USDA Agricultural Marketing Service

APPROVED

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

FEDERAL PURCHASE PROGRAM SPECIFICATION (FPPS) FOR GROUND BEEF ITEMS, FROZEN

Supersedes: FPPS GB March 2015 – Changes from previous requirements in blue

Effective: April 2016

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100 SCOPE

101 This FPPS – Ground Beef (GB) – 2016 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-2016:

210.1 Quality Assessment (QA) Division Procedures Manual.

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

210.3 Applicable Supplement to AMS Master Solicitation.

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.

Approved by CMS
Date Issued: 04/26/04
Date Revised: 04/18/16

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
Ground Beef (10-pound bulk packaged) (LFTB Optional)	110261
Ground Beef, 1-pound packages (LFTB Optional)	110260

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
Lean Beef Patties-5% Fat (LFTB Optional)	110270

320 MATERIAL

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

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 QA Division.

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

322.2.1 Domestic Origin - All beef shall originate from U.S. produced livestock as defined in the Master Solicitation and Supplement.

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 2013.

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 supplier'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 QA Division prior to supplying materials for the program. Additionally, each establishment is subjected to verification audits conducted by the QA Division 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 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.

323.4 Meat Recovery Systems

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

323.4.2 Lean Finely Textured Beef (LFTB) – When specified, LFTB, or meat components produced using similar methods may be used as a raw material provided a scientifically validated intervention is applied during the LFTB manufacturing process that reduces enteric pathogens by at least a three log basis. When LFTB is used, the following criteria shall be met:

323.4.2.1 Red Color – The producer of LFTB shall assure that the product has a discernible redness in color. The LFTB shall maintain the same redness in color until time of processing to minimize the effect of the color to the finished ground beef.

323.4.2.2 Fat Content - Does not exceed 10 percent fat.

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 Except for boneless beef destined for Ground Beef Products to be irradiated, frozen boneless beef may be used provided it is ground into the final product within 60 days from the date of pack. Boneless beef destined for irradiated ground beef shall never be frozen before grinding and shall be ground within five days from harvest.

323.5.2 The contractor shall document all procedures for handling of LFTB and shall use it within 60 days of the date of production.

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.

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 (including LFTB) 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, including LFTB, 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. One sample from every 10 lots of fresh chilled boneless beef (excluding LFTB), 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 Revision 4 (N-60 Sections 8, 9 and NOTE).

323.8.2.2 For every lot of beef Manufacturing Trimmings, two samples shall be prepared from 65 pieces of trim from 65 different pieces of beef product. The sample for co-enrichment of *E. coli* O157:H7, non-O157 STECs and *Salmonella* shall be 60 pieces and weigh 325 grams ± 10 percent; 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 Alternative sampling methods may be used provided they are approved by AMS as equivalent to the manual excision protocols referenced in Section 323.8.2.1. The suppliers' technical proposal shall include and describe any proposed alternative sample collection and preparation methods and procedures.

323.8.2.4 For LFTB – The random sample shall be selected as described within FSIS Directive 10,010.1 Revision 4. The sample for co-enrichment of *E. coli* O157:H7 and *Salmonella* shall weigh 325 grams ± 10 percent; the sample for indicator microorganisms (aerobic plate count, total coliform and generic E*. coli*) shall weigh 25 grams ± 10 percent.

323.8.2.5 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.

323.8.2.6 If the contractor plans to do microbiological testing in addition to that required by AMS, the technical proposal shall identify in detail such testing, including location of sample collection, frequency of sample collection, and intended use of testing results. AMS shall make a determination of whether such additional sampling and testing constitutes "prescreening," in which case it shall not be allowed.

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 FSCS Division 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 an AMS Agent upon request.

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 an AMS Agent upon request.

323.8.3.3 The ADL shall record all results on spreadsheets and calculate the process capability (CPU, Cl) for microbial tests performed on production lots as outlined in Section 323.8.4.

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, Cl) 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 QA Division has been conducted. Upon notification by the FSCS Division that the plan has adequately addressed the issues that resulted in the ineligible status determination, the boneless beef 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 the QA Division agent 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 QA Division has been conducted. Upon notification by the FSCS Division that the plan has adequately addressed the issues that resulted in the ineligible status determination the boneless beef 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 FSCS Division 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 audit by QA Division.

