

SUPPLEMENT 211 TO AMS MASTER SOLICITATION

June 2012

PURCHASE OF FROZEN BEEF PRODUCTS FOR DISTRIBUTION TO CHILD NUTRITION AND OTHER FEDERAL FOOD AND NUTRITION PROGRAMS

This document provides additional USDA requirements and specifications for the purchase of ground beef items described in the attached [CHECKLIST AND REFERENCES TO APPLICABLE BID AND CONTRACT PROVISIONS \(Exhibit A\)](#). In addition to product descriptions, this exhibit also provides information on the Technical Requirements Schedule (TRS)-GB-2012, Ground Beef Items, Frozen, dated May 2012 ([Attachment I](#)).

I. INSTRUCTIONS TO POTENTIAL BIDDERS

- A. The ground beef items will be purchased on a competitive bid basis from suppliers who have met the requirements described in Section I.B. Interested suppliers may submit a technical proposal at any time during this purchase program. Suppliers should allow 10 working days from receipt of the technical proposal by USDA for notification of the results of the evaluation of the technical proposal from the Contracting Officer's [Technical Representative \(COTR\)](#). A supplier is deemed eligible to bid after notification by the [COTR](#).

Submission of a technical proposal is not binding on USDA. Actual purchases will be on a competitive bid basis as described in the Master Solicitation, this Supplement, and separately issued solicitation.

B. Documentation and Assessment Requirements

To become an eligible supplier, the following must be submitted [electronically](#) to the [Standardization Division, Livestock and Seed Program, Agricultural Marketing Service](#), U.S. Department of Agriculture, for evaluation and approval prior to bidding:

1. Technical Proposal Requirement:
 - a. Include a detailed description of the beef item offered and each of the production steps that are taken to meet or exceed the minimum product requirements set forth in the applicable specification. (Plan/Do)
 - b. Describe all the quality assurance methods used to verify conformance to all requirements. This will 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)
 - c. 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)

- d. The technical proposal shall follow the format as describe in Section III. Technical Proposal format. Offeror's proposal should be brief and concise.
- e. The technical proposal shall be preceded by the following, as required by the template:
 - 1) Table of Contents listing the major areas as they appear in the technical proposal template; and
 - 2) List of attachments, forms provided with the proposal, if appropriate.
- f. The technical proposal should be written in the following format:
 - 1) Plan and Do - A description of the planning and production steps taken to meet each requirement.
 - 2) Check - Describes all the quality assurance methods that will be used to verify conformances to each requirement. This will include the monitoring and measurement taken during the process (all measurements results shall be recorded and made available to AMS upon request).
 - 3) Act - Identifies all corrective actions to be taken if deviations from contractual and specification requirements occur during production and all preventative actions taken to preclude reoccurrences.

The COTR will review each technical proposal to determine if the proposal is adequate and will notify the supplier of the status of their technical proposal. [See Section III for instructions for submission of technical proposals.](#)

Once a supplier is notified by the [COTR](#) that the technical proposal meets the applicable criteria, the [Grading and Verification Division \(GVD\)](#) will contact the supplier to set up a pre-award onsite capability assessment.

2. Assessment by the [GVD](#)

After the technical proposal(s) are evaluated and approved, a [GVD](#) auditor will perform an onsite assessment of the facility(s), processes, food security plan, and quality control program used to produce the product(s) to determine the supplier's ability to meet contractual requirements. The following assessments will apply:

a. Pre-Award Onsite Capability Assessment

The pre-award onsite assessment (audit) will include, but is not limited to, a thorough evaluation of the potential contractors' and subcontractors' facility(s), processes, food security plan, quality control program, equipment, procedures, and the appropriate documents and forms used during the production of the beef item. Documentation must support: 1) the production of the beef item that complies with the applicable specification and the potential contractor's approved technical proposal, and 2) the contractor's or subcontractor's food security plan. In addition, the audit will consist of the review of records related to purchasing, receiving, production, quality control, inventory and shipping records, and interviews with management and production personnel.

Upon completion of the onsite capability assessment, the auditor will provide a report to the Contracting Officer for final review. After the supplier has satisfactorily completed the pre-award onsite capability assessment, the supplier will receive written notification from the Contracting Officer of their eligibility to bid.

If the report demonstrates that the process or food security plan is inadequate, the applicant will be notified by the Contracting Officer that they are ineligible to bid. The applicant will have an opportunity to correct identified deficiencies, modify their process, food security plan, and/or technical proposal, and resubmit for further consideration. Eligibility will depend on whether the modifications demonstrate that: 1) the process is capable of delivering frozen beef products in compliance with the applicable specification, 2) they are in compliance with their food security plan, 3) includes the applicable assessment by USDA, and 4) they comply with other applicable contractual requirements.

b. Post-Award Assessment

Eligible suppliers who receive contracts must have their documented food security plan, technical proposals, and supporting documentation readily available for review by the COTR or AMS agents. Records may be maintained on hard copy or electronic media. However, records maintained as electronic media will be made available in printed form immediately upon request by AMS or its agents.

The [GVD](#) will conduct an onsite audit of the contractor's and subcontractor's facility(s) and processes when production commences for the first contract awarded. Additional audits will be conducted as determined by the Contracting Officer, but not less than once per month for contractors or subcontractors with continuous or multiple contracts, or once per contract for intermittent contractors. At the discretion of the Contracting Officer, more frequent audits may be conducted when audit deficiencies are detected.

c. Post-Award Actions

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

Contractor will assure that the delivered product complies with the provisions of the applicable specification, the applicable assessment by USDA, and the contractor's technical proposal approved by the [COTR](#).

Once a supplier is eligible to bid, the [supplier must follow instructions stated in the AMS Master Solicitation](#).

C. Animal Welfare Requirements

All contractors and subcontractors must meet the animal handling and welfare requirements set forth in [Attachment II- Technical Requirements Schedule - Animal Handling and Welfare 2010 \(TRS-AHW-2010\)](#), effective May 2010.

D. Responsibility/Eligibility

Facilities used in fulfilling USDA contracts must be operating under the provisions of the Federal Meat Inspection Act (FMIA), 21 U.S.C. 601 et seq., and the regulations issued thereunder.

Subcontractors or suppliers of beef are: (1) ineligible if they are currently delivering late on USDA contracts, or USDA-approved subcontracts and late delivery is not due to causes beyond their control; and (2) nonresponsible if they are not operating under the provisions of the Federal Meat Inspection Act or have been suspended or debarred under the provisions of 48 C.F.R. Subpart 9.4

E. Past Performance

1. Contractor Monitoring Program Requirements

Contractors' performance on contracts awarded by the Department of Agriculture (USDA) will be evaluated on a 30 consecutive day (rolling) cycle. The evaluation will consist of non-conformances (NC) identified by the [GVD](#) agent, or customer complaints identified through the Food and Nutrition Service (FNS) complaint system. The NC's will be categorized as critical, major, or minor based on their impact on the quality, safety, or value of the involved product.

The accumulation of at least two critical NC's, one critical/two major NC's, three major NC's, or a total of five NC's in any combination, (i.e., critical, major, or minor) within the 30-day cycle will result in the Contractor being ruled ineligible by the [COTR](#) to submit offers for consideration, and must immediately cease production on any current USDA contracts.

To regain eligible status, the Contractor must submit appropriate corrective and preventative measures to the Agricultural Marketing Service (AMS) [COTR](#) for evaluation and the measures must be verified by AMS as effective. The [COTR](#) will notify the contractor when eligibility has been reinstated to submit offers and begin or resume production on current contracts. The microbial and fat content test results will be analyzed separately under statistical process controls.

The criteria for the three categories of non-conformances are as follows:

a. [Critical](#)

Production NC – a complete breakdown of the production process has occurred. It is apparent that the company cannot produce product that complies with contract requirements.

Consumer complaints – product that does not meet specification requirements and is not useable to the end recipient or is a food safety risk.

b. **Major**

Production NC – 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.

Consumer complaints – product that does not meet the quality standards of the specifications and affects the use of the product by the end recipient. The product does not pose a food safety risk.

c. **Minor**

Production NC – 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.

Consumer complaints – product that does meet the quality standards of the specifications and does not affect the use of the product by the end recipient. The product does not pose a food safety risk. Information is provided by FNS as part of a trend analysis and no vendor response is required by FNS.

2. Supplier Monitoring Program Requirements

Boneless beef suppliers' performance as a subcontractor on contracts awarded by the Department of Agriculture (USDA) will be evaluated on a 180 consecutive day (rolling) cycle. The evaluation will consist of all non-conformances (NC) that were identified by the **GVD** auditor. The NC's will be categorized as critical, major, or minor based on their impact on the quality, safety, or value of the involved product.

