



United States Department of Agriculture

JAN 24 2014

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Dear Dr. Takimoto:

The Food Safety and Inspection Service (FSIS) conducted an onsite audit of Japan's Meat inspection system from May 13 through May 28, 2013. Enclosed is a copy of the final audit report. The comments received from the government of Japan are included as an attachment to the final report.

If you have any questions regarding the FSIS audit or need additional information, please contact me by telephone at (202) 720-6400, facsimile at (202) 720-7990, or e-mail at international.audit@fsis.usda.gov.

Sincerely,

Dr. Shaukat H. Syed
Director
International Audit Staff
Office of Investigation, Enforcement and Audit

Enclosure

JAN 24 2014

JAPAN
FINAL AUDIT REPORT

January 24, 2014

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from May 13-28, 2013, to determine whether Japan's food safety system governing the production of meat continues to be equivalent to that of the United States, with the ability to produce products that are unadulterated, safe, wholesome, and properly labeled.

The audit was designed to determine the equivalence of Japan's meat inspection system and focused on six main system components: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. In addition, the audit also included two special emphasis areas: First, FSIS verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the July 2009 FSIS audit findings were being implemented. Second, FSIS sought to verify the CCA's Radioactive Control Program for cattle in association with the 2011 earthquake/tsunami and consequent radioactive contamination from the Fukushima Nuclear Plant, addressed in the Chemical Residue Control Programs component.

The onsite audit findings are summarized below and further addressed in the respective sections of the report.

- The CCA did not have a written staffing standard based on species slaughter and line speeds to meet FSIS equivalency requirements and to ensure sufficient staffing in the event of increased production volume in certified establishments for export to the United States. This was a system-wide finding.
- The CCA did not provide clear written instructions to its auditors concerning the methodology of monthly audits of microbiological laboratory quality system or monthly supervisory reviews of the U.S.-eligible establishments. This was identified at the CCA and one regional office audited.
- The CCA did not provide clear written instructions to inspection personnel specifying documentation of all identified noncompliances. This was identified during document review, interviews, and observations at the CCA, one regional office, and three audited establishments.
- The CCA did not follow its own residue monitoring testing guidance when it did not schedule any testing for hormones in 2013 residue monitoring testing plan. This was a system-wide finding.
- The CCA provided only limited ongoing training related to FSIS requirements to inspection personnel. The audit identified significant variances in the level of knowledge, skills, and abilities (KSA) among inspection personnel working in different regions related to:
 - Ongoing verification of the establishment's HACCP systems, including review of decision making documents used to support critical control point location selection and development. The HACCP noncompliances were identified in all three audited establishments.
 - The methodology to verify the effectiveness of stunning procedures of livestock, including the complete loss of sensibility and accompanying physiological signs.

This was identified in one establishment where the in-plant inspection personnel were unable to describe the methodology. No improper stunning was observed during this onsite visit.

- The ability to identify and preclude the development of insanitary conditions that may lead to the direct contamination and adulteration of product. The sanitation noncompliances were identified in two of the three audited establishments.

The audit results indicate that Japan's inspection system is performing at an "adequate" level in maintaining its equivalence. The CCA meets most of the core criteria for all six equivalence components; however, the above audit findings indicate a need for improvement of the CCA's government oversight. During the exit meeting, the CCA noted that it had taken immediate actions to address the above audit findings and had begun to implement long-term remedies for all findings as well. The CCA proffered corrective actions, attached under appendix C, in response to the draft final audit report. If these actions are effectively implemented, the system weaknesses should be remedied.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite equivalence verification audit of Japan's meat inspection system from May 13-28, 2013. The FSIS auditor was accompanied throughout the entire audit by representatives from the Central Competent Authority (CCA), Ministry of Health, Labor, and Welfare (MHLW), including members from the regional or local inspection offices. In addition, the FSIS auditor was accompanied by two observers as part of the Beyond-the-Border (BtB) initiative project,¹ with the full consent of Japan. This initiative articulates a shared approach to security in which the United States and Canada work together to improve food safety and enhance cooperation in a variety of other sectors that impact the shared border. FSIS and the Canadian Food Inspection Agency (CFIA) shared audit-related information prior to conducting the audit. CFIA's presence during the onsite audit was limited strictly to an observer capacity. A joint FSIS-CFIA audit report is not being issued. The FSIS auditor conducted the entire onsite audit and issued this report.

Japan is eligible to export intact cuts of boneless beef products to the United States. On April 22, 2010, the Animal and Plant Health Inspection Service (APHIS) placed restrictions on the export of product from Japan to the United States because of Foot and Mouth Disease (FMD); and as a result the United States stopped accepting raw beef from Japan. The FMD animal disease restriction was removed by APHIS on August 15, 2012, and FSIS authorized Japan to resume exports to the United States on August 17, 2012. Between September 7, 2012, and April 30, 2013, Japan exported 117,192 pounds of beef products to the United States, of which 50,852 pounds were re-inspected by FSIS's import inspectors at point-of-entry (POE). A total of 511 pounds were rejected at POE for non-food safety-related reasons, including labeling issues or packaging/transportation damages. No product was rejected for food safety reasons.

The audit standards applied to Japan's meat inspection system included all applicable legislation determined by FSIS as equivalent and part of the initial equivalence process, as well as any subsequent equivalence determinations that have been made under provisions of the Sanitary/Phytosanitary Agreement. This audit was conducted pursuant to the specific provisions of U.S. laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Title 7)
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulations

¹ On February 4, 2011, President Obama and Prime Minister Harper announced the United States - Canada joint declaration, *Beyond the Border: A Shared Vision for Perimeter Security and Economic Competitiveness*. This initiative articulates a shared approach to security in which the U.S. and Canada work together to improve food safety. One project included under the BtB umbrella calls for harmonizing audit criteria and procedures and developing joint audit methodology for conducting food safety systems-based audits as well as sharing audit related information between FSIS and Canadian Food Inspection Agency (CFIA). Sharing audit information should minimize burdens on both the U.S. and Canada, as well as on the country audited because redundancies in the audits conducted by the U.S. and Canada should be eliminated. Japan is the third country that actively exports meat products to both the United States and Canada that agreed to participate in this project.

II. AUDIT GOAL AND OBJECTIVES

FSIS's overall goal for the audit was to verify that Japan's food safety inspection system governing meat products continues to be equivalent to that of the United States, with the ability to produce and export products that are unadulterated, safe, wholesome, and properly labeled. To achieve this goal, the audit focused on the six equivalence components with the objectives of determining whether each component continues to be equivalent to that of the United States. The six equivalence components are the following: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. In addition, FSIS verified that the corrective actions proffered by the CCA in response to the July 2009 FSIS audit were being implemented. Then, FSIS sought to verify the CCA's Radioactive Control Program for cattle in association with 2011 earthquake/tsunami resulting in radioactive contamination due to the Fukushima Nuclear Plant incident. This was examined as part of the review of the Chemical Residue Control Programs component.

III. AUDIT METHODOLOGY

In conducting this equivalence verification audit, FSIS utilized its established four-phase process: plan, execution (onsite), evaluation, and feedback. Each phase is described below.

Plan: The first phase was the in-depth planning phase, involving document and data review of all available information. The auditor began with an analysis of previous July 2009 onsite audit findings to gain information for follow-up examination of the CCA's corrective actions. The FSIS auditor continued examination of CCA's performance within the six equivalence components, data on exported product types and volumes, POE testing results and self-reporting tool (SRT) data collected by FSIS since the last onsite audit in 2009. During the 2009 audit, no notice of intent to delist (NOID) or delistment was issued. However, the FSIS auditor reported noncompliances in regard to sanitation and HACCP implementation, which was an indication of inadequate oversight by the CCA. During the 2013 audit, the FSIS auditor conducted a follow-up verification of 2009 audit findings. A detailed description of FSIS' follow-up verification is explained in the Sanitation and HACCP Component sections of this report.

In addition, FSIS reviewed information obtained directly from the CCA, through a self-reporting process, outlining the current structure of the inspection system and identifying any significant changes that have occurred since the last FSIS audit. This analysis served as the basis for planning the onsite audit itinerary and was utilized in determining the performance level of the CCA's equivalent system.

Execution (Onsite): The second phase was the onsite audit or execution phase. FSIS conducted this onsite audit to verify the CCA's oversight activities through onsite document reviews, interviews, observations, and site visits.

