

Agricultural Marketing Service (AMS)
Livestock, Poultry and Seed (LPS) Program
Food Safety and Commodity Specification (FSCS) Division
Room 2624 S-Bldg, Phone: (202) 692-0342

**SUPPLEMENT 212 TO THE
AMS MASTER SOLICITATION
FOR PURCHASE OF FRESH
CHILLED BONELESS BEEF
PRODUCTS FOR FURTHER
PROCESSING INTO FULLY
COOKED ITEMS FOR
DISTRIBUTION TO FEDERAL
FOOD AND NUTRITION
ASSISTANCE PROGRAMS**

Supersedes: Supplement 212 April 2016 – Changes
from previous requirements in [blue](#)

Effective: [August 2017](#)

100 OVERVIEW

110 This document provides additional program requirements for the purchase of Fresh Chilled Boneless Beef Products by the Department of Agriculture (USDA), including the applicable Federal Purchase Program Specification (FPPS) (**Exhibit A**).

200 INSTRUCTIONS TO POTENTIAL SUPPLIERS

210 The fresh chilled boneless beef products shall be purchased on a competitive bid basis from qualified suppliers who have met the requirements described in this Section. Interested suppliers may submit a technical proposal at any time during the purchase program. Suppliers should allow 10 working days, from USDA's receipt of the technical proposal for notification of evaluation results. A supplier is deemed eligible upon notification of approval of the technical proposal by the Food Safety and Commodity Specification (FSCS) Division.

220 Submission of a technical proposal is not binding on USDA. Actual purchases shall be described in the AMS Master Solicitation [for Commodity Procurements](#) and Solicitations.

230 Documentation Requirements

231 Technical Proposal Requirement

231.1 Include a detailed description of the boneless beef product offered and each of the production steps that are taken to meet or exceed the minimum product requirements set forth in the FPPS. (Plan/Do)

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- 231.2 Describe all the quality assurance methods used to verify conformance to all requirements. This shall include the monitoring and measurements taken during the process to verify conformance with each requirement. All measurement results shall be recorded and made available to AMS. (Check)
- 231.3 Identify all corrective actions to be taken if deviations from contractual and specification requirements occur during production, and all preventative actions to be taken to preclude a reoccurrence. (Act)
- 231.4 The technical proposal shall follow the format as shown in **Exhibit C**. Technical proposals should be brief and concise.
- 231.5 The technical proposal shall be preceded by the following, as required by the template:
- 231.5.1 Table of Contents listing the major areas as they appear in the technical proposal; and
- 231.5.2 List of attachments, forms provided with the technical proposal, if appropriate with the applicable document name and reference number.
- 232 The FSCS Division shall review each technical proposal to determine if it is adequate and shall notify the supplier of the status and their eligibility to bid.

233 Animal Welfare Requirements

- 233.1 All eligible suppliers shall meet the animal handling and welfare requirements set forth in the FPPS for Animal Handling and Welfare, effective **August 2017 (Exhibit B)**.

300 INSTRUCTIONS FOR SUBMISSION OF TECHNICAL PROPOSAL

- 310 The following procedures establish the acceptable minimum requirements for the format and content of the technical proposal:
- 310.1 The Government has provided a technical proposal format to be used in preparing the technical proposal (see **Exhibit C**). The supplier shall submit the technical proposal as an email file attachment to AMS (Darin.Doerscher@ams.usda.gov and Steve.Whisenant@ams.usda.gov). The technical proposal shall be saved in a non-portable document file format (not PDF; e.g., Microsoft Word). The technical proposal **shall** be submitted in its entirety. If the file size of the technical proposal is too large to send in a single email, it may be divided and sent in multiple emails (i.e., Part 1, Part 2, Part 3, etc.). The collection of attachments and appendices may be submitted as a separate document as well.
- 310.2. The technical proposal shall be submitted by an authorized agent of the company.
- 310.3 While it is not the desire of the Government to penalize a supplier for non-compliance with formatting instructions, technical evaluators may have difficulty evaluating the

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technical proposal to the fullest extent possible if the proposal is not presented in the proper format. Technical evaluators shall not be required to search other subsections or sections of the supplier's technical proposal for information requested in the evaluation.

320 Technical Proposal Revisions

321 Changes to a supplier's technical proposal may be submitted at any time or at the request of the FSCS Division. All technical proposal revisions shall meet the following criteria:

321.1 Any changes to a technical proposal made by the supplier after its initial submittal shall be accomplished by submitting an entire technical proposal. A cover letter shall be submitted with the changes identified and an explanation of the need for the change. The supplier shall include the revision date and the appropriate page number(s).

321.2 Changes from the original technical proposal shall be **highlighted** and deletions in ~~strikeouts~~.

400 ASSESSMENT BY THE QUALITY ASSESSMENT (QA) DIVISION

410 Once a supplier is notified by the FSCS Division that the technical proposal meets the applicable criteria, the Quality Assessment (QA) Division shall contact the supplier to set up a pre-award onsite capability assessment audit of the facility's processes, food defense plan, and quality control program used to produce the product(s) to determine the supplier's ability to meet contractual requirements.

420 Pre-Award Onsite Capability Assessment Audit

421 Food Defense Assessment

421.1 The QA Division shall conduct a food defense audit that shall include, but is not limited to, a thorough evaluation of the supplier's food defense plan. Documentation shall support the supplier's food defense plan. If the report demonstrates that the food defense plan is inadequate, the supplier shall be notified by the FSCS Division that they are ineligible to bid. The supplier shall have an opportunity to correct identified deficiencies, modify their food defense plan and resubmit a brief description for further consideration. Eligibility shall depend on whether the modifications demonstrate compliance with the food defense plan.

422 Harvesting Requirement

422.1 The QA Division shall conduct monthly harvesting and humane handling audits based on the requirements stated in the attached FPPS and the company's approved technical proposal. Documentation shall support the supplier's adherence to meeting the harvesting and humane handling requirements as set forth in the FPPS.

