APPROVED

Agricultural Marketing Service (AMS)
Livestock and Poultry (LP) Program
Standards and Specifications Division (SSD)
Room 2702-S, STOP 0249
Phone: (202) 690-3148

Supplement 211 to the AMS Master Invitation for the Purchase of Frozen Ground Beef Products for Distribution to Federal Food and Nutrition Assistance Programs

Supersedes: Supplement 211 March 2023 – Changes from previous requirements in blue

Effective: May 2025

100 Overview

110 This document provides additional program requirements for the purchase of Frozen Ground Beef Products by the Department of Agriculture (USDA), including the applicable Federal Purchase Program Specification (FPPS) (**Exhibit A and A1)**.

200 Instructions to Potential Contractors

210 The frozen ground beef products shall be purchased on a competitive bid basis from qualified contractors who have met the requirements described in this Section. Interested contractors may submit a technical proposal at any time during the purchase program. Contractor should allow 10 working days, from USDA's receipt of the technical proposal for notification of evaluation results. A contractor is deemed eligible upon notification of approval of the technical proposal by the Standards and Specifications Division (SSD).

220 Submission of a technical proposal is not binding on USDA. Actual purchases shall be described in the AMS Master Invitations for Bids - Domestic Commodity Procurement – (MIFB-D) and Solicitations.

230 Documentation Requirements

231 Technical Proposal Requirement

231.1 Include a detailed description of the ground beef product(s) 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)

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 and C1**. 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 and forms provided in the technical proposal with the applicable document name and reference number.

232 SSD shall review each technical proposal to determine if it is adequate and shall notify the contractor of the status and their eligibility to bid.

233 Animal Welfare Requirements

233.1 All eligible contractors shall meet the animal handling and welfare requirements set forth in the FPPS for Animal Handling and Welfare, effective April 2025 (**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 and C1)**. The contractor shall submit the technical proposal as an email file attachment to AMS (TechnicalApprovals@usda.gov and Kym.Allen@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 contractor for non-compliance with formatting instructions, technical evaluators may have difficulty evaluating the 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 contractor's technical proposal for information requested in the evaluation.

320 Technical Proposal Revisions

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

321.1 Any changes to a technical proposal made by the contractor 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 contractor 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 Division (QAD)

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

420 Pre-Award Onsite Capability Assessment Audit

421 Food Defense Assessment

421.1 An AMS agent shall conduct a food defense audit that shall include, but is not limited to, a thorough evaluation of the contractor's food defense plan. Documentation shall support the contractor's food defense plan. If the report demonstrates that the food defense plan is inadequate, the contractor shall be notified by the SSD that they are ineligible to bid. The contractor shall have an opportunity to correct identified deficiencies, modify the 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 QAD 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 contractor's adherence to meeting the harvesting and humane handling requirements as set forth in the FPPS.

423 Documentation shall support:

423.1 The production of the ground beef product that complies with the applicable FPPS and the potential contractor's approved technical proposal, and

423.2 the contractor's food security 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 SSD to determine (based on the audit findings), contractor eligibility to bid. Contractor shall be notified by the SSD and the official final report shall be sent once released from QAD.

424.1 If the audit findings demonstrate that the process or food security plan is inadequate, the applicant shall be notified by the SSD that they are ineligible to bid. The contractor shall have an opportunity to correct identified deficiencies, modify the process, food security 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 ground beef product(s) in compliance with the FPPS;

424.2.2 The contractor is in compliance with the food security plan;

424.2.3 A successful QAD corrective action audit is conducted; and

424.2.4 The contractor complies with other applicable contractual requirements.

430 Post-Award Assessment Audit

431 Eligible contractors who receive contracts shall have their documented food security plan, technical proposal, and supporting documentation readily available for review by 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 AMS agents.

432 QAD shall conduct an onsite audit of the contractor's facility(s) and processes when production commences for the first contract awarded. Additional audits shall be conducted as determined by the SSD, but not less than once per month for contractors with continuous or multiple contracts, or once per contract for intermittent contractors. At the discretion of the SSD, more frequent audits may be conducted when audit deficiencies are detected.

440 Post-Award Actions

441 Any deviation from contractual requirements shall be immediately reported by the contractor to the Contracting Officer and SSD. The Contracting Officer or SSD shall notify the contractor regarding eligibility to continue to participate as a contractor.

442 contractors shall assure that the delivered product complies with the provisions of the FPPS, the applicable assessment by QAD, and the contractor's technical proposal approved by the SSD.

450 The cost of all audits, product monitoring, and certification services performed by the AMS agents shall be borne by the contractor. 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 a USDA/AMS, LP Program's Quality Assessment Division (QAD) field office or to:

USDA, AMS, LP, QAD Business Operations Branch
1200 Cherry Brook Drive, Suite 100
Little Rock, AR 72211
Phone: 501-312-2962
Email: QAD.BusinessOps@usda.gov

500 Past Performance

510 Contractor Monitoring Program Requirements

511 Ground beef contractors' performance as a vendor on contracts awarded by the Department of Agriculture (USDA) shall be evaluated monthly on a 30-day (1 month) basis or cycle.

512 The evaluation shall consist of all non-conformances (NC) that were identified by the QAD auditor. The NCs 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 NCs, or a total five NC's in any combination, (i.e., critical, major, or minor) within the monthly 30-day (1 month review) shall result in the ground beef contractor being deemed ineligible by the SSD to supply frozen ground beef product to AMS contractors to fill USDA contracts.

513.1 To regain eligibility status, the ground beef contractor shall submit appropriate corrective and preventative measures to SSD for evaluation and the measures shall be verified by QAD auditor as effective. The SSD shall notify the ground beef contractor when eligibility to supply ground 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:

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 contractor shall be deemed ineligible to supply fresh boneless beef products or ground beef for the USDA purchase programs if:

521.1 The contractor 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 and A1**).

522 If deemed ineligible, a contractor shall:

522.1 Perform a cause-and-effect analysis;

522.2 Submit the corrective and preventative actions to SSD for review and approval;

522.3 Have a successful corrective action audit conducted by QAD; and

522.4 SSD shall notify the ground beef contractor when eligibility to supply ground beef has been reinstated.

600 Domestic Origin Certification Clause

610 The contractor shall include this 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 MIFB-D. The burden of proof of compliance is on the Contractor. All raw materials shall be shipped in containers labeled as “Domestic Only Product” on the principal 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 MIFB-D, 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 and Purchase Order Line Item Number;

810.2 Sales Order and Sales Order Item Number;

810.3 Destination of shipment;

810.4 Name of product and applicable Material Number;

810.5 Shipping Date;

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

810.7 Count of shipping containers and total projected net weight in each production lot and delivery unit;

810.8 Identity of car or transportation trailer numbers, letters, license, etc., including all serially numbered door seal(s), as applicable;

810.9 Contractor certification that product conforms with the FPPS;

810.10 Count and projected net weight verified; and

810.11 Signature of company official responsible for checkloading.

900 Exhibits

USDA Agricultural Marketing Service

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Federal Purchase Program Specification (FPPS) for Ground Beef Items, Frozen

Supersedes: FPPS GB March 2023 – Changes from previous requirements in blue

Effective: May 2025

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100 Scope

110 This FPPS – Ground Beef (GB) – 2025 is for use by the Department of Agriculture (USDA), AMS, Commodity Procurement (CP) Staff to procure frozen Ground Beef products.

200 Applicable Documents

210 The following documents are incorporated as part of this USDA FPPS-GB-2025:

210.1 Quality Assessment Division (QAD) Procedures Manual;

210.2 Food Safety and Inspection Service (FSIS) Directive 10,010.1 and Notice 05-23; and

210.3 Applicable Supplement to AMS Master Invitations for Bids - Domestic Commodity Procurement (MIFB-D).

300 Checklist of Requirements

310 Items

311 The contractor's technical proposal shall declare which items shall be offered to USDA. Bulk or patties shall be specified within USDA procurement documents.

312 Bulk

Item	Material Number
Ground Beef (10-pound bulk packaged)	100158
Ground Beef-Irradiated (10-pound bulk packaged)	110085
Ground Beef, 1-pound packages	100159

313 Patties

Item	Material Number
Ground Beef Patties-85/15 – 2.8 oz. (Meat / Meat Alternate (MMA) 2.0 oz.)	110349
Ground Beef Patties-85/15 – 2.1 oz. (MMA 1.5 oz.)	110350
Ground Beef Patties-Irradiated-85/15 – 2.8 oz. (MMA 2.0 oz.)	110082
Beef Patties with Soy Protein Product-85/15 – 2.8 oz. (MMA 2.0 oz.)	110348
Beef Patties with Soy Protein Product-85/15 – 2.1 oz. (MMA 1.5 oz.)	110347
Ground Beef Patties-90/10 – 2.8 oz. (MMA 2.0 oz.) (Not to Exceed 10% Fat)	110346
Lean Beef Patties-5% Fat	100163

320 Material

321 All items shall be produced in accordance with Food Safety and Inspection Service (FSIS) regulations. The contractor's technical proposal, submitted to the Standards and Specification Division (SSD), 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.

322 Domestic Origin and Harvest (Slaughter) Requirements

322.1 Quality Control Program - The harvester's quality control program shall be documented in each contractor's technical proposal and have received a satisfactory onsite capability assessment by QAD. Additionally, each establishment is subjected to verification audits conducted by the QAD during production activities that demonstrate their adherence to the documented quality control program.

322.2 Boneless beef shall be derived from carcasses that are derived from cattle harvested at establishments that comply with the following origin and harvest requirements.

322.2.1 **Domestic Origin** – All meat shall originate from livestock that are born, raised, and harvested in the United States, its territories or possessions (U.S.) If the establishment receives and processes livestock from outside the U.S., a segregation plan shall be put in place to preclude non-conforming product from being introduced into Federal nutrition assistance programs.

322.2.2 **Humane Handling** – All cattle shall be humanely handled in accordance with all applicable FSIS regulations and AMS requirements.

322.2.3 **Residue Prevention** – Harvest and production establishments shall have a Hazard Analysis Critical Control Point (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 June 2024.

322.2.4 **Spinal Cord Removal** – All spinal cord tissue shall be removed during the harvesting process.

322.2.5 **Pathogen Intervention Steps** – 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 contractor's FSIS recognized harvest process HACCP plan and the CCP intervention(s) shall be scientifically validated to achieve a three-log reduction of enteric pathogens.

323 **Boneless Beef Requirements**

323.1 Quality Control Program - The boneless beef supplier's quality control program shall be documented within each contractor's technical proposal and have received a satisfactory onsite capability assessment by QAD, prior to supplying materials for the program. Additionally, each establishment is subjected to verification audits conducted by the QAD, during production activities that demonstrate their adherence to the documented quality control program.

323.2 **Traceability** – Boneless beef shall be traceable to sources that comply with the above domestic origin and harvest requirements.

323.3 **XF Trimmings** - 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.

323.4 Meat Recovery Systems

323.4.1 Mechanical Separation - Boneless beef that is mechanically separated from bone with automatic deboning systems or advanced lean (meat) recovery (AMR) systems is not allowed.

323.5 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.

323.5.1 Frozen Boneless beef destined for Ground Beef products may be used provided it is ground into the final product within 90 days from the date of pack. Except for Boneless beef destined for irradiated Ground Beef shall never be frozen before grinding and shall be ground within five days from harvest.

323.6 Objectionable Materials – The following objectionable materials shall be excluded:

323.6.1 Major lymph glands (*prefemoral*, *popliteal*, and *prescapular*), thymus gland, and the sciatic (*ischiatic*) nerve (lies medial to the outside round). All bone, cartilage, and the following heavy connective tissues;

323.6.1.1 White fibrous – Shoulder tendon, elbow tendon, silver skin (from the outside round), *sacrosciatic* ligament, opaque periosteum, serous membrane (*peritoneum*), tendinous ends of shanks, *gracilis* membrane, *patellar* ligament (associated with the stifle joint), and *achilles* tendon; and

323.6.1.2 Yellow elastin – Back strap and *abdominal tunic*.

323.7 Lot – A lot shall consist of approximately 2,000 pounds of boneless beef produced within a day, between "cleanup to cleanup" (see APPENDIX D) and that is from a single harvester or processor.

