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

FSIS DIRECTIVE

5500.1 | 10-11-01

Conducting Targeted In-Depth Verification Reviews

I. PURPOSE

What is the purpose of this directive?

This directive describes FSIS' In-Depth Verification (IDV) reviews. It explains what an IDV review is, the procedures for performing **targeted** IDV reviews, how an IDV review team is formed, the team's responsibilities, and the components and purpose of an IDV report. This directive also provides a specific set of procedures to be followed when reviews are being performed because an establishment has failed two consecutive *Salmonella* performance standard sets.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

9 CFR Part 416, 417, 500

FSIS Directives 5000.1 and 5400.5

V. BACKGROUND

A. What is an FSIS IDV review?

1. An IDV review is an assessment as to whether an establishment is carrying out activities that meet the requirements of the Pathogen Reduction/HACCP (PR/HACCP) final rule, published July 25, 1996. The IDV review is one of several tools that enable FSIS personnel to judge the level of compliance in individual establishments.

2. At present, in-plant inspection program personnel use the Basic Compliance Checklists for HACCP Systems, Sanitation SOPs, and generic *E. coli* testing to determine whether establishments meet minimum regulatory requirements. In-plant inspection program personnel also perform PBIS HACCP 01 and 02 procedures, as

described in FSIS Directive 5400.5, on selected HACCP system features or the entire system to determine whether the system is functioning as planned and is having its intended effect. In-plant inspection program personnel take samples from carcasses or ground products and send them to FSIS laboratories for *Salmonella* analyses. The results indicate whether the establishment is meeting the pathogen reduction performance standards for these raw products, and whether the HACCP system is accomplishing its pathogen reduction purposes. In-plant inspection program personnel also take samples of ready-to-eat (RTE) products to verify that the establishment's HACCP system is effectively controlling the pathogens of concern in these products.

3. IDV reviews supplement these existing verification tools and address, in a more rigorous and integrated manner, the technical and scientific merit of an establishment's HACCP system. The IDV review is not designed, and will not be used, to assess any aspect of the performance of inspection program personnel.

4. IDV reviews will be conducted by multi-disciplinary teams or by individuals but will not be done by the establishment's in-plant inspection program personnel or their immediate supervisor.

VI. The Components of the IDV review

A. Is the IDV review an audit?

The IDV review is not an audit, although it is designed to incorporate some features of audits, including:

1. The IDV review is conducted over a specific period of time by a team or an individual not involved with inspecting the plant. It results in a carefully and accurately presented account of the non-conformances identified in the establishment's system. Determinations of non-conformance are based on established regulatory, technical, and scientific standards with which team members are thoroughly familiar;

2. The IDV review will include entrance and exit conferences with the establishment. At or slightly before the entrance conference, the establishment will be provided with a copy of the IDV review checklists so that it can begin to assemble and organize its documents. The exit conference will include an oral report by the team to the establishment of the team's observations and findings.

3. The IDV report prepared by the team consists principally of team members' findings based on **observations** of nonconformance with regulatory, technical, and scientific standards. Finally, the IDV report may include other factual information necessary to understand the establishment 's situation.

B. What instruments are used in conducting IDV reviews?

The IDV review Protocol consists of two sets of information gathering instruments: Attachment 1 addresses the Sanitation Standard Operating Procedures (Sanitation SOPs) and HACCP systems; Attachment 2 addresses Pathogen Reduction activities and their outcomes.

1. Attachment 1 consists of 10 separate checklists, each focusing on one of the elements of HACCP or the Sanitation SOPs. Each checklist has a Documents review and a Systems review section. At the beginning of each checklist, there are both regulatory citations and references to the technical/scientific measures of adequacy that are the standards against which establishment performance is judged.

2. Attachment 2 consists of three forms designed to record and analyze microbial data that provide insight into pathogen reduction efforts and accomplishments in the establishment.

3. Attachment 1 checklists may be used as a complete set, or a subset may be used in cases where certain aspects of an establishment's activities are to be targeted. For example, it may be decided by Field Operations (FO) and the team to focus the review on reassessment efforts and only use the reassessment checklist; or the team may decide to use several checklists but to apply them to only one product or one process category that is of particular concern. The Documents review portions of the checklists may be used without proceeding with the Systems review portions. Attachment 2 forms may be used in conjunction with Attachment 1 or independently. The team should not alter the checklists.