423 Documentation shall support:

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- 423.1 the production of the fresh boneless beef product that complies with the FPPS and the potential supplier's approved technical proposal, and
- 423.2 the supplier's food defense plan. In addition, the audit shall consist of the review of records related to purchasing, receiving, production, quality control, inventory and shipping records, and interviews with management and production personnel.
- 424 Upon completion of the onsite capability assessment, the auditor shall provide either a verbal or email notification of the audit findings to the FSCS Division to determine (based on the audit findings), supplier eligibility to bid. Supplier shall be notified by the FSCS Division and the official final report shall be sent once released from the QA Division.
- 424.1 If the audit findings demonstrate that the process or food defense plan is inadequate, the applicant shall be notified by the FSCS Division that they are ineligible to bid. The supplier shall have an opportunity to correct identified deficiencies, modify the process, food defense plan, and/or technical proposal, and resubmit for further consideration.
- 424.2 Eligibility shall depend on whether the modifications demonstrate that:
 - 424.2.1 the process is capable of delivering fresh boneless beef products in compliance with the FPPS,
 - 424.2.2 the supplier is in compliance with the food defense plan,
 - 424.2.3 a successful QA Division corrective action audit is conducted, and
 - 424.2.4 the supplier complies with other applicable contractual requirements.
- 430 Post-Award Assessment Audit
- 431 Eligible suppliers who receive contracts shall have their documented food defense plan, technical proposal, and supporting documentation readily available for review by the FSCS Division or AMS agents. Records may be maintained on hard copy or electronic media. However, records maintained as electronic media shall be made available in printed form immediately upon request by the FSCS Division or AMS agents.
- 432 The QA Division shall conduct an onsite audit of the supplier's facility(s) and processes when production commences for the first contract awarded. Additional audits shall be conducted as determined by the FSCS Division, but not less than once per month for supplier's with continuous or multiple contracts, or once per contract for intermittent supplier's. At the discretion of the FSCS Division, more frequent audits may be conducted when audit deficiencies are detected.
- 440 Post-Award Actions

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- 441 Any deviation from contractual requirements shall be immediately reported by the supplier to the Contracting Officer and FSCS Division. The Contracting Officer or FSCS Division shall notify the supplier regarding eligibility to continue to participate as a contractor.
- 442 Suppliers shall assure that the delivered product complies with the provisions of the FPPS, the applicable assessment by USDA, and the supplier's technical proposal approved by the FSCS Division.
- 450 The cost of all audit, product monitoring, and certification services performed by the AMS agents shall be borne by the supplier. This includes, but is not limited to, audits, examinations, supervision, official documentation, and related services.
- 451 Questions concerning charges and the availability of AMS agents can be directed to USDA/AMS, LPS Program's QA Division field office or the Director of the QA Division, LPS Program, AMS, USDA, Room 3953-S, STOP 0258, 1400 Independence Avenue, SW, Washington, DC 20250-0258, telephone (202) 720-3271.

500 PAST PERFORMANCE

- 510 Supplier Monitoring Program Requirements
- 511 Boneless beef suppliers' performance as a supplier on contracts awarded by the Department of Agriculture (USDA) shall be evaluated monthly on a 180 day (6 month) basis or cycle.
- 512 The evaluation shall consist of all non-conformances (NC) that were identified by the QA Division auditor. The NC's shall be categorized as critical, major, or minor based on their impact on the quality, safety, or value of the involved product.
- 513 The accumulation of at least two critical NC's, one critical/two major NC's, three major NC's, or a total five NC's in any combination, (i.e., critical, major, or minor) within the monthly 180 day (6 month review) shall result in the boneless beef supplier being deemed ineligible by the FSCS Division to supply fresh boneless beef product to AMS contractors to fill USDA contracts.
- 513.1 To regain eligibility status, the boneless beef supplier shall submit appropriate corrective and preventative measures to FSCS Division for evaluation and the measures shall be verified by QA Division as effective. The FSCS Division shall notify the boneless beef supplier when eligibility to supply boneless beef has been reinstated.
- 514 The microbial test results shall be analyzed separately under statistical process controls.
- 515 The criteria for the three categories of non-conformances are as follows:

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515.1 Critical

515.1.1 **Production non-conformances**--a complete breakdown of the production process has occurred. It is apparent that the company cannot produce product that complies with contract requirements.

515.2 Major

515.2.1 **Production non-conformances**--major deviation from the production process has occurred that significantly impacts the quality or performance of the product. It is questionable if the company can consistently produce product that complies with contract requirements.

515.3 Minor

515.3.1 **Production non-conformances**--minor deviation from the production process has occurred that minimally impacts the quality or performance of the product. It is likely that the company can produce a product that complies with contract requirements.

520 Sustained Acceptable Performance

521 **A supplier shall be deemed ineligible to supply fresh boneless beef products or ground beef for the USDA purchase programs if:**

521.1 The supplier is subject to a Class I recall; or

521.2 Based on an evaluation of all AMS test results for *E. coli* O157:H7 and *Salmonella* during the previous calendar quarter, the incident rate for either boneless beef or ground beef exceeds the central line (cl) values set forth in Appendix B of the referenced FPPS (**Exhibit A**).

522 If deemed ineligible, a supplier shall:

522.1 perform a cause-and-effect analysis,

522.2 submit the corrective and preventative actions to FSCS Division for review and approval,

522.3 have a successful corrective action audit conducted.

522.4 FSCS Division shall notify the boneless beef supplier when eligibility to supply boneless beef has been reinstated.

600 **DOMESTIC ORIGIN CERTIFICATION CLAUSE**

610 The supplier shall include the below domestic origin certification clause in its entirety in all subcontracts for meat or meat products used in fulfilling any contracts awarded under this Supplement and Master Solicitation. The burden of proof of compliance is

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on the Contractor. All raw materials shall be shipped in containers labeled as "Domestic Only Product" on the principle display panel and the bill of lading accompanying the shipment shall contain the statement "Domestic Only Product."

700 CERTIFICATE OF CONFORMANCE (COC)

710 In addition to the referenced payment documents required in the Master Solicitation, please include a copy of the Contractor's Certificate of Conformance (**Exhibit D**).

800 CONTRACTOR CHECKLOADING

810 Contractor shall perform checkloading examinations as described in the FPPS at the time of shipment and issue contractor's certificate to accompany each shipment that includes all of the following information:

810.1 Purchase Order Number,

810.2 Sales Order and Sales Order Item Number,

810.3 Name of product,

810.4 Shipping Date,

810.5 Production lot number(s) and date each lot was produced,

810.6 Count of shipping containers and total projected net weight in each production lot,

810.7 Identity of car or truck (car numbers and letters, seals, truck license, etc.) as applicable

810.8 Contractor certification that product conforms with the FPPS,

810.9 Count and projected net weight verified, and

810.10 Signature of company official responsible for checkloading.

900 EXHIBITS

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APPROVED

**FEDERAL PURCHASE
PROGRAM SPECIFICATION
(FPPS) FOR FRESH
CHILLED, BONELESS BEEF
FOR FURTHER
PROCESSING INTO FULLY
COOKED ITEMS**

Agricultural Marketing Service (AMS)
Livestock, Poultry, and Seed (LPS) Program
Food Safety and Commodity Specification (FSCS) Division
Room 2628 S-Bldg, Phone: (202) 692-0342

Supersedes: FPPS BB April 2016 – Changes from previous requirements in [blue](#)

Effective: [July 2017](#)

100 SCOPE

110 This FPPS – Boneless Beef (BB) – [2017](#) is for use by a contractor of the Department of Agriculture (USDA), AMS, Commodity Procurement (CP) Staff to deliver fresh-chilled (never previously frozen) boneless beef for further processing into fully cooked items.