Auditor reviewed management, supervision, and administrative functions at the CCA headquarters, Kyushu Regional Office, and three bovine slaughter/cutting establishments to verify that the national system of inspection, verification, and enforcement is being implemented as described by Japan. During the onsite audit of the above offices, particular attention was paid to the extent to which the CCA ensures the control of hazards and prevent non-compliances that

threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with the Title 9 of the U.S. Code of Federal Regulations (CFR), section 327.2.

The FSIS auditor assessed the CCA's oversight activities for approved chemical residue and microbiology laboratories both during the planning phase and this execution phase. FSIS reviewed laboratory-related data collected prior to the 2013 audit through analysis of supporting documents provided with the SRT. FSIS conducted onsite interviews of inspection personnel and reviewed the CCA's laboratory audit reports at the CCA's headquarters and one regional office. In addition, FSIS conducted an onsite audit of Japan's Food Research Residue Laboratory (TAMA), a private residue laboratory located in Tokyo, which was conducting analytical testing as part of Japan's national residue program. An onsite visit of a microbiology laboratory was not within the scope of this audit; therefore, FSIS verified the CCA's oversight activities over microbiology laboratory through review of available documents at the CCA's headquarters and the Kyushu regional office.

Evaluation: FSIS conducted a post-audit evaluation of all data collected onsite to determine whether the CCA's performance was consistent with the information provided to FSIS in the SRT and other submitted documents. When evaluating the audit data cumulatively, FSIS determined that the CCA provides an equivalent level of protection to that provided by the U.S. inspection system, though problems were noted. FSIS conducted an exit meeting with the CCA representatives to convey all findings and discuss next steps.

Feedback: The final phase was the official submission of FSIS' feedback in the form of this draft audit report that provides the CCA with an opportunity for comment. The CCA reviews the report and submits its comments. FSIS reviews CCA's submission, follows up with the CCA as needed, and then prepares a final audit report². During this time, FSIS and the CCA mutually develop an action plan to address any issues raised by the audit. These issues will be tracked by FSIS and appropriate follow-up actions will be taken.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the six equivalence components that the FSIS auditor reviewed was Government Oversight. FSIS import eligibility requirements for Japan states that the foreign inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the system of meat inspection in the United States.

The evaluation of this component includes a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT, as well as onsite record reviews, interviews, and observations made by the FSIS auditor at government offices and audited establishments.

Japan's administration of food safety is divided between national and local government levels.

² For additional information about any of the USDA final audit reports for Japan's Food Safety System, please see the FSIS' website at:
<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>

At the national level, the Ministry of Health, Labor, and Welfare (MHLW) is Japan's CCA. The MHLW has one central and seven regional offices. At the central level, the Inspection and Safety Division (ISD) of the Department of Food Safety of MHLW prepares the national residue plan, contracts with private laboratories for residue analysis, issues all directives and guidelines concerning meat export to other countries, certifies or decertifies slaughter establishments for export, and is responsible for the translation, distribution, and implementation of all the U.S. requirements in certified establishments.

The regional level consists of seven Regional Bureau of Health and Welfare (RBHW) offices across the country. Three of these offices have authority over the establishments that are certified to export beef to the United States. The Food Sanitation Division of these regional offices is responsible for conducting periodic supervisory reviews of the U.S.-eligible establishments and recommending the approval and withdrawal of establishments.

At the local government level, there are 47 prefectural and municipal governments. Local governments, through its Meat Inspection Centers (MIC), are in charge of the control of meat slaughter establishments. Each MIC has the responsibility to implement and enforce inspection laws at the U.S.-eligible establishments. The meat inspectors assigned to the MIC are responsible for carrying out all daily inspection activities. There is a specific number of meat inspectors assigned to each of the U.S.-eligible establishments to carry out inspection activities. These meat inspectors complete specific training in food safety controls and meat inspection techniques provided by the CCA and local governments. All of the meat inspectors in certified slaughter establishments are veterinarians.

The CCA's authority to enforce inspection laws are outlined in the *Abattoir Law (Law No. 114, August 1, 1953, as of June 27, 2007)*, *Abattoir Law Enforcement Regulation (Law No. 44, September 28, 1953, as of February 1, 2013)*, and *Ordinance for Enforcement of the Food Sanitation Act (Ordinance No. 23, July 13, 1948)*. These laws delineate responsibilities for each of the inspection levels, as well as enforcement of the *Food Sanitation Act*. In addition, a supplemental document entitled "*Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States*" is implemented and enforced for those establishments certified to export to the United States.

The CCA has the legal authority and responsibility to enforce requirements equivalent to those governing the system of meat inspection organized and maintained in the United States. All meat exported to the United States, in all three audited establishments, is segregated from domestic production.

During the current audit, the FSIS auditor identified negative findings related to oversight at various levels of Japan's inspection system pertaining to each equivalence components. Below are some examples of audit findings related to three equivalence criteria cited in 9 CFR 327.2.

Assignment of Competent Qualified Inspectors: The CCA has provided limited ongoing training related to the U.S. requirements for inspection personnel since the last FSIS audit in 2009. The FSIS auditor interviewed inspection personnel and reviewed their training records during the onsite audit. Only a small portion of inspection personnel assigned to the U.S.-eligible establishments could demonstrate that they had received classroom training since the last FSIS audit. This is particularly important in that the CCA, in order to maintain an equivalent inspection system, implements numerous requirements related to United States export that do not

exist within the domestic system. For example, although specific requirements for HACCP and humane handling of livestock do not exist within Japan's domestic inspection system, requirements equivalent to those of the U.S. are enforced at the U.S.-eligible establishments in order to meet FSIS' import regulations outlined in 9 CFR 327.2. The audit identified that the CCA depends heavily on in-plant "pass-down" training for these specific requirements, rather than standardized training courses. Although beneficial in some regards, this type of training, as presented to the auditor, also lacked feedback mechanisms through which the CCA could assess overall effectiveness of its training program by evaluating the level of KSA of inspection personnel in implementing HACCP requirements. As a result, the FSIS auditor identified significant variances in the level of knowledge among inspection personnel in different regions resulting in inadequate implementation of regulatory requirements concerning HACCP in audited establishments.

During the onsite document reviews and interviews of establishment and inspection personnel, the FSIS auditor identified several HACCP problems as follows:

- At two establishments, the HACCP verification records for calibration of monitoring instruments did not document the time.
- At three establishments, the HACCP verification records documenting the record review and direct observation of monitoring did not include the time of entry or the results of the ongoing verification activities conducted by the establishment's personnel.
- At one establishment, the HACCP plan set the frequency of direct observation of monitoring procedures at every two weeks. However, this frequency was not being followed as intended.
- At two establishments, the HACCP monitoring records did not document the time of monitoring activities.
- At one establishment, the HACCP plan did not include direct observation of monitoring procedures as part of its ongoing verification activities.

In order to ensure ongoing compliance with respect to HACCP recordkeeping requirements, FSIS expects that the CCA provide corrective actions that reflect improvements, both within the CCA's in-plant HACCP verification activities and the manner in which each region conducts its periodic supervisory reviews. In addition, FSIS recommends that the CCA ensure that its inspection personnel have appropriate educational credentials and appropriate training and experience to carry out their inspection tasks. System-wide oversight is also warranted.

Supervisory, Administrative, and Technical Support: Each RBHW office has a number of regional auditors who conduct both monthly audits at local MIC microbiological laboratories and periodic supervisory reviews in nearby establishments eligible to export to the United States. During the audit of the Kyushu regional office, the FSIS auditor reviewed inspection documents and interviewed the regional auditors. The FSIS auditor identified the following significant deficiencies related to the level of oversight by the CCA as ongoing problems:

- **Laboratory Audit Frequency:** The regional auditors did not follow the CCA's prescribed monthly frequency of MIC's microbiology laboratory audits. The regional auditors indicated that the monthly audit was not conducted on a consistent basis.
- **Laboratory Audit Reports:** The regional auditors could not produce any microbiology laboratory audit reports. Therefore, the FSIS auditor could not verify any past activities of the regional auditors within the microbiology laboratories.

- Laboratory Audit Methodology: The regional auditors could not confirm whether there was a written procedure or instruction for conducting microbiology laboratory audits. However, the CCA representative identified the "*Manual on How to Manage Examinations, Etc. at Testing Laboratories*" as the source document for assessing the quality system of each laboratory testing product in relation to the U.S. product. The regional auditors were not always implementing the requirements cited in this document.
- Laboratory audit feedback: The regional auditors did not share or communicate the results of their microbiology laboratory audits with the CCA central office. As a result, the CCA did not have any knowledge of the aforementioned shortcomings at the regional level.