324.2 Traceability – All ground beef production shall be traceable to the boneless beef lots (including LFTB) 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 all microbes listed in APPENDIX B 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.

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 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 FSCS Division 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 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 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 FSCS Division 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 an AMS Agent 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 an AMS Agent upon request.

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 FSCSD 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 QA Division has been conducted. Upon notification by the FSCS Division that the plan has adequately addressed the issues that resulted in the ineligible status determination, the 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 FSCS Division prior to sample removal from ADL testing.

330 PROCESSING

331 The contractor's technical proposal and process shall assure 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.

331.2 LFTB – When specified as an option, LFTB shall not exceed 15 percent by weight of each batch of combined fine ground finished products (Material Numbers 110261, 110260, 110270).

331.3 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).

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

331.5 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.

331.6 Equipment – All equipment used to produce ground beef products for USDA shall be maintained and routinely checked for optimal performance.

331.7 Irradiated Ground Beef - When specified by the purchaser, ground beef products to be irradiated shall comply with the additional requirements specified in APPENDIX C.

331.8 Beef Patties with Soy Protein Product (SPP) - The SPP shall be hydrated to yield no less than 18% protein (as-is basis).

[(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.

331.8.1 Texture - The physical characteristics of SPP, in the dry form, shall be either granular or textured.

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

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.

331.8.3 Domestic Origin – SPP ingredients shall be derived from U.S. produced products.

331.9 Ground Beef Patties-90/10 (110346) - The patties shall not have any non-meat ingredients added.

331.10 Lean Beef Patties (100163, 110270) – Non-meat components may be used to enhance the palatability of the 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.

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, 110270). 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, 110270), 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, 110270).

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 randomly select four individual 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 the AMS agent. The processor's capability (Cpk/CPU) shall be one or higher.

353 AMS Process Assessment – For the first 20 production lots, the AMS agent 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 AMS for comparison to the contractor's process assessment. After 20 consecutive results, the contractor shall notify the FSCS Division 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 the FSCS Division 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 AMS 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 AMS for review and approval, implemented and a satisfactory AMS assessment audit has been completed. The FSCS Division 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 AMS agent 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 AMS. 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, 110270 - 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.

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, 110261) – 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, 110260) – 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, 110270, 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:

382.6.1 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.

382.6.2 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.

382.7 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.

382.8 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 immediate 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, 110260) 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 (180 calendar days from the date of production).

385.2.4 The FSIS establishment number.

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

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 (LFTB Opt)[1/]	110261
Ground Beef, 1 pound packages	100159
Ground Beef, 1 pound packages (LFTB Opt)	110260
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
Lean Beef Patties (LFTB Opt)[1/]	110270

[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, 110261, 100159, 110260, 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, 110270).

385.3.7 Ingredient declaration (including single ingredient products).

385.3.8 An allergen statement in a format which complies with the Food Allergen Labeling and Consumer Protection Act (FALCPA) for any product which contains milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, soy or wheat; e.g. Allergen: This product contains _____.

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, 110261, 110260	40,000
110349, 110350, 110348, 110347, 110346, 110082, 100163, 110270	38,000

Note: No tolerances shall be allowed.

388 Sealing

388.1 All products shall be delivered to AMS assigned destinations under seal with tamper proof, tamper resistant, serially numbered, high security seals that meet the American Society for Testing and Materials Standard (ASTM) F1157-04 and/or the International Organization for Standards (ISO) 17712-2010 as required under the Master Solicitation. Seals shall be ⅛th-inch diameter cable, high-security bolt, or equivalent.

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 Master Solicitation.

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 A QA Division agent shall be present during the production of the finished product for all USDA ground beef contracts. The QA Division agent 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 QA Division agent shall be conducting the monitoring and production verification in accordance with applicable QA Division procedures. Any deviations to contractual requirements shall be reported to the contractor and FSCS Division. The FSCS Division shall make all determinations as to the acceptability of the product relative to findings documented by the QA Division agent.