200 APPLICABLE DOCUMENTS

210 The following documents are incorporated as part of this USDA, FPPS-BB-[2017](#):

210.1 Quality Assessment (QA) Division Procedures Manual.

210.2 Food Safety and Inspection Service (FSIS) Directive 10,010.1 Revision 4.

210.3 Applicable Supplement to AMS Master Solicitation [for Commodity Procurements](#).

300 CHECKLIST OF REQUIREMENTS

301 The contractor's technical proposal shall describe a process plan with a documented quality control program that includes procedures, records, forms, etc., that demonstrate conformance with the following AMS Checklist of Requirements.

302 Substitution Programs - Contractors that may produce boneless beef for processing into fully cooked items for direct sales to further processors that hold QA Division substitution plans shall declare this in their technical proposal. It is the contractor's responsibility to ensure that substitutable boneless beef raw materials sold to further processors for use as substitutable product are produced and managed according to provisions outlined in Section 301.

- 310 MATERIAL REQUIREMENTS FOR FRESH-CHILLED BONELESS BEEF**
- 311 Domestic Origin and Harvest (Slaughter) Requirements – The contractor’s quality control program shall be documented and have received a satisfactory onsite capability assessment by QA Division prior to supplying materials for the program. Additionally, each establishment shall be subjected to verification audits conducted by QA Division during production activities that demonstrate its adherence to the documented program. Boneless beef shall be derived **from carcasses that are derived** from cattle harvested at establishments that comply with the following origin and harvest requirements.
- 312 Domestic Origin - All beef shall originate from U.S. produced livestock as defined within the Master Solicitation **for Commodity Procurements** and Supplement.
- 313 Humane Handling - All cattle shall be humanely handled in accordance with all applicable FSIS regulations and AMS requirements.
- 314 Spinal Cord Removal – All spinal cord tissue shall be removed during the harvesting process.
- 315 Pathogen Intervention – The harvest process shall include at least two pathogen intervention steps. One of the intervention steps shall be a critical control point (CCP) in the establishment’s FSIS recognized harvest process Hazard Analysis Critical Control Point (HACCP) plan. The CCP intervention(s) shall be scientifically validated to achieve a three-log reduction of enteric pathogens.
- 316 Grass Fed – When specified in the invitation, boneless beef destined to be labeled as grass fed shall be supported by documentation and the FSIS approved label which substantiates such a claim.
- 317 Residue Prevention – Harvest and production establishments shall have a HACCP system to control veterinary drug, pesticide, and environmental contaminant residues per FSIS regulations. Helpful information is available in the FSIS Compliance Guide for Residue Prevention 2013.
- 318 Boneless Beef Requirements
- 318.1 Traceability – Boneless beef shall be traceable to sources that comply with the above domestic origin and harvest requirements.
- 318.2 Handling - All boneless beef shall be maintained in excellent condition. The contractor’s technical proposal shall include detailed production scheduling that addresses time and temperature controls necessary to maintain excellent condition of the boneless beef.

- 318.3 Boneless beef commonly referred to by the industry as XF trimmings (e.g., Beef Fat with Visible Lean) is not allowed as a raw material source for grinding.
- 318.4 Objectionable materials - The following objectionable materials shall be excluded:
- 318.4.1 Major lymph glands (*prefemoral, popliteal, and prescapular*), thymus gland, sciatic (*ischiatric*) nerve (lies medial to the outside round), and internal fat (kidney, pelvic, and heart fat).
- 318.4.2 All bone, cartilage, shoulder tendon, elbow tendon, silver skin from the outside round, *sacrosciatic* ligament, opaque periosteum, serous membrane (*peritoneum*), tendinous ends of shanks, *patellar* ligament (stifle joint), *gracilis* membrane (from the inside round), *achilles* tendon, back strap and *abdominal tunic*.
- 318.5 **Mechanical Separation - Boneless beef that is mechanically separated from bone with automatic deboning systems or advanced lean (meat) recovery (AMR) systems is not allowed.**
- 318.6 Lot - A lot shall consist of a single combo sized bin of approximately 2,000 pounds of boneless beef produced within a day, between “cleanup to cleanup” (see APPENDIX C) and that is from a single harvester or from a single processor.
- 318.7 Microbial Testing – All lots of fresh chilled boneless beef shall be tested for all indicator microorganisms listed in APPENDIX B. All samples shall be sent to the AMS designated laboratory (ADL).
- 318.7.1 Sample Preparation and Handling - The ADL shall be responsible for supplying procedures for sample preparation, and submission. The ADL shall require contractors to submit this form as an official record with each sample. Samples submitted for boneless beef produced under a substitution plan shall be appropriately identified on the ADL sample submission form. The ADL shall also be responsible for supplying shipping supplies (including sampling bags and shipping materials), to each contractor. Contractor's technical proposal shall include and describe sample collection and preparation procedures provided by the ADL.
- 318.7.2 Sample Selection
- 318.7.2.1 For Beef Manufacturing Trimmings – The composite sample shall be selected as described within FSIS Directive 10,010.1 Revision 4 (N-60 Sections 8, 9 and NOTE).

