

## **Module 3: Development of the HACCP System and Relationship Of HACCP/CGMPs/SSOPs**

### **Host**

The Hazard Analysis and Critical Control Points (HACCP) system is a logical, scientific approach to controlling hazards in food production. When a company adopts HACCP, it puts controls in place at each point in the production system where food safety problems could occur either from biological, chemical, or physical hazards.

We are about to examine how industry may approach developing their HACCP plans. It's important to remember the company develops its own HACCP plan, not FSIS. It's also important to remember companies have flexibility in how they write their HACCP plans.

To start a HACCP system, a company first writes a HACCP plan. This module explains how companies write a HACCP plan using five generally accepted preliminary steps and then applying the seven HACCP principles. Remember that each company is required to make its own decisions on how it will apply the seven principles. Therefore, you will see a wide variety in the HACCP plans you encounter.

Lets look at the five preliminary steps now. We'll discuss the seven principles later. The five preliminary steps are:

First, bring together the HACCP resources.

Second, describe the product and its method of distribution.

Third, develop a complete list of ingredients and raw materials.

Fourth, develop a process flow chart.

And fifth, meet the regulatory requirements for Sanitation Standard Operating Procedures (SOPs).

The first preliminary step the company does, is to assemble HACCP resources. It is important to bring as much knowledge to the table as possible, including the direct involvement of top management. In a small establishment, this might mean bringing together one or two employees, one of whom has had HACCP training. The HACCP resources may include outside expertise, available from a variety of sources. A larger plant may wish to bring in employees from a number of departments, such as production, sanitation, quality control, and engineering. There is no magic number of employees needed to write a HACCP plan.

Lets hear from some trade association representatives about how some real life companies assembled their resources for this first preliminary step.

TAPED INDUSTRY REPRESENTATIVE INTERVIEW SEGMENT—  
FIRST PRELIMINARY STEP

**Host**

The company has flexibility to decide how extensively to document this first preliminary step in its HACCP plan. You will likely see wide differences in the plants where you work.

(Second Preliminary Step)

The second preliminary step the company does, is to describe the product and its method of distribution. This will help identify hazards that may exist.

The following questions might be included:

What is the common name? For example, a cooked sausage could be called franks, hot dogs, or wieners.

Who are the intended consumers? Some products, like canned baby food, are for specific consumer groups.

How is it used? Categories might include "ready to eat," "to be heated prior to consumption," or "for further processing."

What type of package is being used? For example, is it modified-atmosphere packaging?

What is the length of shelf life? In the cooked sausage example, the length of shelf life might be 30 to 50 days for modified-atmospheric packaging. (add carcass sentence)

Where will it be sold? For example, will it be sold wholesale, at retail, or to institutions?

What are the labeling instructions? "Keep Refrigerated" would be a common labeling instruction for meat and poultry products.

How is the product distributed? For instance, should the product be kept refrigerated at or below 40° F?

Here is how our real life companies described their products:

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SECOND PRELIMINARY STEP

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It is important to realize that some HACCP plans you see will contain very detailed product descriptions, while others may not. However, we will see later that companies are required to identify the intended use and consumers of finished product(s).

(Third Preliminary Step) (Develop a Complete List of Ingredients and Raw Materials)

The third preliminary step the company does, is to develop a written list of ingredients and raw materials for each process or product. The establishment may wish to divide the ingredients into just two categories: meat (such as boneless beef or chicken parts with skin) and other ingredients (such as spices and preservatives). This is determined by the complexity of the product or process covered by the plan. Establishments may create their own internal forms and include them in their HACCP plans.

Let's see how our real-life companies addressed this third preliminary step:

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THIRD PRELIMINARY STEP

**Host**

Specifics of how the company lists ingredients and raw materials are left to the company. There is no set format. You will likely see a wide variety in the HACCP plans where you work.

(Fourth Preliminary Step) (Develop a Process Flow Chart)

The fourth preliminary step is for the company to develop a process flow chart that identifies all production steps from receiving through final shipment. The chart should not be so complex that it is difficult to follow and understand. It should be useable, and show the entire process. The flow chart may also include steps that occur before or after operations within the establishment.

