FSIS Compliance Guideline: **Modernization of Poultry Slaughter Inspection**

Microbiological Sampling of Raw Poultry

June 2015

This guidance document is designed to help small and very small poultry establishments in meeting the sampling and analysis requirements under the final rule to modernize poultry slaughter inspection.

This guidance is designed to assist establishments as they:

- Develop a microbiological sampling plan;
- Utilize microbial testing results to monitor their ability to maintain process control; and
- Make decisions on process control throughout the poultry slaughter process.

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This Compliance Guideline follows the procedures for guidance documents in the Office of Management and Budget's (OMB) "Final Bulletin for Agency Good Guidance Practices" (GGP). More information can be found on the Food Safety and Inspection Service (FSIS) Web page:

http://www.fsis.usda.gov/wps/portal/footer/policies-and-links/significant-guidance-documents

This is the **first** edition of the Compliance Guideline: Modernization of Poultry Slaughter Inspection - Microbiological Testing of Raw Poultry. Future editions will continue to reflect feedback received from all stakeholders.

This Compliance Guideline represents FSIS's current thinking on this topic and should be considered usable as of this issuance. Therefore, FSIS encourages establishments slaughtering or producing raw poultry products to incorporate information in this guideline in their decision making process. A final version of this guidance will be issued in response to public comments.

The information in this compliance guideline is provided as guidance to assist poultry slaughter establishments, and is not legally binding from a regulatory perspective.

What is the purpose of this Compliance Guideline?

The purpose of this guidance document is to help small and very small poultry slaughter establishments comply with the new microbiological sampling and analysis requirements that apply to all official poultry slaughter establishments, except for establishments that slaughter ratites (79 FR 49566).

Establishments may also find the references listed at the end of this document useful for further resources as well as background on technical concepts.

Note that establishments can also seek guidance from University Extension Service specialists within the state that the establishment is located on how to design sampling plans, how to collect samples, and how to test raw poultry products.

How can I comment on this Compliance Guideline?

FSIS is seeking comments on this guidance document as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days and the document will be updated in response to the comments received.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to regulations.gov and follow the online instructions at that site for submitting comments.

Mail, including CD-ROMs, and hand - or courier-delivered submittals: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, OPPD, RIMD, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2011-0012. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information to regulations.gov.

Requirements for written procedures and microbiological sampling

Under the final rule to modernize poultry slaughter inspection, all poultry slaughter establishments, except for establishments that slaughter ratites, are required to develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal material throughout the entire slaughter and dressing operation (9 CFR 381.65(g)). At a minimum, these procedures must include sampling and analysis for microbial organisms at prescribed locations and frequencies to monitor the establishment's ability to maintain process control for prevention of contamination with enteric pathogens (e.g., *Salmonella* and *Campylobacter*) and fecal material. Under the new rule, establishments must incorporate their written procedures, including their microbiological sampling plans, into their Hazard Analysis and Critical Control Points (HACCP) plans or Sanitation Standard Operating Procedures (Sanitation SOP) or other prerequisite program. Because this sampling and analysis is part of the procedures to prevent contamination by enteric pathogens and fecal material, the establishment needs to be able to support that the results relate to prevention of enteric pathogens and contamination by fecal material throughout the slaughter and dressing operation.

The new recordkeeping and sampling requirements in 9 CFR 381.65(g) are applicable to poultry establishments that slaughter poultry under any of the exemptions based on religious dietary laws in 9 CFR 381.11 through 9 CFR 381.14 (Confucian, Buddhist, Islamic, or Kosher).

Establishments that slaughter multiple classes of poultry, other than ratites, may test the type of poultry slaughtered in the greatest number to meet the requirements in 9 CFR 381.65(g). However, these establishments are required to have written procedures to prevent enteric pathogen and fecal contamination throughout slaughter and dressing process to address all species slaughtered at the establishment.

Establishments that slaughter poultry other than ratites are responsible for determining which microbial organisms will be most effective in monitoring process control for enteric pathogens and fecal contamination and in supporting their sampling plan. Establishments are required to have a supportable sampling plan, including sampling frequency, microbes for which there will be analysis, and, where appropriate and practical, acceptable microbiological levels. FSIS recommends that establishments conduct baseline sampling periods during which they map the various points in the slaughter operation that could impact microbial and fecal contamination. This baseline sampling and mapping should occur at some regular, defined interval (e.g., seasonally or annually). Such sampling can be used to determine the frequency of testing and set the microbiological levels that are needed to ensure that the food safety system is in control.

The regulations prescribe the minimum requirements for the location and frequency of sampling, based on establishment size and production volume. The microbial testing program may include indicator organisms, enteric pathogens, or both collectively to

meet the minimum sampling frequency requirements. Establishments may combine these sampling data into one sampling program and make process control decisions based on a collective analysis of these data.

As FSIS stated in the final rule, "FSIS considers the microbial characteristics of poultry carcasses at pre-chill to be a valuable source of data about how well an establishment is minimizing contamination with enteric pathogens and fecal material on live birds coming to slaughter and on carcasses throughout the evisceration and dressing process. FSIS considers the microbial characteristics of poultry carcasses post-chill to be a valuable source of data about how well an establishment is minimizing contamination during chilling and the overall effectiveness of any antimicrobial interventions the establishment has chosen to apply throughout its process. Because most establishments apply one or more antimicrobial interventions between the pre- and post-chill sampling points to help control microbiological hazards, FSIS would expect that a reduction in microbiological contamination between these two points to be an indication of the effectiveness of those controls." (79 FR 49602). Therefore, with an exception for very small and very low volume (VLV) establishments operating under the Traditional Inspection System, poultry slaughter establishments are required to collect samples for microbial analysis at the pre-chill and post-chill locations to monitor for process control.