The CCA's lack of proper oversight over one RBHW resulted in identification of the aforementioned negative audit findings by FSIS. As a result of incomplete documentation and reporting process by the regional auditors, the FSIS auditor was not able to evaluate the scope or quality of the monthly microbiology laboratory audits. Therefore, FSIS could not determine whether this lack of oversight was a local or system-wide issue. FSIS expects that the CCA complies with its own requirements by issuing clear instruction, implementing ongoing training, and enforcing proper corrective actions throughout its inspection system, which is verifiable through a comprehensive oversight program.

Authority and Responsibility to Enforce U.S. Requirements: During the onsite visit to the Kyushu regional office and three slaughter establishments, the FSIS auditor reviewed inspector-generated records and interviewed in-plant inspection personnel as well as regional auditors conducting monthly supervisory reviews. At all three slaughter establishments audited, the inspection personnel did not document all noncompliances identified while conducting their inspection verification activities. In general, only noncompliances that could not be corrected immediately were documented by inspection personnel. The auditor's discussions with representatives from the CCA's headquarters indicated that all noncompliances should be documented. However, the CCA lacked clear written instructions to its inspection personnel to communicate these expectations and ensure appropriate direction for ongoing accountability at the audited establishments. Failure to document all noncompliances in the establishment can ultimately impact the CCA's ability to assess noncompliances, conduct accurate analyses of trends, and ensure that requirements related to the U.S. export are continuously implemented.

The FSIS auditor reviewed the last 12 months of periodic supervisory reviews at Kyushu regional office and interviewed the regional auditors who conduct these monthly reviews. During these interviews, FSIS determined that the regional auditors did not properly complete the establishment audit checklist as prescribed by the CCA headquarters instructions. In addition, regional auditors stated that during monthly supervisory reviews they did not verify all of the requirements cited in 9 CFR 327.2 (a)(2)(ii)(A) through (H), and they did not keep track of those activities that were not verified. There were portions of the checklist that were not applicable or not reviewed during a monthly audit that should have been marked as such (i.e., "O" for not applicable). Failure to properly track which elements were not verified will inhibit the CCA's ability to ensure that all FSIS requirements are met on an ongoing basis. This shortcoming is further supported by findings pertaining to a series of conditions leading to mold infestation in an audited establishment and related lack of proper inspection documentation or enforcement actions by either the in-plant inspection personnel or regional auditors who conduct monthly supervisory reviews. The mold infestation is further discussed under sanitation component.

FSIS' onsite audit verification including observations, document reviews, and interviews in combination with pre-audit document analysis of the CCA's control measures demonstrate that the CCA continues to meet FSIS equivalence criteria at an adequate level of performance for this component. However, the onsite audit findings indicate a need for the CCA to improve its oversight activities concerning the above findings related to three equivalence criteria. The FSIS auditor identified other negative findings related to Government Oversight in the five other components: Statutory Authority and Food-Safety Regulations; Sanitation; HACCP Systems; Chemical Residue Control Programs; and Microbiological Testing Programs equivalence components which require the CCA attention. These findings are further discussed in this report.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The inspection system must provide an appropriate regulatory framework to demonstrate equivalence with FSIS requirements, including but not limited to HACCP, sanitation, chemical residue and microbiological sampling, humane handling, slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection and periodic supervisory visits to the U.S.-eligible establishments.

The evaluation of this component included an analysis of information provided by the CCA in the SRT and observations gathered during the onsite audit of the system. The FSIS auditor verified that official inspection and verification activities are in accordance with the responses in the SRT and supporting documentation.

During the CCA's headquarters audit, the FSIS auditor verified the regulatory authority maintained by the CCA, as outlined in official legislation, ordinances, and manuals issued in accordance with Japan's *Abattoir Law*. The auditor confirmed that the CCA, with the exception of periodic supervisory reviews, have provided RBHW and prefecture offices with the appropriate written regulatory authority and guidance to enforce requirements for HACCP, sanitation, chemical residue and microbiological sampling, humane handling and slaughter of livestock, ante-mortem inspection, post-mortem inspection of carcasses and parts, controls over condemned materials, controls over establishment construction, facilities, equipment, and daily inspection.

The implementation of HACCP is not mandatory in Japan's establishments producing for domestic market. However, in order to meet FSIS equivalence requirements, the CCA enforces an equivalent HACCP system in the U.S.-eligible establishments. Japan's document "*Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States*", attachment 3, Standards for Implementation of Sanitation Control by HACCP, part III "*Voluntary Sanitation Control Using HACCP System*" outlines Japan's HACCP requirements which has been recognized as equivalent by FSIS.

The FSIS auditor verified that the CCA exercises its legal authority to require the U.S.-eligible establishments to develop, implement, and maintain sanitation programs sufficient to prevent direct product contamination and the creation of insanitary conditions in accordance with Japan's *Food Sanitation Act, Abattoir Law, Abattoir Law Enforcement Regulation, Ordinance for*

Enforcement of the Food Sanitation Act, and Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States submitted by the CCA in the SRT.

During the onsite visit to the Kyushu regional office, which oversees eight prefecture offices and five of the U.S.-eligible establishments, the FSIS auditor conducted an examination of regional oversight activities, including periodic (monthly) supervisory reviews of the U.S.-eligible establishments, monthly microbiology laboratory reviews, inspection enforcement activities, and ongoing training for inspection personnel by interviewing the regional auditors and reviewing numerous inspection documents.

Periodic supervisory reviews are conducted monthly by regional auditors from the Food Sanitation Division located in each regional office. The supervisory reviews are conducted using a standard form, "Establishment Audit Checklist," a form similar in design and content to FSIS Form 5000-6 (04/04/2002) which consists of a detailed checklist divided into two parts. The first part consists of five sections for evaluating the adequacy of an establishment's food safety system, including items related to inspection verification of SSOP, HACCP, Economic/Wholesomeness, Generic *E. coli*, *Salmonella*, Economic Sampling, and Other Requirements. The second part is the inspection requirements section designed for evaluating the KSA of in-plant inspection personnel to conduct assigned responsibilities at the U.S.-eligible establishments. The periodic supervisory review report is distributed to the audited establishment's management, in-plant inspection, and the related RBHW office. The in-plant inspection personnel are responsible for verification of corrective actions resulting from the periodic supervisory reviews. The RBHW office is responsible for analyzing the results of the review and follow up on the corrective actions proposed by the establishment. The RBHW office also reviews the verification of the corrective actions by the in-plant inspection personnel in order to verify the effectiveness and implementation of action plans. RBHW submits a copy of the monthly supervisory reviews to the CCA headquarters for further review and analysis.

The overall conditions in two of the three audited establishments mirrored their monthly supervisory review reports. However, the overall sanitary condition in the third establishment audited did not fully support the findings in its monthly supervisory review reports. One example is the buildup of mold infestation in one establishment that clearly should have been identified, corrected, and properly documented in the monthly supervisory reviews.

During the onsite audit of three slaughter establishments, the FSIS auditor accompanied and observed the individual responsible for conducting monthly supervisory reviews while they verify requirements for ante-mortem examination, humane handling and slaughter, post-mortem examination, *Salmonella* and generic *E. coli* sample collection, verification of pre-operational and operational sanitation procedures, and HACCP verification activities (including the zero tolerance CCP verification).

The FSIS auditor verified that in-plant inspection personnel at all three audited establishments conduct ante mortem inspection on the day of slaughter by reviewing the incoming registrations and identification documents including individual ear tag numbers. All cattle must be identified by two ear tags each of which must have a 10 digit individual identification (ID) number. Ear tags are applied by the farmer at the time of birth. Each ear tag number must be notified to the National Livestock Breeding Centre (NLBC) System. This system allows the animals and carcasses to be traced back to their farms of origin using the ID number. The complete movement history for each animal is also included in the individual identification information.