The accumulation of at least two critical NC's, one critical/two major NC's, three major NC's, or a total five NC's in any combination, (i.e., critical, major, or minor) within the 180-cycle will result in the boneless beef supplier being deemed ineligible by the Contracting Officer (CO) to supply boneless beef to Agricultural Marketing Service (AMS) contractors to fill USDA contracts.

To regain eligibility status, the boneless beef supplier must submit appropriate corrective and preventative measures to AMS for evaluation and the measures must be verified by AMS as effective. The **COTR** will notify the boneless beef supplier and affected contractors when eligibility to supply boneless beef has been reinstated. The microbial test results will be analyzed separately under statistical process controls.

The criteria for the three categories of non-conformances are as follows:

a. **Critical**

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.

b. **Major**

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.

c. **Minor**

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.

3. Sustained Acceptable Performance

A contractor or subcontractor will be deemed ineligible to supply boneless beef or ground beef for the USDA purchase programs if:

- a. The contractor or subcontractor is subject to a Class I recall; or
- b. 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 referenced in Appendix B of TRS-GB-2012.

If deemed ineligible, a contractor or subcontractor must perform a cause-and-effect analysis and have corrective and preventative actions reviewed, audited, and approved by AMS prior to final consideration for eligibility by the **COTR**.

F. Loading and Sealing of Vehicles ([AMS Master Solicitation, Section G.](#))

Loading of the vehicle may also be conducted by a person authorized in a contractor's approved technical proposal.

G. Domestic Requirements

The contractor agrees to 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 Master Solicitation. The burden of proof of compliance is on the Contractor. All raw materials will be shipped in containers labeled as "Domestic Only Product" on the principle display panel and the bill of lading accompanying the shipment will contain the statement "Domestic Only Product."

II. SUBMISSION OF OFFERS

The following Item will be included in the attribute section of the offer submitted in [Web Based Supply Chain Management \(WBSCM\) system](#) (see Exhibit 2 of the AMS Master Solicitation).

9. Offeror certifies that all product conforms with the (applicable specification) and no changes to the production process or production plan have occurred without proper approval by the [Contracting Officers Technical Representative](#).

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III. INSTRUCTIONS FOR SUBMISSION OF TECHNICAL PROPOSAL

The following procedures establish the acceptable minimum requirements for the format and content of the proposals:

- A. The Government has provided a technical proposal format which is to be used in preparing the technical proposal (see [Exhibit B](#)). The offeror shall submit the technical proposal in an electronic format through the company's external portal site maintained by the AMS Commodity Procurement Division (see [Exhibit C](#) for instructions to obtain an external portal site). When submitting the technical proposal through the company's external portal site, e-mail notification to the COTR must be provided (darin.doersch@ams.usda.gov or steve.whisenant@ams.usda.gov). The production plan shall be saved in a non-portable document file format (not PDF; e.g., Microsoft Word). The technical proposal must be submitted in its entirety. The collection of attachments and appendices may be submitted as a separate document. This format and electronic form provided will aid in the evaluation of the technical proposal.
- B. The technical proposal must be submitted by an authorized agent of the company.
- C. While it is not the desire of the Government to penalize an offeror for noncompliance 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 will not be required to search other subsections or sections of the offeror's technical proposal for information requested for evaluation.
- D. Technical Proposal Revisions

Changes to an offeror's technical proposal may be submitted based on the Government's Amendments, Clarification Request, monitoring program, or at the request of the offeror. Maintenance of the integrity and clarity of each technical proposal is critical. All technical proposal revisions must meet the following criteria:

1. Any changes to a technical proposal made by the offeror after its initial submittal shall be accomplished by submitting the entire technical proposal. A cover letter must be submitted with the changes identified and an explanation of the need for the change. The offeror shall include the revision date and the appropriate page number(s).
2. Changes from the original technical proposal shall be **highlighted** and deletions in ~~strikeouts~~.

Note: When revisions to the approved technical proposal are submitted in their external portal site, the contractor must provide an e-mail notification to the COTR.

IV. PRODUCT SPECIFICATIONS AND AUDIT SERVICES

- A. Specifications for ground beef products are identified in [Exhibit A](#). If documents are amended, appropriate amendments must be referenced.

B. AMS certification agents, under the direction of the LS Program, will perform all applicable examinations and tests as required. AMS agents will conduct all certification services in accordance with the applicable GVD Instruction(s). The cost of all certification and audit services performed by the AMS certification agents must be borne by the contractor. This includes, but is not limited to, examinations, supervision, official documentation, and related services (including charges for microbiology and fat content analyses).

GVD auditors, under the direction of the LS Program, will perform audit services on the portions of the contractor's approved production plan that are not under the control of the AMS certification agent. The frequency of the audits will occur, at a minimum, once per month or, when applicable, once per [purchase order](#).

C. For [certification services](#), AMS will pay per diem and travel expenses including travel time involved in transporting the AMS certification agents from a duty point into the area of a contractor's or subcontractor's plant. However, payment of these charges by USDA will only be made when the services rendered by an AMS certification agent are directly related to production for specific outstanding contracts. Per diem and travel expenses will be prorated to the contractor for any official services performed by the AMS certification agent not related to USDA-purchased commodities to which these provisions apply. When the services of the AMS certification agent are performed for a subcontractor, the contract number in which the product will be used must be declared to the AMS certification agent.

D. The cost of all AMS audits required by **GVD**, including per diem and travel expenses, must be borne by the contractor or subcontractor.

E. All local travel and travel time will be charged to the contractor or subcontractor in accordance with the applicable **GVD** instructions and regulations. The regular hourly rate and established fees for required laboratory analyses will be charged as applicable.

F. Laboratory fees incurred for testing of the ground beef items for the microbial requirements, and fees associated with the AMS process assessment sample for fat as specified in the applicable specification, will be paid by AMS.

G. [Questions concerning GVD auditors should be discussed with the GVD at 202-309-1506.](#)

H. Questions concerning charges and the availability of AMS agents should be discussed with the Office of Field Operations, Denver, Colorado (720) 497-2520.

I. Disposition of Lots Outside Specification Limits

Any lot that, **in any test, including FSIS test**, tests positive for *E. coli O157:H7* or *Salmonella*, or exceeds the critical limit criteria of APPENDIX B of TRS-GB, cannot be used to produce ground beef or any other product purchased by USDA.

V. QUALITY INSPECTION PLAN

Not required under this Supplement.

VI. INVOICES AND PAYMENT

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

Purchases of the materials under this supplement require that a "three-way match" must be completed in WBSCM, i.e., Purchase Order (PO), Good Receipt, and Invoice with supporting documents attached.

VII. AMS CLAUSES**A. Contractor Checkloading**

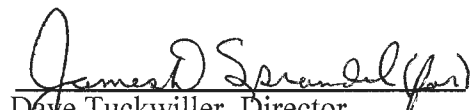
Contractor will perform checkloading examinations as described in the applicable specification at the time of shipment and issue contractor's certificate to accompany each shipment that includes all of the following information:

1. Purchase Order Number and Purchase Order line item number.
2. Sales Order Number and Sales Order Item number.
3. Name of product;
4. Shipping Date;
5. Production lot number(s) and date each lot was produced;
6. Count of shipping containers and total projected net weight in each production lot;
7. Identity of car or truck (car numbers and letters, seals, truck license, etc.) as applicable;
8. Contractor certification that product conforms with the applicable specification;
9. Count and projected net weight verified; and
10. Signature of company official responsible for checkloading.

VI. PROVISIONS INCORPORATED BY REFERENCE

FAR Provisions as show in Section XII of the AMS Master Solicitation are modified as shown below:

- A. 1. 52.204-8 Annual Representations and Certifications (MAR 2012)**
- (a) (1) The North American Industry Classification System code for this acquisition is 311611.
 - (2) The small business size standard is 500 employees.