Establishments may integrate existing sampling programs, such as programs that were part of the *Salmonella* Initiative Program (SIP), to develop one comprehensive sampling program. Such a program could include microbiological sampling from process mapping or other programs that met requirements in previous generic *E. coli* requirements. This program could be acceptable provided that the total number of samples collected and analyzed at pre-chill and post chill is at least equal to the minimum number of samples required in the regulation. These programs could also include sampling of more than one microbe. The written plan should describe how the establishment intends to analyze the data and to make process control determinations. Although an establishment is not required to routinely test for enteric pathogens (e.g., *Salmonella and Campylobacter*), it should maintain data on file to support why the indicator organism it has selected to monitor process control is representative of process control for enteric pathogens, and that it is reaffirming this relationship on a recurring basis (e.g., at least once per quarter).

There are no identified index organisms that directly reflect the presence or absence of enteric pathogens in poultry (e.g., *Salmonella* and *Campylobacter*). Therefore, FSIS recommends that an establishment test for enteric pathogens at least intermittently and compare its results against the presence or absence of other non-pathogenic organisms (i.e., the indicator organisms the establishment is using) to assess whether it is maintaining process control.

An establishment's program for preventing contamination of carcasses and parts by enteric pathogens and fecal material needs to address all edible products, including whole carcasses, reprocessed carcasses, and parts, produced during the slaughter

process. The establishment must include in its design the frequency and location of sampling within its process and which microorganisms to test for to demonstrate process control in preventing contamination of carcasses and parts by enteric pathogens and fecal material.

FSIS has defined very small establishments operating under Traditional Inspection and VLV establishments operating under Traditional Inspection below. These establishments must collect samples for microbial organisms at the post-chill point in the process. In addition, VLV establishments must collect and analyze samples at least once during each week of operation starting June 1 of every year. If, after consecutively collecting 13 weekly samples, a VLV establishment can demonstrate that it is effectively maintaining process control, it may modify its sampling plan. For example, after collecting 13 weekly samples, a VLV establishment could collect samples less frequently, such as once a month, and use visual observation and documentation at control points to monitor process control. In this case, the establishment would need to document the changes and maintain documentation showing that the changes allow the establishment to continue to effectively monitor process control. Additionally, the establishment should identify in a written document conditions that would indicate that there is a failure in its process that requires a return to the higher level of sampling until the source is identified and effectively corrected.

All other establishments are required to collect and analyze a pair of samples - one sample at pre-chill and one sample at post-chill - at the following minimum frequency: Chickens: once per 22,000 carcasses but at a minimum of once during each week of operation; and turkeys, ducks, geese, guineas, and squabs: once per 3,000 carcasses but at a minimum once each week of operation.

Table 1. Establishment Size, Sampling Frequency and Sampling Location Requirements

Establishment size	Defined as	Minimum sampling location	Minimum sampling event frequency
Very low volume (VLV)	Slaughter no more than 440,000 chickens, 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas, or 60,000 squabs annually	A sample at post-chill per sampling event	At least once during each week of operation, starting June 1 of every year. If, after consecutively collecting 13 weekly samples and upon demonstrating effective process control, the sampling plan may be modified.
Very small (VS)	Fewer than 10 employees or annual sales of less than $2.5 million.	A sample at post-chill per sampling event	Chickens: once per 22,000 carcasses, but at a minimum of once during each week of operation. Turkeys, ducks, geese, guineas, and squabs: once per 3,000 carcasses

Small	10 – 499 employees unless annual sales total less than $2.5 million	A sample at pre-chill and a sample at post-chill locations per sampling event	but at a minimum once each week of operation.
Large	500 or more employees		

The effective date of these requirements for establishments was as follows:

- Large establishments: November 19, 2014;
- Small establishments: December 19, 2014; and
- VS and VLV establishments: February 17, 2015.

To provide additional clarification to help establishments meet these sampling requirements, FSIS is providing information concerning how to determine the necessary number of samples on an annual basis. An establishment (other than a VLV slaughter establishment that needs to sample at the minimum frequency specified above) can determine the total number of samples that it would need to collect on a given production day based on its annual production volume over the previous calendar year divided by the total number of production days within the same calendar year. The establishment would then determine the distribution of total number of samples over the total number of production days.

An establishment should consider seasonal increases in production over the calendar year when allocating how many sampling events need to take place on any given production day or production period. For example, many turkey slaughter establishments traditionally experience a seasonal increase in slaughter production volume during the later months of the year. To support their sampling frequency, establishments need to consider this seasonal increase in slaughter volume. Establishments may determine that they need to increase the number of samples collected on production days during this period as compared to other times of the year. This increase would provide increased assurance that testing data will be sufficient to inform the establishment of its process control during these periods of higher production volume. These determinations are required to be in decision making documents that support the establishment's sampling frequency.

An establishment may choose to sample parts (e.g., wings, legs) rather than carcasses to meet the requirements under 9 CFR 381.65(g)(2). If an establishment chooses to do so, the establishment is required to maintain data that demonstrates that its process is preventing contamination of carcasses and parts by enteric pathogens and fecal material throughout the entire slaughter process. The establishment is also required to maintain data that demonstrates that the sampling of parts at pre-chill and post-chill is representative of results that would be observed with sampling of whole carcasses at pre-chill and post-chill locations. The establishment should verify this association at some frequency (e.g., annually).

