particulate and several thermocouple positioning devices to ensure the thermocouple remains in a fixed position within the container.

6.11.6. The most appropriate TMD device for a particular application will depend upon the product, racking system, container type and sealing equipment.

6.11.7. Leakage may be detected by weighing the container before and after processing to determine changes in gross weight. If there is leakage caused by improperly mounted TMDs or the failure of a hermetic seal, data collected for that container should be discarded.

6.12. ***Type and Placement of Containers***

6.12.1. The type and size of container used in the heat penetration study should be the same as that used for the commercial product.

6.12.2. The racking and loading of rigid (e.g., cans), semi-rigid (e.g., plastic bottles, trays and cups) and flexible (e.g., pouches) containers should simulate commercial practice.

6.12.3. Test containers should be placed at the slowest heating location(s) in the retort, as determined by temperature and heat transfer distribution studies.

6.13. ***Temperature of the Heating Medium***

6.13.1. TMDs to measure the heating medium should be positioned so as to prevent direct contact with racks or containers and identified according to their specific locations in the retort.

6.13.2. A minimum of two TMDs are recommended for retort temperature measurement: one situated close to the sensing bulb of the retort reference TID, the other located near the test containers.

6.13.3. In addition, at least one TMD should be placed near the sensor for the temperature controller when that location is remote from the location of the reference TID.

6.14. ***Retort Pressure*** - Worse case overpressure conditions should be used when collecting heat penetration data.

6.14.1. Overpressure conditions during processing will influence package expansion by constraining the expansion of headspace gases. This may be beneficial by improving heat transfer to food in flexible and semi-rigid containers or detrimental by restricting the size of the headspace bubble in rotary processes.

6.14.2. Cooling without overpressure may result in depressurization within a container at the end of a process, leading to accelerated decreases in temperature for fluid foods. Glass packages may also break if overpressure is not properly maintained during cooling.

6.15. ***Cold Spot Determination***

6.15.1. The location of the slowest heating or cold spot in a container is critical to establishing a process and should be determined experimentally. A cold spot location study should be completed to determine the slowest heating location for a specific product/package/process combination. Usually, the cold spot location will be determined from a series of heat penetration tests employing several containers with TMDs inserted at different locations. Alternatively, more than one TMD per container may be used; however, multiple TMDs may influence heating behavior, especially for products in smaller containers (6). Care and judgement based on a number of preliminary experiments, must be exercised to ensure the cold spot location has been identified.

6.16. ***Initial Product Temperature***

6.16.1. Measurement of initial product temperature should be taken immediately prior to testing.

6.17. ***Number of Containers per Test Run***

6.17.1. A heat penetration test should evaluate at least 10 working TMDs for each test run (6). If the retort cannot accommodate this quantity, the number of replicate test runs should be increased.

6.18. ***Number of Test Runs***

6.18.1. Replication of heat penetration test runs is important in order to obtain results which account for run-to-run, product, container and process variability.

6.18.2. After initial cold spot determination tests are completed and all critical factors have been determined, at least two full replications of each test are recommended. Should results from these tests show variation, a minimum of a third test is recommended.

6.18.3. Variation in the results is expected and quite common, especially for products which are non-homogeneous or exhibit complex heating behavior. Variability is generally evaluated based on plots of the heating and cooling curves and/or lethality calculations and should be considered when identifying or predicting the slowest heating behavior of a process.

DATA ANALYSES

6.19. Various methods are available for analyzing heat penetration data (4, 6, 7, and 8). Regardless of the method used, awareness of the potential pros/cons for each method should be understood and addressed.

RISKS, ISSUES AND OTHER CONSIDERATIONS

6.20. Use of self-contained (i.e., wireless data-loggers) TMDs should be evaluated for accuracy, reliability, and applicability prior to use as the product temperature measuring devices for heat penetration studies. In some cases these devices may provide benefits over using wired thermocouples, e.g., in agitating retorts such as continuous rotary sterilizers, batch retorts operated in an agitating mode, and hydrostatic retorts.

6.21. Ecklund (5) reported correction factors for heat penetration data to compensate for errors associated with the use of non-projecting, stainless steel receptacles. While not reported in the literature, this may also be a concern with other fittings.

6.22. **Type of Connectors and Associated Errors:** Connectors used in a thermocouple circuit are fittings attached to a thermocouple within which electrical connections are made. Several types of connectors are available for specific applications and thermocouple type. Caution must be exercised to avoid certain sources of error which may be associated with the use of connectors and extension wires. These include: disparity between thermocouples, connectors and extension wires; temperature differences between two wire junctions; and reversed polarity at the thermocouple-extension wire junction. Thermocouple connectors should be cleaned frequently to remove oxidation from contacts to assure good electrical contact and prevent errors in thermocouple readings. Similar concerns should be addressed when using RTDs and thermistors.

DOCUMENTATION

The following provides a summary of details which may be incorporated in a checklist and documented in their entirety or partially as deemed appropriate for a specific study. Other factors not listed in this section may also be relevant.

6.23. Pre-test Documentation
- **6.23.1.**Product characteristics
- **6.23.2.**Product name, form or style and packing medium
- **6.23.3.**Net weight and volume
- **6.23.4.**Consistency of viscosity of the liquid component
- **6.23.5.**Size, shape and weight of solid components
- **6.23.6.**Size of solid component clusters
- **6.23.7.**pH of solid and liquid components
- **6.23.8.**Methods of preparation prior to filling (ingredient mixing methods, special equipment, etc.)
- **6.23.9.**Matting tendency
- **6.23.10.**Rehydration of components
- **6.23.11.**Acidification procedures
- **6.23.12.**Other characteristics (e.g., % solids, density, etc.)

6.24. Container Description
- **6.24.1.**Container material (brand name and manufacturer)
- **6.24.2.**Type, size and inside dimensions
- **6.24.3.**Container test identification code
- **6.24.4.**Maximum thickness (flexible container)
- **6.24.5.**Gross weight of container
- **6.24.6.**Container nesting characteristics
- **6.24.7.**Slowest heating or cold spot location in container

6.25. Data Acquisition Equipment and Methodology
- **6.25.1.**Identification of data logging system
- **6.25.2.**TMDs and connector plug maintenance
- **6.25.3.**TMDs and connectors numbered
- **6.25.4.**Electrical ground checked (using thermocouples)
- **6.25.5.**Calibration of TMDs placed in heating medium
- **6.25.6.**Type, length, manufacturer and identification code of TMDs and connectors

- **6.25.7.** TMD location in container
- **6.25.8.** Positioning technique for TMDs

6.26. Fill Method

- **6.26.1.** Fill temperature of product
- **6.26.2.** Fill weight of product
- **6.26.3.** Headspace
- **6.26.4.** Filling method (comparison to commercial process)
- **6.26.5.** Sealing operations
- **6.26.6.** Type of sealing equipment
- **6.26.7.** Time, temperature, pressure and vacuum settings (if applicable0
- **6.26.8.** Gas evacuation method
- **6.26.9.** Can vacuum
- **6.26.10.** Volume of residual gases (i.e., flexible containers)

6.27. Retort System

- **6.27.1.** Retort system – still or rotary, type of agitation (end-over-end, axial, oscillatory, none)
- **6.27.2.** Retort identification number
- **6.27.3.** Reel diameter (number of container positions) and rotational speed
- **6.27.4.** Heating medium (steam, steam/air, water immersion, water spray/cascade) and flow rate
- **6.27.5.** Circulation method for water or overpressure media
- **6.27.6.** Temperature distribution records
- **6.27.7.** Where applicable, heat transfer distribution records
- **6.27.8.** Retort venting schedule
- **6.27.9.** Package position study data for batch rotary retorts

6.28. Loading of Retort

- **6.28.1.** Loading or racking system details
- **6.28.2.** Container orientation
- **6.28.3.** Location of thermocouples for retort temperature
- **6.28.4.** Use of ballast containers to ensure fully loaded retort (applicable to some retort systems)
- **6.28.5.** Selected time interval for data logging system
- **6.28.6.** Location of test containers in retort (slowest heating zone)

6.29. Additional Information

- **6.29.1.** Date
- **6.29.2.** Test identification
- **6.29.3.** Processor and location
- **6.29.4.** Individual(s) performing heat penetration test

6.30. Test-Phase Documentation

- **6.30.1.** Test run identification
- **6.30.2.** Initial temperature of product at the start of heating
- **6.30.3.** Rotation speed (if applicable)

6.30.4. Time heating starts
6.30.5. Time vent closed and temperature, if applicable
6.30.6. Time retort reaches set point temperature (t_c)
6.30.7. Temperature indicated on reference TID and when cook starts
6.30.8. Pressure from a calibrated pressure gauge or transducer
6.30.9. Time process begins
6.30.10. Time cooling begins (pressure cooling, if applicable)
6.30.11. Cooling water temperature
6.30.12. Time cooling ends
6.30.13. Any process irregularities or inconsistencies

6.31. <u>Post-Test Documentation</u>

6.31.1. Container location and orientation
6.31.2. Container net and gross weight check for leakage
6.31.3. Thickness of container (flexible pouches)
6.31.4. Measurement of container vacuum or residual air content (if applicable)
6.31.5. Location of the TMD and whether or not it is impaled in a food particle
6.31.6. Post-processing product characteristics (e.g., syrup strength, appearance, viscosity, headspace, drained weight, pH, consistency, shrinkage, matting, clumping, etc.)

APPENDIX A – SELECTED BIBIOGRAPHY

The following references represent a selection of publications that may provide more insight and information regarding thermal processing studies.

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12. Ball C.O. and Olsen F.C.W. 1957. Sterilization in Food Technology. Theory, Practice and Calculation. New York, McGraw-Hill Book Co.
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APPENDIX B - Documenting Processing Equipment and Test Conditions Worksheet

Where possible, drawings, schematics, pictures of the retort and associated equipment could be beneficial to include when documenting test retorts and test retort conditions. The following table is an example of a worksheet that may be used to document processing equipment and test conditions. This example may be modified as needed.

Survey Information Date ________________ Location _________________ Done by _____________________ Altitude ___________________ Height above sea level _____________________
TYPE OF RETORT ' Continuous Reel ' Hydrostat – Saturated Steam ' Batch – Steam/Air ' Batch – Water Spray ' Batch – Water Cascade ' Batch – Water Immersion ' Batch – Crateless ' Other (Describe) ___________________________
PRODUCT INFORMATION (optional) Product Name __________________________ Product Heating ' Simple, Convection ' Simple, Conduction ' Broken ' Other (describe) _______________ Container – Material ________ Dimensions _________ Orientation for processing ' Vertical ' Horizontal ' Jumbled Fill/Net/Drained Weight _____________________ List product critical factors, targets, and limits ____
PACKAGE INFORMATION (optional) Type of package - ' Rigid ' Semi-Rigid ' Flexible ' Paperboard ' Other, describe ____________________________ Material of construction (describe) - ____ For metal cans - ' 2pc ' 3pc Side seam construction ___________________________________ Loading Patterns - ' Jumble Pack ' Arrayed ' Other (describe) _____________________________________

Package Information, continued

Seal/Closure – Type ________________

Container Vacuum - ' Yes ' No If yes, allowed limits _____________________________________

RETORT OPERATION

Throughput (CPM) _____________________________________ Containers/load ________________________

Cook Temperature Set-point _________________ Pressure Set-point during Cook _______________________

Rotation Set-point _______________________________

Partial Loads ' Yes ' No If yes, describe allowed conditions ____

____

Where applicable, include retort control program.

For Water Immersion - ' Full Immersion ' Partial Immersion Water recirculation rate __________________

For Water Spray – Number and type of nozzles _________________________________ Flow Rate ____________________

For Water Cascade – Number and type of spreader/manifold __________________________ Flow Rate ________________

For Steam/Air – Fan location ____________________ Fan RPM __________________ Shroud - ' Yes ' No

Pre-heating of overpressure air/nitrogen - ' Yes ' No If yes, describe how heated, how controlled, and to what temperature
____

Steam/Air Ratio ____________________ Is venting part of the process - ' Yes ' No If yes, when is vent closed ________________

LOADING CONSIDERATIONS (where possible secure drawings, schematics, pictures)

Loading Configuration - ' Layered ' Nested ' Compartmented ' Offset ' Other (describe) _________________________________

Loading considerations, continued

Water displacement requirements (ballast) ____

Cassette, Basket, or Rack - Dimensions ____________________ Distance between (if applicable) _____________________

Orientation in retort during processing ________________________ Percent open area _______________

Separator/Divider Trays – Material of construction __________________________ Hole Size (if applicable) _______________

Percent open area _____________________________

Hole Open Area, Spacing and Pattern – Base plate _______________ Sides of cassettes/baskets/rack __________________________

Separator/divider Sheets ________________________

RETORT SPECIFICS (where possible secure factory blueprints/schematics of the retort and all attendant piping as well as any alterations since the retort was installed)

Manufacturer _______________________ Date Installed ______________ Physical Dimensions of shell _______________

Capacity – Continuous Reel: Zone 1 _________ Zone 2 __________ Zone 3 _________ Zone 4 ________ Cooker _________
Cooler _________ Pressure Cooler __________ Total _________

Capacity – Hydrostatic: Preheat _____________ Sterilization _____________ Cooling ____________ Total __________

Number of flights _______________________

Capacity – Batch: No. of Baskets/Crates per Retort ____________ No. of packages per load _______________

Capacity – Crateless: Maximum number of containers per load _________________________________

Heat Transfer Medium: ' Saturated Steam ' Steam/Air ' Water ' Other ________________

Method of Heating Heat Transfer Medium (describe) - ____

Retort specifics, continued

Cooling Medium : ' Ambient well water ' Chilled water ' Other (describe) ____

Method of process water microbial control ____

Method of distributing/mixing heat transfer medium: ' Fan ' Pump(s) ' Air plenum/shroud ' Nozzles ' Not Applicable

' Other (describe) __________________________________

Controls (e.g., PLC, Computer Control, etc.) - (Describe):
____

Note any differences between retorts in the test group.

List of all controlling/sensing devices (note that ideally a schematic/drawing should be available): ______________________________

____

Rotation: ' Yes ' No Continuous Reel – RPM ______________________________ Hydrostatic – CPM ___________________________

Batch – RPM __________________________________ Batch – Oscillatory ____________________________

Vents – Type ___________________________ Size ___________________________ Location _____________________________________

Pipe size and connection to drain headers or channels ____

Vent manifold/manifold header – Location ___________________ Pipe size(s) including connecting pipes ________________________

Bleeders/Mufflers – Number ___________ Size(s) _________________________ Location(s)_____________________________________

Construction ____

Drains – Valve Type ___________________ Valve Size _________________ Pipe size ____________ Pipe Length _______________

Connections to drain headers or channels _______________________________________ Location(s) _____________________________

Retort specifics, continued

Condensate Removal System(s) – Type _________________________ Size ________________________ Location ________________

Check Valves ' Yes ' No If yes, Size _______________________ Type ______________________ Location(s) ___________________

Safety Valves – Size ___________________ Type ___________________________ Location(s) ______________________________

Centering guides or baffles present ' Yes ' No If yes, indicate location ____

Water re-circulation system (if applicable) – Pump type ______________ Pump Size ____________ Pump Capacity ________________

Inlet/outlet port – Locations ___________________ Size ________________ Filters ______________________ Recirculation line size _________

Flow meter (if applicable) – type ___________________ Capacity _______________

Horsepower _________ Pipe diameter for pump inlet ___________ and for pump outlet _____________

UTILITIES TO/FROM RETORT

Steam Supply

Boiler Capacity _____________ Method of Firing _____________________ Pressure ________________

Steam header pressure (peak usage) ______________________ Pipe Size _______________ Length ____________________

Steam header pressure (off-load hour usage) ______________________

Steam injection chamber (if applicable) _________________________________

Valve Type ____________ Valve Size _________________

Pipe fittings including steam by-pass pipes from main line to retort (presence, type, size) ____

Size of all connecting steam pipes to the main line ____

Note all equipment using steam from same supply line ____

Utilities to/from retort, continued

Pressure Reducing Valve/Regulator ' Yes ' No If yes, type and pressure into retort ____

Size and Type of Valve for Steam entry into Retort ____

Steam distribution system in retort – Number, location and size of steam spreaders/distributors _______________________________________

Steam injection points – Size ___________ Type _______________________ Location(s) __________________________________

Steam spreader or nozzle – Shape ________________ Size ______________ Location(s) ________________________________

Configuration ___________________________ Number of _________________ Size and location in pipe _________________________

Size of "T" _____________________ Size of other pipe fittings ____

<u>Water Supply</u> (where possible, attach a P&ID)

Water pressure to retort _______________________________________ Water temperature to retort _____________

Water distribution system in retort – Number, size and location of water spreaders/manifolds _______________________________________

____

Process Water Supply – Source __________________ Quality ____________ Temperature _______ Controls (if any) ____________________

Cooling water supply – Source _____________ Quality ______________ Temperature _______ Controls (if any) ________________________

Method of heating processing water (describe) ____

Heat exchanger – Size ______________ Type __________________

Pump – Size ________ Type __________ Location ____________________

<u>Air/Nitrogen Supply</u>

Compressor Type ______________________________ Capacity __________________ Operating Pressure ____________________________

Utilities to/from retort, continued

Filter Type _________________________ Filter Size _____________________ Dryer Type ____________________ Dryer Size _________________

Tank Type _______________________ Tank Size _________________________________

Line – Size _____________ Pressure ____________ Filters and dryers for instrument air ____

Process air header – Line size ______________ Pressure ________________ Regulation (if applicable) _________________

Entry – Location _______________________ Inlet Size __________________

Control Valve – Size _____________________ Type _______________________ Pressure setting _____________ Flow rate ________________

Indicate availability to supply instruments ____

Air heated ' Yes ' No Indicate if air lines are in close proximity to steam or water lines ____

For Overpressure – Pipe location(s) ________________ Pipe size _________________ Valve type _______________ Valve size _______________

Method of control (describe) ____

SENSORS

Temperature

Type of Reference TID ______________________________ Model of TID ________________________ Location(s) ___________________________

Range ________________________________ Response time ___________________ Length of insertion ___________________________

Length of scale (MIG) _________________________________ Increments (MIG) _____________________________________

Calibration status – Date last calibrated __________________ Next calibration date _______________________

Size, shape, location of wells ____

Sensors, continued

Temperature Control Sensing Device – Type ___________________ Location __________________ Relationship to TID _____________________

For Water Spray and Water Cascade – Is this device in the water spray/cascade ' Yes ' No

For Steam/Air – Is this device in the retort or in the air (return) plenum - ' Retort ' Air return/plenum

Pressure

Type of PID ___________________________________ Model of PID _____________________________ Location(s) ___________________________

Range _____________________________________ Calibration status – Date last calibrated ______________

Next calibration date _____________________

Water

Water level indicator type (if applicable) _______________________________________ Location(s) _________________________________

Other

Rotation sensor Type ____________________________ Location ______________________________ Drive system _______________________

Throughput/speed sensor Type ______________________________ Location __________________________

Type and size of flow meter ____________________________________ Location(s) _________________________________

RECORDING DEVICES

Recorder/Recorder Controller – Type _________________________ Resolution ____________________________

Parameters recorded ____ Calibration status _____________________________

List Process critical factors and their associated limits - ____

____

WATER SPRAY AND WATER CASCADE RETORT – These are items that may not be covered in other areas of the survey.

Water Spreader(s) – Type ______________ Size _________________ Location ___________________________

Water recirculation system – Pump Type _______________ Pump Capacity _________________ Pump Impeller Size _______________

Pump Motor size ____________________

Inlet/Outlet port Location ____________________ Size _______________________

Water flow rate - ________________________________

Process water retention channel or trough in bottom of retort ' Yes ' No If yes, Length ________ Width ______ Water depth ________

Process water retained for cooling - ' Yes ' No

Process water retained for re-use - ' Yes ' No

Amount of process water at start of process - _____________ Controlled by _____________________ Measured by ______________________

Steam distributors (if applicable) – Location in relation to channel or trough ____

Water Distribution Plate(s) – Water Cascade only – Inlet pipe to manifold location : ' Top/center of retort shell ' Top/rear of retort shell

Dimensions of manifold ____________________________ Material of Construction __________________________________

Number of holes _____________ Size of holes ___________ Location (hole pattern) ____

Percent open area __________________________________

Water distribution pipes (Water Spray only) – Location of water inlet pipe to retort shell ____

Location of water distribution pipes in relation to circumference of interior of retort ____

Water spray/cascade retorts, continued
Length of pipes (do they extend length of shell) ____

Number of holes ______________ Size of holes ___________________ Location of holes _______________________________

Nozzles – Type (if applicable) _____________________________ ' Fixed ' Oscillatory ' Other (describe) ___________________________

Restrict hole opening ' Yes ' No If yes, how much ____

STEAM/AIR RETORTS –

Air plenum and fan shroud – Distance (length) from retort shell to plenum if designed as a "shell in shell" _____________

If not designed as "shell in shell", describe: ____

Fan shroud details (describe) _______________________________

APPENDIX C – Temperature Distribution Data Collection/Monitoring Points

The following table is a compilation of suggested data collection/monitoring points when collecting temperature distribution data in different types of retorts.

Data Collection/Monitoring Points	Retort Type				
	ST	**SA**	**WS**	**WC**	**WI**
Temperature and Pressure Controller set point(s), including if there is an overshoot set point for come-up and a lower set point for processing	(	(	(	(	(
Product or Ballast Initial Temperature.	(	(	(	(	(
Time process cycle starts, Time 0.	(	(	(	(	(
Time when the end of come-up, start of thermal processing/cook step has been achieved, as indicated by either the step change in a control program or the achievement of process set-point temperature at both the reference TID and the recorder/controller.	(	(	(	(	(
Reference TID readings at sufficient intervals during the entire cycle, including the point in time it reaches the process temperature set point.	(	(	(	(	(
Monitor rotation or agitation rate at sufficient intervals using an accurate calibrated stopwatch or calibrated device including any points where rotation rate changes during processing or on a continuous chart where rotation or agitation is used.	(	(	(	(	(
Time at the end of thermal process and start of cool.	(	(	(	(	(
Actual basket/crate/rack orientation in the retort.	(	(	(	(	(
Operating activity of other retorts including the number of retorts entering come-up during the study.	(	(	(	(	(
Numbers and descriptions of other equipment using steam (e.g., blanchers) at the time of the study and before, during, and after come-up.	(	(	(	(	(
Temperature of air supply entering the retort.		(			
Water level in relation to spreaders and lowest level of containers in the retort.	(	(	(		
Time when the pressure set-point(s) is achieved.		(	(	(	(
Time and temperature when the drain is closed, if it is open during a portion of the vent.	(	(			
Time and temperature, if or when the vent closes, taken from the reference TID.	(	(			
Air flow in scfm or liters per minute, if applicable and available.		(			(
Line steam pressure at the time of the test and before, during, and after come-up, if possible.	(	(			
Retort pressure, throughout the test cycle at sufficient intervals or on continuous chart.		(	(	(	(
Time steam bypass valve closes.	(				
Temperature of initial process water.			(	(	(
Flow or recirculation rate of water as determined by flow meter or other acceptable means.			(	(	(
Fill time (displacement) in those systems dropping water from a storage drum or tank into the working processing vessel.					(
Water level in process vessel in relation to the top surface of containers, stated as a minimum or an actual level throughout the process.					(
Line air pressure at the time of the test and before, during, and after come-up, if possible.					(

ST – Saturated Steam **SA** – Steam/Air **WS** – Water Spray **WC** – Water Cascade

WI – Water Immersion

APPENDIX D – Heat Penetration Documentation Checklist

The following table is an example of a checklist that may be used for Heat Penetration Studies. This example may be modified as needed.

Pre-Test Documentation

Item/Parameter	Data	Done By
Product characteristics		
Product name, form, style, packing medium		
Net weight and volume		
Consistency or viscosity of the liquid component		
Size, shape, and weight of solid components		
Size of solid component clusters		
pH of solid and liquid components		
Methods of preparation prior to filling (e.g., ingredient mixing methods, special equipment, etc.)		
Matting tendency		
Rehydration of components		
Acidification procedures		
Other characteristics (e.g., % solids, density, etc.)		

Container Description

Container material (brand name and manufacturer)		
Type, Size, and Inside dimensions		
Container test identification code		
Maximum thickness (flexible container)		
Gross weight of container		
Container nesting characteristics		
Slowest heating or cold spot location in container		

Data Acquisition Equipment and Methodology		
Identification of data logging system		
TMD type and where applicable, connector plug maintenance		
Type, length, manufacturer and identification code of TMDs and connectors		
Electrical ground checked (using thermocouples)		
Calibration of TMDs placed in heating medium		
TMD location in container		
Positioning technique for TMDs		
Fill Method		
Fill temperature of product		
Fill weight of product		
Headspace		
Filling method (comparison to commercial process)		
Sealing operations		
Type of sealing equipment		
Time, temperature, pressure, and vacuum setting (if applicable)		
Gas evacuation method		
Can vacuum		
Volume of residual gases (i.e., flexible container)		

Retort System		
Retort system – still or rotary, type of agitation (end-over-end, axial, oscillatory, none)		
Retort identification number		
Reel diameter (number of container positions) and rotational speed		
Heating medium (steam, steam/air, water immersion, water spray/cascade, hydrostatic) and flow rate		
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Heat transfer distribution records (if applicable)		
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Package study position for batch retorts		
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Loading or racking system details		
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Location of TMDs for retort temperature		
Use of ballast containers to ensure fully loaded retort (applicable for some retort systems)		
Selected time interval for data logging system		
Location of test containers in retort		

Additional Information		
Date		
Test identification		
Processor and location		
Individuals performing test		
Test Phase Documentation		
Test run identification		
Initial temperature of product at the start of heating		
Rotation speed (if applicable)		
Time heating starts		
Time vent closed and temperature, if applicable		
Time retort reaches set point temperature (t_c)		
Temperature indicated on reference TID when cook starts		
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Time process begins		
Cooling water temperature		
Time cooling begins (pressure cooling, if applicable)		
Time cooling ends		
Any process irregularities or inconsistencies		

Post-Test Documentation		
Container location and orientation		
Container net and gross weight check for leakage		
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Measurement of container vacuum or residual air content (if applicable)		
Location of the TMD and whether or not it is impaled in a food particle (if applicable)		
Post-processing product characteristics (e.g., syrup strength, appearance, viscosity, etc.)		

GUIDE[1] TO INSPECTIONS OF LOW ACID CANNED FOOD MANUFACTURERS Part 3-Containers/Closures

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INTRODUCTION

The Guide to Inspection of Low-Acid Canned Foods consists of three separate documents; Part 1 covers Administrative Procedures\Scheduled Processes; Part 2 covers Manufacturing Procedures/Processes and Part 3 covers Container/Closures. In addition to providing guidance for inspections of low acid canned foods (LACF) manufacturers, the guide(s) also contains background and general information on LACF regulations and procedures.

In addition to the information and instructions provided in IOM Subchapter 530, 21CFR 108 and 113, and applicable compliance programs, direct attention to areas covered in this Guide when covering LACF manufacturers. Another good reference is the Food Processors Institute 'Canned Foods' manual, which should be available from anyone in your district who has attended a Better Process Control School.

At the current time DEIO has available, for loan only, the following NFPA manuals:

1. Thermal Processes For Low-Acid Foods in Metal Containers (NFPA Bulletin 26-L, 13th Edition)
2. Thermal Processes For Low-Acid Foods in Glass Containers (Bulletin 30-L)
3. Flexible Package Integrity Bulletin (Bulletin 41-L)
4. Guidelines for Thermal Process Development for Foods Packaged in Flexible Containers
5. Continuous Rotary Sterilizers-Design and Operation (Bulletin 44-L)

[1] Note: This document is reference material for investigators and other FDA personnel. The document does not bind FDA and does not confer any rights, privileges, benefits or immunities for or on any person(s).

6. Automatic Control Guidelines For Aseptic System Manufacturers and Companies Using Aseptic Processing and Packaging for Preserving Foods (Bulletin 43L)

DEIO also has a supply of Institute for Thermal Processing Specialists (IFTPS), 'Protocol for Carrying Out Heat Penetration Studies'.

The AOAC Chart "Classification of Visible Can Defects (Exterior)" is helpful when performing field exams. Districts should have this chart available (usually the labs have them).

The sampling schedule for canned and acidified foods is in the Investigations Operations Manual and the Guide to Inspections of Low Acid Canned Food Manufacturers , Part 2

CODING OF CONTAINERS

See Guide to Inspections of Low Acid Canned Food Manufacturers Part 2, pg. 46.

EMPTY CONTAINER HANDLING:

Empty containers for low acid canned food processing are typically received in bulk quantities, packaged to avoid container damage in transit, by the food manufacturer. For example, metal cans are typically received on pallets with a cardboard divider between each can layer or nested in paper sleeves on pallets; glass jars are received in boxes with separate compartments for each jar; plastic bowls and cups are received nested in cardboard boxes; and empty pouches are received securely packed in cardboard boxes.

It is important that empty containers are handled during receipt and processing in a manner that precludes container damage. For example, if the flange of a metal can is damaged during shipment, receipt, or filling, it can result in a can seam defect. Therefore, it is important that the LACF manufacturer has a program for inspecting incoming containers for defects prior to the filling operation. This inspection program should include a visual examination and when appropriate, a tear down examination for defects that could affect product and/or package integrity. Incoming container inspection programs range from a small manufacturer checking every container before filling, to large manufacturers that may follow a statistically valid sampling plan (e.g., mil-standard 105E) to inspect their incoming containers for defects.

During the inspection determine if the firm has a program and/or procedure for handling and inspecting incoming containers and if the program is followed. Also, inspect empty containers prior to filling for damage that may result in container defects. Any damage should be noted, and follow-up visual examination of finished containers should be performed to determine if the damage caused defects in the containers. Evidence of container damage causing defects in the finished containers should be reported on the FDA-483 if no corrective actions had been taken by the firm on the affected lots. (Reference individual container type sections of this guide for definitions and discussion of container defects.)

Empty containers (except pouches) should be inverted and cleaned prior to fill. Typically containers are cleaned using vacuum, air, or a water spray to remove possible foreign material prior to filling.

CONTAINER CLOSING:

After filling the container, a can cover (end or lid) is placed onto the container and seamed. The closing operation is what produces a hermetic seal; i.e., a seal designed to be secure against the entry of microorganisms. For cans, to secure the hermetic seal an appropriate sealing compound is applied to the inside of metal can ends at the curl; and for glass jars the sealing compound is applied to the metal closures during container lid manufacturing. It is very important that the seam is adequate to prevent entry of microorganisms. A brief description of the different container types and closing operations for these container types is as follows:

METAL CANS

Container Structure:

The container structures that help form and become a part of the finished double seam are the body flange and the end curl (refer to Attachment 1). Attachment 1 also illustrates and defines double seam terminology:

Flange: The flange is the edge of the body cylinder that is flared outward resulting in a rim or ledge. The flange is formed into the body hook during double seaming and becomes interlocked with the cover hook. The width and radius of the flange are determined by the container manufacturer and are designed to form a proper body hook when using the container manufacturer's specifications for the double seaming operations.

End Curl: The end curl is the extreme edge of the can end (cover) that is turned inward after the end is formed. It is the structure used to form the cover hook and is designed to provide sufficient metal and proper contour for a good cover hook, and easy feeding of end units into the closing machine.

Double Seam Structure:

The double seam structure is judged by measurement and evaluation of specific components comprising the seam. These measurements are based on guidelines provided by the container manufacturer to the low-acid canned food manufacturer to assist in maintaining acceptable seams during production. The final evaluation of the double seam can only be made by a visual inspection of the torn down seam in conjunction with the measurements. The seam measurements that can be performed to evaluate the double seam are as follows (refer to Attachment 2):

Countersink: The countersink is the distance measured from the top of the double seam to the end panel adjacent to the inside wall of the double seam.

Seam thickness: Seam thickness is the maximum dimension measured across or perpendicular to the layers of material in the seam. This measurement is one, but not the only indication of the tightness of the double seam.

Seam width (length or height): Seam width (also referred to as seam length or seam height) is the dimension measured from the top to the bottom of the double seam (parallel to the hooks of the seam).

Body and cover hook: These are internal measurements. As previously referenced the body hook is formed from the body flange, and the cover hook is formed from the end curl during the double seaming operation. These structures, observed in a cross section, have an interlocking relationship to each other.

Overlap: The degree or length of interlock between the body hook and cover hook is known as overlap.

Tightness: Seam tightness is judged by the degree of wrinkling at the end of the cover hook. During double seam formation, the cover curl is guided around and up under the body flange. This crowds the cut edge of the curl into a smaller circumference, resulting in a wavy cut edge with accompanying wrinkles around the seam. The second operation in the formation of the double seam presses the body and cover hooks together to such a degree that the wrinkles should be ironed out sufficiently to ensure a hermetic seal.

In a completed double seam, any remaining wrinkles help to indicate double seam tightness. Tightness rating is a numerical designation which indicates the relative freedom from wrinkles or % smoothness of the cover hook. Refer to Attachment 3.

After the coverhook is removed, the can body should be examined for body wall impression or what is commonly referred to as pressure ridge. This impression is caused by the seaming roll pressure during the seaming operation. Visual inspection of the pressure ridge provides additional assurance of the tightness of the can seal. The body wall impression or pressure ridge should be visible and complete around the inside periphery of the can body where the coverhook was removed. Refer to Attachment 4.

Double Seam Formation:

The seal for the metal can is made in two operations, hence the term "double seam". The can seamer (or closing machine) has four basic parts that are directly involved in forming the double seam. These parts are:

1. Seaming Chuck: A flat round plate which fits inside the can cover and supports the can against the seaming rolls.
2. Can Lifter or Base Plate: a round plate which lifts the can and can end to the seaming chuck and applies upward pressure during the seaming cycle.
3. First Operation Seaming Roll: A roller adjacent to the seaming chuck that has a deep, narrow groove (forming tool).
4. Second Operation Seaming Roll: A roller adjacent to the seaming chuck with a wide and shallow groove (tightening, flattening tool).

These four basic parts of the can seamer are adjustable, and precise adjustment is critical in obtaining a well formed double seam.

The double seaming operation is a form of metal spinning. The sequence of steps in the two-seaming-roll operation is as follows:

1. Either the can is placed on the can lifter (base plate) and the cover is automatically placed on the can; the can cover is placed on the can as it moves onto the can lifter; or if the cover is placed

on the can during the clinching operation, the can with the cover is placed on the can lifter.

2. The base plate raises the can and cover onto the seaming chuck tightly clamping the cover onto the can.

3. The first operation seaming roll(s) is brought into contact with the can and cover, and the metal spinning groove forms the first operation seam. The first operation seam can be defined as curling the cover (end) hook around the inside of the body hook to form a loose interlock of the can end and can body.

4. The second operation seaming roll(s) is brought into contact with the can and cover, and the metal spinning groove forms the second operation seam. The second operation seaming roll flattens the seam and seals the can.

Attachment 5 illustrates the sequence of operation in seaming a can end onto a can body. Attachment 1 illustrates a completed double seam and details double seam terminology.

Can double seamers are generally of two types:

The can spin type: The seaming rolls are stationary and the can spins as it is held between the base plate and the seaming chuck. In this type of seamer the base plate and chuck both spin at a high rate of speed while the stationary rolls swing in to make contact with the can and cover and then swing back out after the seaming operations are complete.

The can stationary type: The can, base plate and chuck are all stationary and one or two first and second operation seaming rolls roll around the stationary can forming the double seam.

With either type of double seamer, a can may be placed by hand onto the base plate, or fed mechanically onto the base plate in the seamer.

First Operation Seaming

The first roll seaming operation is the most critical part in the formation of a good seam. The second roll seaming operation simply flattens the closure fold made during the first roll seaming operation; so deficiencies in the first seaming roll operation cannot be corrected during the second roll seaming operation.

The first operation roll has a narrow and deep groove profile. The body hook and cover hook are determined by the first operation roll and the base plate pressure. Upward pressure on the base plate should be sufficient to force the cover right onto the chuck and hold the can firmly in contact. The first operation seaming roll then engages the cover and curls the cover curl (which becomes the cover hook) into the flange of the body which then becomes the body hook in the finished seam. In a good or normal first operation roll, the cover hook is rounded at the bottom and is in contact with the body of the can. The ends of the cover hook and body hook are essentially parallel. There should be no curvature in the extremities of the cover and body hooks. Refer to Attachment 11.

Second Operation Seaming:

The second operation roll has a shallow and flat profile in comparison to the narrow and deep groove profile of the first operation roll. The second operation roll flattens the fold resulting from the first operation and presses the folds together tightly enough to compress and force the sealing to flow into the seam voids. Refer to Attachment 6.

Seam Guidelines (Specifications)::

Can seam guidelines (specifications) are provided to the low acid canned food manufacturer by the supplier of the container and end being used. The guidelines detail the measurements, in thousands of an inch, of each attribute of the double seam for both the first and second seaming operations. They also provide a set-up aim or ideal starting dimensions for the set up of the seamer. The operating limits set the range for good practice. Attachment 7 provides an example of a seam guideline.

It is extremely important to understand that seam guidelines by themselves cannot be used for determining the quality of a double seam. The seam guidelines are to be used in setting up the double seams initially and maintaining seam integrity during production. Final acceptability of the double seam should be based on total evaluation of the seam by a qualified person and not on dimensions alone. Good seaming practice requires constant visual examination, frequently scheduled tear-down evaluation, machine maintenance, and immediate correction of unacceptable conditions.

Since seam guidelines will vary depending on the source of the container (i.e., Crown Cork & Seal, Ball, Siligan, etc.), the guidelines should always be provided by the container manufacturer. If the LACF manufacturer cannot provide a copy of the appropriate seam guidelines, they have nothing on which to evaluate the double seam. This can be listed as an objectionable condition on the FDA-483.

Seamer Maintenance and Adjustment :

It is important that the LACF manufacturer has in place a preventative maintenance program for the seamer. Under normal use conditions, the seaming rolls, bearings, base plate, chuck etc. can become worn resulting in the possibility of defective double seams. Seaming rolls are evaluated and changed routinely because they wear during production, thus altering the groove profiles. For example, a badly worn first operation roll can result in a loose first operation seam and when a normal second operation roll pressure is applied, can cause droops (see Attachment # 8) in the finished double seam.

<u>Adjustment of Closing Machine to Correct Out-Of-Guideline Measurements and/or Defective Seams</u>:

Whenever the set-up aim or operating limit checks indicate that seams are not meeting the guidelines or when an obvious seam defect is found on visual inspection, the manufacturer must know what steps to take to correct the condition. The FDA investigator must also be aware of seaming conditions that could result in container defects in order to evaluate whether the firm took the appropriate corrective action. Evaluation of the firm's actions are made through review of their container records. Container records will be discussed later in this section.

If an obvious and recurring can seam defect is found on visual inspection and in a second sample, it usually signifies that some mechanical fault has developed and the production line should be stopped in order to take corrective action. Product from previous production that may have been affected should also be isolated.