Dave Tuckwiller, Director
Commodity Procurement Division
Agricultural Marketing Service

Attachments



Room 3932-S, STOP 0256
 1400 Independence Avenue, SW
 Washington, DC 20250-0201

SUPPLEMENT 211

EXHIBIT A
 DATED MAY 2012

**CHECKLIST AND REFERENCES TO APPLICABLE BID AND CONTRACT PROVISIONS
 SUPPLEMENT 211 TO AMS MASTER SOLICITATION
 For
 GROUND BEEF ITEMS, FROZEN**

PRODUCT DESCRIPTION					OFFER/CONTRACT PROVISIONS			
WBSM Material Description	Specifications Listed in Priority Order	WBSM Material Number	Packaging and Packing	Minimum Offer Unit Size/Shipping Unit	Tolerance Section	Delivery Period	Federal/State Plants Section I.D.	Competition (See Solicitation)
BEEF FINE GROUND FRZ CTN-40 LB	Technical Requirements Schedule-GB-2012, Ground Beef Items, Frozen, May 2012	100158	Packed in 10-lb. packages to a net weight of 40 lbs. (18.1 kg) per shipping container	40,000 lbs. 1000 cases	NONE	First Half/Last Half of month delivery period	Federal & State	Small Business Set Aside
BEEF FINE GROUND LFT OPT FRZ CTN-40 LB		110261	Packed in 10-lb. packages to a net weight of 40 lbs. (18.1 kg) per shipping container	40,000 lbs. 1000 cases	NONE	First Half/Last Half of month delivery period	Federal & State	Small Business Set Aside
BEEF FINE GROUND FRZ PKG-40/1 LB		100159	Packed in 1-lb. packages to a net weight of 40 lbs. (18.1 kg) per shipping container	40,000 lbs. 1000 cases	NONE	12-day delivery period	Federal Plants Only	Small Business Set-Aside
Ground Beef (LFTB Opt)/ 110260		110260	Packed in 1-lb. packages to a net weight of 40 lbs. (18.1 kg) per shipping container	40,000 lbs. 1000 cases	NONE	12-day delivery period	Federal Plants Only	Small Business Set-Aside
BEEF COARSE GROUND FRZ CTN-60 LB		100154	Packed into a shipping container (without bags or liners) to a net weight of 60 lbs. (27.2 kg). Containers must be wax impregnated or interior panels wax lined or plastic film laminated.	42,000 lbs. 700 cases	NONE	First Half/Last Half of month delivery period	Federal Plants Only	Full & Open
BEEF IRRADIATED FINE GRND FRZ CTN-40 LB		110085	Packed in 10-lb. packages to a net weight of 40 lbs. (18.1 kg) per shipping container	40,000 lbs. 1000 cases	NONE	First Half/Last Half of month delivery period	Federal & State	Full & Open
BEEF 100% PATTY FRZ CTN-40 LB		100161	3 oz. (85.0 g) portions, packed to a net weight of 40 lbs. (18.1 kg) per shipping container; IQF required	38,000 lbs. 950 cases	NONE	First Half/Last Half of month delivery period	Federal & State	Full & Open



Room 3932-S, STOP 0256
 1400 Independence Avenue, SW
 Washington, DC 20250-0201

SUPPLEMENT 211

EXHIBIT A (continued)

DATED MAY 2012

**CHECKLIST AND REFERENCES TO APPLICABLE BID AND CONTRACT PROVISIONS
 SUPPLEMENT 211 TO AMS MASTER SOLICITATION
 For
 GROUND BEEF ITEMS, FROZEN**

PRODUCT DESCRIPTION					OFFER/CONTRACT PROVISIONS			
WBSM Material Description	Specifications Listed in Priority Order	WBSM Material Number	Packaging and Packing	Minimum Offer Unit Size/Shipping Unit	Tolerance Section	Delivery Period	Federal/State Plants Section I.D.	Competition (See Solicitation)
BEEF SPP PATTY FRZ CTN-40 LB		100160	3 oz. (85.0 g) portions, packed to a net weight of 40 lbs. (18.1 kg) per shipping container; IQF required	38,000 lbs. 950 cases	NONE	First Half/Last Half of month delivery period	Federal & State	Full & Open
BEEF PATTY 90/10 FRZ CTN-40 LB		100162	3 oz. (85.0 g) portions, packed to a net weight of 40 lbs. (18.1 kg) per shipping container; IQF required	38,000 lbs. 950 cases	NONE	First Half/Last Half of month delivery period	Federal & State	Full & Open
BEEF IRRADIATED PATTY FRZ CTN-40 LB		110082	3 oz. (85.0 g) portions, packed in either 1- 20 lb. or 2-10 lb. sealed packages, to a net weight of 20 lbs. (9.05 kg) per shipping container; IQF required	38,000 lbs. 1900 cases	NONE	First Half/Last Half of month delivery period	Federal & State	Full & Open
BEEF PATTY LEAN FRZ CTN-40 LB		100163	3.1 oz. (85.0 g) portions, packed to a net weight of 40 lbs. (18.1 kg) per shipping container; IQF required	38,000 lbs. 950 cases	NONE	First Half/Last Half of month delivery period	Federal & State	Full & Open
BEEF LEAN PATTY LFT OPT FRZ CTN-40 LB		110270	3.1 oz. (85.0 g) portions, packed to a net weight of 40 lbs. (18.1 kg) per shipping container; IQF required	38,000 lbs. 950 cases	NONE	First Half/Last Half of month delivery period	Federal & State	Full & Open

Cover Page:

[Company Name]

[Company Address]

Contact Person, including title, phone number, including emergency contact information, e-mail address (must be authorized to represent the company).**Technical proposal for: [Supplement Number] and [Specification]****Table of Contents (all pages and attachments must be number and identified--any attachments must be identified and referenced in the Technical proposal)***The technical proposal should include all phases of production that meets or exceeds the requirements stated in the specification to produce complying product.***I. SCOPE**

Brief Description of what the company plans to do to meet the requirements stated in the applicable specification (including the applicable documents).

II. APPLICABLE DOCUMENTS**III. APPLICABLE DOCUMENTS**

- A. ITEMS** - Please provide a brief description of the product that will be addressed in the technical proposal.
- B. MATERIAL** - Please provide a brief description of the planning, production steps (do), check and corrective/preventive (act) measures that the company will do to assure compliance with the material section of the specification.
1. Domestic Origin and Harvest (slaughter) Requirements – (plan, do, check, act)
 - a. Quality Control Program
 - b. Boneless Beef
 - 1) Domestic Origin
 - 2) Humane Handling
 - 3) Non-Ambulatory Disable Cattle
 - 4) Spinal Cord Removal
 - 5) Pathogen Intervention Steps
 - 6) Carcass Testing
 2. Boneless Beef Requirements – (plan, do, check, act)
 - a. Quality Control Program (QCP) – **for each boneless beef supplier** – QCP must include at a minimum (plan, do, check, act) for the “Material” section that applies to the production of the boneless beef.
 - b. Traceability
 - c. XF Trim
 - d. Meat Recovery Systems
 - 1) Mechanical Separation

- 2) Finely Textured Beef
- e. Handling
- f. Objectionable Materials
- g. Lot
- h. Microbial Testing
 - 1) Sample Preparation and Handling
 - 2) Sample Selection
 - 3) Testing and Results
 - 4) Statistical Process Capability
 - 5) Contractor's Responsibility
- 3. Ground Beef Requirements – (plan, do, check, act)
 - a. Quality Control Program
 - b. Traceability
 - c. Handling
 - d. Lot
 - e. Microbial Testing
 - 1) Sample Preparation and Handling
 - 2) Sample Selection
 - 3) Testing and Results
 - f. Statistical Process Control Evaluation
 - g. Irradiated Ground Beef
 - h. Beef Patties with Soy Protein Product (SPP)
 - 1) Texture
 - 2) Type and Combination Rate
 - i. Ground Beef Patties, NTE 10% Fat
 - j. Ground Lean Beef Patties

C. PROCESSING - Please provide a brief description of the planning, production steps (do), check and corrective/preventive (act) measures that the company will do to assure compliance with the processing section of the specification.

- 1. Grinding and Blending – (plan, do, check, act)
 - a. Ground Beef
 - b. Coarse Ground Beef
 - c. Fat Break-Outs
 - d. LFTB
- 2. Bone Collector/Extruder Systems – (plan, do, check, act)
- 3. Shape and Waffling of Patties – (plan, do, check, act)
- 4. Metal Detection – (plan, do, check, act)
- 5. Equipment - (plan, do, check, act)

D. STATE OF REFRIGERATION - Please provide a brief description of the planning, production steps (do), check and corrective/preventive (act) measures that the company will do to assure compliance with the State of Refrigeration section of the specification.

- 1. Bulk Packaged Ground Beef Items – (plan, do, check, act)
- 2. Patties – (plan, do, check, act)

3. Shipping – (plan, do, check, act)

E. FAT LIMITATIONS - Please provide a brief description of the planning, production steps (do), check and corrective/preventive (act) measures that the company will do to assure compliance with the Fat Limitations section of the specification.

1. Contractor Process Assessment – Sampling plan and recording results (plan, do, check, act)
2. AMS Process Assessment
3. Continuous AMS Assessment

F. PATTY WEIGHT, THICKNESS, SHAPE, AND COLOR- Please provide a brief description of the planning, production steps (do), check and corrective/preventive (act) measures that the company will do to assure compliance with the Patty Weight, Thickness, and Shape section of the specification.

