

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

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3/25/22

LISTERIA RULE VERIFICATION ACTIVITIES

CHAPTER I - GENERAL

I. PURPOSE

FSIS verification of establishment compliance with *Listeria* controls is an important food safety verification activity that supports FSIS' food safety and public health goals. This directive provides instructions for inspection program personnel (IPP) to verify that establishments that produce post-lethality exposed Ready-to-Eat (RTE) products control *Listeria monocytogenes* (*Lm*) through a Hazard Analysis and Critical Control Point (HACCP) plan or prevent *Lm* through a Sanitation Standard Operating Procedure (Sanitation SOP) or other prerequisite program. This directive also includes instructions for verifying RTE products that are not post-lethality exposed (e.g., cook-in-bag) are properly classified.

This directive has been revised in its entirety to provide updated instructions to IPP for verifying that meat and poultry establishments are complying with the regulatory requirements of [9 CFR 430.4](#), *Control of Listeria monocytogenes in Post-Lethality Exposed Ready-to-Eat Products* (the "*Listeria* Rule"). The directive has also been revised to reflect changes that were made when the Agency affirmed the interim final *Listeria* Rule, including clarifying that establishments may not release into commerce product that the establishment collected under its *Lm* control program and has tested positive for *Lm* or has been in contact with *Lm*-contaminated surfaces without reprocessing the product ([80 FR 35178](#)). The directive also clarifies how IPP are to verify [9 CFR 417.2\(a\)\(2\)](#) compliance for products that are not post-lethality exposed (e.g., cook-in-bag) in response to several recent outbreaks implicating products that were incorrectly classified as not post-lethality exposed. The directive no longer contains supplemental information task tables which were moved to [IPP Help](#), *RTE Verification*. Instructions concerning sampling of RTE products are contained in a new [FSIS Directive 10,240.3](#), *FSIS Ready-to-Eat Sampling Programs*.

KEY POINTS:

- *Verifying an establishment's compliance with the Listeria Rule, 9 CFR 430*
- *Verifying establishment sampling and testing programs meet the regulatory requirements of the Listeria Rule in both design and execution*

II. CANCELLATION

FSIS Directive 10,240.4, Revision 3, *Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-To-Eat (RTE) Sampling Program*, 1/10/14

III. BACKGROUND

A. On June 6, 2003, FSIS published an interim final rule that established requirements for establishments to follow when testing for *Lm* in order to produce safe RTE products ([68 FR 34208](#)). On June 19, 2015, FSIS published another rule that affirmed the interim final rule with small changes ([80 FR 35178](#)). Specifically, FSIS clarified in [9 CFR 430.4\(a\)](#) that establishments may not release into commerce product that has been in contact with *Lm*-contaminated surfaces without reprocessing the product. In addition, FSIS removed the requirement for establishments to report production volume and related information previously in [9 CFR 430.4\(d\)](#) to FSIS because the Agency now routinely collects this information through its Public Health Information System (PHIS).

B. The *Listeria* Rule states that *Lm* is a hazard that establishments producing post-lethality exposed RTE meat and poultry products must control through HACCP plans, prevent in the processing environment through a Sanitation SOP, or prevent through another prerequisite program. To maintain the sanitary conditions necessary to meet this requirement, establishments must comply with the regulations for one of three *Listeria* alternatives ([9 CFR 430.4\(a\) and \(b\)](#)).

C. Under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), FSIS considers any RTE product to be adulterated if it contains a pathogen of public health concern (depending on the type and level) or its toxin that can cause illness in humans. There are some pathogens where any level would make the RTE product adulterated (such as *Lm* and *Salmonella*) because it could be injurious to health (21 U.S.C. 601(m)(1) and 453(g)(1)). If any level of *Lm* or *Salmonella* is detected in an RTE product or on a food contact surface (FCS) that post-lethality exposed RTE product has passed over, the product is adulterated.

CHAPTER II - VERIFYING COMPLIANCE WITH THE LISTERIA RULE

I. REQUIREMENTS OF THE *LISTERIA* RULE

According to the *Listeria* Rule, establishments producing post-lethality exposed RTE products must comply with the requirements included in one of the *Listeria* Control Alternatives ([Table 1](#)). [Table 1](#) includes the *Listeria* Control Alternative type, description, and the regulatory testing requirements. Note that for Alternatives 2b and 3, establishments are required under the regulations to test for *Listeria* and can choose to test for either *Lm* or an indicator organism. Most establishments choose to test for *Listeria* spp. The establishment's corrective actions and response to a positive test will differ depending on whether the establishment tests for *Lm* or *Listeria* spp. ([Chapter III, Section III, Verifying Corrective Actions in Response to Positive Results from Establishment Food Contact Surface Sampling](#)). In contrast, for Alternatives 1 and 2a, establishments are not required to test, although many choose to do so.

NOTE: Indicator organisms as described in [9 CFR 430.4](#) can include *Listeria* spp., *Listeria*-like organisms, *Enterococcus*, and *Lactobacillus*. *Listeria* spp. are members of the genus *Listeria*, which includes both pathogenic *Lm* and non-pathogenic strains. The presence of *Listeria* spp. indicates conditions where *Lm* could be present or grow. When an establishment finds *Listeria* spp. further confirmation tests would be needed to determine if *Listeria* spp. positive tests are also positive for *Lm*, although for FCS this is not a requirement for establishments to perform. A finding of *Listeria* spp. by an establishment on an FCS indicates conditions where *Lm* may be present, but the product is not considered adulterated. However, establishments are required to take corrective action, according to their control alternative, to address *Listeria* spp. positives so that product does not become adulterated.