The most critical attributes to consider in judging the quality of the double seam are overlap and tightness (wrinkle). If one of the can seam measurements (i.e. body hook) is slightly beyond the specified guidelines but the rest of the seam is evaluated and the overlap and tightness (wrinkle) are within specified guidelines, then adjustments to the seamer can be made at the next scheduled shut-down. In this instance, the manufacturer should identify the out-of-guideline measurement and document they have evaluated the rest of the double seam, but did not find immediate corrective action necessary. However, if overlap measurement or tightness rating evaluation are below the minimum guidelines a resample from the questionable seaming station should be made. If the resample continues to show out-of-guideline measurements in overlap and/or wrinkle the machine should be stopped and adjusted.

A LACF manufacturer should have experienced, competent personnel to adjust the seamer and evaluate double seams.

Container Defects - Metal Cans:

Container defects are seam abnormalities that are generally serious and may result in the loss of the hermetic seal. Following is a description of some of the more common container defects:

<u>Droop (Refer to Attachment 8)</u>: A droop is a smooth projection of a double seam below the bottom of a normal seam. The droop may occur at any point of the double seam. If the container has a side seam it is common to have a slight droop where the double seam crosses over the lap of the side seam. This area of cross over is referred to as the "juncture". A slight droop at the juncture may be considered normal, however, if the droop is excessive the overlap may be too short or non-existent. Some possible causes of droops are listed in Attachment 8.

<u>Vee or Lip (Refer to Attachment 8):</u> "Vees" or "lips" are projections of the double seam below the bottom of a normal seam that resemble a "V" shape. There is usually no overlap of the cover hook with the body hook and these defects usually occur in small areas of the seam. The probable causes for "vees" or "lips" is the same as for "droop".

<u>Sharp seam (Refer to Attachment 9)</u>: A "sharp seam" refers to a sharp edge at the top inside portion of the seam. Usually a sharp seam is noticeable at the side seam juncture in a three piece container, however, a sharp seam can be felt at any point along the inside top of the seam. The sharp seam is caused by a portion of the end (cover) being forced over the top of the seaming chuck during double seaming. A sharp seam can usually be felt more easily than seen. A sharp seam can be the first indication of a more serious defect known as a cut-over.

<u>Cut-over (Refer to Attachment 9)</u>: A "cut-over" is a seam defect where the top of the inside portion of the seam has become sharp enough to fracture the metal. As in the definition of "sharp seam", this condition usually occurs at the side seam juncture of a three piece container. Some

possible causes of both sharp seams and cut-overs are listed on Attachment 9.

Jumped seam or Jump over (Refer to Attachment 10): A jumped seam or jump-over is a portion of the double seam which is not rolled tight enough. This defect occurs adjacent to the side seam or juncture area in a three piece container and is caused by the seaming rolls jumping at the juncture. Wrinkles will be left in the coverhook at the point where the rolls jumped. During examination of the seams the area immediately adjacent to either side of the juncture should be carefully inspected for excessive wrinkle. Possible causes of a jumped seam are listed on Attachment 10.

Deadhead or spinner (Refer to Attachment 11): A deadhead or spinner (also referred to as slips or skids) is an incomplete seam caused by the chuck spinning in the countersink during the seaming operation. Some causes of deadheads are listed on Attachment 11.

Mis-assembly: A "mis-assembly" is the result of the can body and the can end having been improperly aligned in the closing machine. Therefore, the seam is completely disconnected partway around the can. The most common cause of a mis-assembly is incorrect closing machine timing or settings.

False seam (Refer to Attachment 12): A "false seam" is a seam or portion of the seam which is completely unhooked, and in which the folded cover hook is compressed against the folded body hook. A false seam is not always detectable in an external examination. Some causes of false seams are listed on Attachment 12.

There are other terms that more specifically describe a false seam condition. They are:

Knocked down flange: which is usually caused by a bent can flange before double seaming.

Damaged end curl: is a defect resulting when the end curl is flattened in one or more spots, causing the curl to fold back on itself. This is usually caused by handling damage to ends or improper cover feed.

Can body buckling: The can body directly under the double seam is buckled or twisted.
Possible causes are:

1. Excessive baseplate pressure
2. Improper pin-gauge height (distance between base plate and chuck)

Cocked body (Refer to Attachment 12): A "cocked body" is a can manufacturing defect. It occurs when the can body blank is manufactured out of square causing an unevenness at the lap or juncture in three piece cans.

Cut seam (Refer to Attachment 13): A "cut seam" is a fractured double seam where the outer layer (cover hook) of the double seam is fractured. Possible causes are listed on attachment 13.

Fractured embossed codes: "Fractured embossed codes" are fractures through the metal end of the can at the code mark. Possible causes for the fractured metal are:

1. Mis-alignment of male and female coding dies.
2. Intermixing of new and old type code characters.
3. Improper matching of male and female type code characters.
4. Too deep a code mark.

Broken chuck: A "broken chuck" defect occurs when a portion of the seaming chuck lip has broken and results in an excessively loose seam at the broken part due to a lack of backup support for the seaming roll. Possible causes are:

1. Severe jam in the closing machine.
2. Seaming rolls binding on chuck.
3. Metal fatigue in chuck lip.
4. Prying against the seaming chuck to clear a jam.

FDA, in cooperation with the Association of Official Analytical Chemists, published a brochure titled "Classification of Visible Can Defects". The brochure defines metal can defects in three categories. They are:

1. Critical: Defects which provide evidence that the container has lost its hermetic seal (e.g., holes, fracture, puncture etc.)
2. Major: Defects that result in cans which do not show visible signs of having lost their hermetic seal, but are of such magnitude that they may have lost their hermetic seal.
3. Minor: Defects which have had no adverse effect on the hermetic seal.

The brochure also provides a pictorial of can seam defects and rates the defects as critical, major and minor. If you cannot locate a copy of this brochure in your district, contact your servicing lab.

Double Seam Evaluation Requirements:

Visual Seam Examination (Non-Destructive Test):

21 CFR Part 113.60(a) requires a visual examination of at least 1 can per seaming head by

a qualified container closure inspector at intervals of sufficient frequency. The regulation requires that double seamed containers be visually inspected for gross closure defects such as sharp seams, cut-overs, deadheads, false seams, droops and broken chuck. The frequency of the visual examination should be made at intervals not to exceed 30 minutes (of operational time); and additional visual examinations must be performed immediately following a jam in a closing machine, after closing machine adjustment, or after startup of a machine following a prolonged shut-down. An example of a prolonged shut down may be when the plant ceases production at 6:00 PM and restarts production at 8:00 AM the next day.

Double Seam Teardown Examination Requirements (Destructive Test):

The double seam teardown examination is a destructive test. Tools that are used to perform this test include a seam micrometer, countersink gauge, can opener and nippers. Optional equipment for seam teardown examinations include a seam saw, seam projector and seam scope. Although it is not imperative the investigator carry this equipment to each LACF inspection, it is very important that they know how to operate this equipment and read measurements from the micrometer, seam projector or seam scope. It is also important that the investigator know how to determine the tightness or wrinkle rating of the cover hook. Knowledge of the procedures used to perform double seam teardown examination are essential to evaluating the firm's knowledge and ability to do this examination. Attachment 14 explains the procedure for using a seam projector for examining a cross section of the seam. Attachment 15 explains the can seam micrometer and procedure for use, and Attachment 16 explains the use of a seamscope for the same exam.

The requirements for double seam examinations are specified in 21 CFR Part 113.60(a)(1). The regulation states that teardown examinations shall be performed by a trained closure technician at intervals of sufficient frequency to ensure proper closure. The teardown examinations shall be made on the packer's end double seams on at least 1 can from each seaming head to ensure maintenance of seam integrity. Sufficient frequency is defined in the regulation as intervals not to exceed 4 hours (operational time).

The regulation allows for 2 different methods of double seam examination; the "micrometer" method or the "optical" method.

If the processor is using the micrometer method the regulation requires that 3 measurements are taken at points approximately 120^0 apart around the double seam. On 3 piece cans the first measurement can be taken directly across from the side seam and the next two measurements are then taken 120^0 to either side of the first measurement. On 3 piece cans the measurements must be taken at least one-half inch from the side seam juncture as the juncture may interfere with a true seam measurement.

Micrometer measurements are made and recorded in thousandths of an inch. The high and low measurements are recorded on the double seam teardown examination record. If the manufacturer is using the micrometer method the required

measurements are:

Cover hook length
Body hook length
Width (also referred to as length or height)
Tightness (by observation for wrinkle)
Thickness

Optional measurements are:

Overlap (by calculation)
Countersink

The regulation specifies the formula used to calculate overlap when micrometer measurements are used:

CH + BH + T (.010in)* - W, where
CH = cover hook
BH = body hook
T = cover thickness *(general practice use .010 inches for tin plate thickness)
W = width

Measurements used to calculate the overlap should not be averaged. In fact, the lowest values should be used to determine the worst case scenario. For example, to calculate the worst case scenario you should use the lowest measurements for CH and BH and the highest measurements for W.

If a seam scope or seam projector is used (optical method) to make the seam measurements, the required measurements are:

Body hook length
Overlap

Tightness (observation for wrinkle)
Thickness (determined by micrometer measurement if the optical instrument cannot read this value)

Optional measurements are:
Width (also referred to as length or height)
Cover hook
countersink

Visual Seam and Double Seam Teardown Examination Record Requirements:

The regulations require that the results of visual seam and double seam teardown examinations along with any corrective action taken shall be recorded. 21CFR Part 113.100(c) details

the minimum requirements for visual and double seam examination records as follows: "Written records of all container closure examinations shall specify the product code, the date and time of container closure inspection, the measurements obtained, and all corrective actions taken." Records must be signed or initialed by the container closure inspector and reviewed by management with sufficient frequency to ensure that the containers are hermetically sealed.

Sufficient frequency can be defined as, at least prior to shipment of the product. However, FDA investigators should encourage LACF processors to review the container records at the same time as the thermal processing records; or not later than 1 working day after the process, and prior to shipment of the product.

Attachment 17 and 18 respectively, are examples of a visual examination record and double seam teardown examination records.

When reviewing visual and double seam examination records it is important the investigator knows how to interpret the information provided on the records. For example, if a visual or teardown examination found a defective container or measurements outside of guidelines, the processor should have taken a repeat sample from the questionable seaming station to evaluate before any machine adjustments are attempted. If the repeat sample shows the same defect or out of guideline measurement then the processor will have to determine whether the nature of the defect is of sufficient magnitude to warrant immediate shut down of the production line to make adjustments, or to continue processing until the next scheduled break in the production period.

Some examples under which processing could continue with little risk to the product are:
1 . If visual inspection indicates a slight sharpness, especially in the junction area.
2. If the container guidelines require body hook measurements in the range of .072" - .088" and 1 measurement was taken and recorded as .071 for a low and .076 for a high. All other measurements are within guidelines including overlap, wrinkle, and pressure ridge.
3. When the thickness guidelines require a range of .046" to .052" and measurements show thickness up to .053", but the cover hook displays a 100% wrinkle (tightness) rating. Refer to Attachment 3.

Some examples under which processing should be shut down and corrective action taken are:
1. During visual seam examination a cut-over is found around the periphery of the inside of the seam.
2. During visual seam examination and on a repeat sample, vees or lips are found protruding below the bottom of the double seam.
3. Evidence of skidding or deadheading.
4. During both initial and repeat teardown examination on one seaming head, calculated overlap is below the minimum guideline requirement.

Good seam formation cannot be judged solely by mechanical means or measurements. The evaluation of good double seams requires experience and skill. This is why it's important for a firm to have experienced and well trained can seam mechanics. If observations indicate the individual(s) performing can seam examinations lack adequate training or skills this should be discussed with plant management.

Post Process Container Handling

See Guide to Inspections of Low Acid Canned Food Manufacturers, Part 2, pg. 44.

Glass Jars:

Container Structure:

Glass container:

There are 3 basic parts to a glass container (Refer to Attachment 19):

1 . Finish: The finish is the very top part of the jar

that contains threads or lugs that contact and hold the cap or closure. Specific areas identified in the "finish" are sealing surface, glass lug, continuous thread, transfer bead, vertical neck ring seam and the neck ring parting line.

2. Body: The body of the container is that portion which is made in the "body mold". It is the largest part of the container and lies between the finish and the bottom. The characteristic parts of the "body" are the shoulder, heel, side wall, and mold seam.

3. Bottom: The bottom of the container is made in the "bottom plate" part of the glass-container mold. The designated parts of the bottom area are normally the bottom plate parting line and the bearing surface.

Metal closure:

Among the terms commonly used for describing parts of metal vacuum closures are the following (Refer to Attachment 19):

Face: The outside of the cap

Reverse: The inside of the cap

Panel: The flat center area in the top of the cap.

Radius/Shoulder: The rounded area at the outer edge of the panel connecting the panel and skirt.

Skirt: The flat side of the cap. The skirt may be smooth, knurled, or fluted and serves as the gripping surface.

Curl: The rounded portion at the bottom of the skirt that adds rigidity to the cap and serves to protect the cut edge of the metal.

Lug: A horizontal inward protrusion from the curl that seat under the thread or lug on the finish of the glass container and holds the cap in position.

Coatings: Coatings and inks used on the inner and outer surfaces of the cap to protect the metal from attack, adhere gasket materials, and decorate the closure.

Gasket: The actual sealing member of the cap which must make intimate contact with the glass finish at the proper point to form an effective seal. Gaskets are made of either rubber or plastisols.

Safety Button or Flip Panel: A raised, circular area in the center of the panel which is used only for vacuum packed products and serves two principle purposes which are detection of low or no vacuum packages and an indicator to the consumer of a properly sealed package.

Vacuum Formation:

Almost all low-acid foods packaged in glass containers are sealed with vacuum-type closures. The vacuum within the package and the overpressure in the retort on the outside of the cap play an important role in forming and maintaining a good seal. There are two basic types of cappers which apply caps while forming a vacuum in the container:

1. Mechanical Vacuum Capper: applies the cap to the jar in an evacuated chamber (usually used on dry products and rarely on low-acid processed foods).

2. Steam Flow Capper: the container is subjected to a controlled steam flow that displaces the headspace gases from the jar by a flushing action. The steam is trapped in the headspace as the cap is applied, then condenses to form a vacuum which helps hold the closure in place.

There are four primary factors that affect vacuum formation (however, 1-3 are considered critical factors only if designated critical by the process authority):

1. Headspace: There must be sufficient void or headspace at the top of the container to allow adequate steam to be trapped in the container for forming a vacuum, and to accommodate product expansion during retorting. The correct amount of headspace varies with products, processes, and package design, but a rule-of-thumb in the industry is that it should be not less than 6% of the container volume. Inadequate headspace can result in displacement or deformation of the closure during retorting.

2. Product fill/sealing temperature: Product filling temperature affects the final vacuum in the container (due to product contraction upon cooling). The higher the product temperature at the time of sealing, the higher the final package vacuum. Higher filling temperatures also result in less air being entrapped in the product.

3. Residual air in the product: Air can have a direct effect on the final package vacuum and should be kept at a minimum for good sealing. The more air that is trapped in the product, the lower the vacuum. Expansion of residual air in the container during processing can exert pressure against the closure and adversely affect seal integrity. Air in the container can also impede heat penetration into

the container during retorting.

4. Capper vacuum efficiency: Capper vacuum efficiency refers to the ability of a steam flow capper to produce a vacuum in sealed glass containers. The most convenient, routine check on the vacuum efficiency of a steam-flow capper is the "cold-water vacuum check." This measurement is required by 21CFR 113.60(a)(2), and must be performed before actual filling operations, and results must be recorded.

The method of cold-water vacuum check requires a series of jars to be filled with cold tap water to the approximate headspace that will be maintained with the product to be run. A series means 4 to 6 containers for a straight-line capper, and 1 container for each capping head on a rotary capper. The capper is allowed to warm up to operating temperature and normal steam setting and these jars are then sealed in the capper. The jars are then opened and re-run through the capper and then checked for vacuum. By running the jars through the capper the first time the water is de-aerated, and thus a truer vacuum reading is obtained after the second run. Vacuum is measured using a standard vacuum gage. The range of vacuum is recommended by the container manufacturer, but typically should be 22 inches or more.

Vacuum Closures:

Currently, two primary types of vacuum closures are used on low-acid food products (refer to Attachment 20):

1. Lug type closure: This closure is the predominate vacuum-cap type. It is a convenient closure because it can be removed without a tool and forms a good reseal for storage.

Structurally, the lug cap consists of a steel shell and can have four, six, or eight metal lugs depending on its diameter. Normally it contains a flowed-in plastisol gasket.

During closure application the headspace is swept by steam and lug caps are secured to the glass finish by turning or twisting the cap onto the finish to seat the lugs of the cap under the threads on the glass finish.

With this lug type of closure the top of the glass finish makes contact with the gasket on the inside of the lid. In most instances the lids are heated with steam to soften the compound and facilitate sealing. Both the lugs and vacuum hold the cap in place on the glass finish, but vacuum is the most important.

2. Press on-Twist off (PT) closures: This closure is in widespread use on baby foods as well as other products. Structurally, the PT cap consists of a steel shell with no lugs. The gasket is molded plastisol on the inside vertical wall and covers a sealing area extending from the outer edge of the top panel to the curl of the cap. These closures typically have a safety button or flip panel.

The cap is first heated to soften the plastisol. It is then pushed directly down on the glass finish after air is swept from the headspace with steam. The glass threads form impressions in the skirt of the cap gasket and allow the cap to be cammed-off and on. The PT closure is held in place on the finish primarily by vacuum, with some assistance from the thread impressions in the gasket wall when the cap is cooled.

3. Plastisol-Lined Continuous Thread (PLCT) Cap: The PLCT cap consists of a metal shell with a threaded skirt curled at the end. It contains a flowed-in plastisol gasket on the inside that makes intimate contact with the top of the finish when the cap is screwed onto the jar finish. The PLCT cap may be used in both steam and non-steam applications. Security measurements on this type of container closure can be performed. However, pull-up cannot be determined.

Closure Evaluation Requirements:

Generally closure application inspections are performed either visually (non-destructive), or by cap removal (destructive). It is important to know the tests and observations on the different types of closures as well as the defects that can occur (refer to Attachment 21).

Visual Examinations (Non-Destructive):

As with metal cans, requirements for visual examination of closures for glass containers include regular observations for gross closure defects of at least one container from each capper head by a qualified container closure inspection person.

Required frequency of the visual examination is as often as necessary to ensure proper closure and should not exceed 30 minutes of operational time. Additional visual examination must be performed immediately following a container jam, machine adjustments or a prolonged shut down. An example of a prolonged shutdown may be when the plant ceases production at 6:00 PM and restarts production at 8:00 AM the next day.

Gross closure defects for glass jars include:

Loose or cocked caps: "Cocked cap" is a condition of the lug-type cap and is caused by a lug failing to seat under the glass thread. It is apparent during a visual examination as it usually results in an unlevel or tilted cap.

Cap tilt: On PT and lug caps, the cap should be approximately level, not cocked or tilted, and seated well down on the finish. This is judged in relation to the transfer bead located at the bottom of the container finish . The distance between the bottom of the closure and the transfer bead should not exceed 3/32"

Crushed lug: A crushed lug on a lug-type cap may or may not be visible during a visual examination as it does not necessarily result in a tilted cap. It is caused by a lug being forced down over the glass thread during the closure process. The lugs appear bent inward.

Stripped cap: On a lug-type cap, a stripped cap refers to a lug cap that has been over-applied to the extent that the lugs have been stripped through the glass threads on the finish. On visual examination the lugs appear scrapped or scratched.

Low vacuum by visual examination

Physical Examination (Destructive):

The regulation requires that physical or destructive testing be performed by a trained closure technician at intervals of sufficient frequency to ensure proper closure. Sufficient frequency is defined as intervals not to exceed 4 hours of continuous closing machine operation. 21 CFR Part 113.60(a)(2) also requires that for glass containers with vacuum closures, capper efficiency be checked by measurement of the cold water vacuum (See Vacuum Formation section). The regulation requires that the cold water vacuum check be performed before actual filling operations, and the results recorded.

Physical examinations can include:

Vacuum: Generally there will be vacuum in the package when it comes out of the capper and the panel of the cap will be concave. For a PT cap, there must be at least 3" vacuum after capping to avoid loose caps. Determining vacuum is a destructive test and a standard vacuum gauge is used.

Temperature: The temperature of the product should be within the normal range for the product being run or as specified by the process authority. The product temperature should be recorded in conjunction with the vacuum.

Headspace: Generally, headspace should not be less than 6% of the container volume at the sealing temperature.

Gasket: After the cap is removed there should be a visible, continuous, and even impression in the plastisol gasket on the underside of the lid. The impression is made by tight contact with the glass finish.

Cut-thru: "Cut-thru" is a term used to describe when the top of the glass finish has pushed completely through the gasket compound to the metal coating. A cut-thru can result in a leaking seam and requires immediate corrective action.

Removal torque: Removal torque is the force required to remove the cap. It is typically measured using a torque meter. Removal torque is considered a valuable quality control check but is not recommended as a control for cap application.

Pull-up (Refer to Attachment 22): Pull-up is a non-destructive test for measuring the position of the closure lug on the threads of the glass finish. It is the distance between the leading edge of the cap lug and the vertical neck ring seam on the glass finish in 1/16 inch increments. When measuring this position, first find the vertical neck ring seam on the glass finish remembering the vertical neck ring does not always correlate with the two vertical seams on the glass finish. Then measure the distance from the vertical neck ring seam to the leading edge of the nearest cap lug. A lug positioned to the right of the vertical line is referred to as positive (+) and to the left of the vertical line as negative (-). A positive measurement means the cap has been properly applied. A negative lug position can indicate an over-application of the cap and may result in a stripped cap. Generally, a cap lug will be about 1/4 inch to the right of the vertical line, however, the distance can vary and measurements between 0" to 8/16" can still result in a good security value. It is not recommended that pull-up measurements replace the "security" measurements described below, but are useful once the relationship between pull-up and security has been established.

Security (Refer to Attachment 22): Security values (lug tension of an applied closure) are the most reliable measurement of proper lug cap application. Security value ranges are supplied by the closure manufacturer to the processor. Generally, if measured values are always higher that the range specified, it indicates a secure package with some degree of over-application. If measured values are always lower than the range specified usually indicate under-application. Some factors that may affect the measured values are, type of plate, compound, and glass surface treatment applied by the container manufacturer.

Security measurement is a destructive test. There is no requirement as to the number of containers that should be tested; however, being a destructive test there are practical limits to the number of containers that one would test. A security test is performed as follows:

-Mark a vertical line on the cap and a corresponding line on the container.

-Turn cap counter-clockwise until the vacuum is broken.

-Reapply the cap until the closure is finger-tight.

-Measure the distance between the marked vertical lines in 1/16 inch increments.

Security is considered positive if the line on the cap is to the right of the line on the container and negative if the line on the cap is to the left of the line on the container. A high positive security can indicate under application; a negative security value can indicate over application. The cause of negative security should be determined and corrective action taken immediately.

Security can be measured at the capper and after processing and cooling. The range of measurement, however, should be lower after processing due to compound sink that occurs with heat and high pressure.

Visual and Physical Examination Record Requirements:

21 CFR Part 113.60(a) requires that observations made during visual seam examinations be recorded. Any defects found during the examinations shall also be recorded as well as steps taken for corrective action.

21 CFR Part 113.100(c) outlines the minimum required information for the visual and physical examination record by stating "Written records of all container closure examination shall specify the product code, the date and time of container closure inspection, the measurements obtained, and all corrective actions taken." The regulation requires that the records be signed or initialed by the container closure inspector and reviewed by management with sufficient frequency to ensure that the containers are hermetically sealed.

Sufficient frequency can be defined as prior to shipment of the product. However, FDA investigators should encourage LACF processors to review the container records at the same time as the thermal processing records or not later than one working day after the actual process, and prior to shipment or release of the product.

Refer to Attachment 23 which is an example of glass examination records.

Other Quality Control Equipment:

Other equipment including mechanical headspacers (which control headspace limits in the container) cocked-cap detectors and ejectors, and dud detectors (which detect low vacuums) are commonly found on glass-container closing lines and can affect sealing of the container. For example, if a headspacer is incorporated in the processing line, it is imperative that it is set properly. A headspacer can contribute to product overhanging the finish by dripping liquid and product on the glass finish, which may affect good sealing. Cocked-cap detectors/ejectors and dud detectors, if used, maintained, and set properly, can serve as useful tools in the evaluation of defective seals and sealing problems.

Retortable Pouch

Container Structure and Sealing Method:

Preformed pouches are received by the food processor from the pouch manufacturerer, who has sealed 3 sides under ideal conditions at the pouch manufacturing plant. The pouches are filled by hand, in a straight line fashion or on a rotary carousel. After filling the packer's end seam is fusion sealed by the food manufacturer. Prior to sealing, the two sides of the pouch are pulled taut by mechanical grippers to assure that the two sealing surfaces are smooth and parallel to avoid wrinkle in the seal area. It is very important to prevent food, grease, moisture and other containants from becoming entrapped in the seal area; such contaminants can prevent or weaken a fusion seal.

Two common types of heat sealers are hot bar (also called bar or conductance) and impulse sealers:

1. Hot bar: (jaw type sealing with one or two heated opposed bars) is the most widely used method for heat sealing. Each heated bar contains a heater element that heats up and remains hot during production. A thermocouple is implanted in each bar near the surface which is connected by wire to the instrument control panel where the temperature near the sealing surface is digitally displayed. The steel bars are usually covered with teflon to prevent plastic contamination of the bars. Often there is a second cold bar station where the sealed pouch is pressurized by a set of cold bars to set the seal.

2. Impulse bar: Heating and cooling dwell times are achieved with one set of sealing bars at one station. Impulse sealers have 2 bars covered with a resilient surface such as silicone rubber. A taut Nichrome ribbon (wire) covered with an electrically insulating layer of thin heat resistant material ,such as Teflon coated fiberglass, is laid over one or both of the resilient bars. The bars press the two sealing surfaces through the Nichrome ribbon for a few seconds which heats the wire to the desired temperature for heat sealing. After the specified heating dwell time, the voltage (heat) is turned off and the resilient bars and pouch seal cools (cooling dwell time). The bars are then opened and the sealed pouch removed.

Retort pouches can also be produced on site. This is typically called a "form/fill/seal" operation, where a multi-layered laminated web of polyester/polypropylene/aluminum foil is run along a horizontal plane and molded into concave (bowl) shapes. The pouches are then filled and a continuous web of multi-layer plastic is fed from an overhead roller on top of the filled pouches. The top web is then heat sealed onto the pouches by heat sealing bars that descend from above. A vacuum is pulled on each pouch just prior to sealing the two material webs. After sealing, the individual pouches are cut from the web by a cutter wheel as the web exits the vacuum heat sealer.

Critical Factors in Sealing:

Critical factors in heat sealing the retort pouch include:
1. Seal bar temperature
2. Pressure exerted on the seal by the sealing bars
3. Dwell time (time seal bar pressure is exerted on seal)

These critical factors are interdependent. For example, increased production line speeds and shorter dwell time can be compensated for by increased seal bar temperature.

It is also very important to ensure that the seal area is not contaminated with food, grease, moisture or some other contaminant which may contribute to a weak or defective seal. The sealing surface should be smooth, parallel, wrinkle and contaminant free.

During inspections, investigators should determine if the food processor has validated the heat sealing equipment being used to assure that the seal bar temperature, pressure and dwell time parameters are adequate to create a well fused seal. Validation can be accomplished by burst testing a number of filled and sealed pouches using different heat sealing parameters and choosing the most ideal parameters (seal bar temperature, pressure and dwell time) for production runs.

SEMI-RIGID RETORTABLE TRAYS AND BOWLS:

Sealing Method:

Semi-rigid trays and bowls are filled and sealed in a manner similar to the form/filled/sealed web system previously described under pouches. The trays are filled and vacuum heat sealed using hot seal bars. Some of these fill/seal machines include a nitrogen gas flush just before fusion heat sealing a plastic or plastic/foil closure onto the container body.

Critical Factors in Sealing:

Critical factors in attaining a good heat seal with semi-rigid trays are similar as those for retort pouches. They are:
1. Seal bar temperature
2. Seal bar pressure
3. Seal bar dwell time
4. Smooth, continuous, non-contaminated sealing material surfaces

CONTAINER DEFECTS - POUCHES AND SEMI-RIGID RETORTABLE TRAYS / BOWLS AND PAPERBOARD HEAT SEALED PACKAGES:

National Food Processors Association (NFPA) has developed a Flexible Package Integrity Bulletin (BUL 41-L) that defines three classes of defects for flexible packages. These are:

Class I Defects:

Class I defects are defined as critical. They are gross closure or package defects that result in a hole or leak through the package including a leaky seal. Some of the more common Class I defects for pouches and semi-rigid containers are:

Channel leaker: A patch or pathway of non-bonding across the width of the seal, creating a leak.

Cut: A mechanical slash or slicing that goes into the package with a loss of hermetic seal.

Fracture: A break through the packaging material.

Leaker: A container that is unsealed or exhibiting evidence of lost integrity.

Non-bonding: Failure of two sealant films to combine during the sealing process.

Notch leaker: A leak at a manufactured notch used for easy opening.

Puncture: A mechanical piercing that goes into the package with a loss of hermetic integrity.

Swollen package: A package the shape of which has been altered due to gas formation within the package.

Class I defects for paperboard heat sealed packages are similar to those for pouches and semi-rigid containers and include channel leaker, cut, puncture, and swollen packages. Additional Class I defects for paperboard heat sealed packages are:

Corner leaker: A leak occurring in one of the corners of the package.

Perforation leaker: Leakage through or around a perforated area.

Pull tab leaker: Leakage through or around pull tab.

Seal leaker: Product leaking along the seal.

Class II Defects:

Class II defects are defined as major. These defects show no sign of visible leakage but are of such magnitude that the container may have lost its hermetic seal. Class II defects for pouches and semi-rigid containers are:

Abrasion: A scratch partially through the surface layer(s) of the package caused by mechanically rubbing or scuffing.

Blister: A void within the bonded seal caused by entrapped grease or moisture vaporizing during seal formation and then condensing.

Compressed seal: A seal formed by excessive pressure and/or heat and evidenced by cracking and delamination.

Contaminated seal: Foreign matter in the seal areas, such as water, grease, or food.

Delamination: A separation of the laminate materials forming the package.

Misaligned seal: Improper seal position.

Seal creep:. Partial opening of the inner border of seal compromising seal width.

Wrinkle: A fold of material in the seal area.

Crushed package: Alteration of the packages' original dimensions caused by force.

Uneven impression: Impression from seal bar is uneven around the periphery of container. This could be due to uneven thickness of container flange resulting in uneven pressure during heat sealing.

Seal width variation: Seal width varies from specification around the periphery of container.

Class II defects for paperboard heat sealed packages are as defined above: abrasion; crushed; and misaligned seal.

Class III Defects:

A Class III defect is defined as a defect that has no adverse effect on the hermetic seal.

NFPA in cooperation with FDA and the Association of Official Analytical Chemists published a pictorial brochure titled "Classification of Visible Exterior Flexible Package Defects. The brochure along with NFPA BUL 41-L provide valuable information concerning flexible package defects. The FDA investigator should be familiar with the information contained in these documents.

Seam Evaluation Requirements:

21 CFR Part 113.60(a)(3) specifies that for closures other than double seamed and glass containers, appropriate detailed inspections and tests shall be conducted by qualified personnel at intervals of sufficient frequency to ensure proper closing machine performance and consistently reliable hermetic seal production. The regulation also states that records of such tests shall be recorded.

Part 113 does not specify what tests are required. The following guidelines are used by the LACF industry for performing both visual and destructive tests for flexible and semi-rigid containers.

1. FDA Bacteriological Analytical Manual (BAM), 7th Edition/1992.

2. NFPA Flexible Package Integrity Bulletin, BUL 41-L with an accompanying Flexible package Defect Pictorial Guide, 1989. (As previously mentioned.)

3. Military Specification "Packaging and Thermal Pocessing of Foods in Flexible Pouches".

4. USDA Regulations 9, CFR Parts 431 "Canning of Meat and Poultry Products".

5. 1982 USDA bulletins "Test Cycles for Small Size Semirigid Containers", "Test Cycles for Small Size Flexible Retortable Pouches" and "Test Cycles for Large Size Flexible and Semirigid Containers".

Visual Seam Examination (Non-Destructive Test):

As with metal cans and glass jars, 21 CFR Part 113.60(a) requires that regular observations shall be made during production runs for gross closure defects. The top seal of 1 container from each seaming head or lane (for pouches) shall be visually examined at intervals of sufficient frequency and the results recorded. The frequency of the visual examination should not exceed 30 minutes of operational time and additional visual examination must be performed immediately following a jam in the closing machine, after closing machine adjustment, or after startup of a machine following a prolonged shut down. A prolonged shut down can be when the plant ceases production at 6:00pm and restarts production at 8:00 am the next day.

Visual and destructive testing methods and frequencies for flexible and semi-rigid containers are outlined in the guidelines referenced above. For example, NFPA BUL 41-L recommends the following examinations:

Retort pouch: Visual on-line examination of the retort pouch container and seals at a rate of 1 pouch from each filling station at start-up and every 30 minutes thereafter. The visual examination includes a "squeeze test" whereby 1 pouch is manually kneaded 10 times in succession. After kneading, the seal areas are examined for evidence of product leakage or delamination.

Plastic containers with heat sealed lids: BUL 41-L recommends a visual examination for defects every 15 minutes; and at intervals of 30 minutes recommends the sides of each plastic test container be manually squeezed to cause the lid to bulge 1/8 inch. The seal area is then visually examined for defects such as contamination and non-bonding.

Paperboard cartons: BUL 41-L recommends that for web fed systems, the material web be checked at 15 to 30 minute intervals for correct alignment of the longitudinal seal. After sealing the cartons should be checked for proper alignment of transverse seals and for evidence of container defects.

Physical examination (destructive and non-destructive testing):

As stated previously, 21 CFR Part 113.60(a)(2) states that for closures other than double seams and glass containers, appropriate detailed inspections and tests shall be conducted at intervals of sufficient frequency to ensure proper closing machine performance and consistently reliable hermetic seal production. For physical testing of the reliability of the hermetic seal the regulation does not specify test methods or frequency of testing. Again, we rely on the guidelines, previously referenced, that have been published for these containers. Some of the common destructive and non-destructive testing methods for flexible and semi-rigid containers that are described in the guidelines are as follows:

Destructive testing:

Burst testing (Refer to Attachment 24): The burst test is a good overall test for seal integrity (especially for retortable containers). The test stresses a package uniformly in all directions and identifies the location of the weakest point and the pressure at which it fails. The burst test can be used for retort pouches to test the seal strength along the two sides and one end as well as all four sides.

Vacuum or bubble test (Refer to Attachment 24): The vacuum or bubble test (also referred to as air pressure testing), is performed inside a transparent vacuum chamber such as a bell jar connected to a vacuum source. A vacuum is pulled on the inside of the chamber for a period of time and a container or seal leak is indicated if the container fails to swell to normal dimensions. This can also be done with the container submerged under water in the bell jar (bubbles emanating from the container would indicate a leak). This test is most commonly used for aseptically filled containers with fusion or peelable lidstock.

Tensile (seal strength) testing (Refer to Attachment 24): The tensile test is used to measure seal strength of the retort pouch. The test involves taking 3 strips (1"x3") from the seal area of the pouch and attaching the two ends of each strip to a tensile testing device. The device slowly pulls apart the seam and the force required to separate the seam is measured. The disadvantage of tensile testing is it tests only sampled portions of the seam area. For this reason, it is used only for surveillance of material sealability and to spot check equipment operations and sealing conditions.

Drop testing (Refer to Attachment 25): The drop test (also referred to as an immediate container abuse test) is commonly used to test the package and seal integrity of flexible containers, and semirigid trays and bowls. This test was designed to simulate the dropping of individual containers under a controlled and reproducible basis. After drop testing, each container is visually inspected for evidence of leakage. After the visual inspection, the container is then "peel tested". Peel testing is described below.

Peel testing (Refer to Attachment 26): The peel test is intended to measure the pounds of force necessary to peel a fused or sealed lid off a plastic container body. For the form/filled/sealed plastic containers, the peel test is conducted by peeling back the lid on each container held at a 45 degree angle and observing the area for a general frosty appearance on both the lid and sealed surfaces. This frosty material is polypropylene residue from the lid sealing layer. The presence of this material on the flange, around the periphery of the container, indicates a well fused seam. Peel testing can be performed by hand or with the use of a tensile testing device. This test is often performed after drop testing as previously described.

Residual Gas testing (Refer to Attachment 27): The quantity of residual gas in retortable flexible pouches and semirigid plastic containers is normally measured prior to retorting. Too much residual air can exert excessive pressure on the inner seal area during retorting, which results in weakened seals and reduced heat penetration to the product cold spot. To much air in the product can also shorted the product shelf life.

Electroconductivity testing (Refer to Attachment 27): Electroconductivity testing tests a container's ability to prevent the flow of electric current through the package. A tight inner layer of plastic material will not allow the flow through of electric current unless there is a hole or crack in the plastic material. Electroconductivity tests are commonly run to confirm leaks in packages detected by other non-destructive tests such as incubation.

Dye testing: Dye tests are usually conducted to identify the location of micro size holes in food packages that have tested positive for leaks by electroconductivity, incubation or biotest methods.

Non-destructive testing:

Incubation testing : Incubation testing involves the storage of finished product samples for a week or more at temperatures within the range required for growth of spoilage microorganisms. The growth of microorganisms indicates either insufficient processing or a loss of hermetic seal.

Biotesting: Biotesting is a means of challenging a containers's ability to prevent leakage under the worst case conditions of processing and/or storage. Biotesting involves filling containers with a broth or other food conducive to growth of gas producing microorganisms and then subjecting the container to processing or abuse, followed by immersion in a solution heavily contaminated with the target spoilage organism. The containers are then incubated. After incubation, a leak would be evidenced by a swollen container.

On-Line non-destructive tests: There are a number of on-line non-destructive tests designed to detect leaks in semi-rigid and flexible packages after filling and sealing. Most of these tests involve the measurement of pressure differential between the pressure inside the container and the external pressure. After establishing a set differential pressure, any change in pressure would indicate a leak.

These test methods although not required by regulation, are presented in detail in various guidelines, as previously referenced.

Visual and Physical Seam Examination Record Requirements:

The regulation requires that observations made during visual and physical examinations be recorded. Any defects found during the visual examination shall also be recorded, as well as steps taken for corrective action.

Although the regulation does not specify what test methods or frequency of examination is required, it does say that tests will be performed and "Records of such tests shall be maintained. 21 CFR Part 113.100(c) requires the written container closure records must specify the product code, date and time of container closure inspection, any measurements obtained, and all corrective actions taken. These records must also be signed or initialed by the container closure inspector and reviewed by management with sufficient frequency to ensure adequate hermetic seal production.