The inspection personnel also observed all animals from both sides at rest and in motion in designated holding pens prior to slaughter in order to determine whether they are fit for slaughter and for human food purposes. The designated holding pen for sick or suspect animals is maintained in each establishment audited for further examination of these animals, as needed. The FSIS auditor observed and verified that all animals have access to water in all holding pens (including that used for suspect animals) and are provided with feed if held for more than 24 hours. The auditor concluded that the implementation of the ante-mortem inspection is in compliance with Japan's *Guideline of Meat Inspection, Abattoir Law*, article 14 and 19, and *Abattoir Law Enforcement Regulation*, article 10 and 16. Japan's document titled "*Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States*" has provisions concerning requirements for humane handling and slaughter of livestock. Japan's requirements include the following main criteria:

- Repair and maintenance of stock yards and path ways;
- Access to water and feed for animals;
- Use of a single blow stunner that causes unconsciousness in an animal;
- Induction and maintenance of unconsciousness until completion of bleeding; and
- Implementation of action when inhumane handling or slaughter has been identified by inspection personnel.

At one establishment audited, the in-plant inspection personnel were unable to describe how to properly verify and assess that effective stunning occurs, including the complete loss of sensibility of livestock and appropriate accompanying physiological signs. Although the FSIS auditor did not observe any improper stunning during the observation of stunning process and the steps that follow, this lack of knowledge cannot ensure that proper stunning occurs on a consistent basis, and that sufficient corrective action will take place. The lack of standardized ongoing training regarding HACCP, sanitation, and this particular criterion related to export to the United States has already been described under *Assignment of Competent Qualified Inspectors* findings in the Government Oversight section.

FSIS auditor also assessed post mortem inspection examinations through onsite record reviews, interviews, and observations of in-plant inspection personnel performing post-mortem examinations in all three slaughter establishments audited. The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts are being implemented. In-plant inspection personnel are adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditor observed the performance of the inspection personnel examining the heads, viscera, and carcasses in which the proper incision, observation, and palpation of required organs and lymph nodes are made in accordance with Japan's *Manual of procedures of Meat Inspection and Re-inspection of Dressed carcasses, Food Sanitation law (article 11), Abattoir Law (article 5, 14 and 19), and Abattoir Law Enforcement Regulation (article 10 and 16)*. The design of the post-mortem inspection stations, including proper lighting meets Japan's equivalent requirements.

In Japan, the U.S.-eligible establishments slaughter an average of 70 cows per day. In general, the MIC for each audited establishment assigns one inspector for head examination, two inspectors for viscera examination, one inspector for carcass examination, one off-line inspector, and one inspector for conducting ante-mortem examination. The number of inspection personnel conducting post-mortem inspection activities is sufficient for the existing production volume and line speed. However, the CCA did not have a written staffing standard based on species slaughter

and line speeds to meet FSIS equivalency requirements and to ensure sufficient staffing in the event that there is an increased production volume in the U.S.-eligible establishments in Japan. This finding was identified as a system-wide concern.

The FSIS auditor also observed the functions of the off-line inspectors who conduct daily inspection verification activities in all three audited establishments. These daily verification activities include direct observation and review of establishment records, including HACCP, SSOP, Sanitation Performance Standards (SPS), and generic *E. coli* sampling techniques and records.

Japan's meat inspection system has legal authority and a regulatory framework to implement requirements equivalent to those governing the U.S. system of meat inspection. FSIS' onsite audit verification methodology including observations, document reviews, and interviews in combination with FSIS' pre-audit SRT document analysis of the CCA's statutory authorities demonstrate that the CCA continues to meet FSIS equivalence criteria at an adequate level of performance for this component. However, FSIS identified several weaknesses related to the CCA's oversight functions concerning instructions for conducting supervisory reviews in the audited establishments and microbiological laboratories, the lack of written standards for staffing of the U.S.-eligible slaughter establishments, and insufficient inspection verification activities to ensure proper stunning of livestock.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. To be considered equivalent to FSIS' program, the CCA must provide requirements for all areas of sanitation, sanitary handling of products, SPS, and SSOP. The FSIS auditor verified that the in-plant inspection personnel at three audited establishments conduct verification of sanitary conditions in accordance with requirements cited in "*Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States,*" attachment 2, Sanitation Control Standards, parts I, II, and III. This document provides instructions to the official inspection personnel to conduct a continuous and systematic assessment of inspection activities during routine verifications of sanitation issues, including Sanitation Control of Facilities, Equipment, Etc.(part I); Sanitary Slaughter, Dressing, Division, Etc.(part II); and Sanitation Control System (part III).

During the assessment of this component, the FSIS auditor observed the inspection personnel conducting pre-operational sanitation verification of slaughter and processing areas in one of the audited establishments. The in-plant inspection personnel's hands-on verification procedures begin after the establishment had conducted its pre-operational sanitation and determined the facility is ready for in-plant inspector pre-operational sanitation verification activities. The FSIS auditor also shadowed the regional auditor and observed inspection verification of operational sanitation procedures at three audited establishments. These verification activities include direct observation of operations and review of the establishment's associated records. In addition, the FSIS auditor reviewed each establishment's sanitation monitoring and corresponding inspection verification records for the same time period. The audited establishments maintain sanitation records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken. The establishment's employees, specified as being responsible for the

implementation and monitoring of the SSOP procedures, authenticate these records with their initials or signatures and the date.

In two of the establishments audited, the in-plant inspection personnel's verification of the establishment's monitoring sanitation records did not mirror the FSIS auditor's onsite observation of actual sanitary condition of these establishments on the day of the audit. In one establishment, the FSIS auditor observed extensive black discoloration marks on the ceiling of several carcass coolers and transit areas that were identified by the establishment's personnel as mold. In response to the auditor's request for related documents, the establishment was not able to present any document concerning the frequency or procedures for cleaning of the ceiling of these areas. The establishment management estimated that these areas were last cleaned in September 2012, but no records concerning the cleaning of these areas were generated or provided to either the in-plant inspector or the FSIS auditor. A review of the establishment's daily sanitation records for both pre-operational and operational procedures for the past five months revealed that the sanitary condition of the ceilings had been checked and always marked as acceptable by the responsible establishment's employees. In addition to mold infestation, in several locations rust was identified on overhead and surrounding structures, indicating a high level of moisture in these areas. Furthermore, the establishment's walls and ceilings in several areas were covered with sprayed foam insulation-type materials which could absorb moisture and aggravate the mold infestation. The application of foam-type materials to cover walls or ceilings is in direct contradiction with Japan's document "*Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States,*" attachment 1, part II. The inspection personnel did not fully implement the requirements noted in this document, which states that walls and ceilings of places where moisture or steam may accumulate shall have surfaces with structure that is capable of preventing the occurrence of condensation or mold. The FSIS auditor interviewed both the inspection and establishment personnel and reviewed related sanitation records. The mold infestation in carcass coolers had never been identified or documented in establishment's pre-operational/operational records or inspection verification records since January 2013.

In another establishment, numerous gaps between the ceiling and protruding metal bars holding attached structures were observed in the ceiling above exposed products and food contact surfaces in the cutting room. This condition is not in compliance with Japan's document "*Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States*" attachment 1, part II, which states that ceilings of the facilities shall have an easy-to-clean structure and be made of materials that are smooth, impermeable, corrosion-resistant and various pipe work or lighting equipment shall not have uncovered structure. The inspection personnel did not fully enforce the construction and maintenance requirements cited in this document.

The FSIS auditor did not note any direct product contamination during the onsite audit. However, the audit findings indicate a weakness in the CCA's enforcement of sanitation requirements. The results of the overall assessment of the sanitation programs demonstrates that the CCA inspection system provides requirements equivalent to that of the United States for sanitary handling of products and for the development and implementation of sanitation standard operating procedures. The CCA has addressed the mold infestation in the establishment by implementing a verification action plan of establishment's corrective action. FSIS reviewed this plan and found it to be satisfactory. FSIS document review and onsite verification of inspection

activities supports that the CCA continues to meet the core equivalence requirements for sanitation and operates at an adequate level of performance in meetings its equivalence determination.

VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEMS

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. To be considered equivalent to FSIS' program, the CCA must require that each official establishment develop, implement, and maintain a HACCP plan or an equivalent measure for each operation.

The FSIS auditor visited one RBHW office and audited three meat slaughter establishments to determine whether the CCA maintained adequate government oversight for the implementation of HACCP requirements. FSIS also assessed the adequacy of HACCP program verification activities conducted by inspection personnel and establishment management at all three audited establishments. The auditor observed inspection verification activities and reviewed the monitoring and verification records generated by the establishment's operators and in-plant inspection personnel. The auditor noted that the in-plant inspection personnel at three audited establishments conduct daily verification of the establishment's HACCP plans. This verification includes such activities as the evaluation of written HACCP programs and observing the establishment personnel perform monitoring, verification, corrective actions, and recordkeeping activities. The FSIS auditor's review of the establishment's corrective actions in response to deviations from critical control point (CCP) critical limits indicated that all four parts of the corrective actions are addressed in accordance with Japan's requirements meeting FSIS' equivalence criteria.