Statistical Process Control and Indicator Organisms

Statistical process control provides a powerful mechanism for establishments to monitor and interpret the data collected for ongoing HACCP verification. Statistical process control can provide establishments with an early warning that their process may not be functioning as designed. This warning can allow establishments to take corrective actions or make other process modifications to bring their process back into control without actually failing the individual establishment-identified pre-determined performance criteria. Statistical process control can also provide establishments with reasonable assurance that their HACCP system is functioning as designed, and that they are likely to meet applicable establishment-identified performance criteria.

A number of methods and approaches are available for establishments to follow. Establishments should consider available guidance and develop a statistically valid approach for interpreting sample results (Saini et al. 2011; De Vries and Reneau 2010).

In cases where an establishment does not have the resources or capacity to conduct baseline sampling that would be used to develop and implement their own statistical control limits or procedures, establishments can utilize the results from FSIS nationwide poultry surveys, provided in Tables 2 (chicken) and 3 (turkey). As the establishment continues to collect its own data, FSIS recommends that the establishment consider these data to modify their statistical process control parameters to be more useful within their own establishment.

The results in Tables 2 and 3 come from nationwide surveys conducted between 2007 and 2012[1]. During these surveys, FSIS collected samples from multiple points during processing; both chicken and turkey carcasses at rehang; and post chill. In these studies, FSIS sampled chicken by rinsing the carcass with 400 mL of solution and turkeys by swabbing two 50 cm^2 areas on the carcass. The tables show the median enumeration values for four common indicator bacteria: generic *E. coli*, APC, Enterobacteriaceae, and total coliforms. The median indicates that 50% of the samples in the FSIS surveys had enumeration values below the ones in the table, and 50% had values above the ones in the table.

Table 2 - Indicator Organism Median Values for Chickens

	Median (CFU/mL)			
	Generic *E. coli*	**APC**	**Enterobacteriaceae**	**Total Coliform**
Carcass – *Rehang*	540	28,000	1,600	940
Carcass – *Post Chill*	20	260	20	20

[1] FSIS Young Chicken Survey; FSIS Young Turkey Survey.

Table 3 - Indicator Organism Median Values for Turkeys

	Median (CFU/mL)			
	Generic *E. coli*	**APC**	**Enterobacteriaceae**	**Total Coliform**
Carcass – *Rehang*	22	1,800	50	40
Carcass – *Post Chill*	<1.2	18	<1.2	<1.2

If an establishment uses the data from these tables, it is important that its sampling methodology (i.e., amount of solution to rinse the chicken carcass) be comparable to the FSIS method. When establishments compare their sample results to the ones in the table, a sample value that is higher than the corresponding one listed in the table indicates that the establishment may not be maintaining process control and may be less likely to meet the applicable performance criteria. Sample values lower than the one listed in the table indicate that the establishment is maintaining process control unless there is evidence that there are other problems in the establishment's procedures or production environment, such as evidence that the establishment's product has been associated with illnesses. When illnesses are associated with a particular establishment, achievement of a lower frequency of contamination, along with a lower level of contamination, has been demonstrated to be essential in reducing or eliminating illness from the establishment's products and protecting public health.

Very small and VLV slaughter establishments operating under Traditional Inspection can choose to continue to conduct generic *E. coli* testing at post-chill to meet these requirements. FSIS considers the requirements under the former regulations for generic *E. coli* testing of poultry to be a scientifically validated "safe harbor" for monitoring process control specifically for fecal contamination. However, an establishment may choose to perform additional testing to monitor for process control of enteric pathogens to meet the new regulatory requirements.

Former provisions that FSIS considers to be safe harbors:

A. Each very small or VLV establishments that slaughters poultry under Traditional Inspection may test for *Escherichia coli* Biotype I (also referred to as generic *E. coli*) at the post-chill point in the process.

B. To collect the sample, the establishment should collect a whole bird from the end of the chilling process. If this is impracticable, the whole bird can be taken from the end of the slaughter line. The sample is collected by rinsing the whole carcass in an amount of buffer appropriate for that type of bird. Samples from turkeys may also be collected by sponging the carcass on the back and thigh.

C. Laboratories analyzing the samples should use any quantitative method for analysis of generic *E. coli* that is validated by a recognized independent testing body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

D. An establishment is operating within the criteria when the most recent *E. coli* test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken as in Table 4 below. For classes of poultry that do not have established M and m values, an establishment can use Statistical Process Control to determine its upper and lower control limits:

Table 4 – Upper and Lower Limits for Generic *E. coli* testing in Chickens

Type of poultry	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of Samples tested (n)	Maximum number permitted in the Marginal range
Chickens	100 cfu/ml	1,000 cfu/ml	13	3

Written microbiological sampling program

The following elements should be included in the written sampling program:

1. A description of the sample collection procedures, including how random sampling is achieved, how the sample is taken, and how samples are handled to ensure sample integrity; and the name or title of the establishment employees designated to collect the samples for testing.

2. Information on the analytical method used to analyze the samples and identify the laboratory performing the analysis. The method used should validated by a recognized independent testing body.

3. The microbiological organisms (i.e., *Salmonella, Campylobacter*, or indicator organisms, such as aerobic plate count (APC), total coliform, Enterobacteriaceae, and generic *E. coli*) that it will test for to monitor the effectiveness of its process control procedures.

4. The locations within the process where samples are collected. Establishments, except for very small establishments or VLV establishments operating under Traditional Inspection, must collect samples at pre-chill and post-chill points in their process (9 CFR 381.65(g)(1)). Very small establishments or VLV establishments operating under Traditional Inspection must collect samples at post -chill point in their process.

5. The frequency of sample collection (9 CFR 381.65(g)(2)) (See Table 1).

6. Scientific and technical documentation to support the design of the sampling program. Further information on scientific and technical documentation can be found in the FSIS Compliance Guideline: HACCP Systems Validation, May 2013.