- 318.7.2.2 For every lot of beef Manufacturing Trimmings, one sample shall be prepared from five different pieces of trim from five different pieces of beef product. The sample for indicator microorganisms (aerobic plate count, total coliform and generic *E. coli*) shall weigh 25 grams \pm 10 percent.
- 318.7.2.3 Alternative sample collection methods may be used provided they are approved by AMS as equivalent to the manual excision protocols referenced in Section 319.7.2.1. The supplier's technical proposal shall include and describe any proposed alternative sample collection and preparation methods and procedures.
- 318.7.2.4 When boneless beef has been exposed to any anti-microbial treatment, no sample units shall be selected for at least 15 minutes after such treatment. All anti-microbial treatments (e.g. techniques and procedures) administered during production and post-production shall be described in the supplier's technical proposal.
- 318.7.2.5 If the contractor plans to do microbiological testing in addition to that required by AMS, the technical proposal shall identify in detail such testing, including location of sample collection, frequency of sample collection, and intended use of testing results. AMS shall make a determination of whether such additional sampling and testing constitutes "prescreening," in which case it shall not be allowed.
- 318.7.3 Testing and Results
- 318.7.3.1 The microbiological testing for all indicator microorganisms shall be in accordance with the applicable AMS-approved testing methodologies.
- 318.7.3.2 When the critical limit is exceeded for indicator microorganisms, the boneless beef contractor shall document the removal of the affected lot(s) and make such documentation available to an AMS Agent upon request.
- 318.7.3.3 The ADL shall record results of all indicator microorganisms' analysis in a format that can be easily captured and analyzed.
- 318.7.3.4 The ADL shall record all results on spreadsheets and calculate the process capability (CPU) for indicator organism tests performed on production lots as outlined in Section 318.7.4.
- 318.7.3.5 Any lot that exceeds the critical limit criteria of APPENDIX B shall not be delivered to USDA.
- 318.7.4 Statistical Process Capability – The statistical process capability of a boneless beef contractor to comply with microbial requirements shall be based on the assessment of calculated process capability (CPU) derived from the individual combo test results representing one 2,000 pound combo lot randomly selected by the ADL from every five consecutive individual 2,000 pound combo lots produced each production day. In the

event that a production day concludes with less than five consecutive individual 2,000 pound combo lots, a randomly selected test result shall be utilized from one of the remaining lots. The spreadsheets shall be maintained so that process capability assessment on the 20 lots can be determined as described within APPENDIX B. Test results involving all boneless beef offered for testing for AMS purchase programs shall be monitored by AMS and the contractor, to determine individual lot acceptance and/or capability of the contractor's process according to APPENDIX B. Ineligible boneless beef contractors may re-enter the program under conditional status provided corrective actions have been submitted for review and approved, implemented and a satisfactory onsite corrective action audit by QA Division has been conducted. Upon notification by the FSCS Division that the plan has adequately addressed the issues that resulted in the ineligible status determination, the boneless beef contractor may re-enter the program under conditional status.

318.7.5 Contractor's Responsibility - The contractor shall provide results and process capability status (as applicable) involving each lot of boneless beef to be delivered to the USDA. Test results and process capability status (as applicable) for individual lots shall be provided to the QA Division agent upon request. In the event a boneless beef contractor has been deemed ineligible, and wants to continue in the program, the ineligible boneless beef contractor may re-enter the program under conditional status provided corrective actions have been submitted for review and have been deemed approved, implemented and a satisfactory onsite corrective action audit by QA Division has been conducted. Upon notification by the FSCS Division that the plan has adequately addressed the issues that resulted in the ineligible status determination the boneless beef contractor may re-enter the program under conditional status.

318.7.6 Supplier requests to remove samples from AMS testing shall be submitted and approved by FSCS Division prior to sample removal from ADL testing.

318.8 Lots of boneless beef tested for indicator microorganisms only (as described in Section 318.7) shall not be diverted for use in ground beef products for delivery to USDA under FPPS-GB or for Type II under FPPS-CGB.

320 STATE OF REFRIGERATION

321 Fresh-chilled boneless beef shall be maintained and delivered at a temperature not to exceed 40°F.

330 FAT LIMITATIONS

- 331 Requirements - The contractor shall establish a target average of 15 percent fat of all boneless beef destined for USDA. The upper and lower specifications limits shall be 18.0 and 12.0 percent fat respectively. Production lots with average fat results that are not within the upper and lower specification limits shall not be shipped to USDA.
- 332 Process Capability -The processor's capability (Cpk) value shall be one (1) or higher when the average results from 20 consecutive production lots (which always shall include the last production lot) are calculated.
- 333 Documentation - The contractor shall declare within its technical proposal:
- 333.1 Lot size, number of samples, selection and preparation procedures,
- 333.2 The laboratory and a test method,
- 333.3 Data management and storage of fat results,
- 333.4 Statistical Process Control (SPC) charting methods which shall include a process capability report (histogram) that is capable of calculating a Cpk value (see Exhibit A).
- 334 Assessment by AMS - AMS reserves the right to:
- 334.1 Check production records of the recipient where the contractor's boneless beef is further processed;
- 334.2 Select and analyze samples at the further processor. The results may be used by the contracting officer as a "check" to determine if fat content is in compliance with the fat limitation requirements; and/or
- 334.3 Deem a contractor unreliable for failure to comply with the above requirements.
- 340 PACKAGING AND PACKING**
- 341 The contractor's technical proposal and process shall assure that all packaging, packing, closure, marking, and palletizing comply with the National Motor Freight Regulations and FSIS regulations and the requirements listed below. The contractor also shall have procedures for verifying the net weight of shipping containers.
- 342 Packaging and Packing – The contractor shall bulk package the boneless beef within lined "combo bins" in such a manner to maintain the product in excellent condition. The combo bins of boneless beef shall be covered so that the container arrives at the destination intact.

343 Net Weight – The contractor shall have procedures that accurately determine the net weight of the boneless beef. Each filled combo bin shall weigh from 1850 to 2250 pounds. AMS reserves the right to perform net weight examinations at destination.

344 Marking of Containers – All shipping container markings shall include all information required by FSIS regulations and the following information:

344.1 The following statement: “Complies with FPPS-BB-2017 - Boneless Beef for Further Processing into Fully Cooked Items”:

344.2 A code number that shall indicate traceability to production lot and date.

344.3 USDA Shield (at least 2 inches high).



344.4 Purchase Order Number.

344.5 Fat Declaration.

344.6 The appropriate material number listed in the table below for each of the items:

<u>Item</u>	<u>Material Number</u>
Boneless Beef Combo, Fresh	100155
Boneless Beef Combo, Grass Fed, Fresh	110091

Note: All labeling shall be illustrated in the Contractor’s technical proposal.

345 Total net weights per delivery unit - The delivery unit shall be 40,000 pounds.

346 Sealing - All products shall be delivered to AMS assigned destinations under seal with tamper proof, tamper resistant, serially numbered, high security seals that meet the American Society for Testing and Materials Standard (ASTM) F 1157-04 and/or the International Organization for Standards (ISO) 17712-2010 as required under the Master Solicitation. Seals shall be $\geq \frac{1}{8}$ th inch diameter cable, high-security bolt, or equivalent.

400 CONTROL OF NON-CONFORMING PRODUCT

401 The contractor shall include a plan and supporting documentation to assure that non-conforming product is not delivered under USDA contracts. The plan shall address 1) control and segregation of non-conforming product, 2) removal of any USDA markings, and 3) disposition of non-conforming product, including documentation of final disposition (e.g., diverted to cooked product or destroyed).