The plant may choose to verify its process flow chart to ensure that the steps listed on the chart describe what really occurs in daily operations.

Here's how our real-life companies chose to address process flow charts:

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FOURTH PRELIMINARY STEP

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Remember, the purpose for doing these flow charts is to help find places in the establishment at which hazards could occur. You will encounter a variety of process flow charts that companies have done. There is no standardized format. Some will be more complex, and others less complex. However companies must include them in their HACCP plans.

(Fifth Preliminary Step) (Meet Sanitation Standard Operating Procedure requirements)

The fifth preliminary step is for the company to meet requirements for Sanitation Standard Operating Procedures. Good sanitation is the most basic way to ensure that a safe product is produced. Maintaining good sanitation serves as an excellent foundation for building a HACCP plan. It also demonstrates that plant management has the commitment and resources to successfully implement their HACCP plan. Because it is so important, meeting the regulatory requirements for Sanitation Standard Operating Procedures (SSOPs) is a pre-HACCP requirement that must be carried out in all establishments. In addition to the SSOP's, other prerequisite programs for HACCP can be developed that are extremely useful, such as Good Manufacturing Practices (GMP's) covering operating procedures and equipment maintenance. A written plan describing how a recall will be handled, if one is necessary, is also a valuable prerequisite to developing a HACCP plan.

Let's hear about the experience of real-life companies with their SSOP's.

**TAPED INDUSTRY REPRESENTATIVE INTERVIEW SEGMENT—  
FIFTH PRELIMINARY STEP**

**Host**

You have had experience with Sanitation SOP requirements as regulators of industry. We'll have further information about SSOP's when we discuss HACCP compliance.

Now the seven HACCP principles are ready to be applied to produce a HACCP plan suited to the plant and its process. Remember, they are:

- Principle 1: Conduct a hazard analysis.
- Principle 2: Identify critical control points.
- Principle 3: Establish critical limits for each critical control point.
- Principle 4: Establish monitoring procedures.
- Principle 5: Establish corrective actions.
- Principle 6: Establish recordkeeping procedures.
- Principle 7: Establish verification procedures.

**(Principle 1—Conduct a Hazard Analysis)****Host**

HACCP Principle No. 1 states:

*"Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures."*

The regulation defines a food safety hazard as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption."

In this section we will further define the hazards, discuss in general where they may occur, and talk about how companies might identify hazards within their establishments. We'll end Principle One with preventive measures for the hazards.

*(Biological Hazards)*

Biological hazards are living organisms, including microorganisms, that can put human health at risk. Biological hazards include bacteria, parasites, protozoa, and viruses. Their numbers and types vary from one species to another, from one geographic region to another, and with production and slaughter methods. Contamination can occur throughout production, processing, packaging and storage.

Some of the major pathogenic bacterial organisms that can cause foodborne illness from eating meat or poultry are: *Salmonella*, *Clostridium perfringens*, *Listeria monocytogenes*, *Staphylococcus aureus*, *Campylobacter jejuni*, *Yersinia enterocolitica*, *Bacillus cereus*, *Clostridium botulinum*, and *Escherichia coli* O157:H7.

To thoroughly identify significant biological hazards in the establishment, management needs to evaluate each specific ingredient and processing step in the operation.

*(Chemical Hazards)*

Chemical hazards can be naturally occurring substances, like mycotoxins or shellfish toxins, or they can be added substances, like pesticides, fungicides, fertilizers, lubricants, or cleaners.

To identify any chemical hazards, plant management needs to determine any chemical residues that might be in the animal. This could be from animal production related chemicals or water. Plant management also needs to determine processing points involving chemicals, their in-plant storage, and procedures for cleaning, sanitizing or maintenance.

*(Physical Hazards)*

A physical hazard is any physical material not normally found in a food that causes illness or injury to the individual using the product. Physical hazards include a variety of foreign materials or objects, such as glass, metal, and plastic. However, foreign objects that cannot cause illness or injury are not hazards, even though they may not be aesthetically pleasing to customers.

