AMENDMENT NO. 1

SUPPLEMENT 212 TO AMS MASTER SOLICITATION

PURCHASE OF FRESH BONELESS BEEF PRODUCTS
FOR FURTHER PROCESSING
FOR DISTRIBUTION TO CHILD NUTRITION AND
OTHER FEDERAL FOOD AND NUTRITION PROGRAMS
Dated MAY 2012

This Amendment is issued in order to update Supplement 212 attachments, as follows:


Note: TRS-AHW-2013 does not become effective until July 2013. The following information will clarify how the new requirements relate to contractor /supplier eligibility in AMS Commodity Procurement Programs (solicitations and contract awards):

a. Approved suppliers will remain eligible to participate in AMS Commodity Procurement Programs under TRS-AHW-2010 on any solicitation issued on or before June 30, 2013.

b. Meanwhile, approved suppliers (and, likewise, any supplier currently in the process of becoming approved) may address the animal welfare portion of their technical programs according to the updated TRS-AHW-2013, have it reviewed by LPS Program’s Food Safety and Commodity Specification (FSCS) Division, and approved pending a successful onsite capability assessment conducted by the LPS Program’s Grading and Verification Division (GVD). This will have no effect on their eligibility to bid during this period of time.

c. Approved suppliers must revise their technical programs according to the updated TRS-AHW-2013 and be re-approved before July 1, 2013 to be eligible to bid on any solicitations issued on or after that date.

All other terms and conditions remained unchanged.

Attachments
TECHNICAL REQUIREMENTS SCHEDULE – BB - 2013

FOR USDA PURCHASES OF FRESH CHILLED, BONELESS BEEF FOR FURTHER PROCESSING

Effective: MAY 2013

Preparing Activity:
USDA, AMS, LPS, FSCSD--Rm. 2628-S
Supersedes: TRS-BB-2012
Changes - In blue
LPS-FSCSD-TRS-BB-2013

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1.0 SCOPE

1.1 This Technical Requirements Schedule (TRS)–Boneless Beef (BB)–2013 is for use by a contractor of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Commodity Procurement Division (CPD) to deliver fresh-chilled (never previously frozen) boneless beef for further processing.

2.0 APPLICABLE DOCUMENTS

2.1 The following documents are incorporated as part of this USDA, TRS-BB-2013:

2.1.1 Grading and Verification Division (GVD) Procedures Manual.

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

2.1.3 Applicable Supplement to AMS Master Solicitation.

3.0 CHECKLIST OF REQUIREMENTS

3.1 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 MATERIAL REQUIREMENTS FOR FRESH-CHILLED BONELESS BEEF

3.2.1 Domestic Origin and Harvest (Slaughter) Requirements – The harvester’s quality control program must be documented 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 GVD during production activities that demonstrate its adherence to the documented program. Boneless beef shall be derived from cattle harvested at facilities that comply with the following origin and harvest requirements.

3.2.1.1 Domestic Origin - All beef will originate from U.S. produced livestock as defined within the Supplement.

3.2.1.2 Humane Handling - All cattle shall be humanely handled in accordance with all applicable FSIS regulations and AMS requirements.
3.2.1.3 Residue Prevention – Slaughter and production establishments must have a Hazard Analysis Critical Control Point (HACCP) system to control veterinary drug, pesticide, and environmental contaminant residues per FSIS regulations. Helpful information is available in the FSIS Compliance Guide for Residue Prevention 2012.

3.2.1.4 Spinal Cord Removal – All spinal cord tissue must be removed during the harvesting process.

3.2.1.5 Pathogen Intervention – The harvest process must include at least two pathogen intervention steps. One of the intervention steps must be a critical control point (CCP) in the contractor’s FSIS recognized harvest process HACCP plan and the CCP intervention(s) must be scientifically validated to achieve a three log reduction of enteric pathogens.

3.2.1.6 Carcass Testing - Routinely test carcasses for Shiga-toxigenic Escherichia coli O157:H7 (including O157:H7 and O157:Non-Motile (NM); herein referred to as E.coli O157:H7) at CCP to verify effectiveness of interventions.