Table 1: *Listeria* Control Alternatives

<i>Listeria</i> Control Alternative Type	<i>Listeria</i> Control Alternative Description	Regulatory Testing Requirements	Regulatory Citation
Alternative 1 (Alt. 1)	The establishment uses a post-lethality treatment (PLT) to reduce or eliminate <i>Lm</i> in the product and an Antimicrobial Agent or Antimicrobial Process (AMAP) to limit or suppress growth of <i>Lm</i> in the product	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • 9 CFR 430.4(b)(1)
Alternative 2, Choice 1 (Alt. 2a)	The establishment uses a PLT to reduce or eliminate <i>Lm</i> in the product	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • 9 CFR 430.4(b)(2)(i)
Alternative 2, Choice 2 (Alt. 2b)	The establishment uses an AMAP to limit or suppress growth of <i>Lm</i> in the product	<ul style="list-style-type: none"> • Testing FCS in post-lethality processing environment for <i>Lm</i> or an indicator organism • State testing frequency • Identify size and location of sites to be sampled • Explain why testing frequency is sufficient to ensure <i>Lm</i> or indicator organism control • Identify conditions for hold and test, when FCS (+) for an indicator organism 	<ul style="list-style-type: none"> • 9 CFR 430.4(b)(2)(ii)
Alternative 3 (Alt. 3)	The establishment relies on sanitation alone to prevent <i>Lm</i> in the processing environment and on the product	<ul style="list-style-type: none"> • Testing FCS in post-lethality processing environment for <i>Lm</i> or an indicator organism • State testing frequency • Identify size and location of sites to be sampled • Explain why testing frequency is sufficient to ensure <i>Lm</i> or indicator organism control • Identify conditions for hold and test, when FCS (+) for an indicator organism 	<ul style="list-style-type: none"> • 9 CFR 430.4(b)(3)(i)
Alternative 3 (Alt. 3) Additional Requirements for Deli Meats and Hot Dogs	The establishment relies on sanitation alone to prevent <i>Lm</i> in the processing environment and on the product	<ul style="list-style-type: none"> • Testing FCS in post-lethality processing environment for <i>Lm</i> or an indicator organism • State testing frequency • Identify size and location of sites to be sampled • Explain why testing frequency is sufficient to 	<ul style="list-style-type: none"> • 9 CFR 430.4(b)(3)(ii)

- ensure *Lm* or indicator organism control
- Hold and test product after a second consecutive FCS (+) for an indicator organism

II. IPP RESPONSIBILITIES

A. When IPP rotate into an assignment or are newly assigned to an establishment or the establishment makes changes to their process or practices, they are to:

1. Determine whether the establishment produces RTE product, and if so, if the product is post-lethality exposed;
2. Update the establishment's profile, as needed and described in [FSIS Directive 5.000.1, Verifying an Establishment's Food Safety System](#) and [FSIS Directive 5.300.1, Managing the Establishment Profile in the Public Health Information System \(PHIS\)](#), if the establishment produces RTE product routinely or on an intermittent basis;
3. Hold a weekly meeting with the establishment (at the first weekly meeting when IPP rotate into an assignment or are newly assigned to an establishment), and document the discussion in a Memorandum of Interview (MOI), as described in [FSIS Directive 5.000.1](#). During the weekly meeting IPP are to:
 - a. Discuss the establishment's *Lm* control procedures 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; and
 - b. Discuss the results from samples collected in the last six months by the establishment and any corrective actions the establishment took in response to those results to look for trends.
4. During subsequent weekly meetings, as described in [FSIS Directive 5.000.1](#) and [FSIS Directive 5.000.2, Review of Establishment Testing Data by Inspection Program Personnel](#), IPP are to discuss the following:
 - a. Results from establishment sampling and any corrective actions the establishment took in response to positive results;
 - b. Results of any FSIS sampling that was recently performed and notify the establishment when they will be collecting samples following the instructions in [FSIS Directive 10.240.3, FSIS Ready-to-Eat Sampling Programs](#); and
 - c. Instances when establishments change practices as further described in [FSIS Directive 10.240.3, FSIS Ready-to-Eat Sampling Programs](#) Chapter III, Section II. D.3. In addition, IPP are to enter changes, such as construction events, in PHIS following [FSIS Directive 5.300.1](#).

III. IPP VERIFICATION OF *LISTERIA* CONTROL ALTERNATIVES

A. IPP are to use the Gather, Assess, and Determine (GAD) thought process 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.

B. If the establishment has chosen Alternative 1 and applies a post-lethality treatment (PLT) and an Antimicrobial Agent or Antimicrobial Process (AMAP), IPP are to verify that:

1. 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\(b\)\(1\)](#));
 - a. A post-lethality treatment is a lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.
 - b. An antimicrobial agent is a substance in or added to an RTE product, such as potassium lactate or sodium diacetate, that has the effect of reducing or eliminating a microorganism, including a pathogen such as *Lm*, or that has the effect of suppressing or limiting growth of a pathogen in the product throughout the shelf life of the product.
 - c. An antimicrobial process is an operation, such as freezing, that is applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *Lm*, in the product throughout the shelf life of the product.
2. The establishment has included the PLT in its HACCP plan and the AMAP in its HACCP plan, Sanitation SOP, or other prerequisite program ([9 CFR 430.4\(b\)\(1\)\(i\)](#)); and
3. The establishment has validated the effectiveness of the PLT (e.g., FSIS recommends the establishment achieve at least 1-log reduction of *Lm* before the product leaves the establishment) 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\(b\)\(1\)\(ii\)](#)) (e.g., will allow no more than 2-log outgrowth of *Lm*).