1. Patty weight – (plan, do, check, act).
2. Patty thickness – (plan, do, check, act)
3. Shape – (plan, do, check, act)
4. Color – (plan, do, check, act)

G. PREPARATION FOR DELIVERY - Please provide a brief description of the planning, production steps (do), check and corrective/preventive (act) measures that the company will do to assure compliance with the Preparation for Delivery section of the specification.

1. Packaging and Packing – (plan, do, check, act)
 - a. Immediate containers
 - b. BEEF FINE GROUND FRZ CTN-40 LB (100158)
 - c. BEEF FINE GROUND LFT OPT FRZ CTN-40 LB (110261)
 - d. BEEF FINE GROUND FRZ PKG-40/1 LB (100159)
 - e. BEEF FINE GROUND LFT OPT FRZ PKG-40/1 LB (110260)
 - f. BEEF COARSE GROUND FRZ CTN-60 LB (100154)
 - g. BEEF IRRADIATED FINE GRND FRZ CTN-40 LB (110085)
 - h. BEEF 100% PATTY FRZ CTN-40 LB (100161)
 - i. BEEF SPP PATTY FRZ CTN-40 LB (100160)
 - j. BEEF PATTY 90/10 FRZ CTN-40 LB (100162)
 - k. BEEF IRRADIATED PATTY FRZ CTN-40 LB (110082)
 - l. BEEF PATTY LEAN FRZ CTN-40 LB (100163)
 - m. BEEF LEAN PATTY LFT OPT FRZ CTN-40 LB (110270)
 - n. Style and Size of Shipping Containers
2. Shipping Container Net Weight – (plan, do, check, act)
 - a. Ground Beef
 - b. Coarse ground beef
3. Closure – (plan, do, check, act) - Shipping containers
4. Marking of Containers – (plan, do, check, act)
 - a. Ground Beef, 1- Pound Package Labels
 - b. Shipping Containers

All labeling shall be illustrated in the Offeror's technical proposal.

5. Palletized Unit Loads
6. Total New Weights Per Delivery Unit
7. Sealing

H. USDA QUALITY ASSURANCE - Please provide a brief description of the planning, production steps (do), check and corrective/preventive (act) measures that the company will do to assure compliance with the USDA Quality Assurance section of the specification.

1. Warranty and Complaint Resolution - (plan, do, check, act)
 - a. Warranty
 - b. Complaint Resolution
 - 1) AMS Monitoring & Production Assessment
 - 2) Control of Non-Conforming Product
 - 3) Checkloading – Contractor must address Check-loading in their Technical Proposal.

IV. 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 SEED PROGRAM

CERTIFICATE OF CONFORMANCE FOR
THE PROCUREMENT OF GROUND BEEF ITEMS, FROZEN

CERTIFICATE OF CONFORMANCE

I certify the following:

- (1) On [shipping date(s)], [Contractor's name] furnished the (insert the appropriate commodity description) called for by Purchase Order/Purchase Order Item Number: _____/_____ via [Carrier] under Sales Order Number(s)/Sales Order Item Number: _____/_____ .
- (2) The (insert the appropriate material name) is of the quality specified and conforms in all respects with the purchase order requirements, including [Contractor's name] Technical Proposal or Production Plan as approved by the AMS Standardization Division, COTR.
- (3) Product identification, (i.e. production lot number(s)) is in the quantity shown on the attached acceptance document.
- (4) Contractor assures all meat or meat products used in fulfilling this contract was produced in the United States as defined in the Supplement 211, section I.G, and the AMS Master Solicitation, Section I.E.

Date: _____

Signature: _____
(Signed by an officer or representative authorized to represent the company)

Title: _____



APPROVED



TECHNICAL

REQUIREMENTS

SCHEDULE - GB - 2012



UNITED STATES
DEPARTMENT OF
AGRICULTURE

AGRICULTURAL
MARKETING
SERVICE

LIVESTOCK AND
SEED PROGRAM

Washington, D.C.
20250-0254

FOR USDA PURCHASES OF

GROUND BEEF ITEMS, FROZEN

Effective: **May 2012**

Preparing Activity:
USDA, AMS, LS, SD--Rm. 2607-S
Supersedes: TRS-GB-2010
Changes - **In blue**
LSP-SD-TRS-GB-2012

Approved by MEO MEO
Date Issued: 04/30/03
Date Revised: **05/22/12**

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Approved by MEO MEO
Date Issued: 04/30/03
Date Revised: 05/22/12

1.0 SCOPE

1.1 This Technical Requirements Schedule (TRS)–Ground Beef (GB)–[2012](#) is for use by the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), [Commodity Procurement Division](#) to procure frozen ground beef products.

2.0 APPLICABLE DOCUMENTS

2.1 The following documents are incorporated as part of this USDA, TRS-GB-[2012](#):

2.1.1 [Grading and Verification Division \(GVD\) Procedures Manual.](#)

2.1.2 [Applicable Supplement to AMS Master Solicitation.](#)

2.1.3 Food Safety and Inspection Service (FSIS) Directive 10,010.1 Revision 3.

3.0 CHECKLIST OF REQUIREMENTS

3.1 ITEMS

3.1.1 The contractor’s technical proposal will declare which items will be offered to USDA. Bulk or patties to be specified within USDA procurement documents.

3.1.1.1 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
Coarse Ground Beef	100154
Ground Beef (10-pound bulk packaged) (LFTB Optional)	110261
Ground Beef, 1-pound packages (LFTB Optional)	110260

3.1.1.2 Patties

Item	Material Number
Ground Beef Patties	100161
Ground Beef Patties-Irradiated	110082
Beef Patties with Soy Protein Product	100160
Beef Patties-90/10 (Not to Exceed 10% Fat)	100162
Lean Beef Patties-5% Fat	100163
Lean Beef Patties-5% Fat (LFTB Optional)	110270

3.2 MATERIAL

3.2.1 The contractor’s technical proposal must describe a process plan with a documented quality control program that includes procedures, records, forms, etc., that demonstrate conformance with the following Checklist of Requirements. The [Contracting Officer’s Technical Representative \(COTR\)](#) may request changes to the technical proposal at any time.

3.2.1.1 Domestic Origin and Harvest Requirements

3.2.1.1.1 Quality Control Program - The harvester’s quality control program must be documented in each contractor’s technical proposal and have received a satisfactory onsite capability assessment by [GVD](#).


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

3.2.1.1.2.1 Domestic Origin - All beef will originate from U.S. produced livestock as defined in the Supplement, as amended.

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

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

3.2.1.1.2.4 Pathogen Intervention Steps – The harvest process must include at least two pathogen intervention steps. One of the intervention steps must be a critical control point (CCP) in their FSIS recognized harvest process Hazard Analysis Critical Control Point (HACCP) plan and the CCP intervention(s) must be scientifically validated to achieve a three log reduction of enteric pathogens.

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- 3.2.1.1.2.5** Carcass Testing - Routinely test carcasses for Shiga-toxigenic *Escherichia coli* O157 (including O157:H7 and O157:Non-Motile (NM); herein referred to as *E. coli* O157:H7) at CCP to verify effectiveness of interventions.
- 3.2.2** Boneless Beef Requirements
- 3.2.2.1** Quality Control Program - The boneless beef supplier's quality control program must be documented within each contractor's technical proposal and have received a satisfactory onsite capability assessment by GVD prior to supplying materials for the program. Additionally, each plant is subjected to verification audits conducted by the GVD during production activities that demonstrate their adherence to the documented quality control program.
- 3.2.2.2** Traceability – Boneless beef shall be traceable to sources that comply with the above domestic origin and harvest requirements.
- 3.2.2.3** 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.
- 3.2.2.4** Meat Recovery Systems
- 3.2.2.4.1** Mechanical Separation - Boneless beef that is mechanically separated from bone with automatic deboning systems, advanced lean (meat) recovery (AMR) systems or powered knives, will not be allowed.
- 3.2.2.4.2** 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 must be met:
- 3.2.2.4.2.1** 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.
- 3.2.2.4.2.2** Fat Content - Does not exceed 10 percent fat.
- 3.2.2.5** Handling - All boneless beef must 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.

- 3.2.2.5.1** 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 (5) days from harvest.
- 3.2.2.5.2** The contractor shall document all procedures for handling of LFTB and must use it within 60 days of the date of production.
- 3.2.2.6** Objectionable Materials – The following objectionable materials shall be excluded:
- 3.2.2.6.1** Major lymph glands (prefemoral, popliteal, and prescapular), thymus gland, and the sciatic (ischiatric) nerve (lies medial to the outside round). All bone, cartilage, and the following heavy connective tissues:
- 3.2.2.6.1.1** White fibrous – Shoulder tendon, elbow tendon, silver skin (from the outside round), sacrociatic ligament, opaque periosteum, serous membrane (peritoneum), tendinous ends of shanks, gracilis membrane, patellar ligament (associated with the stifle joint), and achilles tendon.
- 3.2.2.6.1.2** Yellow elastin – Back strap and abdominal tunic.
- 3.2.2.7** 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.
- 3.2.2.8** Microbial Testing – All lots of fresh chilled boneless beef, including LFTB, must be tested for all microbes listed in APPENDIX B. All samples will be sent to an AMS designated laboratory (ADL).
- 3.2.2.8.1** Sample Preparation and Handling - The ADL will be responsible for supplying procedures for sample preparation, and submission. The laboratory shall require suppliers to submit a sample submission form as an official record with each sample. The laboratory will also be responsible for supplying shipping supplies (including sampling bags and shipping materials) to each supplier. Suppliers’ technical proposal will include and describe sample collection and preparation procedures provided by the ADL.