3.2.1.7 Grass Fed – When specified in the invitation, boneless beef destined to be labeled as grass fed shall be supported by documentation and the FSIS approved label which substantiates such a claim.

3.2.2 Boneless Beef Requirements

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

3.2.2.2 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.

3.2.2.3 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.

3.2.2.4 Objectionable materials - The following objectionable materials shall be excluded:

3.2.2.4.1 Major lymph glands (prefemoral, popliteal, and prescapular), thymus gland, sciatic (ischiatic) nerve (lies medial to the outside round), internal fat (kidney, pelvic, and heart fat).

3.2.2.4.2 All bone, cartilage, and the following heavy connective tissues:
3.2.2.4.2.1 White fibrous – Shoulder tendon, elbow tendon, silver skin from the outside round, *sacrociatic* ligament, opaque periosteum, serous membrane (*peritoneum*), tendinous ends of shanks, *patellar* ligament (stifle joint), *gracilis* membrane (from the inside round), and achilles tendon.

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

3.2.2.5 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.

3.2.2.6 Lot - A lot shall consist of a single combo sized bin of approximately 2,000 pounds of boneless beef produced within a day, between "cleanup to cleanup" (see APPENDIX C) and that is from a single harvester or from a single processor.

3.2.2.7 Microbial Testing – All lots of fresh chilled boneless beef must be tested for all microbes listed in APPENDIX B. All samples will be sent to the AMS designated laboratory (ADL).

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

3.2.2.7.2 Sample Selection

3.2.2.7.2.1 For Beef Manufacturing Trimmings – The composite sample will be selected as described within FSIS Directive 10,010.1 Revision 3 (N-60 Sections 8, 9 and NOTE).

3.2.2.7.2.2 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 ± 10 percent; the sample for Salmonella will be five (5) pieces and weigh 25 grams ± 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 ± 10 percent.
3.2.2.7.2.3 When boneless beef has been exposed to any anti-microbial treatment, no sample units shall be selected for at least 15 minutes after such treatment. All anti-microbial treatments (e.g. techniques and procedures) administered during production and post-production shall be described in the contractor's technical proposal.

3.2.2.7.2.4 AMS defines the practice of “prescreening” as a boneless beef contractor collecting and testing product samples for the presence of *E. coli O157:H7*, *Salmonella*, and other pathogens; and based on the results, determine whether to allow the product to remain in AMS production and whether to collect and/or submit the official AMS product sample for microbiological testing by the ADL. Contractors must declare in their technical proposals and describe in detail all microbiological sampling they plan to do prior to collecting and submitting the official AMS sample to the ADL.

3.2.2.7.3 Testing and Results

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

3.2.2.7.3.2 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:

3.2.2.7.3.2.1 The ADL will immediately notify FSIS (pathogens only) and the COTR.

3.2.2.7.3.2.2 When pathogen results are positive, FSIS and the COTR will be notified by the boneless beef contractor of the final disposition of the affected lot.

3.2.2.7.3.2.3 When the critical limit is exceeded for indicator organisms, the boneless beef contractor will notify the COTR of the final disposition of the affected lot.

3.2.2.7.3.2.4 Confirmed pathogen - The boneless beef contractor shall conduct a cause and effect analysis to determine the appropriate corrective action necessary to eliminate the probable cause. A written copy of the cause and effect analysis will be provided to AMS.

3.2.2.7.3.3 The ADL will record results of all microbial analysis in a format that can be easily captured and analyzed.
3.2.2.7.3.4 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 3.2.2.7.4.

3.2.2.7.3.5 Any lot that tests positive for *E. coli* O157:H7 or *Salmonella*, or exceeds the critical limit criteria of APPENDIX B cannot be delivered to the USDA.