323.8 Microbial Testing – Samples from all lots of fresh chilled boneless beef, shall be sent to an AMS designated laboratory (ADL). Samples from each lot shall be tested for *E. coli O*157:H7*, Salmonella*, and indicator microorganisms as listed in Appendix B. One sample from every 10 lots of fresh chilled boneless beef, selected at random by the ADL, shall be tested for non-O157 STECs (O26, O45, O103, O111, O121, O145).

323.8.1 Sample Preparation and Handling - The ADL shall be responsible for supplying procedures for sample preparation, and submission. The ADL shall require suppliers to submit a sample submission form as an official record with each sample. The ADL shall also be responsible for supplying shipping supplies (including sampling bags and shipping materials) to each supplier. Suppliers' technical proposal shall include and describe sample collection and preparation procedures provided by the ADL.

323.8.2 **Sample Selection**

323.8.2.1 For Beef Manufacturing Trimmings – The sample shall be selected as described within FSIS Directive 10,010.1 and Notice 05-23.

323.8.2.2 For every lot of beef Manufacturing Trimmings one sample shall be prepared using one cloth sample unit for pathogen testing and one sample shall be prepared from five different pieces of trim from five different pieces of beef product for indicator microorganism testing. The sample for co-analysis of *E. coli* O157:H7, non-O157 STECs and *Salmonella* shall be one cloth sample unit; the sample for indicator microorganisms (aerobic plate count, total coliform and generic *E. coli*) shall be five pieces and weigh 25 grams ± 10 percent.

323.8.2.3 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.

323.8.2.4 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 determine whether such additional sampling and testing constitutes "prescreening," in which case it shall not be allowed.

323.8.3 **Testing and Results**

323.8.3.1 The microbiological testing for all microbes shall be in accordance with the applicable AMS-approved testing methodologies.

323.8.3.2 Notification for presence of pathogens and exceeding critical limit criteria - When presence of *E. coli* O157:H7, non-O157 STECs, or *Salmonella* is confirmed positive, or any critical limit is exceeded for indicator microbes:

323.8.3.2.1 The ADL shall immediately notify FSIS and the Standards and Specifications Division (SSD) of all confirmed pathogens;

323.8.3.2.2 When pathogen results are positive, FSIS shall be notified by the boneless beef supplier of the final disposition of the affected lot. The supplier shall document the removal of the affected lot(s) and make such documentation available to AMS upon request; and

323.8.3.2.3 When the critical limit is exceeded for indicator microorganisms, the boneless beef supplier shall document the removal of the affected lot(s) and make such documentation available to AMS upon request.

323.8.3.3 The ADL shall record all results on spreadsheets and calculate the process capability (CPU, CI) for microbial tests performed on production lots as outlined in Section 323.8.5.

323.8.3.4 Any lot that tests positive for *E. coli* O157:H7, non-O157 STECs, or *Salmonella*, or exceeds the critical limit criteria of Appendix B cannot be used to produce Ground Beef or any other product purchased by USDA.

323.8.4 Statistical Process Capability – Boneless beef supplier compliance with microbial requirements shall be based on the assessment of the calculated process capability (CPU, CI) values 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 Ground Beef purchase programs shall be monitored by AMS, the contractor, and the boneless beef supplier to determine individual lot acceptance and/or capability of their process according to Appendix B. Ineligible boneless beef suppliers 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 QAD has been conducted. Upon notification by SSD that the plan has adequately addressed the issues that resulted in the ineligible status determination, the boneless beef supplier may re-enter the program under conditional status.

323.8.5 Contractor's Responsibility - The contractor shall require its boneless beef supplier(s) to provide results and process capability status (as applicable) involving each lot of boneless beef to be processed into Ground Beef for USDA. Test results and process capability status (as applicable) for individual lots shall be provided to AMS upon request. In the event a boneless beef supplier has been deemed ineligible, and wants to continue in the program, the ineligible boneless beef supplier 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 QAD has been conducted. Upon notification by the SSD that the plan has adequately addressed the issues that resulted in the ineligible status determination the boneless beef supplier may re-enter the program under conditional status.

323.8.6 Supplier request to remove samples from AMS testing shall be submitted and approved by SSD prior to sample removal from ADL testing.

324 Ground Beef Requirements

324.1 **Quality Control Program** - The Ground Beef quality control program shall be documented within the contractor's technical proposal and have received a satisfactory onsite capability assessment by QAD.

324.2 **Traceability** – All Ground Beef production shall be traceable to the boneless beef lots and their associated microbial test results.

324.3 **Handling** - The contractor's technical proposal shall include detailed production scheduling that addresses time and temperature controls necessary to maintain excellent condition of the Ground Beef. Except for Ground Beef, 1-pound packages, all other Ground Beef items shall be delivered within 60 days from date of pack. Ground Beef 1-pound packages shall be delivered within 30 days from date of pack.

324.4 **Lot** - For the purpose of microbiological testing, a lot is defined as the amount of finished Ground Beef product, for each material number, produced within a day, between "cleanup to cleanup" (see Appendix D) which shall be further divided into sub-lots not to exceed 10,000 pounds.

324.5 **Microbiological Testing** – All sub-lots of Ground Beef shall be tested for *E. coli O*157:H7*, Salmonella*, and indicator microorganisms as listed in Appendix B (aerobic plate count, total coliform and generic *E. coli*) after final grinding and before freezing, except for Ground Beef products that are irradiated. The irradiated products shall be tested for *Salmonella* and *E. coli* O157:H7 after the irradiation process, and the other microbes listed in Appendix B prior to irradiation. All samples shall be sent to the ADL. One sample from every 10 sub-lots of ground beef, selected at random by the ADL, shall be tested for non-O157 STECs (O26, O45, O103, O111, O121, O145).

324.5.1 Sample Preparation and Handling - The ADL shall be responsible for supplying procedures for sample preparation, and submission. The laboratory shall require contractors to submit a sample submission form as an official record with each sample. 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.

324.5.2 **Sample Selection** – Production processes of Ground Beef shall be subject to the following sampling strategy:

324.5.2.1 Sub-lot Microbial Testing – For every sub-lot, two original and reserve samples shall be prepared from four individual sample units for each microbial test. The sub-lot samples shall be 325 grams ± 10 percent for co-enrichment of *E. coli* O157:H7, non-O157 STECs and *Salmonella* and 25 grams ± 10 percent for indicator organism tests, respectively of finished Ground Beef, randomly selected throughout each 10,000 pounds of production. The four individual sample units shall be composited to produce a sample that represents each microbial test for each sub-lot. The contractor shall describe in their technical proposal the procedure in which the four sample units shall be selected throughout the sub-lot to be composited for each microbial test. These samples shall be submitted to the ADL for analysis. The reserve samples shall be held for testing in case the SSD deems it necessary. The contractor shall describe, in their technical proposal the method to be used to maintain the identity and traceability of each sub-lot. No more than 10,000 pounds shall be produced during each sub-lot, except for the last sub-lot produced in the lot may exceed the 10,000-pound limitation by five percent.

324.5.3 **Testing and Results** - The samples from each sub-lot shall be analyzed by the ADL for all microbes listed in Appendix B.

324.5.3.1 The microbiological testing for all microbes shall be in accordance with the applicable AMS-approved testing methodologies.

324.5.3.2 Any sub-lot that tests positive for *E. coli* O157:H7, non-O157 STECs or *Salmonella,* or any critical limit criteria noted in Appendix B that is exceeded shall result in that sub-lot and adjoining sub-lots (one preceding and one following within a day, between “clean up to clean up”) being ineligible for this program or any other USDA purchase program. Other sub-lots produced within the lot unit shall be deemed ineligible for this program unless the contractor can demonstrate a scientific or other data-supported basis for defining the sub-lot(s) relative to test results and why Ground Beef produced from same source material that resulted in the ineligible determination should not be considered affected by the test results.

324.5.3.3 Notification for presence of pathogens or when critical limit is exceeded – When presence of *E. coli* O157:H7, non-O157 STECs or *Salmonella* is presumptive positive or confirmed positive; or any critical limit is exceeded for indicator microbes:

324.5.3.3.1 The ADL shall immediately notify FSIS and the SSD of all confirmed pathogens;

324.5.3.3.2 When pathogens results are positive, FSIS shall be notified by the contractor of the final disposition of the product and document the removal of the affected lot(s) and have available to AMS upon request;

324.5.3.3.3 When the critical limit is exceeded for indicator microorganisms, FSIS shall be notified by the contractor of the final disposition of the product and document the removal of the affected lot(s) and have available to AMS upon request; and

324.5.3.3.4 Ground Beef associated with the positive pathogen test results or critical limit exceeded results shall be ineligible for any USDA purchase program.

324.5.3.4 The ADL shall record all results on spreadsheets and calculate the process capability (CPU, CI) for microbial tests performed on sub-lots as outlined in Section 324.5.3.5.

324.5.3.5 Statistical Process Capability - The ADL shall record the results on spreadsheets and calculate the process capability (CPU or CI) value for all sub-lot microbial tests performed. The spreadsheets shall be maintained so that process capability may be determined according to the requirements within Appendix B. The spreadsheets shall be maintained so that process capability assessment on each 20 sub-lot grouping can be determined as described within Appendix B. Test results shall be monitored by the contractor and SSD to determine acceptability of the process according to Appendix B. Ineligible 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 QAD has been conducted. Upon notification by the SSD that the plan has adequately addressed the issues that resulted in the ineligible status determination, the contractor may re-enter the program under conditional status.

324.5.3.6 Contractor request to remove samples from ADL testing shall be submitted and approved by SSD prior to sample removal from ADL testing.

330 Processing

331 The contractor's technical proposal and process shall ensure compliance with the following requirements:

331.1 Grinding and Blending

331.1.1 Ground Beef - Boneless beef shall be ground twice, with the final grind passing through a ⅛-inch grinding plate. Blending after final grinding is allowed only to the extent that it doesn't affect the appearance of the finished Ground Beef;

331.1.2 Fat Break-Outs - The grinding, blending, and packaging process shall be conducted in a manner that precludes large fat “break outs” (solid chunks of fat greater than 1.0 cubic inch) or objectionable fat “smears” in the finished product;

331.1.3 Bone Collector/Extruder Systems – A bone collector/extruder system shall be in operation to remove remaining bone, cartilage, and heavy connective tissue during the final grind. For those collector/extruder systems that have a secondary lean recovery system, the product from the secondary recovery system shall be allowed provided it does not exceed more than 2.0 percent of finished product weight (on a batch weight basis); and

331.1.4 Shape and Waffling of Patties - All patties shall be round or oval in shape and waffled or scored on both sides.

331.2 Metal Detection - All product shall be free of metal contaminates. Detection of stainless steel, ferrous, and non-ferrous (e.g., lead, copper, and aluminum) metals is required. The contractor's technical proposal shall identify and describe the equipment, location, detection procedure, sensitivity levels, frequency of equipment validation, and corrective action procedures.

331.3 Equipment – All equipment used to produce Ground Beef products for USDA shall be maintained and routinely checked for optimal performance.

331.4 Irradiated Ground Beef - When specified by the purchaser, Ground Beef products to be irradiated shall comply with the additional requirements specified in Appendix C.

331.5 For Material Number 110347 & 110348 (Beef Patties with Soy Protein Product (SPP)) - The SPP shall be hydrated to yield no less than 18% protein (as-is basis); and

[(Percent Protein of SPP on “as-is” Basis / 18) – 1] = x x = maximum pounds of water to be added to each pound of dry SPP.

331.5.1 Texture - The physical characteristics of SPP, in the dry form, shall be either granular or textured; and

331.5.2 Type and Combination Rate - The types of soy that may be used and combination rates shall be as set forth below; and

Type of Soy (% Protein "As is Basis")	Maximum % of Hydrated SPP in each batch of Combined Finished Product
Granular Concentrate (65%)	20.0
Flaked Textured Concentrate (65%)	25.0
Textured Isolate (85%)	25.0

Note: SPP (of any texture) that has been hydrated by the SPP manufacturer may be used provided that: The product is frozen and the protein content (as is basis) of the hydrated SPP is stated on the manufacturer's label.