During the previous FSIS audit in 2009, the auditor reported that one meat slaughter establishment was conducting its monitoring and verification activities for controlling fecal, ingesta, and milk (zero tolerance CCP) after the final carcass wash. Upon FSIS auditor request, the establishment could not provide supporting documentation for the selection of zero tolerance CCP after the final carcass wash. In addition, in-plant inspection personnel were also conducting the verification of this CCP after the final wash.

During this 2013 onsite audit, the FSIS auditor closely examined the CCA's previous corrective actions and responses to this issue in order to verify the effectiveness of implemented corrective actions and its compliance with HACCP requirements. The FSIS auditor verified that the CCA has instructed its inspection personnel to place the physical point of government verification for the zero tolerance standards before the final carcass wash in all U.S.-eligible slaughter establishments. The auditor verified that this change had been made in all three of the audited meat slaughter establishments in 2013. The FSIS auditor also reviewed each audited slaughter establishment's zero tolerance CCPs records, including monitoring and verification records generated by establishments within the last five months. In addition, the auditor reviewed the in-plant inspection personnel's zero tolerance CCP verification records for the same timeframe. Following the review of CCP records, the FSIS auditor stood at the physical location of zero tolerance CCP and observed inspection personnel conducting hands-on verification of this CCP. No deviation from the critical limits was observed by either the inspection personnel or the FSIS auditor during this time. In two of the audited establishments, the establishment's CCP monitoring location is before the final carcass wash for the zero tolerance CCP monitoring and

verification by the establishment as well as verification of the CCP by inspection personnel. However, the management of the third slaughter establishment elected to place its zero tolerance CCP monitoring and verification location after the final carcass wash. The FSIS auditor requested and reviewed the establishment's decision making documents, which included monitoring data collected before the final carcass wash. The data indicated that there had been an average of three bovine carcasses per month identified with fecal contamination before the final carcass wash station. The analysis of data does not support the establishment's decision for placing the CCP monitoring location after the final wash. This is a repeat audit finding, similar to 2009 FSIS' finding, which should have been identified prior to this audit and remedied by the inspection personnel. At this establishment, the in-plant inspection personnel conduct their verification of this CCP before the final carcass wash as it is instructed by the CCA. This finding is another indication of the lack of proper HACCP training of inspection personnel to allow them to make an accurate assessment of the establishment's decision making documents.

Specified Risk Materials Controls

The 2009 FSIS audit of Japan's meat inspection system reported that in both meat slaughter establishments audited, inspection personnel did not adequately verify the implementation of the establishments' SSOP program concerning the removal of Specified Risk Materials (SRM) (brain leakage due to stunning procedures). During this 2013 audit, the FSIS auditor conducted a follow-up verification of the CCA's corrective actions by interviewing inspection personnel and reviewing inspection documents at the CCA's headquarters office. Through this approach, FSIS verified that the CCA has adequately addressed the previous audit finding throughout its inspection system. The FSIS auditor observed and verified that in all three meat establishments audited, corrective actions have been implemented by covering bovine's skull knocking hole with a piece of sponge to prevent brain leakage. The corrective action appeared to be effective since the FSIS auditor did not observe any brain leakage from the knocking hole.

The FSIS auditor also reviewed the CCA's Specified Risk Materials (SRM) control programs. The auditor not only reviewed records provided by establishment's management and in-plant inspection personnel, but also toured the slaughter establishments to observe and verify the actual operations concerning removal, segregation, and disposal of SRM in all three audited establishments. The auditor noted that the CCA has requirements for removal, segregation, and disposal of SRM in cattle and requires that all SRM must be removed prior to export to the United States. The FSIS auditor also reviewed and verified the CCA's verification and control program of SRMs at both the ante-mortem and post-mortem inspection examinations. The FSIS auditor verified, through review of verification records generated by inspection personnel or direct observation of inspection verification activities, that the in-plant inspection personnel are responsible to identify and secure all animals that are exhibiting clinical signs of central nervous system (CNS) disorders at the ante-mortem inspection examination. At all establishments visited, the auditor confirmed that the onsite veterinarians could appropriately identify the clinical signs associated with central nervous system disorders that include, but are not limited to: excitement or depression; deviation or rotation of the head; drooping of the lips, eyelids, cheeks, and ears; convulsions and tremors; paralysis; sudden onset of fainting; head pressing; aimless walking; ataxia; and blindness. The auditor also verified through direct observation that all three audited establishments are complying with the prohibition on injecting compressed air into the cranium of cattle during stunning in compliance with Japan's document "*Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States.*"

The FSIS auditor verified, through review of verification records generated by inspection personnel or direct observation of inspection verification activities, that the in-plant inspection personnel are verifying the establishment's removal, segregation, and disposal of SRM in accordance to their written procedures. The in-plant inspection personnel document these activities on a daily inspection SRM verification form.

The pre-audit document analysis and onsite audit verification of HACCP component criteria indicate that the CCA continues to meet the equivalence requirements at an adequate level of performance for this component. However, based on the nature of the audit findings, the CCA must ensure that the regulatory requirements are fully implemented, verified for effectiveness, and communicated through the chain of command to ensure proper oversight. As part of ongoing equivalence verification, FSIS will verify compliance by requesting inspection information such as periodic supervisory reviews for the U.S.-eligible exporting establishments to determine that the corrective actions have been properly implemented throughout the inspection system.

VIII. COMPONENT FIVE: CHEMICAL RESIDUE CONTROL PROGRAMS

The FSIS auditor reviewed Chemical Residues Control Programs as the fifth of the six equivalence components. The FSIS criteria for this component include the design and implementation of a program managed by the CCA that carries out effective regulatory activities to prevent contamination of food products with chemical residues. To be considered equivalent to FSIS' residue control program, the CCA's program must include random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. In addition, the CCA must identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of the program; provide a description of its residue sampling and testing plan and the process used to design the plan; describe the actual operation of its residue plan and actions taken to deal with unsafe residues as they occur; and provide oversight of laboratory capabilities and analytical methodologies to assure the validity and reliability of test data.

The CCA maintains oversight of its residue laboratory system through an annual audit of residue laboratories conducted by RBHW regional auditors. The CCA's document "*Manual on How to manage Examination, Etc. at Testing Laboratories*" outlines requirements to address operational procedures and laboratory audit criteria including review of laboratory facilities, equipment, and personnel qualifications. FSIS determined that the CCA could contract with private residue laboratories for analysis of meat samples for its national residue testing program.

The residue laboratory network consists of Japan Food Research Laboratories (JFRL), which is an independent, private institution accredited by the CCA as a testing laboratory to inspect imported foods for pesticides, antibiotics, heavy metals, environmental contaminants, and food additives. JFRL has seven branches distributed across Japan. All are expected to follow the same policies and procedures. The FSIS auditor visited JFRL Tama Laboratory located in Tama-shi, Tokyo. TAMA Laboratory is accredited by the Japanese Accreditation Board (JAB) according to ISO 17025. JFRL Tama Laboratory is in charge of carrying out the analysis according to the national residue monitoring program. The FSIS auditor verified that Kanto Shinetsu RBHW's regional auditors conduct the prescribed annual audit of laboratory quality system in accordance with Japan's *Food Sanitation Law* and the aforementioned manual. This laboratory is also conducting species verification testing with a frequency of one test per year in accordance with

Japan's requirements. During the TAMA residue laboratory audit, the FSIS auditor interviewed one of the BRHW regional auditors, who has participated in the annual audits, and reviewed the last three years annual audit reports. The BRHW 2010 annual audit identified one nonconformance in which the regional auditor verified and accepted the laboratory proposed corrective actions. There were no negative findings reported in the 2011, and 2012, residue laboratory annual audit reports.