The Appendix on page 25 contains a self-assessment checklist that highlights the key elements that an establishment should address as part of their written microbiological sampling program.

Definitions

Pre-chill: a point in the slaughter process between and including rehang and just prior to the carcass entering the chiller. Allow appropriate drip time after interventions before collecting sample.

Post-chill: a point in the slaughter process after the carcass exits the chiller and after all slaughter interventions are completed, which is the same point in the process that FSIS collects samples for Salmonella and Campylobacter verification testing. If water immersion chilling is used, allow appropriate drip time before collecting the sample.

Random selection of carcasses

Samples should be collected randomly at the frequency determined by the establishment as part of its sampling plan. At a minimum, the establishment must collect samples at the frequency specified under 9 CFR 381.65(g)(2). If more than one shift is operating at the establishment, the sample can be taken on any shift provided there are samples collected from all shifts randomly over time, and there are not notable differences in the outcome.

Different methods of selecting the specific carcass for sampling could be used, but the method used should include the use of random numbers to ensure that testing data are not biased. Examples of methods include random number tables, calculator or computer-generated random numbers, or drawing cards.

The carcass that is sampled should be selected at random from all eligible carcasses and should include reconditioned, trimmed and reprocessed whole carcasses as well as “major portions” since these carcasses can be a significant source of redistribution of contamination prior to chilling. If there are multiple lines or chillers, randomly select the line or chiller for sample collection for that interval. Each line or chiller should have an

equal chance of being selected at each sampling interval within the relevant time frame (based on the sampling frequency for the establishment).

Carcasses should be selected at the identified points in the process (pre- and post-chill). At the post-chill site, samples should be collected after the final wash and the application of any final antimicrobial interventions. A drip time of at least 60 seconds should be observed before sample collection to prevent excessive antimicrobial carryover in the collected sample. A longer drip time prior to sample collection may better ensure that the technical effect of the antimicrobial treatment is neutralized. Establishments should seek guidance from the manufacturer of the antimicrobial treatment as to the optimal drip time and process to counter adverse outcomes of the treatment.

Pre-sampling preparation and aseptic technique

Extraneous organisms from hands, clothing, sampling equipment, or the processing environment may contaminate samples and lead to erroneous analytical results. Aseptic sampling techniques should be followed to ensure accurate results that are representative of the product and process.

Before beginning sample collection, it is important to assemble sampling supplies, such as sterile gloves, sterile sampling solutions, and sanitizing solution. Sterile sampling solutions, such as Butterfield's phosphate diluent (BPD) or buffered peptone water (BPW), should be stored according to the manufacturer's instruction at room temperature; however, at least the day before sample collection, check such solutions for cloudiness and do not use solutions that are cloudy or turbid or that contain particulate matter.

An area should be designated as a staging site for preparing the sampling supplies. A sanitizable surface, such as a stainless steel table or wheeled cart, can be used. A small plastic tote may also be useful for transporting sampling supplies to sample collection sites.

Sterile gloves should be used when handling carcasses or sterile sampling equipment (e.g., sampling sponge) during the sample collection process. Care should be taken to prevent contamination of the external surface of the gloves prior to or during the sample collection process. Step-by step instructions on aseptic gloving are included as an attachment to this document (Attachment 1).

Examples of non-destructive sample collection techniques that an establishment may choose to use to collect samples are included as attachments to this document. The methods describe a nondestructive sponge technique for sample collection from turkeys and a whole bird rinse technique for sample collection from chickens (Attachments 2 and 3).

Sample analysis

To obtain the most accurate results, samples should be analyzed as soon after collection as possible. If samples must be transported to an off-site laboratory, they should be refrigerated and then shipped refrigerated, on the same day they were collected, via an overnight delivery or courier service to the laboratory. NOTE: *Campylobacter* is particularly sensitive to freezing conditions. Thus, frozen samples may significantly under estimate whether this pathogen was present in the unfrozen sample. Multiple samples collected on the same day can be shipped together to the laboratory in the sample shipping container. A sample should arrive at the laboratory and be analyzed no later than the day after it is collected.

If sample collection, pick-up or shipment, and laboratory analysis cannot be carried out within this timeframe, the carcass or product selected for sampling should be held under refrigeration until the process can be accomplished in the appropriate span of time. The same principle applies for samples that are analyzed in-plant: If a carcass cannot be sampled and the sample analyzed by the day after it is collected, the carcass should be held under refrigeration until this is possible. Rinsate from a collected sample should not be held for an extended period of time. It should be either analyzed in-plant the same day as it is collected or by the following day or immediately shipped for overnight delivery to the laboratory that will conduct the analysis. Rinsate, sponge, or product samples should be held at refrigerated temperature, not frozen, and shipped cold to the laboratory in an insulated shipping container with frozen gel packs.

Key Question

Question: How soon after the samples are collected should they be analyzed to ensure the accuracy of the test results?

Answer: To obtain the most accurate results, samples should be analyzed as soon after collection as possible. If samples must be transported to an off-site laboratory, they should be refrigerated and then shipped refrigerated, on the same day they were collected, via an overnight delivery or courier service to the laboratory. A sample should arrive at the laboratory and be analyzed no later than the day after it is collected.

FSIS recommends that multiple samples collected on the same day be analyzed individually and not composited into one sample. However, an establishment may consider compositing samples collected from the same

day and at the same point in the process as an option if a quantitative test is used.

To help establishments meet regulatory requirements, FSIS is clarifying that establishments may composite samples. Additional information may be required to support compositing of pre-chill samples. If an establishment composites samples, it will need to demonstrate that it has collected sufficient data at various points throughout the pre-chill process over time in order to understand process variations that may be present at the various points in pre-chill where contamination may be redistributed. If the establishment has information to support that minimal variation exists within its pre-chill process then an establishment may elect to composite its pre-chill samples over a production day. However, the compositing of pre-chill and post-chill samples together would not be considered an acceptable practice.