VII. Conducting IDVs

A. How will the Agency decide when to perform IDV reviews?

1. IDV reviews will be either targeted or random.

2. FSIS will perform targeted IDV reviews when problems are identified within an establishment, and these problems persist in spite of repeated efforts by the in-plant inspection program personnel to secure appropriate and effective company responses and actions. There are other circumstances that could suggest the need for a targeted IDV review:

a. before the Agency makes a decision on instituting proceedings for the withdrawal of inspection;

b. after the Technical Assessment Group (TAG) has requested specific information from an establishment in order to determine regulatory compliance and the

TAG needs to know whether the information is accurate, and whether the HACCP outcome has been achieved;

c. if the company's products have been repeatedly implicated in recalls or illnesses, or when the Agency testing has found repeated RTE product positive results; or

d. because of a general policy decision, such as the decision to perform IDV reviews in all slaughter or processing establishments that have failed two consecutive *Salmonella* sample sets.

3. FSIS will also perform IDV reviews on a random basis, after the Agency has established a full complement of trained FSIS personnel. All establishments will be subject to such a review within a 5-year time frame.
(**Note:** This document focuses on the conduct of targeted reviews.)

B. What steps will the Agency use to initiate a targeted IDV review?

1. On a case-by-case basis, FO personnel will recommend targeted IDV reviews. District Managers (DM) who believe that an establishment in their jurisdiction should be the subject of a targeted review will describe the situation in the establishment and furnish this information to the Assistant Deputy Administrator (ADA) for District Inspection Operations. FSIS will consider the facts surrounding the DM recommendation as well as available resources in determining whether there will be an IDV review, and whether it will be a comprehensive or a limited IDV review.

2. At the beginning of each quarter, the designated FO ADA will confer with other FO leadership and then convene the Deputy Administrators and Associates who will establish priorities and a rough schedule for the IDV reviews that FO has decided are needed. Such prioritizing and scheduling will permit the programs whose participation is expected in the IDV reviews to identify and plan for their participation in an orderly manner. The Office of Public Health and Science (OPHS) and the Office of Policy, Program Development and Evaluation (OPPDE) will supply technical experts to participate in targeted IDV reviews.

VIII. The IDV team

A. What is the expected team composition for a targeted IDV review, and what skills and competencies should be included?

1. Teams will usually include FSIS personnel with the following expertise:

a. a person with experience and expertise in synthesizing scientific and technical judgments about HACCP with regulatory enforcement protocols as they are applied in inspected establishments (frequently, this person is the Inspection Coordinator (IC) in the DO);

b. a person with experience and expertise in documenting in-plant findings and explaining them and their significance in plain language (this person is expected to be from FO);

c. persons with scientific or technical credentials and experience relevant to the processes performed and under review in the subject establishment (these persons should be from OPHS or OPPDE);

d. a person with expertise in interpreting FSIS regulations, directives, notices, and guidance material, and recognizing issues that present novel policy questions requiring further development.

2. FSIS expects that IDV review team members will receive training that includes appropriate auditing and analytic techniques as well as report writing skills.

(**Note:** Sometimes the team may need to include several people to ensure that there is relevant scientific, technical, and policy experience. In other cases, one person may be able to fill multiple roles. In forming teams, FSIS will take care to ensure representation from all relevant Agency program areas. FSIS will also avoid an overly large team that may be difficult to manage and disruptive to establishment activities. FSIS will not use targeted IDV reviews for training purposes.)

B. How will the team operate before, during, and after the on-site visit?

The Deputy Director of the TSC will determine team membership by using lists of potential participants supplied by OPPDE, OPHS, and FO. In forming a team, FO may consult with any program area about the availability or special expertise of specific individuals. FO will designate a team leader (TL). In most cases the TL will be the DO representative. The Deputy Director of the TSC will notify the TL, and he or she will assume leadership of the effort at that time.

C. What are the TL's responsibilities?

1. If the TL is the DO's representative, he or she will assist in start-up of the review. The TL will facilitate accommodation arrangements, identify and secure an appropriate workspace for the team, notify the subject establishment of the IDV review, and provide the establishment with advance copies of checklists and procedures. (**Note**: If the DO's representative is not the TL, someone from the DO will need to perform these tasks. When making these arrangements, local conditions, including the establishment's size and resources will need to be considered.)