Physical hazards may result from contaminated raw materials, from poorly designed or maintained facilities that deteriorate, or from improper procedures or employee practices.

*(Conducting a Hazard Analysis)*

The hazard analysis is the identification of any hazardous biological, chemical, or physical property in raw materials and processing steps, and an assessment of its likely occurrence and potential to make food unsafe for consumption.

This is so important to HACCP, it bears repeating. For each step, possible hazards are identified and assessed for their likely occurrence and their potential for harm.

A hazard analysis needs to be very specific to the establishment and how it makes its product, since hazards may vary greatly from one establishment to another. This is due to differences in sources of ingredients, product formulations, processing equipment, processing methods, duration of the processes, storage, distribution, and employee experience, knowledge, and attitude.

In fact, a hazard analysis of the same product produced by different companies may come out differently for each company.

Hazard analysis can be confusing, since it is easy to suggest that any hazard that compromises food safety should be controlled. However, HACCP focuses specifically on significant hazards that **are reasonably likely to result in an unacceptable health risk to consumers**. Without this focus, it would be tempting to try to control too much and thus lose sight of the truly relevant hazards.

Companies may elect to have consultants or specially trained employees assist with analyzing their hazards. The importance of proper hazard analysis can't be overemphasized. Also, plant management needs to review<sup>3/4</sup> and revise if appropriate<sup>3/4</sup> the hazard analysis whenever they make any changes in raw materials suppliers, product formulation, preparation procedures, processing steps, packaging materials or procedures, distribution, or intended use of the product.

As the hazard analysis progresses, each hazard is evaluated based on **the likely occurrence of the hazard** and the severity of the consequences of exposure to the hazard. The estimate of **likelihood of occurrence** is usually based upon a combination

of experience, epidemiological data, and information in the technical literature. When conducting the hazard evaluation, it is helpful to consider the likelihood of exposure and severity of the potential consequences if the hazard is not properly controlled. During the evaluation of each potential hazard, the food, its method of preparation, distribution, storage, and the nature of the consumers likely to purchase the product should be considered to determine how each of these factors may enhance or diminish the public health impact of the hazard being considered. The team must determine if the manner in which the food is likely to be stored and prepared or whether the food is specifically intended for consumption by a group that may be more susceptible to a particular agent will influence the safety of the food.

A summary of the HACCP team deliberations and the rationale developed during the hazard analysis should be kept for future reference. These documents provide information that will be useful during the periodic review and updating of the hazard analysis and the HACCP plan as well as for conducting a hazard analysis on a similar product.

Finally, preventive measures are identified for each individual hazard. Examples include temperature control, proper maintenance and operation of equipment, rinsing contact surfaces between carcasses, proper chlorination, letters of guarantee from suppliers, and using metal detectors and stone and bone traps.

This has been a lot of information. But it's very important to understand that plant management has a lot to consider when doing its hazard analysis. Let's hear about real life application of Principle One.

**TAPED INDUSTRY REPRESENTATIVE INTERVIEW SEGMENT—PRINCIPLE ONE**

**Host**

Later with the inspector's role, you will again see the importance of hazard analysis. You will learn that the plant must have a food safety hazard analysis available.....

...it must include food safety hazards....

...it must include preventive measures for the hazards.....

...and the food safety hazards must be listed in the HACCP plan.

Now on to Principle Two.

HACCP Principle No. 2 states:

*"Identify the Critical Control Points in the process."*

A Critical Control Point, or CCP, is defined as "a point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels."

Identifying Critical Control Points builds on the hazard analysis. Points in the process are identified at which hazards exist and preventive measures can be applied to prevent, eliminate, or reduce the hazard. Then a logical decision process is applied to determine whether these points are, in fact, critical control points. Not every identified point with hazards and preventive measures will become a critical control point.

The logical decision process for determining CCP's may consider factors such as:

Whether control at this particular step is necessary for safety.