331.5.3 Domestic Origin – SPP ingredients shall be derived from U.S. produced products; and

331.5.4 Other than beef and the hydrated SPP, no other ingredients shall be permitted in the formulation.

331.6 For Material Number 110346 – (Ground Beef Patties – 90/10) - The patties shall not have any non-meat ingredients added.

331.7 For Material Number 100163 – (Lean Beef Patties 5% fat)

331.7.1 Non-meat components may be used to enhance the palatability of the lean beef patties comprising no more than 15 percent of the raw formula. The contractor's technical proposal shall list all ingredients (i.e., water, processing aids, binders, seasonings, etc.) within their formula. Significant ingredients (more than 1 percent) shall be derived from U.S. produced products; and

331.7.2 Sodium – Maximum sodium content shall be 200 mg per 100 gram basis.

340 State of Refrigeration

341 Bulk Packaged Ground Beef Items - Shall be frozen to 0°F within 72 hours after completion of the final grinding of the involved lot.

342 Patties - Shall be individually quick frozen (IQF) to 10°F or below prior to packaging and then frozen to 0°F or lower within 24 hours after completion of packaging and packing of the lot. Patties shall not stick together after they are packaged and packed.

343 All USDA Ground Beef products shall be stored, shipped, and delivered at temperatures that do not exceed 0°F.

350 Fat Limitations

351 The contractors shall establish a target average of 15 percent fat for all Ground Beef products except for the Ground Beef patties-90/10 and lean beef patties (100163). The upper and lower specifications limits shall be 18 and 12 percent fat respectively. The target fat content shall be declared on the shipping container label and the nutrition facts panel. For Ground Beef patties-90/10, the upper specification limit shall be 10 percent and the contractor shall declare their target. For lean beef patties (100163), the average fat target shall be five percent with upper and lower specification limits being six and four percent fat respectively. Separate Statistical Process Control (SPC) assessments shall be conducted on Ground Beef products with a targeted average of 15 percent fat, the Ground Beef patties-90/10, and the lean beef patties (100163).

352 **Contractor Process Assessment** - The contractor shall declare the production lot size, laboratory, test method, and SPC methodologies in their technical proposal.

352.1 Sampling and testing - The contractor shall select at least four internal individual fat sample units (selected after initial grinding or blending) to be analyzed for fat content from each production lot destined for USDA. The sample unit size shall be determined by the testing method used by the contractor's laboratory.

352.2 Recording results - The contractor shall record the results on spreadsheets. The calculated process capability (Cpk/CPU) value (as discussed in Appendix A) shall be used to determine if the process is in statistical control. Under contractor process assessment, no production lots shall be allowed delivery to USDA with average test results that are outside the upper or lower specification limits.

352.3 Process Capability Assessment - Twenty (20) consecutive production lot results (that include the last production lot) shall be recorded on spreadsheets for capability assessment by the contractor and made available to AMS agents upon request. The processor's capability (Cpk/CPU) shall be one or higher.

353 AMS Process Assessment – For the first 20 production lots, the QAD grader shall direct the contractor to randomly select samples, each consisting of four sample units. For Ground Beef items, each initial sample unit shall not exceed two pounds. Initial sample units may be blended and/or further reduced in size. From each initial sample unit, a final sample unit shall consist of 200 – 300 grams each. Each sample unit shall be independent from those samples selected for contractor process assessment and sent to the ADL for fat analysis. The ADL shall be responsible for supplying sampling protocol, all sample handling materials, and sampling methods (including sample unit size to be submitted to the ADL, preparation, handling of reserve samples, etc.) for sample preparation and submission. The ADL shall record the results on spreadsheets and submit them to the contractor and SSD for comparison to the contractor's process assessment. After 20 consecutive results, the contractor shall notify SSD immediately and declare what immediate corrective and preventative actions shall be taken when:

353.1 The ADL calculated process average fat results (mean) varies more than one percent from the contractor's calculated process average results; or

353.2 The calculated process capability (Cpk/CPU) is less than one for results from either the contractor's designated laboratory or the ADL.

353.3 The contractor shall notify SSD that the process is not capable for fat and then sample and test an additional 20 consecutive results that shall meet the criteria for AMS Process Assessment. Change in status begins after a cause-and-effect analysis has been performed and corrective actions have been implemented. If the contractor remains in Unreliable Status after the additional 20 consecutive lots, a cause-and-effect analysis shall be performed, and corrective actions submitted within five business days to the SSD for review and approval. If the contractor still remains in Unreliable Status after the second round of 20 consecutive lots, a cause-and-effect analysis shall be performed and corrective actions submitted within five business days to SSD for review and approval, implemented and a satisfactory QAD assessment audit has been completed. The SSD reserves the right to deem a contractor as Unreliable for consideration on future contract awards when corrective or preventative actions are not adequate or effective or the contractor is unresponsive in declaring status or submitting corrective actions.

354 Continuous AMS Assessment – If AMS process assessment is satisfactory, the QAD grader shall direct the contractor when to randomly select samples (each consisting of four sample units) from a production lot. No more than two production lot samples are sent to the ADL on a weekly basis. The ADL shall continually record 20 consecutive results (always including the last recorded result as defined within APPENDIX D) on spreadsheets and submit the calculated process capability (Cpk/CPU) value to the contractor and QAD grader. The ADL's calculated process capability (Cpk/CPU) value shall continually be compared to the contractor's calculated process capability (Cpk, CPU) value as each contractor's test result is recorded to conduct the AMS Process Assessment as described above (using 20 consecutive results).

360 Patty Weight, Thickness, Shape, and Color

361 The contractor's technical proposal and process shall assure, using SPC tools, that the following requirements are met:

362 Patty Weight;

362.1 Material Numbers 110349, 110348, 110082, 110346 - Target weight shall be 2.8 ounces. Acceptable weight tolerance range shall be 2.7 to 2.9 ounces;

362.2 Material Numbers 110350, 110347 - Target weight shall be 2.1 ounces. Acceptable weight tolerance range shall be 2.0 to 2.2 ounces;

362.3 Material Number 100163 - Target weight shall be 3.1 ounces. Acceptable weight tolerance range shall be 3.0 to 3.2 ounces;

363 Patty Thickness – 5/16 inch (+/- 1/16);

364 Shape - Patties shall be round or oval in shape and waffled or scored on both sides; and

365 Color – Color of patties shall be monitored for normal appearance and color. When cooked to an internal temperature of 160°F by the end user, patties with internal or external pink appearance shall not be allowed.

370 Meat / Meat Alternates

371 Patties shall comply with the following MMA designations:

Material Number	Portion Weight (oz.)	MMA (oz.)
110349	2.8	2.0
110082	2.8	2.0
110348	2.8	2.0
110346	2.8	2.0
110350	2.1	1.5
110347	2.1	1.5

380 Preparation for Delivery

381 The contractor's technical proposal and process shall assure that all packaging, packing, closure, marking, and palletization 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.

382 Packaging and Packing

382.1 All immediate containers (casings or packages) shall function as a tamper evidence indicator to provide added assurance of product integrity through the method of sealing or closure.

382.2 Fine Ground Beef (Material Number 100158) – Fine Ground Beef shall be vacuum packaged or packaged in casings and sealed. All packages shall weigh 10 pounds. The casings or packages shall be closed by metal clips or by a heat-sealing method. Four packages shall be placed into each shipping container.

382.3 Fine Ground Beef (Material Number 100159) – Fine Ground Beef shall be vacuum packaged or packaged in casings and sealed. All packages shall weigh one pound. 40 packages shall be placed into each shipping container.

382.4 Fine Ground Beef-Irradiated (Material Number 110085) – Fine Ground Beef shall be vacuum packaged in a thermo-formed plastic container. Each package shall weigh 10 pounds. The package shall be rectangular in shape and shall be made from materials that have been approved by FDA for irradiation application. Packages shall be packed into shipping containers with net weights of 40 pounds. The depth, width, and length of the containers shall be considered depending on the type of ionizing radiation used.

382.5 Patties (Material Numbers 110347, 110348, 110349, 110350, 110346, 100163, 110082) –Separation material between patties is not required provided the IQF patties do not stick together at the time of shipment. Patties shall be placed into immediate containers following either of the following methods:

382.5.1 Flexible Containers - Either four 10-pound, five 8-pound, or eight 5-pound flexible (plastic) vacuum packaged, or sealed containers shall be placed into each shipping container. Hand twisting or hand tying is not acceptable.

382.5.2 Fiberboard Containers – When fiberboard is used for immediate containers, either four 10-pound or two 20-pound fiberboard containers shall be placed into each shipping container. Patties may either be vacuum packaged or within sealed flexible containers (hand twisting or hand tying is not acceptable) when placed into the fiberboard immediate container or, placed into the fiberboard immediate container that is lined with a plastic bag to completely cover the product. For this option, fiberboard immediate containers shall then have to be sealed with tape or glue.

382.6 Ground Beef Patties-Irradiated (Material Number 110082) – Patties shall be packaged into sealed flexible (plastic) immediate containers. They may weigh either 20 pounds or 10 pounds. Packaging materials shall be approved by FDA for irradiation application. Separation material between patties is not required provided the IQF patties do not stick together at the time of shipment. Packages shall be packed into shipping containers with net weights of 40 pounds. Consideration of the depth, width, and length of the containers shall be considered depending on the type of ionizing radiation is used.

382.7 Style and Size of Shipping Containers - Only one style and size of immediate and shipping container may be used in any one delivery unit.

383 Shipping Container Net Weight

383.1 Using SPC tools, the contractor shall assure the following net weights:

383.1.1 Ground Beef (fine ground bulk and patties) - shall be packed to a net weight of 40 pounds.

384 Closure

384.1 Shipping containers shall be closed by strapping, taping or gluing. When strapping is used, the initial closure (usually the bottom of container) shall be secured by the gluing or taping method.

385 **Marking of Containers***

385.1 Both primary and shipping containers shall have a printed code that includes the establishment number and is traceable to the production lot and date. All container markings shall include all information required by FSIS along with the additional information listed below:

385.2 Ground Beef, 1-pound package labels (100159) shall have the following information included on commercially labeled packages:

385.2.1 Safe handling instructions;

385.2.2 Nutrition Facts panel (to include fat declaration of 15 grams of fat per 100 gram serving);

385.2.3 The “best if used by” date (365 calendar days from the date of production);

385.2.4 The FSIS establishment number; and

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

385.2.6 Labels for the immediate containers shall include at least one color, other than black and white, exclusive of the package color.

385.3 **Shipping Containers** - Commercially marked shipping containers shall include the information as follows:

385.3.1 USDA Shield (at least 2 inches high and appearing on the top of the container or on the principal display panel);

385.3.2 Applicable Purchase Order Number;

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

385.3.3 The product name shall include no additional disclaimers and qualifiers to the name and material numbers listed below;

Product Name That Shall Appear on the Label	Material Number
Ground Beef [1/]	100158
Ground Beef, 1-pound packages	100159
Ground Beef – Irradiated[1/]	110085
Ground Beef Patties-85/15[1/]	110350
Ground Beef Patties-85/15[1/]	110349
Beef Patties with SPP-85/15[1/,2/]	110348
Beef Patties with SPP-85/15[1/,2/]	110347
Ground Beef Patties-Irradiated-85/15[1/]	110082
Ground Beef Patties-90/10[1/]	110346
Lean Beef Patties[1/]	100163

[1/]Shall include the statement “For Institutional Use Only” on the principal display panel.
[2/]The ingredient statement shall include the identification of the added hydrated SPP.