2. The TL will lead and manage the team from the time of its identification as a team through the development and delivery of the IDV report.

3. The TL will engage the cooperation and collaboration of local in-plant inspection program personnel, without drawing them into the IDV review, by requesting their assistance in an initial walk-through of the establishment to familiarize the team

with the operation and layout. (**Note:** The TL will promptly refer to local personnel any team observations that might involve immediate food safety problems. In-plant inspection program personnel are expected to take any necessary actions)

4. The TL will correlate with all members of the team about their understanding of the technical, scientific, and regulatory standards against which establishment activities are to be measured.

5. If the IDV does not involve all operations in the establishment, the TL will determine and define the scope of the review. During the course of the review, the TL may change the scope of the review. For example, if the team determines that a fundamental requirement, such as conducting the hazard analysis and identifying critical control points (CCPs) for all "food safety hazards reasonably likely to occur," has not been met, the TL should terminate the IDV review and inform the establishment, as well as the DM, of this determination and its basis.

6. The TL will make assignments for performing various aspects of the IDV review, taking into account the expertise of individual team members and the sensitivity of the review. Wherever possible, more than one person should be involved in the review and in the analysis of documents or activities.

7. The TL will hold team meetings as necessary during the course of the IDV review to ensure that work is proceeding on time and on target.

8. The TL will serve as, or designate a single person to serve as, the team's contact with the establishment regarding follow-up questions, requests for further information, etc., during the course of the review. All individual team member requests should go through the TL.

9. The TL will schedule and lead the exit meeting with the establishment.

10. The TL will ensure that the draft team report is finished within one week of completing the on-site review, and that the report is submitted to team members and the DM, plus the DAs of OPPDE, FO, and OPHS. The TL is not expected to write the report alone. All team members should contribute, and members with skills in documentation should be major contributors.

D. What are the team members' responsibilities?

1. The team will be fully available for this priority effort by ensuring that their routine/on-going assignments have been delegated to colleagues for the relevant time period.

2. The team will study, in advance, the checklists and the reference materials that define the benchmarks. This will prepare team members to perform the review efficiently and effectively.

3. The team will bring with them technological tools, such as portable computers, that will enable them to record their observations and perform data analyses.

4. The team will bring or have ready access to any information pertaining to the subject establishment that is important to their areas of expertise.

5. The team will be skilled in objective reporting of facts without making judgments. Team members are expected to provide factual descriptions of what they read in documents or of what they observe in operations. Team members should not formulate judgments in circumstances where only facts are necessary.

6. The team will assist in writing the report within specified time frames.

IX. The IDV review report

A. What are the key characteristics of a good IDV report?

1. Good IDV reports are clear and understandable to a general audience, including attorneys, consumer groups, and the interested public. Many people who will review and use the report will not have extensive technical or scientific experience and education. This means that the report must both communicate the technical and scientific findings and provide insightful analysis that supports their significance. The report should be written in a way that will be useful both to the Agency in deciding what follow-up action with respect to the establishment is necessary and appropriate and to an establishment that wants to use the report as a basis for improving its design and execution of HACCP systems and Sanitation SOPs.

2. Good IDV reports are concise and present findings supported with factual observations. Such reports do not speculate about what might have happened or what might have been the thinking of establishment management or personnel.

3. Good IDV reports present scientific and technical analyses that explain why observations rise to the level of findings. These scientific and technical discussions are framed within the principles of HACCP, as articulated in FSIS regulatory requirements.

4. Good IDV reports contain regulatory citations from the checklists but do not rely on extensive quotations from the regulations or Agency Directives and Notices. This scientific and technical emphasis is appropriate because the Agency has other verification tools to address regulatory compliance. Personal interpretations of regulatory requirements are not appropriate.

B. How will the Agency review and use IDV reports?

1. After the IDV review team has formulated its report, the report will be submitted to the DM. The DM will direct the IC to analyze the report and make recommendations about how to proceed with the establishment based on the report's findings. In performing this analysis, the IC should draw on the following resources as

necessary: the IDV review team itself; scientific and technical experts; regulatory and policy experts; and colleagues who might have had experience in performing such analyses.