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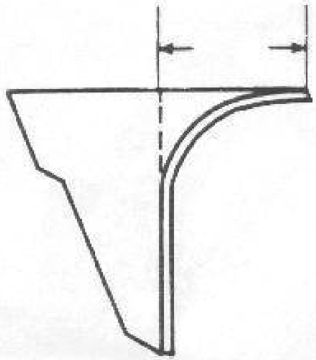
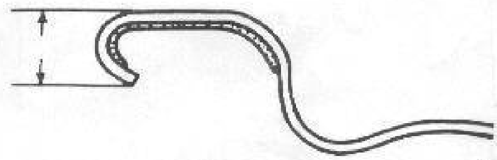
ATTACHMENTS:

1. Metal Can Flange/ Metal Can End Curl/ Double Seam Structure and Terminology
2. Double Seam - Countersink/Thickness/ Width/Body Hook and Cover Hook/Overlap/Cover Hook Wrinkles
3. Seam Tightness Evaluation
4. Body Wall Impression
5. Formation of the Double Seam
6. Stages in the Formation of the Double Seam-1st and 2nd Operation Roll
7. Example- Double Seam Guidelines
8. Can Seam Defects - Droop, Lips, Vees
9. Can Seam Defects - Sharp Seams, Cut-Overs
10. Can Seam Defect - Jumpover
11. Can Seam Defects - Deadheads, Spinner, Slips and Skids
12. Can Seam Defects - False Seam/ Knocked Down Flange/Body Buckle/Cocked Body
13. Can Seam Defect - Cut Seam
14. Can Seam Projector
15. Can Seam Micrometer
16. Seamscope
17. Example-Visual Seam Examination Record-Cans
18. Double Seam Examination Records - Cans
19. Glass Container Structure and Terminology/ Metal Vacuum Closure Structure and Terminology
20. Metal Vacuum Closures
21. Glass Container Defects
22. Security Test/Pull-Up Test
23. Example-Glass Closure Evaluation Records
24. Sealed Pouches and Semi-Rigid Containers-Burst Test/Bubble Test
25. Sealed Pouches and Semi-Rigid Containers-USDA Drop Test
26. Sealed Pouches and Semi-Rigid Containers-Peel Test
27. Sealed Pouches and Semi-Rigid Containers- Residual Gas Test/Electroconductivity Test

Metal Can Flange and End Curl



The outward flare of the body cylinder is called a flange.



The end curl forms the cover hook and is the area where the sealing compound is placed.

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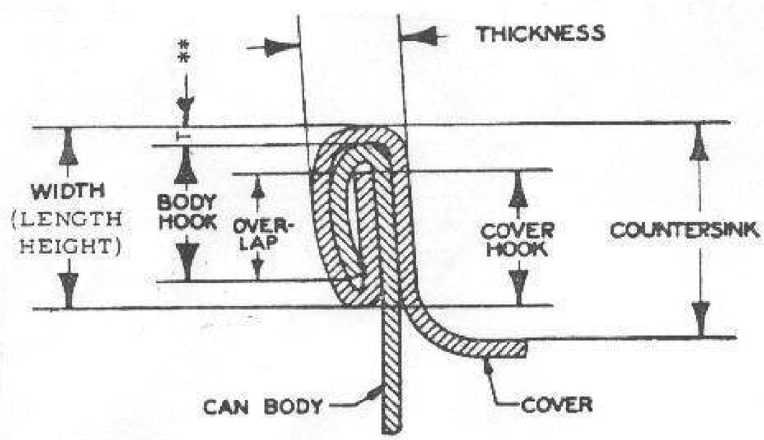
Double Seam Terminology and Calculation of Overlap



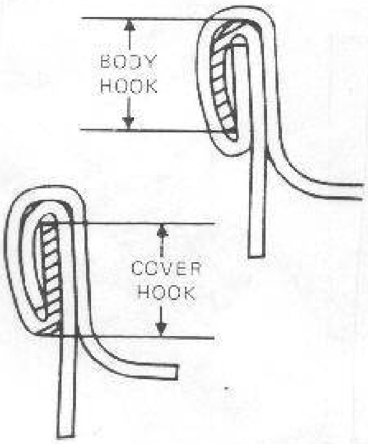
Calculation of Overlap Length

Overlap length = CH+BH+T-W
Where CH = cover hook
BH = body hook
T**= cover thickness, and
W = seam width

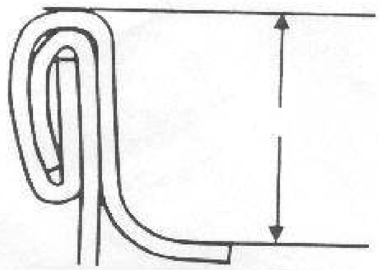
** In general practice 0.010 may be used for the tin plate thickness

ATTACHMENT 1

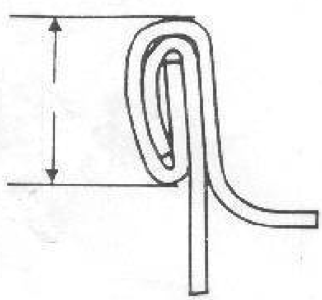
Measurements Performed to Evaluate the Double Seam



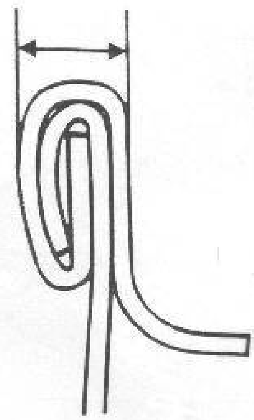
The body hook and cover hook.



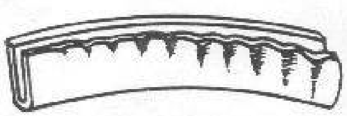
Countersink depth.



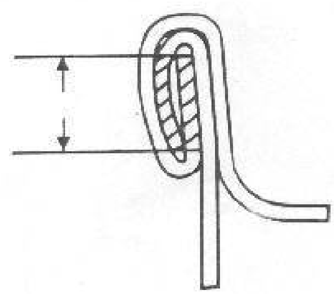
The seam width (length or height).



Seam thickness.



Cover hook wrinkles.



Overlap.

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ATTACHMENT 2

Seam Tightness Evaluation

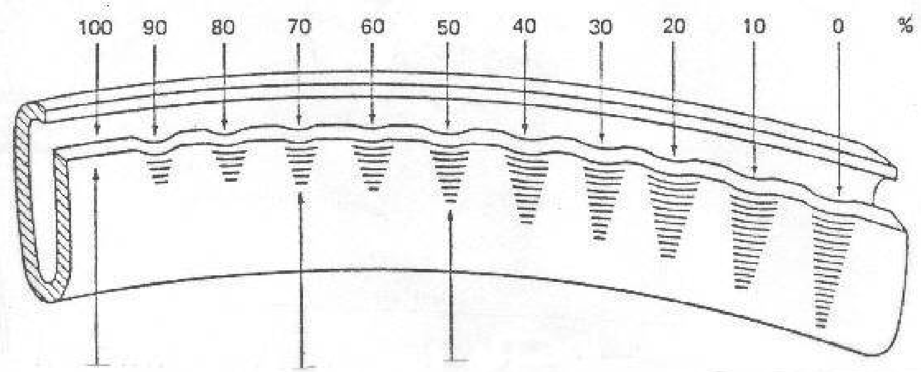
The tightness rating of the seam is most important and should be evaluated carefully. During formation of the seam proper tightness assures that the sealing compound will fill all spaces not occupied by the metal.

The tightness is evaluated by the degree of wrinkle in the cover hook. A wrinkle is the degree of waviness. In hemming a straight edge of plate no wrinkles are formed. On curved edges wrinkling increases as the radius of curvature decreases. For this reason different wrinkles are specified as acceptable for small diameter cans as compared to large diameter cans.

Wrinkles are classified by a tightness rating as illustrated below. (Other wrinkle rating systems : 0-10 or 0-3, where 3 was equivalent to more than a 50% wrinkle should no longer be used). The rating is based on the deepest wrinkle, for it is in this area that the seam is most
vulnerable to abuse, leakage, and penetration by bacteria.

Note the wrinkle immediately adjacent to the side seam should not be considered in arriving at a wrinkle rating that is to be used as a guide for making adjustments in the tightness of the second roll operation. Any loose wrinkle adjacent to the side seam should be considered a major defect at the juncture and call for other adjustments.

TIGHTNESS (WRINKLE) RATING IN %



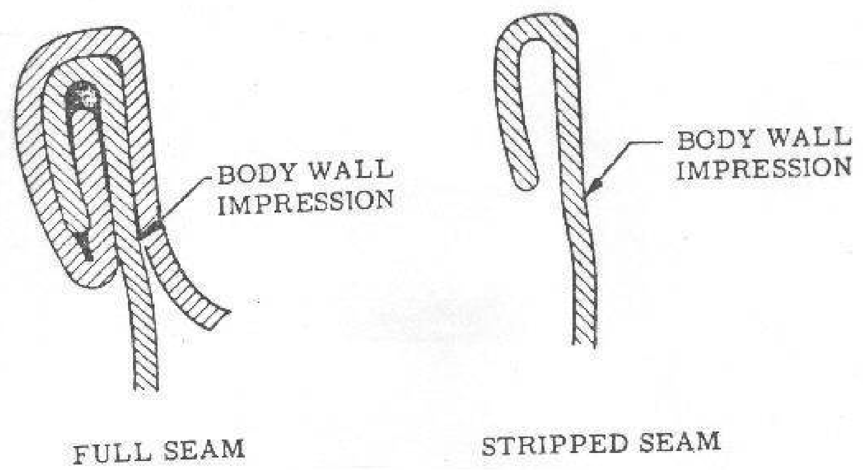
ATTACHMENT 3

Body Wall Impression

After the cover hook is removed the can bodies should be examined for body wall impression, also called pressure ridge. This impression is caused by seaming roll pressure during the seaming operation.

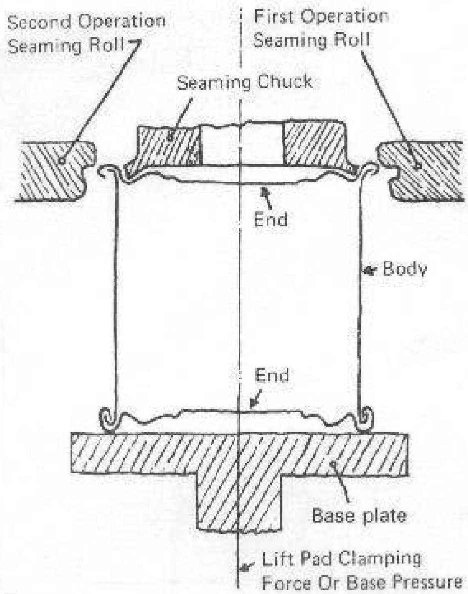
The practice of visually inspecting the pressure ridge when a can is stripped is an additional safeguard against approving double seams which may not be as tight as they should be even though the measurements of the double seam and the cover hook are within tolerance.

The body wall impression or pressure ridge should be impressed around the complete inside periphery of that portion of the can body which is exposed when the cover hook countersink wall is removed during teardown . An excessively deep pressure ridge should be avoided on enameled (inside) cans; however the pressure ridge should be visible. A suggested rating scale is extra heavy, heavy, good, fair, poor.



ATTACHMENT 4

Forming the Double Seam



-Diagram of seamer head chuck and rolls.

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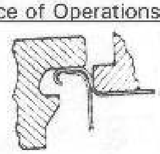
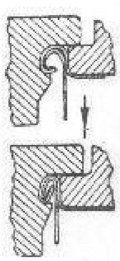
Sequence of Operations in Seaming a Can End onto a Can Body

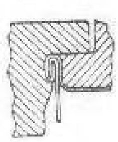


1. The can is placed on the lifter plate and the cover is automatically placed on the can; or the can with a cover is placed on the lifter plate.



2. The lifter plate raises the can and cover onto the seaming chuck , tightly clamping the cover onto the can.

3. The first operation seaming roll is brought into contact with the can and cover, and the metal spinning groove forms the first operation seam...curling the end hook around the inside of the body hook to form an interlock.



4. The second operations seaming roll flattens the seam and seals the can.

Attachment 5

Stages in the Formation of the Double Seam

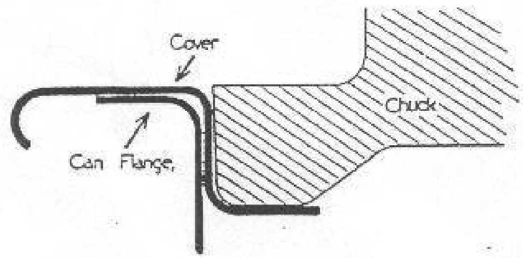


Figure 1.

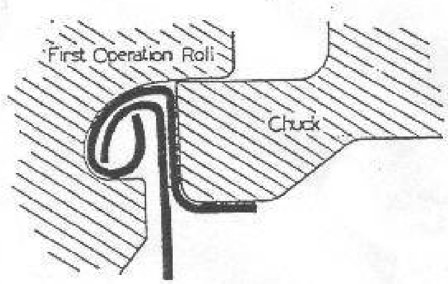


Figure 2.

Figure 3.

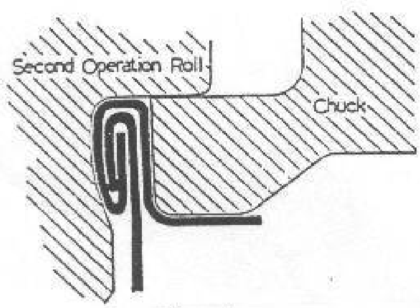


Figure 4.

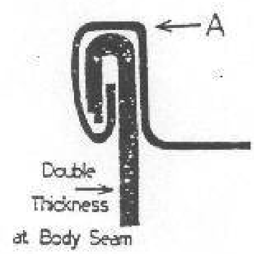


Figure 5.

Attachment 6

CONTAINER EQUIPMENT SERVICE

CUSTOMER DOUBLE SEAM GUIDELINES

CAN: SANITARY NON BEADED DRAWN	CAN SIZE: 301 X 106
BODY PLATE WT.: .0110" FLANGE THICKNESS	END PLATE WT: 85#
SEAMER MODEL NO.: CANCO 300B SEAMING CHUCK NO.: C2608C 1ST OPER. ROLL NO.: R145EC	LIP THICKNESS: .120" 2ND OPER. ROLL NO.: R246C
PIN GAUGE HEIGHT AT END OF 1ST OPERATION: 1.205" ± .005" BASE PLATE SPRING PRESSURE: 200 LBS ± 25 AT .030" DEF.	

SEAM DIMENSIONS	SET-UP	OPERATING
1ST OPER. SEAM THICKNESS	.089" ± .005"	
1ST OPER. SEAM WIDTH	.104" MAX	
1ST OPER. COUNTERSINK DEPTH	.123" MAX	
2ND OPER. SEAM THICKNESS	.055" ± .002"	.055" ± .003"
2ND OPER. SEAM WIDTH	.118" ± .003"	.125" MAX
2ND OPER. COUNTERSINK DEPTH	.125" MAX	.130" MAX
BODY HOOK LENGTH	.080" ± .004"	.080" ± .008"
COVER HOOK LENGTH	.076" MIN	.070" MIN
COVER HOOK TIGHTNESS RATING	95% - 100%	85% - 100%
OVERLAP, ACTUAL	.045" MIN	.040" MIN
JUNCTURE RATING	DOES NOT APPLY FOR 2 PIECE CAN	
PRESSURE RIDGE	VISIBLE AND CONTINUOUS	

NOTE 1. The quality of the double seam is the responsibility of the customer.
NOTE 2. A good first operation seam must be made to obtain a satisfactory finished seam.
NOTE 3. Final appraisal of a seam should be based on visual examination of the "torn" down seam of three (3) samples.
NOTE 4. Seams are to be tightened when cover hook tightness falls below minimum operating limits.
NOTE 5. Pressure ridge or area should be examined closely. Extreme body wall impression can cause body wall fractures or perforations.
NOTE 6. The above dimensions are based upon ANC recommended roll grooves. Different roll grooves are acceptable if operating limits are maintained.

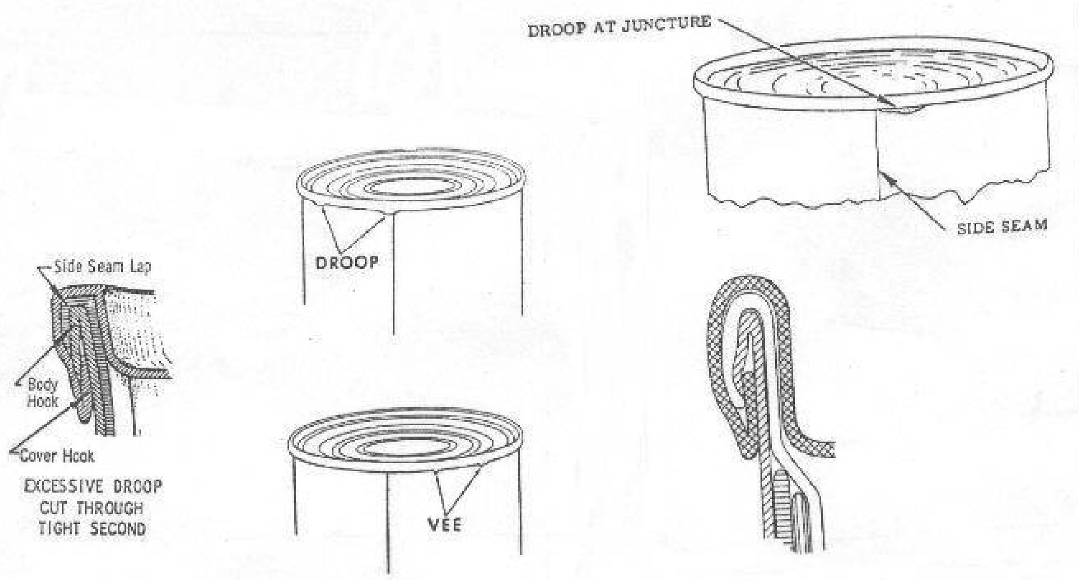
Attachment 7

Droops, Lips, Pinlips, Vees

A smooth projection of a double seam below the bottom of a normal seam is called a droop. A droop may occur at any point, but is most likely to occur at the point where the double seam crosses over the lap of the side seam.

A slight droop at the side seam lap may be considered normal because of the additional plate thickness incorporated into the side seam structure. However, if the droop is excessive the cover hook will be too short or non-existent.

Causes:
1. Excessive body hook (excessive base plate pressure)
2. First operation too loose, worn, or too tight
3. Too much solder in side seam
4. Second operation too tight
5. Cocked bodies
6. Product trapped in seam
7. Excessive amount or unequal distribution of sealing compound in cover
8. Hard or brittle plate



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Attachment 8

Sharp Seams and Cut-Overs

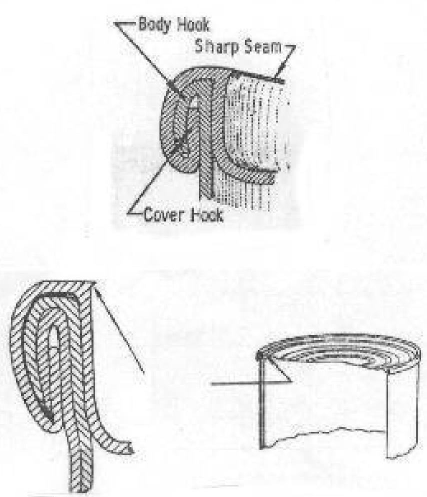
The terms sharp seam and cut-over are frequently used interchangeably, however cut-over is defined as a fractured or broken sharp seam.

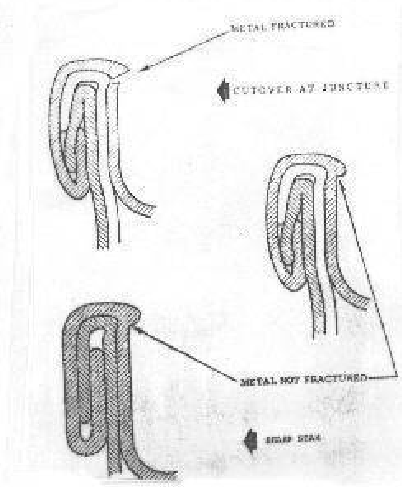
A sharp seam is a sharp fin of the cover formed over the top of the seaming chuck during the seaming operation (. If there is any evidence of a sharp seam it is likely to be noticeable at the side seam lap. It can be felt by running a finger around the top part of the countersink; it is more easily felt than seen. See the next page for causes of sharp seams and cut-overs.

A slight sharpness at the can body lap is not indicative of a defective seam, but a severe sharp fin , as illustrated is dangerous, for fracture is likely to occur.

Some possible causes of both sharp seams and cut-overs are:

1. Worn and/or broken seaming chuck.
2. Excessive base plate pressure.
3. First or second operation rolls to tight.
4. Worn seaming roll grooves.
5. Excess solder at can body lap (three piece container).
6. Product in the seam.
7. Excessive vertical play of first operation roll or incorrect alignment of the first operation roll grove to seaming chuck.





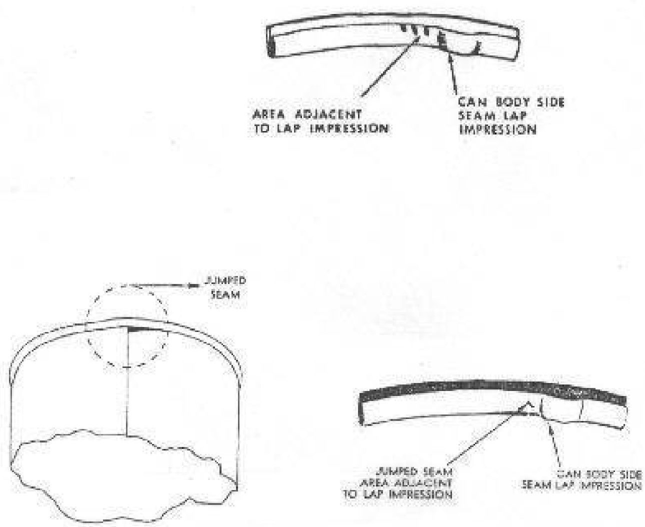
Attachment 9

Jumpover

A jumpover is a portion of a double seam which is not rolled tight enough adjacent to the lap. This is caused by the jumping of the seaming rolls after passing over the lap. During inspection of seams the structure immediately adjacent to either side of the lap should be minutely inspected since this is the most critical area of the seam from a leakage standpoint. Any evidence of jumped seam, as illustrated below requires that immediate corrective action be taken. For the most part, this problem has been eliminated with the introduction of the welded side seam can.

Causes of jumped seams:

1. Excessive speed of closing machine, especially when using large diameter seaming rolls.
2. Thick lap or excessive solder at the side seam juncture.
3. Sluggish acting or broken second operation seaming roll cushion springs.
4. Excessively tight first operation roll.



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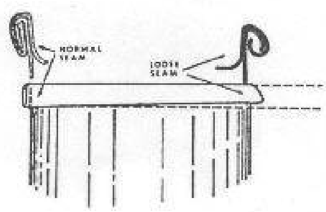
Attachment 10

Deadheads, Spinners, Slips, Skids

A deadhead is an incomplete seam caused by the chuck spinning in the countersink during the seaming operation. The incomplete seam usually begins at the side seam.

Causes:
1. Not enough pressure by lifter through formation of seams , as can shortens in overall length
2. Base pressure too high
3. Broken lifter spring
4. Improper end fit with chuck, cover too loose or too tight on chuck
5. Worn seaming chuck
6. Rolls too tight or binding
7. Short body hook
8. Chuck too high in relation to lifter plate-improper pin gage height setting
9. Oil or grease on seaming chuck or lifter
10. Excessive vertical play of seaming chuck spindle
11. Improper timing
12. Seaming roll not rotating freely; lifters not rotating freely



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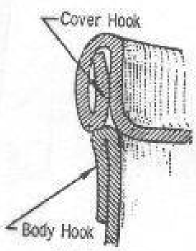
Attachment 11

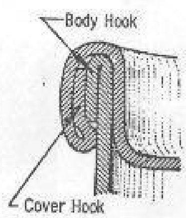
False Seams

A false seam is a seam or part of a seam which is completely unhooked, and in which the folded cover hook is compressed against the folded body hook. A false seam is not always detectable in an external examination.

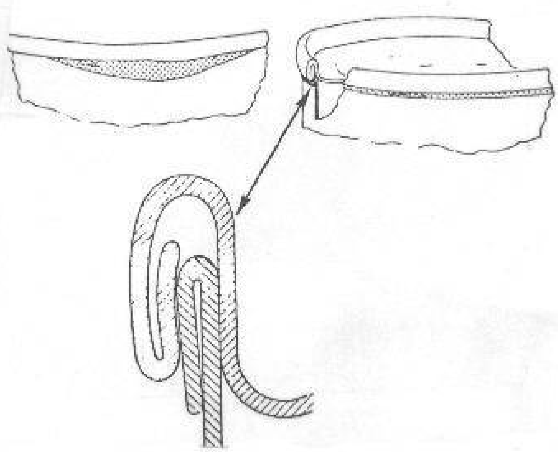
Causes:
1. Can not centered to chuck
2. Centering ring worn or out of line with chuck
3. Cans out of round or with badly dented or mushroomed flange
4. Damaged or bent cover curl
5. Machine out of time
6. Misassembly of can and cover
7. Poor hook formation with either a loose base plate, or a loose first operation with a tight second
8. Knockout not correctly set
9. No tension of spring on lifter front plate guide



FALSE SEAM



FALSE SEAM



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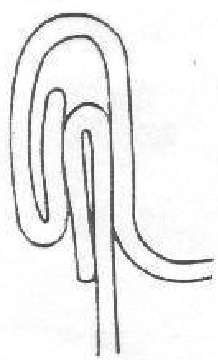
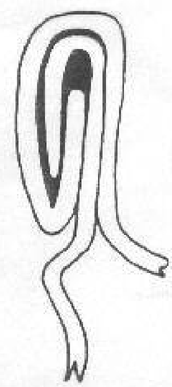
Attachment 12

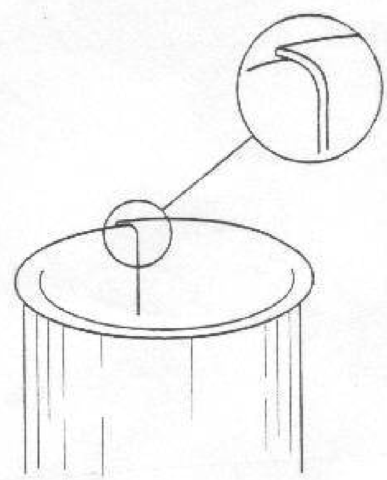
False Seams



False seam.



Body buckle.



Cocked body.

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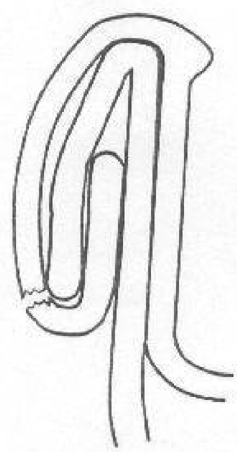
Attachment 12

Cut Seams

A fractured outer layer of the double seam as shown in the diagram is known as a cut seam. Immediate correction should be made.

Causes:

1. Brittle end plate
2. Seam too tight
3. Excess solder at can body lap
4. Improper chuck setting
5. Tight second operation roll
6. Excess pressure



–Cut seam.

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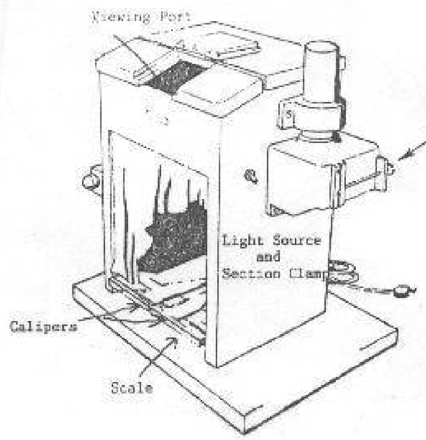
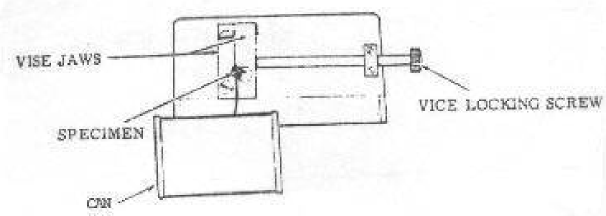
Attachment 13

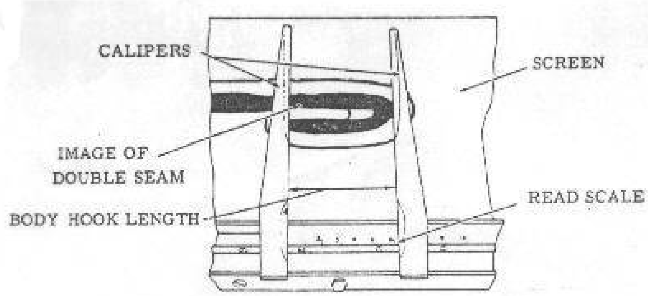
Examining Cross Section with Seam Projector

A cross section of the seam is held in a vice clamp. When brightly illuminated its image, greatly enlarged, is projected onto a screen at the base of the projector. Measurements of cover hook, body hook and overlap are made on this image by use of calipers mounted on the viewing screen. The seam projector should be routinely calibrated in accordance with manufacturer's instructions.

The seam cross section is prepared by making two saw cuts, about 3/8" apart, after removing center metal of the lid. The strip obtained is bent away from the can body and inserted into the vice clamp of the projector as illustrated.



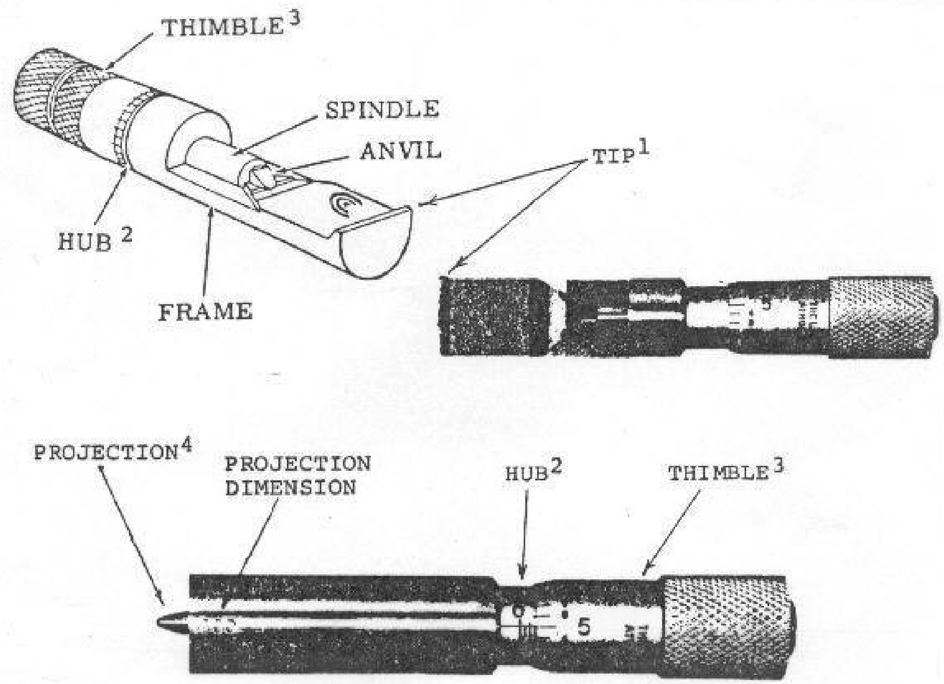




To make a measurement, the caliper arms are moved to the position shown below and read. As illustrated the reading is 6.2 thousandths, or 0.062.

Attachment 14

The Can Seam Micrometer

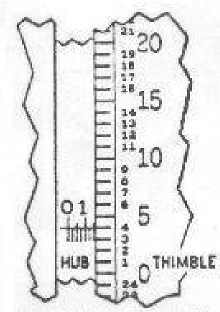


1. Tip rests on body of can when measuring seam length (height, width) of body hook.

2. Hub, also called barrel, is divided into numbered tenths of an inch; each tenth of an inch is subdivided into unnumbered markings that represent 0.025 inch.

3. Thimble is rotatable and each rotation of thimble correspond to 0.025 inch. There are 25 divisions on thimble so that each division on thimble corresponds to 0.001 inch.

The spindle has 40 precision ground threads per inch, so when the thimble (which is attached to the spindle) is given one complete turn, you have moved the spindle 1/40th (.025) of an inch. As the thimble is divided into 25 equal parts, the movement of one graduation of the thimble results in a one-thousandth change in reading, because 1/40 x 1/25 equals 1/1000, or expressed in decimals, .025 x.040 =.001.



READING TO .154

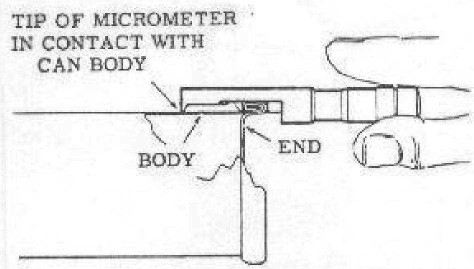
Continued on next page

Attachment 15

Reading shown on the lower micrometer is 0.025 plus 0.025 plus 0.025 plus 0.005 or 0.080

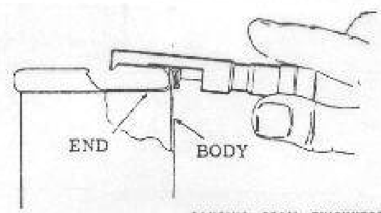
4. Some can seam micrometers have a projection tip for measuring countersink depth. Length of projection is stamped on barrel. Reading shown for countersink depth is 0.200-0.080 or 0.120.

Measuring Seam Height (width , length)
In measuring the seam height the tip of the can seam micrometer is rested on the can body so the anvil is at the radius of the cover hook. The thimble is gently tightened clockwise until the double seam is held snugly.



GAUGING SEAM HEIGHT

Measuring Seam Thickness
The micrometer should be held or balanced over the seam with the aid of the index finger so that the anvil of the micrometer conforms to the 4-6° taper of the chuck wall. The tip of the micrometer should not be resting on the lid . The thimble is gently tightened clockwise until the double seam is held snugly between the anvil and the spindle screw- just tight enough to hold an empty can without additional support.



GAUGING SEAM THICKNESS

Adjusting For Zero Setting
Periodically the micrometer should be checked for its zero setting. Surfaces of the anvil and spindle should be cleaned with a piece of non-abrasive paper. Then these surfaces should be brought into contact with normal pressure. If the reading is not zero, insert wrench supplied with micrometer into the hole in the barrel and holding the frame with one hand turn the barrel with the other until a zero reading is obtained.

Continued on next page

Attachment 15

Countersink Depth Measured with Micrometer

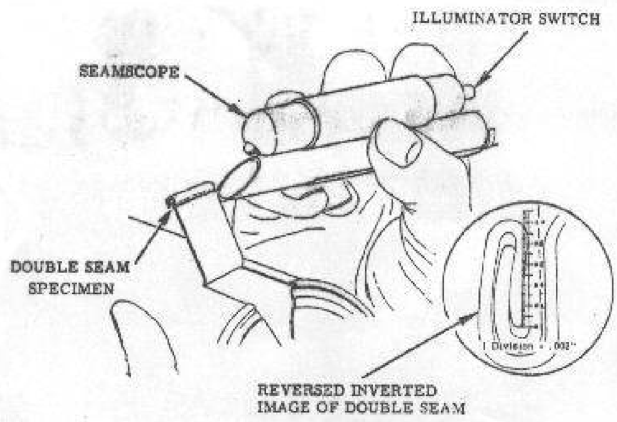
Some can seam micrometers have a projection or pointed shaft at the anvil end of the micrometer for measuring the countersink depth. After the can is placed upright on a flat surface, the end of the micrometer, which should be held in a vertical position, is rested on the top part of the double seam. Then the thimble is very gently turned until the tip of the pointed shaft makes contact with the lowest part of the lid adjacent to the double seam. The reading on the micrometer subtracted from 0.200 (number stamped on side of micrometer near the end) is the countersink depth. Three measurements should be made, avoiding the side seam.

The accuracy of this measurement depends on holding the micrometer exactly vertical as the micrometer is moved to located the lowest part of the lid adjacent to the chuck wall, making a positive but not a forced contact with the pointed shaft.

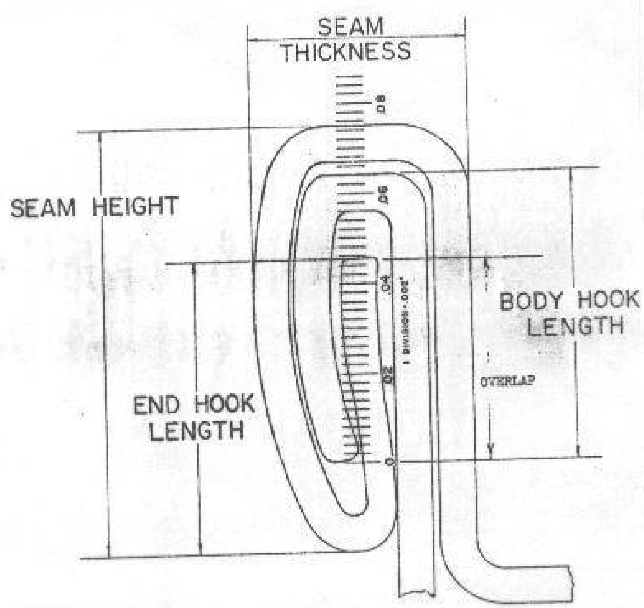
Attachment 15

Use of Seamscope

1. Make two saw cuts across seam after removing center metal of lid to obtain a seam specimen as illustrated.
2. Place the double seam specimen to be examined near the Seamscope, as illustrated. Push in and lock the illuminator switch.
3. Look into the eyepiece. Vary the positions of the magnifier and illuminator relative to the double seam specimen to obtain the clearest image.



SEAMSCOPE AND DOUBLE SEAM SPECIMEN



Attachment 16

RECORD OF VISUAL SEAM EXAMINATION

Date 7-4-89 Line No. 2 Can Size 307 x 200.25 Can Code 110/P21 Inspector Cannery Jane Smith

Time	Head No.	DECISION ON SEAMS: Top Reject	Top Accept	Bottom Reject	Bottom Accept	Side Reject	Side Accept	Corrective Action
7:15am	1		/		/		/	
	2		/		/		/	DROOP CAUSED BY SKIN
	3	/			/		/	RESAMPLE!
8:25am	1		/		/		/	
	2		/		/		/	RESAMPLE O.K.
	3		/		/		/	
8:55	1		/		/		/	
	2		/		/		/	
	3		/		/		/	
9:15	1		/		/		/	CHECKED AFTER
	2		/		/		/	CLINCHER JAM O.K.
	3		/		/		/	DROOP CAUSED BY
9:45	1	/			/		/	BONE RESAMPLE!
	2		/		/		/	
	3		/		/		/	
9:55	1		/		/		/	RESAMPLE OK. TALKED TO PATCH
	2		/		/		/	TABLE LEAD.
	3		/		/		/	
10:15	1		/		/		/	
	2		/		/		/	
	3		/		/		/	CODE CHANGE
10:35	1		/		/		/	TO 110/P22
	2		/		/		/	
	3		/		/		/	DDD 7-5-89

Attachment 17

DOUBLE SEAM INSPECTION REPORT

Date 7-4-90 Line No. 2 - cannery Inspector Jane Smith Plant False Pass

Can Size 307 X 200.25 Bottom End N/A Top End American Tin Stock Code N/A

All Measurements in Thousandths of an Inch.

