FSIS Directive 10240.4:
Verification Activities for the *Listeria monocytogenes* (*Lm*) Regulation and the Ready-to-Eat (RTE) Sampling Program

TABLE OF CONTENTS

VERIFICATION ACTIVITIES FOR THE *Listeria monocytogenes* (*Lm*) REGULATION AND THE READY-TO-EAT (RTE) SAMPLING PROGRAM

CHAPTER I – GENERAL

I. PURPOSE

This directive provides inspection program personnel (IPP) with instructions to verify that meat and poultry establishments are complying with the regulatory requirements of 9 CFR 430.4, Control of *Listeria monocytogenes* (*Lm*) in Post-Lethality Exposed Ready-to-Eat (RTE) Products (the *Listeria* Rule). In addition, it provides IPP with instructions on verifying that establishments sampling programs meet the requirements of the *Listeria* Rule. It also provides instructions for collecting and submitting RTE meat and poultry products under the RTEPROD sampling project and for taking enforcement action in response to positive results. FSIS has provided additional information from FSIS guidelines that IPP can use in their decision-making when verifying the requirements of the *Listeria* Rule.

KEY POINTS:

- Verification of the establishment's compliance with the *Listeria* Rule
- Verification that establishment's sampling and testing programs meet the requirements of the *Listeria* Rule
- Collecting and submitting FSIS verification samples
- Enforcement actions in response to a positive sample result

II. CANCELLATION

FSIS Directive 10,240.4, Revision 2, Verification Procedures for Consumer Safety Inspectors for the *Listeria monocytogenes* (*Lm*) Regulation and *Lm* Sampling Programs

III. REASON FOR REISSUANCE

FSIS has revised this directive to:

A. Incorporate and clarify previously issued instructions for:

1. Collecting samples under the RTEPROD sampling project
2. Verifying that establishments hold or control RTE products that FSIS has tested for pathogens, or that have passed over direct food contact surfaces that FSIS has tested for pathogens, pending the results of FSIS testing.
3. Collecting samples in establishments that temporarily alter their routine practices.

B. Provide new instructions for:

1. Submitting samples when interventions such as high-pressure processing (HPP) are applied.

2. Verifying that establishments meet the requirements of the *Listeria* Rule when performing inspection tasks under the Public Health Information System (PHIS).

3. Taking action in response to a *Listeria* spp. positive result in the product when an establishment chooses to sample products as well as food contact surfaces (Chapter III, Section II.B).

IV. BACKGROUND

A. The *Listeria* Rule states that *Lm* is a hazard that establishments producing post-lethality exposed RTE meat and poultry products must control through their Hazard Analysis and Critical Control Point (HACCP) plans, or prevent in their processing environment through their Sanitation Standard Operating Procedure (Sanitation SOP) or other prerequisite programs. In order to maintain the sanitary conditions necessary to meet this requirement, establishments must comply with the requirements for one of three *Listeria* alternatives (9 CFR 430.4(a) and (b)).

B. *Lm*, *Salmonella*, and other pathogens of public health concern adulterate RTE products. If any level of *Lm* or *Salmonella* is detected in RTE product or on food contact surfaces that RTE product has passed over, the product is considered to be adulterated.

C. Under the RTE Sampling Program, FSIS operated two sampling projects: ALLRTE and RTE001. As of August 1, 2013, FSIS combined its random ALLRTE and risk-based RTE001 product sampling projects into a single project, RTEPROD. The RTEPROD project uses two project codes: RTEPROD_RAND for product samples selected randomly and RTEPROD_RISK for post-lethality-exposed product samples selected based on risk. FSIS designed the RTEPROD sampling project to increase response rates and to conserve laboratory resources.

D. Through an analysis of sampling data, FSIS determined that some establishments may temporarily alter their routine production, sanitation, or food safety practices when FSIS collects an RTE sample. By altering routine practices, establishments may make changes that are not consistent with their documented food safety system. Such changes may impede FSIS's ability to assess the safety of the product and the adequacy of the routine process. This directive provides IPP with instructions for taking action in establishments that change their routine practices.

E. An analysis of data from Food Safety Assessments (FSAs) showed that sanitation and HACCP non-compliances, followed by *Listeria* Rule non-compliances were the most common cause of deficiencies in RTE establishments. Therefore, FSIS revised this directive to include updated instructions for IPP to verify that establishments have sufficient support for decisions made in their hazard analysis, and are properly implementing their sanitation programs to control *Lm*. These updated instructions should help IPP identify and address issues that can lead to *Listeria* contamination of RTE products, thereby decreasing the risk of foodborne illness.

F. On December 10, 2012, FSIS issued a *Federal Register* notice (FRN), Not Applying the Mark of Inspection Pending Certain Test Results. It announced that FSIS was changing its procedures and would withhold its determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination are received. The policy and procedures announced in this FRN became effective February 8, 2013. FSIS requires establishments to hold or control RTE products that FSIS has tested or that have passed over food contact surfaces that FSIS has tested, pending the results of FSIS testing of products or food contact surfaces for *Lm* or *Salmonella*.

V. TERMINOLOGY

FSIS has provided the definitions and program descriptions in this section in response to questions received through askFSIS. IPP are to familiarize themselves with the terminology provided in this section before performing the inspections tasks, as described in this directive.

A. RTE Sampling Program

For the RTE Sampling Program, IPP are to collect samples under the RTEPROD project using the following project codes.

RTEPROD_RAND: Random sampling of RTE products, including both post-lethality exposed and non post-lethality exposed products (e.g., cook-in bag products).

RTEPROD_RISK: Risk-based sampling of post lethality exposed RTE products.

B. Products Subject to Sampling under the RTE Sampling Program

1. FSIS considers a product to be **RTE** if it meets some or all of the following criteria:

    a. The product meets the definition of an RTE product in the *Listeria* Rule (9 CFR 430.1). The *Listeria* Rule defines an RTE product as a meat or poultry product that is in a form that is edible without additional preparation to achieve food safety.

    b. There is a standard of identity requiring that the product be fully cooked according to 9 CFR 319 (e.g., hot dogs or barbeque) or a common or usual name that consumers understand to refer to RTE product (e.g., pâtés). IPP are to be aware that not all RTE products are required to meet a standard of identity.

NOTE: The establishment may consider certain products (e.g., hams) as either RTE or not ready-to-eat (NRTE) if there is no standard of identity defining the product as RTE or common or usual name under which the product is understood to be RTE.

    c. The product is not labeled with safe handling instructions (SHI), as required for NRTE products by 9 CFR 317.2(l) and 381.125(b). According to 9 CFR 430.1, RTE products are not required to bear SHI or other labeling that directs that the product be cooked or otherwise treated for safety. FSIS considers products labeled with SHI and cooking instructions to be NRTE (see Section V.C of this chapter).

    d. The product has been processed to meet the requirements of 9 CFR 318.17, 318.23, or 381.150 or undergone other processing to render it RTE, and it does not bear SHI or cooking instructions. For more information, see Chapter II, Section IV of this directive. IPP are to be aware that not all RTE products are required to be cooked to be considered RTE. Establishments may use other validated processes (e.g., fermenting and drying) to render the product RTE.

NOTE: A product (e.g., meat casserole) may receive a full heat treatment by the establishment and be labeled as NRTE as long as there is no standard of identity defining it as RTE or common or usual name under which the product is understood to be RTE, as described in the note above.

    e. The establishment's HACCP plan, intended use statement in its hazard analysis, and flow chart are consistent with a RTE product. According to FSIS PHIS Directive 5300.1, FSIS considers products in the Fully Cooked – Not Shelf Stable HACCP category to be RTE. HACCP categories that may contain either RTE or NRTE products include Not Heat-Treated - Shelf Stable, Heat Treated – Shelf Stable, and Product with Secondary Inhibitors – Not Shelf Stable.

2. FSIS considers the product to be post-lethality exposed if it is RTE, and it meets the following criteria:

    a. The product is exposed to the environment of the establishment after the lethality step.

    b. The product does not remain in a cooking bag, and it comes in contact with food contact surfaces, brine, or other environmental conditions during cooling, processing, slicing, or packaging steps.

NOTE: FSIS samples only post-lethality exposed RTE products under the RTEPROD_RISK project code.

3. FSIS considers the product to be non-post-lethality exposed if it meets the following criteria**:**

    a. The product is cooked in a bag and remains in the cooking bag until it leaves the establishment.

    b. The product is treated with a process (e.g., high pressure processing (HPP) that achieves a full lethality (e.g., 5-log reduction of *Salmonella*) in the product, once it is in its final packaging.

    c. The product is hot filled (e.g., lard) at a temperature sufficient to achieve full lethality of the product (e.g., using one of the time/temperature combinations in Appendix A).

NOTE: FSIS samples both non-post-lethality exposed products and post-lethality exposed products under the RTEPROD_RAND project code to verify that the product meets all safety standards, in accordance with 9 CFR 417.8(g).

C. Products Not Subject to Sampling under the RTE Sampling Program

FSIS does not sample NRTE products under the RTE sampling program. NRTE products are not edible without further preparation to achieve food safety and are required to bear SHI in accordance with 9 CFR 317.2(l) and 381.125(b). NRTE products may include products containing a meat or poultry component that is RTE in combination with nonmeat or poultry components that need to receive a lethality treatment by the intended user (e.g., meals containing meat and vegetables). In addition, NRTE products may include products that receive a partial or full heat treatment and do not have a standard of identity defining them as RTE or common or usual name that consumers understand to refer to RTE products (see Section V.B.1.b of this chapter).

D. The Sampled Lot

1. The sampled lot is product that is represented by the sample collected by FSIS and analyzed for *Lm* and *Salmonella*. The establishment is responsible for defining the sampled lot.

2. FSIS generally considers the sampled lot to be the product produced from "**clean-up to clean-up**" for RTE products, unless the establishment has a different supportable definition of the lot (e.g., products produced on different lines that are microbiologically separate from one another).

3. IPP are to be aware of the following factors or conditions that may determine a sampled lot:

    a. Frequency of cleaning and sanitizing – the establishment may perform a complete cleaning and sanitizing (following the procedures in its Sanitation SOP) to differentiate between lots.

NOTE: An official establishment may reduce its lot size on a day when FSIS collects a routine RTE sample to facilitate holding the product, as long as the change does not interfere with FSIS's ability to collect a representative sample.

b. Separation between processing lines

i. Products produced in the same room can be considered part of the same lot or different processing lots depending on how the lots are separated by time and space.

ii. Products produced on different processing lines can be considered different lots if the lines are microbiologically and physically independent of one another (e.g., equipment, personnel, utensils, and RTE source materials are not shared among the lines).

iii. Likewise, products produced on the same line can be considered different processing lots if they are separated by complete cleaning and sanitizing, as well as the other factors described above.

iv. Products stored in a common cooler would not necessarily be considered part of the same lot. IPP are to be aware that the establishment's Sanitation SOP should address possible cross-contamination if products from different lots are stored in the same cooler.

4. Although FSIS generally considers the sampled lot to be the product produced from "clean-up to clean up" (unless the establishment has another supportable lot definition), in the event of a positive result, additional product may be implicated. The following factors may be used to determine implicated product:

a. Use of RTE source materials and brine

i. If an establishment uses RTE source materials received from another establishment, and one of the lots containing a common RTE source material tests positive by FSIS, a scientific basis is necessary to justify why the other lots should not be implicated (e.g., because the source material was not the cause of the positive).

NOTE: Common raw source materials are not taken into account when determining the lot for RTE products because the products are cooked or otherwise processed to achieve food safety.

ii. The establishments' re-use of brine across lots can cross-contaminate the lots and prevent them from being microbiologically separate.

b. Processing steps employed

i. Because *Salmonella* can contaminate RTE products as a result of under-processing, if one lot of RTE product tests positive by FSIS and another lot of product received the same lethality treatment, a scientific basis is necessary to justify why the later lot should not be implicated.

ii. Ingredients (e.g., pepper or other spices) added to post-lethality exposed RTE products can affect the lot definition. The establishment is required to evaluate the possible hazards from all ingredients it uses, per 9 CFR 417.2(a)(1).

E. Sampling Results

1. If an RTE product or food contact surface tests positive for *Lm*, *Salmonella*, or another pathogen of public health concern or its toxins, the product from the tested lot or product that passed over the food contact surface is considered adulterated.

2. FSIS will withhold its determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all FSIS test results that bear on the determination have been received.

3. Products that test positive for *Listeria* spp may be considered adulterated if the establishment cannot support that the product is not adulterated, or if insanitary conditions exist (see Chapter III, Section II.C).

4. If a product passes over a surface that tests positive for *Listeria* spp., the product is not summarily considered adulterated, and the establishment is not required to confirm whether the sample is positive for *Lm*. However, the establishment is required to take corrective actions with respect to the food contact surface. See Chapter III, Section I.D, for the actions that the establishment is expected to take in this circumstance and the verification actions that IPP are to take.