500 QUALITY ASSURANCE

510 Warranty and Complaint Resolution

511 Warranty – The contractor shall guarantee that the product complies with all specification requirements, technical proposal declarations, and provisions set forth in the Master Solicitation.

512 Complaint Resolution – Customer complaint resolution procedures shall be included in the technical proposal. These procedures shall include: a point of contact, investigation steps, intent to cooperate with AMS, and product replacement or monetary compensation. The procedures shall be used to resolve product complaints from recipient agencies or AMS.

520 Contractor Checkloading - Contractor shall perform checkloading examinations at the time of shipment and issue a contractor's certificate to accompany each shipment that includes all of the following information:

520.1 Purchase Order Number/Purchase Order Line Item Number;

520.2 Sales Order Number/Sales Order Line Item Number;

520.3 Destination of shipment;

520.4 Name of Product and applicable Material Number;

520.5 Shipping Date;

520.6 Production lot number(s) and date each lot was produced along with shipping container code(s) and the code used that provides traceability to production lot and date;

520.7 Count of shipping containers and total projected net weight in each production lot;

520.8 Identity of car or truck (car numbers and letters, seals, truck license, etc.) as applicable;

520.9 Contractor certification that product conforms with the applicable specification (FPPS-BB-[2017](#));

520.10 Count and projected net weight verified and;

520.11 Signature of company official responsible for checkloading.

APPENDIX A

DATA ENTRY AND PROCESS CAPABILITY VALUE

Data Entry

The ADL shall record microbiological test results on spreadsheets and make those spreadsheets readily available to AMS and its contractors/suppliers. Quantitative (plate count) results shall be expressed as colony forming units (CFU) per gram or per ml reflecting the original sample measurement. Test results shall be entered as a whole number (i.e., no decimal places, no preceding < (less than) symbol).

The ADL shall provide the calculated process capability values (CPU, CI) in the spreadsheets so that the supplier's process capability assessment can be determined, as described in APPENDIX B.

Process Capability Values – CPU or Cpk

The process capability value (CPU) shall be calculated by the ADL. CPU shall be used for microbiological tests, given these requirements only have an upper specification limit. Cpk shall be used for fat testing requirements that have an upper and lower specification limit (see **Section 332**). The upper specification limits (USL) for microbiological requirements are in APPENDIX B. The calculations for CPU and Cpk are as follows:

<u>Calculation of process capability (CPU) with an upper specification limit only</u>	<u>Calculation of process capability (Cpk) with an upper and lower specification limit</u>
Step 1. The first calculation shall determine the Z-value (upper): $Z\text{-value (upper)} = (USL - \text{Process Average}) / \text{Standard Deviation}$	Step 1. The first set of calculations shall determine the smaller value of the two Z-values (upper or lower): $Z\text{-value (upper)} = (USL - \text{Process Average}) / \text{Standard Deviation}$
Step 2. The Z-value divided by 3 shall calculate the CPU: $CPU = Z\text{-value (upper)} / 3$	$Z\text{-value (lower)} = (\text{Process Average} - LSL) / \text{Standard Deviation}$ Step 2. The smaller of the two Z-values (upper or lower) divided by 3 shall calculate the Cpk. $CPU = Z\text{-value (smaller value of the upper or lower)} / 3$

APPENDIX B

AMS BONELESS BEEF PROCESS REQUIREMENTS FLOW CHART

Quality Control Program – Prior to bidding on boneless beef contracts with the USDA, the documented quality control program as described within the approved technical proposal shall have received a satisfactory onsite capability assessment by QA Division. AMS shall audit and monitor the program. The quality control program shall specifically address management of microbial data to comply with the AMS Process Requirements Flow Chart and the following descriptions.

Process Assessment Status - A process assessment involves sampling and testing of 20 consecutive lots (which shall include the last recorded result as defined within APPENDIX C) of boneless beef (see **Section 319.7.4**) destined for USDA contracts for the organisms listed within the table below.

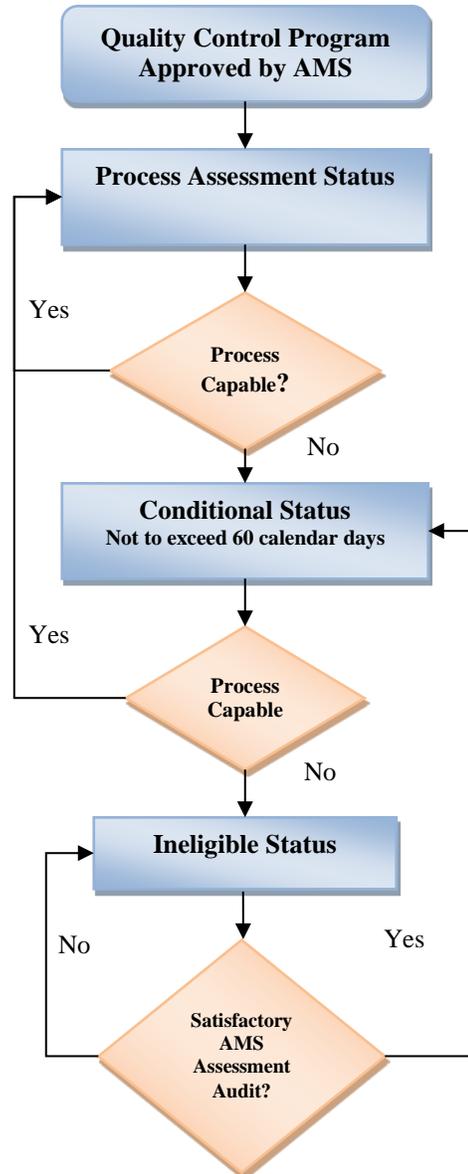
Process Capable? – Flow chart decision step that involves test results for up to 20 consecutive lots (which shall include the last recorded result) recorded in spreadsheets, where the process capability (CPU) value is calculated (See APPENDIX A) for evaluation. A process that is not capable shall be declared to the FSCS Division immediately when results are known and shall result in switching from **process assessment** status to **conditional status** or switching from **conditional status** to **ineligible status** when:

- The CPU values do not meet the levels specified in the table below;
- Two results exceed any of the critical limits in the table below; * or
- After 2 or more results, the CPU value is negative.*

*Immediate action shall be taken prior to completion of 20 lots.

Conditional Status –To regain **process capable** status, the boneless beef contractor shall notify the FSCS Division that the process is not capable, and then have 20 consecutive results that meet the ‘**Process Capable**’ criteria within 60 calendar days or in accordance with a production schedule pre-approved by the FSCS Division. Change in status begins after a cause and effect analysis has been performed and corrective actions have been implemented. The boneless beef contractor may also declare itself ineligible at any time.