Can Code	Time	Head No.	Vacuum	Thickness	Width	Body Hook	Cover Hook	Overlap	Wrinkle	Pressure Ridge	Corrective Action
110/P21	8:40 am	1	17	.054 - .056	.118 - .119	.081 - .082	.073 - .078	.045	95	m	
		2	20	.052 - .054	.119 - .120	.079 - .081	.072 - .076	.041	90	m	
		3	17	.054 - .057	.118 .119	.078 - .082	.075 .076	.044	85	m	
110/P23	1:30 pm	1	21	.054 - .057	.117 - .120	.076 .078	.069 .073	.035	90	m	*TALKED TO SEAMERMAN ABOUT LOW COVER HOOK. HE WILL ADJUST SEAMER TONITE ALL OTHER MEASUREMENTS OK.
		2	16	.052 .053	.118 - .119	.080 - .082	.074 .076	.045	95	m	
		3	14	.054 .058	.118 - .120	.075 .078	.078 .079	.043	100	m	
											Reviewed by: DDD
											DATE: 7-5-90
Recommended Ranges of Tolerances				.055±.003	MAX .125	.080±.008	MIN .070	MIN .040	MIN. 80%		

General Insructions:

Overlap = Shortest Body Hook (+) Shortest Cover Hook (+) .010 (-) Highest Width

Attachment 18

DOUBLE SEAM INSPECTION REPORT

Date 7-4-90 Line No. 2 - cannery Inspector Jane Smith Plant False Pass

Can Size 307 x 200.25 Bottom End N/A Top End American Tin Stock Code N/A

All Measurements in Thousandths of an Inch.

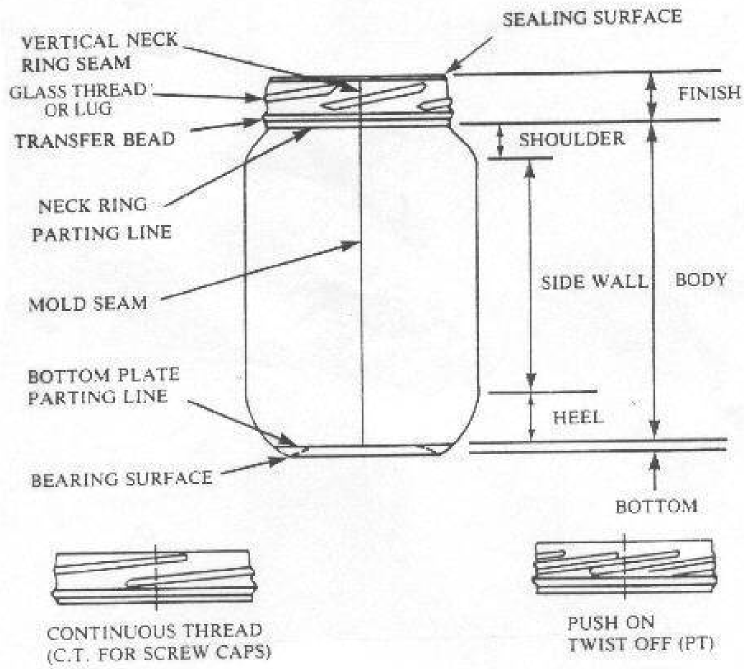
Can Code	Time	Head No.	Vacuum	Thickness	Width	Body Hook	Cover Hook	Overlap	Wrinkle	Pressure Ridge	Corrective Action
110/P21	8:40 am	1	17	.054 - .056	.118 - .119	.081 - .082	.073 - .078	.045	95	m	
		2	20	.052 - .054	.119 - .120	.079 - .081	.072 - .076	.041	90	m	
		3	17	.054 - .057	.118 .119	.078 - .082	.075 .076	.044	85	m	
110/P23	1:30 pm	1	21	.054 - .057	.117 - .120	.076 .078	.069 .073	.035	90	m	*TALKED TO SEAMERMAN ABOUT LOW COVER HOOK. HE WILL ADJUST SEAMER TONITE ALL OTHER MEASUREMENTS OK.
		2	16	.052 .053	.118 - .119	.080 - .082	.074 .076	.045	95	m	
		3	14	.054 .058	.118 - .120	.075 .078	.078 .079	.043	100	m	
											Reviewed by: DDD
											DATE: 7-5-90
Recommended Ranges of Tolerances				.055 ± .003	MAX .125	.080 ± .008	MIN .070	MIN .040	MIN. 80%		

General Insructions:

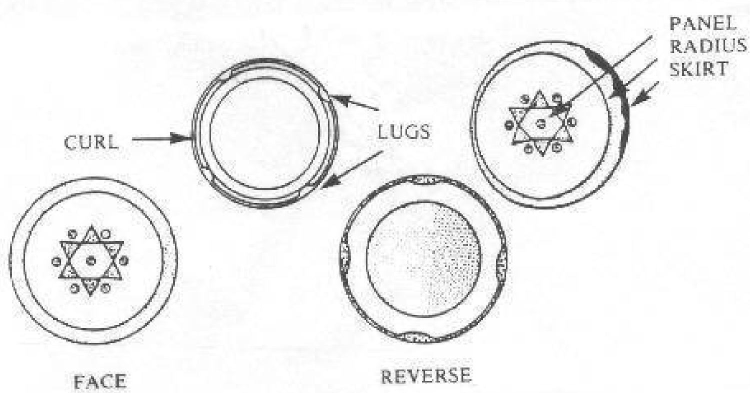
Overlap = Shortest Body Hook (+) Shortest Cover Hook (+) .010 (-) Highest Width

Attachment 18

Parts of a Glass Container



Parts of Metal Vacuum Closures



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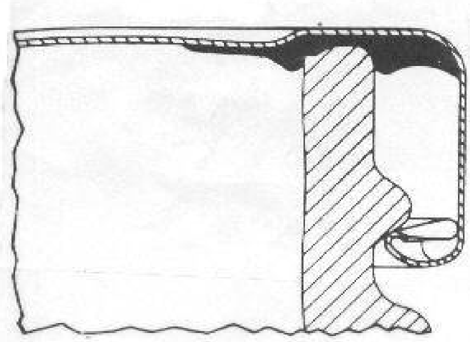
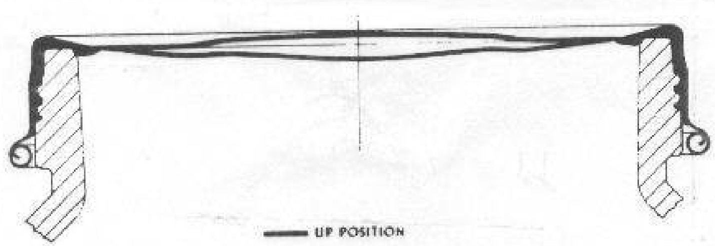
Attachment 19

Vacuum Closures

Regular Lug Type or Twist Cap



Press On -Twist Off Cap



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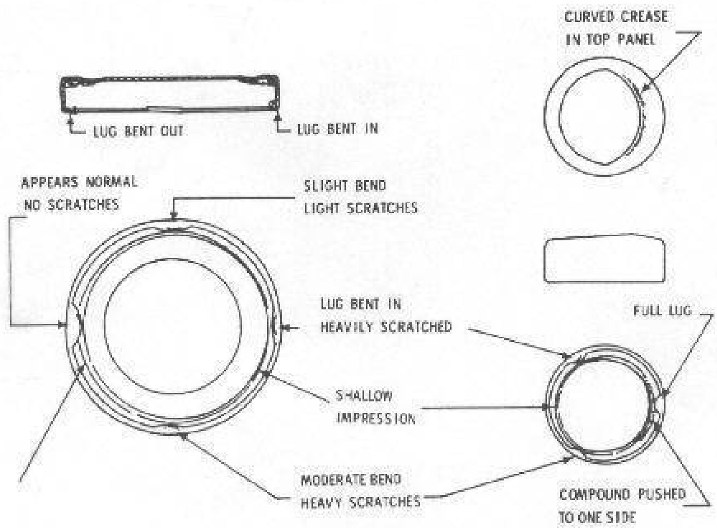
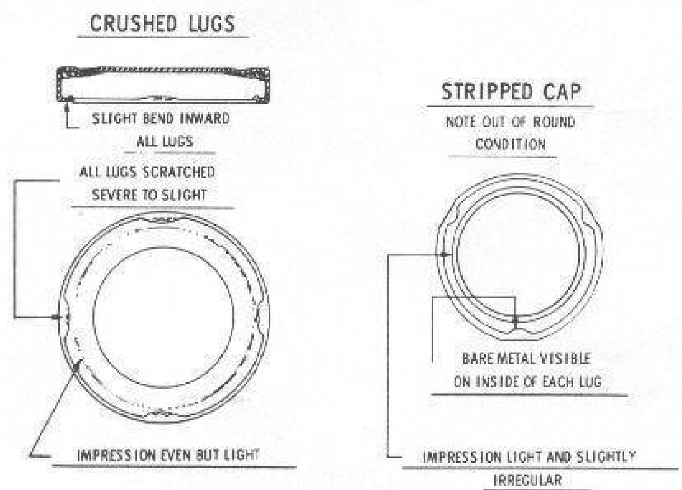
Attachment 20

Glass Container Defects



Typical cocked caps.



Crushed lugs and stripped caps.

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Attachment 21

Security and Pull-Up Test

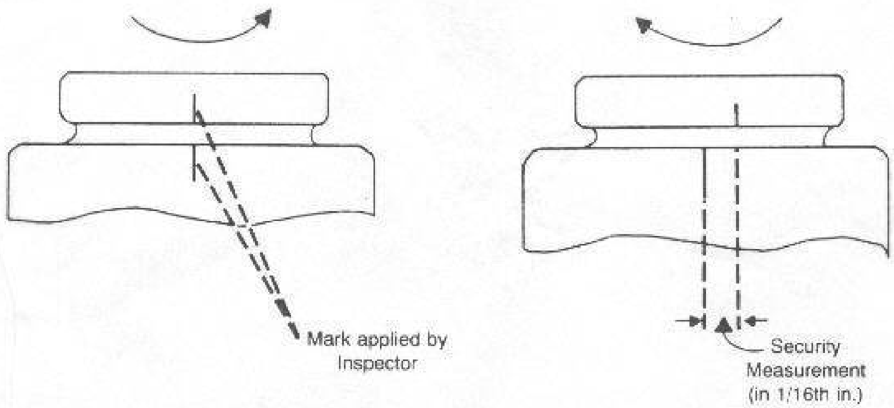
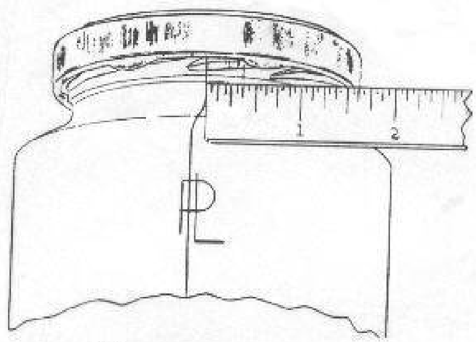


Illustration of security measurement.



Pull-up measurement of +6.

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Attachment 22

PACKAGE EVALUATION RECORD – AT CAPPER

Plant ____________ Line No. ________ Product ____________

Container Size & Mfg. ____________ Closure Size ____________

Date ____________ Code ____________

Time	Type Capper	Product Vac. and IT	Cold Water Vac.	Head Space	Cap Tilt	Pull Up	Sec.	Closure Impressions	Remarks

Signed by (Container Closure Inspt.)

Reviewed by (Management Rep.)

Columnar form for recording glass closure evaluation.

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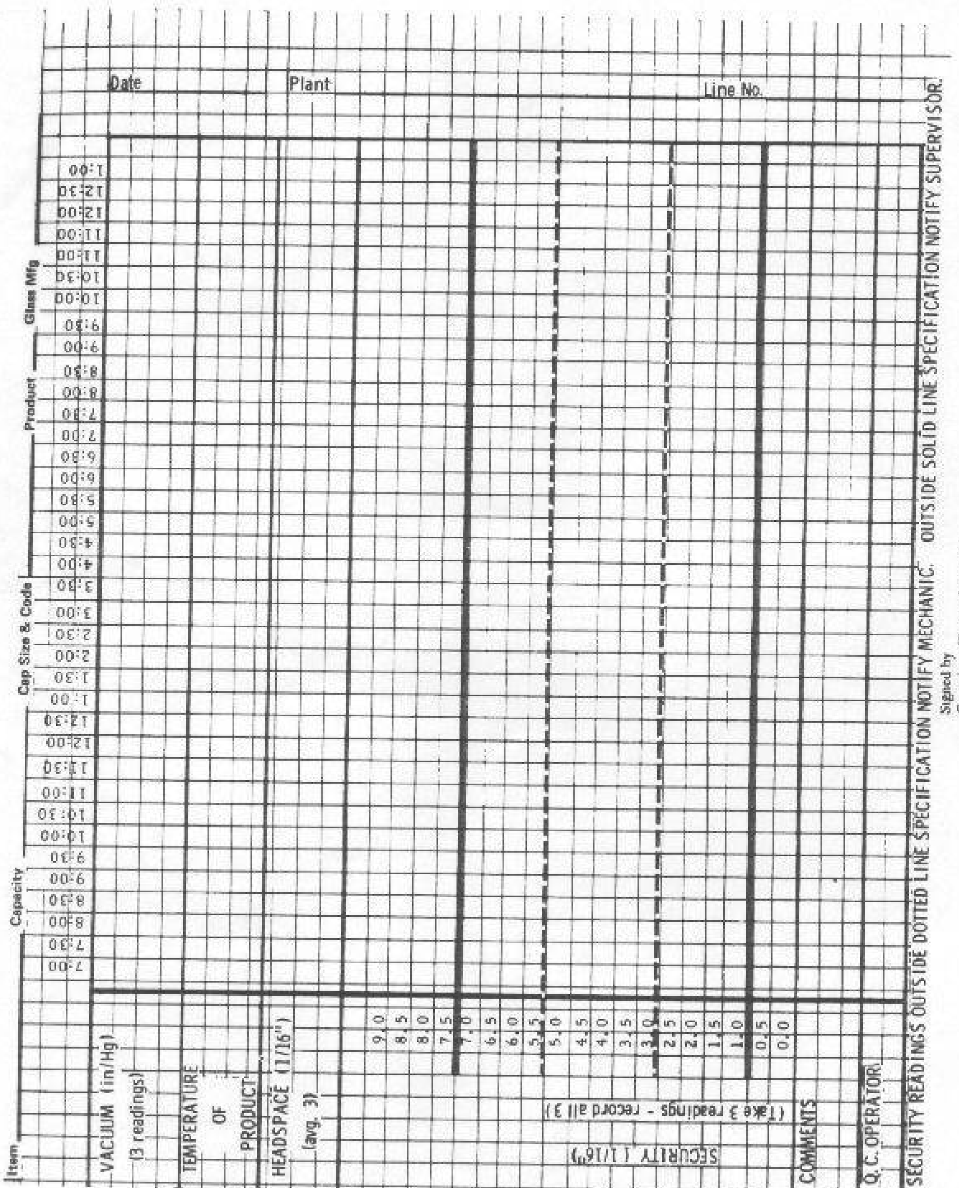
Attachment 23

Statistical Control Chart for Recording Glass Closure Evaluation



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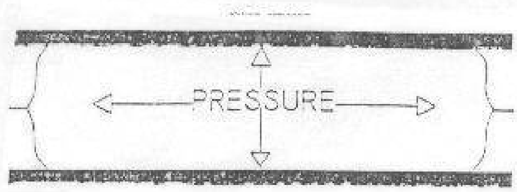
Attachment 23

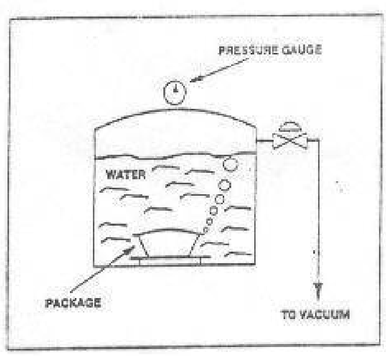
Testing-Fusion Sealed Pouches and Semi-Rigid Containers

Burst Testing

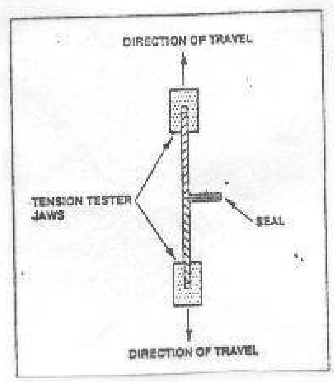


The burst test is a good overall test for seal integrity because it stresses a package uniformity in all directions and identifies the location of the weakest point and the pressure at which it fails.

Bubble or Air Pressure Test



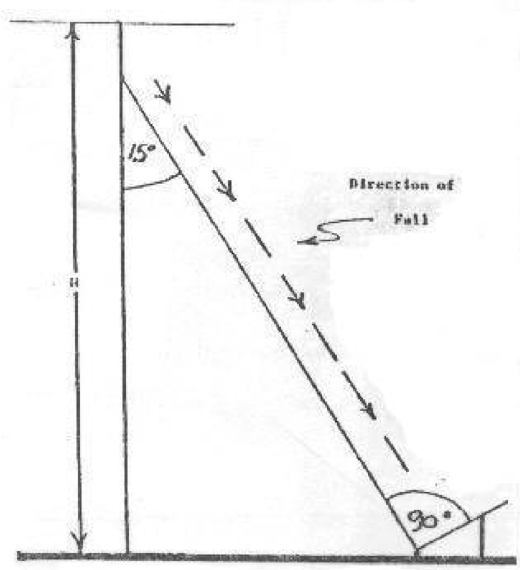
Tensile Test



Attachment 24

USDA Drop Test

Drop Chute Apparatus

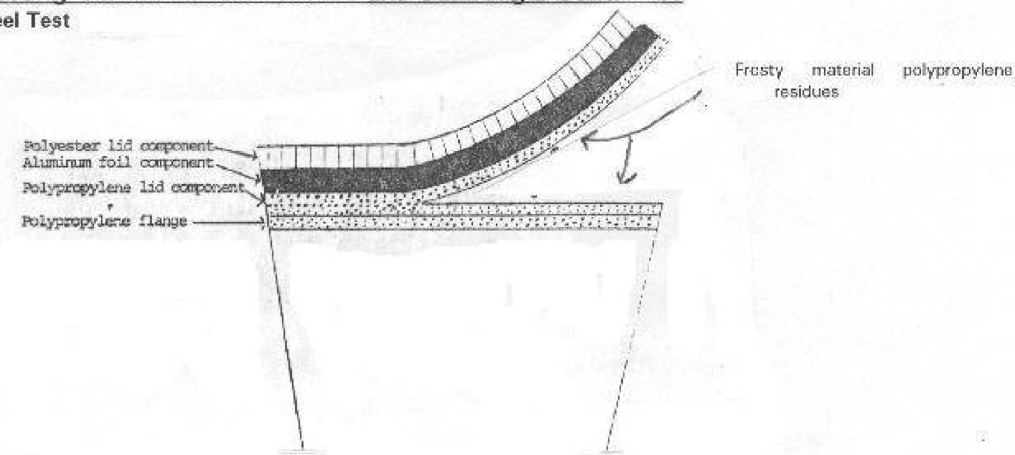


H = Height of drop adjusted for 20 inch pounds by the formula: H = F/0.97W
Where H = height (inches)
F = 20 (inch-pounds)
W = gross weight of container (pounds)

Attachment 25

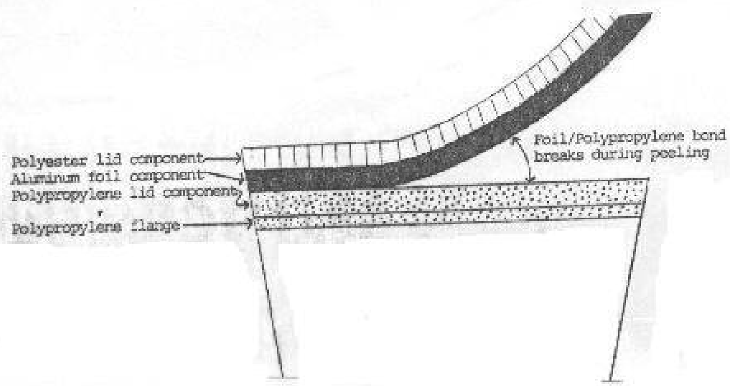
Testing -Fusion Sealed Pouches and Semi-Rigid Containers

Peel Test



The polypropylene sealing layer of lid is fusion sealed to the polypropylene flange of the container. When lid is peeled the polypropylene sealing layer of lid breaks within itself and splits-half of the sealing layer removed with the lid and about half remains on the flange surface. Frosty material on the sealing surface area of the lid and flange after peeling is the polypropylene sealing layer of lid and indicates a well fused area.

Peel Test -Break-Away Seals

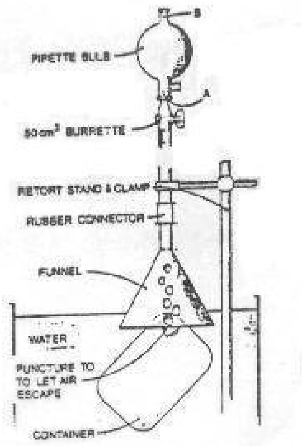


The polypropylene sealing layer of lid is fusion sealed to the polypropylene flange of container. When lid is peeled the propylene sealing layer of lid breaks away from the foil component of lid and remains permanently fused to the container flange. The continuous presence of lid polypropylene residues on the flange indicates a well fused seal.

Attachment 26

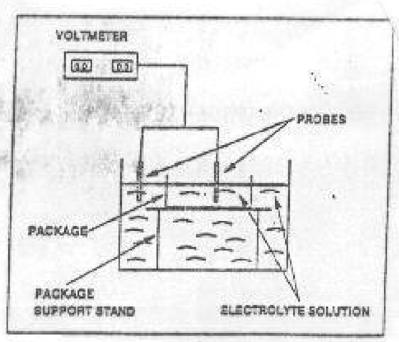
Testing-Fusion Sealed Pouches and Semi-Rigid Containers

The Residual Gas Test

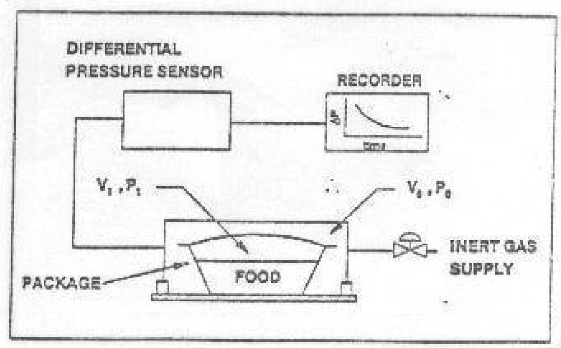


from Rivera et al, (1988) Sealing of retortable containers 1988 polymers, Laminations and Coatings Conference Book 2, TAPPI, Technology Park, Atlanta, GA)

Electroconductivity Test



Differential Pressure (Non-destructive Test)



Attachment 27

U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition

Bacteriological Analytical Manual *Online*

January 2001

Chapter 21A
Examination of Canned Foods

Authors

(Return to Table of Contents)

The incidence of spoilage in canned foods is low, but when it occurs it must be investigated properly. Swollen cans often indicate a spoiled product. During spoilage, cans may progress from normal to flipper, to springer, to soft swell, to hard swell. However, spoilage is not the only cause of abnormal cans. Overfilling, buckling, denting, or closing while cool may also be responsible. Microbial spoilage and hydrogen, produced by the interaction of acids in the food product with the metals of the can, are the principal causes of swelling. High summer temperatures and high altitudes may also increase the degree of swelling. Some microorganisms that grow in canned foods, however, do not produce gas and therefore cause no abnormal appearance of the can; nevertheless, they cause spoilage of the product.

Spoilage is usually caused by growth of microorganisms following leakage or underprocessing. Leakage occurs from can defects, punctures, or rough handling. Contaminated cooling water sometimes leaks to the interior through pinholes or poor seams and introduces bacteria that cause spoilage. A viable mixed microflora of bacterial rods and cocci is indicative of leakage, which may usually be confirmed by can examination. Underprocessing may be caused by undercooking; retort operations that are faulty because of inaccurate or improperly functioning thermometers, gauges, or controls; excessive contamination of the product for which normally adequate processes are insufficient; changes in formulation or handling of the product that result in a more viscous product or tighter packing in the container, with consequent lengthening of the heat penetration time; or, sometimes, accidental bypassing of the retort operation altogether. When the can contains a spoiled product and no viable microorganisms, spoilage may have occurred before processing or the microorganisms causing the spoilage may have died during storage.

Underprocessed and leaking cans are of major concern and both pose potential health hazards. However, before a decision can be made regarding the potential health hazard of a low-acid canned food, certain basic information is necessary. Naturally, if *Clostridium botulinum* (spores, toxin, or both) is found, the hazard is obvious. Intact cans that contain only mesophilic, Gram-positive, sporeforming rods should be considered underprocessed, unless proved otherwise. It must be determined that the can is intact (commercially acceptable seams and no microleaks) and that other factors that may lead to underprocessing, such as drained weight and product formulation, have been evaluated.

The preferred type of tool for can content examination is a bacteriological can opener consisting of a puncturing device at the end of a metal rod mounted with a sliding triangular blade that is held in place by a set screw. The advantage over other types of openers is that it does no damage to the double seam and therefore will not interfere with subsequent seam examination of the can.

Table 1. Useful descriptive terms for canned food analysis.

Exterior can condition	**Internal can condition**
leaker	normal
dented	peeling
rusted	slight, moderate or severe etching
buckled	slight, moderate or severe blackening
paneled	slight, moderate or severe rusting
bulge	mechanical damage

Micro-leak test	**Product odor**	**Product liquor**
packer seam	putrid	cloudy
side panel	acidic	clear
side seam	butyric	foreign
cut code	metallic	frothy
pinhole	sour	
	cheesy	
	fermented	
	musty	
	sweet	
	fecal	
	sulfur	
	off-odor	

Solid product	**Liquid product**	**Pigment**	**Consistency**
digested	cloudy	darkened	slimy
softened	clear	light	fluid
curdled	foreign	changed	viscous
uncooked	frothy		ropy
overcooked			

Flat - a can with both ends concave; it remains in this condition even when the can is brought down sharply on its end on a solid, flat surface.
Flipper - a can that normally appears flat; when brought down sharply on its end on a flat surface, one end flips out. When pressure is applied to this end, it flips in again and the can appears flat.
Springer - a can with one end permanently bulged. When sufficient pressure is applied to this end, it will flip in, but the other end will flip out.
Soft swell - a can bulged at both ends, but not so tightly that the ends cannot be pushed in somewhat with thumb pressure.
Hard swell - a can bulged at both ends, and so tightly that no indentation can be made with thumb pressure. A hard swell will generally "buckle" before the can bursts. Bursting usually occurs at the double seam over the side seam lap, or in the middle of the side seam.

The number of cans examined bacteriologically should be large enough to give reliable results. When the cause of spoilage is clear-cut, culturing 4-6 cans may be adequate, but in some cases it may be necessary to culture 10-50 cans before the cause of spoilage can be determined. On special occasions these procedures may not yield all the required information, and additional tests must be devised to collect the necessary data. Unspoiled cans may be examined bacteriologically to determine the presence of viable but dormant organisms. The procedure is the same as that used for spoiled foods except that the number of cans examined and the quantity of material subcultured must be increased.

A. Equipment and materials

1. Incubators, thermostatically controlled at 30, 35, and 55°C
2. pH meter, potentiometer
3. Microscope, slides, and coverslips
4. Can opener, bacteriological can opener, and can punch, all sterile
5. Petri dishes, sterile
6. Test tubes, sterile
7. Serological pipets, cotton-plugged, sterile
8. Nontapered pipets, cotton-plugged (8 mm tubing), sterile
9. Soap, water, brush, and towels, sterile and nonsterile
10. Indelible ink marking pen
11. Diamond point pen for marking cans
12. Examination pans (Pyrex or enamel baking pans)

B. Media and reagents

1. Bromcresol purple (BCP) dextrose broth (M27)
2. Chopped liver broth (M38) or cooked meat medium (CMM) (M42)
3. Malt extract broth (M94)
4. Liver-veal agar (without egg yolk) (LVA) (M83)
5. Acid broth (M4)
6. Nutrient agar (NA) (M112)
7. Methylene blue stain (R45), crystal violet (R16), or Gram stain (R32)
8. Sabouraud's dextrose agar (SAB) (M133)
9. 4% Iodine in 70% ethanol (R18)

C. Can preparation

Remove labels. With marking pen, transfer subnumbers to side of can to aid in correlating findings with code. Mark labels so that they may be replaced in their original position on the can to help locate defects indicated by stains on label. Separate all cans by code numbers and record size of container, code, product, condition, evidence of leakage, pinholes or rusting, dents, buckling or other abnormality, and all identifying marks on label. Classify each can according to the descriptive terms in Table 1. Before observing cans for classification, make sure cans are at room temperature.

D. Examination of can and contents

Classification of cans. **NOTE**: Cans must be at room temperature for classification.

1. **Sampling can contents**

   a. **Swollen cans**. Immediately analyze springers, swells, and a representative number (at least 6, if available) of flat and flipper cans. Retain examples of each, if available, when reserve portion must be held. Place remaining flat and flipper cans (excluding those held in reserve) in incubator at 35°C. Examine at frequent intervals for 14 days. When abnormal can or one becoming increasingly swollen is found, make note of it. When can becomes a hard swell or when swelling no longer progresses, culture sampled contents, examine for preformed toxin of *C. botulinum* if microscopic examination shows typical *C. botulinum* organisms or Gram-positive rods, and perform remaining steps of canned food examination.

b. **Flat and flipper cans**. Place cans (excluding those held in reserve) in incubator at 35°C. Observe cans for progressive swelling at frequent intervals for 14 days. When swelling occurs, follow directions in l-a, above. After 14 days remove flat and flipper cans from incubator and test at least 6, if available. (It is not necessary to analyze all normal cans.) Do not incubate cans at temperatures above 35°C. After incubation, bring cans back to room temperature before classifying them.

2. **Opening the can**. Open can in an environment that is as aseptic as possible. Use of vertical laminar flow hood is recommended.

   a. **Hard swells, soft swells, and springers**. Chill hard swells in refrigerator before opening. Scrub entire uncoded end and adjacent sides of can using abrasive cleanser, cold water, and a brush, steel wool, or abrasive pad. Rinse and dry with clean sterile towel. Sanitize can end to be opened with 4% iodine in 70% ethanol for 30 min and wipe off with sterile towel. **DO NOT FLAME**. Badly swollen cans may spray out a portion of the contents, which may be toxic. Take some precaution to guard against this hazard, e.g., cover can with sterile towel or invert sterile funnel over can. Sterilize can opener by flaming until it is almost red, or use separate presterilized can openers, one for each can. At the time a swollen can is punctured, test for headspace gas, using a qualitative test or the gas-liquid chromatography method described below. For a qualitative test, hold mouth of sterile test tube at puncture site to capture some escaping gas, or use can-puncturing press to capture some escaping gas in a syringe. Flip mouth of tube to flame of Bunsen burner. A slight explosion indicates presence of hydrogen. Immediately turn tube upright and pour in a small amount of lime water. A white precipitate indicates presence of CO_2. Make opening in sterilized end of can large enough to permit removal of sample.

   b. **Flipper and flat cans**. Scrub entire uncoded end and adjacent sides of can using abrasive cleanser, warm water, and a brush, steel wool, or abrasive pad. Rinse and dry with clean sterile towel. Gently shake cans to mix contents before sanitizing. Flood end of can with iodine-ethanol solution and let stand at least 15 min. Wipe off iodine mixture with clean sterile towel. Ensure sterility of can end by flaming with burner in a hood until iodine-ethanol solution is burned off, end of can becomes discolored from flame, and heat causes metal to expand. Be careful not to inhale iodine fumes while burning off can end. Sterilize can opener by flaming until it is almost red, or use separate presterilized can openers for each can. Make opening in sterilized end of can large enough to permit removal of sample.

3. **Removal of material for testing**. Remove large enough portions from center of can to inoculate required culture media. Use sterile pipets, either regular or wide-mouthed. Transfer solid pieces with sterile spatulas or other sterile devices. Always use safety devices

for pipetting. After removal of inocula, aseptically transfer at least 30 ml or, if less is available, all remaining contents of cans to sterile closed containers, and refrigerate at about 4°C. Use this material for repeat examination if needed and for possible toxicity tests. This is the reserve sample. Unless circumstances dictate otherwise, analyze normal cans submitted with sample organoleptically and physically (**see** 5-b, below), including pH determination and seam teardown and evaluation. Simply and completely describe product appearance, consistency, and odor on worksheet. If analyst is not familiar with decomposition odors of canned food, another analyst, preferably one familiar with decomposition odors, should confirm this organoleptic evaluation. In describing the product in the can, include such things as low liquid level (state how low), evidence of compaction, if apparent, and any other characteristics that do not appear normal. Describe internal and external condition of can, including evidence of leakage, etching, corrosion, etc.

4. **Physical examination**. Perform net weight determinations on a representative number of cans examined (normal and abnormal). Determine drained weight, vacuum, and headspace on a representative number of normal-appearing and abnormal cans (1). Examine metal container integrity of a representative number of normal cans and all abnormal cans that are not too badly buckled for this purpose (**see** Chapter 22). **CAUTION**: Always use care when handling the product, even apparently normal cans, because botulinal toxin may be present.

5. **Cultural examination of low-acid food (pH greater than 4.6)**. If there is any question as to product pH range, determine pH of a representative number of normal cans before proceeding. From each container, inoculate 4 tubes of chopped liver broth or cooked meat medium previously heated to 100°C (boiling) and rapidly cooled to room temperature; also inoculate 4 tubes of bromcresol purple dextrose broth. Inoculate each tube with 1-2 ml of product liquid or product-water mixture, or 1-2 g of solid material. Incubate as in Table 2.

Table 2. Incubation times for various media for examination of low acid foods (pH > 4.6).

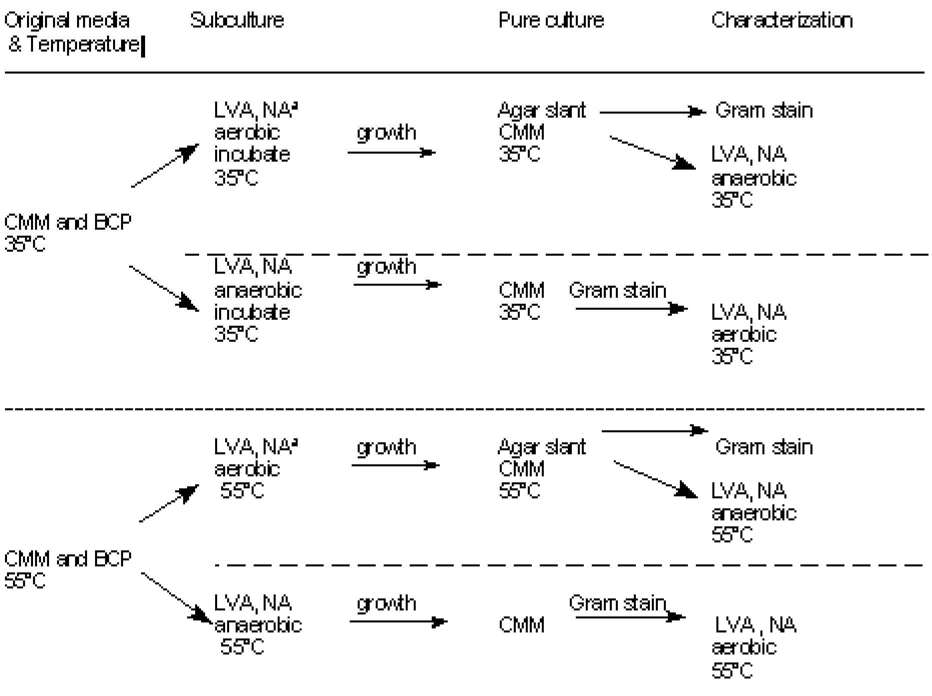
Medium	No. of tubes	Temp. (°C)	Time of incubation (h)
Chopped liver (cooked meat)	2	35	96-120
Chopped liver (cooked meat)	2	55	24-72
Bromcresol purple dextrose broth	2	55	24-48
Bromcresol purple dextrose broth	2	35	96-120

After culturing and removing reserve sample, test material from cans (other than those classified as flat) for preformed toxins of *C. botulinum* when appropriate, as described in Chapter 17.

a. **Microscopic examination**. Prepare direct smears from contents of each can after culturing. Dry, fix, and stain with methylene blue, crystal violet, or Gram stain. If product is oily, add xylene to a warm, fixed film, using a dropper; rinse and stain. If product washes off slide during preparation, examine contents as wet mount or hanging drop, or prepare suspension of test material in drop of chopped liver broth before drying. Check liver broth before use to be sure no bacteria are present to contribute to the smear. Examine under microscope; record types of bacteria seen and estimate total number per field.

b. **Physical and organoleptic examination of can contents**. After removing reserve sample from can, determine pH of remainder, using pH meter. **DO NOT USE pH PAPER**. Pour contents of cans into examination pans. Examine for odor, color, consistency, texture, and overall quality. **DO NOT TASTE THE PRODUCT**. Examine can lining for blackening, detinning, and pitting.

Table 3.Schematic diagram of culture procedure for low-acid canned foods

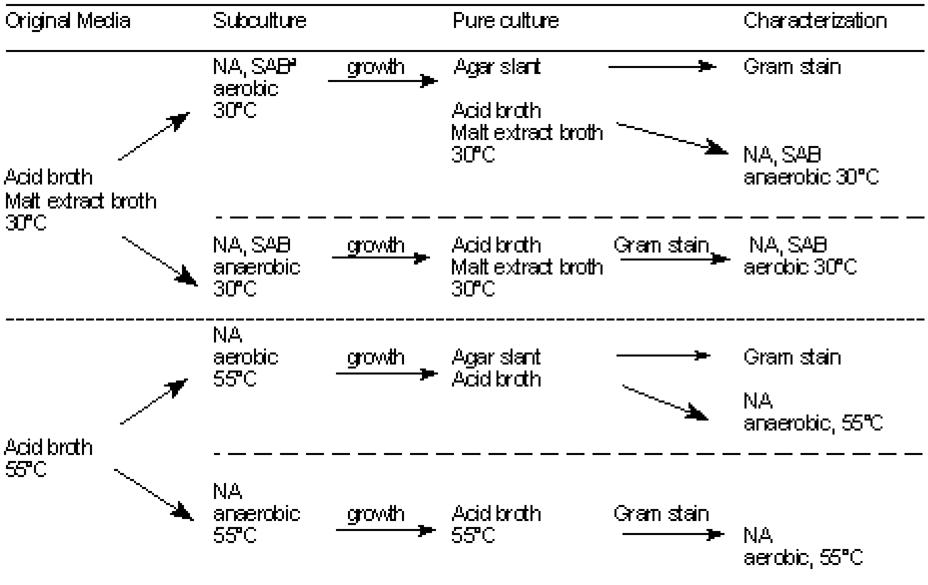


[a] LVA, liver-veal agar; NA, nutrient agar; CMM, cooked meat medium; BCP, bromcresol purple dextrose broth.