F. *Listeria* Control Alternatives

According to the *Listeria* Rule, establishments producing post-lethality exposed RTE products must adopt one of the following *Listeria* Control Alternatives:

***Listeria* Control Alternatives**	
Alternative 1 (Alt. 1)	The establishment uses a post-lethality treatment (PLT) to reduce or eliminate *Lm* in the product and an antimicrobial agent or process (AMAP) to limit or suppress growth of *Lm* in the product.
Alternative 2, Choice 1 (Alt. 2a)	The establishment uses a PLT to reduce or eliminate *Lm* in the product.
Alternative 2, Choice 2 (Alt. 2b)	The establishment uses an AMAP to limit or suppress growth of *Lm* in the product.
Alternative 3 (Alt. 3)	The establishment relies on sanitation alone to prevent *Lm* in the processing environment and on the product. There are separate requirements for deli meat and hot dogs under this alternative.

CHAPTER II – IPP VERIFICATION OF ESTABLISHMENTS' COMPLIANCE WITH THE *LISTERIA* RULE

I. GENERAL

A. Background

1. This chapter provides IPP with an overview of the requirements of the *Listeria* Rule and instructions for verifying these requirements when performing inspection tasks, according to FSIS PHIS Directive 5000.1, Verifying the Establishment's Food Safety System. IPP are to

use the information in this directive when performing inspection tasks in establishments that produce RTE product.

NOTE: IPP are to be aware that the instructions in this directive supplement, but do not replace, the instructions in FSIS PHIS Directive 5000.1and the other directives referenced in this document.

2. When performing verification tasks, IPP are to be aware that the requirements of the *Listeria* Rule work with the requirements of 9 CFR 416 -- Sanitation and 9 CFR 417-- HACCP Systems to control the safety of the product.

EXAMPLE: An establishment has condensation dripping from the ceiling in its post-lethality exposed processing environment. Harborage of *Lm* occurs in non-food contact surfaces, spreads *Lm* through the condensate to food contact surfaces, and cross-contaminates the product with *Lm*. If the establishment's post-lethality treatment is designed to achieve a 1-log reduction of *Lm*, it may be overwhelmed by the additional contamination and no longer be sufficient to ensure the safety of the product. In that case, the establishment may no longer be able to demonstrate that its Sanitation SOP or HACCP system is effective in preventing or controlling *Lm*.

3. To assist IPP in performing verification tasks, FSIS has provided information from the FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products (*Listeria* Guideline) throughout this document. This information is being provided so that IPP are aware of the recommendations FSIS has made to establishments to meet the requirements of the *Listeria* Rule. When reviewing this information, IPP are to keep in mind that establishments may choose to adopt different practices than those outlined in the guidelines. In those cases, establishments would need to support why those procedures are effective in controlling hazards from *Lm* in post-lethality exposed RTE products. If the establishment meets the recommendations in the guidance, it would not need to provide further support for its process.

B. The Requirements of the *Listeria* Rule

1. If the establishment has chosen Alternative 1, IPP are to verify that:

    a. The establishment has applied both a PLT to reduce or eliminate *Lm* in the product and an AMAP to limit or suppress the growth of *Lm* in the product (9 CFR 430.4(b)(1)).

    b. The establishment has included the PLT in its HACCP plan and the AMAP in its HACCP plan or Sanitation SOP or other prerequisite program (9 CFR 430.4(b)(1)(i).

    c. The establishment has validated the effectiveness of the PLT incorporated in its HACCP program in accordance with 9 CFR 417.4. The establishment has documented in its HACCP plan or Sanitation SOP or other prerequisite program that the AMAP is effective in limiting or suppressing the growth of *Lm* in the product (9 CFR 430.4(b)(1)(ii)).

NOTE: IPP are to be aware that the *Listeria* Guideline recommends that the PLT will be validated to achieve at least a 1-log reduction of *Lm* before the product leaves the establishment, and that the AMAP will allow no more than 2-log outgrowth of *Lm* over the shelf life of the product. Validation is described further in Section III.D.7 of this chapter.

2. If the establishment has chosen Alternative 2, IPP are to verify that:

    a. The establishment has applied either a PLT to reduce or eliminate *Lm* in the product or an AMAP to limit or suppress the growth of *Lm* in the product (9 CFR 430.4(b)(2)).

b. If the establishment has applied a PLT, it has included the PLT in its HACCP plan (Alt. 2a). If the establishment has applied an AMAP, it has included the AMAP in its HACCP plan or Sanitation SOP or other prerequisite program (9 CFR 430.4(b)(2)(i).

c. The establishment has validated the effectiveness of the PLT incorporated in its HACCP program in accordance with 9 CFR 417.4. The establishment has documented in its HACCP plan or Sanitation SOP or other prerequisite program that the AMAP is effective in limiting or suppressing the growth of *Lm* in the product in accordance with 9 CFR 430.4(b)(2)(ii).

d. If the establishment chooses Alternative 2 and applies an AMAP (Alt. 2b), IPP are to verify that the establishment:

    i. Tests food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or an indicator organism (e.g., *Listeria* spp.), in accordance with 9 CFR 430.4(b)(2)(iii)(A). A food contact surface is defined as any surface that comes in direct contact with post-lethality exposed RTE product.

NOTE: IPP are to be aware that the *Listeria* Guideline recommends that establishments identify all possible food contact surfaces for sampling. If the establishment does not identify all possible food contact surfaces for sampling, it should provide supporting documentation to show why product or food contact surfaces would not likely be contaminated. More information for evaluating establishment's sampling programs is provided in Chapter III.

    ii. Identifies the conditions under which the establishment will hold and test the product in response to a positive result for *Lm* or an indicator organism, in accordance with 9 CFR 430.4(b)(2)(iii)(B).

    iii. States the frequency with which testing will be done, in accordance with 9 CFR 430.4(b)(2)(iii)(C).

NOTE: IPP are to be aware that *Listeria* Guideline recommends minimum sampling frequencies and number of samples to collect, provided in Chapter III. The guidelines recommend that establishments use these frequencies or provide other support that the frequencies they have selected will be sufficient to control the safety of their products.

    iv. Identifies the size and location of the sites that will be sampled in accordance with 9 CFR 430.4(b)(2)(iii)(D).

    v. Includes an explanation of why the testing frequency is sufficient to ensure that effective control of *Lm* or an indicator organism is maintained, in accordance with 9 CFR 430.4(b)(2)(iii)(E).

3. If the establishment has chosen Alternative 3 (sanitation alone), IPP are to verify that the establishment:

    a. Provides for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or an indicator organism (e.g., *Listeria* spp.), in accordance with 9 CFR 430.4(b)(3)(i)(A). See note above for guidance on identifying all possible food contact surfaces.

    b. Identifies the conditions under which the establishment will hold and test the product in response to a positive test of a food contact surface, in accordance with 9 CFR 430.4(b)(3)(i)(B).

c. States the frequency with which testing will be done, in accordance with 9 CFR 430.4(b)(3)(i)(C).

d. Identifies the size and location of the sites that will be sampled, in accordance with 9 CFR 430.4(b)(3)(i)(D).

e. Includes an explanation of why the testing frequency is sufficient to ensure that effective control of *Lm* or an indicator organism is maintained, in accordance with 9 CFR 430.4(b)(3)(i)(E).

4. If the establishment has chosen Alternative 3 and produces deli or hot dog products, IPP are to verify that:

a. The establishment verifies that the corrective actions it takes in response to an initial positive result on a food contact surface are effective by conducting follow up testing of the specific site that tested positive, as well as the surrounding food contact surfaces as necessary to ensure the effectiveness of the corrective actions (9 CFR 430.4(b)(3)(ii)(A)).

b. If the establishment receives a second positive result on a food contact surface, it holds lots of product that may have been contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result (9 CFR 430.4(b)(3)(ii)(B)).

c. The establishment tests the lots of product that may have been contaminated using a sampling method and frequency that will provide statistical confidence that the product is not adulterated (9 CFR 430.4(b)(3)(ii)(C)).

NOTE: If a food contact surface tests positive for *Lm,* the product is adulterated. IPP are to be aware that establishments may not use product sampling as a means to release the product. Instructions for verifying the establishment's reprocessing or disposition of adulterated product are provided in Chapter VI.

5. Under the *Listeria* Rule (9 CFR 430.4(c)), establishments in Alternatives 1, 2, or 3:

a. May use verification testing for *Lm* or an indicator organism (e.g., *Listeria* spp.) to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.

b. May incorporate sanitation measures for controlling *Lm* and AMAPs or PLTs into their HACCP plan (required for PLTs) or in their Sanitation SOP or other prerequisite program. When the measures for addressing *Lm* are incorporated into the Sanitation SOP or other prerequisite program, establishments must have documentation that supports the decision in their hazard analysis that *Lm* is not a hazard that is reasonably likely to occur.

c. Must maintain sanitation in the post-lethality processing environment in accordance with 9 CFR Part 416.

d. Must validate and verify the measures in accordance with 9 CFR 417.4, when the *Lm* control measures are included in its HACCP plan.

e. Must evaluate the effectiveness of the measures in accordance with 9 CFR 416.14, when the *Lm* control measures are included in the Sanitation SOP.

f. Must include the program and the results produced by the program, which show that the program renders the hazard not reasonably likely to occur, in the documentation that it is required to maintain under 9 CFR 417.5. This requirement applies when the measures for addressing *Lm* are included in a prerequisite program other than the Sanitation SOP.

g. Must make verification results available upon request to FSIS personnel.

6. Under 9 CFR 430.4(d), establishments producing RTE post-lethality exposed products must provide FSIS with annual production volume and related information for the meat and poultry products they produce under the three alternatives.

NOTE: Starting in 2011, FSIS began collecting this information through the PHIS. FSIS no longer requires establishments to submit FSIS Form 10240.1, Production Information on Post-Lethality Exposed Ready-to-Eat Products, to provide this information.

7. Under 9 CFR 430.4(e), establishments that control *Lm* by using a PLT or an AMAP may declare this fact on the product label, provided they have a validated claim.

C. IPP Routine Inspection Tasks to Verify the Requirements of the *Listeria* Rule

IPP are to use a "systems" approach when reviewing the requirements of the regulations. IPP are to verify that the design and execution of the establishment's programs meet the requirements of the *Listeria* Rule when performing the routine inspection tasks according to the table below. FSIS has provided instructions for reviewing the establishment's corrective actions by performing the appropriate directed HACCP Task in Chapter III, Section I.D and Chapter V, Section III of this directive.

Routine Inspection Tasks

Inspection Task	General Description	RTE Establishment
Sanitation Performance Standards (SPS) Verification	Verify that the establishment maintains its facility in a manner to prevent insanitary conditions and to ensure that the product is not adulterated, in accordance with 9 CFR 416.1 through 416.5.	Verify that the establishment maintains its facility in a manner to prevent contamination of food contact surfaces or adulteration of RTE products with *Lm* and other pathogens.
Pre-Op Sanitation SOP Record Review and Review and Observation	Verify that the establishment has developed, implemented, and maintained the Sanitation SOP prior to operations, in accordance with 9 CFR 416.11 through 416.16.	Verify that the establishment has designed and executed its Sanitation SOP to prevent contamination of food contact surfaces or adulteration of RTE product with *Lm* and other pathogens prior to operations in the post-lethality environment.
Operational Sanitation SOP Record Review and Review and Observation	Verify that the establishment has developed, implemented, and maintained the Sanitation SOP during operations, in accordance with 9 CFR 416.11 through 416.16.	Verify that the establishment has designed and executed its Sanitation SOP to prevent contamination of food contact surfaces or adulteration of RTE products with *Lm* and other

		pathogens during operations in the post-lethality environment.
HACCP Verification	Verify that the establishment has met HACCP regulatory requirements, in accordance with 9 CFR 417.	Verify that the establishment has designed and executed its HACCP plan to control contamination of food contact surfaces or adulteration of RTE products with *Lm* and other pathogens.
Hazard Analysis Verification	Verify that an establishment meets the regulatory requirements related to the development and implementation of the hazard analysis, and that the establishment has addressed the relevant food safety hazards for all the establishment's processes, products, and intended uses in accordance with 9 CFR 417.2(a).	Verify that the establishment has designed and executed its hazard analysis, prerequisite programs, and Critical Control Points (CCPs) effectively to control contamination of food contact surfaces or adulteration of RTE products with *Lm* and other pathogens.
General Labeling	Verify that the establishment meets the regulatory requirements related to labeling the product and the product is not misbranded as described in 9 CFR 301.2.	Verify that the establishment has incorporated procedures into its food safety system and meets the requirements for accurately labeling RTE products.

II. VERIFYING THE ESTABLISHMENT'S COMPLIANCE WITH SPS AND SANITATION SOP REQUIREMENTS

A. General

1. IPP are to verify whether establishments have met the requirements for SPS and Sanitation SOPs by following the instructions in FSIS PHIS Directive 5000.1. Because *Lm* is an environmental contaminant, sanitary controls are extremely important to control the safety of post-lethality exposed RTE products. As stated in Section I.A of this chapter, the SPS and Sanitation SOP requirements work with the requirements of the *Listeria* Rule to control *Lm*. As previously stated, IPP are to use the instructions in this directive along with the instructions in PHIS Directive 5000.1 and the other cited directives.