385.3.4 Fat Declaration;

385.3.5 Shipping containers containing irradiated Ground Beef shall bear the required FSIS markings for irradiated products and a “best if used by date” (180 calendar days from date of production);

385.3.6 Nutrition Facts panel to include fat declaration of:

385.3.6.1 15 grams of fat per 100 grams serving size for bulk items (100158, 100159, 110085),

385.3.6.2 12 grams of fat per 80 grams serving size for patty items -15% fat (110349, 110350, 110348, 110347, 110082),

385.3.6.3 8 grams of fat per 80 grams serving size for patty item - NTE 10% fat (110346), and

385.3.6.4 4.5 grams of fat per 88 grams serving size for patty items – 5% fat (100163);

385.3.7 Ingredient declaration (including single ingredient products); and

385.3.8 The allergen statement shall be provided in the format which complies with the Food Allergen Labeling and Consumer Protection Act (FALCPA) and the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act which define milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils, as "major food allergens"; e.g. Contains: _____.

For additional information refer to the FSIS Compliance Guidance at: https://www.fsis.usda.gov/sites/default/files/import/Allergens-Ingredients.pdf

386 Palletized Unit Loads.

386.1 All products shall be stacked on new or well-maintained pallets and palletized with shrink wrap plastic;

387 Total Net Weights Per Delivery Unit.

387.1 The delivery units for each of the respective material numbers are as follows:

Material Number	**Pounds Per Delivery Unit**
100158, 100159, 110085	40,000
110349, 110350, 110348, 110347, 110346, 110082, 100163	38,000

Note: No tolerances shall be allowed.

388 Sealing

388.1 Sealing – All products shall be delivered to AMS assigned destinations, including multi-stop deliveries, under seal(s) with tamper proof, tamper resistant, serially numbered seals as required under the current AMS MIFB-D. The seal number(s) must be recorded on the Bill of Lading (BOL) and correspond with the applied seal at the time of arrival at each destination when destined for multiple recipients.

390 USDA Quality Assurance

391 Warranty and Complaint Resolution

391.1 Warranty - The contractor shall guarantee that the product complies with all specification requirements, technical proposal declarations, and provisions set forth in the MIFB-D.

391.2 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.

392 AMS Monitoring and Production Assessment

392.1 An QAD grader shall be present during the production of the finished product for all USDA Ground Beef contracts. The QAD grader shall monitor and verify the processing steps, quality assurance activities, and any corrective actions to assure that all requirements outlined in the approved technical proposal are complied with. The QAD grader shall be conducting the monitoring and production verification in accordance with applicable AMS procedures. Any deviations to contractual requirements shall be reported to the contractor and SSD. The SSD shall make all determinations as to the acceptability of the product relative to findings documented by the QAD grader and/or auditor.

393 Control of Non-Conforming Product

393.1 The contractor shall include a plan and supporting documentation to assure that non-conforming product (i.e., boneless beef, Ground Beef) 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 vendor documentation of final disposition (e.g., diverted to cooked product or destroyed).

394 Contractor Checkloading

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

394.1.1 Purchase Order Number and Purchase Order Line Item Number;

394.1.2 Sales Order Number and Sales Order Line Item Number;

394.1.3 Destination of shipment;

394.1.4 Name of Product and applicable Material Number;

394.1.5 Shipping Date;

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

394.1.7 Count of shipping containers and total projected net weight in each production lot and delivery unit;

394.1.8 Identity of car or transportation trailer numbers, letters, license, etc., including all serially numbered door seal(s), as applicable;

394.1.9 Contractor certification that product conforms with the applicable specification (FPPS-GB-2025);

394.1.10 Count and projected net weight verified; and

394.1.11 Signature of company official responsible for checkloading.

Appendix A

Data Entry and Process Capability Values

Data Entry

The ADL shall record microbiological and fat test results on spreadsheets and to have 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). Qualitative results for *E. coli* O157:H7, each of the non-O157 STEC serotypes, and *Salmonella* shall be recorded as a 1 for a positive result and as a 0 for negative results.

The ADL shall provide the calculated process capability values (CPU, Cpk and Cl) 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 or Cpk) is calculated by the ADL. CPU shall be used for microbiological tests and for Beef Patties – 90/10 fat tests since 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 3.5). The upper specification limits (USL) for microbiological requirements shall be found in APPENDIX B. The calculations for CPU and Cpk are as follows: **Calculation of process capability (CPU) with an upper specification limit only** Step 1. The first calculation shall determine the Z-value (upper): **Z-value (upper) = (USL – Process Average) / Standard Deviation** Step 2. The Z-value divided by 3 shall calculate the CPU: **CPU = Z-value (upper) / 3**	**Calculation of process capability (Cpk) with an upper and lower specification limit** Step 1. The first set of calculations shall determine the smaller value of the two Z-values (upper or lower): **Z-value (upper) = (USL – Process Average) / Standard Deviation** **Z-value (lower) = (Process Average – LSL) / Standard Deviation** Step 2. The smaller of the two Z-values (upper or lower) divided by 3 shall calculate the Cpk. **CPU = Z-value (smaller value of the upper or lower) / 3**

Process Capability Value – Cl

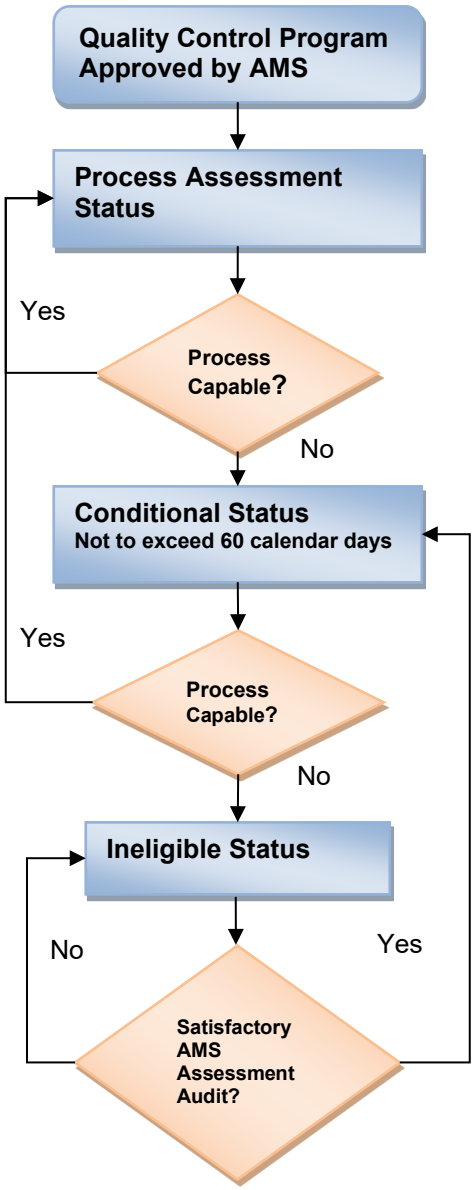
The central line (Cl; x-bar) is the process average or arithmetic mean that indicates the incidence of positive *E. coli* O157:H7 and *Salmonella* results. Results from non-O157 STECs are not used to calculate process capability.

Appendix B

AMS Boneless and Ground Beef Process Requirements Flow Chart

Quality Control Program – Prior to bidding on Ground Beef contracts with the USDA, the documented quality control program as described within the approved technical proposal (raw material suppliers and grinders) shall have received a satisfactory onsite capability assessment by QAD. 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.

AMS Process Requirements Flow Chart



Process Assessment Status - A process assessment involves sampling and testing of 20 consecutive lots or sub-lots (which shall include the last recorded result as defined within Appendix D) of boneless beef (see Section 323.8.4) or Ground Beef (see Section 324.5.3.5) destined for USDA contracts for the microbes listed within the table below.

Process Capable? – Flow chart decision step that involves test results for up to 20 consecutive SPC only lots or sub-lots (which shall include the last recorded result) recorded in spreadsheets, where the process capability (CPU or CI) value is calculated (See APPENDIX A) for evaluation. A process that is not capable shall be declared to the SSD 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;
- The CI values do not meet the levels specified in the table below for *Salmonella* or *E. coli* O157:H7;
- 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 or sub-lots.

Conditional Status –To regain **process capable** status, the boneless beef supplier or contractor shall notify the SSD 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 SSD. Change in status begins after a cause-and-effect analysis has been performed and corrective actions have been implemented. The boneless beef supplier or contractor may also declare itself **ineligible** at any time.

Ineligible Supplier/Contractor – An **ineligible** Boneless Beef Supplier or Ground Beef Contractor shall not be allowed to supply boneless or Ground Beef products under USDA contracts 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 SSD reserves the right to declare a boneless beef supplier or Ground Beef contractor ineligible at any time.

AMS MICROBIAL REQUIREMENTS FOR BONELESS & GROUND 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
E. coli	100 / gram	500 / gram	CPU $\geq$ 1
Salmonella		Positive (+) result / 325 grams	CI $\leq$ 0.05
E. coli O157:H7		Positive (+) result / 325 grams	CI $\leq$ 0.05

Appendix C

Requirements for Ground Beef-Irradiated Products

Ground Beef-Irradiated products shall be subjected to ionizing radiation from gamma ray, electron beam, or x-ray sources. The following requirements are in addition to all requirements specified within this FPPS.

Handling

Products shall be packaged and placed into shipping containers and frozen to 0°F within 72 hours from time of completion of the production lot prior to irradiation. Products shall be maintained in a frozen state from the time of leaving the shipping freezer and throughout the irradiation process. After irradiation, the products shall be palletized, reloaded, and dispatched to the final destination.

Dosimetry

Ground Beef shall be subjected to ionizing radiation to receive a dosage that is no less than 1.35 kilograys (kGy) and no more than 3.00 kGy. Irradiation facilities shall:

- Submit the initial dosimeter data verifying minimum and maximum dosages received within the technical proposal, and
- Maintain and provide confirmation dosimeter data to AMS upon request for each unit of Ground Beef irradiated.

Microbial Testing

Irradiated Ground Beef Products (patties and bulk) - shall be tested for Standard Plate Count, Total Coliforms, and *E. coli* after final grinding and before freezing and tested for *E. coli* O157:H7, and *Salmonella* after completion of the irradiation process.

Appendix D

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).

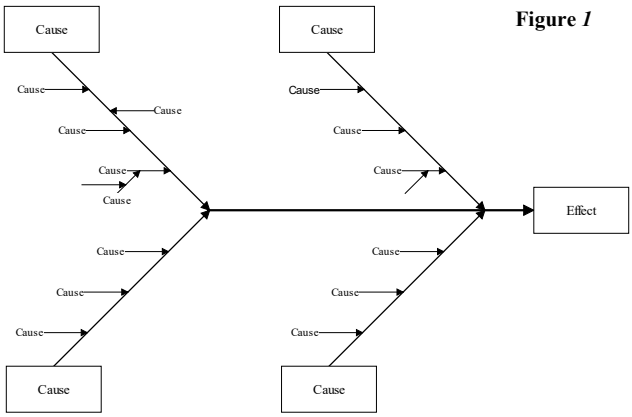


Figure *1*

"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. "Cleanup to cleanup" may be an effective means of preventing cross contamination of one part of production to another with *E. coli O157:H7*. 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).

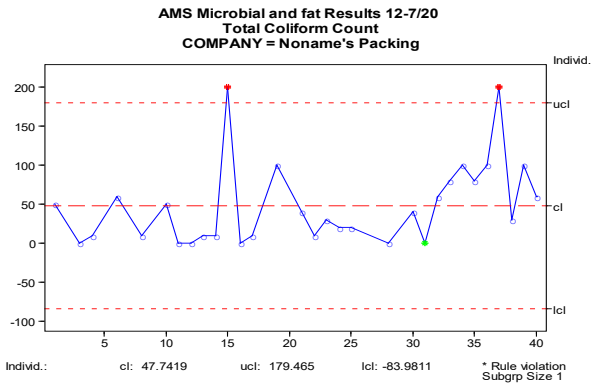
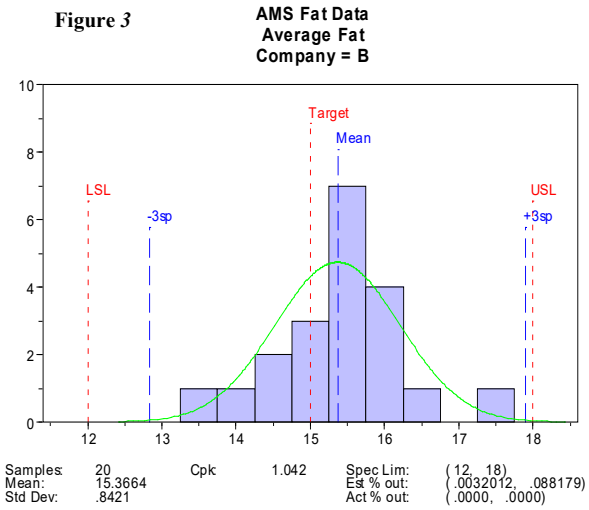


Figure *2*

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.