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

1. 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\(b\)\(2\)](#));
2. If the establishment has applied a PLT (Alt. 2a), it has included the PLT in its HACCP plan. If the establishment has applied an AMAP (Alt. 2b), it has included the AMAP in its HACCP plan or Sanitation SOP or other prerequisite program ([9 CFR 430.4\(b\)\(2\)\(i\)](#)); and
3. 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:

1. Tests FCS 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 post-lethality exposed FCS is any surface that comes in direct contact with post-lethality exposed RTE product;

2. Identifies the conditions under which the establishment will hold and test the product in response to a positive result for an indicator organism, in accordance with [9 CFR 430.4\(b\)\(2\)\(iii\)\(B\)](#);
3. States the frequency with which testing will be done, in accordance with [9 CFR 430.4\(b\)\(2\)\(iii\)\(C\)](#);
4. Identifies the size and location of the sites that will be sampled in accordance with [9 CFR 430.4\(b\)\(2\)\(iii\)\(D\)](#); and
5. 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\(b\)\(2\)\(iii\)\(E\)](#).

E. If the establishment has chosen Alternative 3 and relies on sanitation alone, IPP are to verify that the establishment:

1. Provides for testing of FCS 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\(b\)\(3\)\(i\)\(A\)](#);
2. Identifies the conditions under which the establishment will hold and test the product in response to a positive test of an FCS, in accordance with [9 CFR 430.4\(b\)\(3\)\(i\)\(B\)](#);
3. States the frequency with which testing will be done, in accordance with [9 CFR 430.4\(b\)\(3\)\(i\)\(C\)](#);
4. Identifies the size and location of the sites that will be sampled, in accordance with [9 CFR 430.4\(b\)\(3\)\(i\)\(D\)](#); and
5. 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\(b\)\(3\)\(i\)\(E\)](#).

F. If the establishment has chosen Alternative 3 and produces deli or hot dog products, IPP are to verify that the establishment's HACCP plan includes corrective actions in response to a positive test result and that the establishment:

1. Verifies that the corrective actions it takes in response to an initial positive result on an FCS are effective by conducting follow-up testing of the specific site that tested positive, as well as the surrounding FCS as necessary to ensure the effectiveness of the corrective actions ([9 CFR 430.4\(b\)\(3\)\(ii\)\(A\)](#));
2. Holds lots of product that may have been contaminated by contact with the FCS, if the establishment receives a second positive result on an FCS, until the establishment corrects the problem indicated by the test result ([9 CFR 430.4\(b\)\(3\)\(ii\)\(B\)](#)); and
3. 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 an FCS 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 III, Section IV, FSIS Actions After a Positive Establishment Product and Environmental Sampling Result.

G. IPP are to be aware that under the *Listeria* Rule ([9 CFR 430.4\(c\)](#)), establishments using Alternatives 1, 2, or 3:

1. May use establishment verification testing for *Lm* or an indicator organism (e.g., *Listeria* spp. or *Listeria*-like organisms) to verify the effectiveness of their sanitation procedures in the post-lethality processing environment;
2. 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 are to have documentation that supports the decision in their hazard analysis that *Lm* is a hazard that is not reasonably likely to occur (NRLTO);
3. Must maintain sanitation in the post-lethality processing environment in accordance with [9 CFR Part 416](#);
4. Must validate and verify the measures in accordance with [9 CFR 417.4](#), when *Lm* control measures are included in the establishment's HACCP plan;
5. 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;
6. Must include the program and the results produced, which show that the hazard is NRLTO, in the documentation that it is required to maintain under [9 CFR 417.5](#). This requirement applies regardless of whether the measures are in the Sanitation SOP or other prerequisite program;
7. Must make verification results available upon request to FSIS personnel; and
8. 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 (e.g., sprayed with a solution of sodium lactate to prevent the growth of *Lm*). IPP are to be aware that an establishment wanting to make a claim under [9 CFR 430.4\(e\)](#) is required to submit the label to FSIS for approval per [9 CFR 412.1\(c\)\(3\)](#).

IV. IPP VERIFICATION OF SANITATION PERFORMANCE STANDARDS (SPS) AND SANITATION STANDARD OPERATING PROCEDURES REQUIREMENTS

A. IPP are to verify whether establishments have met the requirements for Sanitation Performance Standards (SPS) and Sanitation SOPs by following the instructions in [FSIS Directive 5,000.1](#). Because *Lm* is an environmental contaminant, sanitary controls are extremely important to control the safety of post-lethality exposed RTE products. SPS and Sanitation SOP requirements work with the requirements of the *Listeria* Rule to control *Lm*. IPP are to use the instructions in this directive along with the instructions in [FSIS Directive 5,000.1](#) and the other cited directives when conducting verification activities. More information on specific questions to consider when verifying SPS and Sanitation SOP requirements can be found in [IPP Help](#), *RTE Verification Job Aids*.

B. Sanitation Performance Standards (SPS): When performing the SPS verification task in PHIS, according to [FSIS Directive 5,000.1](#), IPP are to determine whether the situations they observe are likely to cause insanitary conditions or adulteration of RTE products.

1. When making this determination, IPP are to keep in mind that improper sanitation can lead to harborage or reintroduction of *Lm* in the establishment's environment. This can lead to cross-contamination of FCS and product with *Lm*. IPP are to evaluate the establishment's sanitation programs to determine if they are designed to control harborage and prevent product adulteration with *Lm*.
 - a. IPP are to be aware and discuss with establishment management that harborage or reintroduction of *Lm* occurs when *Lm* persists in the processing environment or is continually brought into the processing environment from an external site. 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-FCS) to an FCS or product in the establishment.
 - b. IPP are to be aware that biofilms are thin layers of microorganisms that adhere to product contact surfaces. *Lm* and other bacteria can adapt to the environment and can form biofilms on FCS and non-food contact environmental surfaces and, as a result, persists on these surfaces despite aggressive cleaning and sanitizing. *Lm* can form biofilms on solid surfaces, such as stainless steel and rubber, and can survive adverse conditions on smooth surfaces. Once *Lm* has established a niche, it may persist in the environment for long periods of time until the niche is identified and eliminated. Biofilms are difficult to remove, and they may protect *Lm* from the effects of sanitizers.
2. As stated in [FSIS Directive 5.000.1](#), if IPP find that an establishment systematically fails to maintain sanitary conditions, and that *Lm* contamination of FCS or product may occur as a result, they are to issue a noncompliance record (NR) and 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 of the product and issue an NR after applying the GAD thought process and instructions in [FSIS Directive 5.000.1](#) to determine what regulations are noncompliant.