2. The following sections provide questions that IPP are to ask when verifying SPS and Sanitation SOPs in establishments that produce post-lethality exposed RTE products, to ensure that they maintain sanitary controls necessary to meet the requirements of the *Listeria* Rule.

3. When IPP rotate into an assignment or are newly assigned to an establishment, they are to determine:

    a. Whether the establishment produces RTE product, and if so, if the product is post-lethality exposed.

    b. If the establishment produces RTE product routinely or on an intermittent basis. IPP are to update the establishment's profile, as described in FSIS PHIS Directive 5000.1

and FSIS PHIS Directive 5300.1, Managing the Establishment Profile in the PHIS, as appropriate. They are to hold an entrance meeting with the establishment.

c. Hold an entrance meeting with the establishment (at the first weekly meeting), and document the discussion in a Memorandum of Interview (MOI), as described in FSIS PHIS Directive 5000.1. During the entrance meeting IPP are to:

i. Review the establishment's *Lm* control procedures, in order to determine which *Lm* control alternative the establishment has adopted, and whether the establishment has incorporated its measures for controlling *Lm* into its HACCP program, Sanitation SOP, or other prerequisite program.

ii. Discuss the establishment's lotting procedures for the production of RTE product and determine the amount of notice the establishment needs to hold the product (as described in Chapter IV.B).

iii. Review the results from any recent samples collected by the establishment and the corrective actions the establishment took in response to those results.

4. During subsequent weekly meetings, as described in FSIS PHIS Directive 5000.1and FSIS Directive 5000.2, Review of Establishment Testing Data by Inspection Program Personnel, IPP are to discuss results from establishment sampling and any corrective actions the establishment took in response to positive results. IPP also are to discuss the results of any FSIS sampling that was recently performed and notify the establishment when they will be collecting samples. IPP are also to discuss instances when establishments change practices, as described in Chapter IV.B.

B. Sanitation Performance Standards (SPS)

1. When performing the SPS verification task in PHIS, according to Chapter II of FSIS PHIS Directive 5000.1, IPP are to determine whether the conditions they observe are likely to lead to creation of insanitary conditions or adulteration of RTE products.

2. When making this determination, IPP are to keep in mind that improper sanitation can lead to harborage in the establishment's environment and cross-contamination of food contact surfaces and product with *Lm*. IPP are to evaluate the establishment's sanitation programs to determine whether they are designed to control harborage and prevent product adulteration with *Lm*. Some examples of harborage sites are included in Attachment 3.

NOTE: Harborage occurs when *Lm* persists in the processing environment over time. Harborage may occur in areas that are infrequently cleaned, inadequately drained, or in poor repair. Cross-contamination occurs when *Lm* moves from one site (e.g., a non-food contact surface) to a food contact surface or product in the establishment.

3. As stated in FSIS PHIS Directive 5000.1, if IPP find that the that an establishment systematically fails to maintain sanitary conditions, and that contamination of food contact surfaces or product with *Lm* may occur as a result, they are cite 9 CFR 416.1, as well as the appropriate SPS citation (9 CFR 416.2 to 416.5).

EXAMPLE: The establishment has poor ventilation and cracks in the ceiling in the RTE production room, allowing condensation to form over RTE product. The condensation occurs each time it is raining outside, and the establishment's corrective actions have been insufficient to address it. IPP observe condensation dripping on exposed RTE product. IPP are to take regulatory control action of the product and issue an NR, citing 9 CFR 416.1 and 416.2(d).

SPS Task Table: IPP are to use this table when performing an SPS Task in an RTE establishment.

SPS Requirement	Questions	Regulatory Citation (9 CFR)
Construction	• Does the establishment clean and sanitize the walls, floors, and ceilings as necessary to prevent conditions that could lead to *Listeria* harborage in the establishment? • Do the establishment's structures, rooms, and compartments cause insanitary conditions or product adulteration because they are not of sound construction, maintained in good repair, or are too small to allow appropriate processing, handling, or storage of RTE product? • If RTE and raw products are produced or handled in the same rooms, is the size large enough to provide separation between the products? • Could RTE products come in contact with raw products in the establishment's processing rooms, hallways, or coolers? Do employee restrooms or other areas open into areas where RTE products are handled or held? • If employees are designated to work in RTE areas, is there enough space so that they do not pass through raw areas to work in RTE areas? • Are there holes in the walls, cracks in the floors, gaps in the ceiling, or other issues that could create harborage and result in cross-contamination of the product with *Lm*? **EXAMPLE**: *Lm* has been shown to form harborages in wet insulation behind walls. If there is a crack or hole in the wall, contamination could be transferred from this area to the product. • If the establishment performs construction in the RTE area, could dust, *Lm*, or other contaminates spread to the product? Are doors and air curtains designed so that they maintain the temperature of the room, are easily cleanable, and are in good repair so that they do not form harborage points for *Lm*?	416.2(b) **NOTE**: The same citation applies to all of the items in this category.
Ventilation	• If condensation occurs in an RTE processing area, does the establishment take action to ensure that exposed product and food contact surfaces are not contaminated? Are these actions effective in protecting the product? **EXAMPLE:** During the summer months,	416.2(d)

	condensation gathers in the ceiling of an RTE processing room. The establishment assigns an employee to mop the ceiling periodically. However, dripping occurs from the mop onto FCS. This would be an example of insanitary conditions. • If condensation does fall on RTE product or a FCS, does the establishment take corrective actions to address possible cross-contamination? These actions may include stopping production, removing affected product, taking actions to address condensation, re cleaning and sanitizing equipment, and assessing the safety of the product. • Does the establishment have controls in place (e.g., filters, positive or negative airflow) to ensure that air does not move from raw to RTE areas? • If fans are used to increase ventilation in RTE areas, are they cleaned and sanitized regularly to avoid build-up of dust and grime that can be spread through the air?	
Plumbing	• Are water, ice, and solutions (e.g., brine) used and reused according to Section 416.2(g)(2) and evaluated according to the instructions in FSIS PHIS Directive 5000.1? • Are drains maintained so that they do not back up and create pools of water on the floor or flooding that could lead to *Lm* contamination of processing areas? • Are pipes and other fixtures properly insulated so that condensation does not occur which could contaminate the product? Is there exposed insulation that could be a harborage point for *Lm*?	416.2(e)
Dressing rooms, Lavatories, and Toilets	• Do employees wear coats, gloves, or other equipment into lavatories or other areas of the establishment (e.g., cafeterias or break rooms)? • Are stations provided for employees to leave coats, gloves, or other items when leaving the RTE processing areas? • Are employees provided with instructions for washing hands after use of the lavatories and other areas of the establishment?	416.2(h)
Equipment and Utensils	• Do the equipment or utensils contain rusty welds, peeling paint, gaps, grooves, or hard to clean areas that could lead to *Lm* contamination?	416.3

	• Is different equipment or utensils used for RTE product and for raw product? If this is not possible, are equipment and utensils cleaned and sanitized before being used for RTE production? • If equipment or utensils are cleaned or stored in another area of the establishment (e.g., washroom), is the room or storage area cleaned and sanitized as necessary to avoid contamination? Are items stored so they are not touching the floor (e.g., on a pallet) and away from the walls? • If maintenance personnel work on an RTE piece of equipment, do they clean and sanitize their tools? Does the establishment clean and sanitize the equipment after repairing it and before using it?	
Sanitary Operations	• Are items stored in or near RTE areas (e.g., wooden pallets) that could contaminate RTE products? • Are pallet jacks, carts, or other items used to transport RTE equipment cleaned and sanitized at a sufficient frequency to keep RTE product from becoming contaminated? • Is exposed RTE product transported through the establishment in such a way that it may become contaminated (e.g., comes in contact with doors, walls, or floors) during transportation? • Are product-packaging materials stored so that they will not be contaminated during sanitation and production? • Are packaged RTE products protected from contamination during packing, storage, loading, unloading, and transportation? **NOTE***: Lm* contamination on the outside of a package could spread to retail and other environments, and the product could become contaminated when the package is opened. • Are designated traffic patterns in place so that employees working in the raw areas do not travel through RTE areas and vice versa?	416.4
Employee Hygiene	• Are employees required to wear gloves, hairnets, coats, and cleanable footwear to help protect the safety of the product? • Does the establishment have procedures in place for washing and sanitizing hands and boots when entering an RTE area?	416.5

	• Are employees designated for RTE areas? If so, do they have separate aprons, frocks, or other outer clothing specific to the RTE area? If not, do they change these items and follow other sanitary protocols before working in RTE areas?	

C. Sanitation SOPs

1. When performing the Pre-Op Sanitation Records Review and Pre-Op Sanitation Review and Observation tasks, IPP are to determine whether the establishment has taken steps to control *Listeria* contamination during sanitation, according to the following table.

Sanitation SOP Task Table: IPP are to use this table when performing a Pre-OP or Operational Sanitation Task in an RTE establishment.

Task	Questions	Regulatory Citation (9 CFR)
Pre-OP Sanitation Records Review and Review and Observation	Does the establishment have procedures in place and implement its procedures to:	
	• Clean equipment and utensils at a frequency sufficient to avoid *Lm* contamination and build-up of product residue that could render the product unwholesome?	416.12(c), (d), 416.13, 430.4(b), (c)(3)
	• Scrub hard-to-clean areas to avoid the formation of biofilms? **NOTE**: A biofilm is a bacterial film formed by *Lm* that protects the organism. Biofilms may occur on surfaces that are cleaned infrequently or inadequately and may make sanitizers less effective.	416.12(c), 416.13, 430.4(b), (c)(3)
	• Disassemble complex pieces of equipment (when possible) to access hard-to-reach areas for cleaning?	416.12(c), 416.13 430.4(b), (c)(3)
	• Clean walls, floors, drains, ceilings, coolers, freezers, and other areas where RTE product is stored or held at a sufficient frequency to avoid contamination of food contact surfaces and product?	416.12(c), 416.13, 430.4(b), (c)(3)
	• Clean and sanitize indirect food contact surfaces (e.g., areas that are not food contact surfaces but may be touched by employees that handle product), such as equipment, control panels, conveyor guardrails, and scales at a frequency sufficient to avoid contamination of food contact surfaces and product?	416.12(c), (d), 416.13, 430.4(b), (c)(3)
	• Clean and sanitize cleaning aids such as cloths, squeegees, and mops used to remove condensation? Does the establishment monitor the sanitizer level in footbaths regularly (if applicable)?	416.12(c), 416.13, 430.4(b), (c)(3) 416.12(c), 416.13,

	• Rotate sanitizers to ensure that *Lm* does not develop resistance to the sanitizer? Does it have a system in place to sanitize floors (e.g., floor foamer) and other non-food contact surfaces?	430.4(b), (c)(3)
Operational Sanitation Records Review and Review and Observation	Does the establishment have procedures in place and implement its procedures to:	
	• Ensure that harborage of *Lm* in the environment and cross-contamination to food contact surfaces and product does not occur? (For examples of possible harborage sites, see Attachment 3). **EXAMPLE:** Controls are in place so that product does not touch floors, walls, plastic flaps, or other areas; utensils, packaging material, and other items are stored away from walls or floors, and raw product is separated from RTE product so that cross-contamination does not occur.	416.12(a), 416.13, 430.4(b), (c)(3)
	• Ensure that employees working in RTE areas do not contaminate the product? **EXAMPLE**: Employees are trained to wash their hands after coughing or sneezing, tying their shoes, or picking items up off the floor.	416.12(a), 416.13, 430.4(b), (c)(3)
	• Prevent contamination of the product if the establishment performs a mid-shift clean up? **EXAMPLE:** The establishment removes all exposed product from the room during cleaning, avoids the use of high-pressure hoses near food contact surfaces and product, and uses separate cleaning equipment (e.g., brushes or scrub pads) on food contact surfaces and non-food contact surfaces.	416.12(a), 416.13, 430.4(b), (c)(3)
	• Control sanitation during construction so that product does not become contaminated? Does it increase its verification sampling in response to construction or other conditions that could increase risk in the establishment?	416.12(a), 416.13, 416 .14, 430.4(b), (c)(3)
	• If the establishment temporarily changes its sanitation practices when FSIS collects samples, IPP are to determine whether the establishment revised its Sanitation SOP to reflect these changes (see Chapter IV, Section I.B.6).	416.14

2. If the establishment has incorporated its *Lm* control procedures into its Sanitation SOP, IPP are to verify:

    a. The design of the program to ensure that it meets the requirements of the *Listeria* Rule (Section I of this chapter and Chapter III). As part of this verification, IPP are to review the establishment's scientific support for its PLTs or AMAPs to ensure that it meets the

requirements of the *Listeria* Rule and provides sufficient support for the decisions made in its hazard analysis. If the establishment's scientific support is inadequate, IPP are to issue a Noncompliance Record (NR), as described in Section III.B of this chapter.

b. The execution of the program to ensure that the establishment is following its sampling program as written, following the directions in Chapter III of this directive. As part of this verification, IPP are to observe an establishment employee collecting a sample and are to verify that the establishment is collecting samples according to the specified frequency and number of samples in the written plan. If the establishment is not following its program, IPP are to document noncompliance with 9 CFR 416.13(b), and 9 CFR 430.4(b)(2)(iii)(C) or 430.4(b)(3)(i)(C).

c. That the establishment has adequate support for the relevant decisions in its hazard analysis. During this verification activity, if IPP find that the establishment is not collecting samples at the frequency it has identified or find other deficiencies with the sampling program, they are to verify the establishment's support. Failure to support hazard analysis decisions is cause for IPP to document noncompliance with 9 CFR 417.5(a)(1) and may result in additional enforcement action (see FSIS PHIS Directive 5000.1).