- 3.2.2.8.2** Sample Selection
- 3.2.2.8.2.1** For Beef Manufacturing Trimmings – The sample will be selected as described within FSIS Directive 10,010.1 Revision 3 (N-60 Sections 8, 9 and NOTE).
- 3.2.2.8.2.2** For every lot of beef Manufacturing Trim, three (3) samples will be prepared from seventy (70) pieces of trim from seventy (70) different pieces of beef product. The sample for *E. coli* O157:H7 will be sixty (60) pieces and weigh 325 grams \pm 10 percent; the sample for *Salmonella* will be five (5) pieces and weigh 25 grams \pm 10 percent; the sample for indicator organisms (aerobic plate count, total coliform and generic *E. coli*) will be five (5) pieces and weigh 25 grams \pm 10 percent.
- 3.2.2.8.2.3** For LFTB – The random sample will be selected as described within FSIS Directive 10,010.1 Revision 3. The sample for *E. coli* O157:H7 will weigh 325 grams \pm 10 percent; the sample for *Salmonella* will weigh 25 grams \pm 10 percent; the sample for indicator organisms (aerobic plate count, total coliform and generic *E. coli*) will weigh 25 grams \pm 10 percent.
- 3.2.2.8.2.4** When boneless beef has been exposed to any anti-microbial treatment, no sample units shall be selected for at least 15 minutes after such treatment. All anti-microbial treatments (e.g. techniques and procedures) administered during production and post-production shall be described in the supplier's technical proposal.
- 3.2.2.8.3** Testing and Results
- 3.2.2.8.3.1** The microbiological testing for all microbes will be in accordance with the applicable AMS-approved testing methodologies.
- 3.2.2.8.3.2** Notification for presence of pathogens and exceeding critical limit criteria - When presence of *E. coli* O157:H7 or *Salmonella* is presumptive positive or confirmed positive or any critical limit is exceeded for indicator microbes:
- 3.2.2.8.3.2.1** The ADL will immediately notify FSIS (pathogens only) and the COTR.
- 3.2.2.8.3.2.2** When pathogen results are positive, FSIS and the COTR will be notified by the boneless beef supplier of the final disposition of the affected lot.

- 3.2.2.8.3.2.3** When the critical limit is exceeded for indicator organisms, the boneless beef supplier will notify the COTR of the final disposition of the affected lot.
- 3.2.2.8.3.2.4** Confirmed pathogen - The boneless beef supplier shall conduct a cause and effect analysis to determine the appropriate corrective action necessary to eliminate the probable cause.
- 3.2.2.8.3.3** The ADL will record all results on spreadsheets and calculate the process capability (CPU, CI) for microbial tests performed on production lots as outlined in Section 3.2.2.8.4.
- 3.2.2.8.3.4** Any lot that tests positive for *E. coli* O157:H7 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.
- 3.2.2.8.4** Statistical Process Capability – Boneless beef supplier compliance with microbial requirements will be based on the assessment of the calculated process capability (CPU, CI) values derived from the individual combo test results representing one (1) 2,000 pound combo lot randomly selected by the ADL from every five (5) consecutive individual 2,000 pound combo lots produced each production day. In the event that a production day concludes with less than five (5) consecutive individual 2,000 pound combo lots, a randomly selected test result will be utilized from one of the remaining lots. The spreadsheets will be maintained so that process capability assessment on the twenty (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 will 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 petition AMS to re-enter the program under conditional status provided corrective actions have been submitted for review and approved, implemented and a satisfactory onsite assessment audit by GVD has been conducted. Upon notification by the COTR 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.

- 3.2.2.8.5** Contractor's Responsibility - The contractor will require their 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 GVD 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 petition AMS to 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 capability assessment audit by GVD has been conducted. Upon notification by the COTR 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.
- 3.2.3** Ground Beef Requirements
- 3.2.3.1** Quality Control Program - The ground beef quality control program must be documented within the contractor's technical proposal and have received a satisfactory onsite capability assessment audit by GVD.
- 3.2.3.2** Traceability – All ground beef production must be traceable to the boneless beef lots (including LFTB) and their associated microbial test results.
- 3.2.3.3** 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.
- 3.2.3.4** 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 must be further divided into sub-lots not to exceed 10,000 pounds.
- 3.2.3.5** Microbiological Testing – All sub-lots of ground beef will 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 will 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 will be sent to the ADL.

- 3.2.3.5.1** Sample Preparation and Handling - The ADL will 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 laboratory will also be responsible for supplying shipping supplies (including sampling bags and shipping materials) to each contractor. Contractor's technical proposal will include and describe sample collection and preparation procedures provided by the ADL.
- 3.2.3.5.2** Sample Selection – Production processes of ground beef will be subject to the following sampling strategy:
- 3.2.3.5.2.1** Sub-lot Microbial Testing – For every sub-lot, three (3) original and reserve samples will be prepared from four (4) individual sample units for each microbial test. The sub-lot samples will be 325 grams ± 10 percent, 25 grams ± 10 percent, and 25 grams ± 10 percent each for *E. coli* O157:H7, *Salmonella*, and indicator organism tests, respectively of finished ground beef, randomly selected throughout each 10,000 pounds of production. The four (4) individual sample units shall be composited to produce a sample that represents each microbial test for each sub-lot. The contractor will describe in their technical proposal the procedure in which the four (4) sample units will 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 will be held for testing in case the COTR deems it necessary. The contractor will 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 (5) percent.
- 3.2.3.5.3** Testing and Results - The samples from each sub-lot will be analyzed by the ADL for all microbes listed in APPENDIX B.
- 3.2.3.5.3.1** The microbiological testing for all microbes will be in accordance with the applicable AMS-approved testing methodologies.

- 3.2.3.5.3.2** 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 will 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 will 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.
- 3.2.3.5.3.3** 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:
- 3.2.3.5.3.3.1** The ADL will immediately notify FSIS (pathogens only) and the COTR.
- 3.2.3.5.3.3.2** When pathogens results are positive, FSIS and the COTR will be notified by the contractor of the final disposition of the product.
- 3.2.3.5.3.3.3** When the critical limit is exceeded for indicator organisms, FSIS and the COTR will be notified by the contractor of the final disposition of the product.
- 3.2.3.5.3.3.4** Confirmed Pathogen - The contractor shall conduct a cause and effect analysis to determine the appropriate corrective action necessary to eliminate the probable cause.
- 3.2.3.5.3.3.5** Ground beef associated with the positive pathogen test results or critical limit exceeded results will be ineligible for any USDA purchase program.
- 3.2.3.5.3.4** The ADL will record all results on spreadsheets and calculate the process capability (CPU, CI) for microbial tests performed on sub-lots as outlined in Section 3.2.3.5.3.5.

3.2.3.5.3.5 Statistical Process **Capability** - The ADL will record the results on spreadsheets and calculate the process capability (CPU or CI) value for all sub-lot microbial tests performed. The spreadsheets will be maintained so that process capability may be determined according to the requirements within APPENDIX B. The spreadsheets will be maintained so that process capability assessment on each twenty (20) sub-lot grouping can be determined as described within APPENDIX B. Test results will be monitored by the contractor and COTR to determine acceptability of the process according to APPENDIX B. Ineligible contractors may petition AMS to re-enter the program under conditional status provided corrective actions have been submitted for review and approved, implemented and a satisfactory onsite assessment audit by GVD has been conducted. Upon notification by the COTR 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.

3.3 PROCESSING

3.3.1 The contractor's technical proposal and process shall assure compliance with the following requirements:

3.3.2 Grinding and Blending

3.3.2.1 Ground Beef - Boneless beef shall be ground twice, with the final grind passing through an 1/8-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.

3.3.2.2 Coarse Ground Beef - Boneless beef shall pass at least once through a grinding plate that is no smaller than 3/4 inch or no larger than a 1.0 inch. Blending after final grinding is allowed only to the extent that it doesn't affect the appearance of the finished ground beef.

3.3.2.3 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.