3. More information with images and examples of potential *Lm* harborage can be found in [IPP Help](#), *RTE Verification Job Aids*.

C. Sanitation SOP: When performing inspection tasks (i.e., Pre-Operational (Pre-Op) Records Review, Operational Sanitation Records Review, Pre-Op Sanitation Review and Observation, and Operational Sanitation Review and Observation), IPP are to determine whether the establishment has taken steps to control *Listeria* contamination through adequate sanitation.

EXAMPLE: Does the establishment control sanitation during construction so that product does not become contaminated? Does it increase verification sampling in response to construction or other conditions that could increase risk in the establishment? If the establishment does not control *Lm* during construction or does not increase its verification sampling in response to the construction, IPP are to issue an NR (cite only pertinent regulations, which may include [9 CFR 416.12\(a\)](#), [416.13](#), [416.14](#), [430.4\(b\)](#), and [\(c\)\(3\)](#)).

1. If the establishment has incorporated its *Lm* control procedures in its Sanitation SOP, IPP are to verify:
 - a. The design of the program to ensure that it meets the requirements of the *Listeria* Rule. 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 an NR (cite [9 CFR 417.5\(a\)\(1\)](#)).
 - b. The execution of the program to ensure that the establishment is following its sampling program as written. 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 in an NR citing [9 CFR 416.13\(b\)](#) and [9 CFR 430.4\(b\)\(2\)\(iii\)\(C\)](#) or [430.4\(b\)\(3\)\(i\)\(C\)](#).
 - c. 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 stated in the written program or finds other sampling program deficiencies, IPP are to verify the establishment's support. Failure to support hazard analysis decisions is cause for IPP to document noncompliance citing [9 CFR 417.5\(a\)\(1\)](#) and may result in enforcement action ([FSIS Directive 5,000.1](#)).
2. If the establishment has incorporated its *Lm* sampling and testing procedures in its Sanitation SOP, IPP are to review [Chapter III, Section II, Verifying the Execution of the Establishment's Sampling and Testing Program](#).
3. Each time IPP issue an NR in an RTE establishment, he or she is to review the establishment's history and consider whether there is a pattern of sanitation issues that could lead to product contamination. 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, cracked rubber seals and gaskets, cracks in equipment). Repeated *Listeria* spp. positive results can also be an indicator of sanitation issues. IPP are to consider whether the establishment's actions were effective in addressing these repetitive issues.

NOTE: If the product became adulterated due to insanitary conditions, such as ceiling condensation dripping on the product, reprocessing to include a subsequent lethality process alone may not be sufficient due to the presence of ceiling particles, dust, dirt, biofilm formation, and other contaminants. Other hazards, such as chemical and physical hazards, may have been introduced by the insanitary condition and need to be addressed by the establishment as part of corrective actions.

If IPP have concerns that the establishment's food safety system may be inadequate to control *Lm* 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, in correlation with the Recall Management and Technical Analysis Division (RMTAD), according to [FSIS Directive 8,080.1, Recall of Meat and Poultry Products](#). The DO is also to determine whether other actions, such as a Public Health Risk Evaluation (PHRE; [FSIS Directive 5,100.4, Enforcement, Investigations, and Analysis Officer \(EIAO\) Public Health Risk Evaluation \(PHRE\) Methodology](#)) should be scheduled and performed. As part of the PHRE, Intensified Verification Testing (IVT; [FSIS Directive 10,300.1, IVT Protocol for Sampling of Product, Food Contact Surfaces, and Environmental Surfaces for *Lm*](#)) may be recommended.

V. VERIFYING COMPLIANCE WITH HACCP REQUIREMENTS

A. IPP are to verify that RTE establishments meet HACCP regulatory requirements by following the HACCP Verification Task instructions in [FSIS Directive 5,000.1](#). When conducting a Hazard Analysis Verification (HAV) Task, IPP are to follow [FSIS Directive 5,000.6, Performance of the Hazard Analysis Verification Task](#). More information on specific questions to consider when verifying HACCP requirements can be found in [IPP Help](#), *RTE Verification Job Aids*.

B. HACCP Verification Task: Each HACCP Verification Task has two components, a recordkeeping component and a review and observation component.

1. 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 the support meets the requirements of the *Listeria* Rule.
 - a. For not post-lethality exposed (i.e., cook-in-bag product; *sous vide* is a type of cook-in-bag) IPP are to verify that the establishment:
 - i. Includes the cook-in-bag step in the flow chart and hazard analysis according to [9 CFR 417.2\(a\)\(2\)](#); and
 - ii. Ensures that the cooking bag is completely sealed (impermeable) so that moisture is contained within the bag or contaminants do not enter the bag. Cooking bags may be compromised during steps such as molding or shaping. The establishment must support that any hazards associated with the cook-in-bag process are addressed. Establishments may have a process to verify package integrity, and if leakers are observed, they may reprocess or recook the product.

EXAMPLE: In 2018, two listeriosis outbreaks occurred associated with cook-in-bag products where the establishments' practices were related to incorrectly classifying products as not post-lethality exposed. After analysis and observation of the establishments' practices, FSIS determined that the products were not sealed to prevent post-lethality contamination. One establishment was using a plastic wrap to cover the product, but not sealing it. Another establishment was damaging the package integrity during molding and shaping, so the products at both establishments were post-lethality exposed.