NOTE: If the establishment's *Lm* control program is included in its HACCP plan or prerequisite program, IPP will review it as part of a HACCP Verification Task, as described in Section III below.

3. Each time IPP issue a NR in an RTE establishment, they are to review the establishment's history and consider whether there is a pattern of sanitation issues that could lead to contamination of the products. These sanitation issues could include repeated Sanitation SOP NRs and ongoing SPS NRs that could lead to *Lm* harborage (e.g., ceiling leaks, holes in the wall, rusty equipment). Repeated *Listeria* spp. positive results can also an indicator of sanitation issues. IPP are to consider whether the establishment's actions were effective in addressing these repetitive issues.

4. If IPP have concerns that there may be systemic problems with the establishment's food safety system or there is reason to believe that product may have become adulterated, they are to bring the issues to the attention of the District Office (DO) through their supervisory chain. The DO is to determine whether a recall is warranted, or whether other actions, such as an Intensified Verification Testing (IVT) with a "for cause" food safety assessment (FSA), should be performed at the establishment, according to FSIS Directive 10,300.1, IVT Protocol for Sampling of Product, Food Contact Surfaces and Environmental Surfaces for *Lm*.

III. VERIFYING AN ESTABLISHMENT'S COMPLIANCE WITH HACCP REQUIREMENTS

A. General

1. IPP are to verify RTE establishments meet HACCP regulatory requirements by performing the HACCP Verification Task as instructed in FSIS PHIS Directive 5000.1, and a Hazard Analysis Verification (HAV) Task, when implemented, as described in FSIS Directive 5000.6. .

NOTE: FSIS plans to implement the HAV procedure for all establishments at a later date. IPP are not to perform a HAV Task until they receive an instruction to do so through PHIS.

2. As stated in Section I.A of this chapter, the requirements of the *Listeria* Rule work together with the requirements of the HACCP regulation. When verifying the establishment's food safety system, IPP are to keep in mind that noncompliance in one part of the system (e.g., HACCP) can affect compliance in other parts of the system (e.g., *Listeria* control). In some

cases, it may be appropriate to cite both the HACCP regulation and the *Listeria* Rule (see table below).

B. HACCP Verification Task

1. As stated in FSIS PHIS Directive 5000.1, each HACCP Verification Task has two components, a recordkeeping component and a review and observation component.

    a. When performing the recordkeeping component of the HACCP Verification Task, IPP are to review the establishment's records associated with its *Lm* control program if the *Lm* control program is incorporated into the establishment's HACCP plan or prerequisite program. IPP also are to review the establishment's support for its PLTs and AMAPs to ensure that it meets the requirements of the *Listeria* Rule (as described in Section I of this chapter).

NOTE: If the establishment's *Lm* control program is incorporated into its Sanitation SOP, it will be reviewed under a Sanitation Task, as described in Section II above.

    b. When performing the observation component of the HACCP Verification Task, IPP are to verify that the establishment is collecting the samples at the frequency it has identified in its *Lm* Control Program and is using proper sampling techniques (see Chapter III).

2. Performing the HACCP Verification Task

When performing the HACCP Verification Task in an RTE establishment, IPP are to follow the instructions in FSIS PHIS Directive 5000.1, according to the table below.

HACCP Verification Task Table: IPP are to use this table when performing a HACCP Verification Task in an RTE establishment.

Step	Description	RTE Verification	Regulatory Citation (9 CFR)
Step 1	Select the product type and specific production.	• First, IPP are to select the highest risk post-lethality exposed RTE products, using the risk levels in Attachment 2. • Next, IPP are to review the list of products, to ensure all product types are selected over time.	None
Step 2	Review and become familiar familiarize the hazard analysis and HACCP plan for the specific product type.	• IPP are to review the hazard analysis and HACCP plan for RTE products to determine whether the establishment has properly classified the product as RTE and post-lethality exposed (if applicable). See Chapter I for more information. • In establishments that produce post-lethality exposed RTE products, IPP are to review the hazard analysis to determine whether the establishment has	417.2(a)(1), 430.4(a) 417.2(a)(1), 430.4(a)

		addressed possible hazards from *Lm*. • If the establishment has determined that *Lm* is reasonably likely to occur in the product, IPP are to review the establishment's CCPs to determine whether it has implemented at least one CCP designed to control *Lm*. • If IPP determine that the establishment has not considered possible hazards from *Lm*, or is not controlling it through its HACCP plan or preventing it through its Sanitation SOP or prerequisite program, they are to contact the DO.	417.2(c)(2), 430.4(b)(1)(i) 417.2(a)(1), 430.4(a)
Step 3	Verify the monitoring requirements.	• IPP are to review the establishment's HACCP plan design to ensure that it includes the monitoring procedures and frequencies that it uses to monitor the CCPs. • If the establishment has included its *Lm* control procedures as a CCP (e.g., PLT) IPP are to verify that the establishment has included a written monitoring procedure in its HACCP plan and implements the procedure as written.	417.2(c)(4) 430.4(b)(1)(i)
Step 4	Verify the verification requirements.	• If the establishment has included its *Lm* control procedures in its HACCP plan, IPP are to: --Determine whether the establishment's sampling and testing procedures meet the requirements of the *Listeria* Rule (See Chapter III). --Observe the establishment employee collecting the sample.	417.4(2) 430.4(b)(2)(iii)(A), (b)(3)(i)(A), (b)(3)(ii)(A)
Step 5	Verify the recordkeeping requirements.	• IPP are to review sampling records to determine whether the establishment collected the number of samples at the frequency documented in its program.	417.5(a)(2) 430.4(c)(6)
Step 6	Verify the implementation of prerequisite programs.	• If the establishment has incorporated its *Listeria* program in a prerequisite program, IPP are to	417.5(a)(1) 430.4(b)(2)(iii)(A), (b)(3)(i)(A),

		review the program to verify that: --It meets the requirements of the *Listeria* Rule and is implemented correctly, --The program supports the hazard analysis decisions.	(b)(3)(ii)(A
Step 7	Verify the corrective action requirements.	• IPP are to verify that the establishment has included corrective actions as part of its HACCP plan. IPP are to verify the implementation of the corrective actions as part of a directed HACCP Verification Task (See Chapter V).	417.3 430.4(b)(2)(iii)(B), 430.4(b)(3)(i)(B), 430.4(b)(3)(ii)(A-C)
Step 8	Verify the pre-shipment review requirements.	• IPP are to determine whether the establishment applied its HACCP controls (e.g., PLT) to the products and reviewed the records for the PLT or other controls prior to shipping the product into commerce.	417.5(c)
Step 9	Consider the implications of any noncompliance.	• IPP are to document noncompliance as instructed in Chapter V of FSIS PHIS Directive 5000.1	See Directive 5000.1

C. Hazard Analysis Verification (HAV)

Upon implementation of FSIS Directive 5000.6, when performing a HAV Task in an RTE establishment, IPP are to follow the steps in the table below to evaluate the design of the establishment's hazard analysis and HACCP plan.

Hazard Analysis Verification (HAV) Table: IPP are to use this table when performing a HAV Task in an RTE establishment (further information describing each step is below this table).

Step	Description	RTE Verification Questions	Regulatory Citation (9 CFR)
Step 1	Review flowchart and compare to production process.	• Has the establishment considered all possible hazards from ingredients (e.g., pepper) added after the lethality treatment (e.g., cooking)?	417.2(a)(1)
Step 2	Review the hazard analysis and consider guidance in the FSIS Meat and Poultry Hazards and Controls Guide.	• Does the flowchart or hazard analysis identify the intended use of the product as RTE? • If the establishment produces post-lethality exposed RTE product, has it considered whether *Lm* is a hazard in its	417.2(a)(1), (a)(2) 430.4(a)

		product? • If the establishment has incorporated its *Lm* control procedures into its HACCP plan, has it included them in its hazard analysis or flow chart? • If the establishment temporarily changes its food safety systems when FSIS collects samples, IPP are to determine whether the establishment considered the changes in its hazard analysis and supported the changes (see Chapter IV, Section I.B.6).	417.2(a)(1) 417.2(a)(1), 417.5(a)(1)
Step 3	For each hazard that the establishment considers reasonably likely to occur, verify that the HACCP plan includes one or more CCPs to control it. *If no hazards are reasonably likely to occur, skip to step 4.*	• If the establishment considers *Lm* a hazard reasonably likely to occur, has the establishment included one or more CCPs (e.g., PLT) to control the hazard either at that step or a later step? • Are the CCPs that the establishment has identified sufficient to control the hazards that could be introduced before, during, and after entry into the establishment?	417,2(c)(2), 430.4(b)(1)(i) 417.2(c)(2)
Step 4	For each hazard, the establishment considers not reasonably likely to occur, determine what evidence the establishment uses to support the decision.	• If the establishment determines that *Lm* is not a hazard reasonably likely to occur in its product, does it prevent *Lm* through a prerequisite program or its Sanitation SOP? **NOTE**: If the establishment prevents *Lm* through a Sanitation SOP, the establishment's program will be verified through the Sanitation SOP verification task. • Does the establishment's supporting documentation for its PLTs and AMAPs meet the requirements of the *Listeria* Rule (as stated in Section I of this chapter)?	417.5(a)(1), 430.4((a) 430.4(b)(1)(i), (b)(2)(ii)

Step 5	Review prerequisite programs and other supporting programs, including written programs, records, and employee activities.	• Does the establishment use sampling as a prerequisite program? • Do the records and your observations indicate the sampling is consistently being implemented as written? • Do the records and your observations indicate that the sampling prevents *Lm* contamination on an ongoing basis?	417.5(a)(1) 430.4(b)(2)(iii)(A-E), (b)(3)(i)(A-E), (b)(3)(ii)(A-C) 430.4(a)
Step 6	Review other supporting documentation.	• Does the establishment have the sampling program and its results referenced in the hazard analysis?	417.5(a)(1), 430.4(c)(6)
Step 7	Review establishment validation documents, including scientific supporting documents and validation data. Verify implementation of the pre-requisite program is as described in the written program.	• Does the establishment have validation data demonstrating that its PLT is effective in reducing or eliminating *Lm*? • Does the validation data show that the establishment's CCPs and prerequisite programs can effectively control or prevent *Lm*?	417.4(a)(1), 430.4(c)(4) 417.4(a)(2), 430.4(a)
Step 8	Verify reassessment requirements. Check the most recent signature and date for each HACCP plan.	• Has the establishment reassessed its HACCP plan (if necessary) and documented the reassessment, in response to a positive *Lm* or *Listeria* spp. change in the process or other testing result?	417.4(a)(3), 430.4(c)(4)

D. Further Description of the HAV Steps

1. **Step 1**: When reviewing the establishment's flowchart, IPP are to determine whether the establishment adds ingredients to RTE products after the lethality step (e.g., spices). If ingredients are added, IPP are to verify that the establishment included the ingredients in its flow chart and considered all possible hazards from the addition of the ingredients in its hazard analysis. In addition, if an establishment applies a PLT, IPP are to verify that the establishment has included the PLT as a CCP in its HACCP plan.

2. **Step 2**: As part of reviewing the establishment's hazard analysis, IPP are to verify that the establishment has considered the possible hazards from *Lm,* and that the flow-chart or hazard analysis identifies the intended use of the product as RTE. RTE products are required to be safe for consumers without any additional preparation steps (e.g., cooking).

3. **Step 3**: If the establishment determines that *Lm* is a hazard reasonably likely to occur in its product, IPP are to verify that the establishment has included one or more CCPs to control the hazard in its HACCP plan (e.g., PLT).

4. **Step 4**: If the establishment determines that *Lm* is not a hazard reasonably likely to occur in its product because of a prerequisite program, IPP are to verify that the establishment includes the program and the results of the program in the documentation that it is required to maintain under 9 CFR 417.5, in accordance with 9 CFR 430.4(c)(6). IPP are to verify the effectiveness of the documentation in steps 5 and 7 below.

5. **Step 5**: If the establishment uses a testing program as a prerequisite program, IPP are to evaluate the program as described in Chapter III. If IPP find that the establishment is not collecting samples at the frequency it has identified or find other deficiencies with the sampling program, they are to determine whether the establishment has adequate support for the relevant decisions in its hazard analysis. Failure to support hazard analysis decisions is cause for IPP to document noncompliance with 9 CFR 417.5(a)(1) and may be grounds for additional enforcement action (see FSIS PHIS Directive 5000.1).