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

- 3.3.3 Bone Collector/Extruder Systems - Except for Coarse Ground Beef, a bone collector/extruder system must 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).
- 3.3.4 Shape and Waffling of Patties - All patties must be round or oval in shape and waffled or scored on both sides.
- 3.3.5 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 must identify and describe the equipment, location, detection procedure, sensitivity levels, frequency of equipment validation, and corrective action procedures.
- 3.3.6 Equipment – All equipment used to produce ground beef products for USDA shall be maintained and routinely checked for optimal performance.
- 3.3.7 Irradiated Ground Beef - When specified by the purchaser, ground beef products to be irradiated shall comply with the additional requirements specified in APPENDIX C.
- 3.3.8 Beef Patties with Soy Protein Product (SPP) - The SPP will be hydrated to yield no less than 18% protein (as-is basis).

$$[(\text{Percent Protein of SPP on "as-is" Basis} / 18) - 1] = x$$
 x = maximum pounds of water to be added to each pound of dry SPP.

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

3.3.8.2 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.

3.3.8.3 [Domestic Origin – SPP ingredients shall be derived from U.S. produced products.](#)

3.3.9 [Beef Patties-90/10 \(100162\)](#) - The patties shall not have any non-meat ingredients added.

3.3.10 [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 must 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.](#)

3.4 STATE OF REFRIGERATION

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

3.4.2 Patties - will 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 will not stick together after they are packaged and packed.

3.4.3 All USDA ground beef products will be stored, shipped, and delivered at temperatures that do not exceed 0°F.

3.5 FAT LIMITATIONS

- 3.5.1** The contractors will establish a target average of 15 percent fat for all ground beef products except for the [beef patties-90/10](#) and [lean beef patties \(100163, 110270\)](#). The upper and lower specifications limits will be 18 and 12 percent fat respectively. The target fat content will be declared on the shipping container label and the nutrition facts panel. For [beef patties-90/10](#), the upper specification limit will be 10 percent and the contractor will declare their target. For [lean beef patties \(100163, 110270\)](#), the average fat target shall be 5 percent with upper and lower specification limits being 6 and 4 percent fat respectively. Separate Statistical Process Control (SPC) assessments will be conducted on ground beef products with a targeted average of 15 percent fat, the [beef patties-90/10](#), and the [lean beef patties \(100163, 110270\)](#).
- 3.5.2** Contractor Process Assessment - The contractor shall declare the production lot size, laboratory, test method, and SPC methodologies in their technical proposal.
- 3.5.2.1** Sampling and testing - The contractor will 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 will be determined by the testing method used by the contractor's laboratory.
- 3.5.2.2** Recording results - The contractor will record the results on [spreadsheets](#). The [calculated process capability \(Cpk/CPU\) value \(as discussed in APPENDIX A\)](#) will 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.
- 3.5.2.3** Process Capability Assessment - Twenty (20) consecutive production lot results (that include the last production lot) will 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.

- 3.5.3** AMS Process Assessment – For the first 20 production lots, the AMS agent will direct the contractor to randomly select samples, each consisting of four sample units, 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 will 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 will 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 COTR immediately and declare what immediate corrective and preventative actions will be taken when:
- 3.5.3.1** The ADL calculated process average fat results (mean) varies more than one (1) percent from the contractor’s calculated process average results, or
- 3.5.3.2** The calculated process capability (Cpk/CPU) is less than one for results from either the contractor’s designated laboratory or the ADL.
- 3.5.3.3** The COTR 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. If the COTR determines that such actions are adequate, then the COTR will request sampling and testing of an additional 20 consecutive lots.
- 3.5.4** Continuous AMS Assessment – If AMS process assessment is satisfactory, the AMS agent will 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 will 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 will 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).

3.6 PATTY WEIGHT, THICKNESS, SHAPE, AND COLOR

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

3.6.2 Patty Weight

3.6.2.1 [Material Numbers 100161, 100160, 110082, 100162](#) - Target weight will be 3.0 ounces. Acceptable weight tolerance range will be 2.9 to 3.1 ounces.

3.6.2.2 [Material Number 100163, 110270](#) - Target weight will be 3.1 ounces. Acceptable weight tolerance range will be 3.0 to 3.2 ounces.

3.6.3 Patty Thickness – 5/16 inch (+/- 1/16).

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

3.6.5 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 will not be allowed.

3.7 PREPARATION FOR DELIVERY

3.7.1 The contractor's technical proposal and process will 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 must have procedures for verifying the net weight of shipping containers.

3.7.2 Packaging and Packing

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

3.7.2.2 Fine Ground Beef ([Material Number 100158, 110261](#)) – Fine ground beef must be vacuum packaged or packaged in casings and sealed. All packages will weigh 10 pounds. The casings or packages shall be closed by metal clips or by a heat-sealing method. Four (4) packages will be placed into each shipping container.

- 3.7.2.3** Fine Ground Beef ([Material Number 100159](#), [110260](#)) – Fine ground beef must be vacuum packaged or packaged in casings and sealed. All packages will weigh 1 pound. Forty (40) packages will be placed into each shipping container.
- 3.7.2.4** Fine Ground Beef-Irradiated ([Material Number 110085](#)) – Fine ground beef must 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.
- 3.7.2.5** Coarse Ground Beef ([Material Number 100154](#)) - Coarse ground beef must 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.
- 3.7.2.6** Patties ([Material Numbers 100160](#), [100161](#), [100162](#), [100163](#), [110082](#)) –Separation material between patties is not required provided the IQF patties do not stick together at the time of shipment. Patties must be placed into immediate containers following either of the following methods:
- 3.7.2.6.1** Flexible Containers - Either four 10-pound, five 8-pound, or eight 5-pound flexible (plastic) vacuum packaged or sealed containers will be placed into each shipping container. Hand twisting or hand tying is not acceptable.
- 3.7.2.6.2** Fiberboard Containers – When fiberboard is used for immediate containers, either four 10-pound or two 20-pound fiberboard containers will 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 will then have to be sealed with tape or glue.

- 3.7.2.7** Ground Beef Patties-Irradiated - ([Material Number 110082](#)) – Patties must 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 will 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.
- 3.7.2.8** Style and Size of Shipping Containers - Only one style and size of immediate and shipping container may be used in any one delivery unit.
- 3.7.3** Shipping Container Net Weight
- 3.7.3.1** Using SPC tools, the contractor shall assure the following net weights:
- 3.7.3.1.1** Ground Beef (fine ground bulk and patties) - will be packed to a net weight of 40 pounds.
- 3.7.3.1.2** Coarse Ground Beef - will be packed to a net weight of 60 pounds.
- 3.7.4** Closure
- 3.7.4.1** Shipping containers will 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.
- 3.7.5** Marking of Containers*
- 3.7.5.1** Both, immediate and shipping containers will 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:
- 3.7.5.2** Ground Beef, 1-pound package labels ([100159](#), [110260](#)) will have the following information included on commercially labeled packages:
- 3.7.5.2.1** Safe handling instructions.
- 3.7.5.2.2** Nutrition Facts panel (to include fat declaration of [17](#) grams of fat per [112](#) gram serving).
- 3.7.5.2.3** The “best if used by” date (180 calendar days from the date of production).

- 3.7.5.2.4 The FSIS establishment number.
- 3.7.5.2.5 A code number that will indicate traceability to production lot and date.
- 3.7.5.3 Shipping Containers - Commercially marked shipping containers will include the information as follows:
 - 3.7.5.3.1 USDA Shield (at least 2 inches high and appearing on the top of the container or on the principle display panel).
 - 3.7.5.3.2 Applicable [Purchase Order Number](#).
 - 3.7.5.3.3 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
Coarse Ground Beef	100154
Ground Beef Patties ^{1/}	100161
Beef Patties with SPP ^{1/,2/}	100160
Ground Beef Patties-Irradiated ^{1/}	110082
Beef Patties – 90/10 ^{1/}	100162
Lean Beef Patties ^{1/}	100163
Lean Beef Patties (LFTB Opt) ^{1/}	110270

^{1/} Shall include the statement “For Institutional Use Only” on the principle display panel.

^{2/} The ingredient statement must include the identification of the added hydrated SPP.

- 3.7.5.3.4 Fat Declaration.
- 3.7.5.3.5 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).
- 3.7.5.3.6 Nutrition Facts panel to include fat declaration of:
 - 3.7.5.3.6.1 [17 grams of fat per 112 grams serving size for bulk items \(100158, 110261, 100159, 110260, 110085,100154\),](#)

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- 3.7.5.3.6.2 13 grams of fat per 85 grams serving size for patty items -15% fat (100161, 100160, 110082),
- 3.7.5.3.6.3 8 grams of fat per 85 grams serving size for patty item - NTE 10% fat (100162), and
- 3.7.5.3.6.4 4.5 grams of fat per 88 grams serving size for patty items – 5% fat (100163, 110270).
- 3.7.5.3.7 Ingredient declaration (including single ingredient products).
- 3.7.5.3.8 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 _____.