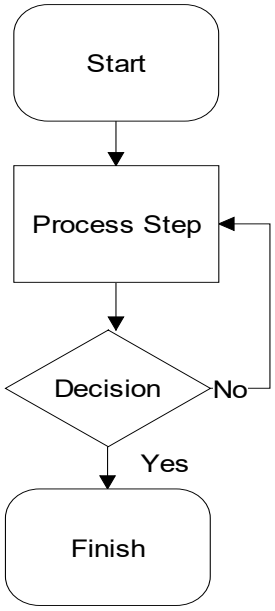
Figure *3*



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.

Figure *4*



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).

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).

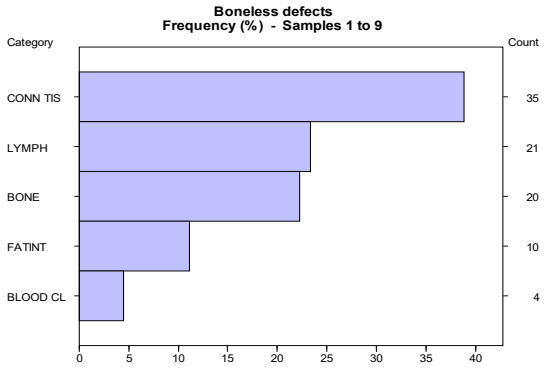
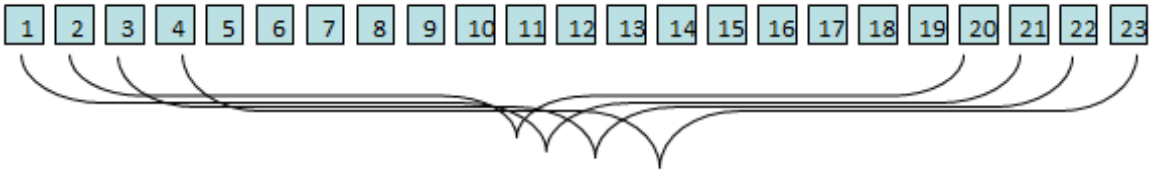


Figure 5

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 is 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 Ground 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 Ground Beef Purchase Program is to procure from Ground Beef processors that are statistically capable of meeting the upper specification limits specified within the FPPS-GB. The specification limits reflect customer needs (See Figure 3).

USDA Agricultural Marketing Service

APPROVED

Agricultural Marketing Service (AMS)
Livestock and Poultry (LP) Program
Standards and Specifications Division (SSD)
Room 2702-S, STOP 0249
Phone: (202) 690-3148

Federal Purchase Program Specification (FPPS) for Coarse Ground Beef Items, Frozen

Supersedes: FPPS CGB March 2023 – Changes from previous requirements in blue

Effective: May 2025

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100 Scope

110 This FPPS – Coarse Ground Beef (CGB) – 2025 is for use by the Department of Agriculture (USDA), AMS, Commodity Procurement (CP) Staff to procure frozen Coarse Ground Beef products.

200 Applicable Documents

210 The following documents are incorporated as part of this USDA, FPPS-CGB-2025:

210.1 Quality Assessment Division (QAD) Procedures Manual;

210.2 Food Safety and Inspection Service (FSIS) Directive 10,010.1 and Notice 05-23; and

210.3 Applicable Supplement to the AMS Master Invitations for Bids - Domestic Commodity Procurement – (MIFB-D).

300 Checklist of Requirements

310 Material

311 All items shall be produced in accordance with Food Safety and Inspection Service (FSIS) regulations. The contractor's technical proposal, submitted to the Standards and Specifications Division (SSD), 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.

312 Domestic Origin and Harvest (Slaughter) Requirements

312.1 Quality Control Program - The harvester's quality control program shall be documented in each contractor's technical proposal and have received a satisfactory onsite capability assessment by QAD.

312.2 Boneless beef shall be derived from carcasses that are derived from cattle harvested at establishments that comply with the following origin and harvest requirements.

312.2.1 Domestic Origin – All meat shall originate from livestock that are born, raised, and harvested in the United States, its territories or possessions (U.S.) If the establishment receives and processes livestock from outside the U.S., a segregation plan shall be put in place to preclude non-conforming product from being introduced into Federal nutrition assistance programs.

312.2.2 Humane Handling – All cattle shall be humanely handled in accordance with all applicable FSIS regulations and AMS requirements.

312.2.3 Residue Prevention – Harvest and production establishments shall have a Hazard Analysis Critical Control Point (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 June 2024.

312.2.4 Spinal Cord Removal – All spinal cord tissue shall be removed during the harvesting process.

312.2.5 Pathogen Intervention Steps – 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 contractor's FSIS recognized harvest process HACCP plan and the CCP intervention(s) shall be scientifically validated to achieve a three-log reduction of enteric pathogens.

320 Boneless Beef Requirements

320.1 Quality Control Program - The boneless beef supplier's quality control program shall be documented within each contractor's technical proposal and have received a satisfactory onsite capability assessment by QAD prior to supplying materials for the program. Additionally, each establishment is subjected to verification audits conducted by the QAD during production activities that demonstrate their adherence to the documented quality control program.

320.2 Traceability – Boneless beef shall be traceable to sources that comply with the above domestic origin and harvest requirements.

320.3 **XF Trimmings** - Boneless beef commonly referred to by the industry as XF trimmings (e.g., Beef Fat with Visible Lean) is not allowed as a standalone raw material source for grinding.

320.4 **Meat Recovery Systems**

320.4.1 Mechanical Separation - Boneless beef that is mechanically separated from bone with automatic deboning systems or advanced lean (meat) recovery (AMR) systems is not allowed.

320.4.2 Lean Finely Textured Beef (LFTB) – Use of LFTB is not permitted.

320.5 **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.

320.5.1 Frozen boneless beef may be used provided it is ground into the final product within 90 days from the date of pack.

320.6 **Objectionable Materials** – The following objectionable materials shall be excluded:

320.6.1 Major lymph glands (*prefemoral*, *popliteal*, and *prescapular*), thymus gland, and the sciatic (*ischiatic*) nerve (lies medial to the outside round). All bone, cartilage, and the following heavy connective tissues;

320.6.1.1 White fibrous – Shoulder tendon, elbow tendon, silver skin (from the outside round), *sacrosciatic* ligament, opaque periosteum, serous membrane (*peritoneum*), tendinous ends of shanks, *gracilis* membrane, *patellar* ligament (associated with the stifle joint), and *achilles* tendon; and

320.6.1.2 Yellow elastin – Back strap and *abdominal tunic*.

320.7 **Lot** – A lot shall consist of approximately 2,000 pounds of boneless beef produced within a day, between "cleanup to cleanup" (see Appendix D) and that is from a single harvester or processor.

320.8 **Microbial Sampling and Testing –**

320.8.1 The Contracting Officer shall specify in the purchase solicitation and corresponding documents Type 1 and Type 2 Coarse Ground Beef Products, which shall determine the level of microbial testing required.

320.8.2 Microbial Testing for Beef Manufacturing Trimmings to be used for – **Type 1** - Coarse Ground Beef for Further Processing into Fully Cooked Items - Samples from all lots of fresh chilled boneless beef, shall be sent to an AMS designated laboratory (ADL). Samples from all lots of fresh chilled boneless beef shall be tested for all indicator microorganisms as listed in Appendix B (aerobic plate count, total coliform and generic *E. coli*). All samples shall be sent to an AMS designated laboratory (ADL).

320.8.3 Sample Preparation and Handling - The ADL shall be responsible for supplying procedures for sample preparation, and submission. The ADL shall require suppliers to submit a sample submission form as an official record with each sample. Samples of boneless beef for production of Type 1 Coarse Ground Beef for Further Processing into Fully Cooked Items 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 supplier. Suppliers' technical proposal shall include and describe sample collection and preparation procedures provided by the ADL.

320.8.4 **Sample Selection**

320.8.4.1 For Beef Manufacturing Trimmings – The sample shall be selected as described within FSIS Directive 10,010.1.

320.8.4.2 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 as listed in Appendix B (aerobic plate count, total coliform and generic *E. coli*) shall be five pieces and weigh 25 grams ± 10 percent.

320.8.4.3 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.

320.8.4.4 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 determine whether such additional sampling and testing constitutes "prescreening," in which case it shall not be allowed.

320.8.5 **Testing and Results**

320.8.5.1 The microbiological testing for all indicator microorganisms shall be in accordance with the applicable AMS-approved testing methodologies.

320.8.5.2 When the critical limit is exceeded for indicator microorganisms, the boneless beef supplier shall document the removal of the affected lot(s) and have such documentation available to AMS upon request.

320.8.5.3 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 320.8.5.

320.8.5.4 Any lot that exceeds the critical limit criteria of Appendix B shall not be used to produce ground beef or any other product purchased by USDA.

320.8.6 Statistical Process Capability – Boneless beef supplier compliance with microbial requirements shall be based on the assessment of the calculated process capability (CPU) values 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 ground beef purchase programs shall be monitored by AMS, the contractor, and the boneless beef supplier to determine individual lot acceptance and/or capability of their process according to Appendix B. Ineligible boneless beef suppliers 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 QAD has been conducted. Upon notification by the SSD, that the plan has adequately addressed the issues that resulted in the ineligible status determination, the boneless beef supplier may re-enter the program under conditional status.

320.8.7 Contractor's Responsibility - The contractor shall require its boneless beef supplier(s) to provide results and process capability status (as applicable) involving each lot of boneless beef to be processed into Coarse Ground Beef for USDA. Test results and process capability status (as applicable) for individual lots shall be provided to AMS upon request. In the event a boneless beef supplier has been deemed ineligible, and wants to continue in the program, the ineligible boneless beef supplier 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 QAD has been conducted. Upon notification by the SSD that the plan has adequately addressed the issues that resulted in the ineligible status determination the boneless beef supplier may re-enter the program under conditional status.

320.8.8 Supplier requests to remove samples from ADL testing shall be submitted and approved by SSD prior to sample removal from ADL testing.

320.8.9 Lots of boneless beef tested for indicator microorganisms only (as described in Type 1 only) shall not be diverted for use in Type 2 Coarse Ground Beef or Ground Beef products for delivery to USDA under the FPPS-GB program. Lots shall be designated and labeled "For Use in Coarse Ground Beef for Further Processing into Fully Cooked Items Only".

320.10 Microbial Testing for Beef Manufacturing Trimmings to be used for – **Type 2** - Coarse Ground Beef - Samples from all lots of fresh chilled boneless beef, shall be sent to an AMS designated laboratory (ADL). Samples from each lot shall be tested for *E. coli O*157:H7*, Salmonella*, and indicator microorganisms as listed in Appendix B. One sample from every 10 lots of fresh chilled boneless beef, selected at random by the ADL, shall be tested for non-O157 STECs (O26, O45, O103, O111, O121, O145).

320.10.1 Sample Preparation and Handling - The ADL shall supply procedures for sample preparation, and submission. The ADL shall require suppliers to submit a sample submission form as an official record with each sample. The ADL shall also supply shipping supplies (including sampling bags and shipping materials) to each supplier. Suppliers' technical proposal shall include and describe sample collection and preparation procedures provided by the ADL.

320.10.2 **Sample Selection**

320.10.2.1 For Beef Manufacturing Trimmings – The sample shall be selected as described within FSIS Directive 10,010.1 and Notice 05-23.