6. **Step 6:** When reviewing the establishment's other supporting documentation (e.g., for product sampling or non-food contact surface sampling programs), IPP are to determine whether the establishment has the sampling program and its results referenced in the hazard analysis. IPP are also to determine whether the establishment is implementing the program in a manner that supports the hazard analysis decisions.

7. **Step 7**: When verifying an establishment's validation for its PLT, IPP are to determine whether the establishment can support that its process is effective in reducing or eliminating *Lm*, in accordance with 9 CFR 430.4(b)(1)(i) and (b)(2)(ii). FSIS expects that the validation will show that the PLT achieves at least a 1-log reduction of *Lm* before the product leaves the establishment.

    a. As stated in FSIS Directive 5000.6, Attachment 6, validation is composed of two parts:

        i. The scientific or technical support for the HACCP system (design). This consists of having scientific and technical documentation that demonstrates that the designed process can control the identified hazard. In other words, will the HACCP plan work in theory?

        ii. The initial practical in-plant demonstration proving that the HACCP system can perform as expected (execution). The demonstration consists of having records that show that the HACCP plan achieves what it is expected to achieve. In other words, does the plan work in practice?

    b. During the HAV procedure, IPP are to review both the documents that provide the scientific support and the documents associated with the initial in-plant demonstration. IPP are to verify that the establishment maintains both types of validation documents. If IPP find that the establishment does not comply with the regulatory requirements, they are to take enforcement actions as described in Chapter V of FSIS PHIS Directive 5000.1.

8. **Step 8**: When verifying the reassessment requirements in an RTE establishment, IPP are to determine whether the establishment has reassessed its HACCP plan in response to positive results for *Lm* or *Listeria* spp. in product or on food contact surfaces as described in Chapter III.

IV. VERIFYING AN ESTABLISHMENT'S LABELING OF RTE PRODUCTS

A. When performing a General Labeling Verification task according to FSIS Directive 7000.1, Verification of Non-Food Safety Consumer Protection Regulatory Requirements, IPP are to verify the establishment's labeling of RTE products.

B. If the establishment controls *Lm* by using a PLT or an AMAP and declares this fact on the product label, then IPP are to verify that the establishment's supporting documentation is sufficient to support this claim. If the establishment does not have adequate data to support its claim, IPP are to issue an NR (cite 430.4(e) and 417.5(a)(1)).

C. In addition, if the establishment labels the product as RTE (e.g., does not include safe handling instructions, see Resource 1), IPP are to review the establishment's supporting documentation. IPP are to determine whether the establishment's supporting documentation demonstrates that it has met the requirements in 9 CFR 318.17, 318.23, or 381.150 or undergone other processing to render it RTE, in accordance with 9 CFR 317.2(l) and 381.125(b). If IPP have questions about the establishment's supporting documentation, they are to submit them to askFSIS, following the instructions in Chapter VIII of this directive.

NOTE: Establishments may use alternative means of achieving lethality, as long as they can support the effectiveness of their process. See the FSIS *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products for more information.

D. If the establishment does not have documents supporting the effectiveness of its process to achieve a full lethality of *Salmonella*, IPP are to perform a directed HACCP Verification Task according to FSIS PHIS Directive 5000.1. If IPP find that the establishment is unable to support that its system addresses possible hazards from *Salmonella* and other pathogens of public health concern, IPP are to issue an NR (citing 9 CFR 301.2, 417.5(a)(1), and 417.2(a)(1)). IPP also are to contact the DO through their supervisors to determine if further actions, including an FSA, are warranted in the establishment.

CHAPTER III – VERIFICATION OF THE ESTABLISHMENT'S SAMPLING AND TESTING PROGRAMS

I. VERIFYING AN ESTABLISHMENT'S SAMPLING AND TESTING PROGRAMS ARE ADEQUATE

A. General

1. As described in Chapter II, establishments may sample for *Lm* or an indicator organism (e.g., *Listeria* spp.) to verify the effectiveness of their sanitation programs. In addition, establishments in Alternative 2b and 3 are required to sample in the post-lethality exposed processing environment to ensure that surfaces are sanitary and free of *Lm* or an indicator organism.

2. When performing inspection tasks as described in Chapter II, IPP are to verify the adequacy of the design and execution of the establishment's sampling and testing programs as described below.

3. As stated previously, FSIS has included information for the FSIS *Listeria* Guideline in this section to assist IPP in understanding FSIS's recommendations to help establishments meet the requirements of the *Listeria* Rule. The guidance represents best practice recommendations by FSIS, based on the best scientific and practical considerations, and does not represent requirements that establishments must meet. If establishments meet the recommendations in the guidance, they do not need to provide further support for their process.

B. Verifying the Design of the Establishment's Sampling and Testing Program

When verifying that the design of the establishment's sampling and testing program are adequate, IPP are to take into account the following.

1. Has the establishment identified all possible food contact sites as part of its sampling program? If the establishment has not identified all possible food contact surfaces for sampling, can it provide supporting documentation to show why product or food contact surfaces would not be contaminated? If the establishment has not identified all possible food contact sites and can't support that the other sites would not be contaminated, then the establishment would not be in compliance with 9 CFR 430.4(b)(2)(iii)(A) or (b)(3)(i)(A).

NOTE: Although the establishment is required to identify all possible food contact sites, it is not required to sample them at the same frequency. The establishment may sample the sites based on risk. In addition, the establishment is not required to perform further confirmatory testing on *Listeria* spp. positives to determine whether they are positive for *Lm*.

2. Has the establishment identified the sample size for the food contact surface samples it will collect? If the establishment has not identified the sample size or cannot support why the sample size it has selected is representative of the equipment or other food contact sites, then the establishment would not be in compliance with 9 CFR 430.4(b)(2)(iii)(D) and (b)(3)(i)(D).

NOTE: IPP are to be aware that the *Listeria* Guideline recommends that establishments sample a 12" x 12" area, when possible. The guideline also states that if the surface area is smaller than 12" x 12", then the entire surface should be sampled. If the establishment does not use the recommended sampling size and cannot support the sampling size it has selected, then its procedure may not be sufficient to detect low levels of *Lm*, if present.

3. Has the establishment identified the sampling frequency and the number of samples it will routinely collect? If so, has the establishment included a justification of why the sampling frequency is sufficient to ensure that it has maintained effective control of *Lm* or *Listeria* spp.? If the establishment has not identified a sampling frequency and number of samples, or cannot justify why the sampling frequency is sufficient, it would not be in compliance with 9 CFR 430.4(b)(2)(iii)(C) and (E), or (b)(3)(i)(C) and (E), and IPP are to issue an NR.

NOTE: IPP are to be aware that the *Listeria* Guideline recommends that establishments collect samples by processing line (see the table below). A line refers to the flow of a product during production. This includes all of the equipment, personnel, and utensils that contact a specific RTE product. Multiple individual product lines can share a piece of equipment (e.g., packaging machine), but they are still considered to be different lines.

This table below provides the recommended minimum sampling frequencies and numbers of samples to collect. FSIS recommends that establishments use this table when designing their *Listeria* Control Program. If the establishment uses the minimum sampling frequencies and number of samples indicated in the table, it would not need to provide further support for its sampling frequency.

Minimum Routine Sampling Frequencies for Testing of Food Contact Surfaces for Alternatives 1, 2, and 3

Alternative	Daily Production Volume Ranges (lb)**	Food Contact Surface Testing
		Minimum Frequency*
Alternative 1		2 times/year/line (every 6 months)
Alternative 2a and 2b		4 times/year/line (quarterly)

Alternative	Daily Production Volume Ranges (lb)**	Food Contact Surface Testing
		Minimum Frequency*
Alternative 3 Non-deli, non-hot dogs		1 time/month/line (monthly)
Alternative 3 Deli, hot dogs HACCP Size:		
Very small	1-6,000	1 time/month/line (monthly)
Small	6,001 – 50,000	2 times/month/line (every 2 weeks)
Large	50,001->600,000	4 times/month/line (weekly)

*At least **3-5 samples** per production line should be collected each time (every 6 months, quarterly, monthly, biweekly, or weekly).
**Establishments producing deli or hot dogs under Alt 3 may decide to collect samples based on HACCP size or production volume.

NOTE: IPP are to be aware that establishments that produce post-lethality exposed RTE products intermittently (e.g., 2-3 day a week) may be able to support sampling at a lower frequency (e.g., quarterly rather than monthly).

4. If the establishment is in Alternative 2b or 3 (non-deli or hot dog producer), has it identified conditions under which it will hold and test the product following a positive test of a food contact surface for *Listeria* spp.? If the establishment has not identified when it will hold and test the product, it would not be in compliance with 9 CFR 430.4(b)(2)(iii)(B) or (b)(3)(B).

NOTE: IPP are to be aware that the *Listeria* Guideline recommends that establishments in Alternative 2b and 3 hold and test the product after the 3rd consecutive positive food contact surface sample. If the establishment chooses to hold and test the product after a greater number of positive results, it should support why the frequency is sufficient to ensure the safety of the product.

5. If the establishment is in Alternative 3 (deli or hot dog producer), has it included the following as part of its sampling program design?

    a. Follow-up sampling to include a targeted sample of the specific food contact surface that tested positive, as well as additional food contact surface samples in the surrounding area as necessary to ensure the effectiveness of the establishment's corrective actions. If the establishment has not included follow-up sampling as part of its program, it would not be in compliance with 9 CFR 430.4(b)(3)(ii)(A), and IPP are to issue an NR.

    b. Holding the product that may have been contaminated until the establishment corrects the problem if a second positive result was obtained during the follow-up sampling. If the establishment has not included provisions for holding the product as part of its sampling program, it would not be in compliance with 9 CFR 430.4(b)(3)(ii)(B).

    c. Testing the held product for *Lm* or *Listeria* spp. using a sampling method and frequency that provides a level of statistical confidence that each lot is not adulterated. If the establishment has not included testing the held product as part of its sampling program, it would not be in compliance with 9 CFR 430.4(b)(3)(ii)(C).

NOTE: IPP are to be aware that the *Listeria* Guideline recommends that establishment test for *Lm* using a sampling plan recommended by the International Commission on Microbiological Specifications for Foods (ICMSF).

C. Verifying the Execution of the Establishment's Sampling and Testing Program

When verifying the execution of the establishment's sampling and testing program is adequate and follows the written program, IPP are to take into account the following.

1. Is the establishment following its sampling program, including meeting the sampling frequency and collecting the number of food contact surface samples that it has identified in its sampling program? If the establishment has stated that it will collect a certain number of samples at a particular frequency (e.g., monthly), and it did not collect the samples, can it support why its sampling frequency is sufficient to ensure that control of *Lm* or an indicator organism is maintained? If the establishment did not collect the stated number of samples or follow the frequency it identified, and cannot support why it's number of samples or frequency is sufficient, then it would not be in compliance with 9 CFR 430.4(b)(2)(iii)(C) and (E), or (b)(3)(i)(C) and (E).

NOTE: Establishments are not required to collect samples in weeks or months when they are not producing post-lethality exposed RTE product. .

2. Does the establishment increase its sampling frequency or collect additional samples in response to increased positives from routine sampling or other events that could increase the probability of product positives (e.g., construction, roof leaks, condensation, or equipment breakdowns)? If the establishment did not increase its sampling frequency or collect additional samples, and it cannot support its sampling frequency because of the change in risk, it would not be in compliance with 9 CFR 430.4(b)(2)(iii)(E) or (b)(3)(i)(E).

NOTE: IPP are to be aware that the sampling frequency recommendations in Section I.B above are minimum sampling frequencies. FSIS recommends that establishments increase the sampling frequencies or add intensified samples if there is a increase in risk (e.g., construction).

3. Is the establishment collecting food contact surface samples that are representative of the routine processing conditions at the establishment (e.g., during the production of FSIS regulated post-lethality exposed RTE meat and poultry products)? If the establishment is not collecting food contact surface samples that are representative of the routine processing conditions at the establishment, it may miss finding harborage or other areas of cross-contamination. Unless the establishment can provide other support that the samples it collects represent routine processing conditions, it would not be able to demonstrate that its food contact surfaces are sanitary and free of *Lm* and would not be in compliance with 9 CFR 430.4(b)(2)(iii)(A) or (b)(3)(i)(A).

NOTE: IPP are to be aware that the *Listeria* Guideline recommends that establishments collect samples 3 hours after operations have started, if possible, to allow *Lm* to work its way out of the equipment. If the establishment typically produces RTE product for less than 3 hours, then it can collect samples less than 3 hours into operations.

4. Are the establishment's sampling or testing methods sufficient to detect low levels of *Listeria* in the environment? When evaluating the establishment's sampling and testing methods, IPP are to consider the following:

NOTE: If IPP find that the establishment is not meeting the criteria below, it does not automatically mean there is a noncompliance. IPP are to consider all available information at the establishment to

determine whether their findings regarding the establishment's sampling and testing programs could lead to noncompliance.

a. Is the establishment following the manufacturer's instructions when collecting the samples? If not, the sampling method may be not be sensitive enough (see the note below) to detect low levels of *Listeria*, and the establishment may be unable to support its decision that *Listeria* is not a hazard reasonably likely to occur.