Whether this step eliminates or reduces the likely occurrence of the hazard to an acceptable level.

Whether contamination with the identified hazard could occur in excess of acceptable levels.

Whether subsequent steps will eliminate or acceptably reduce the hazard.

Fortunately, a great deal of work has already been done in identifying CCPs. Many CCPs are already recognized in various food processing and production systems. Some common CCPs are:

Chilling, when appropriate.

Cooking that must occur for a specific time and temperature in order to destroy microbiological pathogens.

Product formulation controls, such as addition of culture or adjustment of pH or water activity.

Certain processing procedures, such as filling and sealing cans.

Certain slaughter procedures, such as evisceration.

These are just a few examples of measures that may be CCPs.

There are many more possibilities. Different facilities, preparing the same food, can differ in the number and location of hazards and the points, steps, or procedures that are critical control points. This is due, in part, to differences in plant layouts, equipment used, selection and sources of raw materials and ingredients, or the process that is used.

Let's see how real-life companies made their decisions about steps that are Critical Control Points

## TAPED INDUSTRY REPRESENTATIVE INTERVIEW SEGMENT—PRINCIPLE TWO

### Host

Later in your training, you will learn that CCP's must be listed for each food safety hazard. Remember the recurring message that you will encounter a wide variety of approaches and documentation of CCP's in different plants.

Critical Limits, Principle Three, comes next.

HACCP Principle Three states: *"Establish critical limits for preventive measures associated with each identified CCP."*

The regulation defines critical limit as "the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard."

Examples include setting levels for time, temperature, humidity, water activity, pH, salt, or chlorine concentration.

Many critical limits for identified CCPs have already been established. These limits are found in sources such as regulatory requirements, scientific literature, experimental studies, and through consultation with experts.

Companies may wish to establish critical limits that differ from regulatory requirements. This is permitted, provided the limits are based on sound scientific data. Critical limits must always ensure that the result produces a safe and unadulterated product.

In some cases, more than one critical limit is needed to control a particular hazard. For example, the critical limits for cooked beef patties are time and temperature, patty thickness, and conveyor speed.

It's important for companies to adequately document their critical limit decisions. They will likely also keep on file any test results that show their critical limits are working.

Later in your training, you will learn that companies must list critical limits for each food safety hazard. Once again, there is no required format, and you will encounter a wide variety of approaches in different plants.

The next HACCP Principle is Number Four—Establish Monitoring Procedures

It states "*Establish procedures for using the results of monitoring to adjust the process and maintain control.*"

Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Monitoring is essential to a HACCP system. Monitoring can warn the plant if there is a trend towards loss of control, so that it can take action to bring the process back into control before a critical limit is exceeded. For example, say that an establishment tests the pH of a batch of product at 6 a.m., 7 a.m., and 8 a.m. Each time, the pH is within acceptable limits, but it is steadily climbing towards the high end of the range. This information is showing a trend and the establishment should take action to prevent the pH from exceeding the critical limits.

Monitoring by the plant may be continuous or noncontinuous. Continuous monitoring at a CCP usually is done with measuring equipment, such as automatic time-temperature equipment used at a cooking step. Noncontinuous monitoring can include visual examinations; monitoring of ingredient specifications; measurements of pH, water activity (Aw), and product temperatures; and attribute sampling. Noncontinuous monitoring must ensure that the frequency of monitoring is appropriate to ensure that the hazard is under control.

Each establishment has the responsibility to establish a frequency that ensures that the CCP is under control. In some cases, it may have to perform tests at a CCP or use statistically based sampling.

Monitoring will go much more smoothly if the plant clearly identifies and adequately trains employees responsible for monitoring, and ensures they understand the purpose and importance of monitoring.

Let's see how monitoring was addressed in real-life companies.

TAPED INDUSTRY REPRESENTATIVE INTERVIEW SEGMENT—PRINCIPLE FOUR

**Host**

Later in your training, you will learn that companies must list procedures for monitoring critical control points, the frequency with which they will be performed, and document the monitoring of all CCP's using actual values and observations. Once again, there is no required format, and you will encounter a wide variety of approaches in different plants.