2. When performing the recordkeeping component of the HACCP Verification Task, IPP are to review the establishment's records associated with its sampling and testing program as described in [Chapter III, Section II, Verifying the Execution of the Establishment's Sampling and Testing Program](#).
3. When performing the observation component of the HACCP Verification Task, IPP are to verify that the establishment is collecting the samples at the frequency stated in its *Lm* Control Program and is using proper sampling techniques (as described in [Chapter III, FSIS Verification of Establishment Sampling and Testing Programs](#)). For not post-lethality exposed (e.g., cook-in-bag) product, IPP are to verify through observation that the establishment maintains the integrity of the product container (the sealed bag).

VI. HAZARD ANALYSIS VERIFICATION (HAV)

A. When performing the HAV task as described in [FSIS Directive 5,000.6](#) in an RTE establishment, IPP are to follow steps in the directive to evaluate the design of the establishment's hazard analysis and HACCP plan. The following steps describe additional information for IPP verification when performing the HAV task.

B. Step 1: When reviewing the establishment's flowchart ([9 CFR 417.2\(a\)\(2\)](#)), 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 considered all possible hazards from the addition of the ingredients in its hazard analysis.

C. 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*, such as those at the receiving step for RTE source materials (RTE meat and poultry) and ingredients. The flowchart or hazard analysis must also identify 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) as described in [Chapter I, Section IV, Background](#).

D. 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 critical control points (CCP) to control the hazard in its HACCP plan (e.g., PLT).

E. Step 4: If the establishment determines that *Lm* is not a hazard reasonably likely to occur in its product because a prerequisite program prevents it, IPP are to verify that the establishment includes the program and the results of the program in the documentation that is required to be maintained under [9 CFR 417.5](#), in accordance with [9 CFR 430.4\(c\)\(6\)](#).

1. If the establishment uses a testing program as a prerequisite program, IPP are to evaluate the design of the program considering the information in [Chapter III, Section II, Verifying the Execution of the Establishment's Sampling and Testing Program](#).
2. If IPP find that the establishment is not collecting samples at the frequency it has stated or find other sampling program deficiencies, 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 result in enforcement action ([FSIS Directive 5,000.1](#)).

F. Step 5: When reviewing the establishment's other supporting documentation (e.g., for product sampling or non-FCS sampling programs), IPP are to determine whether the establishment has referenced the sampling program and its results 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.

G. Step 6: When verifying an establishment's validation for its PLT, IPP are to determine whether the establishment can support the effectiveness of its process in reducing or eliminating *Lm*, in accordance with [9 CFR 430.4\(b\)\(1\)\(i\)](#) and [\(b\)\(2\)\(ii\)](#). Establishments must validate the effectiveness of the PLT. FSIS recommends the PLT achieve at least a 1-log reduction of *Lm* before the product leaves the establishment.

1. Under [9 CFR 417.4\(a\)\(1\)](#), establishments are required to assemble two types of supporting documentation to demonstrate a HACCP system has been validated:
 - a. The scientific or technical support for the HACCP system (design). This consists of scientific and technical documentation that demonstrates that the designed process can control the identified hazard. In other words, scientific support that the HACCP plan should work in theory.
 - b. 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, data that shows the plan works in practice.
2. 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 [FSIS Directive 5,000.1](#).

H. Step 7: When verifying the reassessment requirements in an RTE establishment, if an unforeseen hazard ([9 CFR 417.3\(b\)](#)) occurs, such as positive test results for *Lm* or *Listeria* spp. in product or on FCS, IPP are to determine whether the establishment has reassessed its HACCP plan. IPP are to follow instructions in [FSIS Directive 5,000.1](#) if the establishment fails to reassess.

VII. VERIFYING LABELING OF RTE PRODUCTS

A. When performing a General Labeling Verification task according to [FSIS Directive 7,221.1](#), *Prior Labeling Approval*, 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. IPP are to verify that the establishment's label record includes a sketch approval from FSIS Labeling and Program Delivery Staff (LPDS). If the establishment does not have adequate data to support its claim, IPP are to issue an NR (cite [9 CFR 430.4\(e\)](#) and [417.5\(a\)\(1\)](#)). If the establishment does not have sketch approval, IPP are to issue an NR (cite [9 CFR 412.1](#)).

C. In addition, if the establishment labels the product as RTE, IPP are to review the establishment's supporting documentation according to [FSIS Directive 7,111.1](#), *Verification Procedures for Lethality and Stabilization*. IPP are to determine whether the establishment's supporting documentation demonstrates that the product has met the requirements in [9 CFR 318.17](#), [318.23](#), or [381.150](#) or undergone other processing to render it RTE and support decisions made in the hazard analysis ([9 CFR 417.5\(a\)\(1\)](#)). If IPP have questions about the establishment's supporting documentation, they are to submit them to [askFSIS](#), following the instructions in [Chapter IV, Questions](#).

NOTE: Establishments may use alternative means of achieving lethality if they can support the effectiveness of their process. See [FSIS Directive 7,111.1](#) for more information.

CHAPTER III – FSIS VERIFICATION OF ESTABLISHMENT SAMPLING AND TESTING PROGRAMS

I. VERIFYING THE DESIGN OF THE ESTABLISHMENT'S SAMPLING AND TESTING PROGRAM

A. When performing the HAV task, IPP are to verify the adequacy of the design of the establishment's sampling and testing programs. If the establishment's program is in a Sanitation SOP, prerequisite program, or the HACCP plan, IPP are to review the adequacy of the design when conducting a HAV task as described in [Chapter II, Section VI, Hazard Analysis Verification \(HAV\)](#).

B. Establishments using Alternative 2b and 3 are required to sample FCS in the post-lethality exposed processing environment to ensure that the surfaces are sanitary and free of *Lm* or indicator organisms.