**AMS PROCESS
REQUIREMENTS FLOW CHART**



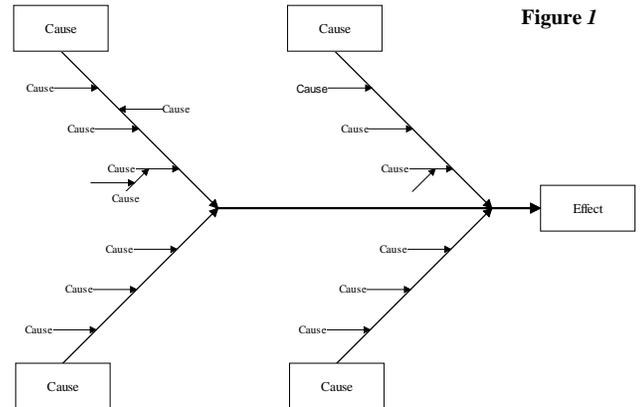
Ineligible Supplier/Contractor – An ineligible boneless beef contractor shall not be allowed to supply boneless beef to USDA until a cause and effect analysis has been performed and corrective actions have been submitted to AMS for review and approved, implemented and a satisfactory AMS assessment audit has been completed. Once satisfactorily becoming eligible, subsequent production shall be under **Conditional Status**. The AMS FSCS Division reserves the right to declare a boneless beef contractor **ineligible** at any time.

AMS MICROBIAL REQUIREMENTS FOR BONELESS BEEF			
Microbial Test	USL (cfu)	Critical Limits (cfu)	CPU or CI Value
Standard Plate Count	50,000 / gram	100,000 / gram	CPU \geq 1
Total Coliforms	200 / gram	1,000 / gram	CPU \geq 1
<i>E. coli</i>	100 / gram	500 / gram	CPU \geq 1

APPENDIX C

GLOSSARY OF TERMS

Cause and Effect Diagrams – A cause and effect analysis is used to identify the cause or source of non-conformities. It categorizes the source as derived from impact on a process presented by Human, Machinery, Material, Methods, Environment, and Measurement (Test). The Cause and Effect Diagram shall assist in evaluating a process and assigning the appropriate control point (see Figure 1).



"Cleanup to cleanup" - Part of a HACCP program that the establishment has in place to support statistically distinguishing one portion of production from another. Production destined for USDA contracts is to be commenced on clean equipment. However, "cleanup to cleanup" without other supporting documentation may not be adequate to statistically distinguish one portion of production from another. If a sample analysis yields a positive result, any product produced in the same time frame with the same process or equipment is suspect, unless an intervention occurred that would indicate a change in the status of the process/equipment.

Control Charts – A control chart is a run chart with statistically derived upper and lower control limits (ucl and lcl). The control chart demonstrates if a process is in statistical control. When properly designed, control charts provide an early warning of problems allowing for adjustments to be made before production of non-conforming products. Microbial test results may be plotted on control charts for individual measurements and fat test results may be plotted on control charts featuring average and range of the fat test results (See Figure 2).

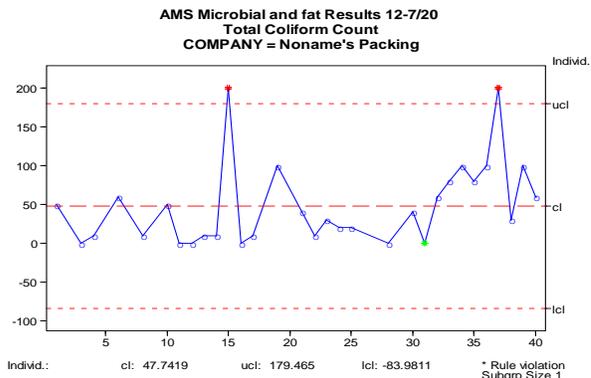


Figure 2

Cpk – Process Capability Value (Cpk) is a capability analysis index used to determine if a process can meet specification limits. A Cpk value of 1 indicates that the process is producing at least 99.73% within the specification limit. Cpk values of 1 for many organizations have become the minimum requirement. However, the larger the Cpk values the better. Cpk differs from other process capability analyses since it considers the process average along with the distribution of test results. Since there is no lower specification limit for USDA microbial requirements, the calculation for Cpk shall not involve relating the process average with a lower specification limit.

CPU - Process Capability Value (CPU) is the same as Cpk except that there is no lower specification limit. The process performance index is correctly known as a Centered Process Capability Upper Specification Limit only (CPU) (See Figure 3).

Excellent Condition - All product shall be in excellent condition (e.g., exposed lean and fat surfaces shall be of a color and bloom normally associated with the class, grade, and cut of meat and typical of meat which has been properly stored and handled). Cut surfaces and naturally exposed lean surfaces shall show no more than slight darkening or discoloration due to dehydration, aging, and/or microbial activity. The fat shall show no more than very slight discoloration due to oxidation or microbial activity. No odors foreign to fresh meat shall be present. Changes in color and odors characteristically associated with vacuum packaged meat in excellent condition shall be acceptable. Also, product shall show no evidence of mishandling. Beef shall be maintained in excellent condition through processing, storage, and transit.

Flow Charts – Flow charts depict all of the steps of a process. Standard symbols are used to identify the start, finish, processing steps and decision steps. It can be used to simplify a complex process so that it can be analyzed (Figure 4).

Histograms – The histogram shows a pictorial representation of the frequency of distribution of microbial test results over time. Sometimes referred to as process capability charts, histograms compare the distribution of the test results with AMS specification requirements. Use histograms along with control charts to better understand process capability (See Figure 3).

Figure 3

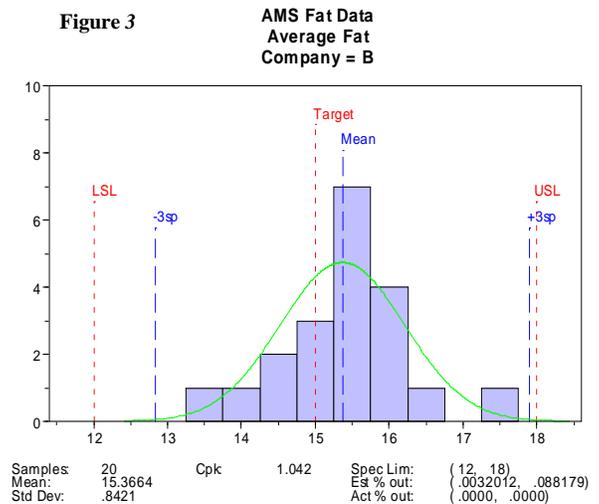
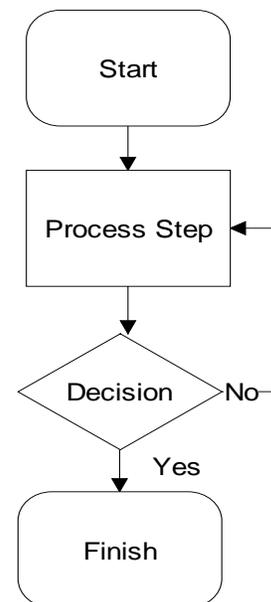


Figure 4



Pareto Diagrams – The Pareto diagram ranks the importance of different non-conformities. Typically, non-conformities are measured against frequency of occurrence. The Pareto analysis is helpful in identifying and justifying which problems shall need to be solved first (see Figure 5).