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, LFTB, 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/Purchase Order Line Item Number;

394.1.2 Sales Order Number/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;

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

394.1.9 Contractor certification that product conforms with the applicable specification (FPPS-GB-2016);

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 results 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 & 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 QA Division. AMS shall audit and monitor the program. The quality control program shall specifically address management of microbial data to comply with the AMS Process Requirements Flow Chart and the following descriptions.

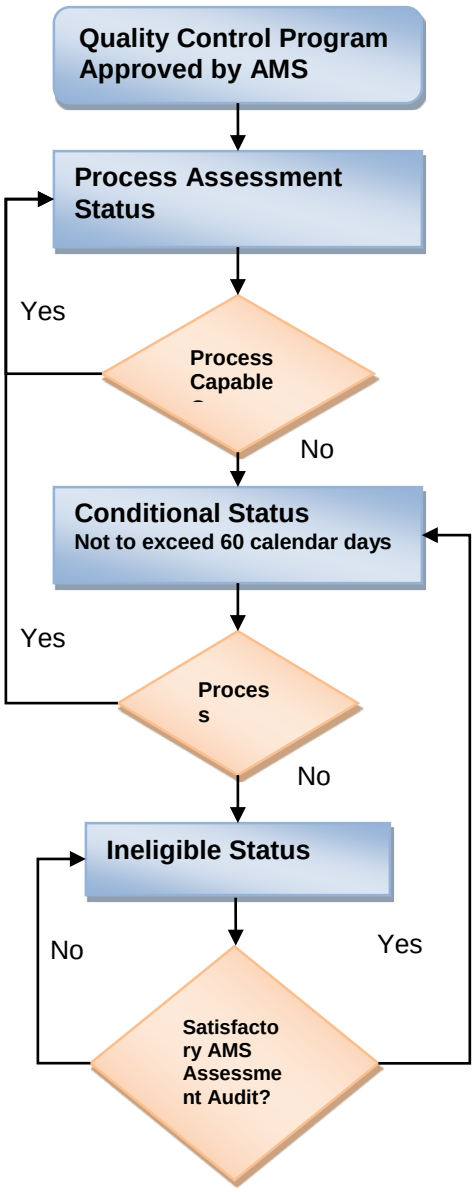
Process Assessment Status - A process assessment involves sampling and testing of 20 consecutive lots or sub-lots (which shall include the last recorded result as defined within APPENDIX D) of boneless beef (see Section 323.8.4) or ground beef (see Section 324.5.3.5) destined for USDA contracts for the 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 Cl) value is calculated (See APPENDIX A) for evaluation. A process that is not capable shall be declared to the FSCS Division immediately when results are known and shall result in switching from **process assessment** status to **conditional status** or switching from **conditional status** to **ineligible status** when:

- The CPU values do not meet the levels specified in the table below;
- The Cl 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.

AMS PROCESS REQUIREMENTS FLOW CHART



Conditional Status –To regain **process capable** status, the boneless beef supplier or contractor shall notify the FSCS Division that the process is not capable, and then have 20 consecutive results that meet the **'Process Capable'** criteria within 60 calendar days or in accordance with a production schedule pre-approved by the FSCS Division. Change in status begins after a cause and effect analysis has been performed and corrective actions have been implemented. The boneless beef 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 FSCS Division 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 Cl Value**
Standard Plate Count	50,000 / gram	100,000 / gram	CPU $\geq$ 1
Total Coliforms	100 / gram	1,000 / gram	CPU $\geq$ 1
E. coli	100 / gram	500 / gram	CPU $\geq$ 1
Salmonella		Positive (+) result / 325 grams	Cl $\leq$ 0.05
E. coli O157:H7		Positive (+) result / 325 grams	Cl $\leq$ 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).

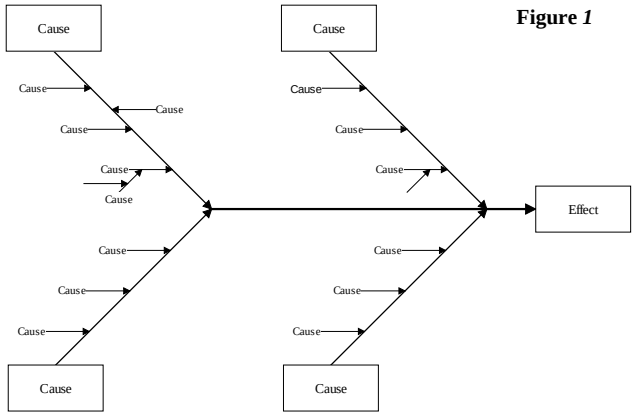


Figure *1*

"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).