If an establishment uses a microbiological test that enumerates an organism, each of the individually composited samples would contribute to the final result. Therefore if the results are normalized (e.g., CFU/g) then these values can be applied to each of the individual samples with the understanding that these results are the average value among all of the composited samples.

Microbiological Testing Method

The establishment should ensure that microbiological testing meets its food safety needs. An establishment needs to determine whether sample analysis will be performed by an outside laboratory or in its own microbiological testing laboratory onsite (if available).

Because of the costs and the logistics involved with maintaining an onsite microbiological testing laboratory, establishments may choose to have samples analyzed by an outside laboratory. FSIS has available the compliance guideline, *Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory*. This guidance document should be particularly useful to very small establishments when they are selecting a commercial or private laboratory to analyze establishment microbiological samples. Establishments should clearly communicate their needs to the testing laboratory and direct them to any necessary testing protocols or other guidance, including this document, on the FSIS Web site. Establishments that select a laboratory that does not apply appropriate testing methods or effective Quality Control/Quality Assurance (QC/QA) practices may not receive reliable or useful testing results. FSIS has also made available a list of *Foodborne Pathogen Test Kits Validated by Independent Organizations* for the detection of relevant foodborne pathogens (i.e., *Salmonella*, *Campylobacter*, *E. coli* O157:H7, and *Listeria spp*. including *L.*

monocytogenes). These lists are intended to be informational and are not an endorsement or approval of any particular method, regardless of its inclusion in the list.

To prevent cross contamination, FSIS recommends that a microbiological testing laboratory be segregated from manufacturing areas and that access to the laboratory space be limited. If the establishment will be performing testing for pathogens onsite, then they should have the following additional safeguards in place to ensure food safety and security:

- Follow requirements for Biosafety Level II laboratory operation as outlined in *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) available at: http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf;
- Restrict access to the laboratory to trained staff; and
- Ensure the laboratory is operating under the supervision of a qualified microbiologist or equivalent.

NOTE: Establishments can (and often do) analyze samples for non-pathogenic organisms such as generic *E. coli* and aerobic plate counts (APC) on-site. The test method used should be validated for the target organisms and for the sample matrix being analyzed to ensure accuracy of the results. It should also be a method validated by a recognized independent body, such as the Association of Official Analytical Chemists (AOAC).

Recordkeeping

Upon implementation of the sampling program, the establishment must maintain records sufficient to document the implementation and monitoring of sample collection. Records should include the testing procedures, including support for the adequacy of the testing frequency, and the test results and information such as the:

- Time, date, and location of the sample collection.
- Sample collector's name.
- Name or description of the product or sample source.
- Lot information and producer.

All entries should be dated and initialed by the sample collector immediately upon completion of the entry. If an outside laboratory is used for testing, then these records should also include information such as date the sample was shipped to the laboratory for analysis. The outside laboratory should document the:

- Date received;

- Condition of the sample upon receipt, including sample temperature, if applicable;
- Date the analysis was started and completed; and the
- Analytical result.

Test results should also be recorded and linked to the sample collection records by a sample number, form number, or some other unique identifier. These records should be maintained in a way that ensures the integrity of the data. These records can be maintained in an electronic format, provided there are measures in place to ensure the security of the information. These records should be readily accessible for review by the establishment and FSIS inspection program personnel upon request.

Charting and Interpreting Test Results

Specific techniques of statistical process control include the use of a control chart, which plots data over time but also displays an upper control limit for specific measurements and a centerline, above and below which there is an equal number of sample results (the centerline is in effect an average). A sample result above the upper control limit would indicate the likely presence of a special cause of variation that should be addressed. Results within control limits indicate simply that the process is in control. Control charts are used to (1) analyze and understand variables that affect the process, (2) determine process capabilities, and (3) monitor effects of the variables on the difference between target and actual performance. In most situations more than one type of control chart would be applicable. Detailed information on the use of control charts can be found in texts on statistical process control, under the topic “control charts”.

The following control charts are hypothetical examples of using quantitative microbiological test results, collected over time, to verify the effectiveness of a food safety system (Buchanan).

Chart 1 - System under control

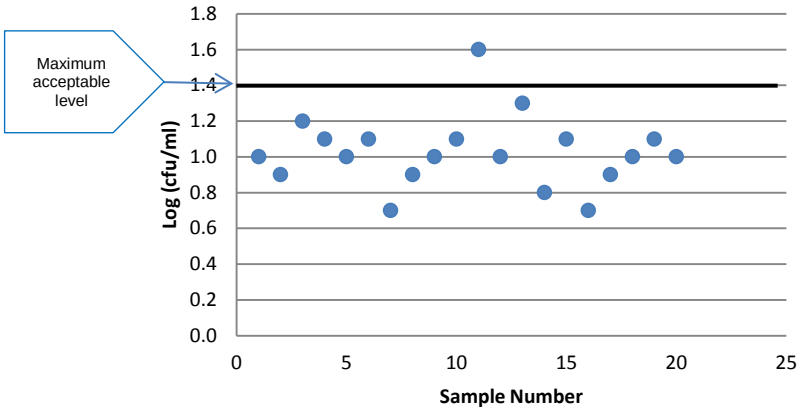

Chart 1 depicts a pattern of test results that would be seen in a well-controlled system.

In a well-controlled system, the majority of test results will be clustered around a central value.

It is important to note that even in a well-controlled system; there is some frequency of isolated results above the acceptable level.