Table 4. Incubation of acid broth and malt extract broth used for acid foods (pH 4.6)

Medium	No. of tubes	Temp. (°C)	Time of incubation (h)
Acid broth	2	55	48
Acid broth	2	30	96
Malt extract broth	2	30	96

Table 5. Pure culture scheme for acid foods (pH 4.6).



[a] NA, nutrient agar; SAB, Sabouraud's dextrose agar.

E. Cultural findings in cooked meat medium (CMM) and bromcresol purple dextrose broth (BCP)

Check incubated medium for growth at frequent intervals up to maximum time of incubation (Table 2). If there is no growth in either medium, report and discard. At time growth is noted streak 2 plates of liver-veal agar (without egg yolk) or nutrient agar from each positive tube. Incubate one plate aerobically and one anaerobically, as in schematic diagram (Table 3). Reincubate CMM at 35°C for maximum of 5 days for use in future toxin studies. Pick representatives of all morphologically different types of colonies into CMM and incubate for appropriate time, i.e., when growth is sufficient for subculture. Dispel oxygen from CMM broths to be used for anaerobes but not from those to be used for aerobes. After obtaining pure isolates, store cultures to maintain viability.

1. **If mixed microflora is found only in BCP**, report morphological types. If rods are included among mixed microflora in CMM, test CMM for toxin, as described in Chapter 17. If Gram-positive or Gram-variable rods typical of either *Bacillus* or *Clostridium* organisms are found in the absence of other morphological types, search to determine whether spores are present. In some cases, old vegetative cells may appear to be Gram-negative and should be treated as if they are Gram-positive. Test culture for toxin according to Chapter 17.

Table 6. Classification of food products according to acidity

Low acid--pH greater than 4.6	**Acid pH 4.6 and below**
Meats	Tomatoes
Seafoods	Pears
Milk	Pineapple

Meat and vegetable Mixtures and "specialties" Spaghetti Soups	Other fruit Sauerkraut
Vegetables Asparagus Beets Pumpkin Green beans Corn Lima beans	Pickles Berries Citrus Rhubarb

Table 7. Spoilage microorganisms that cause high and low acidity in various vegetables and fruits

Spoilage type	pH groups	Examples
Thermophilic		
Flat-sour	$\geq$5.3	Corn, peas
Thermophilic[a]	$\geq$4.8	Spinach, corn
Sulfide spoilage[a]	$\geq$5.3	Corn, peas
Mesophilic		
Putrefactive anaerobes[a]	$\geq$4.8	Corn, asparagus
Butyric anaerobes	$\geq$4.0	Tomatoes, peas
Aciduric flat-sour[a]	$\geq$4.2	Tomato juice
Lactobacilli	4.5-3.7	Fruits
Yeasts	$\leq$3.7	Fruits
Molds	$\leq$3.7	Fruits

[a] The responsible organisms are bacterial sporeformers.

Table 8. Spoilage manifestations in low-acid products

Group of organisms	Classification	Manifestations
Flat-sour	Can flat	Possible loss of vacuum on storage
	Product	Appearance not usually altered; pH markedly lowered, sour; may have slightly abnormal odor; sometimes cloudy liquor
Thermophilic anaerobe	Can swells	May burst
	Product	Fermented, sour, cheesy or butyric odor

Sulfide spoilage	Can flat	H_2S gas absorbed by product
	Product	Usually blackened; rotten egg odor
Putrefactive anaerobe	Can swells	May burst
	Product	May be partially digested; pH slightly above normal; typical putrid odor
Aerobic sporeformers	Can flat or swollen	Usually no swelling, except in cured meats when nitrate and sugar present; coagulated evaporated milk, black beets

Table 9. Spoilage manifestations in acid products

Type of organism	Classification	Manifestation
Bacillus thermoacidurans (flat, sour tomato juice)	Can flat	Little change in vacuum
	Product	Slight pH change; off-odor
Butyric anaerobes (tomatoes and tomato juice)	Can swells	May burst
	Product	Fermented, butyric odor
Nonsporeformers (mostly lactic types)	Can swells	Usually burst, but swelling may be arrested
	Product	Acid odor

Table 10. Laboratory diagnosis of bacterial spoilage

	Underprocessed	Leakage
Can	Flat or swelled; seams generally normal	Swelled; may show normal defects[(a)]
Product appearance	Sloppy or fermented	Frothy fermentation; viscous
odor	Normal, sour or putrid, but generally consistent from can to can	Sour, fecal; generally varying from can to can
pH	Usually fairly constant	Wide variation
Microscopic and cultural	Cultures show sporeforming rods only	Mixed cultures, generally rods and cocci; only at usual temperatures
	Growth at 35 and/or 55°C. May be characteristic on special growth media, e.g., acid agar for tomato juice. If product misses retort completely, rods, cocci,yeast or molds, or any combination of these may be present.	
History	Spoilage usually confined to certain	Spoilage scattered

	portions of pack	
	In acid products, diagnosis may be less clearly defined; similar organisms may be involved in understerilization and leakage.	

[a] Leakage may be due not to can defects but to other factors, such as contamination of cooling water or rough handling, e.g., can unscramblers, rough conveyor system.

Table 11. pH range of a few selected commercially canned foods

Food	pH range	Food	pH range
Apples, juice	3.3 - 3.5	Jam, fruit	3.5 - 4.0
Apples, whole	3.4 - 3.5	Jellies, fruit	3.0 - 3.5
Asparagus, green	5.0 - 5.8	Lemon juice	2.2 - 2.6
Beans		Lemons	2.2 - 2.4
Baked	4.8 - 5.5	Lime juice	2.2 - 2.4
Green	4.9 - 5.5	Loganberries	2.7 - 3.5
Lima	5.4 - 6.3	Mackerel	5.9 - 6.2
Soy	6.0 - 6.6	**Milk**	
Beans with pork	5.1 - 5.8	Cow, whole	6.4 - 6.8
Beef, corned, hash	5.5 - 6.0	Evaporated	5.9 - 6.3
Beets, whole	4.9 - 5.8	Molasses	5.0 - 5.4
Blackberries	3.0 - 4.2	Mushroom	6.0 - 6.5
Blueberries	3.2 - 3.6	Olives, ripe	5.9 - 7.3
Boysenberries	3.0 - 3.3	Orange juice	3.0 - 4.0
Bread		Oysters	6.3 - 6.7
White	5.0 - 6.0	Peaches	3.4 - 4.2
Date and nut	5.1 - 5.6	Pears (Bartlett)	3.8 - 4.6
Broccoli	5.2 - 6.0	Peas	5.6 - 6.5
Carrot juice	5.2 - 5.8	**Pickles**	
Carrots, chopped	5.3 - 5.6	Dill	2.6 - 3.8
Cheese		Sour	3.0 - 3.5
Parmesan	5.2 - 5.3	Sweet	2.5 - 3.0
Roquefort	4.7 - 4.8	Pimento	4.3 - 4.9
Cherry juice	3.4 - 3.6	**Pineapple**	
Chicken	6.2 - 6.4	Crushed	3.2 - 4.0
Chicken with noodles	6.2 - 6.7	Juice	3.4 - 3.7

Chop suey	5.4 - 5.6	Sliced	3.5 - 4.1
Cider	2.9 - 3.3	Plums	2.8 - 3.0
Clams	5.9 - 7.1	Potato salad	3.9 - 4.6
Cod fish	6.0 - 6.1	**Potatoes**	
Corn		Mashed	5.1
Cream style	5.9 - 6.5	White, whole	5.4 - 5.9
On-the-cob	6.1 - 6.8	Prune juice	3.7 - 4.3
Whole grain		Pumpkin	5.2 - 5.5
Brine-packed		Raspberries	2.9 - 3.7
Vacuum-packed	6.0 - 6.4	Rhubarb	2.9 - 3.3
Crab apples, spiced	3.3 - 3.7	Salmon	6.1 - 6.5
Cranberry		Sardines	5.7 - 6.6
Juice	2.5 - 2.7	Sauerkraut	3.1 - 3.7
Sauce	2.3	Juice	3.3 - 3.4
Currant juice	3.0	Shrimp	6.8 - 7.0
Dates	6.2 - 6.4	**Soups**	
Duck	6.0 - 6.1	Bean	5.7 - 5.8
Figs	4.9 - 5.0	Beef broth	6.0 - 6.2
Frankfurters	6.2 - 6.2	Chicken noodle	5.5 - 6.5
Fruit cocktail	3.6 - 4.0	Clam chowder	5.6 - 5.9
Gooseberries	2.8 - 3.1	Duck	5.0 - 5.7
Grapefruit		Mushroom	6.3 - 6.7
Juice	2.9 - 3.4	Noodle	5.6 - 5.8
Pulp	3.4	Oyster	6.5 - 6.9
Sections	3.0 - 3.5	Pea	5.7 - 6.2
Grapes	3.5 - 4.5	Spinach	4.8 - 5.8
Ham, spiced	6.0 - 6.3	Squash	5.0 - 5.8
Hominy, lye	6.9 - 7.9	Tomato	4.2 - 5.2
Huckleberries	2.8 - 2.9	Turtle	5.2 - 5.3
		Vegetable	4.7 - 5.6
Strawberries	3.0 - 3.9	**Miscellaneous products**	
Sweet potatoes	5.3 - 5.6	Beers	4.0 - 5.0
Tomato juice	3.9 - 4.4	Ginger ale	2.0 - 4.0
Tomatoes	4.1 - 4.4	**Human**	
Tuna	5.9 - 6.1	Blood plasma	7.3 - 7.5
Turnip greens	5.4 - 5.6	Duodenal contents	4.8 - 8.2
Vegetable juice	3.9 - 4.3	Feces	4.6 - 8.4
Vegetables, mixed	5.4 - 5.6	Gastric contents	1.0 - 3.0

Vinegar	2.4 - 3.4	Milk	6.6 - 7.6
Youngberries	3.0 - 3.7	Saliva	6.0 - 7.6
		Spinal fluid	7.3 - 7.5
		Urine	4.8 - 8.4
		Magnesia, milk of	10.0 -10.5
		Water	
		Distilled, CO_2	6.8 - 7.0
		Mineral	6.2 - 9.4
		Sea	8.0 - 8.4
		Wine	2.3 - 3.8

2. **If no toxin is present**, send pure cultures for evaluation of heat resistance to Cincinnati District Office, FDA, 1141 Central Parkway, Cincinnati, OH 45202, if cultures meet the following criteria:

   - Cultures come from intact cans that are free of leaks and have commercially acceptable seams. (Can seams of both ends of can must be measured; visual examination alone is not sufficient.)

   - Two or more tubes are positive and contain similar morphological types.

3. **Examination of acid foods (pH 4.6 and below) by cultivation**. From each can, inoculate 4 tubes of acid broth and 2 tubes of malt extract broth with 1-2 ml or 1-2 g of product, using the same procedures as for low-acid foods, and incubate as in Table 4. Record presence or absence of growth in each tube, and from those that show evidence of growth, make smears and stain. Report types of organisms seen. Pure cultures may be isolated as shown in Table 5.

F. Interpretation of results (**see** Tables 6-11)

1. The presence of only sporeforming bacteria, which grow at 35°C, in cans with satisfactory seams and no microleaks indicates underprocessing if their heat resistance is equal to or less than that of C. *botulinum*. Spoilage by thermophilic anaerobes such as *C. thermobutylicum* may be indicated by gas in cooked meat at 55°C and a cheesy odor. Spoilage by *C. botulinum*, *C. sporogenes*, or *C. perfringens* may be indicated in cooked meat at 35°C by gas and a putrid odor; rods, spores, and clostridial forms may be seen on microscopic examination. Always test supernatants of such cultures for botulinal toxin even if no toxin was found in the product itself, since viable botulinal spores in canned foods indicate a potential public health hazard, requiring recall of all cans bearing the same code. Spoilage by mesophilic organisms such as *Bacillus thermoacidurans* or *B. coagulans* and/or thermophilic organisms such as *B. stearothermophilus*, which are flat-sour types, may be indicated by acid production in BCP tubes at 35 and/or 55°C in high-acid or low-acid canned foods. No definitive conclusions may be drawn from inspection of cultures in broth if the food produced an initial turbidity on inoculation. Presence or absence of growth in this case must be determined by subculturing.

2. Spoilage in acid products is usually caused by nonsporeforming lactobacilli and yeasts. Cans of spoiled tomatoes and tomato juice remain flat but the products have an off-odor, with or without lowered pH, due to aerobic, mesophilic, and thermophilic sporeformers. Spoilage of this type is an exception to the general rule that products below pH 4.6 are immune to spoilage by sporeformers. Many canned foods contain thermophiles which do not grow under normal storage conditions, but which grow and cause spoilage when the product is subjected to elevated temperatures (50-55°C). *B. thermoacidurans* and *B. stearothermophilus* are thermophiles responsible for flat-sour decomposition in acid and low-acid foods, respectively. Incubation at 55°C will not cause a change in the appearance of the can, but the product has an off-odor with or without a lowered pH. Spoilage encountered in products such as tomatoes, pears, figs, and pineapples is occasionally caused by *C. pasteurianum*, a sporeforming anaerobe which produces gas and a butyric acid odor. *C. thermosaccolyticum* is a thermophilic anaerobe which causes swelling of the can and a cheesy odor of the product. Cans which bypass the retort without heat processing usually are contaminated with nonsporeformers as well as sporeformers, a spoilage characteristic similar to that resulting from leakage.

3. A mixed microflora of viable bacterial rods and cocci usually indicates leakage. Can examination may not substantiate the bacteriological findings, but leakage at some time in the past must be presumed. Alternatively, the cans may have missed the retort altogether, in which case a high rate of swells would also be expected.

4. A mixed microflora in the product, as shown by direct smear, in which there are large numbers of bacteria visible but no growth in the cultures, may indicate precanning spoilage. This results from bacterial growth in the product before canning. The product may be abnormal in pH, odor, and appearance.

5. If no evidence of microbial growth can be found in swelled cans, the swelling may be due to development of hydrogen by chemical action of contents on container interiors. The proportion of hydrogen varies with the length and condition of storage. Thermophilic anaerobes produce gas, and since cells disintegrate rapidly after growth, it is possible to confuse thermophilic spoilage with hydrogen swells. Chemical breakdown of the product may result in evolution of carbon dioxide. This is particularly true of concentrated products containing sugar and some acid, such as tomato paste, molasses, mincemeats, and highly sugared fruits. The reaction is accelerated at elevated temperatures.

6. Any organisms isolated from normal cans that have obvious vacuum and normal product but no organisms in the direct smear should be suspected as being a laboratory contaminant. To confirm, aseptically inoculate growing organism into another normal can, solder the hole closed, and incubate 14 days at 35°C. If any swelling of container or product changes occur, the organism was probably not in the original sample. If can remains flat, open it aseptically and subculture as previously described. If a culture of the same organism is recovered and the product is normal, consider the product commercially sterile since the organism does not grow under normal conditions of storage and distribution.

Headspace Gas Determination by Gas-Liquid Chromatography

Nitrogen, the principal gas normally present in canned foods during storage, is associated with lesser quantities of carbon dioxide and hydrogen. Oxygen included in the container at the time of closure is initially dissipated by container corrosion and/or product oxidation. Departure from this normal pattern can serve as an important indication of changes within the container, since the composition of headspace gases may distinguish whether bacterial spoilage, container corrosion, or product deterioration is the cause of swollen cans (2). Use of the gas chromatograph for analyzing headspace gases of abnormal canned foods has eliminated the possibility of false-negative tests for different gases. It has also allowed the analyst to determine the percentage of each gas present, no matter what the mixture is. By knowing these percentages, the analyst can be alerted to possible can deterioration problems or bacterial spoilage. A rapid gas-liquid chromatographic procedure is presented here for the determination of carbon dioxide, hydrogen, oxygen, nitrogen, and hydrogen sulfide from the headspace of abnormal canned foods.

The analysis of 2352 abnormal canned foods, composed of 288 different products by a gas-liquid chromatography showed viable microorganisms in 256 cans (3). Analysis of this data showed that greater than 10 percent carbon dioxide in the headspace gas was indicative of microbial growth. Although greater than 10 percent carbon dioxide is found in a container, long periods of storage at normal temperatures can result in autosterilization and absence of viable microorganisms. Carbon dioxide my be produced in sufficient quantities to swell the container. Storage at elevated temperatures accelerates this action. Hydrogen can be produced in cans when the food contents react chemically with the metal of the seam (3).

A. Equipment and materials

1. Fisher Model 1200 Gas Partitioner, with dual thermal conductivity cells and dual in-line columns. Column No. 1 is 6-1/2 ft x 1/8 inch, aluminum packed, with 80-100 mesh Columpak™ PQ. Column No. 2 is 11 ft x 3/16 inch, aluminum packed, with 60-80 mesh molecular sieve 13X (Fig. 1).

   NOTE: Other gas chromatograph instruments equipped with the appropriate columns, carrier gas, detector and recorder or integrator may also be suitable for this analysis.

   Operating conditions: column temperature, 75°C; attenuation, 64/256; carrier gas, argon, with in-let pressure of 40 psig; flow rate, 26 ml/min through gas partitioner and 5 ml/min through flush line; bridge current, 125 mA; column mode, 1 & 2; temperature mode, column; injector temperature, off.

   NOTE: **Installation of flush system**. Injection of gas samples through either sample out port or septum injection port may lead to damaged filaments in detector and excessive accumulation of moisture on columns due to bypassing the sample drying tube. To avoid this, make all injections in the sample in port. To avoid cross-contamination, install a flush line off the main argon line (Fig. 2), and flush sample loop between injections.

2. Strip chart recorder, with full scale deflection and speed set at 1 cm/min, 1 mv

3. Can puncturing press (Fig. 3)

4. Sterile stainless steel gas piercers (Fig. 4)

5. Miniature inert valve, with 3-way stopcock and female luer on left side (Popper & Sons, Inc., 300 Denton Ave., New Hyde Park, NY 11040), or equivalent (Fig. 5)

6. Plastic disposable 10-50 ml syringes, with restraining attachment for maximum volume control (Fig. 6). Syringes may be reused.

7. Gas chromatograph and caps, for capping syringes (Alltech Associates, Inc., 202 Campus Drive, Arlington Heights, IL 60004), or equivalent (Fig. 6)

8. Beaker, 1 liter, glass or metal

9. Plastic gas tubing, 3 ft x 1/8 inch id, for exhaust tubing

10. Soap solution, for detecting gas leaks ("SNOOP" Nuclear Products Co., 15635 Saranac Road, Cleveland, OH 44110), or equivalent

11. Small pinch clamp, to weigh down exhaust tubing in beaker

12. Nupro Valve, flow-regulating valve for flush line, 1/8 inch, Angle Pattern Brass (Alltech), or equivalent (Fig. 2)

13. Silicone rubber tubing, seamless, red, autoclavable, 1/8 inch bore x 3/16 inch wall thickness (Arthur H. Thomas Co., Vine St. at 3rd, Philadelphia, PA), or equivalent

B. Calibration of gas chromatograph

Calibration gases of known proportions are commercially available. Construct calibration curves from analysis of pure gases and at least 2-3 different percentage mixtures of gases. Plot linear graph of various known concentrations of each gas as peak height (mm) vs percent gas (Fig. 7).

C. Preparation of materials

Prepare gas collection apparatus as illustrated in Figs. 8 and 9. Adjust height of gas collection apparatus to height of can to be examined. Attach male terminal of miniature valve to female Luer-Lok terminal mounted on top of brass block on can-puncturing press. Attach one end of gas exhaust tubing to female terminal of miniature valve. Attach small pinch clamp to other end of gas exhaust tubing and place in beaker partially filled with water. Attach disposable syringe to other female Luer-Lok terminal on miniature valve. Turn 2-way plug so that gas entering from piercer will flow toward disposable syringe. Place sterile gas piercer in position on male terminal mounted on bottom of brass block on can-puncturing press.

D. Collection of headspace gas

Place can under gas press (cans to be cultured should first be cleaned and sterilized). Lower handle until gas piercer punctures can and seals. Hold in position until adequate volume of gas has been collected (minimum of 5 ml); then turn 2-way plug to release excess gas through exhaust tubing. Release handle, remove syringe, and cap immediately. Identify syringe appropriately.

E. Injection of gas into gas chromatograph

Turn on gas chromatograph and recorder. Let stabilize for about 2 h. Make sure flush line is attached and gas sampling valve is open to allow flushing of sample loop. Turn on chart drive on recorder. Remove flush line, uncap, and immediately attach syringe to Sample-In Injection Port. Inject 5-10 ml of gas and immediately close gas sampling valve. Remove syringe and cap. Reattach flush line onto Sample-In Port and open gas sample valve to allow flushing of system before next injection. Observe chromatogram and switch attenuation from 64 to 256 after carbon dioxide peak has been recorded and returned back to base line. This allows hydrogen peak to be retained on scale. After hydrogen peak returns to base line, switch attenuation back to 64. After instrument has separated gases (about 6 min), determine retention time and peak height for each gas recovered from unknown sample and percent determined from standard graph by comparing retention times and peak heights with known gases, usually associated with headspace gases from abnormal canned food products. Mount chromatogram on mounting paper and identify properly as in Fig. 10. For each sample examined, inject control gases for each type of headspace gas recovered.

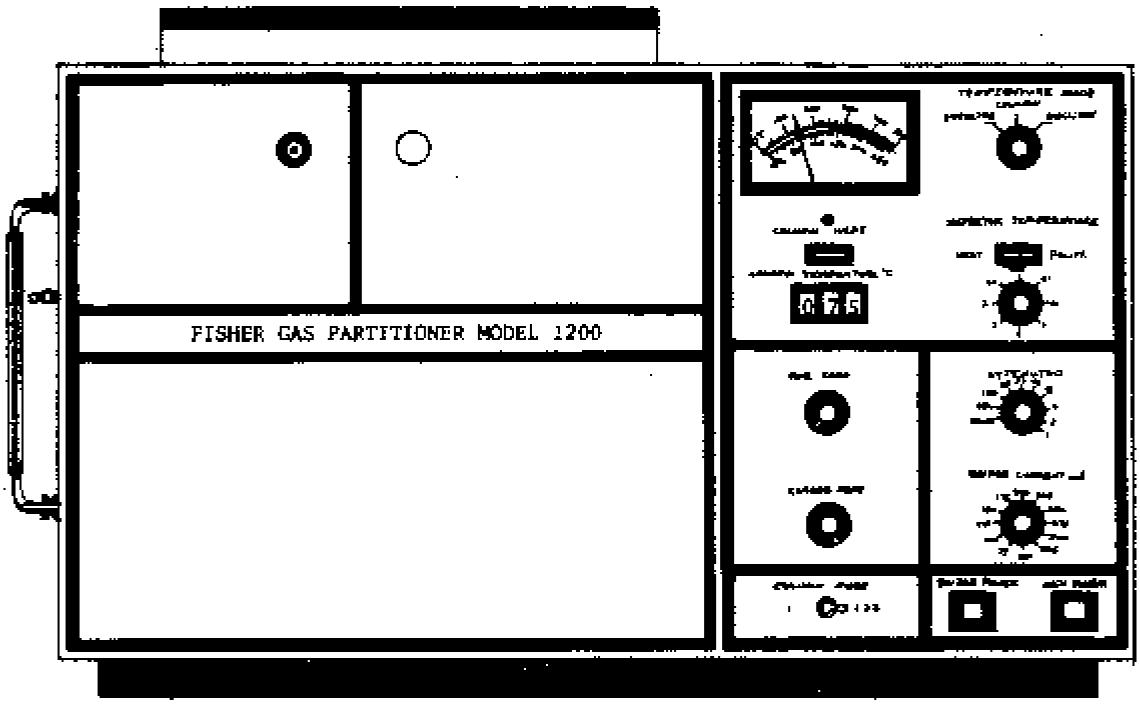


Figure 1. Fisher Model 1200 gas partitioner.

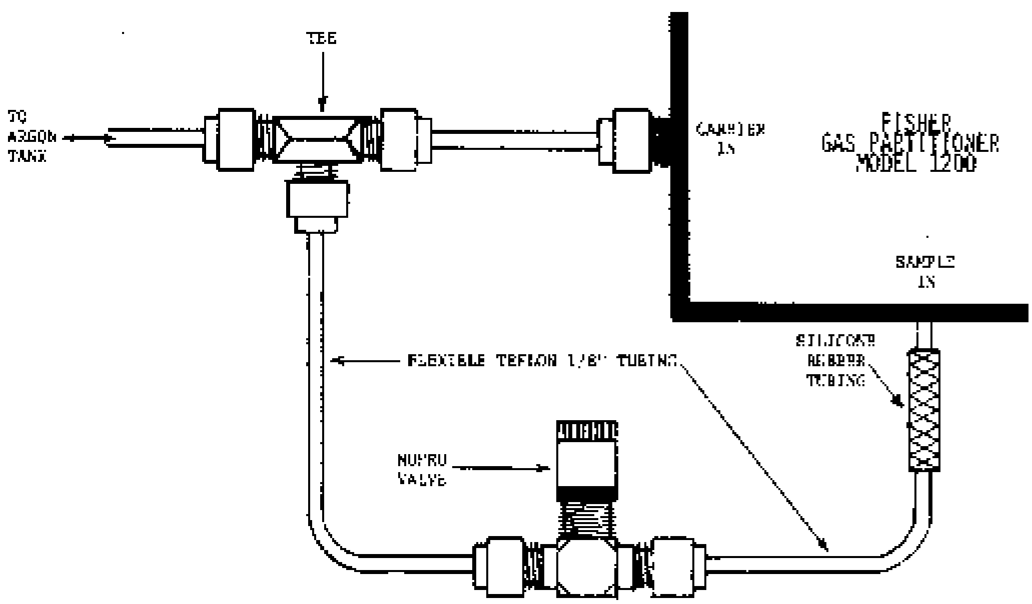


Figure 2. Flush System.

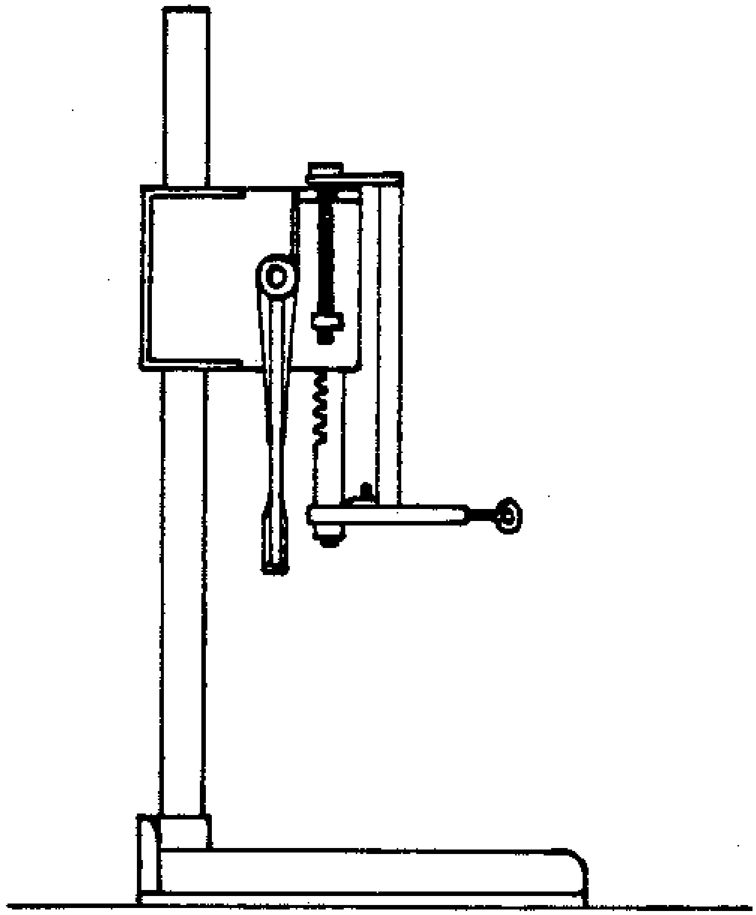


Figure 3. Can puncturing press.

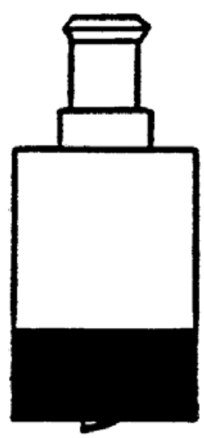


Figure 4. Stainless steel gas piercer.

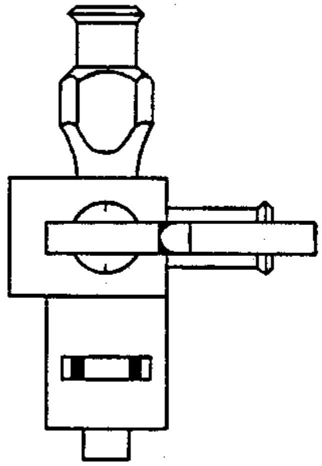


Figure 5. Miniature inert valve.

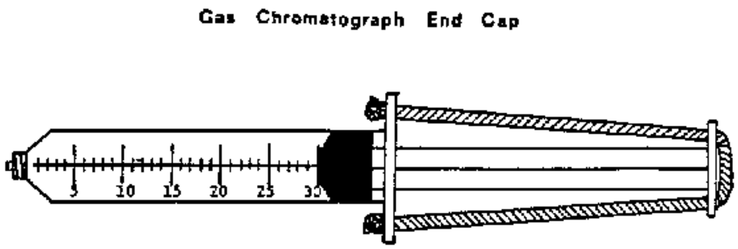


Figure 6. Plastic disposable syringe with restraining attachment.

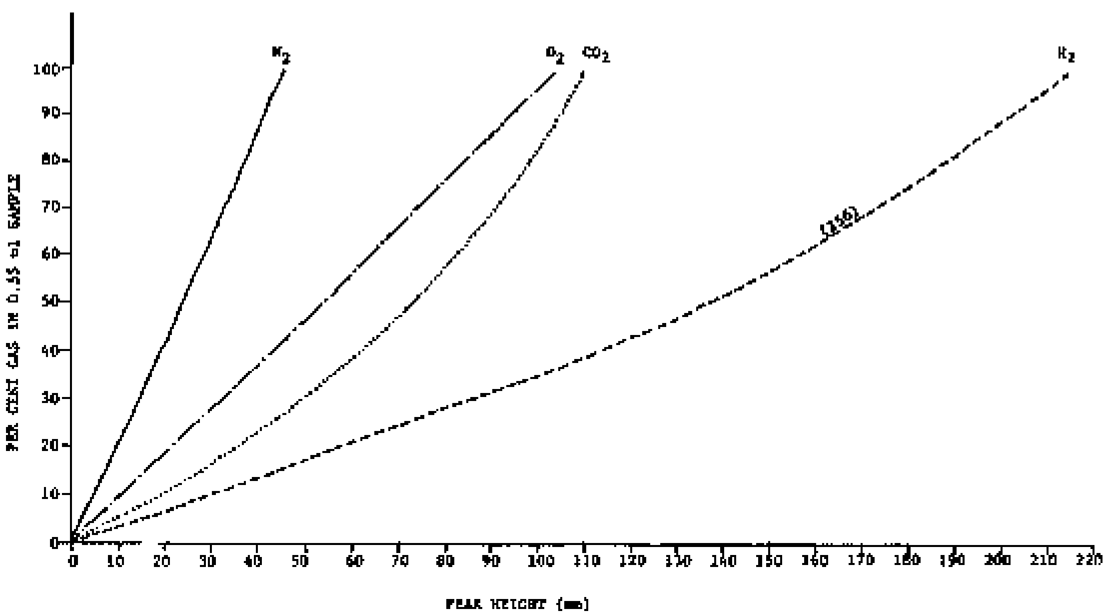


Figure 7. Calibration graph for gas chromatography of headspace gas, using pure and unknown mixtures.

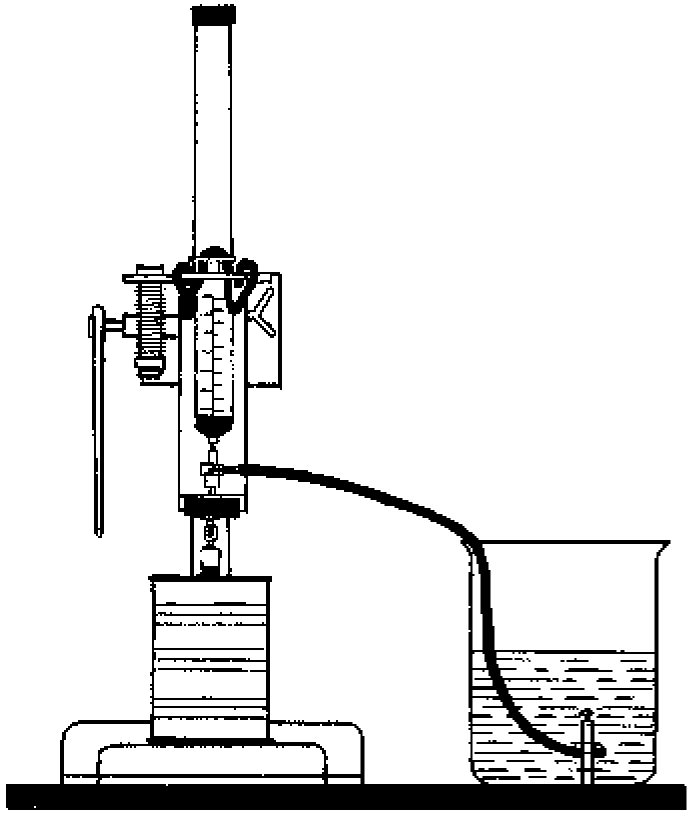


Figure 8. Gas collection apparatus.

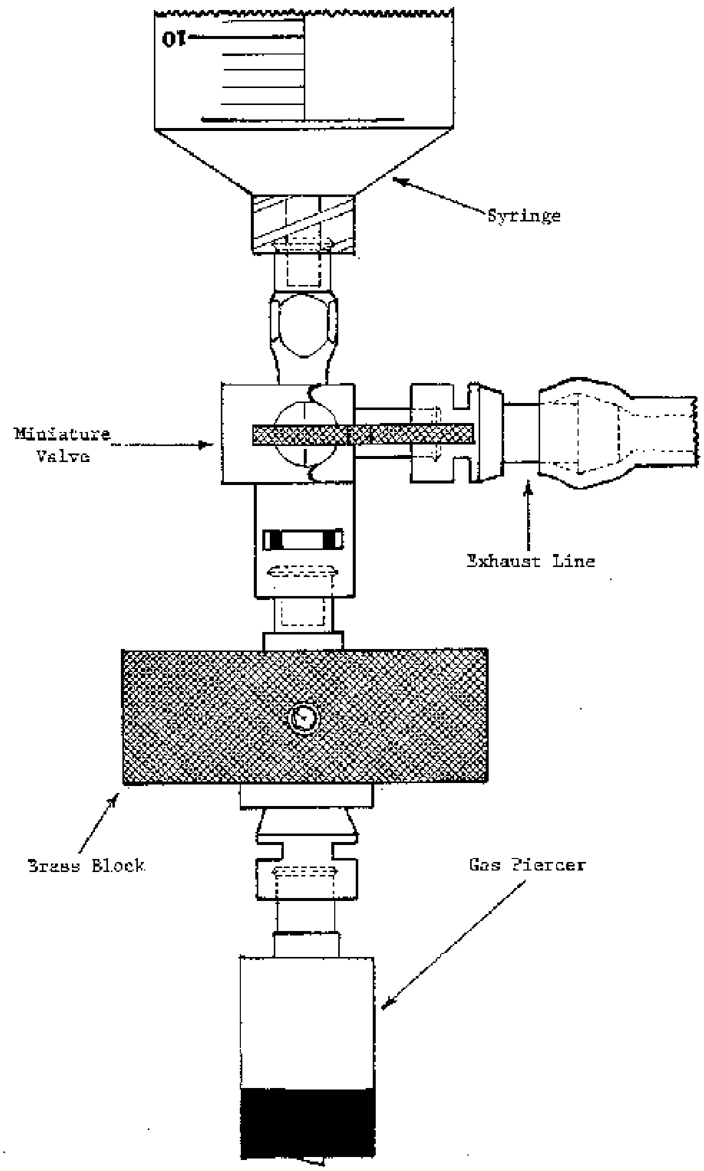


Figure 9. Gas collection apparatus (detail).

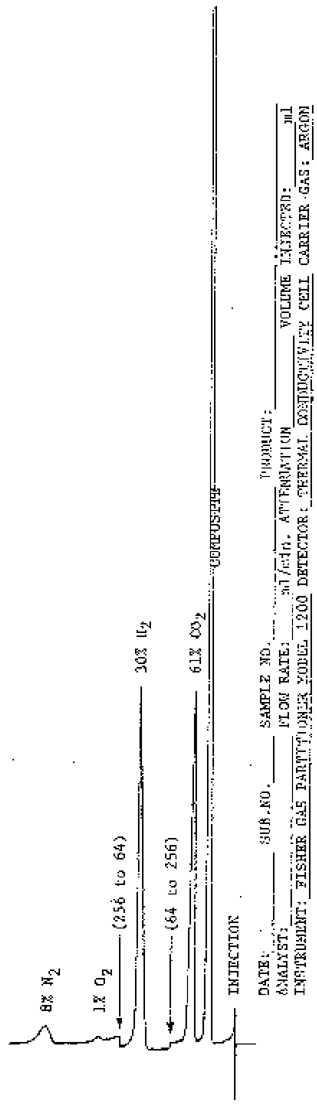


Figure 10. Gas chromatograph of headspace gas.

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1. Association of Official Analytical Chemists. 1990. Official Methods of Analysis, 15th ed. AOAC, Arlington, VA.

2. Vosti, D.C., H.H. Hernandez, and J.G. Strand. 1961. Analysis of headspace gases in canned foods by gas chromatography. Food Technol. 15:29-31.

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Authors: Warren L. Landry, Albert H. Schwab, and Gayle A. Lancette

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U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition

Bacteriological Analytical Manual *Online*

January 2001

Chapter 22B
Examination of Containers for Integrity

II. Examination of Glass Containers for Integrity

Authors

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Almost all low-acid foods packaged in glass containers are sealed with vacuum-type closures. Currently 4 types of vacuum closures are widely used on low-acid food products: LT (lug-type twist) cap, PT (press-on twist-off) cap, pyr-off (side seal) cap, and CT (continuous thread) screw cap (Fig. 25). Packers' tests and examinations to ensure a reliable hermetic seal of containers are required by 21 CFR 113.60 (a) (2) and (3).