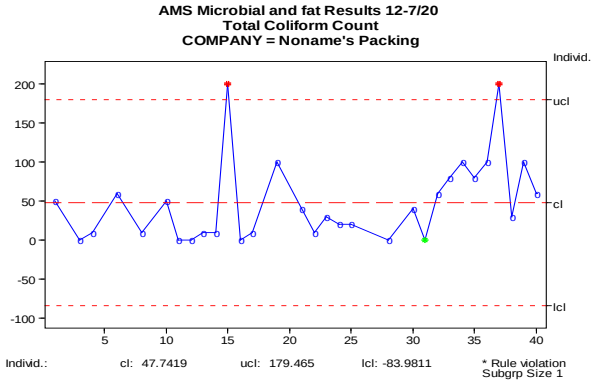
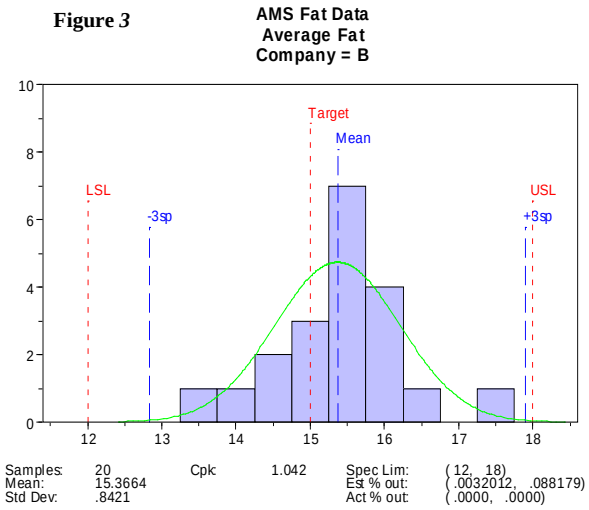


Figure *2*

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.

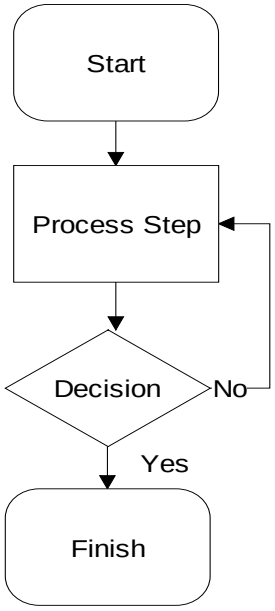
Figure *3*



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).

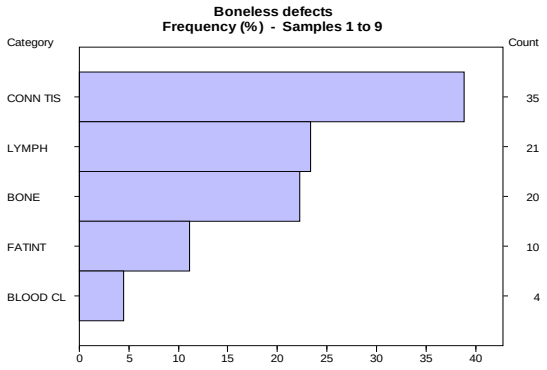
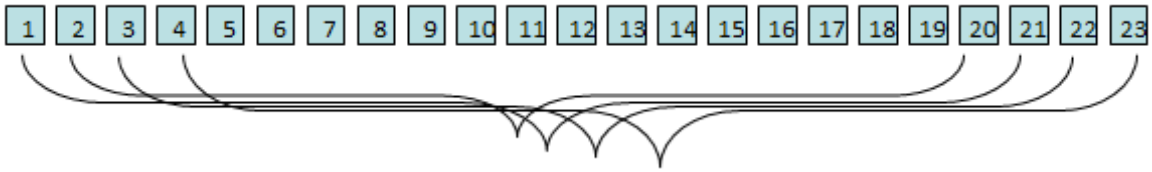


Figure 5

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).