3.2.2.7.4 Statistical Process Capability – The statistical process capability of a boneless beef contractor to comply with microbial requirements will be based on the assessment of calculated process capability (CPU, CI) 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 purchase programs will be monitored by AMS and the contractor, to determine individual lot acceptance and/or capability of their process according to APPENDIX B. Ineligible boneless beef contractor 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 contractor may re-enter the program under conditional status.

3.2.2.7.5 Contractor’s Responsibility - The contractor will provide results and process capability status (as applicable) involving each lot of boneless beef to be delivered to the USDA. Test results and process capability status (as applicable) for individual lots shall be provided to the GVD agent upon request. In the event a boneless beef contractor has been deemed ineligible, and wants to continue in the program, the ineligible boneless beef contractor may 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 contractor may re-enter the program under conditional status.
3.3 STATE OF REFRIGERATION

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

3.4 FAT LIMITATIONS

3.4.1 Requirements - The contractor will establish a target average of 15 percent fat of all boneless beef destined for all USDA destinations. The upper and lower specifications limits will be 18.0 and 12.0 percent fat respectively. Production lots with average fat results that are not within the upper and lower specification limits will not be shipped to USDA.

3.4.2 Process Capability - The processors capability (Cpk) value shall be one (1) or higher when the average results from twenty (20) consecutive production lots (which always will include the last production lot) are calculated.

3.4.3 Documentation - The contractor shall declare within their technical proposal:

3.4.3.1 Lot size, number of samples, selection and preparation procedures,

3.4.3.2 The laboratory and a test method,

3.4.3.3 Data management and storage of fat results,

3.4.3.4 Statistical Process Control (SPC) charting methods which will include a process capability report (histogram) that is capable of calculating a Cpk value (see Exhibit A).

3.4.4 Assessment by AMS - AMS reserves the right to:

3.4.4.1 Check production records of the recipient where the contractor’s boneless beef is further processed;

3.4.4.2 Select and analyze samples at the further processor. The results may be used by the contracting officer as a “check” to determine if fat content is in compliance with the fat limitation requirements; and/or

3.4.4.3 Deem a contractor as unreliable for failure to comply with the above requirements.
3.5 PACKAGING AND PACKING

3.5.1 The contractor's technical proposal and process will assure that all packaging, packing, closure, marking, and palletizing comply with the National Motor Freight Regulations and FSIS regulations and the requirements listed below. The contractor also must have procedures for verifying the net weight of shipping containers.

3.5.1.1 Packaging and Packing – The contractor shall bulk package the boneless beef within lined “combo bins” in such a manner to maintain the product in excellent condition. The combo bins of boneless beef shall be sealed so that the container is tamper proof and arrives at the destination intact.

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

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

3.5.1.3.1 “Complies with TRS - BB - 2013 - Boneless Beef for Further Processing”:

3.5.1.3.2 A code number that will indicate traceability to production lot and date.

3.5.1.3.3 USDA Shield (at least 2 inches high).

3.5.1.3.4 Purchase Order Number.

3.5.1.3.5 Fat Declaration.

3.5.1.3.6 The appropriate material number listed in the table below for each of the items.

<table>
<thead>
<tr>
<th>Item</th>
<th>Material Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boneless Beef Combo, Fresh</td>
<td>100155</td>
</tr>
<tr>
<td>Boneless Beef Combo, Grass Fed, Fresh</td>
<td>110091</td>
</tr>
</tbody>
</table>

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

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3.5.1.4  Total net weights per delivery unit - The delivery unit will be 40,000 pounds.

3.5.1.5  Sealing - 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.

4.0  CONTROL OF NON-CONFORMING PRODUCT

4.1  The contractor must include a plan to assure that non-conforming product 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).

5.0  QUALITY ASSURANCE

5.1  Warranty and Complaint Resolution

5.1.1  Warranty – The contractor will guarantee that the product complies with all specification requirements, technical proposal declarations, and provisions set forth in the program Supplement.

5.1.2  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.