1. A food contact surface (FCS) is any surface that may come in direct contact with exposed meat or poultry product. Examples include conveyor belts, tabletops, gloves, slicers, slicer blades, saw blades, augers, and stuffers.
2. Under [9 CFR 430.4\(b\)\(2\)\(iii\)\(D\) and \(b\)\(3\)\(i\)\(D\)](#), the establishment is to identify all possible post-lethality FCSs for sampling.

C. An establishment may sample for *Lm* or an indicator organism (e.g., *Listeria* spp.) to verify the effectiveness of its sanitation program. The establishment is not required to perform further confirmatory testing on *Listeria* spp. positives to determine whether they are positive for *Lm*.

D. IPP are to consider the following:

1. Has the establishment identified all possible post-lethality FCSs as part of its sampling program? The establishment is required to identify all possible post-lethality FCSs; however, the establishment is not required to sample them at the same frequency. The establishment may sample the sites based on risk, although all sites should be sampled over time. If the establishment has not identified all possible FCSs for sampling, can the establishment provide supporting documentation to show why the product or FCS would not be contaminated? If the establishment has not identified all possible FCSs 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 \(b\)\(3\)\(i\)\(A\)](#) and IPP are to issue an NR.
2. Has the establishment identified the sample size for the FCS samples to be collected? If the establishment has not identified the sample size or cannot support why the sample size selected is representative of the equipment or other FCS, then the establishment would not be in compliance with [9 CFR 430.4\(b\)\(2\)\(iii\)\(D\) and \(b\)\(3\)\(i\)\(D\)](#) and IPP are to issue an NR.
3. Has the establishment identified the sampling frequency (e.g., 3-5 samples per month per line) and the number of samples to collect routinely? If so, has the establishment included a justification of why the sampling frequency is sufficient to ensure that effective control of *Lm* or *Listeria* spp. is maintained? If the establishment has not identified a sampling frequency and number of samples, or cannot justify why the sampling frequency is sufficient, the establishment 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 a line refers to the flow of a product during production. This includes all 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.

4. If the establishment uses Alternative 2b or 3 (e.g., non-deli or non-hot dog producer), does the establishment identify conditions under which it will hold and test the product following a positive test of an FCS for *Listeria* spp.? If the establishment has not identified when it will hold and test the product, the establishment would not be in compliance with [9 CFR 430.4\(b\)\(2\)\(iii\)\(B\) or \(b\)\(3\)\(B\)](#) and IPP are to issue an NR.
5. If the establishment uses Alternative 3 (e.g., deli or hot dog producer), does the establishment include the following as part of its sampling program design?
 - a. Follow-up sampling to include a targeted sample of the specific FCS that tested positive, as well as additional FCS samples in the surrounding area as necessary to ensure the effectiveness of the establishment's corrective actions. If the establishment does not include follow-up sampling as part of the sampling program, the establishment would not be in compliance with [9 CFR 430.4\(b\)\(3\)\(ii\)\(A\)](#) and IPP are to issue an NR.

NOTE: Establishments conducting follow-up sampling should consider designing the sampling to identify the source of the *Lm* to target cleaning and sanitation procedures to eliminate harborage, which may be at a point in the process upstream of the previous FCS positive.

- b. Provisions for holding product that may have been contaminated if a second positive result is obtained during the follow-up sampling. The establishment would hold the product until after the problem is corrected. If the establishment does not include provisions for holding the product as part of its sampling program, the establishment would not be in compliance with [9 CFR 430.4\(b\)\(3\)\(ii\)\(B\)](#) and IPP are to issue an NR.
- c. Testing the held product for *Lm* or *Listeria* spp. using a sampling method and frequency that provides statistical confidence that each lot is not adulterated (e.g., the International Commission on Microbiological Specifications for Foods (ICMSF) sampling plans for *Lm*). If the establishment does not include testing the held product as part of the sampling program, the establishment would not be in compliance with [9 CFR 430.4\(b\)\(3\)\(ii\)\(C\)](#) and IPP are to issue an NR.

II. VERIFYING THE EXECUTION OF THE ESTABLISHMENT'S SAMPLING AND TESTING PROGRAM

A. IPP are to verify the execution of the establishment's sampling and testing program is adequate and that the establishment follows the written program when conducting a Sanitation SOP Operational Sanitation task (if the establishment's sampling program is included in its Sanitation SOP) or when conducting the HACCP Verification Task (if the establishment's sampling program is included in its HACCP plan or other prerequisite program).

B. IPP are to consider the following:

1. Is the establishment following its sampling program, including meeting the sampling frequency and collecting the number of FCS samples identified in the sampling program? If the establishment has stated that it will collect a certain number of samples at a particular frequency (e.g., monthly), and did not collect the samples, can the establishment support why the sampling frequency is sufficient to ensure control of *Lm* or an indicator organism? If the establishment did not collect the stated number of samples or follow the frequency identified, and cannot support why the number of samples or the sampling frequency is sufficient, then the establishment 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: Establishments are not required to collect samples in the weeks or months when they are not producing post-lethality exposed RTE product.

2. As described in the establishment's sampling plan, does the establishment increase its sampling frequency or collect additional samples in response to events that could increase the probability of product positives (e.g., construction, roof leaks, condensation, or equipment breakdowns)? If the establishment did not increase the sampling frequency or collect additional samples, and cannot support the sampling frequency because of the change in risk, the establishment may not be in compliance with [9 CFR 430.4\(b\)\(2\)\(iii\)\(E\) or \(b\)\(3\)\(i\)\(E\)](#) and IPP are to discuss with their supervisor, and if additional help is needed, submit questions through [askFSIS](#).

NOTE: FSIS recommends that establishments also conduct intensified sampling and intensified cleaning and sanitation if there is an increase in risk (e.g., construction occurring at the facility) or an unforeseen hazard.