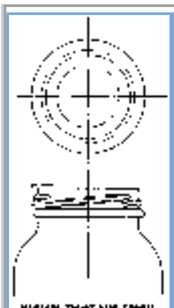
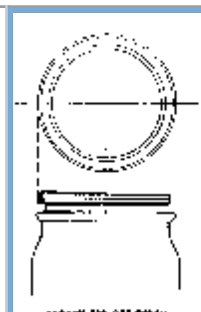
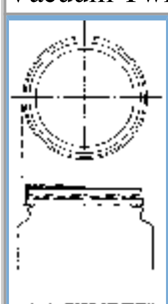
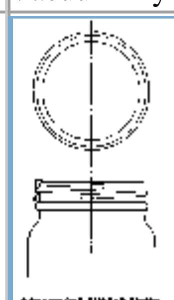
	
Vacuum Twist Lug Finish	Vacuum Pry Off Finish
	
Press On Twist Off Finish	Continuous Thread Finish

Figure 25. Types of vacuum closures and glass finishes.

A. Visual examination for closure and glass defects (for definition of terms, **see** the glossary section of this chapter)

   cap tilt
   crushed lug
   chipped glass finish
   cut-through
   cocked cap
   stripped cap
   cracked glass finish

B. Seal integrity examination

   1. **Vacuum**. Use standard open-closed type of vacuum gauge or USG No. 12118 gauge with both vacuum and pressure scales (Fig. 26). Wet rubber gasket on piercing device with water. Shake off excess water. Puncture closure, using piercing needle attached to vacuum gauge. Read and record vacuum in inches (0-30 inches), or pressure (0-15 psi).

   Figure 26. Vacuum gauge for seal integrity examination.

   2. **Removal torque (cam-off) for PT or LT type closures (Fig. 27)**. Properly secure jar on torque meter. Ease closures off in smooth, continuous motion rather than rapid, jerking motion. Use one hand to twist cap counterclockwise to open cap from sealed jar while avoiding any downward pressure on cap. Record maximum torque in inch-pounds required to open cap.

   Figure 27. Torque meter.

   3. **Security values (lug tension) on lug-type twist cap (Fig. 28)**. Make vertical line on cap and corresponding line on container wall with marking pen. Turn closure counterclockwise just until vacuum is broken. Reapply closure to container just until gasket compound

touches glass finish and closure lug touches glass thread (or until closure is at 2 inch-pound reapplication torque to achieve uniformity for application). Measure and record, in 1/16 inch increments, distance in front of vertical lines that were made before opening. Security is considered positive if line on cap is to right of line on container, and negative if line on cap is to left of line on container.

Figure 28. Security measurement for lug type twist closure.

4. **Pull-up (lug position) for lug-type twist cap (Fig. 29)**. Mark vertical neck ring seam on glass finish. Measure distance from this vertical line, in 1/16 inch increments, to leading edge of cap lug position nearest it. Record lug position measurements made on right side of vertical neck ring seam (as analyst looks at package) as positive (+) and those to left side of parting line as negative (-).

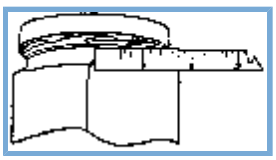


Figure 29. Pull-up lug position of LTD measurement.

Hypertext Source: Bacteriological Analytical Manual, 8th Edition, Revision A, 1998. Chapter 22.
*Authors: Rong C. Lin, Paul H. King, and Melvin R. Johnston

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updated by bap/kwg/cjm 2001-OCT-24

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Bacteriological Analytical Manual *Online*

January 2001

Chapter 22C
Examination of Containers for Integrity

III. Examination of Flexible and Semirigid Food Containers for Integrity

George W. Arndt, Jr. (NFPA)

Author

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Flexible and semirigid food packages are composed mainly or in part of plastic materials. Closure is achieved by heat sealing or double seaming. The 4 main groups of packages that cause similar integrity concerns and that are examined by common methods are paperboard packages, flexible pouches, plastic cups and trays with flexible lids, and plastic cans with double-seamed metal ends.

The purpose of a hermetic closure is to provide a barrier to microorganisms and to prevent oxygen from degrading the food. Closure integrity is significant because sealing surfaces may contain food particles and moisture that contribute to heat-seal and double-seam defects. Critical control must be exercised in this operation. Visual examination will reveal most defects. For many flexible packages, seal strength may be ascertained by squeezing.

A. Package examination

   Note condition of package (exterior and interior) and quality of seals or seams; observe and feel for gross abnormalities, mechanical defects, perforations, malformations, crushing, flex cracks, delamination, and swelling. Measure dimensions as recommended by manufacturer of closing equipment or packaging material. Perform teardown procedure as described. Note condition of package and closure. If there is evidence that a package may lose or has lost its hermetic seal, or that microbial growth has occurred in the package contents, further investigation is required.

   1. Visual examination

      Use hand as well as eye. A magnifying glass with proper illumination is helpful. Rub thumb and forefinger around seal area, feeling for folds and ridges. Rub fingers over flat surfaces to feel for delamination, roughness, or unevenness. By sight and touch, determine presence of defects. Mark location of defects with indelible ink. **See** Fig. 30 for visual inspection criteria for closure seal.

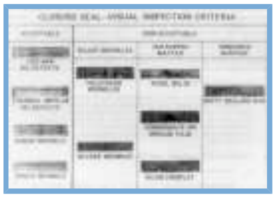

Figure 30. Visual inspection criteria for closure seal.
(**Courtesy of Brik Pak, Inc.**)

2. Examination of packages (**see** Tables 1 and 2)

Table 1. Test methods for plastic packages containing food (5)

	Package type			
Test methods	**Paper board**	**Flexible pouch**	**Plastic, heat-sealed lid**	**Plastic, double-seam metal end**
Air leak testing	O	O	O	O
Biotesting	O	O	O	O
Burst testing	O	R	R	O
Chemical etching	O	O	O	NA
Compression, squeeze testing	R	O	O	O
Distribution (abuse) test	O	O	O	O
Dye penetration	R	O	R	O
Electester	O	NA	NA	NA
Electrolytic	R	O	R	NA
Gas leak detection	O	O	O	O
Incubation	R	R	R	R
Light	NA	O	O	O
Machine vision	O	O	O	O
Proximity tester	O	O	O	R
Seam scope projection	NA	NA	NA	R
Sound	R	NA	R	R
Tensile (peel) testing	NA	R	R	NA
Vacuum testing	NA	O	R	O
Visual inspection	R	R	R	R

Abbreviations: R, test method is recommended by NFPA Bulletin 41-L, Flexible Package Integrity Bulletin; O, other commercially accepted test method applications; NA, test method is inappropriate for this style package.

Table 2. List of visible package defects provided by National Food Processors Association (5)

	Package type[(a)]			
Defect	**Paper board**	**Flexible pouch**	**Plastic, heat-sealed lid**	**Plastic, double-seam metal end**
Abrasion	+	+	+	+
Blister	-	+	-	-
Burnt seal	-	-	+	-
Channel leak(er)	-	+	+	-
Clouded seal	-	+	-	-
Compressed seal	-	+	-	-
Contaminated seal	-	+	+	-
Convolution	-	+	-	-
Corner dent	+	-	-	-
Corner leaker	+	-	-	-
Crooked seal	-	+	-	-
Crushed	+	-	+	+
Defective seal	-	-	+	-
Deformed	+	-	-	-
Deformed seal	+	-	-	-
Delamination	+	+	+	+
Embossing	-	+	-	-
Flexcracks	-	+	+	+
Foreign matter (inclusion)	-	-	+	+
Fracture	-	+	+	+
Gels	-	-	+	+
Hotfold	-	+	-	-
Incomplete seal	-	-	+	-
Label foldover	-	-	+	-
Leaker	-	+	-	-
Loose flaps	+	-	-	-
Malformed	-	-	+	+
Misaligned seal	-	-	+	+
Nonbonding	-	+	-	-
Notch leaker	-	+	-	-
Puncture	+	+	+	+
Seal creep	-	+	-	-
Seal leaker	+	-	-	-
Seal width variation	-	-	+	-
Shrinkage wrinkle	-	-	+	-

Stringy seal	-	+	-	-
Swell (swollen package)	+	+	+	+
Uneven impression	-	-	+	-
Uneven seal junction	-	+	-	-
Waffling	-	+	-	-
Weak seal	+	-	-	-
Wrinkle	-	+	+	-
[a] +, Definition is applicable to that package type; -, definition is not applicable.				

a. Paperboard packages (20)

   Teardown procedures. Unfold all flaps (except gable top packages); check integrity and tightness of transverse (top and bottom) and side (vertical or longitudinal) seals by firmly squeezing package. If package has longitudinal sealing (LS) strip, pull off overlapping paper layer at side (longitudinal) seal. Check air gap of longitudinal sealing strip application (about 1 mm). Squeeze package and check that there are no leaks or holes in the LS strip.

   Next, on side opposite side seal, puncture container with sharp scissors and empty contents. Saving side seal portion, cut near fold at each end of package and down length of package to remove a large rectangular body portion. Observe this large rectangular body portion for holes, scratches, or tears anywhere on the surface. Pay close attention to corners of package, particularly directly under end seals and near the straw hole or pull tab, if present. Now cut remaining package in half through the center of the side seam. Wash both halves of remaining package and dry them with a paper towel. Mark to identify the package.

   Evaluation procedures for seal quality differ between package designs, constructions, and sealing methods. Obtain specific procedures for a given package from the manufacturer. For example, seal evaluation may consist of starting at one end of the seal, and very slowly and carefully pulling the seal apart. In some packages the seal is good if the polymer stretches the entire length of the seal (that is, stretching of polymer film continues to a point beyond which paper and laminates have separated). In other packages, fiber tear can be seen the entire length of the seal (that is, raw paperboard is visible on both sides of the separated seal areas). This is known as 100% fiber tear and indicates a good seal. Test all 3 seals of each package half. Problems to look for are absence of (or narrow) fiber tear, lack of polymer stretch, "cold spots" (no polymer bond in seal area), and "tacking" (polymer melt but no stretch or fiber tear). For longitudinal sealing strip-type packages, additional tests (such as centering examination, heat mark examination, and appearance of aluminum foil examination when stripped) should be made according to manufacturer's directions.

   Electrolytic and dye testing. These tests differ according to each system manufacturer's filed procedure. Contact the individual manufacturer, obtain recommendations, and follow them.

b. Flexible pouches (20)

   1. **Teardown procedures**. Check tightness of both head and side seals by

squeezing each package from each fill tube or sealing lane. Important points are corners and crossing of head and side seals. This is a rapid determination of obvious defects. Each seal must be accurately torn apart and evaluated for correct integrity. Carefully inspect edges of each head and side seal for evidence of product in seal areas. No product should be visible.

Observe width of each seal area. Width must comply with machine-type specifications: for example, 1/16 inch minimum on all head and side seals for fill tube or sealing lane machines. Look for presence of smooth seal junction along inside edge of seal. Open each package to check side seals and head seals. Visually inspect for such defects as misaligned seal, flex cracking, nonbonding, and seal creep. If applicable, tear the seals by doing a seal tensile strength test or a burst test. Then observe appearance of tear at each seal. Seals should tear evenly so that foil and part of laminated layer from one side of package tears off, adhering to seal on other side of package. The seal should appear rough and marbleized. The seal is also adequate if the foil is laid bare across entire length of seal. Retain records of test results as required.

2. Other test procedures

   Squeeze test. Apply manual kneading action that forces product against interior seal surface. The sealing surface must be smooth, parallel, and free of wrinkles. Examine all seal areas for evidence of product leakage or delamination. Packages that exhibit delamination of the outer ply on seal area but not at product edge should be tested further by manually flexing the suspect area 10 times and examining all seal areas for leakage or reduction in the width of the seal area to less than 1/16 inch.

   Seal tensile strength. Results to be expressed in pounds per linear inch, average of sample (that is, 3 adjacent specimens cut from that seal) should not be less than specified for the material and application.

   Burst strength test. With internal pressure resistance as the measurement to check all seals, apply uniform pressure, under designated test conditions, to a level of not less than specified for a material or application, for 30 s. Then evaluate seals to ensure that proper closure seal is still in effect.

c. Plastic package with heat-sealed lid (20)

   Container integrity testing. Peel test procedures of form fill and seal containers. Squeeze container side walls of entire set from a mold. Squeeze each cup to cause 1/8 inch bulge of lid area. Lid should not separate from package when package is squeezed. Observe sealing area for fold-over wrinkles in sealant layer of lidstock. From a first set of containers, visually observe embossed ring in sealed area for completeness. (Embossed ring should be at least 90% complete if present.) Remove a second set of containers (1 cup per mold) and gently peel back each lid at approximately a 45 angle. Observe the peeled area for a generally frosty appearance on both the lid and cup sealed surfaces. Observe entire package for holes, scratches, even flange widths, smooth inside surfaces, and any deformities caused by dirty mold or sealing die.

   Leak test procedures (optional). These tests differ according to each system manufacturer's filed procedure. Contact the individual manufacturer, obtain recommendations, and follow them.

Electrolytic test. Plastic packages generally do not conduct a flow of low-voltage electricity unless a hole is present. Use a volt meter or amp meter to determine the presence of a closed circuit. If a voltage flow can be measured, use a dye solution to identify the presence of a hole.

Dye penetration test. Use a dye to locate leaks in packages or to demonstrate that no leaks exist.

Air pressure or vacuum test. Apply pressure or vacuum to a closed package to test for holes and to observe any loss of pressure or vacuum. Underwater vacuum testing may reveal a steady stream of small bubbles emitting from a hole in a package.

d. Plastic cans with double-seamed metal ends (20)

Procedures for examining metal cans with double seams are described in Chapter 21 and in 21 CFR, Part 113. Use these methods to examine plastic cans with double-seamed metal ends. Make the following changes to 21 CFR 113.60 (a,1,i,a and b).

B. Micrometer measurement system

Metal cans. Required: cover hook, body hook, width (length, height), tightness (observation for wrinkle), and thickness. Optional: overlap (by calculation) and countersink.

Plastic cans with double-seamed metal ends. Required in addition to seam scope examination: thickness and tightness. Compare seam thickness to that calculated from individual thicknesses of plastic flange and neck and metal end, excluding compound. Optional: cover hook, countersink, and width (length, height).

Seam scope of projector

Metal cans. Required: body hook, overlap, tightness (observation for wrinkle), and thickness by micrometer. Optional: width (length, height), cover hook, and countersink.

Plastic cans with double-seamed metal ends. Required: overlap, body hook, countersink, width (length, height). Optional: cover hook.

Visual examination for plastic cans with double-seamed metal ends. Required: tightness. Note compression of pressure ridge or flange during overlap measurement. Remove entire cover and examine pressure ridge for continuity. Under 21 CFR 113.60 (a,1,i,c) add the following: pressure ridge for plastic cans with double-seamed ends; impression around complete inside periphery of can body in double seam area.

C. Microleak detection

Microleak testing methods are not listed in order of sensitivity, nor is it necessary to use them all. Each test has advantages and disadvantages, depending on the package, equipment, and set of conditions. Optional methods are appropriate when additional information will clarify the nature of various package defects. Some test methods are not appropriate for some package materials, closures, or package styles. Refer to the manufacturer of the package or closure system for recommended test methods or see Table 1. Common methods are presented to provide the analyst with procedures and options. Visible defects of the 4 flexible package groups are summarized in Fig. 30.

Measure packages before testing for microleaks. Mark visually detected defects to aid location during or after microleak testing (non-water soluble markers are recommended). Record all results, methods used, and environmental conditions (temperature, relative humidity) and retain these records. Conduct all tests in the standard laboratory atmosphere of 23 **+** 2°C and 50 **+** 5% relative humidity. When this is not possible, report temperature and relative humidity along with test results (14).

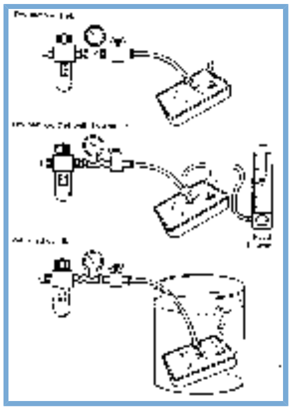

Figure 31. Air leak testing of packages.

1. Airleak testing (5) (Fig. 31)

    a. Dry method

        1. Materials

            Compressed air with regulator
            Needle, valve, hoses
            Pressure gauge or flow meter

        2. Procedure

            Puncture container wall with needle. Inject air while increasing at 1 psi/s until a standard pressure is reached. Standard pressure used for testing should be less than the normal unrestrained burst pressure for the package. Observe pressure gauge for loss of internal pressure over a 60 s period. If a flow meter is used, observe for airflow, which indicates presence of openings in the test package. Dye testing may be used to locate air leaks that are not visible with the dry method. Inject air to create internal pressure within the package without causing it to burst. Observe all surfaces and seals for air leaks. Observe flow meter for indication of air loss from the package.

    b. Wet method

        1. Materials

            Compressed air with regulator
            Needle, valve, hoses
            Water
            Transparent container to observe bubbles

        2. Procedure

Inject air to create internal pressure within the package without causing it to burst. Immerse package in water and inspect visually for a stream of bubbles emitting from a common source.

c. Results

Positive. - A steady stream of bubbles comes from the package at one or more locations.

Negative. - No bubbles are emitted from the package.

False positive. - Bubbles are emitted from point at which needle entered package; or bubbles cling to surface of the package after package is submerged in water.

False negative. - Food particles block holes through which air might escape from defective package; or air pressure used is insufficient to force air through minute holes in package.

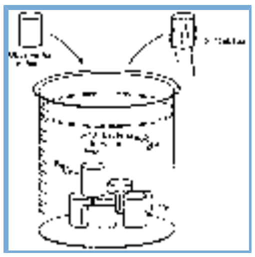

Figure 32. Biotesting of packages.

2. Biotesting (5,21) (Fig. 32)

The objective of biotesting is to detect the presence of holes in hermetic packages by placing them in an agitated solution of fermentation bacteria in water for an extended period of time.

Obtain representative packages and submerged them in an agitated solution of active bacteria. The bacterial concentration should be $>10^7/cm^3$. The temperature of the solution that surrounds the packages should be maintained at a temperature that permits rapid growth of the bacteria within any packages they may enter. However, growth of the bacteria in the liquid surrounding the submerged packages is not desirable. The bacteria must cause fermentation of the product within the package if they penetrate and must not be pathogenic. Packages should be flexed during immersion to expose cracks and holes to incursion. The solution that surrounds the packages should be maintained at a temperature that permits rapid growth of bacteria within defective packages. After biotesting, packages are incubated for 3 weeks at 95-100F. This test should be used only to evaluate new package designs or to validate packaging systems. It should not be used as routine quality control procedure. Other methods are cheaper, simpler, and just as reliable.

a. Materials

Water bath with temperature control and agitation solution of
Enterobacter aerogenes for foods, pH >5.0. Solution of
Lactobacillus cellobiosis for foods, pH <5.0
Sample packages
Apparatus to flex packages

Incubator

b. Procedure

Obtain representative samples. Mix active bacteria in water at about 1.0 x 10^7/ml. Immerse samples in mixture. Agitate water bath and flex sample for 30 min. Remove packages and rinse with chlorinated water. Incubate samples for 2 weeks at 95-100F. Observe packages for swelling for 3 weeks. Open each package by cutting in half across the middle, leaving a hinge and observe contents for spoilage. Thoroughly wash insides of both halves from each spoiled package. Subject each half to a dye test to locate leaks.

c. Results. Report location of leaks.

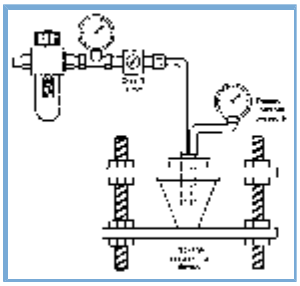

Figure 33. Burst tester.

Figure 34. Pouch air burst tester.

3. Burst testing (5) (Figs. 33 and 34)

The objective of burst testing is to provide a means for determining the ability of a hermetically sealed package to withstand internal pressure (psig). The entire package is subjected to uniform stress and failure generally reveals the weakest point. Both restrained and unrestrained burst testing may be used. Restraint limits expansion by minimizing the angle of the package seal, which becomes greater as a package is inflated. With restraint, packages with strong seals fail at greater internal pressure than do packages with weak seals. Thus, use of a restraining device during burst testing permits noticeable separation between packages having strong or weak seals.

Fused seals are stronger than the walls of a flexible package. Burst failure generally occurs adjacent to fused seals. Peelable seals are weaker than the walls of a flexible package, and less pressure is needed to induce pressure failure. Lower pressure and a longer time increment are required to burst test peelable seals.

Dynamic burst testing involves a steady increase of internal pressure until failure occurs.

Static burst testing involves a steady increase in internal pressure to a pressure less than failure, followed by a 30-s hold. Both methods are used for packages with fused seals. Peelable seals are burst-tested by inflating at a steady rate to a point less than failure pressure and held for 30 s, followed by a 0.5 psig pressure increase and another 30-s hold. Pressure and time indexing is continued with observation of the seal area for seal separation (peeling) until failure occurs.

a. Materials

   Compressed air or water
   Regulation valve
   Needle with gasket and pressure tubing
   Solenoid with timer(s)
   Pressure indicator(s), digital or gauge with sweep hand
   Restraining device (optional)

b. Procedure

   Use empty sealed package, or cut and remove contents of a filled package. Place package in restraining fixture (if used). Pierce package with gasketted needle(s) and inject air or water. Inflate at 1 psig/s.

   Dynamic method. Continue inflation at 1 psig/s until failure occurs. Record internal pressure at failure.

   Static method. Inflate at 1 psig/s to specified internal pressure, and hold at specified pressure for 30 s. Record as pass or fail.

   Indexed method. Inflate to 5 psig and hold for 30 s, inflate additional 0.5 psig and hold for 30 s. Continue increase and hold sequence until failure occurs. Observe peelable seal separation. Report internal pressure at failure.

c. Results

   Positive. Pressure failure occurs below specified level of performance, indicating a hole in the package.

   Negative. No pressure failure occurs below specified level of performance.

   False positive. A leak is present at point where air or water is injected into package and pressure cannot be maintained.

   False negative. A small leak occurs, but is not sufficient to reduce pressure noticeably.

4. Chemical etching (5)

Multilaminate and composite packaging materials may be etched to remove overlying layers, revealing the hermetic seal of packages that have polyolefin heat seals. This allows comparison of visually detected package defects on the external surface before etching and within the seal area after all external layers have been removed.

Composite paperboard packages. The outer layers of a package are removed by tearing, abrasion, and chemical action to expose the sealant layer intact. By photographing or photocopying the package before etching, the etched seal can be compared with the photograph to determine the significance of visually discernible defects.

a. Materials

Water bath and heater with thermostat
Three l-L Pyrex glass beakers
Running tap water
Graduated cylinder
Automatic stirring device (heated is preferred)
Drying oven equilibrated to 65°C (150F)
Paper towels
Rubber gloves, protective goggles, apron, tongs
Fume hood with chemical-resistant surface

Chemicals for etching of paperboard aseptic packages:
hydrochloric acid (HCl) solution, 3.7 N
acidified solution of copper chloride ($CuC1_2$)
saturated solution of bisodium carbonate (Na_2CO_3) in water

b. Preparation of solutions. **CAUTION**: Always pour acid into water; never pour water into acid.

Pour 0.5 L of concentrated HCl into 1 L of cold distilled water. Pour slowly, as heat will be produced when acid and water mix. Stir until mixed completely. Cover to prevent evaporation. Solution will be 3.7 N HCl.

Pour 0.5 L of concentrated HCl into 1.5 L of cold distilled water. Add 10 g of $CuC1_2$. Stir until completely mixed. Cover beaker and let warm to room temperature before using.

Pour enough Na_2CO_3 into a container to make a saturated solution at room temperature. Some undissolved Na_2CO_3 should remain on bottom of beaker after stirring.

c. Procedure

Cut transversal seal from package approximately 1 inch from end. Identify multiple samples by notching cut edge with scissors. Manually strip paper from sample to be etched. Place sample in hot HCl solution (65°C) for 5 min. Remove sample with tongs and immerse it in Na_2CO_3 solution to neutralize the acid. Remove sample from the Na_2CO_3 solution with tongs and rinse it in running tap water. Pull off polyethylene layer that lies between paperboard layer and aluminum foil.

Using a glass stirring rod to manipulate the sample, drop it into the $CuC1_2$ solution so that it is completely immersed. Observe closely while stirring to ensure that the heat of the reaction does not damage the polyethylene sealant layer as the foil is dissolved. Remove from solution.

Dip sample in Na_2CO_3 solution to neutralize it, and then rinse it with water. Press sample gently between soft absorbent paper towels and place in oven at 65°C (150F) until dry. Apply alcohol-based dye solution to inner and outer seal edges. (**See** fluorescein dye solution formula, described above).

Observe pattern of ink dispersion and check for leaks and channels within fused seal area. Use overhead projector to enlarge seal samples and provide a more accurate visual inspection.

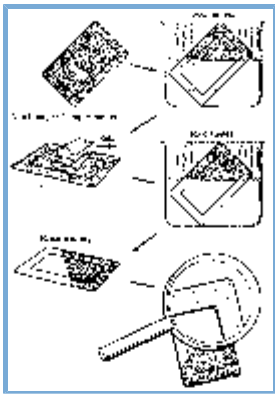

Figure 35. Chemical etching of package seal.

Retortable pouches (Fig. 35)

1. Materials

   Two l-L Pyrex beakers
   Running tap water
   Paper towels
   Rubber gloves, apron
   Protective goggles, tongs
   Fume hood with chemical-resistant surface
   Chemicals for etching retortable pouches
   6 N HCl solution, commercial grade
   Tetrahydrofurant (THF), commercial grade, stabilized

2. Procedure

   Cut off end of pouch and remove contents. Wash inside of pouch. Dry the pouch. Cut all but suspected area away from area of interest, leaving about 1 inch adjacent to seal. Soak sample in tetrahydrofurant (THF) to remove outer polyester layer by softening adhesive and/or inks. Do this in a fume hood; wear protective gloves resistant to THF. (If separation cannot be obtained, proceed to next step.) Remove most of the ink and adhesive from aluminum foil with THF and paper towels. Soak remaining structure in 6 N HCl in a fume hood to remove aluminum foil by etching. Rinse sealant layers with water and dry with paper towels.

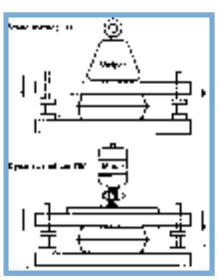

Figure 36. Compression testing of packages.

5. Compression test (5) (Fig. 36)

   Place a filled and sealed food package on flat surface and apply pressure while observing for leaks.

   a. Materials

      Flat surface or conveyor belt
      Sealed package
      Heavy flat object or mechanical press
      Timer

   b. Procedure

      Static method. Place sealed package on flat surface and lay a flat-surfaced weight on it. Observe effect of weight on integrity of package seals over time. A similar test may be performed by applying a constant weight to a package moving on a conveyor belt. The speed of the moving belt determines the time of compression.

      Dynamic method. Use a press to continually increase the force applied to a package at a constant rate. Observe the maximum force required to cause failure of the package.

      Squeeze test. Apply a manual kneading action that forces product against the interior seal surface area. Examine all seal areas for evidence of product leakage or delamination. Packages that exhibit delamination of the outer ply on the seal area but not at product edge should be tested further by again manually flexing the suspect area 10 times and examining all seal areas for leakage or short-width.

   c. Results

      Positive. Holes form in package or its seals or seams, with measurable movement of top plate or deflection on a force gauge.

      Negative. No loss of hermetic integrity, and no measurable movement of top plate or deflection on a force gauge.

      False positive. Underfilled or weak packages deflect in a manner that simulates failure without loss of hermetic integrity.

      False negative. Holes form in package but food product closes off the holes, permitting pressure to increase within package.

6. Distribution (abuse) test (5)

   Packages are subjected to vibration, compression, and impact at levels typical of the distribution system for which they are designed. After the test, which is a conditioning regimen, the packages are examined. Defects are quantified and described in relation to package failures observed in normal distribution. Fragility is eliminated by design changes in the package system. Whenever possible all samples should be incubated for 2 weeks at 100F before abuse-testing (Fig. 37).

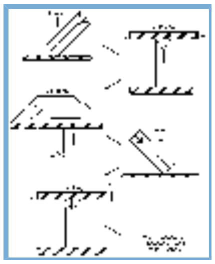

Figure 37. Distribution abuse testing.

a. Materials

   Packages to be tested
   Drop tester
   Vibration table
   Compression tester
   Standard laboratory conditions 23 **+** 2°C, 50 **+** 5% relative humidity
   Incubator at 100F to contain all test packages

b. Procedure. **See** ASTM D-4169 Standard Practice for Performance Testing of Shipping Containers and Systems (15).

   Select distribution cycle 6 for flexible packages in shipping cases transported by motor freight. Before testing, incubate all packages for 14 days at 100F and inspect visually for defects.

   Perform the following 10 steps (**see** Section 9 of ASTM D-4169) (15).

   1. Define shipping unit - Shipping unit to be tested is a typical pallet load.
   2. Establish assurance level - Assurance level II will be used, based on value and volume of shipment.
   3. Determine acceptance criteria at assurance level II: **Criterion 1** - no product damage; **criterion 2** - all packages in good condition.
   4. Select distribution cycle (DC) - DC-6 will be used for pallet shipments.
   5. Write test plan (values for X must be determined before conducting the test). Select representative samples for test. Condition samples to 23 **+** 1°C, 50 **+** 2% relative humidity, in accordance with Practice D 4332 (14).
   6. Perform tests in accordance with test plan in step 5, as directed in the referenced ASTM standards and in the special instructions for each shipment.
   7. Evaluate results - Examine products and packages to determine if acceptance criteria have been met.
   8. Document test results (16) - Write a report to cover all steps in detail.
   9. Report fully all the steps taken. At a minimum, the report should include all the criteria in step 10.
   10. Description of product and shipping unit DC and test plan Assurance levels

and rationale
Number of samples tested
Conditioning used
Acceptance criteria
Variation from recommended procedures
Condition of specimens after test

After testing, examine all failed (positive) packages to determine location and cause of damage. Incubate all containers that do not fail (negative) during testing for 14 days at 100F and inspect visually for defects before destructive testing by other methods listed in this chapter.

c. Results

Positive. A package loses hermetic integrity during any one phase of the testing protocol or during the incubation period that follows.

Type test	ASTM Method	Level
Handling (12)	D-1083	One impact on 2 opposite base edges from X inches
Stacking (10)	D-642	Compression to X lb (individual container) *
Vibration (13)	D-999 Method C	Search 3-100 Hz at 0.5 g peak. Dwell 10 min at 0.5 g peak
Handling (11)	D-959	One impact on 2 opposite base edges from X inches
(12)	D-1083	
(17)	D-997	
(18)	D-775	
Stacking (10)	D-642	Compression to X lb (individual container) *
*Alternative full pallet load compression test, X lb per bottom tier container.		

Negative. A package retains hermetic integrity through the test, and contents do not show evidence of microbial growth after incubation.

False positive. A package appears to be defective, yet confirmational testing by incubation or dye penetration reveals that no loss of the hermetic barrier occurred during the abuse test.

False negative. A package appears to pass testing but later exhibits failure when incubated.

7. Dye testing (5)

Dye or ink is applied to inside surface of a cleaned package at the seal or suspected location of failure and observed to determine whether it can pass through to the outside (Figs. 24, 38, 39).

Figure 24. Can piercer and gas collection apparatus.

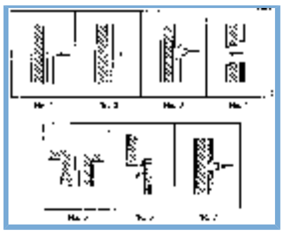

Figure 38. Dye testing.

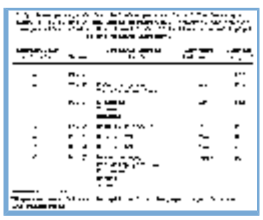

Figure 39. Dye testing results.
(**Courtesy of Brik Pak, Inc**.)

a. Materials

   Disposable plastic gloves
   Dye solution: 1 L of isopropanol (solvent) and 5 g of rhodamine (powder) mixed (or other appropriate dye solution)
   Sink
   Scissors or knife
   Oven to dry sample packages
   Paper towels
   Magnifying glass or low-power microscope

b. Procedure

   Open and empty a package; wash, and dry by wiping or by oven drying (180F, 15 min). Apply low surface-tension solution containing dye along the closure or on side of package at suspected location of hole. The solution moves by capillary action through the hole and appears on opposite side of package wall. After dye is completely dry, cut package with scissors and examine the hole closely.

Cut open cans, tubs, or bowls through bottom (leaving seal areas or double seams untouched) and remove product. Cut pouches and paperboard containers along equator, leaving a hinge (so that both ends can be tested), and remove product. Wash package with water containing mild detergent, rinse thoroughly with tap water, and wipe dry. Holding package upside down and at slight angle, place 1 drop of dye solution at inside edge of seal surface. Rotate to allow dye to wet entire inside seal circumference.

CAUTION: A number of dyes are known or suspected to cause cancer. Rhodamine B is a possible carcinogen. Wear disposable plastic gloves and avoid skin contact with dyes.

Let dye solution dry completely. Very slowly peel the seal completely and observe the frosty, white, sealed surfaces for evidence of dye. In some packages the innermost laminates must be carefully observed for stretching as the seal is peeled.

c. Results

Positive. Dye penetrates hole in package, indicating loss of hermetic barrier.

Negative. Dye does not pass through the package (wall or seal).

False positive. Solution dissolves packaging material, creating hole in package, or dye is accidentally splattered on outside of package, indicating hole or leakage where none exists.

False negative (for paperboard only). Solution penetrates holes in hermetic barrier layers but fails to reach outside of package where it would be visible.

8. Electester (5)

The objective is to determine changes in viscosity of liquid foods after incubation of filled packages (Fig. 40).

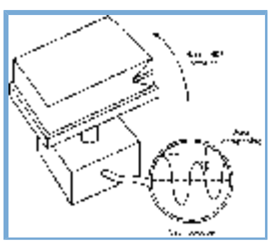

Figure 40. Electester

Microbial fermentation can cause changes in the viscosity of still liquids. If all factors are constant, shock waves will dampen at different rates in liquids with different viscosities. Incubation of shelf-stable liquid foods and nondestructive testing of each package may identify containers that have been subjected to microbial activity.

a. Materials

Packages filled with still, liquid food, incubated
Electesting device
Fixture to restrain test packages

b. Procedure

Remove representative samples from production line and incubate at 95°F for 4 days. Place packages containing still liquids in restraining device with largest flat surface of package facing downward. Rotate package 90 horizontally and back to its original position very rapidly; do this only one time. The motion creates a shock wave. Fixture holding the package is precisely balanced to minimize outside interference and minimize dampening as shock wave moves back and forth within package. Motion is sensed and displayed on an oscilloscope with alarms alerting operator to vibrations that dampen more quickly or more slowly than normal for a specific liquid food product. Examine contents with a microscope and determine pH to confirm spoilage if there is any doubt.

c. Results

Positive. Wave dampens more quickly or slowly than normal, indicating change in product viscosity.

Negative. Rate of wave dampening is within range established by testing "normal" liquid product that did not display microbial spoilage during incubation.

False positive. Range of acceptance is too narrow, and normal product is incorrectly identified as spoiled.

False negative. Range of acceptance is too broad, and spoiled product is incorrectly identified as normal.

9. Electroconductivity (5)

The objective is to detect holes in hermetic packages by sensing the flow of electrical current. Plastics are generally poor conductors of electricity. Consequently, plastic food packages without holes will form an effective barrier to mild electrical current; therefore, this method may be used to detect minute breaks in plastic food packages. A detectable flow of low-voltage electrical current generally indicates that the hermetic barrier has been lost.

a. Materials

1% NaCl in water (brine solution)
Scissors
Battery 9V, three 12-inch lengths of wire, 9V light bulb, or a conductivity meter (VOM). Remove insulation from each end of wires. One wire from positive pole goes to light bulb that has a wire as probe. The second wire from the negative pole is the other probe (Fig. 41).
Plastic bowl large enough to submerge package

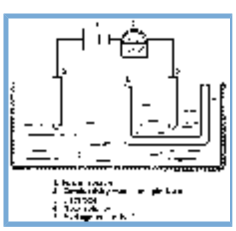

Figure 41. An electrolytic cell for leak examination.

b. Procedure

Obtain sample food package and cut off one end with scissors. Aseptic paperboard packages and flexible pouches may be cut on all but one edge along package equator and folded 180 on uncut side to form 2 equal halves. Wash samples to remove all food contents and any dried plugs that may occlude holes. Oven drying at 180F is recommended but not required before immersion. Wipe the cut edges with a paper towel if necessary, as wet edges may result in false-positive test results. Place samples in bowl containing brine solution and partially fill sample with brine so that it stands upright and is almost completely submerged. Place conductivity meter or light bulb with one probe inside the package and the other outside the package. Submerge both probes into their respective brine solutions. Test the other half of package similarly for current flow.

c. Results

Positive. Current flow indicates break in hermetic barrier.

Negative. No current flow indicates hermetic barrier exists.

False positive. Aluminum foil conducts electricity. A pinhole or partial break through inner layers of a package may expose the foil layer, resulting in false-positive test result. Dye testing will confirm presence or absence of holes. Moisture may form a bridge over cut edge of a package, creating a false positive.**False negative**. Dried product may occlude minute holes in a package. If plugs do not rehydrate quickly, they will not conduct electricity when packages are immersed.

10. Gas detection (5)

The objective is to detect microleaks in hermetically sealed packages with sensors tuned to detect only gas leaking from within package. The package must be a barrier to the test gas so that the rate of gas permeation through the package wall will not raise the normal background concentration in atmosphere of testing area. Gas concentrations may be detected by impact to a sensor. The sensor may be a heated element in which electrical resistance varies in relation to gas molecules removing heat as they impact. Examples of test gases suitable for package include oxygen, nitrogen, hydrogen, carbon dioxide, and helium.

a. Procedure for detecting helium leak

Gas obtained from storage tanks or air fractioning may be used to displace headspace gases within food packages before closure. Concentration of gas within package must be greater than the concentration of that gas in the atmosphere where packages are tested. There are three modes for detection: ASTM E493, inside-out tracer mode (6); ASTM E498, tracer probe testing mode (7); and ASTM E499, detector probe testing mode (8). Slight compression of a package may assist the movement of gas molecules through microleaks.

b. Results

Positive. Detection of gas concentrations greater than the normal atmospheric concentration indicates break in hermetic barrier of sample package. Confirm with dye testing to locate hole in sample package.

Negative. No detection of test gas concentration greater than the normal atmospheric concentration indicates hermetically sealed container.

False positive. Detection of gas concentrations in excess of the normal background level may result from increase in test gas concentration in the testing area. Test background concentration before and after testing sample. Packages with high permeability may lose gas.

False negative. Internal gas concentration may be reduced through absorption by the product, reaction with a component inside the package, or permeability if over an extended storage period.

11. Incubation (5)

The objective is to determine whether a package has lost hermetic barrier by holding containers at an ideal temperature for sufficient time to ensure microbial growth. Hermetic integrity is the condition that bars entry of microorganisms into a package. Growth of microorganisms indicates either insufficient processing or loss of hermetic barrier. Growth may be observed as gas formation, change in pH, growth of viable organisms, or changes in the appearance of food.

a. Materials

Insulated box or room to serve as an incubator
Heater with thermostat
Storage racks
Recording thermometer
Temperature recording charts
Knife, scissors
pH meter
Inoculating loop and flame
Sterile culture dishes and tubes, and culture media

b. Procedure

Obtain representative sample packages containing processed product. Inspect all samples visually for defects. Place packages in incubator for recommended period of time at recommended temperature.