Now let's move on to the next Principle.

HACCP Principle Number Five is to *"Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit."*

The regulation defines corrective action as "procedures to be followed when a deviation occurs." A deviation is a failure to meet a critical limit.

Since HACCP is a preventive system to correct problems before they affect the safety of food, plant management has to plan in advance to correct potential deviations from established critical limits. Any time a critical limit is not met, the plant will need to take corrective actions.

Under HACCP, plant management determines in advance what it will do when a critical limit is not met at a CCP. The employees monitoring CCPs should understand this process and be trained to perform the appropriate corrective actions. It is important that an establishment record all corrective actions and that employees responsible for taking the corrective actions sign all the documentation.

Not all corrective actions can be anticipated. If a corrective action is taken that is not listed in the HACCP plan, it should also be documented.

In some cases, the product in question will be held for further investigation of the deviation. This investigation may require a thorough record review, product testing, or consultation with a processing authority.

To establish corrective actions, plant management must:

1. For each CCP, determine the corrective action to take if the critical limits are exceeded. Determine what should be done with the product if a deviation occurs at this step. There may be more than one corrective action for a CCP.

2. Develop a method to capture all the necessary information on the deviation, and identify the employee responsible for maintaining and signing the record.
3. Ensure that employees conducting the monitoring at each CCP are fully trained and know the corrective actions to take if a deviation occurs.
4. Enter the appropriate corrective actions for each CCP in the corrective action column of the HACCP form and identify the record that will be maintained.

Some examples of corrective actions that companies may plan, are:

Immediately adjust the process and hold product for further evaluation and disposition.

Empower employees to stop the line when a deviation occurs, hold all product not in compliance, and call in the quality control manager, supervisor, other individual.

Rely on an approved alternate process that can be substituted for the one that is out of control at the specific critical control point.

Not every corrective action can be anticipated. Occasionally the plant must decide what to do with product that exceeded a critical limit if the action that was taken was not included in the HACCP plan. When that happens, the plant should segregate and hold the product, further investigate the situation to fully reassess the extent of possible health hazard, decide on the appropriate final action, and document all aspects of the incident.

Regardless of the corrective actions taken, the plant needs to keep records showing:

The deviation that was identified.

The reason for holding the product; the time and date of the hold; the amount of product involved; the disposition and/or release of product; and the individual who made the disposition decision.

Actions to prevent the deviation from recurring. This may involve reassessment and/or revision of the HACCP plan.

Let's see how real-life companies handled Corrective Actions.

TAPED INDUSTRY REPRESENTATIVE INTERVIEW SEGMENT—PRINCIPLE FIVE

## Host

Later in your training, you will learn that companies must identify corrective actions to be followed in response to a deviation from a critical limit for all CCP'S. Once again, there is no required format, and you will encounter a wide variety of approaches in different plants.

Well, we're down to the last two Principles.

HACCP Principle No. 6 states: *"Establish effective recordkeeping procedures that document the HACCP system."*

Maintaining proper HACCP records is an essential part of the HACCP system. Good HACCP records—meaning that they are accurate and complete—can be very helpful because:

Records serve as written documentation of the establishment's compliance with its HACCP plan.

Records allow the plant to trace the history of an ingredient, in-process operations, or a finished product, should problems arise.

Records help identify trends in a particular operation that could result in a deviation if not corrected.

In the event of a product recall, HACCP records could help identify and narrow the scope of such a recall.

In accordance with HACCP principles, the HACCP system should include records for CCPs, establishment of critical limits, handling of deviations, results of verification activities, and the HACCP plan, including the hazard analysis.

In many cases, the records the plant currently maintains may be sufficient to document the HACCP system. Records must contain at least the following information: title and date of record; product identification; critical criteria or limits; a line for the monitor's signature; a place for the reviewer's signature; and an orderly manner for entering the required data.

When establishing recordkeeping procedures, plant management may:

Develop any forms necessary to fully record corrective actions taken when deviations occur.