NOTE: IPP are to be aware that the *Listeria* Guideline does not recommend the use of cotton-tipped swabs for sampling large areas (12" x 12") because they may become easily saturated with microorganisms. If these devices are used, FSIS recommends collecting several smaller sized samples according to the manufacturer's instructions to equal a 12" x 12" area. In addition, FSIS recommends that establishments use neutralizing buffer to hydrate the swabs to counteract the effect of any sanitizers that may be present in the sample.

b. Does the establishment store the samples under refrigeration temperatures before analysis and ship the samples refrigerated to the laboratory (if applicable)? If not, overgrowth of competing microorganisms could occur that could mask the presence of *Listeria* spp., and the establishment may not be able to determine if its surfaces are free of *Lm*.

NOTE: IPP are to be aware that FSIS recommends shipping the samples in insulated shipping containers under refrigeration conditions and initiating laboratory testing within 2-3 days after sample collection.

c. Is the establishment using a validated testing method to detect low levels of *Lm* or an indicator organism in the environment? If not, can the establishment support that its food contact surfaces are sanitary and free of *Lm* or an indicator organism? If the establishment is not using a validated testing method that is fit for this purpose, it may not be able to support that its surfaces are sanitary and free of *Lm*.

NOTE: IPP are to be aware that the *Listeria* Guideline recommends that establishments use a testing method that is used by USDA/FSIS or by another regulatory body (e.g., the Food and Drug Administration (FDA)) or has been validated by a recognized independent body (e.g., the Association of Analytical Communities (AOAC)). The guideline also recommends that the testing method include an enrichment step, and the entire sponge or sampling device is analyzed. Another recommendation is that establishments keep a copy of the testing methodology on file and know whether it meets these testing criteria, even if the analysis is performed off-site.

D. Verifying the Establishment's Corrective Actions in Response to Positive Results from Establishment Sampling

1. If the establishment finds a food contact surface positive for *Listeria* spp., and product passed over the surface, IPP are to verify that the establishment takes the appropriate corrective actions by performing a directed HACCP Verification or Operational Sanitation SOP Review and Observation Task. When performing the directed task, IPP are to take into account the following:

    a. For establishments in Alternative 3 (deli or hot dog producers), did the establishment verify the effectiveness of its corrective actions by:

        i. Collecting follow-up samples according to 9 CFR 430.4(3)(ii)(A)?

ii. If a second positive result was obtained during the follow-up sampling, holding the product that may have been contaminated until the establishment corrects the problem according to 9 CFR 430.4(b)(3)(ii)(B)?

iii. Testing the held product for *Lm* or *Listeria* spp. using a sampling method and frequency that provides a level of statistical confidence that each lot is not adulterated according to 9 CFR 430.4(b)(3)(ii)(C)?

b. For establishments in Alternatives 1, 2, and 3 (non-deli or hot dog producers), did the establishment take corrective actions to address the *Listeria* spp. positive result in accordance 9 CFR 417.3 or 416.15? When evaluating the corrective actions taken by the establishment, IPP are to consider the following:

i. Did the establishment perform intensified sanitation procedures in response to positive results?

NOTE: IPP are to be aware that the *Listeria* Guideline defines intensified sanitation as sanitation measures that are performed in addition to normal sanitation procedures and are escalated in response to continuing findings of positives. Intensified sanitation may include increasing the frequency of cleaning and sanitizing for certain pieces of equipment; breaking down the equipment into its parts for further cleaning; repairing or replacing broken equipment; and construction, if needed.

ii. Did the establishment collect additional samples or increase its sampling frequency?

iii. Did the establishment review its sanitation program to identify any sanitation deficiencies that could have led to the positive results? If the establishment found any deficiencies, did it revise its procedures or perform other actions to correct the issue?

c. Did the establishment's corrective actions include reassessment of the HACCP plan if the *Listeria* control measures are included in a prerequisite program or re-evaluation, and modification of the Sanitation SOP if the *Listeria* control measures are included in the Sanitation SOP (see Chapter V, Section III)?

2. If the establishment samples non-food contact surfaces for *Lm* or *Listeria* spp. as part of its control program and finds a positive result, did it take corrective actions as outlined in its program?

3. As part of verifying the establishment's corrective actions, IPP are to review the establishment's testing results as described in FSIS Directive 5000.2. IPP are to determine whether the positive result represents an isolated case, or whether it is an indicator of *Listeria* trends (e.g., repetitive positive food contact, non-food contact, or product samples over time that are not addressed by routine cleaning and sanitation).

a. If positive *Listeria* trends are found, IPP are to determine whether the establishment addressed the positive results by taking aggressive corrective actions (e.g., intensified cleaning and sanitation, investigative sampling to find sources of contamination, and reassessment of the HACCP program or re-evaluation of the Sanitation SOP).

NOTE: One indicator of positive *Listeria* trends may be matching pulsed-field gel electrophoresis (PFGE) patterns from positive samples over time.

b. If IPP find that the establishment is not adequately addressing continued findings of *Listeria* spp. positives, indicating that its corrective actions are ineffective to control *Lm*,

they are to contact their DO through supervisory channels. The DO is to determine whether Intensified Verification Testing (IVT) along with a "for-cause" FSA is warranted at the establishment, according to FSIS Directive 10,300.1. Additional product samples may also be collected at the establishment.

II. ENFORCEMENT STRATEGY FOR ESTABLISHMENT TESTING

A. General

1. When determining whether to issue an NR in response to establishment testing results, IPP are to consider whether the establishment is effectively carrying out its food safety program by taking effective corrective actions.

2. IPP are to issue an NR if the establishment failed to control adulterated product or did not take corrective actions, as required by 9 CFR 417.3(a) and (b) if its *Listeria* control measures are included in the HACCP plan or prerequisite program, or by 9 CFR 416.15 if its *Listeria* control measures are incorporated in the Sanitation SOP.

3. In addition, IPP are to issue an NR if establishments producing deli and hot dog products under Alternative 3 do not collect follow-up samples to verify the corrective actions they take in response to an initial positive in accordance with 9 CFR 430.4(3)(ii)(A).

B. Food Contact Surface Testing

1. If an establishment finds a positive result for *Listeria* spp. on a food contact surface, IPP are to verify that the establishment took the appropriate corrective actions to address the *Listeria* spp positive result. Post-lethality exposed RTE product passing over a food contact surface testing positive for *Lm* is considered adulterated.

NOTE: If the establishment treats the product that passed over the food contact surface with a post-lethality treatment (e.g., HPP) that has been validated to achieve at least a 5-log reduction of *Lm*, the product would not be considered to be adulterated. IPP are to consider all processing steps before making a determination of adulteration.

2. If the establishment held the affected product, IPP are to verify that the establishment's carries out the corrective actions as specified in its food safety system. If the establishment has not taken the appropriate corrective actions, IPP are to issue an NR.

C. Product Testing

1. There is no regulatory requirement for establishments to test product samples, but if the establishment does test the product, and it tests positive for *Lm*, the product is considered adulterated. IPP are to:

    a. Verify that the establishment takes corrective actions as addressed in the establishment's food safety system. If the establishment has not taken the appropriate corrective actions, IPP are to issue an NR; and

    b. Contact the District Recall Officer (DRO) following the instructions in FSIS Directive 8080.1, Recall of Meat and Poultry Products, if adulterated product in the sampled lot has entered commerce.

2. If a product tests positive for *Listeria* spp., FSIS may determine that the product is adulterated if the establishment cannot support that the product is not adulterated, or if the product has been produced under insanitary conditions. A finding of *Listeria* spp. in the product can

indicate that the Sanitation SOP is inadequate, or that corrective actions taken as a result of a previous sanitation failure may not be effective to prevent product contamination. IPP are to use the following scenarios to make a regulatory decision.

a. IPP are to review the establishment's documentation in response to the positive indicator organism result to determine whether it can support that the product is not adulterated. This documentation may include testing data demonstrating that the original isolate is not positive for *Lm*, or a sampling plan that provides a level of statistical confidence that each product is not contaminated with *Lm* (e.g., using a sampling plan recommended by the ICMSF). The establishment also may dispose of the product or reprocess it with a lethality treatment that has been validated to achieve at least a 5-log reduction of *Lm*.

b. If the establishment provides supporting documentation demonstrating that the product is not positive for *Lm* (i.e., the original isolate is positive for a non-pathogenic strain of *Listeria*), the product is not considered adulterated. However, because *Listeria* spp. was transferred to the product, insanitary conditions may exist that could lead to contamination of the product with *Lm.* IPP are to review the establishment's sanitation records, observations of sanitation, and sanitation NRs and issue an NR if the establishment's Sanitation SOP is inadequate (9 CFR 416.12), or its corrective actions are ineffective (9 CFR 416.15). IPP are to contact the DO through their supervisors to determine whether an IVT- FSA is warranted at the establishment.

c. If the establishment does not provide supporting documentation demonstrating that the product is not adulterated with *Lm*, and the product has been shipped into commerce, IPP are to contact the DRO to determine whether a recall is warranted. The recall would be requested because FSIS concluded that the products are adulterated by being prepared, packed, or held under insanitary conditions. If the product is still at the establishment, IPP are to contact the District Office to determine whether a regulatory control action should be taken according to 9 CFR 500.2(a)(3). If IPP have questions about an establishment's supporting documentation, they are to submit them through askFSIS.

D. Environmental Testing

1. There is no regulatory requirement for non-food contact surface testing in the post-lethality environment. If an establishment chooses to test these surfaces for *Lm* or *Listeria* spp. and the results are positive, IPP are to:

    a. Determine whether insanitary conditions exist that could cause the product to become adulterated (see example below).

EXAMPLE: A drain tests positive for *Lm*. IPP observe an establishment employee spraying a high-pressure hose in the drain. Water droplets landed on a conveyor belt and exposed RTE product. The positive results from the drain, taken along with the observation of possible cross-contamination, would be adequate to support the issuance of an NR (cite 9 CFR 416. 4(b), 430.4(b), and 430.4(c)(3)). The drain positive alone, without any further observations of conditions that could lead to insanitary conditions, would not warrant the issuance of an NR.

    b. Verify that the establishment takes appropriate corrective action as specified in its program.

    c. If insanitary conditions exist that could cause the product to become adulterated, and the establishment has not taken the appropriate corrective actions, IPP are to issue an NR.

CHAPTER IV – COLLECTING AND SUBMITTING FSIS VERIFICATION SAMPLES

I. GENERAL

A. Sampling Eligibility

1. For RTEPROD_RAND sample requests, IPP are to select samples from all of the RTE products produced at the establishment, including non-post-lethality exposed product (e.g., cook-in bag products and both low-risk and high-risk products.

2. For RTEPROD_RISK sample requests, IPP are to select samples from post-lethality exposed RTE meat and poultry products following the Product Priority List (see Attachments 1 and 2).

B. Scheduling the Sample

1. As described in Chapter II, Section II.A.3, when IPP rotate into an assignment or are newly assigned to an establishment, they are to discuss sampling with the establishment at a weekly meeting. As part of this discussion, IPP are to determine:

    a. What RTE products are produced by the establishment, and whether they are post-lethality exposed or non-post-lethality exposed; and

    b. How much notice to give the establishment when collecting a sample. IPP are to familiarize themselves with the establishment's production practices so that they are able to provide adequate time to allow the establishment to hold all product represented by the sample (i.e., the sampled lot) but not alter its production practices. IPP are to provide adequate notice to the establishment in accordance with Section I.B.4 of this chapter below.

2. When IPP receive an RTEPROD_RAND or RTEPROD_RISK request in PHIS, they are to schedule an RTE product sample within the sampling window timeframes given. To schedule the sample, IPP are to randomly select a day, shift, and time within the sample window timeframe. IPP are to schedule samples from all shifts in which the establishment produces RTE products. There should be an equal chance that sampling will occur during any shift where eligible product is produced.

3. IPP are not to wait until the end of the sampling window to schedule the sample. Scheduling the sample at the beginning of the sampling window will allow more time to ensure that the sample is available during the sampling window.

4. Before collecting a sample, IPP are to officially notify the establishment management that they will be collecting a sample and to explain the reason that they are collecting the sample (RTEPROD_RAND or RTEPROD_RISK). To provide establishments enough time to hold the entire sampled lot, but not enough time to alter their production practices, IPP are to:

    a. Generally, provide 1 days notice if such advance notice is sufficient for the establishment to hold the sampled lot, but not to change practices. IPP may provide 2 days' notice if necessary.

    b. Consider the establishment's request for more than 2 days' notice, in the rare case that more notice is needed based on the establishment's product and process flow. If the establishment can support that more notice is necessary because of the innate characteristics of the process (e.g., less than daily sanitation, use of brine, or processes that span more than 2 days), IPP may provide more than 2 days' notice. If

IPP have questions about an establishment's basis for requesting more notice, they are to submit them through askFSIS.

c. Inform the establishment that if it changes routine practices without a justification for doing so, FSIS may provide it with less than 1 days notice, if less time is sufficient to hold the sampled lot, but not change routine practices.

d. Inform the establishment that it is responsible for supporting its basis for defining the product represented by the sample (i.e., the sampled lot); and

e. Inform the establishment that it is required to hold or control the sampled lot when FSIS collects samples of RTE products or food contact surfaces until negative results become available.