Products stored in incubator at 95°F (35°C)
FDA products - 14 days
USDA products - 10 days
Products stored in warehouse
85-95°F (29-35°C) 30 days
70-85°F (21-29°C) 60 days
60-70F (16-21°C) 90 days

Visually inspect packages for evidence of spoilage. Open and inspect all (or some) packages for visible signs of microbial growth, aroma, and change in pH. Never taste incubated product if spoilage may have occurred. Aseptically obtain product samples to culture microbiologically and confirm cause of spoilage. Conduct appropriate integrity test on package to identify presence or absence of microleaks. Dispose of product safely. Autoclave any product or packages showing spoilage before disposal.

c. Results

Positive. Spoilage has occurred and is evident as swelling, putrefactive odor, change in product pH from normal, or change in appearance.

Negative. Spoilage has not occurred.

False positive. Chemical reaction or enzymatic activities alter product characteristics without microbial activity.

False negative. Should not occur because this would be commercial sterility.

12. Light (5)

    a. **Infrared light**. The objective is to observe differences in the absorbance and transmittance of heat energy (infrared light) in a package or seal. Infrared light may be absorbed, transmitted, and emitted by a package or a seal. Differences between these parameters provide a means for visual interpretation when sensed automatically and enhanced for visibility.

        1. Materials

           Infrared light or oven (180F)
           Visual infrared light detector

        2. Procedure: Expose samples to infrared radiation before examining.

    b. **Laser light**. The objective is to measure small changes in the relative position of similar surfaces on separate packages as they are subjected to changes in external pressure. Flexible packages possessing some headspace gas may be flexed by altering the external pressure in a closed chamber. Packages are held by fixtures so that a split laser beam may be directed to the same position on both packages. The reflected beams are recombined with mirrors and prisms. Laser light has a well-defined wave length that does not change by reflection. However, if packages move differently when flexed, one beam segment will travel a greater distance than the other. When beam segments are recombined, differences in position of reflecting surfaces will cause the recombined laser beam to be out of phase. This condition can be sensed and used to segregate packages that do not flex in the normal manner from those that do.

        1. Materials: Laser set up with chamber and means to read the differences.

        2. Procedure: Flex packages in chamber by applying and releasing vacuum. Observe any difference in the 2 packages and determine by controls which package leaks.

    c. **Polarized light**. The objective is to observe differences in the transmittance of visible light through translucent and transparent heat seals (Fig. 42). Polarized light filters are composed of minute parallel lines on a glass surface or plastic film. When 2 polarized filters are rotated to be 90 different, no light will pass through. At 0, both sets of lines are parallel and a light bulb set in line with the 2 polarized filters will be visible.

Figure 42. Visual inspection of transparent seals with polarized light.

During heat sealing of transparent and translucent plastic materials, energy is added, providing free movement of polymer chains. Close packing and increased hydrogen bonding occurs, resulting in alignment of carbon chains and increased crystalline structure. Differences between random, oriented, and crystalline configuration affect both light absorption and transmission in these materials. A seal sample placed between 2 polarizing filters is first illuminated by polarized light. To enhance color changes resulting from differences in crystalline structure, rotate the other filter to block most of the transmitted light. Inspect visually to determine degree of crystalinity within fused seals. Uniform crystalinity, seen as uniform color tone along the inner edge of the primary seal, is one indicator of fusion. Areas that are not fused appear as a different color. Colors differ with materials and thickness.

1. Materials

   Light bulb, white, 40, 75, 100 W
   Polarized camera filters, 2 each
   Frame to hold filters and permit free rotation of both
   filters in line with light bulb and sample

2. Procedure

   Obtain a clean transparent seal sample. Turn on light. Place seal sample between polarized filters. Rotate one filter to obtain maximum difference in color between fused seal and nonseal area. Examine fused seal area for uniformity.

d. **Visible light**. The objective is to detect holes in packages by sensing transmitted and reflected visible light. Package is placed over low-wattage light bulb in darkened room to enhance visual inspection. Aluminum foil will block all light transmission except where holes and flexcracks in foil are present. Close inspection is required to determine whether other lamina overlay holes in foil layer. Dye testing is required to establish presence or absence of minute holes. Chemical etching may be used to remove materials external to polyolefin seals. Magnification of etched seals with backlighting aids inspection.

1. Materials

   Light bulb
   Scissors
   Sink with running water
   Paper towels
   Darkened room
   Indelible marking pen
   Dye (optional)

2. Procedure

Remove contents, wash, and dry container. Inspect package for light leaks. Mark location of light leaks with a marking pen; draw a circle around the defect location. Closely examine defects for presence of holes through all layers. Use dye test to verify presence or absence of holes.

3. Results

   Positive. A hole through all layers is detected in a package.

   Negative. No light leaks are detected.

   False positive. A hole in the foil layers permits light to pass, but no holes exist in overlying layers and hermetic barrier is maintained.

   False negative. A hole through all layers is not aligned so that light can be transmitted.

13. Machine vision (5)

    The objective is to detect holes in hermetic packages by computer evaluation of images with previously defined patterns of acceptance. This system is designed to eliminate visual inspection of packages. Packages are positioned before a camera to present a consistent pattern. The video image obtained is digitized. Both grayscale and color density may be evaluated. The computer compares coded patterns with acceptable patterns stored in memory. Some systems evaluate one image at a time. Others use parallel computers to evaluate different segments of the video image in less time. Patterns that do not match the acceptance criteria are rejected and the package is automatically rejected from the production line.

    a. Materials

       Video imaging system
       Computer with stored images for acceptance criteria
       Strobe light (optional)
       Packages

    b. Results

       Positive. Image does not match acceptance criteria.

       Negative. Image matches acceptance criteria.

       False positive. Image was not presented to camera correctly and does not match acceptance criteria.

       False negative. Acceptance criteria include defects.

14. Proximity devices (5)

    The objective is to detect holes by measuring changes in the shape of hermetically sealed packages as a function of time. The position of a package containing metal may be established by the strength of a magnetic field, detected with a galvanometer. By comparing 2 readings as a function of time, a determination can be made as to whether the shape of a package has changed.

a. Materials

Proximity detection system
Computer with stored acceptance criteria
Packages

b. Procedure

Compare multiple packages to a standard value. Fix limits of acceptance or alter automatically by computing a running average and standard deviation. Packages displaying stronger or weaker disturbances to a magnetic field sensed by a galvanometer may fall outside of the limits of acceptance. Mark these packages for removal from packaging line.

Read magnetic fields of single packages at one location and, after a period of time, make a second reading at a downstream location. If shape of container changes, mark package for removal from packaging line. Confirm with dye testing to locate holes in packages.

c. Results

Positive. Disturbance of magnetic field exceeding limits of acceptance.

Negative. Disturbance of magnetic field within limits of acceptance.

False positive. External disturbance of magnetic field or imprecise positioning of package resulted in values that exceeded limits of acceptance.

False negative. Distortion of package sufficient to cause disturbance of magnetic field outside normal range of acceptance.

15. Seam scope projection (5)

The objective is to measure critical dimensions in the closure profile of plastic packages. Packages are cut in cross-section to reveal all components in their proper thickness and relative position. The cut edge is magnified with a projector to aid measurement and visual inspection.

a. Materials

Knife, saw, or scissors
Microprojector
Micrometer, calipers, ruler, or measurescope

b. Procedure

Cut directly across seal or closure with knife, saw, or scissors and remove section containing adjacent material. Magnify cross section. Compare observed dimensions with criteria for acceptance or rejection provided by manufacturer of package or closure machine. Accept or reject sample.

c. Results

Positive. Dimensions of sample exceed limits of criteria for acceptance.

Negative. Dimensions within limits of criteria for acceptance.

False positive. Magnification with incorrect scale or measuring error results in rejection of acceptable sample.

False negative. Measuring error results in acceptance of defective sample.

16. Sound (5)

Ultrasonic. The objective is to passively sense air moving through small orifices in packages possessing internal vacuum or pressure by monitoring the presence or absence of high-frequency sound waves.

a. Materials

Microphone
Audiofilters
Oscilloscope with alarm system
Packages

b. Procedure

Place packages in a chamber to eliminate external disturbances and subject to changes in external pressure. Air movement through small holes in package wall generates ultrasonic sound waves. A microphone senses the vibration. Audiofilters eliminate all frequencies except those of interest.

c. Results

Positive. Package exhibits ultrasonic whistling sound, indicating a leak is present, permitting air to enter or exit package.

Negative. No sound is emitted by package within range of frequencies monitored.

False positive. Background noise occurred within range monitored.

False negative. Hole does not emit a noise within the range monitored, or hole was occluded by moisture or food.

Echo. The objective is to actively sense the frequency of echoes in hermetically sealed containers. When a package possessing a vacuum is tapped, the tightness of the package creates a sound that is audibly different from that of the same package without a vacuum. Two changes can be monitored: frequency and amplitude. Changes in frequency (vibrations per second) are recognized as differences in tone (pitch). Changes in amplitude are recognized as 2 relative difference in volume. Loss of hermetic integrity will result in microbial growth within the contents of a food package during incubation. Changes in sound accompany changes in viscosity. Consequently, this method may be used as a nondestructive test for a number of product/package combinations.

a. Materials

Control sample
Samples to be evaluated
Tapping device (electronic device or unsharpened pencil to be used like a drumstick)
Incubator

b. Procedure

Obtain sample packages, either newly packed or incubated, and a control package (known to be properly sealed) containing the same product as sample packages. Tap the section of the package covering that is taut. Listen to the echo for differences between packages. Commercial devices are available that electronically monitor the echos, allowing for a less subjective determination.

c. Results

Positive. Package displays audibly different sound, indicating loss of hermetic integrity.

Negative. Package resonates at same frequency as control package.

False positive. Differences in vacuum level or fill volume create different sounds in test packages.

False negative. Audible difference between control package and test package cannot be differentiated.

17. Tensile strength (5)

The objective is to measure the tensile strength required to cause separation of peelable or fused seals. A section of a seal is obtained by cutting a 1/2 or 1 inch strip perpendicular to the seal edge. The strip is then clamped by opposing grippers and pulled at constant speed and defined angle until failure is obtained. The peak force required to fully separate the 2 halves is recorded as the strength of the seal.

a. Materials

Sample packages
Sample cutting apparatus
Scissors (sample dimensions are critical to precision)
Tensile strength testing device

b. Procedure. **See** ASTM D-882 - Standard test methods for tensile properties of thin plastic sheeting (9).

Remove representative sample from production line. Cut open sample and remove contents. Do not disturb seal to be tested. Cut a segment of the seal to produce a test strip. Test strip must be cut perpendicular to the seal to be tested. Secure both ends of test strip in separate clamps. With screwdriver, move one screw clamp away from the other, creating a 180° separation of the seal. Observe force required to fully separate seal. Fixtures are required to hold samples at angles different from 180°.

c. Results

Positive. Sample separates at peak tensile strength less than established standard.

Negative. Sample separates uniformly at peak tensile strength greater than or equal to established standard.

False positive. Sample separates at peak tensile strength less than established standard because of equipment miscalibration or greater separation speed of jaws.

False negative. Sample separates at tensile strength greater than or equal to established standard. However, a different portion of the same sample failed at a tensile strength less than the standard.

18. Vacuum testing (5)

    The objective is to cause the movement of air out of a sealed container through leaks by using external vacuum within a testing chamber. Closed packages are placed inside a sealed testing chamber and vacuum is created to cause movement of air through leaks in the packages. Deflection of the package may be measured as a function of time to determine whether leakage has occurred. If vacuum chamber contains water, bubbles from holes in packages may be observed.

    a. Materials

       Bell jar (glass or plastic) with tight-fitting lid
       Water to cover package within bell jar
       Weighted fixture to keep package below water level during test
       Vacuum pump
       Vacuum gauge
       Valve
       Grease for tight gasketing of lid on chamber

    b. Procedure

       Obtain representative sample from production line. Place one sample inside vacuum chamber. Evacuate chamber. Observe package swelling and any movement of air (bubbles) or product through holes that may be present or may have developed. When vacuum is released, observe packages to determine if original shape is retained or if atmospheric pressure causes sample to appear slightly crushed.

    c. Results

       Positive. Leak in test package causes air or product to escape through holes in container. Container ruptures or lid separates because of weak closure. When vacuum is released, package appears distorted or crushed by atmospheric pressure.

       Negative. Package distorts under vacuum but no loss of product or air is observed. When vacuum is released, package assumes its original configuration.

       False positive. Air clinging to surface of package or within paper laminates is mistaken for bubbles emitting from a defect.

       False negative. Food particles prevent movement of air out of a hole in container while under vacuum.

19. Visual inspection (5)

    The objective is to visually observe defects in food packages. Representative samples are obtained from production line. External surfaces are examined for holes, abrasions, delamination, and correct design. Critical dimensions are measured and observations recorded.

    a. Materials

Strong light without glare, for visual inspection of packages
Measuring devices, such as ruler, calipers, micrometer
Scissors or knife

b. Procedure

Refer to examination procedures for paperboard packages, flexible pouches, plastic packages with heat-sealed lids, and plastic cans with double-seamed metal ends.

c. Results

Positive. Visually detected defect.

Negative. No visually detected defects.

False positive. Visual identification of defect not actually present.

False negative. Defect is present, but not visually detected.

Acknowledgments

We thank the American Can Co. for permission to include various useful items of information. We are grateful to Donald E. Lake, George A. Clark, and Arnold A. Kopetz of American Can Co. for assisting our development of this project in their laboratories.

We also thank the following individuals for reviewing the manuscript and contributing many valuable suggestions: Keith A. Ito, National Food Processors Association; Raymond C. Schick and Robert A. Drake, Glass Packaging Institute; Irvin J. Pflug, University of Minnesota; Fred J. Kraus, Continental Can Co.; Robert M. Nelson, W.R. Grace & Co.; Don A. Corlett, Jr., Del Monte Corp.; Harold H. Hale and J. W. Bayer, Owens-Illinois; Charles S. Ochs, Anchor Hocking; Rachel A. Rosa, Maine Sardine Council; Melvin R. Wadsworth, Consultant; Tedio Ciavarini, U.S. Army Natick R&D Laboratories; Robert A. Miller, U.S. Department of Agriculture; Helen L. Reynolds (retired), Lois A. Tomlinson, Patricia L. Moe, and Dorothy H. Hughley, Technical Editing Branch, FDA; and Thomas R. Mulvaney, Division of Food Chemistry and Technology, FDA.

We acknowledge the following individuals for their valuable comments specific to flexible and semirigid containers: Pete Adams, International Paper Co.; Kent Garrett, Continental Can Co.; Donald A. Lake, Roger Genske, and Stan Hotchner, American National Can Co.; Charles Sizer, Tetra Pak International, Sava Stefanovic, Ex-Cell-O; and Clevel Denny, Jean Anderson, Nina Parkinson, and Jenny Scott, National Food Processors Association.

Hypertext Source: Bacteriological Analytical Manual, 8th Edition, Revision A, 1998. Chapter 22.
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U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition

Bacteriological Analytical Manual *Online*

January 2001

Chapter 22D
Examination of Containers for Integrity

Glossary and References

Authors

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Glossary

BASE PLATE PRESSURE. Force of the base plate that holds the can body and end against the chuck during the double seaming operation. In general, it has the following effect on the seam formation: low pressure, short body hook; high pressure, long body hook.

BODY - The principal part of a container, usually the largest part in one piece comprising the sides. The body may be cylindrical, rectangular, or another shape.

BODY HOOK - The flange of the can body that is turned down in the formation of the double seam.

BOTTOM SEAM - Double seam of the can end put on by the can manufacturer, also known as factory end seam.

CABLE CUTS - Cuts or grooves worn into can ends and bodies by cables of the runway conveyor system.

CAN, SANITARY - Full open-top 2-piece drawn can and 3-piece can with double seamed bottom. Cover or top end is attached with a double seam by the packer after filling. Ends are compound-lined. Also known as packer's can or open-top can.

CANNER'S END - **See** packer's end.

CAP TILT - Cap should be essentially level with transfer bead or shoulder.

CHIPPED GLASS FINISH - Defect in which a piece of glass has broken away (chipped) from the finish surface.

CHUCK - Part of a closing machine that fits inside the end countersink and acts as an anvil to support the cover and body against the pressure of the seaming rolls.

CHUCK WALL - Part of the can end that comes in contact with the seaming chuck (Fig. 2).

COCKED CAP - Cap not level because cap lug is not properly seated under glass lug.

CODE CUT - Fracture in the metal of a can end caused by improper code embossing.

COLD WELD - Weld appears narrower and lighter than normal and may be scalloped. Fails the pull test, possibly exhibiting a zipper or sawtooth type of failure.

CONTAMINATION IN WELD AREA - Any visible burn at one or more points along side seam.

COMPOUND - Sealing material consisting of a water or solvent dispersion or solution of rubber and placed in the curl of the can end. The compound aids in producing a hermetic seal by filling spaces or voids in the double seam

COUNTERSINK DEPTH - Measurement from top edge of double seam to end panel adjacent to chuck wall.

COVER - **See** packer's end.

COVER HOOK - The part of the double seam formed from the curl of the can end. Wrinkling and other visual defects can be observed by stripping off the cover hook.

CRACKED GLASS FINISH - Actual break in the glass over the sealing surface of the finish. Also known as split finish.

CRAWLED LAPS - Occurs when two layers of metal are bent and the outer layer looks shorter because it has a greater radius to traverse than the inner layer, which has a smaller radius, perhaps being bent almost double. Also known as creep.

CROSS-OVER - The portion of a double seam at the juncture with the side seam of the body.

CROSS-SECTION - A section cut through the double seam for the purpose of evaluating the seam.

CRUSHED LUG - Lug on cap forced over glass lug, causing the cap lug not to seat under glass lug.

CURL - Extreme edge of the cover that is turned inward after the end is formed. In metal can double seaming, the curl forms the cover hook of the double seam. For the closure for glass containers, the curl is the rolled portion of metal at the bottom of the closure skirt (may be inward or outward).

CUTOVER - A break in the metal at top of inside portion of double seam caused by a portion of the cover being forced over the top of the seaming chuck. This condition usually occurs at the cross-over. Also known as a cut through by some can manufacturers. These manufacturers refer to a cutover as the same condition without the break.

CUT THROUGH - Gasket damage caused by excessive vertical pressure.

DEADHEAD - An incomplete double seam resulting from the seaming chuck spinning in the end's countersink during the double seaming operation. Also known as a spinner, skidder, or slip.

DELAMINATION - Any separation of plies (laminate materials) that results in questionable pouch integrity.

DOUBLE SEAM - Closure formed by interlocking and compressing the curl of the end and the flange of the can body. It is commonly produced in 2 operations. The first operation roll preforms the metal to produce the 5 thicknesses or folds; the second presses and flattens them together to produce double seam tightness.

DROOP - Smooth projection of the double seam outside and below the bottom of the normal seam. Usually occurs at the side seam lap area.

FACTORY END - **See** manufacturer's end.

FALSE SEAM - Double seam where a portion of the cover hook and body hook are not interlocked, i.e., no hooking of body and cover hooks.

FINISH - That part of the glass container for holding the cap or closures.

FLANGE - Outward flared edge of the can body cylinder that becomes the body hook in the double seaming operation. For weld cans, any flange crack at or immediately adjacent to the weld is a major defect.

FLEXIBLE CONTAINER - A container, the shape or contour of which, when filled and sealed, is affected by the enclosed product.

HEAVY LAP - A lap containing excess solder. Also called a thick lap.

HOOK, BODY - **See** body hook.

HOOK, COVER - **See** cover hook.

IMPROPER POUCH SEAL - A defect (e.g., entrapped food, grease, moisture, voids, or fold-over wrinkles) in that area of the closure seal that extends 1/8 inch vertically from edge of seal on food product side and along full length of seal.

IRREGULAR WELD WIDTH - Any obvious irregularity in weld width along length of side seam.

JUMPED SEAM - **See** jumpover.

JUMPOVER - Double seam that is not rolled tight enough adjacent to the cross-over; caused by jumping of the seaming rolls at the lap.

JUNCTURE - The junction of the body side seam and the end double seam, or that point where the 2 seams come together. Also known as the cross-over.

KNOCKED-DOWN FLANGE - Common term for a false seam where the bottom of the flange is visible below the double seam. A portion of the body flange is bent back against the body without being engaged with the cover hook.

LAP - The section at the end of the side seam consisting of 2 layers of metal bonded together. As the term implies, the 2 portions of the side seam are lapped together to allow for the double seam, rather than hooked, as in the center of the side seam.

LID - **See** packer's end.

LIP - Projection where the cover hook metal protrudes below the double seam in one or more "V" shapes. Also known as a vee.

LUG CAP - Closure with raised internal impressions that intermesh with identical threads on the finish of the glass container. It is a closure with horizontal protrusions that seat under angled threads on the glass container finish.

MANUFACTURER'S END - End of the can that is attached by the can manufacturer.

NOTCH - Small cut-out section in the lap designed to facilitate the formation or the body hook at cross-over.

OPEN LAP - A lap that is not properly soldered or has failed by separating or opening because of various strains in the solder.

OVERLAP - Distance the cover hook laps over the body hook. Any observable loss of overlap along the side seam is a critical defect.

PACKER'S END - End of the can attached and coded by the food packer. Also known as the canner's end.

PLATE - General term for tinplate, aluminum, and the steel sheets from which cans are made. It is usually tin plate, which is black plate with tin applied to it.

PRESSURE RIDGE - Impression (chuck impression) around the inside of the can body directly opposite the double seam.

PULL-UP - Term applied to distance measured from the leading edge of the closure lug to the vertical neck ring seam.

SAWTOOTH - Partial separation of the weld side seam overlap at one or more points along the seam. If observed after performing the pull test, it is considered a critical defect.

SEAM NARROWING - A steadily visible narrowing of the weld at either end of the weld side seam is a critical defect.

SEAM THICKNESS - Maximum dimension of double seam measured across or perpendicular to layers of seam.

SEAM WIDTH (LENGTH OR HEIGHT) - Maximum dimension of double seam measured parallel to folds of seam.

SECURITY - Residual clamping force remaining in the closure application when gasket has properly seated after processing and cooling.

SEMIRIGID CONTAINER - A container, the shape or contour of which, when filled and sealed, is not affected by the enclosed product under normal atmospheric temperature and pressure, but which may be deformed by external mechanical pressure of less than 10 psi (0.7 kg/cm^2) (i.e., normal firm finger pressure).

SIDE SEAM - The seam joining the 2 edges of the body blank to form a can body.

SKIDDER - Can with incompletely finished double seam because the can slipped in the seaming chuck. In this defect, part of the seam will be incompletely rolled out. The term has the same meaning as deadhead when referring to seamers that revolve the can. Also known as a spinner.

SOFT CRAB - Colloquial term used to describe a breakdown in the packer's can resulting in a hole between end and body.

SPINNER - **See** deadhead and skidder.

STRIPPED CAP - Lug closure applied with too much torque, which causes lugs to pass over glass lugs. May have vacuum but has no security value.

TIGHTNESS - Degree to which the double seam is compressed by the second operation roll. Tightness is determined primarily by the degree of freedom from wrinkles in the cover hook. Tightness rating is a percentage that ranges from 100 to 0, depending on the depth of the wrinkle: 100% indicates no wrinkle and 0% indicates a wrinkle extending completely down the face of the cover hook. A well-defined continuous impression around the circumference of the can in the double seam area indicates a tight seam. This impression is known as a pressure ridge.

TOP SEAM - Top of packer's end seam.

UNEVEN HOOK - Body or cover hook that is not uniform in length.

WELD CRACK - Class I corrosion products plus any observable seam crack, and any cracks that extend 25% or more across the width of the weld at any point along the weld seam are considered critical defects.

WELD PROTRUSION - Protrusion of the weld in excess of 1/16 inch beyond the leading or trailing edge of the can body.

WRINKLE (COVER HOOK) - A waviness occurring in the cover hook from which the degree of double seam tightness is determined.

ZIPPER - Gross separation of the side seam overlap along all or any part of the side seam. If observed during pull test, it is a critical defect.

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*Authors:Rong C. Lin, Paul H. King, and Melvin R. Johnston

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updated by bap/kwg/cjm 2001-OCT-24

CHAPTER 10. EXAMINATION OF HEAT PROCESSED, HERMETICALLY SEALED (CANNED) MEAT AND POULTRY PRODUCTS

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10.1 Introduction

Thermally processed meat and poultry products in hermetically sealed containers include both shelf stable products as well as those that must be kept refrigerated (i.e. perishable product). There are a wide variety of packages designed to totally exclude air. These include traditional rigid containers, such as metal cans and glass jars; semi-rigid containers such as plastic cans, bowls and trays; and flexible containers such as retortable pouches and bags. The microbiological examination of these food products requires knowledge and a thorough understanding of food microbiology, food science, and packaging technology and engineering. Many books and scientific articles are available on the processing and the laboratory testing of these products. Individuals who perform these analyses should be familiar with the current procedures and methods. Some of these references are listed in section 10.6.

10.2 Important Terms and Concepts

a. Shelf Stability (commercial sterility):

The term "shelf stability" traditionally has been used by the Agency and is synonymous with the terms "commercial sterility" or commercially sterile". Shelf stability is defined in CFR title 9, part 318, Subpart G, 318.300 (u) of the Food Safety and Inspection Service (meat and poultry) USDA regulations. Shelf stability (commercial sterility) means "the condition achieved by application of heat, sufficient, alone or in combination with other ingredients and/or treatments, to render the product free of microorganisms capable of growing in the product at non-refrigerated conditions (over 50°F, 10°C) at which the product is intended to be held during distribution and storage". Such a product may contain viable thermophilic spores, but no mesophilic spores or vegetative cells. These products usually are stable for years unless stored at temperatures of 115-130°F (46-55°C) which may allow swelling or flat sour spoilage to occur because of germination and growth of the thermophilic spores. Many low acid canned meat/poultry products contain low numbers of thermophilic spores. For this reason, samples of canned foods are not routinely incubated at 55°C because the results usually will be confusing and provide no sound information. Canned food lots that are to be held in hot vending machines or are destined for tropical countries are exceptions to this rule.

b. Hermetically Sealed Container:

A container that is totally sealed to prevent the entry or escape of air and therefore secure the product against the entry of microorganisms.

c. Adventitious contamination:

Adventitious contamination may be defined as the accidental addition of environmental microorganisms to the contents of a container during analysis. This can occur if the microbiologist has not sterilized the puncture site on the container surface or the opening device adequately, or is careless in manipulating equipment or cultures. Strict attention to proper procedures is required to avoid this type of contamination.

d. Cured Meat/Poultry Products:

Many canned meat/poultry products contain curing salts such as mixtures of sodium chloride and sodium nitrite. When included in a canned meat/poultry product formulation, sodium chloride and sodium nitrite inhibit the outgrowth of bacterial spores, particularly clostridial spores. Lowering the pH and increasing the sodium chloride concentration enhance the inhibitory action of sodium nitrite. Thus, most canned, cured meat/poultry products are minimally heat processed and are rendered shelf stable by the interrelationship of heat, pH, sodium chloride, sodium nitrite and a low level of indigenous spores. Spoilage in canned cured meat/poultry products attributed to underprocessing is rare. When it occurs, it is usually the result of improper curing rather than inadequate heating. The heat processes used for canned, cured, shelf stable meat/poultry products are unique in that they usually

are not designed to destroy mesophilic bacterial spores but merely to inhibit their outgrowth.

e. Uncured Meat/Poultry Products:

Canned uncured meat/poultry products are given a much more severe heat treatment than canned cured products. The treatment given to canned uncured meat/poultry products is commonly referred to as a "full retort cook".

10.21 Classification of Containers

a. Metal and plastic cans with metal double sealed end(s):

Cans must be at room temperature for classification. Cans are classified as NORMAL if both ends are flat or slightly concave; FLIPPER when one end of a normal-appearing can is struck sharply on a flat surface, the opposite end "flips out" (bulges) but returns to its original appearance with mild thumb pressure; SPRINGER if one end is slightly convex and when pressed in will cause the opposite end to become slightly convex; SOFT SWELL if both ends are slightly convex but can be pressed inward with moderate thumb pressure only to return to the convex state when thumb pressure is released; HARD SWELL if both ends are convex, rigid and do not respond to medium hard thumb pressure. A can with a hard swell will usually "buckle" before it bursts. Hard swollen cans must be handled carefully because they can explode. They should be chilled before opening except when aerobic thermophiles are suspected. Never flame a can with a hard swell, use only chemical sanitization.

b. Glass jars:

Classify glass jars by the condition of the lid (closure) only. Do not strike a glass jar against a surface as you would a can. Instead shake the jar abruptly to cause the contents to exert force against the lid; doing so occasionally reveals a flipper. Scrutinize the contents through the glass prior to opening. Compare the contents of the abnormal/questionable jar with the contents of a normal jar (e.g., color, turbidity, and presence of gas bubbles), and record observations.

c. Flexible containers (pouches):

Pouches usually are fabricated from laminates consisting of two or more layers (plies) of material. Retortable pouches are the most common type of flexible container used for canned, shelf-stable products. Most pouches are 3-ply: an outer ply of polyester film, a middle ply of aluminum foil, and an inner ply of polypropylene. The polyester functions as the heat resistant, tough protective layer; the aluminum foil as a moisture, gas and light barrier; and the polypropylene functions as the food contact surface and the film for heat sealing. The polypropylene also provides added strength, and protects the aluminum film against corrosion by the food product. Not all retortable pouches contain an aluminum foil ply. Pouches and paperboard containers used for non-retorted, shelf stable products (e.g. pH-controlled and hot-filled product) or aseptically filled containers may be quite different from retortable pouches in construction. Pouches and other flexible containers are either factory-formed and supplied ready for filling, or are formed by the processor from roll stock.

10.22 Container Abnormalities

To determine the cause of product abnormalities, both normal and abnormal containers from the same production lot should be examined. All observed microbiological results should be correlated with any existing product abnormalities (Section 10.46 a) such as atypical pH, odor, color, gross appearance, direct microscopic examination, etc. as well as the container evaluation findings (Section 10.46, b,c). Non-microbial swells (such as hydrogen swells) are usually diagnosed by considering all product attributes because culture results are negative or insignificant.

a. Metal cans, plastic containers and glass jars:

Conditions such as "swells" are defined in Section 10.21 (a). The defects and abnormalities associated with these containers have been extensively detailed by others. Rather than include extensive descriptions for each of them in this section, the analyst is referred to several excellent references presented in Section 10.6. These references provide detailed information on the numerous defects and abnormalities that can occur with these containers. The analyst should be familiar with these conditions before beginning any analysis of a defective or abnormal container. The effect of processing failures, such as overfilling, closure at low temperature or high altitude; container damage; and storage temperature changes, must be taken into consideration as the analyst evaluates possible causes for the defect or abnormality. For quick reference, a Glossary of Terms is provided in Appendices I and II.

b. Pouches:

A Glossary of Terms for these containers can be found in Appendix III. It is imperative to follow uniform procedures (Section 10.46,c) when examining defective or abnormal pouches. The APHA, 1966 reference (Section 10.6) provides detailed information on the analysis of pouch defects.

10.3 Analysis of Containers

The number of containers available for analysis will vary. However, it is important that the number be large enough to provide valid results. Unless the cause of spoilage is clear cut, at least 12 containers should be examined. With a clear cut cause, one half this number may be adequate. If abnormal containers have been reported, but are not available for analysis, incubation of like-coded containers may reproduce the abnormality. The "normal" cans should be incubated at 35°C for 10 days prior to examination. Incubation temperatures in excess of 35°C should not be used unless thermophilic spoilage is suspected. This incubation may reproduce the abnormality, and thereby document progressive microbiological changes in the product. Examine the incubated cans daily. Remove any swells from the incubator as they develop and culture them along with a normal control. After the 10 day incubation period, cool the cans to room temperature and reclassify. Swollen, buckled and blown containers should NOT be incubated but analyzed immediately along with a normal control. All steps in the analysis should be conducted in sequence according to protocol.

10.31 Physical Examination of Metal and Plastic Containers

a. Before opening, visually examine the double end seam(s) and side seam (if present) for structural defects, flaws and physical damage; record pertinent observations.

b. Run thumb and forefinger around the inside and outside of the double seams for evidence of roughness, unevenness, or sharpness.

c. Using a felt marker, make three slash marks at irregular intervals across the label and the code-end seam. Remove the label and copy any label code-numbers to the side of the container along with a mark indicating the code end of the can. Correlate any stains on the label with suspicious areas on the side panel (can body) by returning the label to its exact position relative to the slash marks.

d. Examine all non-seam areas of the can and ends for any evidence of physical damage. If the code is embossed, carefully examine it for any evidence of puncturing. Circle any suspect and/or defective areas with an indelible pen and record this information on the work sheet. For an illustration of these defects see the APHA, 1966 reference (Section 10.6).

10.32 Physical Examination of Glass Jars

a. Before opening, remove the label and, using a good light source such as a microscope light, examine the container for apparent or suspected defects. Microorganisms may enter jars through small cracks in the glass. Make note of any residue observed on the outer surface and the location.

b. Test the closure gently to determine its tightness. After sampling has been completed, examine the lid (closure) and the glass rim (sealing surface) of the jar. Look for flaws in the sealing ring or compound inside the closure; for food particles lodged between the glass and the lid; and for chips or uneven areas in the glass rim.

10.33 Physical Examination of Pouches

a. Pouches should be examined using an illuminated 5X magnifier.

b. Hold the pouch in one hand, examine it for abnormalities, such as swelling, leakage, overfilling, and defects such as delamination and severe distortion. Record any pertinent observations.

c. Hold the pouch at both ends and examine both sides for noticeable cuts, cracks, scratches, food residues, punctures, missing labels, foreign materials or other abnormalities.

d. Carefully examine all seal areas for incomplete fusion. Pay attention to such defects as entrapped product, wrinkles, moisture and foreign material in the seal. Particular attention should be given to the final or closing seal.

e. All actual and suspected defects should be circled with an indelible marking pen for more detailed examination after all sampling is complete.

10.4 Analysis of the Contents

Processing errors occur infrequently with canned products, but may result in the improper processing of large quantities of product. Swollen cans, for instance, may signal a microbial spoilage problem. Each abnormality in a "canned" product must be investigated thoroughly and correctly. The following procedures should be followed carefully.

10.41 Equipment and Material

a. Incubators 20°, 35° & 55 ± 1°C
b. Vertical laminar flow hood
c. Microscope, microscope slides & cover slips
d. pH meter equipped with a flat electrode
e. Felt-tip indelible marker
f. Illuminated 5X magnifier
g. Sterile Bacti-disc cutter or other suitable opening device
h. Large, sterile plastic or metal funnel
i. Large autoclavable holding pans
j. Sterile towels
k. Clean laboratory coat and hair covering(s)
l. Sterile wide bore pipettes or 8 mm glass tubing with cotton plugs
m. Sterile serological pipettes with cotton plugs
n. Safety aspiration device for pipetting (e.g. pro-pipette)
o. Sterile petri dishes, beakers, and large test tubes
p. Sterile triers, cork borers, scissors, knives and 8" forceps. Triers can be made from the tail piece of

chrome finish sink drain pipe, 1 1/2" in diameter, flanged on one end and sharpened on the other end.

q. Sterile cotton swabs with wooden handles in glass test tubes, one per tube, or commercially sterilized swabs in paper sleeves
r. Sterile gloves
s. Small wire basket to hold pouches in an upright position
t. Seam analysis tools (micrometer, calipers, saw, countersink meter, metal plate scissors, nippers).
u. Vacuum gauge
v. Light source such as a microscope light
w. Sonic cleaning apparatus
x. Transparent acrylic plate with a hole and tubing to a vacuum source
y. Bituminous compound in strips (tar type strips usually available in hardware stores) stored in the 35°C incubator
z. Seamtest Type U (Concentrate), Winston Products Co., Inc Box 3332, Charlotte, N.C., Dilute 1:300 with distilled water for use.
aa. Wooden dowels, 1/2" diameter
bb. Gas cylinder clamp
cc. Abrasive chlorinated cleaner or a scouring pad

10.42 Media and Reagents

a. Modified Cooked Meat Medium (MCMM) STEAM JUST BEFORE USE
b. Brom Cresol Purple Broth (BCPB) or Dextrose Tryptone Broth
c. Plate Count Agar
d. APT Agar
e. KF Broth
f. Strong's Sporulation Medium
g. Gram stain reagents
h. Spore stain
i. Dishwashing detergent
j. Chlorine solution, (Commercial Bleach with approximately 5% available chlorine diluted 1:100 with 0.5 M phosphate buffer, pH 6.2)

10.43 Preparation

a. The Analyst

i. The analyst must wear a clean full length laboratory coat.

ii. Hair must be completely covered with a clean, disposable operating room type hair cover. A surgical face mask should be worn; if the analyst has facial hair such as beards and sideburns, the mask must completely cover it.

iii. Hands, forearms and face should be washed with germicidal soap and water.

iv. The analyst should wear safety glasses or goggles, preferably in combination with some type of face shield when opening swollen cans or cans suspected of being contaminated with *Clostridium spp*.

b. Preparing the Environment

i. If possible, the analysis should be done in a vertical laminar flow hood. If a hood is not available, the area used must be clean and draft-free.

ii. Flat cans should be opened in the laminar flow hood.

iii. Swells may explode or spew, therefore they should be opened outside the hood and the container transferred to the hood only after it is opened and all gas released.

iv. Disinfect the work surface before beginning any work.

c. Preparing Metal Cans Prior to Opening

i. Scrub the non-coded end of the metal can with abrasive cleaner or a scouring pad. This removes bacteria-laden oil and protein residues. Rinse well with tap water. Cans with an "easy open" end usually are coded on the bottom. Record the code exactly and prepare the code end as described above.

ii. Sanitize the cleaned end with chlorine solution (Section 10.42 j) either by placing clean tissues over the end and saturating it with chlorine solution or by immersing the end in a shallow pan containing the solution. Allow a 15-minute contact time; wipe dry with sterile towels or tissue. (An alternative sanitization procedure which can be used on Normal-appearing cans ONLY is to heat the entire can surface using a laboratory burner or a propane torch until the metal becomes slightly discolored from the heat.) Proceed as outlined in Section 10.44.

d. Preparing Jars Prior to Opening

i. Scrub the surface of the jar closure with abrasive cleaner or scouring pads. Rinse well with tap water.

ii. Sanitize the jar closure with chlorine (Section 10.42 j) either by placing clean tissues over the closure and saturating it with chlorine solution or immersing the closure in a shallow pan containing the solution. Allow a 15-minute contact time; wipe dry with sterile towels or tissue.

e. Preparing Plastic Containers Prior to Opening

i. Scrub the bottom surface of the container with abrasive cleaner or scouring pads. Rinse well with tap water.

ii. Sanitize the bottom with chlorine solution (Section 10.42 j) by placing clean tissues over the bottom and saturating it with chlorine or immersing the bottom of the container in a shallow pan containing the solution. Allow a 15-minute contact time; then wipe dry with sterile towels or tissue.

f. Preparing Normal and Abnormal-Appearing Flexible Retortable Pouches Prior to Opening

i. Clean the outside of the pouch with a sanitizer and rinse well.

ii. Sanitize the entire pouch in a suitably sized pan with chlorine solution (Section 10.42 j). Allow a 15-minute contact time; then wipe dry with sterile towels or tissue.

g. Preparing Swollen Cans Prior to Opening

i. Scrub the non-coded end of the chilled metal can with an abrasive cleaner or a scouring pad. This removes bacteria-laden oil and protein residues. Rinse well with tap water.

ii. Sanitize the cleaned end with chlorine solution (Section 10.42 j) either by placing clean tissues over the end and saturating it with chlorine solution or immersing the end in a shallow pan containing the solution. Allow a 15-minute contact time; then wipe dry with sterile towels or tissue.

h. Opening Devices

i. The preferred type of opening device is the adjustable Bacti-disc cutter (available from the Wilkens-Anderson Company, 4525 W. Division Street, Chicago, IL.; a similar device is available from the American National Can Co., 1301 Dugdale Rd., Waukegan, IL. Order Number WT2437). The opener should be pre-sterilized or heated in a flame to redness. If this type of device is not available, individually packaged and heat sterilized regular, all metal, kitchen-type can openers may be used. The advantage of the Bacti-disc type opener is that it causes no damage to the double seam (simplifying later examination) and the size of the opening can be adjusted.

ii. Sometimes a large can (e.g. a #10 size can) may be difficult to open. The analyst could be exposed to pathogens or their toxins if the can is not properly secured. The container can be held tightly with a gas cylinder clamp secured in an inverted position in a shallow metal drawer or tray lined with a large disposable poly bag or an autoclavable tray to contain any overflow. Place the #10 container against the clamp and secure the strap. Rotate the can and continue cutting until the opening is completed. The metal tray and liner may be removed for cleaning and the clamp is autoclavable.