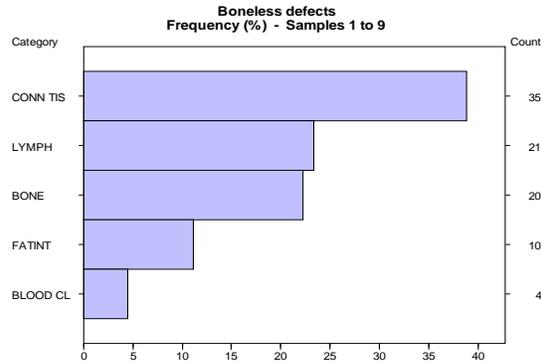
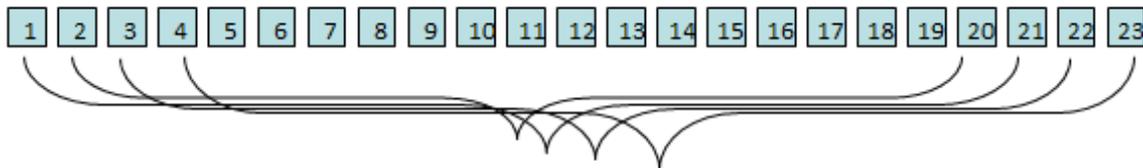


Figure 5

Process – For the purpose of this specification, a single process involves the input of a raw material on a production line with a value added activity resulting in a output that can be further processed or meet a customer’s need. A complex process involves output being another processes input. The production of ground beef is a complex process.

Process Capability Assessment on 20 consecutive lots – For the purpose of this specification, process capability assessments are conducted on data results from each lot for fat and microbial requirements. A process assessment involves sampling and testing of 20 consecutive lots (which always includes the last recorded result). Information from each lot shall be evaluated with information from the preceding 19 lots (i.e., while in process assessment of the first 20 lots, the process was found to be capable, then assessment shall continue on lot numbers 2-21). This has often been referred to as a ‘Rolling 20’. This assessment takes into account process variations that may be attributed to product, management, sources, and time (see Figure 6).

Figure 6



Random Sampling – A process of selecting a sample from a lot whereby each unit in the lot has an equal chance of being selected and is representative of the lot’s production.

Statistical Process Control (SPC) – SPC is the primary analysis tool of quality improvement. The objective of any quality improvement strategy is to identify and reduce the amount of variation. SPC analyzes the variation in a process and is the applied science that assists suppliers to collect, organize and interpret microbial and fat test results on processing of ground beef destined for USDA.

SPC provides tools to help measure, identify, and eliminate variation from customer requirements (see Table 1).

Table 1

Tools for Statistical Process Control	
Flow Charts	Scatter Diagrams
Pareto Diagrams	Run Charts
Cause and Effect Diagrams	Control Charts
Histograms	Capability Assessment

Upper and lower control limits (ucl and lcl) – Control limits are statistical calculations of the distribution of test results. Upper and lower control limits represent +/- 3 standard deviations of the process results. Data plotted outside the limits represent special causes of variation. A process may be considered “out of statistical control” when results are outside these limits. Upper and lower control limits are not to be confused with specification limits. A supplier wishing to be an eligible participant in the Boneless Beef Program shall have a process that is capable of producing within the specification limits (See figure 2).

Upper and lower specification limits (USL and LSL) – Normally, the customer sets the specification limits. The objective of the Boneless Beef Purchase Program is to procure from boneless beef processors that are statistically capable of meeting the upper specification limits specified within the FPPS-BB. The specification limits reflect customer needs (See Figure 3).



APPROVED

FEDERAL PURCHASE PROGRAM SPECIFICATION (FPPS) FOR ANIMAL HANDLING AND WELFARE

Agricultural Marketing Service (AMS)
Livestock, Poultry and Seed (LPS) Program
Food Safety and Commodity Specification (FSCS) Division
Room 2628 S-Bldg, Phone: (202) 692-0342

Supersedes: FPPS-AHW-2015 January 2015 – Changes
from previous requirements in [blue](#)

Effective: [August 2017](#)

100 GENERAL

101 This document is for use by the Department of Agriculture (USDA), AMS, LPS Program to ensure that the animal handling and welfare requirements for Federal nutrition assistance programs reflect industry best practices.

110 PROGRAM APPROACH

111 All animal harvest facilities that supply raw materials from bovine, porcine and ovine species for the production of AMS destined finished products must develop and implement a written program that is consistent with a systematic approach to humane animal handling and welfare as outlined in 69 FR 54625. The program will ensure proper animal handling and welfare techniques are conducted from the time the transportation conveyance enters the facility's premises through the stunning and exsanguination of the animal.

120 PROGRAM SUBMISSION

121 The program will be submitted as a supporting document to the organization's approved technical proposal and must address the requirements outlined in **Section 200 – PROGRAM COMPONENTS**.

200 PROGRAM COMPONENTS

201 The contractor must ensure that any facility that harvests animals has a:

210 MANAGEMENT COMMITMENT

211 Steering Committee (internal) which is ultimately accountable for animal handling and welfare initiatives within the organization.

212 Mission Statement on animal handling and welfare that is distributed to all employees and conspicuously displayed at the premises.

220 TRAINING PROGRAM

221 Training program on Animal Handling and Welfare that:

221.1 is provided to all employees interacting with animals;

221.2 covers the North American Meat Institute (NAMI) *Recommended Animal Handling Guidelines & Audit Guide: A Systematic Approach to Animal Welfare*, dated [June 2017](#);

221.3 is facilitated by an employee that has earned and maintained a certification of animal handling and welfare training, such as that offered through the Professional Animal Auditor Certification Organization (PAACO) or an equivalent.

221.4 is conducted no less frequently than once a year for each designated employee; and,

221.5 requires signed documentation from each employee and confirmation by signature of the designated, certified trainer upon successful completion of training.