5. When notifying the establishment that FSIS will collect a sample, IPP are to:

a. Confirm that the establishment will be producing post-lethality exposed RTE product (RTEPROD_RISK) or RTE product (RTEPROD_RAND) on the day sampling is scheduled. In addition, IPP are to confirm that the establishment is planning to implement its documented routine production, Sanitation SOP, and food-safety practices on the day the sample is scheduled.

b. Inform the establishment that, if it intends to modify its documented routine production, sanitation, or food-safety practices before the sampling, it should inform IPP as soon as possible, so that sampling can be rescheduled. If the establishment continues to change routine practices and cannot support the changes, less than 1 days notice may be provided, or an FSA may be scheduled at the establishment.

NOTE: Justifiable reasons for changing practices may include limiting the lot size to facilitate holding the product, changes in customer orders, or documented changes to Sanitation SOPs or HACCP plans.

c. Verify that the establishment is holding or controlling the product represented by the sampled lot (the product produced from clean-up to clean-up) and record the information in PHIS as:

i. Yes, on-site;

ii. Yes, off-site under company control; or

iii. No.

d. Immediately contact the DO if the establishment does not hold or maintain control the sampled lot.

6. On the day that the sample collection is scheduled, if IPP find that the establishment has altered its documented routine production, sanitation, or food-safety practices, and the establishment cannot provide a supportable rationale, then IPP are not to perform sampling and are to reschedule sampling for another day. IPP are to issue an NR under the following circumstances.

a. If IPP find that the establishment has made changes in its food safety systems (e.g., temporarily changing its supplier of RTE product on the day the sample is collected) and does not have documents supporting the appropriateness of the change, IPP are to issue an NR. The NR would be recommended because the establishment did not

consider the changes in its hazard analysis in accordance with 9 CFR 417.2(a)(1), or did not support the changes to its hazard analysis as in 9 CFR 417.5(a)(1).

b. Likewise, if IPP find that the establishment has made changes in its sanitation practices (e.g., temporarily increasing the use of sanitizer only on the day the sampling is scheduled) and did not revise its Sanitation SOP to reflect these changes, IPP are to issue an NR under 9 CFR 416.14.

NOTE: If an establishment decides to limit its product lot size solely to facilitate holding the product during sampling, it would not be considered to have significantly altered its production practices, as long as IPP can collect samples that accurately represent routine production. If IPP have questions about whether an establishment is altering routine production, sanitation, or food-safety practices, they can submit them through askFSIS at http://askfsis.custhelp.com.

7. At the next weekly meeting, as described in Chapter II, Section II.A.3, IPP are to discuss the altered food safety practices with the establishment. IPP are to inform the establishment that if it continues to change its practices, FSIS may collect more samples and may give less than 1 days notice (if less time is enough to hold the sampled lot) or schedule a "for-cause" FSA.

II. COLLECTING THE SAMPLE

A. When collecting an RTEPROD_RAND sample, IPP are to randomly select a product produced at the time the sample is scheduled, regardless of whether the product is post-lethality exposed or not. IPP are to make efforts to cycle through all the products produced by the establishment.

B. When collecting an RTEPROD_RISK sample, IPP are to collect the highest-risk product produced by the establishment on the day the sample is scheduled (see Attachment 1). If the establishment produces the highest-risk product on multiple lines, IPP are to sample product from each of the lines over time.

C. IPP are to collect the sample after the establishment has applied all interventions except any microbiological testing intervention. If the establishment intends to test the product for *Lm* or *Salmonella*, IPP are not to wait for the establishment to receive the test results.

D. If the establishment treats the product with an intervention (e.g., HPP), either at the establishment or at another establishment, IPP are to review the documentation that the establishment keeps as part of its HACCP program to determine the purpose of the treatment.

1. If the HPP is applied as a *Listeria* intervention, and the establishment has supporting documentation demonstrating that the treatment achieves at least a 1-log reduction of *Lm,* IPP are to collect the sample after the treatment is applied. If the product is not returned to the producing establishment after the HPP treatment, IPP are to sample another product, if possible. If the establishment is not producing any other RTE product at the time the sampling is scheduled, IPP are to cancel the task and enter into PHIS "all interventions have not been applied at this establishment." The product would be subject to sampling at the HPP facility, as long as it has records on file supporting that the treatment was applied as a *Listeria* intervention.

NOTE: If the establishment's validation supports that the HPP treatment achieves at least a 5-log reduction of *Lm,* the product is not considered post-lethality exposed and would only be sampled under the RTEPROD_RAND project code.

2. If the treatment is applied to extend the shelf life of the product, and the establishment does not have supporting documentation describing the treatment as a *Listeria* intervention, then IPP are to collect the product before the treatment. The product would not be subject to

sampling at the HPP facility, as long as it has records on file supporting that the treatment was applied to extend the shelf life.

E. IPP are to collect the product at least three hours after the start of production (if possible), to allow *Lm* to work its way out of the equipment. If the establishment's production lot is typically less than three hours, IPP may collect the samples during the production shift. IPP may collect samples on the first shift or second shift (or other shifts, as applicable). IPP are to vary the shifts in which they collect samples, if possible.

F. IPP are to collect a two-pound sample of product in an intact package. Collecting products in the final package will help ensure that the product does not become contaminated with *Lm* from the environment during the sample collection process.

NOTE: In the past, FSIS has collected one-pound samples at some establishments (e.g., jerky producers). However, because FSIS now enumerates positive RTE samples, a two-pound sample is needed for all products.

G. If the establishment produces reworked product, IPP are to sample the product as part of the production lot, as long as IPP provide the establishment with adequate notice to hold the sample.

NOTE: Rework is the process of re-cooking, reprocessing, or repackaging the product. FSIS considers any process that removes the product from the package and exposes it to the environment as rework.

H. If the finished product contains meat or poultry and non-meat or poultry ingredients, IPP are to follow the instructions in 1 and 2 below.

1. If the meat or poultry and non-meat or poultry ingredients are commingled (in contact) in the final package (e.g., a salad with meat or poultry mixed in), IPP are to collect a two-pound sample of the complete product (including the meat or poultry and nonmeat or poultry component).

2. If the meat and nonmeat ingredients are not commingled (not in contact) in the final package (e.g., an entree with separate compartments for meat or poultry and vegetables), then IPP are to collect a two-pound sample of the meat or poultry component in the final package.

I. IPP are to submit the samples to the laboratory for microbiological analysis in intact packages. The laboratory does not supply sterile bags or gloves for sampling because IPP are not to have direct contact with the exposed, unpackaged RTE product. This is because *Listeria* may be present in the environment and could be transferred to the product if an exposed RTE product is collected.

J. If an intact product or product container is too large, heavy, or costly to ship to the laboratory, IPP can ask the establishment to slack-fill or short-weight a product for a 2-pound sample and send it in the usual establishment packaging such as the container liner.

1. If the slack-filled or intact package is an unsealed bag, IPP are to tie it off (e.g., twist tie or rubber band) so smaller particles (e.g., shredded meat pieces) do not spill into the shipping container. IPP are to place the slack-filled package in a secondary bag. The laboratory will discard the sample if it contains spilled or leaking products.

2. When IPP document the sampling task in PHIS, under the "Additional Info" tab, they are to click "yes" to the question "Is this sample short-weighted/slack-filled?" to ensure that the sample is not discarded as a non-intact sample by the laboratory.

3. IPP are not to use any laboratory-supplied bag as the primary wrap for the sample. Laboratory supplied bags provided by the laboratory are for secondary containment only because they are not sterile. The laboratory-supplied bag protects the box in case the primary container leaks.

4. If IPP cannot collect an intact short-weighted or slack-filled sample, and the establishment is not producing any other type of RTE product that the IPP could collect, IPP are to contact the designated laboratory to discuss other options for collecting the sample.

NOTE: Examples of inappropriate samples for short-weight or slack-filled samples include a sample that would have to be cut to fit inside the shipping container, and samples that are packed in a waxed box without a liner bag that is too large to fit inside a laboratory shipping box.

III. SUBMITTING THE SAMPLE

A. IPP are to safeguard the integrity of samples during submission according to FSIS Directive 7355.1, Use of Sample Seals for Laboratory Samples and Other Applications.

B. IPP are to ship samples overnight. IPP are to ship samples Monday through Friday so that they arrive at the laboratory overnight. IPP are not to ship samples on Saturdays or on the day before a Federal holiday, or as directed by a user notice via e-mail.

CHAPTER V– FSIS ACTIONS AFTER A POSITIVE FSIS VERIFICATION SAMPLING RESULT

I. IPP ACTIONS IN RESPONSE TO A POSITIVE RESULT

A. IPP are to obtain test results through the Laboratory Information Management System (LIMS) Direct and immediately report them to the establishment. IPP are to document this notification in an MOI.

B. Whenever IPP are notified that a sample has been discarded and will not be analyzed by the FSIS laboratory, and product is being held on-site or controlled off-site, IPP are to notify the establishment immediately so it can release the product.

II. BASING ENFORCEMENT ACTIONS ON FSIS AND ESTABLISHMENT TEST RESULTS

A. Enforcement Actions in Response to Positive Results from the RTEPROD Sampling Project

1. If an RTE product sample collected by IPP under the RTEPROD_RAND or RTEPROD_RISK_ project codes tests positive for *Salmonella* or *Lm*, product in the sampled lot is considered to be adulterated.

2. IPP are to follow the instructions in FSIS PHIS Directive 5000.1 when taking enforcement actions in response to positive sampling results. In addition, IPP are to consider the following when issuing NRs:

    a. If FSIS finds the product positive, and the establishment tested the product under its documented sampling programs, IPP are to check the establishment's *Salmonella* or *Lm* testing results to determine whether the establishment also found the sampled product to be positive for *Salmonella* or *Lm*.

    b. IPP are to determine whether the establishment held the product or maintained control of the product (e.g., the establishment moved the product off-site but did not complete pre-shipment review or transfer ownership of the product to another entity) pending its own test results.

c. If IPP find that the establishment did not hold or maintain control of the product, they are to issue an NR. The NR would be warranted because the establishment shipped product before FSIS found that the product was not adulterated, and because the establishment did not complete pre-shipment review following availability of all relevant test results, as set out in 9 CFR417.5(c).

d. Generally, if FSIS finds the product positive for *Salmonella* or *Lm*, IPP are to issue an NR (cite 9 CFR 417.4(a)). However, if the establishment also found the product to be positive for *Salmonella* or *Lm* and held the product, IPP are not to issue an NR. They are to verify that the establishment performs the appropriate corrective actions, using a directed HACCP Verification Task, as described in Section III of this chapter.

B. Enforcement Actions in Response to Results from RLm or IVT Sampling

1. The enforcement strategy in Section II.A of this chapter also applies to product and food contact samples collected by Enforcement, Analysis, and Investigations Officers (EIAOs). These samples are collected as part of Routine Risk-based *Lm* (RLm) and Intensified Verification (IVT) sampling, as described in FSIS Directives 10,240.5, Verification Procedures for EIAOs for the *Lm* Regulation and RLm Sampling Program, and 10,300.1..

2. If an environmental (non-food contact) sample tests positive for *Lm* during a RLm or *Lm* or *Salmonella* during an IVT, the product is not considered to be adulterated. However, IPP are to issue a NR if there is evidence of insanitary conditions that could lead to product contamination (e.g., condensation from a dirty pipe falling on food contact surfaces).

III. VERIFYING THE ESTABLISHMENT'S CORRECTIVE ACTIONS IN RESPONSE TO AN FSIS POSITIVE RESULT

A. If FSIS finds a product or food contact surface positive for *Lm* or *Salmonella*, IPP are to verify that the establishment takes the appropriate corrective actions by performing a directed HACCP Verification Task.

1. When performing a directed HACCP Verification Task in response to a *Lm* positive result, IPP are to review the same information they review during a routine HACCP Verification Task (see Chapter II). IPP are also to verify that the establishment implemented corrective actions according to 9 CFR 417.3 (a) and (b) if the measures for addressing *Lm* are included in the HACCP plan or prerequisite program, or 9 CFR 416.15 if the measures are incorporated in the Sanitation SOP. FSIS will perform an IVT/FSA for *Lm*, as described in FSIS Directive 10,300.1.

2. When performing a directed HACCP Verification Task in response to a *Salmonella* positive result, IPP are to verify that the establishment took the appropriate corrective actions according to 9 CFR 417.3(a) or (b), or 9 CFR 416.15. Although the *Listeria* Rule does not require establishments to specifically control for *Salmonella* in post-lethality exposed RTE products, as stated previously, FSIS considers RTE products to be adulterated if products or food contact surfaces test positive for *Salmonella* or other pathogens. Therefore, establishments are required to take corrective actions in response to positive results and to reassess their HACCP plan. FSIS will perform an IVT/FSA for *Salmonella*, as described in FSIS Directive 10,300.1.