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

3.7.6 Palletized Unit Loads

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

3.7.7 Total Net Weights Per Delivery Unit

3.7.7.1 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
100161, 100160, 100162, 110082, 100163, 110270	38,000
100154	42,000

Note: No tolerances will be allowed.

3.7.8 Sealing

3.7.8.1 All products must 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 F 1157-04 as required under this supplement.

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3.8 USDA QUALITY ASSURANCE

3.8.1 Warranty and Complaint Resolution

3.8.1.1 Warranty - The contractor will guarantee that the product complies with all [specification requirements, technical proposal declarations, and provisions set forth in the program supplement.](#)

3.8.1.2 Complaint Resolution - [Customer complaint resolution procedures will be included in the technical proposal. These procedures will include: a point of contact, investigation steps, intent to cooperate with AMS, and product replacement or monetary compensation. The procedures will be used to resolve product complaints from recipient agencies or AMS.](#)

3.8.2 AMS Monitoring and Production Assessment

3.8.2.1 A [GVD](#) agent must be present during the production of the finished product for all USDA ground beef contracts. The [GVD](#) agent will 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 [GVD](#) agent will be conducting the monitoring and production verification in accordance with applicable [GVD procedures](#). Any deviations to contractual requirements will be reported to the contractor and [COTR](#). [The COTR will make all determinations as to the acceptability of the product relative to findings documented by the GVD agent.](#)

3.8.3 Control of Non-Conforming Product

3.8.3.1 The contractor must include a plan to assure that non-conforming product (i.e., boneless beef, LFTB, ground beef) is not delivered under USDA contracts. The plan must address 1) control and segregation of non-conforming product, 2) removal of any USDA markings, and 3) disposition of non-conforming product, including vendor notification in writing to the [COTR](#) of final disposition (e.g., diverted to cooked product or destroyed).

3.8.4 [Contractor Checkloading](#)

3.8.4.1 [Contractor will perform checkloading examinations at the time of shipment and issue contractor's certificate to accompany each shipment that includes all of the following information:](#)

3.8.4.1.1 [Purchase Order Number/Purchase Order Line Item Number;](#)

3.8.4.1.2 [Sales Order Number/Sales Order Line Item Number;](#)

- 3.8.4.1.3 Destination of shipment;
- 3.8.4.1.4 Name of Product and applicable Material Number;
- 3.8.4.1.5 Shipping Date;
- 3.8.4.1.6 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;
- 3.8.4.1.7 Count of shipping containers and total projected net weight in each production lot;
- 3.8.4.1.8 Identity of car or truck (car numbers and letters, seals, truck license, etc.) as applicable;
- 3.8.4.1.9 Contractor certification that product conforms with the applicable specification (TRS GB 2012);
- 3.8.4.1.10 Count and projected net weight verified and;
- 3.8.4.1.11 Signature of company official responsible for checkloading.

APPENDIX A

DATA ENTRY AND PROCESS CAPABILITY VALUES

Data Entry

The ADL will 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 will be expressed as colony forming units (CFU) per gram or per ml reflecting the original sample measurement. Test results will be entered as a whole number (i.e., no decimal places, no preceding < (less than) symbol). Qualitative results for *E. coli* O157:H7 and *Salmonella* will be recorded as a 1 for a positive results and as a 0 for negative results.

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

Process Capability Values – CPU or Cpk

The process capability value (CPU or Cpk) is calculated by the ADL. CPU will be used for microbiological tests and for Beef Patties – 90/10 fat tests since these requirements only have an upper specification limit. Cpk will 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 will be found in APPENDIX B. The calculations for CPU and Cpk are as follows:

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

Process Capability Value – CI

The central line (CI; x-bar) is the process average or arithmetic mean that indicates the incidence of positive *E. coli* O157:H7 and *Salmonella* results.

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APPENDIX B

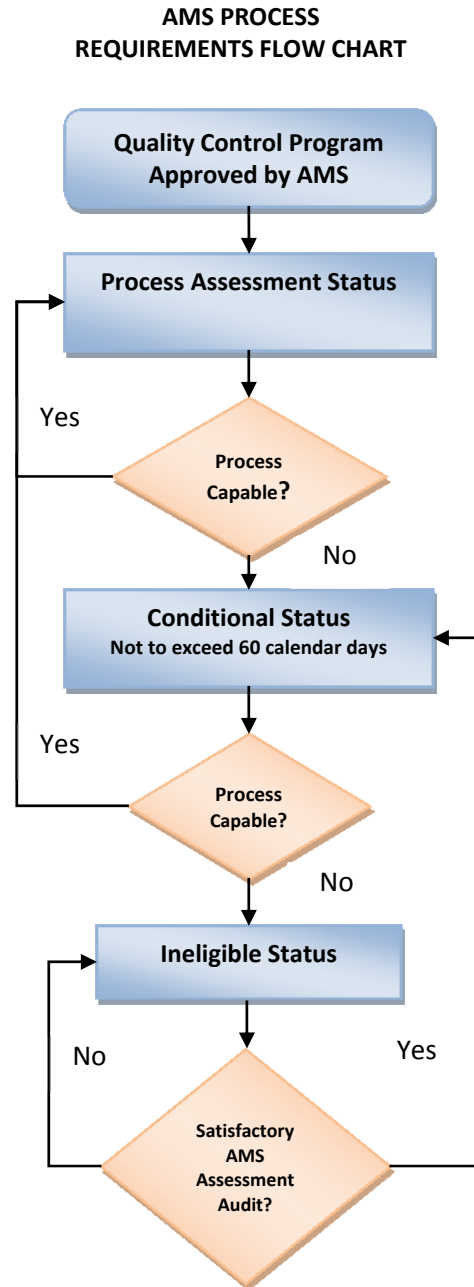
AMS BONELESS & GROUND BEEF PROCESS REQUIREMENTS FLOW CHART

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) must have received a satisfactory onsite capability assessment by GVD. AMS will audit and monitor the program. The quality control program must 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 will include the last recorded result as defined within APPENDIX D) of boneless beef (see Section 3.2.2.8.4) or ground beef (see Section 3.2.3.5.3.5) 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 lots or sub-lots (which will 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 COTR immediately when results are known and will 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 will be taken prior to completion of 20 lots or sub-lots.



Conditional Status –To regain process capable status, the boneless beef supplier or contractor must **notify** the **COTR** 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 **COTR**. 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 will 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 will be under **Conditional Status**. The AMS **COTR** 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 ≥ 1
Total Coliforms	100 / gram	1,000 / gram	CPU ≥ 1
<i>E. coli</i>	100 / gram	500 / gram	CPU ≥ 1
<i>Salmonella</i>		Positive (+) result / 25 grams	CI ≤ 0.05
<i>E. coli O157:H7</i>		Positive (+) result / 325 grams	CI ≤ 0.05

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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 TRS.

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 must be maintained in a frozen state from the time of leaving the shipping freezer and throughout the irradiation process. After irradiation, the products must 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 *Salmonella* and *E. coli* O157:H7 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 will assist in evaluating a process and assigning the appropriate control point (see Figure 1).

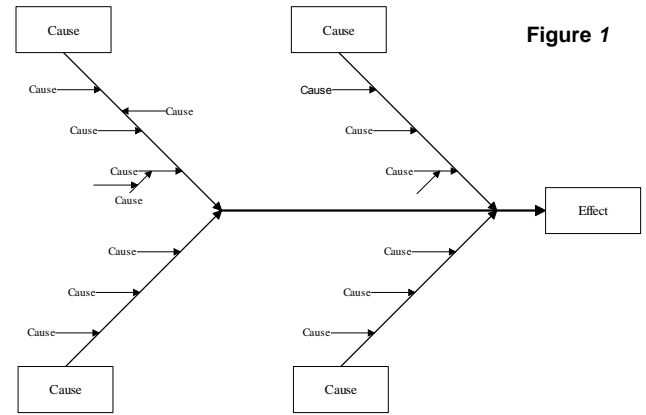


Figure 1

"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).

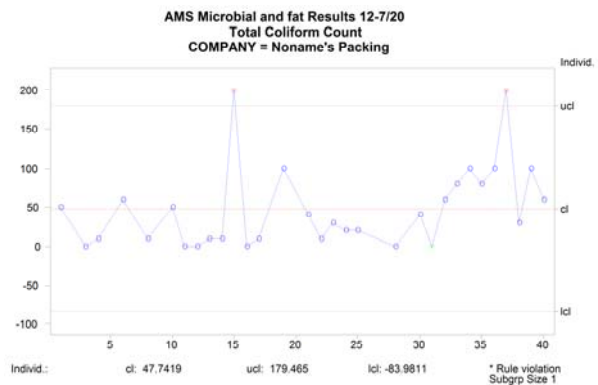


Figure 2

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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 will not involve relating the process average with a lower specification limit.