2. There are various possible outcomes of IC analysis:

a. when the targeted IDV was performed to determine whether selected information indicates that the establishment meets regulatory requirements, IC analysis may confirm that the establishment does meet the requirements or does not meet the requirements;

b. when a targeted IDV was performed because an establishment has multiple, continuing findings of pathogens in RTE products, and such products are implicated in illnesses, IC analysis may develop relationships between in-plant occurrences and RTE product failures;

c. when the targeted IDV was performed for almost any purpose, IC analysis may define issues other than those on which the IDV was focused or, more rarely, may even uncover instances of basic non-compliance;

d. because the potential outcomes of IC analysis are so many and varied, the potential significance of the findings of the IDV will also vary. The Agency may decide, based on the findings, that any of a variety of approaches are in order, from no further action to beginning an action to withdraw inspection. However, establishments generally should be given the opportunity to let their HACCP systems work before FSIS acts.

e. FSIS generally will give the establishment an opportunity to reassess its HACCP plan within a specific timeframe in which this reassessment and any consequent actions are to be accomplished. If the reassessment and consequent actions result in a HACCP system that appears to be adequate, the changes made by the establishment may be described in an addendum to the IDV report that is included as part of the report that is made final, publicly available, and closed.

f. The final IDV reports will be distributed to the DO, TSC, ADADO, OPHS, and OPPDE.

X. IDV reviews and *Salmonella* performance standard verification sets

A. What specific procedures are used in targeted IDVs performed because an establishment has failed two consecutive *Salmonella* performance standard verification sets?

1. The specific procedures to be used in these cases begin with clear notification to the establishment of the second set failure and its consequences, that is:

a. the occurrence of a second consecutive *Salmonella* set failures is rapidly communicated to FO and the establishment by OPHS. The DO receives the Pathogen Reduction Enforcement Program (PREP) Completed Set report;

b. the DO communicates the information from the completed set report to the IIC and prepares a NR that includes a citation to the regulatory requirement (9 CFR 310.25(b)(3)(ii); 381.94(b)(3)(ii)) that an establishment reassess its HACCP plan; and

c. the DO sends a form letter that reiterates this regulatory requirement and gives the establishment information about the Agency's next action and its likely timing.

2. After the establishment has sufficient time to perform the required reassessment, the next Agency activity is the initiation of a targeted IDV review.

3. As in other cases, the DM will receive the team report on the IDV, which contains the team's findings. The DM will have the IC analyze the findings and make recommendations about regulatory outcomes. In targeted IDVs following a second set failure, it is often difficult to determine whether the reassessment that the establishment performed in response to the regulatory requirement has resulted in a HACCP system that is likely to pass the third set. If the IC has any doubt about this outcome, the DM should request that the establishment perform a new reassessment based on the IDV in the 30 days following receipt of the IDV. Most targeted IDVs performed because of two consecutive *Salmonella* set failures have resulted in this type of request. The IC analysis may result in a high level of confidence that the establishment's HACCP system is adequate and likely to be successful in controlling production, so that the next sample set will succeed. In this case, the IDV is transmitted to the establishment, and the third sample set is initiated.

4. The staffing and scope of targeted IDVs that are performed following two *Salmonella* set failures may also be special. The team performing these targeted IDVs may be as few as two people. However, one of them needs to have an understanding of, and experience in, food microbiology sufficient to provide insight about the impact of establishment activities on the prevalence of *Salmonella*. The scope of this IDV may be limited. It may focus on the reassessment checklist only, or it may include several other pertinent checklists but apply them only to some of the establishment's HACCP systems. In this way, available Agency resources can be used to enhance knowledge about which CCPs are successful in controlling this pathogen in various operations.

/s/

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I. S-SOP

Regulatory Standard: 9 CFR 416.11-16
Technical Standards: NACMCF, p. 9, par. 4
Appendix A

A. Documents Review

HACCP principles and Application Guidelines, P. 1248, Prerequisite programs

1. Do S-SOP documents seem to be complete, i.e., to address all likely sources of direct product contamination or adulteration? Make note of potential omissions for follow-up during system review.

2. Do documents reflecting evaluation of the effectiveness of S-SOPs demonstrate careful analysis of relevant data and appropriate conclusions drawn from that data? Note lack of evaluation and instances of poor analysis, weak data or inappropriate conclusions.

B. System Review

1. Does S-SOP implementation match the written plan? Note actual non-conformances.

2. Do employees performing S-SOP tasks carry them out skillfully so they are likely to have their intended effect? Note instances of incomplete or improper execution of planned tasks.