320.10.2.2 For every lot of Beef Manufacturing Trimmings, one sample shall be prepared using one cloth sample unit for pathogen testing and one sample shall be prepared from five different pieces of trim from five different pieces of beef product for indicator microorganism testing. The sample for co-analysis of *E. coli* O157:H7, non-O157 STECs and *Salmonella* shall be one cloth sample unit; the sample for indicator microorganisms as listed in Appendix B (aerobic plate count, total coliform and generic *E. coli*) shall be five pieces and weigh 25 grams ± 10 percent.

320.10.2.3 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.

320.10.2.4 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 determine whether such additional sampling and testing constitutes “prescreening,” in which case it shall not be allowed.

320.10.3 **Testing and Results**

320.10.3.1 The microbiological testing for all organisms shall be in accordance with the applicable AMS-approved testing methodologies.

320.10.3.2 Notification for presence of pathogens and exceeding critical limit criteria - When presence of *E. coli* O157:H7, non-O157 STECs, or *Salmonella* is confirmed positive or any critical limit is exceeded for indicator organisms:

320.10.3.2.1 The ADL shall immediately notify FSIS and the SSD of all confirmed pathogens.

320.10.3.2.2 When pathogen results are positive, FSIS shall be notified by the boneless beef supplier of the final disposition of the affected lot. The supplies shall document the removal of the affected lot(s) and make such documentation available to AMS upon request.

320.10.3.2.3 When the critical limit is exceeded for indicator microorganisms, the boneless beef supplier shall document the removal of the affected lot(s) and make such documentation available to AMS upon request.

320.10.3.3 The ADL shall record all results on spreadsheets and calculate the process capability (CPU, CI) for microbial tests performed on production lots as outlined in Section 323.9.4.

320.10.3.4 Any lot that tests positive for *E. coli* O157:H7, non-O157 STECs, or *Salmonella*, or exceeds the critical limit criteria of Appendix B shall not be used to produce ground beef or any other product purchased by USDA.

320.10.4 Statistical Process Capability – Boneless beef supplier compliance with microbial requirements shall be based on the assessment of the calculated process capability (CPU, CI) values 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 ground beef purchase programs shall be monitored by AMS, the contractor, and the boneless beef supplier to determine individual lot acceptance and/or process capability according to Appendix B. Ineligible boneless beef suppliers 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 QAD has been conducted. Upon notification by the SSD that the plan has adequately addressed the issues that resulted in the ineligible status determination, the boneless beef supplier may re-enter the program under conditional status.

320.10.5 Contractor's Responsibility - The contractor shall require its boneless beef supplier(s) to provide results and process capability status (as applicable) involving each lot of boneless beef to be processed into ground beef for USDA. Test results and process capability status (as applicable) for individual lots shall be provided to AMS upon request. In the event a boneless beef supplier has been deemed ineligible, and wants to continue in the program, the ineligible boneless beef supplier 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 QAD has been conducted. Upon notification by the SSD that the plan has adequately addressed the issues that resulted in the ineligible status determination, the boneless beef supplier may re-enter the program under conditional status.

320.10.6 Supplier request to remove samples from ADL testing shall be submitted and approved by SSD prior to sample removal from ADL testing.

321 Coarse Ground Beef Item Requirements

321.1 Quality Control Program - The Coarse Ground Beef items quality control program shall be documented within the contractor's technical proposal and have received a satisfactory onsite capability assessment audit by QAD.

321.2 Traceability – All Coarse Ground Beef items production shall be traceable to the boneless beef lots and their associated microbial test results.

321.3 **Handling** - The contractor's technical proposal shall include detailed production scheduling that addresses time and temperature controls necessary to maintain excellent condition of the Coarse Ground Beef items. Coarse Ground Beef items shall be delivered within 60 days from date of pack.

321.4 **Lot** - For the purpose of microbiological testing, a lot is defined as the amount of finished Coarse Ground Beef product produced within a day, between "cleanup to cleanup" (see Appendix D) which shall be further divided into sub-lots not to exceed 10,000 pounds.

321.5 **Microbial Sampling and Testing Options** – The Contracting Officer shall specify in the purchase solicitation and corresponding documents Type 1 and Type 2 Coarse Ground Beef Products, which shall determine the level of microbial testing required.

321.6 Microbial Testing – **Type 1** - Coarse Ground Beef for Further Processing into Fully Cooked Items - All sub-lots of Coarse Ground Beef for Further Processing into Fully Cooked Items shall be tested for all indicator microorganisms as listed in Appendix B (aerobic plate count, total coliform and generic *E. coli*) after final grinding and before freezing. All samples shall be sent to the ADL.

321.6.1 Sample Preparation and Handling - The ADL shall supply procedures for sample preparation, and submission. The ADL shall require contractors to submit a sample submission form as an official record with each sample. Samples of Type 1 Coarse Ground Beef for Further Processing into Fully Cooked Items shall be appropriately identified on the ADL sample submission form. The ADL shall supply 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.

321.6.2 Sample Selection – Production processes of Coarse Ground Beef for Further Processing into Fully Cooked Items shall be subject to the following sampling strategy:

321.6.2.1 Sub-lot Microbial Testing – For every sub-lot, one original and reserve sample shall be prepared from four individual sample units for indicator organism (aerobic plate count, total coliform and generic *E. coli*) testing. The sub-lot samples shall be 25 grams ± 10 percent randomly selected throughout each 10,000 pounds of production. The four individual sample units shall be composited to produce a sample that represents the indicator organism test for each sub-lot. The contractor shall describe in its technical proposal the procedure in which the four sample units shall be selected throughout the sub-lot to be composited for the indicator organism test. These samples shall be submitted to the ADL for analysis. The reserve samples shall be held for testing in case the SSD deems it necessary. The contractor shall describe, in its technical proposal the method to be used to maintain the identity and traceability of each sub-lot. No more than 10,000 pounds shall be produced during each sub-lot, except for the last sub-lot produced in the lot may exceed the 10,000-pound limitation by five percent.

321.6.3 Testing and Results - The samples from each sub-lot shall be analyzed by the ADL for all indicator organisms listed in Appendix B.

321.6.3.1 The microbiological testing for indicator microorganisms shall be in accordance with the applicable AMS-approved testing methodologies.

321.6.3.2 Any sub-lot with any critical limit criteria noted in Appendix B that is exceeded shall result in that sub-lot and adjoining sub-lots (one preceding and one following within a day, between “clean up to clean up”) being ineligible for this program or any other USDA purchase program. Other sub-lots produced within the lot unit shall be deemed ineligible for this program unless the contractor can demonstrate a scientific or other data-supported basis for defining the sub-lot(s) relative to test results and why Coarse Ground Beef produced from same source material that resulted in the ineligible determination should not be considered affected by the test results.

321.6.3.3 When any critical limit is exceeded for indicator microorganisms, FSIS shall be notified by the contractor of the final disposition of the product. The contractor shall document the removal of the affected lot(s) and make such documentation available to AMS upon request.

321.6.3.4 The ADL shall record all results on spreadsheets and calculate the process capability (CPU) for microbial tests performed on sub-lots as outlined in Section 321.6.3.5.

321.6.3.5 Statistical Process Capability - The ADL shall record the results on spreadsheets and calculate the process capability (CPU) value for all sub-lot microbial tests performed. The spreadsheets shall be maintained so that process capability may be determined according to the requirements within Appendix B. The spreadsheets shall be maintained so that process capability assessment on each 20 sub-lot grouping can be determined as described within Appendix B. Test results shall be monitored by the contractor and SSD to determine acceptability of the process according to Appendix B. Ineligible 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 QAD has been conducted. Upon notification by the SSD that the plan has adequately addressed the issues that resulted in the ineligible status determination, the contractor may re-enter the program under conditional status.

321.6.3.6 Contractor request to remove samples from ADL testing shall be submitted and approved by SSD prior to sample removal from ADL testing.

321.7 Microbial Testing – **Type 2** - Coarse Ground Beef - All sub-lots of Coarse Ground Beef shall be tested for *E. coli O*157:H7*, Salmonella*, and indicator microorganisms as listed in Appendix B (aerobic plate count, total coliform and generic *E. coli*) after final grinding and before freezing. All samples shall be sent to the ADL. One sample from every 10 sub-lots of coarse ground beef, selected at random by the ADL, shall be tested for non-O157 STECs (O26, O45, O103, O111, O121, O145).

321.7.1 Sample Preparation and Handling - The ADL shall be responsible for supplying procedures for sample preparation, and submission. The ADL shall require contractors to submit a sample submission form as an official record with each sample. The ADL shall also supply 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.

321.7.2 Sample Selection – Production processes of Coarse Ground Beef shall be subject to the following sampling strategy:

321.7.2.1 Sub-lot Microbial Testing – For every sub-lot, two original and reserve samples shall be prepared from four individual sample units for each microbial test. The sub-lot samples shall be 325 grams ± 10 percent for co-enrichment of *E. coli* O157:H7, non-O157 STECs and *Salmonella* and 25 grams ± 10 percent for indicator organism tests and shall be randomly selected throughout each 10,000 pounds of production. The four individual sample units shall be composited to produce a sample that represents each microbial test for each sub-lot. The contractor shall describe in its technical proposal the procedure in which the four sample units shall be selected throughout the sub-lot to be composited for each microbial test. These samples shall be submitted to the ADL for analysis. The reserve samples shall be held for testing in case the SSD deems it necessary. The contractor shall describe in its technical proposal the method to be used to maintain the identity and traceability of each sub-lot. No more than 10,000 pounds shall be produced during each sub-lot, except for the last sub-lot produced in the lot may exceed the 10,000-pound limitation by five percent.

321.7.3 Testing and Results - The samples from each sub-lot shall be analyzed by the ADL for all organisms listed in Appendix B.

321.7.3.1 The microbiological testing for all organisms shall be in accordance with the applicable AMS-approved testing methodologies.

321.7.3.2 Any sub-lot that tests positive for *E. coli* O157:H7, non-O157 STECs or *Salmonella,* or any critical limit criteria noted in Appendix B that is exceeded, shall result in that sub-lot and adjoining sub-lots (one preceding and one following within a day, between “clean up to clean up”) being ineligible for this program or any other USDA purchase program. Other sub-lots produced within the lot unit shall be deemed ineligible for this program unless the contractor can demonstrate a scientific or other data-supported basis for defining the sub-lot(s) relative to test results and why Coarse Ground Beef produced from same source material that resulted in the ineligible determination should not be considered affected by the test results.

321.7.3.3 Notification for presence of pathogens or when critical limit is exceeded – When presence of *E. coli* O157:H7, non-O157 STECs or *Salmonella* is presumptive positive or confirmed positive; or any critical limit is exceeded for indicator organisms:

321.7.3.3.1 The ADL shall immediately notify FSIS and the SSD of all confirmed pathogens;

321.7.3.3.2 When pathogen results are positive, FSIS shall be notified by the contractor of the final disposition of the product. The contractor shall document the removal of the affected lot(s) and make such documentation available to AMS upon request;

321.7.3.3.3 When the critical limit is exceeded for indicator microorganisms, FSIS shall be notified by the contractor of the final disposition of the product. The contractor shall document the removal of the affected lot(s) and make such documentation available to AMS upon request; and

321.7.3.3.4 Coarse Ground Beef associated with the positive pathogen test results or critical limit exceeded results shall be ineligible for any USDA purchase program.

321.7.3.4 The ADL shall record all results on spreadsheets and calculate the process capability (CPU, CI) for microbial tests performed on sub-lots as outlined in Section 321.7.3.5.

321.7.3.5 Statistical Process Capability - The ADL shall record the results on spreadsheets and calculate the process capability (CPU or CI) value for all sub-lot microbial tests performed. The spreadsheets shall be maintained so that process capability may be determined according to the requirements within Appendix B. The spreadsheets shall be maintained so that process capability assessment on each 20 sub-lot grouping can be determined as described within Appendix B. Test results shall be monitored by the contractor and SSD to determine acceptability of the process according to Appendix B. Ineligible 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 QAD has been conducted. Upon notification by the SSD that the plan has adequately addressed the issues that resulted in the ineligible status determination, the contractor may re-enter the program under conditional status.