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

Excellent Condition - All product must 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 must be maintained in excellent condition through processing, storage, and transit.

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

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

Figure 3 AMS Fat Data Average Fat Company = B

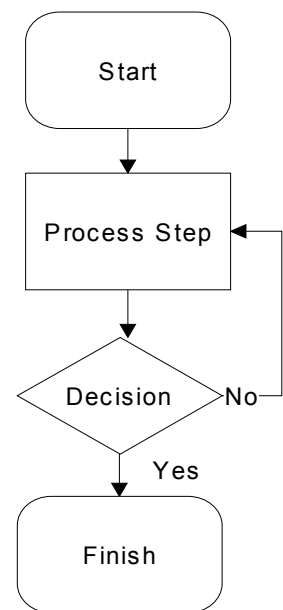
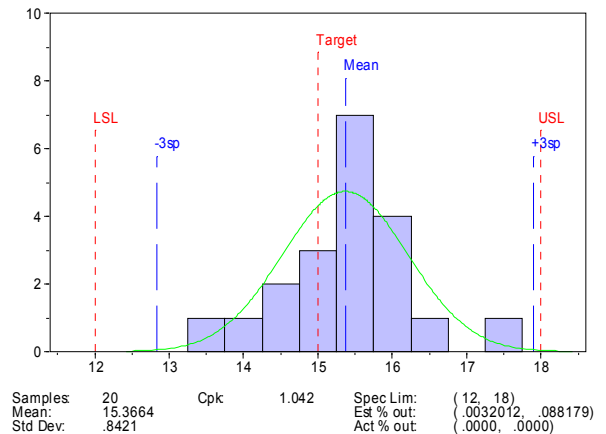


Figure 4

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

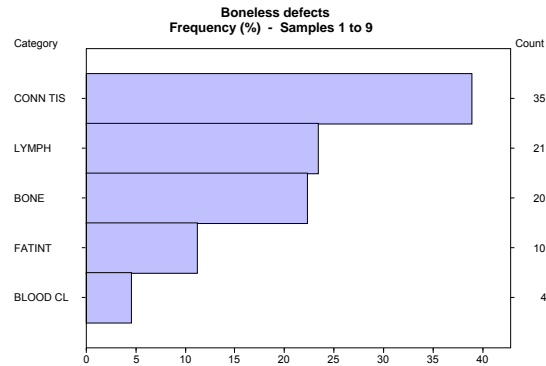
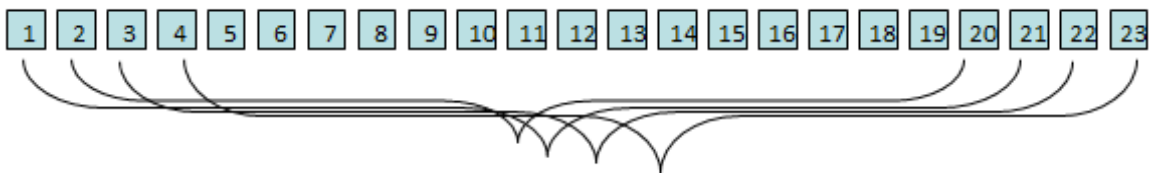


Figure 5

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 will 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 will 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 TRS-GB. The specification limits reflect customer needs (See Figure 3).



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APPROVED

TECHNICAL REQUIREMENTS SCHEDULE – ANIMAL HANDLING AND WELFARE 2010 (TRS-AHW-2010)

Contracting Officer Technical
Representative (COTR) Standards,
Analysis, and Technology Branch
Room 2607 S-Bldg, Phone: (202) 720-
4486

Effective: **May 2010**

Animal Handling and Welfare

1.0 General

1.1 Program Approach

The contractor and all subcontractors must develop and implement a written program that is consistent with a systematic approach to humane 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 processes of the animal.

1.2 Program Submission

The program will be submitted as a supporting document to the firm's approved technical proposal and must address the requirements outlined in **Section 2.0 – Program Components**.

2.0 Program Components

The contractor must ensure that any facility that harvests animals for the program has a:

2.1 Mission Statement

Mission Statement on Animal Handling and Welfare that is distributed to all employees and conspicuously displayed at the premises.

2.2 Training Program

Training program on Animal Handling and Welfare that:

- is provided to all employees interacting with animals;
- [covers Chapter 3: Transportation Audit Guidelines, Core Criteria 1 and 3 of the AMI Recommended Animal Handling Guidelines and Audit Guide 2010 Edition;](#)

- covers Chapter 4: Auditing Animal Handling and Stunning 7 Core Criteria of the AMI *Recommended Animal Handling Guidelines and Audit Guide 2010 Edition*;
- is conducted no less frequently than once a year for each designated employee; and,
- requires signed documentation from each employee and confirmation by signature of the designated trainer upon successful completion of training.

2.3 Quality Management Plan

Written quality management plan (internal) which addresses the provisions of [Chapter 3: Transportation Audit Guidelines, Core Criteria 1 and 3, and Chapter 4: Auditing Animal Handling and Stunning, 7 Core Criteria](#), of the AMI *Recommended Animal Handling Guidelines and Audit Guide 2010 Edition*, found at the following web site:

<http://www.animalhandling.org/ht/d/sp/i/26752/pid/26752>

2.4 Non-Ambulatory and U.S. Suspects

2.4.1 Cattle

Written protocol in-place and enforced that precludes the receipt of or having non-ambulatory, disabled cattle on the harvest facility premise. In the event that animals become non-ambulatory or disabled at any time while present at the harvest facility, the animal will be humanely euthanized and the carcass removed from the premise in a timely manner through contracted services or other means.

2.4.2 Hogs and Sheep

Written protocol in-place and enforced that ensures all animals designated by FSIS as U.S. Suspects (9 CFR 301.2) that are slaughtered are appropriately segregated during the harvest and production processes and precluded from inclusion in any products purchased by AMS.

3.0 Program Evaluation and Eligibility

The program will be audited (external) by a firm accredited by AMS. The accreditation of the firm will be conducted by the Audit, Review and Compliance Branch through the **LS ISO Guide 65 Program**. Alternatively, at the option of the contractor or subcontractor, the audits can be performed by AMS auditors.

3.1 Audit Format

The AMS accredited auditing firm must conduct audits utilizing the following format:

3.1.1 [Transportation Segment \(Chapter 3: AMI Recommended Animal Handling Guidelines and Audit Guide 2010 Edition\)](#)

[Audited firms must pass Core Criteria 1 with a minimum scoring of excellent and Core Criteria 3 with a minimum scoring of acceptable each time an audit is performed.](#)

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3.1.2 **Animal Handling and Stunning Segment (Chapter 4: AMI Recommended Animal Handling Guidelines and Audit Guide 2010 Edition)**

Audited firms must pass Core Criteria 1 through 5 with a minimum scoring of acceptable while Core Criteria 6 and 7 must be adhered to with full compliance (zero tolerance) each time an audit is performed.

3.2 **Initial Audit**

Initial audit must be performed prior to award of contracts.

3.3 **Audit Failure**

If an audit is failed for any of the Core Criteria, the firm is not eligible to provide product until such a time that corrective and preventative actions are approved by the Contracting Officer, implemented and proven effective.

3.4 **Audit Frequency and Status**

- STANDARD - Until four (4) consecutive successfully passed audits are attained, an audit must be conducted within 3 months of the previous audit.
- MONTHLY - If at any time an audit identifies any of the Core Criteria not meeting the pass requirements while in the STANDARD phase, auditing will be required to be conducted on a monthly basis once corrective and preventative actions have been approved by the Contracting Officer, implemented and proven effective. This schedule will be for a period of time until four (4) successive audits are found to meet the pass requirements noted within Chapter 3 (Core Criteria 1 and 3) and Chapter 4 (Core Criteria 1 through 7) of the AMI Recommended Animal Handling Guidelines and Audit Guide 2010 Edition; at which time audits shall be conducted on the STANDARD basis.
- If four successfully conducted audits are sequentially completed within a one year period while in STANDARD auditing phase, the facility may move to a SEMI-ANNUAL audit basis.
- SEMI-ANNUAL - Semi-annual audits may continue until such time that a failed audit is reported or a period of greater than six months has elapsed without any audits being performed; at which time the audits must resume as described for STANDARD audits.

4.0 **Contracting Officer**

The contracting officer can declare a contractor's and/or subcontractor's Animal Handling and Welfare Program out of compliance at any time.

3 *Martin E. O'Connor*