3. Are S-SOP corrective actions performed promptly and skillfully?

4. Are S-SOP records utilized routinely to make system improvements? Is the defined methodology used in practice?

5. Is the production of contaminated or adulterated product prevented by following S-SOPs? Note observed non-conformances.

II. Hazard Analysis

Regulatory Standard: 9 CFR 417.2(a)
417.5(a)(1)
Scientific/technical Measures of Adequacy: NACMCF, P. 1248

A. Documents Review

1. Do documents indicate that the hazard analysis is complete, i.e., that it includes hazards reasonably likely to occur from the raw materials, the process steps, the non-meat materials, the storage and distribution steps?

2. In the collective professional judgement of the team, do documents include hazards reasonably likely to occur from the raw materials, the process steps, the non-meat materials, the storage and distribution steps?

3. Do documents indicate that the hazard analysis has been conducted using the "reasonably like to occur" standard of 417.2(a)?

4. If historical establishment data are indicated as the source of the judgement about whether a food safety hazard is reasonably likely to occur, are the quantity and quality of cited data relevant?

5. Are the conclusions drawn from historical data logical, based on sound analytic principles and appropriate?

6. If other or more general data are indicated as the basis for judgements about whether food safety hazards are reasonably likely to occur, e.g., FSIS Microbiological Baseline studies or surveys, are the cited data relevant and have they been interpreted appropriately? Are the studies provided or cited, as appropriate?

A. System Review

Verify the flow diagram, product and process descriptions. Note any observed non-conformance. If processes or products are different from written documents describing them, review responses above. Note any potential non-conformance and pursue with the establishment further information, which would resolve the issue.

Attachment 1

III. CCP Determination

Regulatory Standard: 9 CFR 417.2 (b)
417.2 (c)
417.5 (a) (2)
Scientific/Technical Measures of Adequacy: NACMCF (Principle 2)
p. 1250

A. Documents Review

1. Do documents indicate that CCP identification is complete? Note potential hazards included in the hazard analysis or indicated by the flow diagram, but not addressed by CCP (s).

2. Do documents indicate any CCPs that, based on reviewer expertise, may not be workable, i.e., practicable? Note potential CCPs identified that, based on reviewer expertise, may not be workable.

A. System Review

1. Are CCPS consistent with the HACCP plan? Note non-conformances.

2. Are they practicable?

3. Are there hazards identified in the hazard analysis where no CCP exists and control at a process step is practicable?

IV. Critical Limits

Regulatory Standard: 9 CFR 417.2 (b) (3)
Scientific/technical Measures of Adequacy: NACMCF (principle 3).

A. Document Review

1. Do documents indicate that CLs reflect all regulatory requirements? Note potential omissions.

2. Do documents indicate that CLs not based on regulatory requirements are based on relevant data, either from the published literature or from studies done specific to the plant's process? Note potential non-conformances.

B. System Review

1. Are CLs being implemented as planned? Note non-conformances.

2. Are records of CL conformance or deviation being created as planned?

V. Monitoring Procedures

Regulatory Standard: 9 CFR 417.2 (b) (4)
417.5 (a) (3)
Scientific/technical Measures of Adequacy: NACMCF

A. Documents Review

1. Do documents indicate that continuous monitoring is used when feasible?

2. If monitoring is not continuous, is its frequency appropriate? Based on statistical principles?

3. Do documents indicate that process monitoring instruments are used appropriately?

4. Do documents indicate that results of monitoring procedures are routinely analyzed to adjust the process and maintain control? Is the adjustment methodology included in the HACCP plan? Is the methodology sound?

5. Do documents indicate exactly what the monitoring procedure is, who performs it, what training has been given to the person, what the person is to do when there is a deviation? Do documents provide the basis for making decisions about the monitoring procedures, which have been selected?

B. Systems Review

1. Are monitoring procedures being conducted as planned?

2. Do employees with such responsibilities perform monitoring procedures consistently and correctly?

3. Do employees with such responsibilities record the outcomes of monitoring procedures consistently and correctly?

4. Do employees analyze monitoring procedures results as per the adjustment methodology (Q.A.4) in the HACCP plan?

IV. Corrective Actions

Regulatory Standard: 9 CFR 417.2 (b) (5)
417.3
Scientific/technical Measures of Adequacy: NACMCF

A. Documents Review

Attachment 1
Corrective Actions Continued

1. Do documents indicate that corrective action procedures are complete? That is, are there specific corrective action procedures to be followed when there is a deviation from any critical limit, do the specified corrective actions include identifying and eliminating the cause of the deviation, provisions that the CCP will be under control after the corrective action has been taken, that measures to prevent recurrence have been established, that adulterated product has not entered commerce and that responsibility for taking these corrective actions has been assigned to an establishment employee?