321.7.3.6 Contractor requests to remove samples from ADL testing shall be submitted and approved by SSD prior to sample removal from ADL testing.

330 Processing

331 The contractor's technical proposal and process shall ensure compliance with the following requirements:

331.1 Grinding and Blending;

331.1.1 Coarse Ground Beef items - Boneless beef shall pass at least once through a grinding plate that is no smaller than ¾-inch or no larger than a 1.0-inch. Blending after final grinding is allowed only to the extent that it does not affect the appearance of the finished Coarse Ground Beef items;

331.1.2 Fat Break-Outs - The grinding, blending, and packaging process shall be conducted in a manner that precludes large fat "break outs" (solid chunks of fat greater than 1.0 cubic inch) or objectionable fat "smears" in the finished product;

331.2 Metal Detection - All product shall be free of metal contaminants. Detection of stainless steel, ferrous, and non-ferrous (e.g., lead, copper, and aluminum) metals is required. The contractor's technical proposal shall identify and describe the equipment, location, detection procedure, sensitivity levels, frequency of equipment validation, and corrective action procedures; and

331.3 Equipment – All equipment used to produce Coarse Ground Beef items for USDA shall be maintained and routinely checked for optimal performance.

340 State of Refrigeration

341 Coarse Ground Beef items shall be frozen to 0°F within 72 hours after completion of the final grinding of the involved lot.

342 Coarse Ground Beef items shall be stored, shipped, and delivered at temperatures that do not exceed 0°F.

350 Fat Limitations

351 The contractors shall establish a target average of 15 percent fat. The upper and lower specifications limits shall be 18 and 12 percent fat respectively. The target fat content shall be declared on the shipping container label and the nutrition facts panel.

352 Contractor Process Assessment - The contractor shall declare the production lot size, laboratory, test method, and SPC methodologies in its technical proposal.

352.1 Sampling and testing - The contractor shall select at least four internal individual fat sample units (selected after initial grinding or blending) to be analyzed for fat content from each production lot destined for USDA. The sample unit size shall be determined by the testing method used by the contractor’s laboratory.

352.2 Recording results - The contractor shall record the results on spreadsheets. The calculated process capability (Cpk/CPU) value (as discussed in Appendix A) shall be used to determine if the process is in statistical control. Under contractor process assessment, no production lots shall be allowed delivery to USDA with average test results that are outside the upper or lower specification limits.

352.3 Process Capability Assessment - 20 consecutive production lot results (that include the last production lot) shall be recorded on spreadsheets for capability assessment by the contractor and the QAD grader. The processor’s capability (Cpk/CPU) shall be one or higher.

353 AMS Process Assessment – For the first 20 production lots, the QAD grader shall direct the contractor to randomly select samples, each consisting of four sample units. For Coarse Ground Beef items, each initial sample unit shall not exceed 10 pounds. Initial sample units may be blended and/or further reduced in size. From each initial sample unit a final sample unit shall consist of 200 – 300 grams. Each sample unit shall be independent from those samples selected for contractor process assessment and sent to the ADL for fat analysis. The ADL shall be responsible for supplying sampling protocol, all sample handling materials, and sampling methods (including sample unit size to be submitted to the ADL, preparation, handling of reserve samples, etc.) for sample preparation and submission. The ADL shall record the results on spreadsheets and submit them to the contractor and QAD grader for comparison to the contractor's process assessment. After 20 consecutive results, the contractor shall notify the SSD immediately and declare what immediate corrective and preventative actions shall be taken when:

353.1 The ADL calculated process average fat results (mean) varies more than one percent from the contractor's calculated process average results, or;

353.2 The calculated process capability (Cpk/CPU) is less than one for results from either the contractor's designated laboratory or the ADL; and

353.3 The contractor shall notify the SSD that the process is not capable for fat and then sample and test an additional 20 consecutive results that shall meet the criteria for AMS Process Assessment. Change in status begins after a cause-and-effect analysis has been performed and corrective actions have been implemented. If the contractor remains in Unreliable Status after the additional 20 consecutive lots, a cause-and-effect analysis shall be performed, and corrective actions submitted within 5 business days to SSD for review and approval. If the contractor still remains in Unreliable Status after the second round of 20 consecutive lots, a cause-and-effect analysis shall be performed and corrective actions submitted within five business days to SSD for review and approval, implemented and a satisfactory QAD assessment audit has been completed. The SSD reserves the right to deem a contractor as Unreliable for consideration on future contract awards when corrective or preventative actions are not adequate or effective or the contractor is unresponsive in declaring status or submitting corrective actions.

354 Continuous AMS Assessment – If AMS process assessment is satisfactory, the QAD grader shall direct the contractor when to randomly select samples (each consisting of four sample units) from a production lot. No more than two production lot samples are sent to the ADL on a weekly basis. The ADL shall continually record 20 consecutive results (always including the last recorded result as defined within Appendix D) on spreadsheets and submit the calculated process capability (Cpk/CPU) value to the contractor and QAD grader. The ADL's calculated process capability (Cpk/CPU) value shall continually be compared to the contractor's calculated process capability (Cpk, CPU) value as each contractor's test result is recorded to conduct the AMS Process Assessment as described above (using 20 consecutive results).

360 Preparation for Delivery

361 The contractor's technical proposal and process shall assure that all packaging, packing, closure, marking, and palletization complies 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.

362 **Packaging and Packing**

362.1 All immediate containers shall function as a tamper evidence indicator to provide added assurance of product integrity through the method of sealing or closure.

362.2 Coarse Ground Beef items shall be bulk packaged (with no packaging materials) directly into leak-proof shipping containers with fiberboard that is wax impregnated, has a moisture barrier coating, or have plastic laminated interior panels.

362.3 Style and Size of Shipping Containers - Only one style and size of immediate and shipping container shall be used in any one delivery unit.

363 Shipping Container Net Weight.

363.1 Using SPC tools, the contractor shall assure the following net weight:

363.1.2 Coarse Ground Beef items - shall be packed to a net weight of 60 pounds.

364 Closure.

364.1 Shipping containers shall be closed by strapping, taping or gluing. When strapping is used, the initial closure (usually the bottom of container) shall be secured by the gluing or taping method.

365 Marking of Containers*

365.1 Shipping containers shall have a printed code that includes the establishment number and is traceable to the production lot and date. All container markings shall include all information required by FSIS along with the additional information listed below:

365.2 **Shipping Containers** - Commercially marked shipping containers shall include the information as follows:

365.2.1 USDA Shield (at least 2 inches high and appearing on the top of the container or on the principal display panel);

365.2.2 Applicable Purchase Order Number;

365.2.3 The product name and material number:

Material Number 100154 –
Type 1: Coarse Ground Beef for Further Processing into Fully Cooked Items;
Type 2: Coarse Ground Beef;

365.2.4 Fat Declaration – 15% Fat;

365.2.5 Nutrition Facts panel to include fat declaration of 15 grams of fat per 100 grams serving size;

365.2.6 Ingredient declaration (including single ingredient products); and

365.2.7 The allergen statement shall be provided in the format which complies with the Food Allergen Labeling and Consumer Protection Act (FALCPA) and the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act which define milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils, as “major food allergens”; e.g. Contains: _____.

For additional information refer to the FSIS Compliance Guidance at:
https://www.fsis.usda.gov/sites/default/files/import/Allergens-Ingredients.pdf

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

370 Palletized Unit Loads

370.1 All products shall be stacked on new or well-maintained pallets and palletized with shrink wrap plastic.

371 Total Net Weights Per Delivery Unit

371.1 The delivery unit shall be 42,000 pounds. No tolerances shall be allowed.

372 Sealing

372.1 Sealing – All products shall be delivered to AMS assigned destinations, including multi-stop deliveries, under seal(s) with tamper proof, tamper resistant, serially numbered seals as required under the current AMS MIFB-D. The seal number(s) must be recorded on the Bill of Lading (BOL) and correspond with the applied seal at the time of arrival at each destination when destined for multiple recipients.

380 USDA Quality Assurance

381 Warranty and Complaint Resolution

381.1 Warranty - The contractor shall guarantee that the product complies with all specification requirements, technical proposal declarations, and provisions set forth in the MIFB-D.

381.2 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.

382 AMS Monitoring and Production Assessment

382.1 A QAD grader shall be present during the production of the finished product for all USDA Ground Beef contracts. The QAD grader shall monitor and verify the processing steps, quality assurance activities, and any corrective actions to assure that all requirements outlined in the approved technical proposal are complied with. The QAD grader shall conduct the monitoring and production verification in accordance with applicable AMS procedures. Any deviations to contractual requirements shall be reported to the contractor and SSD. The SSD shall make all determinations as to the acceptability of the product related to findings documented by the QAD grader and/or auditor.

383 Control of Non-Conforming Product

383.1 The contractor shall include a plan and supporting documentation to assure that non-conforming product (i.e., boneless beef, Coarse Ground Beef) 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 vendor documentation of final disposition (e.g., diverted to cooked product or destroyed).

384 Contractor Checkloading

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

384.1.1 Purchase Order Number and Purchase Order Line Item Number;

384.1.2 Sales Order Number and Sales Order Line Item Number;

384.1.3 Destination of shipment;

384.1.4 Name of Product and applicable Material Number;

384.1.5 Shipping Date;

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

384.1.7 Count of shipping containers and total projected net weight in each production lot and delivery unit;

384.1.8 Identity of car or transportation trailer numbers, letters, license, etc., including all serially numbered door seal(s), as applicable;

384.1.9 Contractor certification that product conforms with the applicable specification (FPPS-CGB-2025);

384.1.10 Count and projected net weight verified; and

384.1.11 Signature of company official responsible for checkloading.

Appendix A

Data Entry and Process Capability Values

Data Entry

The ADL shall record microbiological and fat test results on spreadsheets and to have 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). Qualitative results for *E. coli* O157:H7, each of the non-O157 STEC serotypes, and *Salmonella* shall be recorded as a 1 for a positive result and as a 0 for negative results.

The ADL shall provide the calculated process capability values (CPU, Cpk and Cl) 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 or Cpk) is calculated by the ADL. CPU shall be used for microbiological tests and for Beef Patties – 90/10 fat tests since 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 3.5). The upper specification limits (USL) for microbiological requirements shall be found in APPENDIX B. The calculations for CPU and Cpk are as follows: **Calculation of process capability (CPU) with an upper specification limit only** Step 1. The first calculation shall determine the Z-value (upper): **Z-value (upper) = (USL – Process Average) / Standard Deviation** Step 2. The Z-value divided by 3 shall calculate the CPU: **CPU = Z-value (upper) / 3**	**Calculation of process capability (Cpk) with an upper and lower specification limit** Step 1. The first set of calculations shall determine the smaller value of the two Z-values (upper or lower): **Z-value (upper) = (USL – Process Average) / Standard Deviation** **Z-value (lower) = (Process Average – LSL) / Standard Deviation** Step 2. The smaller of the two Z-values (upper or lower) divided by 3 shall calculate the Cpk. **CPU = Z-value (smaller value of the upper or lower) / 3**

Process Capability Value – Cl

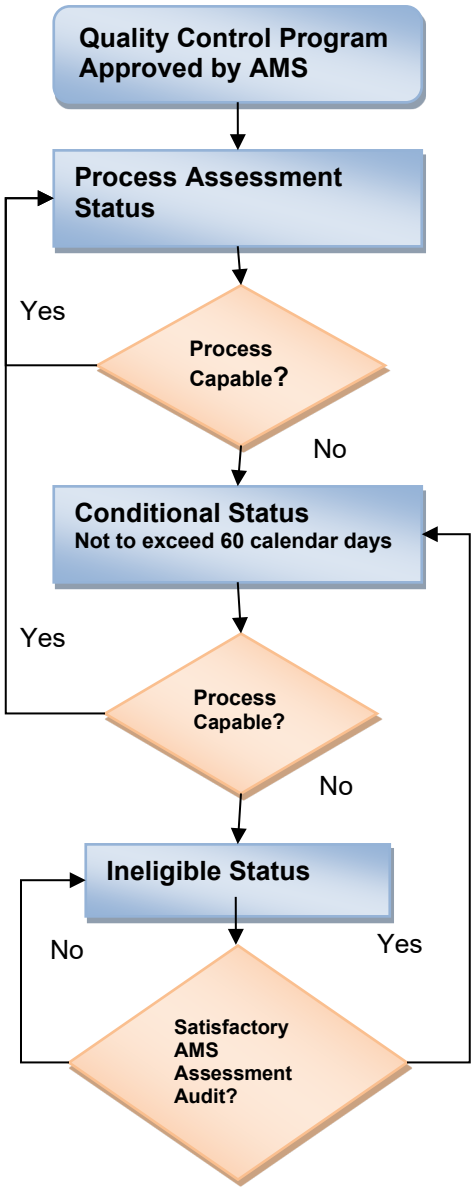
The central line (Cl; x-bar) is the process average or arithmetic mean that indicates the incidence of positive *E. coli* O157:H7, and *Salmonella* results. Results from non-O157 STECs are not used to calculate process capability.