5.2  Contractor Checkloading

5.2.1  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:

5.2.1.1  Purchase Order Number/Purchase Order Line Item Number;

5.2.1.2  Sales Order Number and Sales Order Line Item Number;

5.2.1.3  Destination of shipment;

5.2.1.4  Name of Product and applicable Material Number;

5.2.1.5  Shipping Date;
<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.2.1.6</td>
<td>Production lot number(s) and date each lot was produced;</td>
</tr>
<tr>
<td>5.2.1.7</td>
<td>Count of shipping containers and total projected net weight in each</td>
</tr>
<tr>
<td></td>
<td>production lot;</td>
</tr>
<tr>
<td>5.2.1.8</td>
<td>Identity of car or truck (car numbers and letters, seals, truck license,</td>
</tr>
<tr>
<td></td>
<td>etc.) as applicable;</td>
</tr>
<tr>
<td>5.2.1.9</td>
<td>Contractor certification that product conforms with the applicable</td>
</tr>
<tr>
<td></td>
<td>specification (TRS BB 2013);</td>
</tr>
<tr>
<td>5.2.1.10</td>
<td>Count and projected net weight verified and;</td>
</tr>
<tr>
<td>5.2.1.11</td>
<td>Signature of company official responsible for checkloading.</td>
</tr>
</tbody>
</table>
APPENDIX A

DATA ENTRY AND PROCESS CAPABILITY VALUE

Data Entry
The ADL will record microbiological test results on spreadsheets and 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, Cl) in the spreadsheets so that the contractor’s process capability assessment can be determined, as described in APPENDIX B.

Process Capability Values – CPU or Cpk
The process capability value (CPU) is calculated by the ADL. CPU will be used for microbiological 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 3.4.2). The upper specification limits (USL) for microbiological requirements will be found in APPENDIX B. The calculations for CPU and Cpk are as follows:

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

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

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APPENDIX B

AMS BONELESS BEEF PROCESS REQUIREMENTS FLOW CHART

Quality Control Program – Prior to bidding on boneless beef contracts with the USDA, the documented quality control program as described within the approved technical proposal 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 (which will include the last recorded result as defined within APPENDIX C) of boneless beef (see Section 3.2.2.7.4) destined for USDA contracts for the microbes listed within the table below.

Process Capable? – Flow chart decision step that involves test results for up to 20 consecutive SPC only lots (which will include the last recorded result) recorded in spreadsheets, where the process capability (CPU or Cl) value is calculated (See APPENDIX A) for evaluation. A process that is not capable shall be declared to the 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.

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Conditional Status – To regain process capable status, the boneless beef 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 contractor may also declare itself ineligible at any time.

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

### AMS MICROBIAL REQUIREMENTS FOR BONELESS BEEF

<table>
<thead>
<tr>
<th>Microbial Test</th>
<th>USL (cfu)</th>
<th>Critical Limits (cfu)</th>
<th>CPU or CI Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Plate Count</td>
<td>50,000 / gram</td>
<td>100,000 / gram</td>
<td>CPU &gt; 1</td>
</tr>
<tr>
<td>Total Coliforms</td>
<td>100 / gram</td>
<td>1,000 / gram</td>
<td>CPU &gt; 1</td>
</tr>
<tr>
<td>E. coli</td>
<td>100 / gram</td>
<td>500 / gram</td>
<td>CPU &gt; 1</td>
</tr>
<tr>
<td>Salmonella</td>
<td>Positive (+) result / 25 grams</td>
<td>Cl &lt; 0.05</td>
<td></td>
</tr>
<tr>
<td>E. coli O157:H7</td>
<td>Positive (+) result / 325 grams</td>
<td>Cl &lt; 0.05</td>
<td></td>
</tr>
</tbody>
</table>
Appendix C

GLOSSARY OF TERMS

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

"Cleanup to cleanup" - Part of a HACCP program that the establishment has in place to support statistically distinguishing one portion of production from another. Production destined for USDA contracts is to be commenced on clean equipment. "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).
**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).
**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).

**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 an output that can be further processed or meet a customer’s need. A complex process involves output being another processes input. The production of ground beef is a complex process.