3. Is the establishment collecting FCS 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 FCS 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 represent routine processing conditions, the establishment would not be able to demonstrate that the FCS are sanitary and free of *Lm* and would not be in compliance with [9 CFR 430.4\(b\)\(2\)\(iii\)\(A\) or \(b\)\(3\)\(i\)\(A\)](#) and IPP are to issue an NR.
4. Are the establishment's sampling or testing methods sufficient to detect low levels of *Listeria* in the environment? To determine this, IPP are to consider the following:
 - a. Is the establishment following the manufacturer's instructions when collecting the samples? If not, the sampling method may not be sensitive enough 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.
 - b. Does the establishment store the samples under refrigeration temperatures before analysis, and are samples shipped refrigerated to the laboratory? 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 the surfaces are free of *Lm*. IPP are to be aware that FSIS recommends that the establishment ship the samples in insulated shipping containers under refrigeration conditions and initiate laboratory testing within 2-3 days after sample collection. This is not a regulatory requirement.
 - 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 the FCS 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, the establishment may not be able to support that surfaces are sanitary and free of *Lm*.

NOTE: If IPP find that the establishment is not meeting the criteria above, the finding does not automatically mean there is a noncompliance. IPP are to consider all available information at the establishment to determine whether the findings regarding the establishment's sampling and testing programs could lead to noncompliance. If IPP have questions about an establishment's testing method, they are to discuss with their supervisor, and if additional help is needed, submit questions through [askFSIS](#).

III. VERIFYING CORRECTIVE ACTIONS IN RESPONSE TO POSITIVE RESULTS FROM

ESTABLISHMENT FOOD CONTACT SURFACE SAMPLING

A. *Listeria* Species Establishment FCS Testing: IPP are to verify corrective action in response to a positive result using the appropriate task based on how the establishment has incorporated its procedures in its HACCP system to address *Lm* (i.e., HACCP or Sanitation SOP task as outlined in [FSIS Directive 5.000.1](#)).

B. IPP are to be aware that if an establishment chooses to test for *Listeria* spp., a finding of *Listeria* spp. on an FCS, indicates conditions where *Lm* may be present, but the product is not considered adulterated. IPP are to be aware that repeated *Listeria* spp. positives on FCS, non-FCS, or product indicate positive *Listeria* trends in the establishment. The finding of *Listeria* trends could indicate that the establishment's *Listeria* control program is not effective in controlling the presence of *Lm* in the establishment's post-lethality processing environment.

C. If the establishment finds an FCS positive for *Listeria* spp. and product passed over the surface, IPP are to verify the following:

1. For establishments using Alternative 3 (e.g., deli or hot dog producers), verify the effectiveness of the corrective actions by determining whether the establishment:
 - a. Collected follow-up samples according to [9 CFR 430.4\(3\)\(ii\)\(A\)](#);
 - b. Held the product that may have been contaminated, if a second positive result was obtained during the follow-up sampling, until the problem was corrected according to [9 CFR 430.4\(b\)\(3\)\(ii\)\(B\)](#); and
 - c. Tested the held product for *Lm* or an indicator organism 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\(b\)\(3\)\(ii\)\(C\)](#).
2. For establishments using Alternatives 2b and 3 (non-deli or non-hot dog producers), verify the establishment took corrective actions to address the *Listeria* spp. positive result in accordance with [9 CFR 417.3](#) or [416.15](#). When evaluating the corrective actions taken by the establishment, IPP are to verify if the establishment:
 - a. Performed and documented intensified sanitation procedures in response to positive results;
 - b. Collected additional samples or increased its sampling frequency; and
 - c. Reviewed its sanitation program to identify any sanitation deficiencies that could have led to the positive results and made changes to correct any deficiencies.

NOTE: The above instructions also apply to establishments in Alternatives 1 and 2a that voluntarily test for *Listeria* spp. on FCS.

3. For all alternatives, if the *Listeria* control measures were included in a prerequisite program, IPP are to verify that the establishment reassessed the HACCP plan as part of corrective actions. Alternatively, if the *Listeria* control measures were included in the Sanitation SOP, IPP are to verify that the establishment re-evaluated and modified the Sanitation SOP.

D. *Listeria monocytogenes* Establishment FCS Testing: If the establishment chooses to test for *Lm* and finds an FCS positive and product passed over the surface, the product is considered adulterated. As part of verifying the establishment's corrective actions, IPP are to review the establishment's testing

results as described in [FSIS Directive 5,000.2](#). 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 FCS, non-FCS, or product samples over time were not resolved by routine cleaning and sanitation).

1. If positive *Listeria* trends are found, IPP are to determine whether the establishment addressed the positive results by taking targeted and effective 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).
2. If IPP find that the establishment is not adequately addressing continued findings of *Lm* positives, indicating that the corrective actions are ineffective to control *Lm*, IPP are to contact their DO through supervisory channels. The DO is to determine whether a request for a PHRE is warranted along with IVT sampling at the establishment according to [FSIS Directive 5,100.4](#) and [FSIS Directive 10,300.1](#). Additional product samples may also be collected at the establishment.
3. 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.

E. IPP are to issue an NR if the establishment did not take corrective actions, as required by:

1. [9 CFR 417.3\(a\)](#), if its *Listeria* control measures are included in the HACCP plan as a CCP because the establishment has determined that *Lm* is RLTO;
2. [9 CFR 417.3\(b\)](#) if its *Listeria* control measures are included in a prerequisite program (other than the Sanitation SOP) because the establishment has determined that *Lm* is NRLTO. IPP are to issue an NR if the establishment did not take corrective actions, including if the establishment did not perform or obtain reassessment per 9 CFR 417.3(b)(4), to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan; or
3. [9 CFR 416.15](#) and [9 CFR 417.3\(b\)](#), if its *Listeria* control measures are incorporated in the Sanitation SOP because the establishment has determined that *Lm* is NRLTO. IPP are to issue an NR if the establishment did not take corrective actions, including if the establishment did not perform or obtain reassessment per 9 CFR 417.3(b)(4), to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

F. 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\(3\)\(ii\)\(A\)](#).

IV. FSIS ACTIONS AFTER A POSITIVE ESTABLISHMENT PRODUCT OR ENVIRONMENTAL SAMPLING RESULT

A. Product Testing: IPP are to be aware that there is no regulatory requirement for establishments to routinely test product samples, but if the establishment does test the RTE product and it tests *Lm* positive, the product is adulterated.