2. Do documents indicate that corrective action procedures are effective?

3. Do documents indicate that corrective action procedures records are routinely reviewed as a means of maintaining control?

4. Do documents indicate that if there is a deviation which occurs because of an unforeseen hazard, there is an appropriate set of responses?

B. System Review

1. Are corrective actions specified for each CCP, conducted as planned?

2. Are corrective actions successful in re-establishing process control and preventing recurrence of deviations from the same cause?

3. Are product dispositions appropriate?

4. Are corrective action records routinely reviewed?

5. Are adjustments made when analysis of records shows trends in deviations?

6. Following a deviation caused by an unforeseen hazard, are appropriate decisions made about whether to modify the HACCP plan?

VII. Validation Procedures

Regulatory Standard: 9 CFR 417.4
9 CFR 417.4(a)1)
Scientific/technical Standard: NACMCF

A. Documents Review

1. Do documents indicate that initial validation has confirmed the plan's adequacy in controlling food safety hazards reasonably likely to occur?

2. Do documents include or cite scientific technical studies which support that the CCPs will control the hazards identified?

3. Do documents indicate repeated trials of the CCPs and results which show the system can be operated successfully by this establishment?

4. If the HACCP system has been modified, do documents indicate that the modified system has been validated.

B. System Review

1. Is the HACCP system in operation, the same as the one for which validation documentation exist?

2. At the direction of the team leader, verify that HACCP system is working as intended by taking samples(s) of product and sending to the laboratory so analyses can be performed to determine if all food safety regulatory requirements have been met.

VIII. Verification Procedures

Regulatory Standard: 9 CFR 417.4(a)
9CFR 417.4((a)(2)
Scientific/technical Measures of Adequacy: NACMCF, p. 19, par.2=1252
NACMCF, p. 20, par.1=1253
p.20 Figure 2=1253
Appendix G=1259

A. Documents Review

1. Do documents indicate there is a set of on-going verification activities that is complete, i.e., does this set include observation of monitoring activities and corrective actions, review of records and calibration of process monitoring instruments?

2. Do documents indicate that the frequencies at which verification procedures are performed are appropriate?

B. Systems Review

1. Are verification procedures being performed as documents described?

2. What do employees do if verification procedures are not successful? Is this appropriate?

IX. Reassessment Procedures

Regulatory Standard: 9 CFR 417.4(a)(3)
9 CFR 417.4(b)
9 CFR 417.310.25(b)
9 CFR 381.94(b)

Scientific technical Measures of Adequacy: NACMCF
(Appendix G, p.1255 especially b*)
p. 1259

*Note NACMCF does not use the term reassessment, but includes this activity as part of verification, the occasions for reassessment are identified under B.

A. Document Review

1. Do documents indicate that reassessment of the HACCP plan and hazard analysis are performed on appropriate occasions?

2. Do documents indicate that any reassessment which revealed the existing plan did not meet requirements of 417.2 was promptly followed by a plan modification?

3. Do documents indicate that reassessments following failure to meet a second set of *Salmonella* performance standard samples result in modifications to HACCP plans which enable plants to meet the performance standard on the third set?

B. System Review

1. Which plant employees participate in reassessments? How do they participate?

2. If reassessments result in HACCP plan modifications, how do employees find out about modifications?

3. Who decides if a "for cause" reassessment should be performed? What is the basis of this decision?

X. Record Keeping Systems

Regulatory Standard: 9 CFR 417.5
Scientific technical Measures of Adequacy: NACMCF

Note: Reviewers may find that all these questions have been answered under previous checklists; if so, simply, reference where the information is to be found.

A. Documents Review

1. Do documents indicate that the HACCP system is producing records which show that control systems are effective?

2. Do documents indicate that regular analysis of records is used to maintain an adequate system?

B. Systems Review

1. Do records completely and accurately reflect HACCP system in operation?

2. Are records created as planned?

3. Are records clear, accessible and organized to facilitate analysis? Note non-conformances.