10.44 Sampling

a. **Normal-Appearing Metal Cans and Jars with Metal Closures**

   i. Prepare the area and can or jar closure as described in section 10.43.

   ii. Shake the container to distribute the contents.

   iii. Use a sterilized opening device to cut the desired size entry hole. Transfer samples immediately to the selected media with a sterile pipette or swab and proceed as outlined in Section 10.45.

   iv. Aseptically transfer a representative amount of the product to a sterile test tube or other sterile container as a working reserve. Use a pipet or sterile spoon to accomplish this.

   v. Caution: The contents from overfilled cans may flow out of the hole onto the surrounding lid surface at the time of opening. This material can then drain back into the can when the opening device is removed. Should this occur, terminate the analysis.

b. **Normal and Abnormal-Appearing Plastic Containers**

   i. Immediately after removing the container from the chlorine solution and wiping the excess liquid, use a very hot, sterilized opening device to cut the desired size entry hole. Transfer samples immediately to the selected media with a sterile pipette or swab and proceed as outlined in Section 10.45.

   ii. Aseptically transfer a representative amount of the product to a sterile test tube or other sterile container as a working reserve. Use a pipet or sterile spoon to accomplish this.

c. **Normal and Abnormal Appearing Flexible Retortable Pouches**

   i. Place the disinfected pouch upright in a sterile beaker and cut a two inch strip about one quarter of an inch under the seam edge using a sterile scissors. If possible, use a pipette to remove some of the pouch contents, otherwise use a swab. Transfer the samples immediately to the selected media with a sterile pipet or swab, proceed as in section 10.45.

ii. Aseptically transfer a representative amount of the product to a sterile test tube or other sterile container as a working reserve. Fold the edge of the opened pouch over against itself several times and secure with tape until the microbiological analysis is complete.

d. Swollen Cans

i. Cans displaying a hard swell should be chilled before opening. Most foods spoiled by *Bacillus stearothermophilus* will not produce gas (flat sour spoilage). However, if nitrate or nitrite is present in the meat/poultry product, gas may be produced by this microorganism. Cold usually will kill *B. stearothermophilus* resulting in no growth in Bromcresol Purple Broth. If possible, save one or two cans and store without refrigeration.

ii. NEVER FLAME A SWOLLEN CONTAINER - IT MAY BURST. Place the container to be opened in a large, shallow, autoclavable pan. The side seam, if present, should be facing away from the analyst. A container with a hard swell may forcefully spray out some its contents, posing a possible hazard to the analyst if the contents are toxic. Therefore, these cans should be considered a biohazard and precautions must be taken to protect the analyst. Protective gloves should be worn and the lab coat should be tucked inside the cuffs of the gloves or at least secured around the wrist. Some type of facial shield is also recommended.

iii. Place the sanitized container into a biohazard bag and cover with a sterile towel or invert a sterile funnel with a cotton filter in the stem over the can. Place the point of the sterile opening device in the middle of the container closure. Make a small hole in the center of the sterilized end/closure. Try to maintain pressure over the hole. Release the instrument slowly to allow gas to escape into the towel or funnel.

iv. After the gas pressure has been released, enlarge the opening to the desired size to permit sampling and aseptically remove some of the container contents. Sample as outlined in (a) above.

10.45 Culturing

a. Inoculation of Culture Media

i. The sampling and transfer processes must be conducted aseptically; care must be taken to prevent contamination during the various manipulations.

ii. Transfer the sample at once to the selected media, inoculating each tube at the bottom. Whenever possible, use a pipet and pro-pipette to remove 1-2 ml of product for inoculating each tube of medium. When the nature of the meat/poultry product makes it impossible to use a pipet, use a sampling swab (holding it by the very end of the shaft) to transfer 1-2 g of the product to each tube. This is accomplished by plunging the swab into the product, then inserting the swab as far as possible into the appropriate tube of medium and breaking off the portion of the shaft that was handled. Use one swab for each tube of medium. When inoculating MCMM, force the broken swab to the bottom of the tube by using the tip of another sterile swab.

iii. For each sample, inoculate 2 tubes of MCMM which were steamed (or boiled) for 10 minutes and cooled just before use and 2 tubes of Bromcresol Purple Broth. If a tube of KF medium is inoculated at the same time, the presence of enterococci can be determined rapidly.

iv. As a process control, place uninoculated swabs into each of two tubes of MCMM and BCP and one swab into KF broth (if used). Additionally, label two uninoculated tubes of each medium to serve as controls. If multiple samples are cultured at the same time, only one set of control tubes are needed for each medium and each temperature.

v. After all tubes have been inoculated with a sample, aseptically transfer approximately 30 ml or a 30 g portion of the container contents to a sterile tube, Whirl-Pak® or jar for retention as a working reserve sample. Appropriately label the container and store it in a refrigerator at approximately 4°C.

vi. Finally, transfer a portion of the container contents to a sterile Petri plate, clean jar or beaker for pH, microscopic, organoleptic and other relevant analyses (10.46).

vii. Cover the hole made in the container with several layers of sterile aluminum foil, secure the foil with tape and then store the container in a refrigerator at approximately 4°C. This serves as the primary reserve. Re-enter it only as a last resort. If the sample is a regulatory sample, chain of custody records must be maintained on it.

b. Incubation of Culture Media

i. Incubate one tube each of MCMM and BCP at 35°C and one tube each at 55°C. If used, incubate the tube of KF medium at 35°C. For the MCMM and BCP controls, incubate one tube at 35° and one at 55°C.

ii. Observe all tubes at 24 and 48 h. Tubes incubated at 35°C that show no growth should be incubated for 5 days before discarding. Tubes incubated at 55°C should be incubated for 3 days before discarding. Subculture any questionable tubes, especially if the product under examination contributes turbidity.

c. Identification of Organisms

i. Use conventional bacteriological procedures to characterize the type(s) of microbial flora found in the contents of the container.

ii. Use descriptive terms such as: mixed culture or pure culture, anaerobic or aerobic growth, spore former or non-sporeformer, mesophile or thermophile, cocci or rods.

iii. Cultures should be examined using a Gram stain. Gram stains should be done only on 18-24 h cultures. Record the morphological types observed and their Gram reaction. If the container contents are examined microscopically using a methylene blue stain, record those observations as well. If endospores are present, the spore stain can be used for better definition of spore type and placement.

iv. Record all biochemical test results in addition to any characteristic growth patterns on differential and/or selective media.

v. MCMM tubes showing a bright yellow color with visible gas bubbles, and containing gram positive or gram variable rods should be suspected of containing gas-forming anaerobes. If *Clostridium botulinum* is suspected, sub-cultures should be made and incubated for 4-5 days. The original tube should be reincubated to check for spores. After 4 - 5 days incubation, test the cultures for toxin by the mouse bioassay (see Chapter 14).

10.46 Supportive Determinations

a. Examination of Container Contents

i. Determine the pH of the sample (10.45, a, vii) using a flat electrode. Disinfect the electrode after taking this measurement.

ii. If applicable, determine the water activity of the sample (Section 2.4).

iii. Examine the sample microscopically by making a simple methylene blue or crystal violet stain. A Gram stain is of no value since the age of the cells is not known and Gram-stain reactions may not be dependable in the case of old cells. Prepare a spore stain if the contents of a swollen container show signs of digestion and few bacterial cells.

iv. Note abnormalities observed in the container contents such as off-odors, off-color, changes in consistency and texture when compared with normal product. DO NOT TASTE!

b. Examination of Metal and Plastic Cans

NOTE: Whenever possible a "normal" companion can should be examined along with the abnormal one.

i. After a reserve sample has been taken and all examinations are complete, discard any remaining product into an autoclavable bag and terminally sterilize.

ii. Disinfect the inside of the container with a phenolic disinfectant and carefully clean it with a stiff brush or use an ultra sonic bath. Do not autoclave the container since this may destroy any defects.

iii. Examine the interior lining of metal containers for blackening, detinning and pitting.

iv. The container code should have been recorded prior to analysis; if it was not, do so now. Sometimes embossed codes are poorly impressed and can be revealed by rubbing a pencil on a paper held over the code. If this does not work, place a thin smooth piece of paper over the code, hold securely and rub the paper with a clean finger in order to impress the paper. Rerub the paper with a finger coated with graphite. This is superior to using a pencil to rub the code. If that fails, rub the code with carbon paper. Place transparent adhesive tape over the code and rub the tape with the back of a fingernail. Lift the tape and transfer it to any document requiring the can code. The latter two techniques allow a record to be kept of any partial numbers or symbols. It is also possible to wait until the can is emptied, then view the reverse of the code from the inside. If needed, the code can be viewed in a mirror.

v. When leakage from double seams or side seams is suspected, remove excess metal from the opened end, leaving a 0.5 - 1 cm flange. Dry thoroughly, preferably overnight, in the 55°C incubator. Add leak detection liquid (10.41z) to the can to a depth of 2-4 cm. Place a microleak detector on the open end of the container. The leak detector consists of a transparent acrylic plate with a vacuum gauge and connector for a vacuum source. Place a gasket (cut pieces of an automobile tire inner tube will do) between the apparatus and the can. If the fit is not tight (e.g., end seam is bent), use modeling clay to fill in the gaps. Large cans without beading or thin metal cans having a wider diameter than height may collapse when vacuum is applied. To prevent this from happening, use 1/2" wooden dowels cut to the appropriate length to support the can sides. Bituminous compound on the dowel ends will hold them in place. Generally, 4 dowels are sufficient for a #10 can. Apply the gasket and any bituminous compound, to the open can end and fit the leak detector plate in place. Connect the vacuum and apply 10 inches vacuum to the can. Swirl the liquid to dissipate bubbles formed by gases dissolved in the liquid. Examine seams by covering them with the diluted Seamtest. Leaks are identified by a steady stream of bubbles or a steadily increasing bubble size. After carefully examining all seams for leaks, increase the vacuum to 20 inches vacuum and re-examine the seams. Leave the can under vacuum until a leak appears or for a maximum of 2 h, and examine at half-hour intervals. Mark the location of leaks on the can's exterior using a marking pen. When reporting, note which seam, and the distance from the side seam or some other appropriate reference point. If no leaks were found, note test conditions (time and amount of vacuum drawn).

vi. Perform a tear-down examination of the double seams. The following references in Section 10.6 will guide you through this process: APHA, 1966; Food Processors Institute, 1988; Double Seam Manual; Evaluating a Double Seam, FDA Bacteriological Analytical Manual, 1992.

vii. The tightness of double seams formed by plastic cans and metal can ends may be evaluated by comparing the actual seam thickness to the calculated thickness of the plastic flange, neck, or metal end. This would include three thicknesses of plastic and two of metal. Also, assess tightness by inspecting the pressure ridge, since it reflects the compression of the plastic body wall. The pressure ridge should be visible and continuous. Each packer may have different specifications for the finished seams; if necessary, the analyst must call the in-plant inspector and ask for specifications for the container of interest.

c. Examination of Pouches

i. The best way to determine if a pouch has leaked is by the type of microorganisms recovered.

ii. The pouch should be examined microscopically looking for points of light coming through the film. These are potential leakage sites.

10.47 Interpretation of Results

Use Tables 2, 3 and 4 to arrive at possible causes of spoilage based on all laboratory results. Caution: The tables are based on a single cause of spoilage. If there are multiple causes, the tables may not help.

10.5 Examination of Canned, Perishable Meat/Poultry Products

Perishable meat and poultry products, such as hams, luncheon meats, and loaves are packaged in hermetically-sealed containers and then heat-processed to internal temperatures of not less than 150°F (65.5°C) and usually not greater than 160°F (71°C). "Perishable, Keep Refrigerated" must appear on the label of these products. Although they are not shelf stable, good commercial processing usually will destroy vegetative bacterial cells. The combined effects of sodium nitrite, salt, refrigeration, and low oxygen tension retard the outgrowth of the few vegetative cells and/or spores that may survive the process. Such products can retain their acceptable quality for 1 to 3 years when properly processed and refrigerated.

10.51 Analysis of Containers

See Sections 10.3 - 10.33

10.52 Analysis of the Contents

a. **Equipment and Material**

See Section 10.41

b. **Media and Reagents**

See Section 10.42

c. **Preparation**

See Section 10.43

d. **Sampling**

i. Using procedures already described (Section 10.44) remove approximately 50 g of sample with a sterilized trier, large cork borers, scissors, knife or forceps.

ii. Place the sample into a sterile blender jar or Stomacher bag, add 450 ml of sterile Butterfield's Phosphate Diluent and homogenize for 2 minutes. This is a 1:10 dilution; make additional dilutions through at least 10^{-4}. Proceed with the culturing steps given in Section 10.52 (e, f & g).

iii. After sampling, cover the container opening with sterile aluminum foil several layers thick and secure with tape. Place the opened sample unit in the freezer until the analysis is complete.

e. **Aerobic Plate Counts**

i. Pipet 1 ml of each dilution prepared in 10.52 (d) into each of two sets of duplicate pour plates according to the instructions given in Section 3.4.

ii. Prepare one dilution set with Plate Count Agar. Incubate this set at 35°C for 48 h.

iii. Substitute APT agar for the Plate Count Agar in the other set of plates. Incubate this set at 20°C for 96 h.

iv. Count and record the results from both sets as described in Section 3.4.

f. Gas-Forming Anaerobes (GFAs)

i. Steam tubes of MCMM for 10 minutes and cool just prior to use.

ii. Inoculate each tube with l ml of each dilution prepared in 10.52 (d). Begin with the 1:10 dilution and continue with subsequent dilutions. Use a separate pipet for each dilution. Dilutions must be sufficiently high to yield a negative endpoint. Be sure that the inoculum is deposited near the bottom of the tube.

iii. Incubate these tubes for 48 h at 35°C, but read daily.

iv. Consider any MCMM tubes showing a bright yellow color, containing visible gas bubbles, and containing gram positive or gram variable rods as positive for GFAs.

v. Based upon the highest dilution showing these organisms, report the approximate number of gas-forming anaerobes per gram, calculated as the reciprocal of the highest positive dilution. If skips occur, disregard the final actual dilution and calculate the end point at the dilution where the skip occurred. This is only an approximation of the gas forming anaerobe count. A minimum of three tubes per dilution and an MPN table must be used for a more accurate determination.

vi. If *Clostridium botulinum* is suspected, representative tubes that have not been opened should be reincubated for a total of 4 - 5 days and then tested for botulinum toxin using the mouse bioassay (Chapter 14).

g. Enterococci

i. Transfer 1 ml of each dilution prepared in 10.52(d) to individual tubes of KF broth. Use a separate pipette for each dilution. Begin with the 1:10 dilution and continue with each subsequent

dilution. Dilutions must be sufficiently high to yield a negative end point.

ii. Incubate these tubes at 35°C for 48 h. Tubes showing a yellow color, turbidity and buttoning of growth are presumptive positives.

iii. Confirm all presumptive positives microscopically. Either wet mounts examined under low light or gram stained preparations are suitable for these microscopic determinations. Microscopic determinations yielding cells with ovoid streptococcal morphology shall be considered confirmed positive.

iv. Report the approximate number of enterococci per gram, calculated as the reciprocal of the highest positive confirmed dilution. If skips occur, disregard the final actual dilution and calculate the end point at the dilution where the skip occurred. This is only an approximation of the number of enterococci. A minimum of three tubes per dilution and an MPN table must be used for a more accurate determination of organisms as described in 10.43-10.45 and Tables 2, 3 and 4.

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Appendix I

Glossary of Metal/Plastic Can Seam Terminology for Container Components and Defects

The same terms that are used to describe an all-metal seam apply equally well to the metal end/plastic body seam.

Base Plate: Part of a closing machine which supports cans during seaming operation.

Beaded Can: A can which is re-enforced by having ring indentations around the body. The bead tends to keep the can cylindrical and helps to eliminate paneling of the can body.

Body: Principal part of a container - usually the largest part in one piece containing the sides (thus sidewall or body wall).

Body Hook: Can body portion of double seam. Prior to seaming, this portion was the flange of the can.

Bottom Seam: Factory end seam. The double seam of the can end put on by the can manufacturer.

Buckling: A distortion in a can end.

Can Size: Two systems are commonly used to denote can size:

i. An Arbitrary system (1, 2, etc.) with no relation to finished dimension.

ii. A system indicating the nominal finished dimensions of a can; e.g. "307 x 512." In this example, the first group of digits ("307") refers to the can's diameter and the second set ("512"), the can's height. The first digit in each set represents inches, and the next two digits represent sixteenths of an inch. Hence, the example can has a diameter of 3-7/16 and a height of 5-12/16 (or 5-3/4) inches.

Chuck: Part of a closing machine which fits inside the countersink and in the chuck wall of the end during seaming.

Closing Machine: Also known as a double seamer. Machine which double seams the lid onto the can bodies.

Compound: Rubber or other material applied inside the end curl to aid in forming a hermetic seal when the end is double seamed on the can body.

Contamination in Weld Area: Any visible burn at one or more points along the side seam of a welded can. This is a major defect.

Countersink: On a seamed end, the perpendicular distance from the outermost end panel to the top seam.

Cover: Can end placed on can by packer. Also known as top, lid, packer's end, canner's end.

Cover Hook: That part of double seam formed from the curl of the can end.

Cross Over: The portion of a double seam at the lap.

Cross Section: Referring to a double seam, a section through the double seam.

Curl: The semi-circular edge of a finished end prior to double seaming. The curl forms the cover hook of the double seam.

Cut Code: A break in the metal of a can due to improper embossing-marker equipment.

Cut-Over: During certain abnormal double seaming conditions, the seaming panel becomes flattened and metal is forced over the seaming chuck forming a sharp lip at the chuck wall. In extreme cases the metal may split in a cut-over.

Dead-Head: An incompletely rolled finished seam. Also known as a skip, skid or spinner.

Double Seam: The joint between the end and the can body formed by rolling the curl under the flange (1st operation) and then pressing the metal together (2nd operation).

Droop: A smooth projection of double seam below the bottom of a normal seam. While droops may occur at any point of the seam, they usually are evident at the side seam lap. A

slight droop at the lap may be considered normal because of additional plate thickness incorporated into the seam structure.

Excessive Slivers: One or more slivers which are 1/32" or longer. This is a minor defect of welded cans.

Factory End: Bottom or can manufacturer's end.

False Seam: A seam fault where the end and body hook are not over-lapped (engaged), although they give the appearance of a properly formed seam. Also see Knockdown Flange.

Feather: Beginnings of a cut-over. See Sharp Edge.

First Operation: The first operation in double seaming. In this operation, the curl of the end is tucked under the flange of the can body which is bent down to form cover and body hook, respectively.

Flange: The flared portion of the can body which facilitates double seaming.

Flange Crack: Any crack at the flange or immediately adjacent to the weld of welded cans. This is a major defect.

Headspace: The free space above the contents of a can and the can lid.

Heavy Lap: A lap containing excess solder. Also called a thick lap.

Hook: (i). The bent over edges of a body blank, which form the side seam lock (ii). The body and cover hooks in a double seam.

Internal Enamel: A coating applied to the inside of the can to protect the can from chemical action by the contents or to prevent discoloration. A lacquer is usually clear; an enamel is pigmented and opaque.

Jumped Seam: A double seam which is not rolled tight enough adjacent to the crossover caused by jumping of the seaming rolls at the lap.

Knockdown Flange: A seam defect in which the flange is bent against the body of the can. The cover hook is not tucked inside the body hook, but lies outside of it. False seams, knockdown flanges and soft crabs are degrees of the same effect. In order to distinguish the degree of the defect, the following terminology is suggested:

> False Seam: The cover hook and body hook are not tucked for a distance of less than an inch. Thus it may not be possible to detect a false seam until the can is torn down.
>
> Knockdown Flange: As above, but more than an inch in length. Body hook and cover hook in contact, but not tucked.
>
> Soft Crab: A defect in which the body of the can is broken down and does not contact the double seam. Thus, there is a wide open hole in the can below the double seam where the body was not incorporated into the seam.

Lap: The soldered but not locked portions of a side seam at the ends of the can body before seaming and removing the can from the chuck at completion of the operation.

Lid: See Cover.

Lip, Spurs or Vees: Irregularities in the double seam due to insufficient or sometimes absent overlap of the cover hook with the body hook, usually in small areas of the seam. The cover hook metal protrudes below the seam at the bottom of the cover hook in one or more "V" shapes.

Loss of Overlap: Any observable loss of overlap along the side seam of a welded can. This is a critical defect.

Loose Tin: A metal can which does not appear swollen, but slight pressure reveals a looseness.

Mislock: A poor or partial side seam lock, due to improper forming of the side seam hooks.

Neck: The thickness of the top of the sidewall (body wall) of a plastic tub, one tenth of an inch below the junction of the flange and the sidewall.

Notch: A small cut-away portion at the corners of the body blank. This reduces droop when double seaming.

Oozier: An imperfect can which allows the escape of the contents through the seam.

Open Lap: A lap failed due to various strains set up during manufacturing operations. Also caused by improper cooling of the solder (See Weak Lap). A lap which is not properly soldered so the two halves are not properly joined.

Over Lap: The distance the cover hook laps over the body hook.

Paneling: A flattening of the can side. Also used to define concentric (expansion) rings in can ends.

Peaking: Permanent deformation of the expansion rings on the can ends due to rapid reduction of steam pressure at the conclusion of processing. Such cans have no positive internal pressure and the ends can be forced back more or less to their normal position.

Perforation: Holes in the metal of a can resulting from the action of acid in food on metal. Perforation may come from inside due to product in the can or from outside due to material spilled on the cans.

Pleat: A fold in the cover hook which extends from the edge downward toward the bottom of the cover hook and sometimes results in a sharp droop, vee or spur.

Pressure Ridge: A ridge formed on the inside of the can body directly opposite the double seam, as a result of the pressure applied by the seaming rolls during seam formation.

Pucker: A condition which is intermediate between a wrinkle and a pleat in which the cover hook is locally distorted downward without actual folding. Puckers may be graded the same way as wrinkles.

Sanitary Can: Can with one end attached, the other end put on by the packer after the can is filled. Also known as packer's can or open top can.

Sawtooth: Partial separation of the side seam overlap at one or more points along the side seam after performing the pull test on a welded side seam. This is a critical defect.

Seam Arrowing: A readily visible narrowing of the weld at either end of the can body. This is a major defect.

Seam Width: The maximum dimensions of a seam measured parallel to folds of the seam. Also referred to as the seam length or height.

Seam Thickness: The maximum dimension measured across or perpendicular to the layers of the seam.

Second Operation: The finishing operation in double seaming. The hooks formed in the first operation are rolled tight against each other in the second operation.

Sharp Edge: A sharp edge at the top of the inside portion of the double seam due to the end metal being forced over the seaming chuck.

Side Seam: The seam joining the two edges of a blank to form a body.

Skipper / Spinner: See Deadhead.

Uneven Hook: A body or cover hook which is not uniform in length.

Vee: See Lip.

Weak Lap: The lap is soldered and both parts are together. However, strain on this lap (e.g. by twisting with the fingers) will cause the solderbond to break.

Weld Crack: Any observable crack in a welded side seam. This is a critical defect.

Worm Holes: Voids in solder usually at the end of the side seam. May extend completely through the width of the side seam.

Wrinkle: The small ripples in the cover hook of a can. A measure of tightness of a seam.

Appendix II

Glossary of Glass Container Parts

From a manufacturing standpoint, there are three basic parts to a glass container based on the three parts of glass container molds in which they are made. These are the finish, the body and the bottom.

Finish: The finish is that part of the jar that holds the cap or closure. It is the glass surrounding the opening in the container. In the manufacturing process, it is made in the neck ring or the finish ring. It is so named since, in early hand glass manufacturing, it was the last part of the glass container to be fabricated, hence "the finish". The finish of glass containers has several specific areas as follows:

Continuous Thread: A continuous spiral projecting glass ridge on the finish of a container intended to mesh with the thread of a screw-type closure.

Glass lug: One of several horizontal tapering protruding ridges of glass around the periphery of the finish that permit specially designed edges or lugs on the closure to slide between these protrusions and fasten the number of lugs on the closure and their precise configuration is established by the closure manufacture.

Neck Ring Parting Line: A horizontal mark on the glass surface at the bottom of the neck ring or finish ring resulting from the matching of the neck ring parts with the body mold parts.

Sealing Surface: That portion of the finish which makes contact with the sealing gasket or liner. The sealing surface may be on the top of the finish, or may be a combination of both top and side seal.

Vertical Neck Ring Seam: A mark on the glass finish resulting from the joint of matching the two parts of the neck ring. NOTE: Some finishes are made in a one-piece ring and do not have this seam.

Body: The body of the container is that portion which is made in the "body-mold" in manufacturing. It is the largest part of the container and lies between the finish and the bottom.

The characteristic parts of the body of a glass container are:

Heel: The heel is the curved portion between the bottom and the beginning of the straight side wall.

Mold Seam: A vertical mark on the glass surface in the body area resulting from matching the two parts of the body mold.

Shoulder: That portion of a glass container in which the maximum cross-section or body area decreases to join the neck or finish area. Most glass containers for processed foods have very little neck. The neck would be a straight area between the shoulder and the bottom of the bead or, with beadless finishes, the neck ring parting line.

Side Wall: The remainder of the body area between the shoulder and the heel.

Bottom: The bottom of the container is made in the "bottom plate" part of the glass container mold. The designated parts of the bottom normally are:

Bearing Surface: That portion of the container on which it rests. The bearing surface may have a special configuration known as the "stacking feature" which is designed to provide some interlocking of the bottom of the jar with the closure of another jar on which it might be stacked for display purposes.

Bottom Plate Parting Line: A horizontal mark on the glass surface resulting from the matching of the body mold parts with the bottom plate.

Appendix III

Glossary of terms - Flexible Retortable Pouches.

Adhesive: A substance applied to ply surfaces to cement the layers together in a laminated film: (a). Polyurethane adhesive for the outer layer (b). Maleic anhydride adduct of polypropylene for the inner layer.

Blisters: Bubbles/gaseous inclusions/particulate material, may be present between layers of laminate, usually are found in the seal area.

Bottom of Closing Seal: Portion of closing (packer) seal adjustment to the pouch contents.

Bottom Seal: A seal applied by heat and pressure to the bottom of a flexible pouch.

Cosmetic Seal: Area above the primary seal designed to close the edges of the pouch thus preventing the accumulation of extraneous material.

Cuts, Punctures, Scratches: Mechanical defects that penetrate one or more layers of the pouch.

Delamination: Any separation of plies through adhesive failure. This may result in questionable integrity of the package and safety of the product.

Dirty: Smeared with product or product trapped in top edges (where there are no cosmetic seals).

Disintegrated Container: Evidence of delamination or degradation after retorting.

Final Seal: A seal formed by heat and pressure by the packer after pouch filling and prior to retorting.

Foil Flex Cracks/Foil Roll Holes: Visible cracks in the aluminum foil layer caused by flexing of the pouch or pin holes (roll holes) in the foil caused through manufacture of the aluminum ply.

Foreign Materials: Any material (solid food, condensate, grease, voids, blemishes) that may be entrapped between the plies but usually found in the seal area.

Fusion Seal: A seal formed by joining two opposing surfaces by the application of heat and pressure.

Hard Swell or Blown: Distention or rupture due to internal gas formation.

Inner Ply: Polypropylene coating bonded to the food surface side of the aluminum foil.

Laminate: Two or more layers of material held together by adhesive(s).

Leaker: Product leaking through any area of the pouch.

Outer Ply: The polyester film bonded to the exterior surface of the aluminum foil.

Over Carton: A separate container (usually cardboard) in which the flexible pouch is packaged for additional protection.

Package Dimensions: The measurements of retortable flexible pouches stated as length, the longest dimension (LGT), width the second longest dimension (W), and thickness, the shortest dimension (HGT). All are given as internal measurements.

Pin Holes, Roll Holes: Holes in the aluminum foil layer only, originating during manufacturing; usually do not leak.

Preformed Seals: Seals formed by heat and pressure, by the manufacturer of the pouches, along the sides and at the bottom of the pouches.

Primary Seal: A fusion seal formed by the food processor by applying heat and pressure immediately after filling.

Seal: A continuous joint of two surfaces made by fusion of the laminated materials.

Seal Width: The maximum dimension of the seal measured from the leading outside edge perpendicular to the inside edge of the same seal.

Severely Damaged: Punctures, cuts or ruptures which penetrate all layers of the pouch and expose the product to contamination.

Side Seals: Seals formed by applying heat and pressure to the sides of the pouch's laminates to form the "preformed pouch".

Tear Nicks or Notch: Notches near the final seal to aid the consumer in opening the pouch.

Wrinkle: A crease or pucker in the seal (Packer or Factory) areas.

Appendix IV

Table 1. Normal pH Values for a Few Representative Canned Meat/Poultry Products.

Kinds of Food	pH
Beans with Wieners	5.7
Beef Chili	5.6
Beef Paté	5.7
Beef Stew	5.4 - 5.9
Beef Taco Filling	5.8
Beef and Gravy	5.9 - 6.1
Chicken Noodle Soup	5.8 - 6.5
Chicken Soup with Rice	6.7 - 7.1
Chicken Broth	6.8 - 7.0
Chicken and Dumplings	6.4
Chicken Vegetable Soup	5.6
Chicken Stew	5.6
Chicken Vienna Sausage	6.1 - 7.0
Chorizos	5.2
Corned Beef	6.2
Corned Beef Hash	5.0 - 5.7
Egg Noodles & Chicken	6.5
Ham	6.0 - 6.5
Lamb, Strained Baby Food	6.4 - 6.5
Pork Cocktail Franks	6.2
Pork with Natural Juices	6.2 - 6.4
Pork Sausage	6.1 - 6.2
Roast Beef	5.9 - 6.0
Spaghetti and Meatballs	5.0
Spaghetti Sauce with Beef	4.2
Stuffed Cabbage	5.9
Sloppy Joe	4.4
Turkey, Boned in Bouillon	6.1 - 6.2
Turkey with Gravy	6.0 - 6.3
Vienna Sausage	6.2 - 6.5
Wieners, Franks	6.2

Appendix V

Table 2. KEY TO PROBABLE CAUSE OF SPOILAGE IN CANNED FOODS

Group 1.- Low-Acid Foods
pH Range 5.0 to 8.0

Condition of cans	Characteristics of Material in Cans						
	Odor	Appearance	Gas (CO_2 & H_2)	pH	Smear	Cultures	Diagnosis
Swells	Normal to "metallic"	Normal to frothy (Cans usually etched or corroded)	More than 20% H_2	Normal	Negative to occasional organisms	Negative	Hydrogen swells
	Sour	Frothy; possibly ropy brine	Mostly CO_2	Below Normal	Pure or mixed cultures of rods, cocci, yeasts or molds	Growth, aerobically and/or anaerobically at 35°C., and possibly at 55°C.	Leakage
	Sour	Frothy; possibly ropy brine, food particles firm with uncooked appearance	Mostly CO_2	Below Normal	Pure or mixed cultures of rods, coccoids, cocci and yeasts	Growth, aerobically and/or anaerobically at 35°C., and possibly at 55°C. (If product received high exhaust, only spore formers may be recovered)	No process given
	Normal to sour-cheesy	Frothy	H_2 and CO_2	Slightly to definitely below normal	Rods, med. Short to med. long, usually granular; spores seldom seen	Gas, anaerobically at 55°C., and possibly slowly at 35°C.	Post-processing temperature abuse Thermophilic anaerobes
	Cheesy to putrid	Usually frothy with disintegration of solid particles	Mostly CO_2; possibly some H_2	Slightly to definitely below normal	Rods; usually spores present	Gas anaerobically at 35°C.	Underprocessing - mesophilic anaerobes (possibility of Cl. botulinum)
	Slightly off – possibly ammoniacal	Normal to frothy		Slightly to definitely below normal	Rods; spores occasionally seen	Growth, aerobically and/or anaerobically with gas at 35°C and possibly at 55°C. Pellicle in aerobic broth tubes. Spores formed on agar and in pellicle.	Underprocessing - B. subtilis type

No vacuum and/or Cans buckled	Normal	Normal	No H_2	Normal to slightly below normal	Negative to moderate number of organisms	Negative	Insufficient vacuum, caused by: 1) Incipient spoilage, 2) Insufficient exhaust, 3) Insufficient blanch, 4) Improper retort cooling procedures, 5) Over fill
Flat cans (0 to normal vacuum)	Normal to sour	Normal to cloudy brine		Slightly to definitely below normal	Rods, generally granular in appearance; spores seldom seen	Growth without gas at 55°C. Spore formation on nutrient agar	Post-Processing temperature abuse Thermophilic flat sours.
	Normal to sour	Normal to cloudy brine; possibly moldy		Slightly to definitely below normal	Pure or mixed cultures of rods, coccoids, cocci or mold	Growth, aerobically and/or anaerobically at 35°C., and possibly at 55°C.	Leakage

Appendix VI

Table 3. KEY TO PROBABLE CAUSE OF SPOILAGE IN CANNED FOODS

Group 3. Semi-Acid Foods
pH Range 4.6 to 5.0

Condition of cans	Characteristics of Material in Cans						
	Odor	Appearance	Gas (CO_2 & H_2)	pH	Smear	Cultures	Diagnosis
Swells	Normal to "metallic"	Normal to frothy (Cans usually etched or corroded)	More than 20% H_2	Normal	Negative to occasional organisms	Negative	Hydrogen swells
	Sour	Frothy; possibly ropy brine	Mostly CO_2	Below Normal	Pure or mixed cultures of rods, coccoids, cocci, yeasts or molds	Growth, aerobically and/or anaerobically at 35°C., and possibly at 55°C.	Leakage
Note: Cans are Sometimes flat	Sour	Frothy; possibly ropy brine, food particles firm with uncooked appearance	Mostly CO_2	Below Normal	Pure or mixed cultures of rods, coccoids, cocci and yeasts	Growth, aerobically and/or anaerobically at 35°C., and possibly at 55°C. (If product received high exhaust, only spore formers may be recovered)	No process given
	Normal to sour-cheesy	Frothy	H_2 and CO_2	Slightly to definitely below normal	Rods - med. Short to med. long, usually granular; spores seldom seen	Gas, anaerobically at 55°C., and possibly slowly at 35°C.	Post-processing temperature abuse Thermophilic anaerobes
	Normal to cheesy to putrid	Normal to frothy with disintegration of solid particles	Mostly CO_2; poss-ibly some H_2	Normal to slightly below normal	Rods; possibly spores present	Gas anaerobically at 35°C. Putrid odor	Underprocessing – mesophilic anaerobes (possibility of *Cl. Botulinum)*

	Slightly off - possibly ammoniacal	Normal to frothy		Slightly to definitely below normal	Rods; occasionally spores observed	Growth, aerobically and/or anaerobically with gas at 35°C and possibly at 55°C. Pellicle in aerobic broth tubes. Spores formed on agar and in pellicle.	Under-processing - *B. subtilis* type
	Butyric acid	Frothy, large volume gas	H_2 and CO_2	Definitely below normal	Rods - bipolar staining; possibly spores	Gas anaerobically at 35°C. Butyric acid odor	Under processing - butyric acid anaerobe
No vacuum and/or Cans buckled	Normal	Normal	No H_2	Normal to slightly below normal	Negative to moderate number of organisms	Negative	Insufficient vacuum, caused by: 1) Incipient spoilage, 2) Insufficient exhaust, 3) Insufficient blanch, 4) Improper retort cooling procedures, 5) Over fill
Flat cans (0 to normal vacuum)	Sour to "medicinal"	Normal to cloudy brine		Slightly to definitely below normal	Rods, possibly granular in appearance	Growth without gas at 55°C. and possibly at 35°C. Growth on thermoacidurans agar	Underprocessing *B. coagulans*
	Normal to sour	Normal to cloudy brine; possibly moldy		Slightly to definitely below normal	Pure or mixed cultures or rods, coccoid, cocci or mold	Growth, aerobically and/or anaerobically at 35°C., and possibly at 55°C.	Leakage

Appendix VII

Table 4. Characteristics of Normal and Abnormal Perishable Canned Meat/Poultry Products

Condition of Cans	Odor	Appearance	pH	Smear	Cultures	Probable Cause
Flat Cans (0 to Normal Vacuum)	Normal	Normal	Normal	Negative to occasional organisms	0 to low # APC, APT agar count	Normal product
0 to degrees of swelling	Sour to off odor	Normal to mushy, possible gel liquification	Slightly to definitely below normal	Mixed culture of rods & enterococci	Low # mesophiles, high # psychrophilic non-spore formers (enterococci, lactobacilli	1. Prolonged storage at low temperatures 2. Abnormal high levels in raw materials 3. Substandard process
Swell	Sour or off odor, possibly putrid	Normal to mushy, possible gel liquification	Slightly to definitely below normal	Mixed culture of rods, cocci	High # mesophilic spore formers and non-sporeformers	Product held without refrigeration
Swell	Normal to sour	Normal	Below normal	Cocci, rods or both	Enterococci, rods or both	Leakage if shell higher than core. Underprocessing if core higher than shell
Swell	Off odor	Normal to off color	Below normal	Rods	Psychrotrophic clostridia (rarely occurs in U.S.).	Low brine levels
Swell	Normal to putrid, depending on length of storage.	Ranges from uncooked appearance to digested	Normal to low, depending on length of storage.	Vary	Vary	Missed processing cycle. Most of these are detected soon after distribution.