Develop forms to document the HACCP system.

Identify the employees responsible for entering monitoring data into the records and ensure that they understand their roles and responsibilities.

Enter their internal record form names on the appropriate HACCP Plan Form or HACCP worksheet.

Let's see how real-life companies handled Recordkeeping.

TAPED INDUSTRY REPRESENTATIVE INTERVIEW SEGMENT—PRINCIPLE SIX

**Host**

Later in your training, you will learn that companies must keep certain signed and dated records. Once again, there is no required format, and you will encounter a wide variety of approaches in different plants.

We've made it to the last Principle, number Seven!

HACCP Principle Seven states: *"Establish procedures to verify that the HACCP system is working correctly."*

After a HACCP plan has been put into place, companies do verification activities on an ongoing basis. Verification entails the use of methods, procedures, or tests in addition to those used in monitoring, to determine whether the HACCP system is operating as intended.

Simply stated, the plant needs to verify that the HACCP system is working the way it is expected to work. Several examples are the calibration of process monitoring instruments at specified intervals, direct observation of monitoring activities, and corrective actions. These should be included in the HACCP plan in addition to the critical limits, monitoring, and corrective actions and should be defined at each CCP. Plant management should also make sure that employees are following the procedures for taking corrective actions when a critical limit is exceeded. Finally, plant management should check to see that the employees are keeping specific, accurate, and timely HACCP records.

By doing these things, the plant will evaluate the day-to-day operation of the HACCP system. Plant management should not be surprised to find that it needs to fine-tune the HACCP plan.

Some things it can do to verify the HACCP system are:

Analytically test or audit the monitoring procedures;

Calibrate the temperature equipment;

Sample the product, including microbiological sampling;

Review the monitoring records;

Review the records of deviations and product dispositions;

Inspect and audit the establishment's operations;

Sample for environmental and other concerns.

Validation is the process through which a company assembles data showing that the HACCP plan it will use will work to control the process and prevent food safety hazards.

Data assembled to validate a HACCP plan are usually of two types: (1) theoretical principles, expert advice from processing authorities, scientific data, or other information demonstrating that particular process control measures can adequately address specified hazards, such as studies establishing the temperatures necessary to kill organisms of concern; and (2) in-plant observations, measurements, test results, or other information demonstrating that the control measures, as written into a HACCP plan, can be operated within a particular establishment to achieve the intended food safety objective. This means that the data used to validate a HACCP plan may be derived from various sources, including the scientific literature, product testing results, experimental research results, scientifically based regulatory requirements, FSIS guidelines, computer-modeling programs, and data developed by process authorities. The nature and quantity of information required to validate a HACCP plan will vary depending on factors such as the nature of the hazard and the control measures chosen to address it.

FSIS believes that validation data for any HACCP plan must include some practical data or information reflecting an establishment's actual early experience in implementing the HACCP plan. This is because validation must demonstrate not only that the HACCP plan is theoretically sound, but also that this establishment can implement it and make it work. For example, steam vacuuming has been scientifically demonstrated to be effective in removing visible contamination and associated bacteria from carcass surfaces. A slaughtering establishment using the technology as a control measure at a CCP, however, would still have to demonstrate its ability to use the technology effectively at the CCP.

Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with Sec. 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of Sec. 417.2(c) of this part.

Here's how real-life companies handled Verification

TAPED INDUSTRY REPRESENTATIVE INTERVIEW SEGMENT—PRINCIPLE SEVEN

**Host**

Later in your training, you will learn that companies must list the procedures used to verify that the plan is being implemented effectively, and specifies the frequency with which those procedures will be performed. Once again, there is no required format, and you will encounter a wide variety of approaches in different plants.

After completing the Five Preliminary Steps and Seven HACCP Principles, plant management assembles all the information into the HACCP Plan. The HACCP plan should be reviewed in its entirety and signed and dated by the responsible establishment official. Once again, it's up to the company to decide how to do it, and you will see many different formats.

Now plant management is ready to put its HACCP plan into action and make HACCP a reality in its establishment.