230 QUALITY MANAGEMENT PLAN

231 Written quality management plan (internal) which addresses all provisions of Chapter 3: Transportation Audit Guidelines, 7 Core Criteria and Chapter 4: Auditing Animal Handling and Stunning, 7 Core Criteria, of the NAMI *Recommended Animal Handling Guidelines & Audit Guide: A Systematic Approach to Animal Welfare*, dated [June 2017](#), found at the following web site address:

231.1 <http://www.animalhandling.org/sites/default/files/forms/animal-handling-guidelines-June152017.pdf>

232 This internal quality management plan must also provide for routine assessment and monitoring of humane handling through the use of a numerical scoring system conducted by a trained employee.

233 All animal harvest facilities that supply raw materials from bovine, porcine and ovine species for the production of AMS destined finished products must have a fully functioning back-up stunning device onsite wherever animal stunning is performed.

240 REGULATORY OVERSIGHT

241 [For all species, animals/carcasses that are inspected and passed by the Food Safety Inspection Service \(FSIS\) are eligible for AMS purchase programs.](#)

300 PROGRAM EVALUATION AND ELIGIBILITY

301 The program will be audited (external) by AMS or a firm accredited by AMS. The accreditation of the firm will be conducted by the Quality Assessment Division (QAD) through the [USDA ISO Guide 17065 Program](#).

- 302 [Audit findings will be communicated to the establishment's Food Safety and Inspection Service \(FSIS\) Inspector in Charge \(IIC\) or designee.](#)
- 310 AUDIT FORMAT**
- 311 Audits will be conducted utilizing the following format:
- 312 TRANSPORTATION SEGMENT (*CHAPTER 3: NAMI Recommended Animal Handling Guidelines & Audit Guide: A Systematic Approach to Animal Welfare*, dated [June 2017](#))**
- 312.1 Audited organizations must pass Core Criteria 1 and 6 with a minimum scoring of excellent, Core Criteria 2 through 5 with a minimum scoring of acceptable and Core Criteria 7 must be adhered to with full compliance (zero tolerance) each time an audit is performed.
- 313 ANIMAL HANDLING AND STUNNING SEGMENT (*CHAPTER 4: NAMI Recommended Animal Handling Guidelines & Audit Guide: A Systematic Approach to Animal Welfare*, dated [June 2017](#))**
- 313.1 Audited organizations must adhere to Core Criteria 1, 2, 6 and 7 with full compliance (zero tolerance) and to Core Criteria 3, 4 and 5 with a minimum scoring of Acceptable each time an audit is performed.^{1/}
- 313.2 The auditor shall inform FSIS and organization officials in writing of all audit findings, including any observations of missed stuns and/or animals regaining sensibility following stunning, upon completion of the audit during the exit interview.
- 320 INITIAL AUDIT**
- 321 Initial audit must be performed prior to award of contracts.
- 330 AUDIT FAILURE**
- 331 If an audit is failed for any of the Core Criteria, the organization is not eligible to provide product until such a time that corrective and preventative actions are approved by the Food Safety and Commodity Specification (FSCS) Division, implemented and proven effective.
- 340 AUDIT FREQUENCY AND STATUS**
- 341 STANDARD - Until four (4) consecutive successfully passed audits are attained, an audit must be conducted within 3 months of the previous audit.

^{1/}Religious harvest (Kosher and Halal) shall be exempt from the AMS auditing of Core Criteria 1: Effective Stunning.

- 342 MONTHLY - If at any time an audit identifies any of the Core Criteria not meeting the pass requirements while in the STANDARD phase, auditing will be required to be conducted on a monthly basis once corrective and preventative actions have been approved by the FSCS Division, implemented and proven effective. This schedule will be for a period of time until four (4) successive audits are found to meet the passing requirements noted in **SECTION 310 – AUDIT FORMAT**; at which time audits shall be conducted on the STANDARD basis.
- 343 If four successfully conducted audits are sequentially completed within a one year period while in STANDARD auditing phase, the facility may move to a SEMI-ANNUAL audit basis.
- 344 SEMI-ANNUAL - Semi-annual audits may continue until such time that a failed audit is reported or a period of greater than six months has elapsed without any audits being performed; at which time the audits must resume as described for STANDARD audits.
- 345 FOR-CAUSE – Any official enforcement actions issued by FSIS for missed stuns or for an animal regaining sensibility following stunning shall result in an immediate for-cause animal handling and welfare audit by AMS. Subsequent audit frequency will be determined by results of the AMS audit, as described above.
- 400 FSCS DIVISION**
- 401 The FSCS Division can declare an organization’s Animal Handling and Welfare Program out of compliance at any time.
- 402 The organization shall immediately notify the FSCS Division when any animal handling and welfare official enforcement action is issued by FSIS.

Cover Page:

Company Name

Company Address

Contact Person, including title, phone number, including emergency contact information, e-mail address (shall be authorized to represent the company).

Technical Proposal for: [Supplement Number] and [FPPS]

Table of Contents (all pages and attachments shall be number and identified – any attachments shall be identified and referenced in the Technical Proposal).

The technical proposal should document a quality control program that includes procedures, records, forms, pictures, etc., which demonstrates conformance with the following checklist of requirements:

- 100 ITEM DESCRIPTION
- 200 APPLICABLE DOCUMENTS
- 300 CHECKLIST OF REQUIREMENTS
- 320 MATERIALS
- 330 MEAT COMPONENT
 - 331 IMPS Items
 - 332 Domestic Origin Of Meat Component
 - 333 Grade
 - 334 Harvest (Slaughter)
 - 334.1 Humane Handling
Non-Ambulatory Cattle
 - 334.2 Pathogen Intervention Steps
 - 334.3 Spinal Cord Removal
 - 335 Boneless Beef
 - 335.1 Traceability
 - 335.2 Handling

336	Mechanically Separated
340	NON-MEAT COMPONENTS
370	PREPARATION FOR DELIVERY
380	PACKAGING
390	PACKING
400	CLOSURE
420	LABELING
430	PALLETIZED UNIT LOADS
440	DELIVERY UNIT
450	DELIVERED PRODUCT
460	SIZE AND STYLE OF CONTAINER
470	TEMPERATURE
480	SEALING
500	PRODUCT ASSURANCE
510	WARRANTY AND COMPLAINT RESOLUTION
511	Warranty
512	Complaint Resolution
600	NON-CONFORMING PRODUCT
700	AMS MONITORING AND PRODUCTION ASSESSMENT

Attachments or Appendixes - Please attach all referenced documents with the applicable document name and reference number.