B. In addition, if FSIS develops a verification plan in response to an establishment's proffered corrective actions and preventive measures when enforcement is deferred following the issuance of a

Notice of Intended Enforcement (NOIE), or a suspension is held in abeyance, IPP are to verify that the establishment implements its corrective actions, and that the corrective actions are effective.

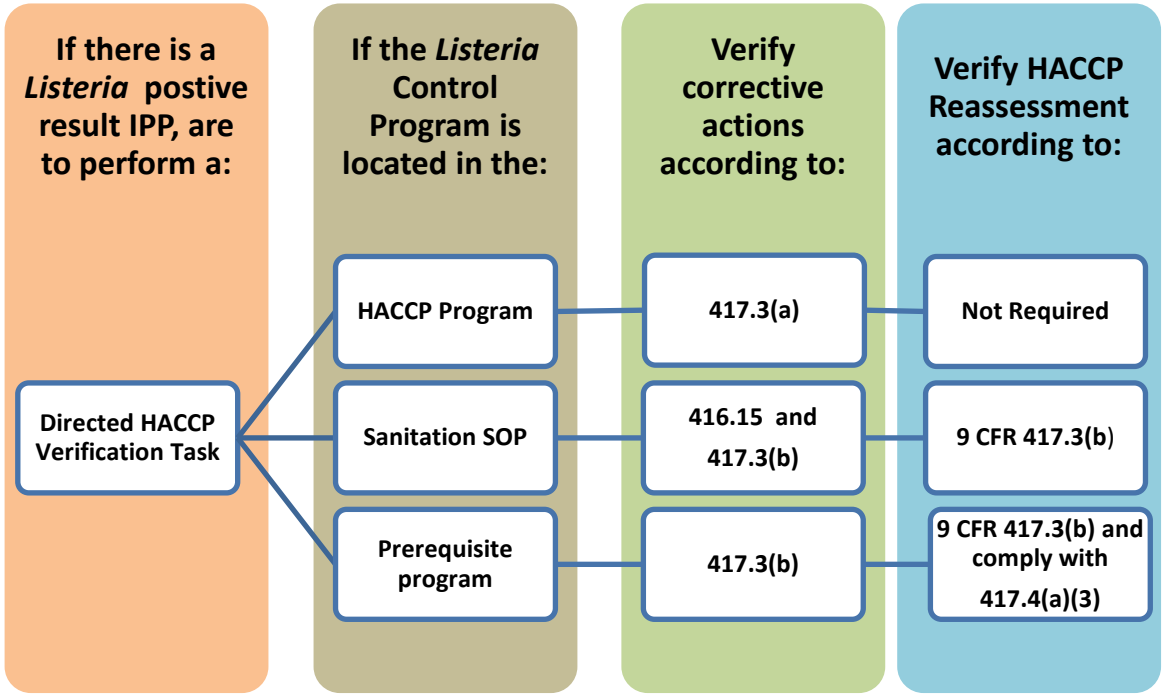
C. IPP are to verify that the establishment reassessed its HACCP plan as follows:

1. If *Lm* control is addressed as a CCP in the HACCP plan (e.g., PLT), the establishment must meet the requirements of 9 CFR 417.3(a), which requires that corrective action be taken but does not require reassessment of the HACCP plan.

2. If *Lm* is addressed in the Sanitation SOP, then the establishment must implement corrective actions in accordance with 9 CFR 417.3(b), which includes reassessment of the HACCP plan. In addition, it must implement the corrective action requirements for the Sanitation SOP in 9 CFR 416.15, which includes appropriate re-evaluation or modification of the Sanitation SOP. If *Lm* is addressed in a prerequisite program (e.g., *Listeria* Control Program) that is used to support the decision that *Lm* is not a hazard reasonably likely to occur in the product, then the establishment must implement the corrective actions in 9 CFR 417.3(b) and comply with 417.4(a)(3). These regulations state that when there is a change in the process (e.g., a positive result) that could impact the hazard analysis, a reassessment must be performed.

3. The establishment is required under 9 CFR 417.4 (a)(3)(ii) to make a record of the reassessment and document the reasons for any changes that it made to its HACCP plan based on the reassessment, or, if it did not make any changes, to document the reasons that it did not.

Steps for Verifying an Establishment's Corrective Actions



CHAPTER VI – VERIFICATION OF PRODUCT DISPOSITION

A. The establishment may reprocess or dispose of adulterated product. If the establishment reprocesses the product, IPP are to verify that it used a process that achieves adequate lethality of pathogens. FSIS considers a process that has been validated to achieve a 5-log reduction of *Lm* sufficient for reworking contaminated product.

B. In addition, establishments may use Appendix A and Appendix B of the final rule, "Performance Standards for the Production of Certain Meat and Poultry Products," FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks, and the Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products, or other supportable processes to reprocess *Lm*-positive product.

NOTE: IPP are to be aware that Appendix A and B, the FSIS Guidance on Safe Cooking of Non-intact Meat Chops, Roasts, and Steaks, and the Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products, are designed to achieve reductions in *Salmonella*. Establishments are not expected to validate that these processes also achieve reductions in *Lm* because *Salmonella* is considered an indicator of lethality for *Lm*.

C. If the establishment chooses to dispose of the product, it may do so either on-site or off-site. If the product is disposed of on-site, IPP are to verify that the establishment maintained records showing that the positive product received the proper disposition.

D. If the establishment transports positive product to another site for appropriate disposition, IPP are to verify that the establishment has met all corrective action requirements by verifying that the establishment:

1. Maintained records identifying the official establishment, renderer, or landfill operation that received positive product;

2. Maintained control of product that was destined for a landfill operation or renderer while the product was in transit (e.g., through company seals);

3. Maintained control of product that was destined for an official establishment while the product was in transit (e.g., through company seals) or ensured that such product moved under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1);

4. Maintained records showing that positive product received the proper disposition, including documentation showing proper disposal of the product from the official establishment, renderer, or landfill operation where disposition occurred; and

5. Completed pre-shipment review for the positive product only after it has received the records described above for that particular product.

E. If IPP find that there is noncompliance with the corrective action requirements for product disposal, they are to document the noncompliance in accordance with FSIS PHIS Directive 5000.1.

F. If an establishment ships adulterated product to a renderer or landfill operation, IPP are to verify the establishment denatures the product before the product leaves the establishment (9 CFR 314).

G. In situations where the establishment has not properly moved or disposed of the product, IPP are to notify their DO through supervisory channels.

CHAPTER VII – DATA ANALYSIS

The Office of Policy and Program Development (OPPD) will work with the Office of Data Integration and Food Protection (ODIFP), Data Analysis and Integration Staff (DAIS), to track *Lm* sampling data every six months. The tracked data will include the number of samples scheduled, the number of samples collected, and the number of positives for each RTE project code. In addition, OPPD will work with the Office of Public Health Science (OPHS), Science Staff (SciS), to track pulsed-field gel electrophoresis (PFGE) results from RTE sampling programs and recalls from RTE meat and poultry products. OPPD will analyze these data to determine whether new policy is needed to address positive results.

CHAPTER VIII – QUESTIONS

Refer questions regarding this directive to the Risk, Innovations, and Management Staff (RIMS) through askFSIS. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided.

Subject Field: Enter **Directive 10240.4**
Question Field: **Enter your question with as much detail as possible.**
Product Field: Select **General Inspection Policy** from the drop-down menu.
Category Field: Select **Sampling: *Listeria monocytogenes*** from the drop-down menu.
Policy Arena: Select **Domestic (U.S.) Only** or **International (Import/Export)** from the drop-down menu.

When all fields are complete, press **Continue**.

Assistant Administrator
Office of Policy and Program Development

Attachment 1: RTEPROD_RISK and RTE_RAND Sampling Instructions

Project Codes:	**RTEPROD_RISK – Risk Based Verification Testing of Only Post-lethality Exposed RTE Meat and Poultry Products**	**RTEPROD_RAND– Random Verification Sampling of RTE Meat and Poultry Products**
SAMPLE COLLECTOR	IPP in establishments that produce post-lethality exposed RTE product.	IPP in establishments that produce all RTE products, regardless of whether the product is post-lethality exposed or not.
PRODUCT TO SAMPLE	IPP are to select the highest-risk post-lethality exposed RTE product produced at the time of collection using the Product Sampling Priority List (Attachment 2). When assigning product categories, IPP are to use the RTE Product Group Flowchart Resource 2.	IPP are to randomly select a product produced at the time of collection. IPP are to make every effort to sample all the RTE products produced at the establishment by rotating through the products.
ANALYZED FOR	*Listeria monocytogenes* and *Salmonella*	
SPECIAL COLLECTION INSTRUCTIONS	IPP are to submit a two-pound sample of product in an intact package. FSIS is not collecting samples of oils, shortening, lard, margarine, oleomargarine, or mixtures of rendered animal fats because there is no validated method for testing these products for *Lm*. FSIS will continue to sample popped pork skins, pork rinds, dried soup bases, concentrated (high salt content) soup mixes, and pickled pig's feet under both RTE project codes. FSIS will collect samples of RTE products that are shipped hot from the establishment. In addition, IPP are not to collect product labeled "For Further Processing," in which the product is expected to receive a lethality treatment at another federally inspected establishment.	
SCHEDULING INSTRUCTIONS	IPP are to randomly select a day, shift, and time within the sample window timeframe. IPP are to collect samples from all shifts the establishment operates. There should be an equal chance that sampling will occur during any particular shift.	
ESTABLISHMENT NOTIFICATION	IPP are to notify the establishment before collecting samples. IPP are to provide enough time for the establishment to hold the sampled lot but not enough time to alter its process.	
SPECIAL SHIPPING INSTRUCTIONS	IPP are to safeguard the integrity of samples during submission according to FSIS Directive 7355.1, Use of Sample Seals for Laboratory Samples and Other Applications. IPP are to ship samples to the designated laboratory as soon as collected and during the next available FedEx pickup. IPP are to ship samples refrigerated or frozen, depending on establishment practices. IPP are to use sufficient frozen coolant to keep samples cold during transit. IPP are to ship samples Monday through Friday so that they arrive at the laboratory overnight. IPP are not to ship samples on Saturdays or on the day before a Federal Holiday	
REFERENCES	Directive 10,240.4, Rev. 3	

Attachment 2: Product Sampling Priority List

HACCP Processing Categories	Finished Product Categories	Production Volume Categories (by Product Groups)	Risk Level
Fully Cooked-Not Shelf Stable	RTE fully-cooked meat (PLE)[1]/ RTE fully-cooked poultry (PLE)	Other Fully Cooked Sliced Product	1
		Hot Dog Products	2
		Salad/Spread/Pate	3
		Diced/Shredded	4
		Meat + Nonmeat Components	5
		Sausage Products	6
		Patties/Nuggets	7
		Other Fully Cooked Not Sliced Product	8
Not Heat Treated-Shelf Stable/Heat Treated-Shelf Stable	RTE acidified/fermented meat (without cooking)-PLE/ RTE acidified/fermented poultry (without cooking)-PLE	RTE fermented meat (sliced or not sliced)/ RTE fermented poultry (sliced or not sliced) (Acidified/Fermented Products)[2]	9
	RTE dried meat (PLE)/ RTE dried poultry (PLE)	RTE dried meat (sliced or not sliced)/RTE dried poultry (sliced or not sliced) (Dried Products)[2]	10
	RTE salt-cured meat (PLE)/ RTE salt cured poultry (PLE)	RTE salt-cured meat (sliced or not sliced)/ RTE salt-cured poultry (sliced or not sliced) (Salt-cured Products)[2]	11
Product with Secondary Inhibitors – Not Shelf Stable	RTE salt-cured meat (PLE)/ RTE salt cured poultry (PLE)	RTE salt-cured meat (sliced or not sliced)/ RTE salt-cured poultry (sliced or not sliced) (Salt-cured Products)[2]	11

[1]PLE is defined as post-lethality exposed product.
[2] Product type to be used on Form 10,210-3.

Attachment 3: Potential *Lm* Harborage Sites

A cart wheel with rust and product residue build up. The wheel can be contaminated with *Lm* when it is rolled across drains and wet areas in the floor. The *Lm* can then spread through the establishment when the cart is pushed into different areas.

A light switch with residue build-up and grime. The switch could be contaminated with *Lm* by employees' hands during operation, and may not be cleaned during sanitation. When the light is turned on the next day, the hands could be re-contaminated.

A drain at the entrance of a cooler doorway. The drain could become contaminated with *Lm*, and when employees step on the drain to enter the cooler, the *Lm* can spread into the cooler.

A conveyor belt with a hollow roller under the belt. *Lm* could be harbored in the hollow roller and spread to the belt.

A rusty water spigot with a dirty, cracked insulated pipe. *Lm* could spread to the hose and be sprayed in the establishment.

A slicer blade with grime and black residue under the blade. The blade can be contaminated with *Lm* and spread to the product that is sliced. The slicer handle, controls, and seals may also be contaminated, as these areas may not be frequently cleaned.