The CCA's document "*Guidance for Implementation of Residual Chemical Monitoring*" states that meat products intended for export to the United States should be analyzed for the following substances: antibiotics, synthetic antimicrobials, antiparasitics, hormones, heavy metals, and pesticides. However, the FSIS auditor through an onsite record review process and interviews of inspection personnel identified that the CCA did not follow its own written guidance document when it did not plan or schedule any testing for hormones as required in its 2013 residue monitoring testing plan. The CCA representatives stated that Japan's inspection system does not allow the use of hormones in livestock. Therefore, it is not required to test for hormones. FSIS expects that the CCA to make immediate modifications to ensure that it follows its 2013 residue testing plan for hormones as intended, or provide scientific supporting documentation for why this would not occur, and modify its existing protocols accordingly. This issue was communicated to the CCA during the exit meeting.

Radioactive Control Program

On March 11, 2011, an 8.9 magnitude earthquake triggered a 30-foot tsunami that struck the Pacific Coast of Japan. The most notable damage from the tsunami affected the Fukushima Daiichi nuclear plant, releasing radioactive nuclides and causing environmental contamination. Beef products from cattle raised in, or exposed to feed from, the Fukushima, Miyagi, Iwate, and Tochigi Prefectures were restricted by Japan from domestic consumption and considered ineligible for export until beef animals and products from affected prefectures were proven not to exceed the Japanese provisional regulation values. The CCA established the provisional regulation for exposure to radioactive cesium in food products as 500 Bq/kg. The same equivalent value is 1,200 Bq/kg in the United States. In April 2012, Japan tightened its standard limits for radionuclides in food from 500 Bq/kg to 100 Bq/kg in order to achieve further consumer confidence.

Japan's oversight activities include monitoring of the radionuclides level in beef and feed to determine the radioactive cesium (Cs) levels in food products. Cattle deriving from farms located in planned evacuation zones and emergency evaluation preparation zones including Miyagi, Iwate, Tochigi and Fukushima prefectures are subject to 100% examination. The FSIS auditor reviewed inspection documents, interviewed the CCA officials, and verified that any movement of cattle from the identified prefectures for slaughter in another prefecture is subject to intergovernmental cooperation. Furthermore, cattle from the four identified prefectures may only be shipped for slaughter to those prefectures that have the capabilities for radioactive testing. This instruction is prescribed in Japan's shipment operating policy, which has been submitted by four prefectural governments to the Prime Minister. The auditor reviewed the relevant documents, including ante-mortem inspection records at establishments G-1, M-1, and K-3 and verified that these establishments had not received any cattle from any of the four identified prefectures. Between April 2012 and March 2013, Japan tested a total of 118,349 cattle in seven U.S.-eligible slaughter establishments of which 118,227 samples were showed test results below

100 Bq/kg. All cattle that show radioactive levels below the 100 Bq/kg are allowed to enter market as food. Japan has reported only two cases in 2012, where the radioactive detection level had been over 100 Bq/kg. Japan disposed of these cattle by incineration.

Japan's meat inspection system has regulatory requirements for a chemical residue control program that is organized and administered by the national government. The CCA has access to and supervises the activities of analytical laboratories that have testing capabilities to ensure the validity and reliability of test data. Therefore, the CCA continues to meet FSIS equivalence criteria at an adequate level of performance for this component.

IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the United States are unadulterated, safe, and wholesome, meeting all equivalence criteria. The onsite audit of Japan's microbiology laboratory system was not within the scope of this year audit. Therefore, the FSIS auditor assessed the implementation of microbiology laboratory's policies and procedures based on information obtained from interviews of regional auditors employed by Kyushu RBHW office.

The evaluation of this component included a review and analysis of Japan's document "*Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States*," previously submitted by the CCA as support for the responses provided in the SRT, and observations made by the FSIS auditor during the onsite audit of the CCA and RBHW government offices and three of the U.S.-eligible establishments. The aforementioned document describes the official inspection methodology for a continuous and systematic assessment of inspection activities during routine verifications of microbiological testing, including *Salmonella* spp. by inspection personnel, and generic *E. coli* by regulated slaughter establishments.

The FSIS auditor accompanied and observed the in-plant inspection verification activities for sponge sampling collection from bovine carcasses for *Salmonella* and generic *E. coli* testing in two audited establishments. The demonstrated methodology is in compliance with Japan's U.S.-export requirements. No concerns arose as the result of these observations.

The CCA has a *Salmonella* sampling and testing program in raw product that mirrors FSIS *Salmonella* Performance Standards requirements cited in 9 CFR 310.25(b). The in-plant inspection personnel collect *Salmonella* samples from chilled bovine carcasses without prior notice. The analytical testing is conducted in the MIC microbiology laboratory which is audited by RBHW regional auditor on a monthly basis. A *Salmonella* set consisted of 82 samples with a maximum number of positives to achieve standard to be ≤ 1 , which is equivalent.

The CCA conducts verification activities that monitor the establishment's generic *E. coli* testing program in chilled bovine carcasses. The testing program complies with FSIS equivalence criteria and is outlined in Japan's document, "*Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States*." The FSIS auditor observed the establishment's generic *E. coli* sampling methodology and verified that the responsible individuals have the knowledge and skill to implement this type of testing on an ongoing basis.

Similarly, both the establishment and inspection personnel are familiar with the upper and lower control limits, as well as what actions are to be taken when the upper limits are exceeded. A review of establishment's testing records indicated that there has not been any loss of process control for the last five months. No concerns arose as the result of these observations. Japan's meat inspection system has regulatory requirements for a microbiological sampling and testing program that is organized and administered by the national government in accordance with Japan's equivalent requirements. However, FSIS identified negative findings (discussed in component one) concerning the CCA oversight. After receipt and review of the CCA's corrective actions, FSIS will make its determination concerning the level of performance for this component.

X. CONCLUSIONS AND NEXT STEPS

In conclusion, the audit results demonstrate that Japan's inspection system is performing at an "adequate" level in maintaining its equivalence. The CCA meets most of the established core criteria for all six equivalence components; however, the audit findings present a need for improvement of the CCA's government oversight. These findings were conveyed by the FSIS auditor to the CCA inspection officials at an exit meeting on May 28, 2013, in Tokyo. The CCA understood and accepted the need to address the following findings in order to maintain its equivalence status:

- The CCA did not have a written staffing standard based on species slaughter and line speeds to meet FSIS equivalency requirements and to ensure sufficient staffing in the event of increased production volume in certified establishments for export to the U. S. This was a system-wide finding.
- The CCA did not provide clear written instructions to its auditors concerning the methodology of monthly audits of microbiological laboratory quality system or monthly supervisory reviews of U.S.-eligible establishments. This was identified at the CCA and one regional office audited.
- The CCA did not provide clear written instructions to its inspection personnel specifying documentation of all identified noncompliances. This was identified during document review, interviews, and observations at the CCA, one regional office, and three U.S.-eligible establishments audited.
- The CCA did not follow its own residue monitoring testing guidance when it did not schedule any testing for hormones in its 2013 residue monitoring testing plan. This was a system-wide finding.
- The CCA provided only limited on-going training related to FSIS requirements to its inspection personnel. The audit identified significant variances in the level of KSA among inspection personnel working in different regions related to:
 - Ongoing verification of the establishment's HACCP systems, including review of decision making documents used to support critical control point location selection and development. The HACCP noncompliances were identified in all three audited establishments.
 - The methodology to verify the effectiveness of stunning procedures of livestock, including the complete loss of sensibility and accompanying physiological signs. This was identified in one establishment where the in-plant inspection personnel were unable to describe the methodology. No improper stunning was observed during this onsite visit.

- The ability to identify and preclude the development of insanitary conditions that may lead to the direct contamination and adulteration of product. The sanitation noncompliances were identified in two of the three audited establishments.

The CCA has taken corrective actions, which, if adequately implemented and effectively executed, should strengthen those weaknesses identified in the audit.

Nader Memarian, DVM
Senior Program International Auditor

XI. APPENDICES

APPENDIX A: Abbreviations and Special Terms

BSE	Bovine Spongiform Encephalopathy
CCA	Central Competent Authority [Ministry of Health, Labor, and Welfare (MHLW)]
CFR	United States Code of Federal Regulations
<i>E. coli</i>	<i>Escherichia coli</i>
FMD	Foot and Mouth Disease
MHLW	Ministry of Health, Labor, and Welfare (MHLW) [Central Competent Authority]
POE	Point-of-Entry
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
RBHW	Regional Bureau of Health and Welfare
<i>Salmonella</i>	<i>Salmonella</i> species
SRM	Specified Risk Materials
SRT	Self Reporting Tool
SSOP	Sanitation Standard Operating Procedures

Appendix B: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Gunma-ken Shokuniku Oroshiuri Shijo Co., Ltd. Sawa-gun, Gunma	2. AUDIT DATE 05/17/2013	3. ESTABLISHMENT NO. G1	4. NAME OF COUNTRY Japan
	5. NAME OF AUDITOR(S) Nader Memarian, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 05/17/2013 Est #: G1 Gunma-ken Shokuniku Oroshiuri Shijo Co., Ltd. ([S/P]) (Gunma, Japan)

22/51: HACCP ongoing requirements based on [9 CFR part 417.5 and 417.8] and [Japan's Requirements for Certification of Abattoirs and Handling of Meat for Exportation to the United States (HACCP requirements)].