Chart 2 - Lack of control due to excess variability

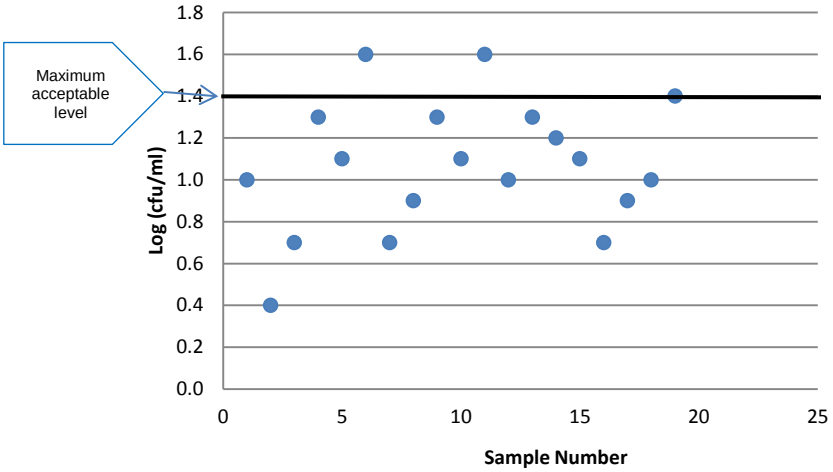

Chart 2 depicts a loss of process control due to excess variability. This is reflected in both an increased number of results above the maximum acceptable level and an increase in the scatter of points below the maximum acceptable level.

This chart suggests either a loss of control at a critical control point or the existence of another critical control point that had not been identified and controlled.

Chart 3 - Loss of control due to gradual process failure

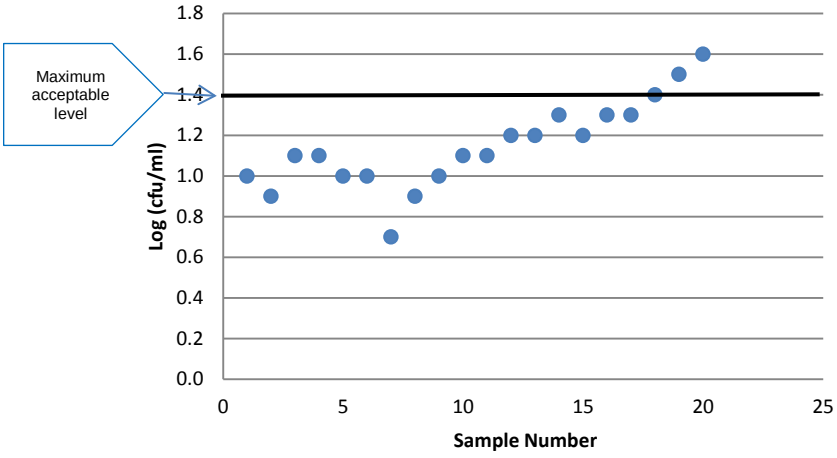

Chart 3 - depicts a situation where a component of the process is losing its effectiveness over time.

This loss of control is apparent by the upward trend in the data points toward the maximum acceptable level.

Chart 4 - Loss of control due to abrupt process failure

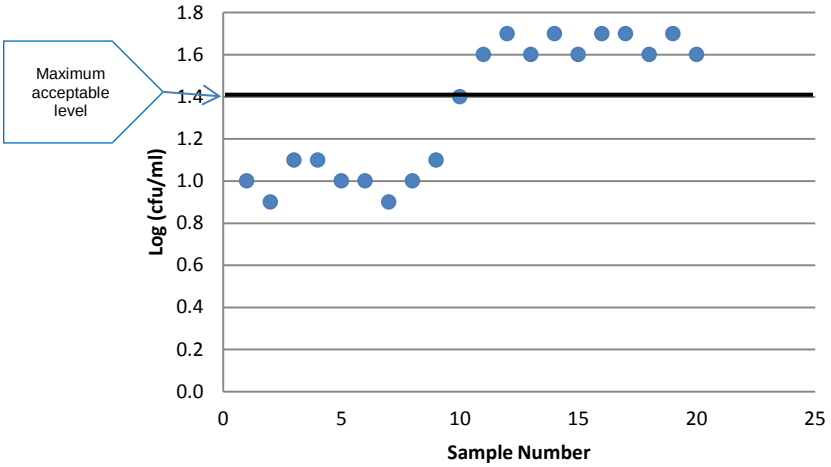

Chart 4 depicts a catastrophic loss of process control.

This pattern of test results would be encountered in a situation such as an abrupt failure of a key piece of equipment, such as an antimicrobial wash cabinet.

Chart 5 -Loss of control due to reoccurring transitory process failure

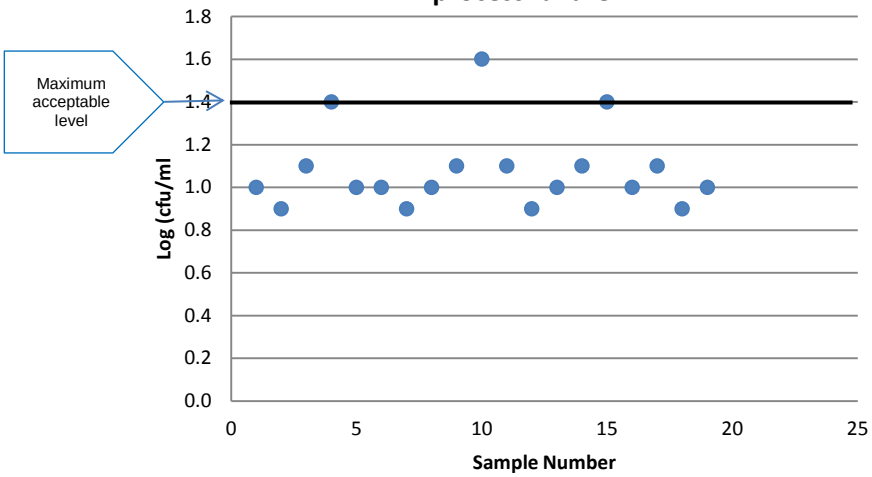

Chart 5 depicts conditions where there is the existence of an intermittent but reoccurring problem within the process. Note the distinct periodicity of the test results over time.