**Process Capability Assessment on 20 consecutive lots** – For the purpose of this specification, process capability assessments are conducted on data results from each lot for fat and microbial requirements. A process assessment involves sampling and testing of 20 consecutive lots (which always includes the last recorded result). Information from each lot 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).

**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 contractors 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).

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**Figure 5**

**Figure 6**
### 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 contractor wishing to be an eligible participant in the Boneless Beef Program shall have a process that is capable of producing within the specification limits (See figure 2).

### Upper and lower specification limits (USL and LSL)

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

### Table 1

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<th>Tools for Statistical Process Control</th>
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**Approved by CMS**

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GENERAL

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

PROGRAM APPROACH

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

PROGRAM SUBMISSION

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

PROGRAM COMPONENTS

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

MANAGEMENT COMMITMENT

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

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

221  Training program on Animal Handling and Welfare that:

221.1 is provided to all employees interacting with animals;

221.2 covers the AMI Recommended Animal Handling Guidelines and Audit Guide 2012 Edition;

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

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

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

230  QUALITY MANAGEMENT PLAN

231  Written quality management plan (internal) which addresses all provisions of Chapter 3: Transportation Audit Guidelines, 7 Core Criteria and Chapter 4: Auditing Animal Handling and Stunning, 7 Core Criteria, of the AMI Recommended Animal Handling Guidelines and Audit Guide 2012 Edition, found at the following web site address:

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

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

240  NON-AMBULATORY AND U.S. SUSPECTS

241  CATTLE

242 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.
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.

PROGRAM EVALUATION AND ELIGIBILITY

The program will be audited (external) by AMS or a firm accredited by AMS. The accreditation of the firm will be conducted by the Grading and Verification Division (GVD) through the USDA ISO Guide 65 Program. Alternatively, at the option of the organization, the audits can be performed by GVD auditors.

Audit findings thought to be in conflict with Food Safety and Inspection Service (FSIS) regulations will be communicated to the establishment’s FSIS Inspector in Charge (IIC) or designee.

AUDIT FORMAT

AMS or the AMS accredited auditing firm will conduct audits utilizing the following format:

TRANSPORTATION SEGMENT (CHAPTER 3: AMI RECOMMENDED ANIMAL HANDLING GUIDELINES AND AUDIT GUIDE 2012 EDITION)

Audited organizations must pass Core Criteria 1 and 6 with a minimum scoring of excellent, Core Criteria 2 through 5 with a minimum scoring of acceptable and Core Criteria 7 must be adhered to with full compliance (zero tolerance) each time an audit is performed.

ANIMAL HANDLING AND STUNNING SEGMENT (CHAPTER 4: AMI RECOMMENDED ANIMAL HANDLING GUIDELINES AND AUDIT GUIDE 2012 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.

INITIAL AUDIT

Initial audit must be performed prior to award of contracts.

AUDIT FAILURE

If an audit is failed for any of the Core Criteria, the organization is not eligible to provide product until such a time that corrective and preventative actions are approved by the COTR, implemented and proven effective.
340 AUDIT FREQUENCY AND STATUS

341 STANDARD - Until four (4) consecutive successfully passed audits are attained, an audit must be conducted within 3 months of the previous audit.

342 MONTHLY - If at any time an audit identifies any of the Core Criteria not meeting the pass requirements while in the STANDARD phase, auditing will be required to be conducted on a monthly basis once corrective and preventative actions have been approved by the COTR, implemented and proven effective. This schedule will be for a period of time until four (4) successive audits are found to meet the passing requirements noted in SECTION 310 – AUDIT FORMAT; at which time audits shall be conducted on the STANDARD basis.

343 If four successfully conducted audits are sequentially completed within a one year period while in STANDARD auditing phase, the facility may move to a SEMI-ANNUAL audit basis.

344 SEMI-ANNUAL - Semi-annual audits may continue until such time that a failed audit is reported or a period of greater than six months has elapsed without any audits being performed; at which time the audits must resume as described for STANDARD audits.

400 COTR

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