B. IPP are to:

1. Verify that the establishment takes corrective actions for the product 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;

- a. If the establishment receives a *Listeria* spp. positive test result and IPP discover this result while performing a HACCP Verification task or Sanitation SOP task (depending on whether the program is included as a CCP, in a prerequisite program, or in a Sanitation SOP), IPP are to confirm corrective actions were taken by the establishment.
 - b. If the establishment informs IPP of *Listeria* spp. positive test results, IPP are to confirm corrective actions using a scheduled HACCP Verification task or Sanitation SOP task if they have one scheduled for that day. Alternatively, if no HACCP Verification task or Sanitation SOP task is scheduled for that day, IPP are to schedule a directed HACCP Verification task or Sanitation SOP task to confirm the establishment's corrective actions.
 - c. If the establishment tests for *Lm* and receives positive *Lm* product results, IPP are to confirm [9 CFR 417.3\(a\)](#) corrective actions using a scheduled HACCP Verification task or if no HACCP Verification task is scheduled for that day, IPP are to schedule a directed HACCP Verification task to confirm the establishment's corrective actions. If the establishment's testing program is in the Sanitation SOP and they have a product positive for *Lm*, then IPP are to verify [9 CFR 417.3\(b\)](#) corrective actions for an unforeseen hazard through a scheduled or directed HACCP verification task.
2. Contact the District Recall Officer (DRO) through supervisory channels following the instructions in [FSIS Directive 8,080.1](#) if adulterated product from the sampled lot has entered commerce. If the product has been shipped into commerce, and the establishment does not provide supporting documentation demonstrating that the product is not adulterated with *Lm*, IPP are to contact the DRO. FSIS may recommend a recall if the products are adulterated by being prepared, packed, or held under insanitary conditions and have been shipped and remain available in commerce. If the product is still at the establishment, IPP are to contact the DO through supervisory channels 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 discuss with their supervisor, and if additional help is needed, submit questions through [askFSIS](#).
 3. If a product tests positive for *Listeria* spp., FSIS may determine that the product is adulterated because the product was produced under insanitary conditions or the establishment cannot demonstrate the product is not positive for *Lm*. A finding of *Listeria* spp. in the product can indicate that the Sanitation SOP is inadequate or that corrective actions taken in response to a previous sanitation failure may not be effective to prevent product contamination.
 - a. IPP are to review the establishment's documentation in response to the positive *Listeria* spp. 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 documentation showing that the product has been reprocessed using a process validated to achieve at least a 5-log reduction in *Lm*.
 - b. If the establishment reprocesses the product due to a positive test result, 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.
 - c. For cooked products, establishments may use the time-temperature tables in the [FSIS Cooking Guideline for Meat and Poultry Products \(Revised Appendix A\)](#) to recook the product. For more information on verifying product disposition, see [FSIS Directive 10,240.3](#), *FSIS Ready-to-Eat Sampling Programs*, Chapter V. If the product is dried before cooking, it would not be appropriate to recook the product multiple times using the

[FSIS Cooking Guideline for Meat and Poultry Products \(Revised Appendix A\)](#) as support for the process. For dried products that are cooked multiple times, the establishment would need to provide additional scientific support for the cooking process.

- d. 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, or *Listeria* may be present in the environment, that could lead to contamination of the product with *Lm*. IPP are to review the establishment's sanitation records, IPP observations of insanitary conditions, 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 supervisory channels to determine whether a PHRE and IVT are warranted at the establishment.

C. Environmental Testing: IPP are to be aware that there is no regulatory requirement for non-FCS 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:

1. Determine whether insanitary conditions exist that could cause the product to become adulterated;

EXAMPLE: A drain tests positive for *Lm* and IPP observe an establishment employee spraying a high-pressure hose in the drain. Water droplets from overspray land 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 and retention of product (cite [9 CFR 416.4\(b\)](#), [430.4\(b\)](#), and [430.4\(c\)\(3\)](#)). The drain positive result alone, without any further observations of conditions that could lead to insanitary conditions, would not warrant the issuance of an NR.

2. Verify that the establishment takes appropriate corrective action as specified in its program. IPP are to issue an NR if the establishment did not take corrective actions, as required by:
 - a. [9 CFR 417.3\(a\)](#), if its environmental sampling is included in the HACCP plan;
 - b. [9 CFR 417.3\(b\)](#) if its environmental sampling is included in a prerequisite program other than the Sanitation SOP; or
 - c. [9 CFR 416.15](#) and [9 CFR 417.3\(b\)](#), if its environmental sampling is incorporated in the Sanitation SOP.
3. 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 follow the instructions in [FSIS Directive 5.000.1](#) to apply the GAD methodology and determine what regulation is noncompliant.

CHAPTER IV – QUESTIONS

Refer questions regarding this directive to your supervisor or as needed to the Office of Policy and Program Development through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, complete the [web form](#) and select “**Sampling**” for the Inquiry Type.

NOTE: Refer to [FSIS Directive 5,620.1](#), *Using askFSIS*, for additional information on submitting questions.

A handwritten signature in black ink, reading "Rachel A. Edelstein". The signature is written in a cursive, flowing style.

Assistant Administrator
Office of Policy and Program Development