An example of a situation where this pattern may be observed is the dripping of condensation onto product as it travels down a conveyor belt

The test results should be charted and evaluated in a “moving window” format. For establishments other than very small and VLV establishments operating under the Traditional Inspection System, the test results for both pre-chill and post-chill samples should be plotted and evaluated in a series over time. The results should be evaluated to determine the effectiveness of process control measures in reducing microbiological levels between these two points.

The test result chart should be updated within the next business day following the reporting of test results by the testing laboratory. Every time a new test result is recorded, the oldest test in the series is dropped from the moving window. For example, an establishment may choose to evaluate their test results in a moving window of 13 tests. The establishment would use this series of 13 tests to evaluate their process control over the period of time represented by the series of 13 tests. The

control chart would be updated with each new test result reported, adding the new test result and removing the oldest test result on the chart.

Microbiological testing provides a measure of the extent of control at the step being evaluated and all preceding steps. By performing microbiological analyses at several points within a process, it is relatively easy to identify the segment of the process where control has been lost. In addition, while it is not required, end-product testing can provide an integrated measure of the performance of the entire process.

Actions in Response to Test Results

As part of its process control procedures, an establishment should define the actions it will take if the test results obtained through its sampling are above the limits it has set. The establishment should delineate what its actions will be, who will take each action, how the outcome of these actions will be documented, and how it will be verified.

FSIS has made available the *FSIS Compliance Guidelines for the Control of* Salmonella *and* Campylobacter *in Raw Poultry*. The guidelines summarize known control points for *Salmonella* and *Campylobacter* in the pre- and post-harvest production process. Establishments should use this compliance guide to improve management practices, to ensure effective sanitary dressing procedures and to assist in investigating when there is a loss of process control. When an establishment makes changes at the appropriate locations, process control should improve. As a result, establishments should produce raw poultry products that have less contamination with pathogens, including *Salmonella* and *Campylobacter*. Generally, those interventions to reduce or prevent *Salmonella* will likewise reduce or prevent *Campylobacter*.

If the establishment determines that the trends in its test results indicate a loss of process control, the establishment should take action to investigate the cause. An establishment should consider how the different parts of its food safety system work together and how they affect the entire food safety system. To do this, establishments should evaluate its process control procedures and sanitary dressing practices to determine whether a root cause can be identified and take steps to correct the problem. This determination should include a review of its process monitoring records as well as evaluation of the process during normal operations. The establishment should consider any implementation problems or changes in its practices, such as sanitary dressing procedures, including but not limited to:

- Procedures for routine cleaning and sanitizing of equipment, including hand tools that are used to remove contamination or to make cuts into the carcass;

- The design, configuration, and calibration of equipment to ensure proper function within operational parameters to prevent the contact between carcasses and parts and prevent contamination of carcasses during operation;

- Employee hygiene practices, ensuring that employees frequently wash hands and aprons that come in contact with carcasses; and

- The implementation of antimicrobial or mechanical intervention treatments, such as carcass washes, sprays, dips, drenches, or brushes, in accordance with the limits selected by the establishment, including effective application to ensure coverage of the entire carcass.

Following its investigation, the establishment should respond appropriately to its findings through the use of decontamination procedures and antimicrobial intervention treatments as necessary to address any contamination that may have occur on the carcasses and parts. The establishment should also take steps to initiate any necessary equipment repair or recalibration and employee training when identified.

Finished Product Standards (FPS) Waivers

On July 13, 2011, FSIS announced the *Salmonella* Initiative Program (SIP) as a voluntary program to provide incentives to establishments to maintain consistent process control to minimize *Salmonella* levels and to conduct microbial testing to demonstrate that they are maintaining process control (76 FR 41186). In return, establishments received one or more waivers of certain provisions of the regulations, such as those on use of alternative Finished Product Standards (FPS) procedures (9 CFR 381.76).

These waivers were authorized under 9 CFR 381.3(b), which provides that the FSIS Administrator may, in specific classes of cases, waive any provisions of the poultry inspection regulations for limited periods in order to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements, provided that such waivers are not in conflict with the purposes or provisions of the Poultry Products Inspection Act (PPIA).

FSIS has granted waivers to establishments with respect to testing and other provisions in the FPS regulations, so that establishments could collect data and assess whether this other data would facilitate definite improvements.

The final rule to modernize poultry slaughter inspection (79 FR 49566) amended the poultry regulations to establish an additional inspection system, called the New Poultry Inspection System (NPIS), for young chicken and turkey slaughter establishments. Under the final rule, NPIS does not replace the Streamlined Inspection System (SIS), New Line Speed Inspection System (NELS), and New Turkey Inspection System (NTIS).

For establishments that choose to operate under NPIS, the final rule replaces FPS with a requirement that establishments maintain records to document that poultry products resulting from its slaughter operation meet the definition of ready-to-cook (RTC) poultry (9 CFR 381.1). Thus, all FPS waivers will be terminated by operation of the final rule. The purpose of the waivers was to gather the information on how non-food safety defects should be handled. The Agency's decision on this matter, to go the ready-to-cook standard in NPIS, was based on the information obtained under these waivers. Therefore, the reason for granting the waiver has been fulfilled.