Appendix B

AMS Boneless and Coarse Ground Beef Items Process Requirements Flow Chart

Quality Control Program – Prior to bidding on ground beef contracts with the USDA, the documented quality control program as described within the approved technical proposal (raw material suppliers and grinders) shall have received a satisfactory onsite capability assessment by QAD. 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.

AMS Process Requirements Flow Chart



Process Assessment Status - A process assessment involves sampling and testing of 20 consecutive lots or sub-lots (which shall include the last recorded result as defined within Appendix D) of boneless beef (see Section 320.8.5) or Coarse Ground Beef items (see Section 324.7.3.5) 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 SPC only lots or sub-lots (which shall include the last recorded result) recorded in spreadsheets, where the process capability (CPU or CI) value is calculated (See Appendix A) for evaluation. A process that is not capable shall be declared to the SSD 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;
- The CI values do not meet the levels specified in the table below for *Salmonella* or *E. coli* O157:H7;
- 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 or sub-lots.

Conditional Status –To regain **process capable** status, the boneless beef supplier or contractor shall notify the SSD 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 SSD. Change in status begins after a cause-and-effect analysis has been performed and corrective actions have been implemented. The boneless beef supplier or contractor may also declare itself **ineligible** at any time.

Ineligible Supplier/Contractor – An i**neligible** Boneless Beef Supplier or Ground Beef Contractor shall not be allowed to supply boneless or ground beef products under USDA contracts 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 SSD reserves the right to declare a boneless beef supplier or ground beef contractor **ineligible** at any time.

AMS MICROBIAL REQUIREMENTS FOR BONELESS & GROUND 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
E. coli	100 / gram	500 / gram	CPU $\geq$ 1
Salmonella		Positive (+) result / 325 grams	CI $\leq$ 0.05
E. coli O157:H7		Positive (+) result / 325 grams	CI $\leq$ 0.05

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).

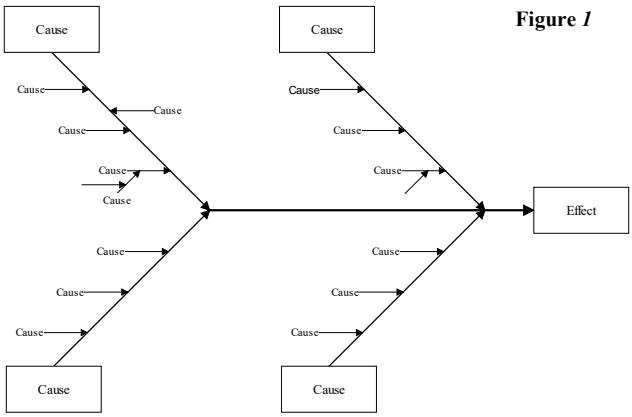


Figure *1*

"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. "Cleanup to cleanup" may be an effective means of preventing cross contamination of one part of production to another with *E. coli O157:H7*. 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).

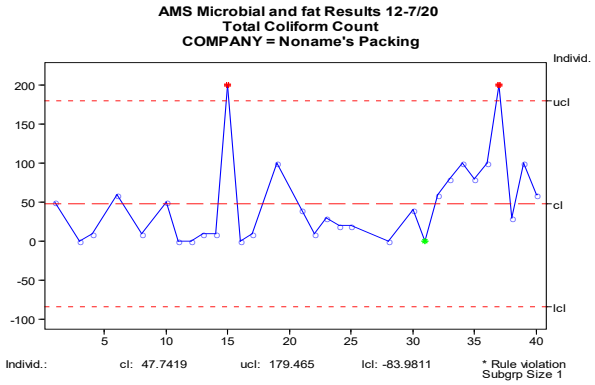
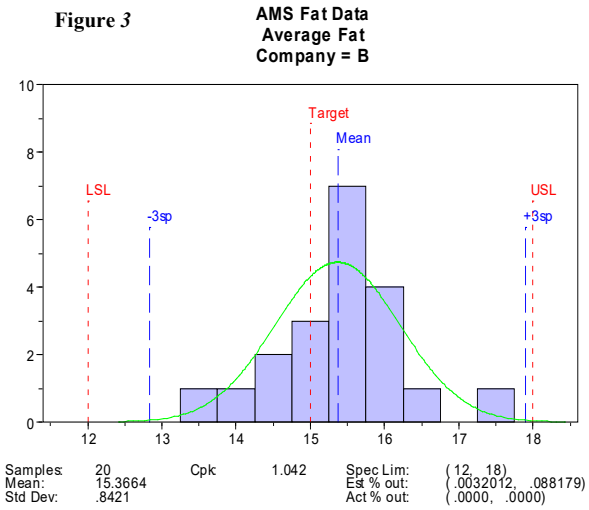


Figure *2*

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.

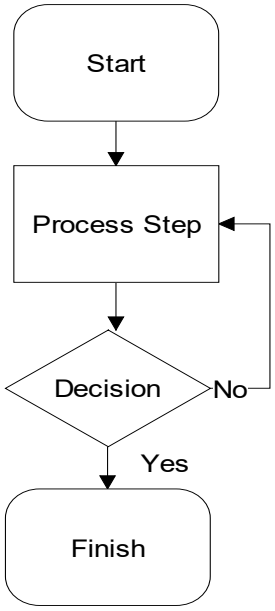
Figure *3*



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.

Figure *4*



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).

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).

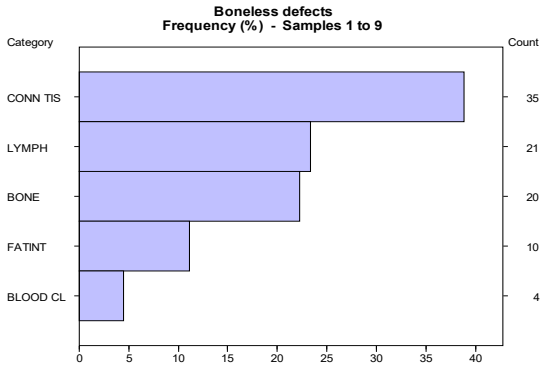
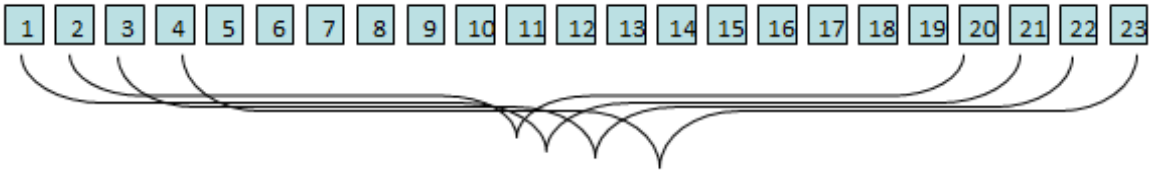


Figure 5

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 is 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 Coarse Ground 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 Ground Beef Purchase Program is to procure from ground beef processors that are statistically capable of meeting the upper specification limits specified within the FPPS-CGB. The specification limits reflect customer needs (See Figure 3).

USDA Agricultural Marketing Service

APPROVED

Agricultural Marketing Service (AMS)
Livestock and Poultry (LP) Program
Standards and Specifications Division (SSD)
Room 2702-S, STOP 0249
Phone: (202) 690-3148

Federal Purchase Program Specification (FPPS) for Animal Handling and Welfare

Supersedes: FPPS-AHW- July 2024 – Changes from previous requirements in blue

Effective: April 2025

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100 General

101 This document is for use by the Department of Agriculture (USDA), AMS, LP 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 **Sections 200 – 241** (Sections 300 & 400 are not required to be listed in the contractor's technical proposal - these sections are provided for information only.)

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 Meat Institute *Recommended Animal Handling Guidelines & Audit Guide: A Systematic Approach to Animal Welfare;*

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 4: Transportation Audit Guidelines, 7 Core Criteria and Chapter 5: Auditing Animal Handling and Stunning, 7 Core Criteria, of the Meat Institute *Recommended Animal Handling Guidelines & Audit Guide: A Systematic Approach to Animal Welfare,* found at the following web site address:

231.1 https://www.meatinstitute.org/Animal_Welfare/Guidelines_and_Audits

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.

Sections 300 – 400 are provided for contractors' information only.

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 4:*** Meat Institute *Recommended Animal Handling Guidelines & Audit Guide: A Systematic Approach to Animal Welfare)***.**

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 5:* Meat Institute *Recommended Animal Handling Guidelines & Audit Guide: A Systematic Approach to Animal Welfare*).

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.

[1/]Religious harvest (Kosher and Halal) shall be exempt from the AMS auditing of Core Criteria 6: Effective Stunning.

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 SSD, 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 three (3) months of the previous audit.

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 SSD, 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 (4) 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 (6) 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 Standards and Specifications Division

401 SSD can declare an organization’s Animal Handing and Welfare Program out of compliance at any time.

402 The organization shall immediately notify SSD 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 211 and FPPS – Ground Beef Items, Frozen.**

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 Scope

200 Applicable Documents

300 Checklist of Requirements

310 Items

320 Material

322 Domestic Origin and Harvest (Slaughter) Requirements.

322.1 Quality Control Program

322.2.1 Domestic Origin

322.2.2 Humane Handling

322.2.3 Residue Prevention

322.2.4 Spinal Cord Removal

322.2.5 Pathogen Intervention Steps

323 Boneless Beef

323.2 Traceability

323.3 XF Trimmings

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

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 211 and FPPS – Coarse Ground Beef Items, Frozen.**

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200 Applicable Documents

300 Checklist of Requirements

310 Material

312 Domestic Origin and Harvest (Slaughter) Requirements.

312.1 Quality Control Program

312.2.1 Domestic Origin

312.2.2 Humane Handling

312.2.3 Residue Prevention

312.2.4 Spinal Cord Removal

312.2.5 Pathogen Intervention Steps

320 Boneless Beef Requirements

320.2 Traceability

320.3 XF Trimmings

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

United States Department of Agriculture
Agricultural Marketing Service
Livestock and Poultry Program

Certificate of Conformance for
the Procurement of Frozen Ground Beef Products

Certificate of Conformance

I certify the following:

(1) On [delivery date(s)], [Supplier's name] furnished the (insert the appropriate commodity description) called for by Purchase Order Number _____via [Carrier] under Sales Order Number & Item number(s): _____.

(2) The (insert the appropriate material name) is of the quality specified and conforms in all respects with the purchase order requirements, including [Supplier's name] Technical Proposal as approved by the AMS, LP Program, Standards and Specifications Division.

(3) Product identification, (i.e., production lot number(s)) is in the quantity shown on the attached acceptance document.

(4) Supplier assures all meat or meat products used in fulfilling this contract was produced in the United States as defined in the AMS Master Invitations for Bids – Domestic Commodity Procurement.

Date: _____

Signature: _____
(Signed by an officer or representative authorized to sign offers)

Title: _____