- The establishment's HACCP monitoring records did not document the time of monitoring activities.

-The establishment's HACCP verification records for review of records component did not document the time or the results of the ongoing verification activities conducted by the establishment's personnel.

-The establishment's HACCP plan did not include direct observation of monitoring procedures as part of its on-going verification activities.

- The establishment's HACCP plan has placed the monitoring of zero tolerance (fecal, ingesta, and milk) after the final carcass wash. The establishment did not provide a valid decision making document to support its decision.

39/51: Other requirements: [9CFR 416.4 and 416.17] and and [Japan's Requirements for Certification of Abattoirs and Handling of Meat for Exportation to the United States (facility structure)].

- Numerous gaps between the ceiling and protruding metal bars holding attached structures observed in the ceiling above exposed products and food contact surfaces in the cutting room. This may create insanitary conditions and a potential for product contamination.

61. NAME OF AUDITOR

Nader Memarian, DVM

62. AUDITOR SIGNATURE AND DATE

5-17-13

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Miyachiku Co. Ltd. Takasaki Plant Miyakonojo-shi, Miyazaki	2. AUDIT DATE 05/23/2013	3. ESTABLISHMENT NO. MI	4. NAME OF COUNTRY Japan
	5. NAME OF AUDITOR(S) Nader Memarian, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 05/23/2013 Est #: MI (Miyachiku Co. Ltd. [S/P]) (Miyazaki, Japan)

22/51: HACCP ongoing requirements based on [9 CFR part 417.5 and 417.8] and [Japan's Requirements for Certification of Abattoirs and Handling of Meat for Exportation to the United States (HACCP requirements)].

- The establishment's HACCP verification records for calibration of monitoring instruments did not document the time.

-The establishment's HACCP verification records for review of records and direct observation component did not document the time or the results of the ongoing verification activities conducted by the establishment's personnel.

-The establishment's HACCP plan set the frequency of direct observation of monitoring procedures at every two weeks. The establishment records showed a higher (more than two weeks) time frame between verification activities.

39/41/51: Other requirements [Japan's Requirements for Certification of Abattoirs and Handling of Meat for Exportation to the United States (facility structure)].

The FSIS auditor observed extensive black discoloration on the ceiling of several carcass coolers and transit areas which was identified by establishment as mold. Further investigation revealed that:

-The establishment was not able to present any records for cleaning of the ceiling of these areas. The establishment management estimated that these areas were last cleaned in September 2012 (no record was provided).

-The establishment's walls and ceilings in several areas were covered with spray foam insulation type materials which could absorb moisture and aggravate the mold infestation.

-In several locations rust was identified on overhead and surrounding structures, indicating a high level of moisture in these areas.

-The establishment's records (pre-operational and operational records/checklists) had never identified mold problems in these areas.

-In-plant inspection daily verification records (since January 2013) did not document any presence of mold in carcass coolers or other areas.

61. NAME OF AUDITOR
Nader Memarian, DVM

62. AUDITOR SIGNATURE AND DATE

Nader Memarian 5-23-13

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Akunc Meat Distribution Center Co., Ltd. Akunc-shi, Kagoshima	2. AUDIT DATE 05/21/2013	3. ESTABLISHMENT NO. K3	4. NAME OF COUNTRY Japan
	5. NAME OF AUDITOR(S) Nader Memarian, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11, and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 05/21/2013 Est #: K3 Akune Meat Distribution Center Co., Ltd. ([S/P]) (Kagoshima, Japan)

22/51: HACCP ongoing requirements based on [9 CFR part 417.5 and 417.8] and [Japan's Requirements for Certification of Abattoirs and Handling of Meat for Exportation to the United States (HACCP requirements)].

- The establishment's HACCP monitoring records did not document the time of monitoring activities.

- The establishment's HACCP verification records for calibration of instruments did not document the time.

-The establishment's HACCP verification records for review of records component did not document the time or the results of the ongoing verification activities conducted by the establishment's personnel.

61. NAME OF AUDITOR

Nader Memarian, DVM

62. AUDITOR SIGNATURE AND DATE



5-21-13

Appendix C: The CCA's response to the Draft Final Audit Report



Inspection and Safety Division

Department of Food Safety

Ministry of Health, Labour and Welfare, JAPAN

1-2-2 Kasumigaseki Chiyoda-ku Tokyo 100-8916 Japan Tel:81-3-3595-2337 fax:81-3-3503-7964

December 20, 2013

Dr. Shaukat H. Syed
Director
International Audit Staff
Office of Investigation, Enforcement and Audit
Food Safety and Inspection Service
United States Department of Agriculture

Subject: Comments for the draft final audit report

Dr. Shaukat H. Syed:

I would like to provide comments regarding the draft 2013 FSIS final audit report.

I hope that you are satisfied with this information. If you have any questions on this matter, please feel free to contact me.

Yours Sincerely,

TAKIMOTO Hiroshi, D. V. M.

Director

Inspection and Safety Division

Department of Food Safety

Ministry of Health, Labour and Welfare, Japan

Comments for the draft final audit report of Japan

page	content of the report	Japan's comment
IV. Component One: Government Oversight		
4	The CCA's authority to enforce inspection laws are outlined in the Abattoir Law (Law No. 114, August 1, 1953, as of <u>February 27, 2004</u>), Abattoir Law Enforcement Regulation (Law No. 44, September 28, 1953, as of <u>April 1, 2004</u>), and Ordinance for Enforcement of the Food Sanitation Act (Ordinance No. 23, Jul 13, 1948).	We would like to request to change the words as follows: Abattoir Law (Law No. 114, August 1, 1953, as of <u>June 27, 2007</u>) Abattoir Law Enforcement Regulation (Law No. 44, September 28, 1953, as of <u>February 1, 2013</u>)
6	Laboratory Audit Frequency: The regional auditors <u>did not follow</u> the CCA's prescribed monthly frequency of MIC's microbiology laboratory audits.	The regional auditors have audited MIC's microbiology laboratory every month and have verified testing methods, testing results and other by verification of written documents, question to a personnel conducting Salmonella test, etc. However, the regional auditors did not leave an appropriate record. So, we will revise the document "Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States" to leave an appropriate
6	Laboratory Audit Reports: The regional auditors <u>could not</u> produce any microbiology laboratory audit reports.	The regional auditors had reports and showed them to the FSIS auditor although the contents of the reports were limited. So, we would like to request to change the text to "The microbiology laboratory audit reports that the regional auditors produce were limited ". We produced the new form of reports to regional auditors to enrich the reports. ※ Please refer to the document of corrective actions for more information.
6	Laboratory audit feedback: The regional auditors <u>did not</u> share or communicate the results of their microbiology laboratory audits with the CCA central office.	The regional auditors shared the reports with CCA although the contents of the reports were limited. So, we would like to request to change the text to "The results of their microbiology laboratory audits that regional auditors shared or communicated with CCA central office were limited ". ※ Please refer to the document of corrective actions for more information.

The findings pointed out by the FSIS inspector during the on-site audit of Japan's meat inspection system from May 13 through May 28, 2013 and corrective actions.

CCA

Findings1

The CCA did not have a written staffing standard based on species slaughter and line speeds to meet FSIS equivalency requirements and to ensure sufficient staffing in the event of increased production volume in certified establishments for export to the U.S. This was system-wide finding.

Corrective actions

The prescript of stuffing standard based on slaughtering heads per hour will be added to the document "Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States" by reference to 9 CFR 310.1.

Findings2

The CCA did not provide clear written inspections to its auditors concerning the methodology of monthly audits of microbiological laboratory quality system or monthly supervisory reviews of U.S.-eligible establishments. This was identified at the CCA and one regional office audited.