The effect of the termination of the waiver will depend on what an establishment elected to do on February 23, 2015 (the opt-in date). Establishments that are operating under FPS waivers and that would like to continue to use their alterative FPS procedures will need to convert to the NPIS.

Establishments that notify FSIS of their intent to operate under NPIS may continue to operate under the waiver from FPS requirements until they start operating under NPIS. If establishments choose to operate under SIS, NELS, or NTIS inspection systems (which require complying with FPS), their FPS waiver ends on February 23, 2015. FSIS will give 30 days written notice of the termination of that waiver. Otherwise, establishments will need to submit a request for a new waiver from FPS requirements under SIS, NELS, or NTIS with information on how the waiver would provide new information that would facilitate definite improvements (9 CFR 381.3(b)). FSIS expects that it will be difficult for establishments to meet requirements necessary to obtain a waiver now that NPIS is available.

Sampling Frequency Waivers (9 CFR 381.65(g)(2)(i))

The Agency will consider granting waivers of provisions of the 9 CFR 381.65(g)(2)(i) requirements that specify sampling frequency for establishments, except for VLV establishments, to reduce the frequency of sampling below the minimum frequency of once per 22,000 chickens and once per 3,000 turkeys. VLV establishments will not need to request a waiver since the regulations (9 CFR 381.65(g)(ii)) provide for VLV

establishments to reduce their sampling frequency if they are able to demonstrate process control after 13 consecutive samples are collected.

These waivers of sampling frequency will be considered provided that the establishment 1) has collected and analyzed data in compliance with 9 CFR 381.65(g)(2)(i) over a minimum of six months (including before or after the effective date of the regulation) to demonstrate consistent process control over time; 2) provides the alternative procedures for reduced sampling frequency that it intends to follow; and 3) provides evidence that its alternative sampling program, along with other control procedures in its plan for preventing contamination by fecal materials or pathogens, will be at least as effective as the required sampling frequency to demonstrate process control. Such establishments may request a waiver of regulations under the *Salmonella* Initiative Program (SIP) (76 FR 41186) as described above**.**

FSIS will not grant waivers to 9 CFR 381.65(g)(2)(i) for a testing frequency that is less than the SIP data testing frequencies [i.e., daily *Salmonella* testing post-chill (one per line per shift) and weekly matched pair at re-hang and post-chill sampling for *Salmonella*, *Campylobacter*, and indicator organism] To obtain additional information, send an email to SIP.Mailbox@FSIS.USDA.gov.

Submitting Monthly SIP Microbial Data: Establishments operating under a waiver of regulations granted under SIP are required to continue to collect and analyze samples according to the SIP frequency and location; record and evaluate test results; take and document corrective actions, if any; and submit monthly test results on the data sheet provided by FSIS to the SIPMailbox@FSIS.USDA.gov.

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Appendix - Microbiological Sampling Program Self-Assessment Checklist	
1.	**Written microbiological sampling program**
	a. Sample Collection ❑ Procedure for random selection of carcasses for sampling ❑ Location within process where samples are collected. ❑ Pre-chill ❑ Rehang ❑ Other ❑ Post-chill ❑ Frequency of sample collection ❑ Aseptic technique for gloving and sample collection ❑ Description of sample collection procedure ❑ Carcass rinse ❑ Sponge sampling ❑ Designated employee to collect the sample ❑ Date and time collected
	b. Sample Handling and Shipping ❑ Proper sample handling and packaging to ensure sample integrity ❑ Sample identification ❑ Held under refrigeration/not frozen ❑ Packed in an insulated shipping container with cold packs ❑ Shipped to the testing laboratory on same day as collected ❑ Name of person or service (e.g., FedEx or courier service) transporting the sample ❑ Chain-of-custody documentation when samples transported from the establishment to an off-site laboratory (e.g., by a delivery service such as FedEx or courier) ❑ Holding time met (time from collection to analysis)
	c. Testing method and Test Results Reporting ❑ Description of the testing method used by laboratory ❑ Microbiological test results report received from testing laboratory ❑ Results reported in appropriate units of measure ❑ Test results recorded on a control chart (moving window format) ❑ Interpretation of results based on defined process control criteria ❑ Acceptable ❑ Unacceptable ❑ Actions taken in response to test results and trends in results over time

2.	**Testing Laboratory**
	a. Establishments should refer to the FSIS *Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory* for guidance on selecting a microbiological testing laboratory. The checklist provided in the guidance is intended to assist establishments to determine whether a microbiological laboratory is capable of producing accurate and reliable results. Some of the general criteria to consider in selecting a testing laboratory include: ❑ Personnel ❑ Facilities ❑ Equipment ❑ Operations ❑ Analytical methods
	b. Laboratory Testing Method FSIS has made available a list of *Foodborne Pathogen Test Kits Validated by Independent Organizations* for the detection of relevant foodborne pathogens (i.e., *Salmonella*, *Campylobacter*, *E. coli* O157:H7, and *Listeria spp*. including *L. monocytogenes*). This list is intended to be informational and is not an endorsement or approval of any particular method, regardless of its inclusion in the list. Some of the general criteria to consider when selecting a method include: ❑ Sample size analyzed ❑ Microorganism tested for (e.g., *Salmonella*, APC, generic *E. coli*) ❑ Analytical method used (e.g., AOAC, NordVal) ❑ Date test was received at the laboratory ❑ Date analysis was started ❑ Date analysis was completed ❑ Analytical results recorded and reported to establishment ❑ Corrective actions related to test results, such as laboratory error, unacceptable sample temperature upon arrival