Corrective actions

Concerning the methodology of monthly audit of microbiological laboratory quality system, in addition to a conventional method, a detailed confirmation item will be established. And yearly audit will be added to "Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States" according to it. Concerning the methodology of monthly audit of certified establishments for export to the U.S., it will be described clearly to auditor by listing requirements of "Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States". MHLW explained and informed about the above to the regional auditors and inspection personnel on December 4.

Findings3

The CCA did not provide clear written instructions to its inspection personnel specifying documentation of all identified noncompliances. This was identified during document review, interviews, and observations at the CCA, one regional office, and three U.S.-eligible establishments audit.

Corrective actions

MHLW informed about specifying documentation of all identified noncompliances again. In addition, MHLW will notify of this.

Findings4

The CCA did not follow its own residue monitoring testing guidance when it did not schedule any testing for hormones in its 2013 residue monitoring testing plan. This was a system-wide finding.

Corrective actions

MHLW has developed a monitoring plan for the next year in light of the previous monitoring results and actual condition of use or distribution.

In Japan, there have been no synthetic hormones accepted to use for livestock since 1999 and these hormones have not been detected in the past results of residue monitoring conducted by local governments. MHLW did not include hormones in the 2013 monitoring plan in the light of above information. MHLW also has understood that FSIS was accepted the 2013 plan of Japan because there were no response from FSIS to the 2012 monitoring result and the 2013 plan MHLW submitted on February 4, 2013.

MHLW will revise the residue monitoring testing guidance that recorded residues only monitored.

Findings5

The CCA provided only limited on-going training related to FSIS requirements to its inspection personnel. The audit identified significant variances in the level of KSA among inspection personnel working in different regions related to:

- Ongoing verification of the establishment's HACCP systems, including review of decision making documents used to support critical control point location

selection and development. The HACCP noncompliances were identified in all three audited establishments.

- The methodology to verify the effectiveness of stunning procedures of livestock, including the complete loss of sensibility and accompanying physiological signs. This was identified in one establishment where the in-plant inspection personnel were unable to describe the methodology. No improper stunning was observed during this onsite visit.
- The ability to identify and preclude the development of insanitary conditions that may lead to the direct contamination and adulteration of product. The sanitation noncompliances were identified in two of the three audited establishments.

Corrective actions

MHLW decided to carry out training class related to FSIS requirements for designed inspectors and RBHW auditor at least once a year. We carried it out on October 7 and December 4 in this year and did full dissemination to the participant about FSIS requirements and all matters which were pointed out in the FSIS audit.

And MHLW ordered them to carry out a transmission class about class these contents in each workplace.

Furthermore, once in a half year, RBHW auditor carries out the class a related to FSIS requirements for designed inspectors in each inspection center.

In addition, MHLW examine the training dispatch to the foreign countries, the practical training, further improvement of existing training to promote personnel training.

MHLW will verify the effect of these training.

Miyachiku Co., Ltd. Takasaki Plant (Est. M-1)

Findings6

The establishment's HACCP verification records for calibration of monitoring instruments did not document the time.

Corrective actions

The HACCP verification records for calibration of monitoring instruments were revised to add the time. The establishment's manager distributed the information of the revised recording form to all workers and checked their level of understanding.

Findings7

The establishment's HACCP verification records for review of records and direct observation component did not document the time or the results of the ongoing verification actions conducted by the establishment's personnel.

Corrective actions

The HACCP verification records for review of records and direct observation component were revised to add the time and the results of the ongoing verification actions. The establishment's manager distributed the information of the revised recording form to all workers and checked their level of understanding.

Findings8

The establishment's HACCP plan set the frequency of direct observation of monitoring procedures at every two weeks. The establishment records showed a higher (more than two weeks) time frame between verification activities.

Corrective actions

The establishment classified the cause of hire time frame between verification activities was short on staff in busy season because they prescribed only plant manager carried out verification. The HACCP plan was revised which two persons carry out direct observation of monitoring procedures at every two weeks.

The verification of the implementation of the HACCP plan was improved.

Findings9

The FSIS auditor observed extensive black discoloration on the ceiling of several carcass coolers and transit areas which was identified by establishment as mold. Further investigation revealed that:

- The establishment was not able to present any records for cleaning of the ceiling of these areas. The establishment management estimated that these area were last cleaned in September 2012 (no record was provided).
- The establishment's walls and ceilings in several areas were covered with spray foam insulation type materials which could absorb moisture and aggravate the mold infestation.

- In several locations rust was identified on overhead and surrounding structures, indicating a high level of moisture in these areas.
- The establishment's records (pre-operational and operational records/checklists) had never identified mold problems in these areas.
- In-plant inspection daily verification records (since January 2013) did not document any presence of mold in carcass coolers or other areas.

Corrective actions

The establishment cleaned up all mold and rust in the facility. They changed the insulation type materials to another one with low moisture retention and placed the dehumidifiers in the carcass pre-chilling room (hot box), packing room and shipping area for products. And they placed hygrometers in these areas and have been verified control of humidity. The establishment checks mold, rust, dew condensation, etc. at pre-operational inspection every day and if found, clean up them immediately. They prescribed to verify that sanitary control of the facility is good condition once a week. If they determine that it is not enough sanitary control, they take additional corrective actions and report to MIC. In addition, they revised the SSOP and wrote the cleaning frequency in the manual. The manager distributed the information of revised SSOP to all workers and checked their level of understanding.

It have been verified that the facilities are maintained in good condition by inspection personnel and the regional auditors, and follow-up activities will be done continuously.

Gunma-ken Shokuniku Oroshiuri Sijo Co., Ltd. (Est. G-1)

Findings10

The establishment's HACCP monitoring records did not document the time of monitoring activities.

Corrective actions

The HACCP monitoring records were revised to add the time of monitoring activities. The establishment's manager distributed the information of the revised recording form to workers.

Findings11

The establishment's HACCP verification records for review of records component did not document the time or the results of the ongoing verification activities conducted by the establishment's personnel.

Corrective actions

The HACCP verification records for review of records component were revised to add the time and the results of the ongoing verification activities. The establishment's manager distributed the information of the revised recording form to workers.

Findings12

The establishment's HACCP plan did not include direct observation of monitoring procedures as part of its on-going verification activities.

Corrective actions

Direct observation of monitoring procedures was included in the HACCP plan. The establishment prescribed that a person in charge of quality control should conduct direct observation once a week and informed the prescription to workers.

Findings13

The establishment's HACCP plan has placed the monitoring of zero tolerance (fecal, ingesta, and milk) after the final carcass wash. The establishment did not provide a valid decision making document to support its decision.

Corrective actions

The establishment verified the monitoring location of CCP 1 and concluded that they should implement the monitoring of zero tolerance before carcass wash in order to find and trim fecal, ingesta and milk more reliably. They implement the monitoring of zero tolerance before the final carcass wash and are in the process of change their HACCP plan. They also are going to move the carcass wash machine to the backward area for hygiene measure and improvement of workability since the space is a little small to implement monitoring. They put the story of change into writing.

On this occasion, MHLW gave guidance that all establishment eligible export to the U.S. should verified the monitoring location of zero tolerance again.

Findings14

Numerous gaps between the ceiling and protruding metal bars holding attached structures observed in the ceiling above exposed products and food contact surfaces in the cutting room. This may create insanitary conditions and a potential for product contamination.

Corrective actions

Maintenance and repair which fill all gaps were conducted. This requirement was informed to workers.

Akune Meat Distribution Center Co., Ltd. (Est. K-3)

Findings15

The establishment's HACCP monitoring records did not document the time of monitoring activities.

Corrective actions

The HACCP monitoring records were revised to add the time of monitoring activities. The establishment's manager distributed the information of the revised recording form to workers.

Findings16

The establishment's HACCP verification records for calibration of instruments did not document the time.

Corrective actions

The HACCP verification records for calibration of instruments were revised to add the time. The establishment's manager distributed the information of the revised recording form to workers.

Findings17

The establishment's HACCP verification records for review of records component did

not document the time or the results of the ongoing verification activities conducted by the establishment's personnel.

Corrective actions

The HACCP verification records for review of records component were revised to add the time and the results of the ongoing verification activities. The establishment's manager distributed the information of the revised recording form to workers.

Findings for each establishment were confirmed to be improved appropriately by MICs and MHLW. MHLW also informed the contents of the draft final report and all findings and took corrective actions against the findings to the regional auditors and inspection personnel.