

APPROVED



**TECHNICAL
REQUIREMENTS**

UNITED STATES
DEPARTMENT OF
AGRICULTURE

SCHEDULE – GB - 2004

AGRICULTURAL
MARKETING
SERVICE

LIVESTOCK AND
SEED PROGRAM

Washington, D.C.
20250-0254

FOR USDA PURCHASES OF

**GROUND BEEF ITEMS,
FROZEN**

**Effective:
May 2004**

Preparing Activity:
USDA, AMS, LS, STDZ--Rm. 2603-S
Supersedes: TRS-GB April 2004 and TRS-GB May 2003

May 21, 2004
All Modifications are italicized
LSP-SB-TRS-GB-04-R2-SCO

I. SCOPE

This Technical Requirements Schedule (TRS)–GB–2004 is for use by the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Livestock and Seed Program (LS) to procure fresh ground beef products, frozen.

II. APPLICABLE DOCUMENTS

The following documents are incorporated as part of this USDA, TRS-GB-2004:

- Meat Grading and Certification (MGC) Branch Instruction Manual.
- Audit Review and Compliance (ARC) Branch Procedures, Series 1000.

III. CHECKLIST OF REQUIREMENTS

A. ITEMS

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

1. Bulk -	Product Code
Ground Beef (10-pound bulk packaged)	A608
Ground Beef-Irradiated (10-pound bulk packaged).....	A579
Ground Beef, 1-pound packages	A609
Coarse Ground Beef to be Further Processed into Cooked Items.....	A594
2. Patties -	
Ground Beef Patties	A626
Ground Beef Patties-Irradiated	A578
<i>Beef Patties with Soy</i> Protein Product	A616
Ground Beef Patties, Not to Exceed (NTE) 10% Fat	A627

B. MATERIAL

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.

1. Domestic Origin and Harvest (Slaughter) Requirements – Boneless beef shall be derived from cattle harvested at facilities that comply with the following origin and harvest requirements. The requirements will be verified in accordance with ARC 1010 Procedure, USDA Supplier Eligibility Programs (<http://www.ams.usda.gov/lsg/arc/dovp.htm>).
 - a) Domestic Origin - All beef will originate from U.S. produced livestock.
 - b) Humane Handling – All cattle shall be humanely handled in accordance with all applicable FSIS regulations, directives, and notices.*
 - c) Non-Ambulatory Disabled Cattle – Meat from carcasses of non-ambulatory disabled cattle will not be included in USDA purchased ground beef products.*
 - d) Spinal Cord Removal – All spinal cord tissue shall be removed during the harvesting process.
 - e) Pathogen Intervention Steps – The harvest process must include at least two pathogen intervention steps. One of the intervention steps shall be steam pasteurization, an organic acid rinse, or a 180°F hot water wash and must be a critical control point (CCP) in their FSIS recognized slaughter process Hazard Analysis Critical Control Point (HACCP) plan.
 - f) Carcass Testing - Routinely test carcasses for *E. coli* O157:H7 to verify effectiveness of interventions at CCP.

2. Boneless Beef Requirements

- a) Quality Control Program - The boneless beef supplier's quality control program must be documented in the contractor's technical proposal and have received a satisfactory onsite capability assessment by the ARC branch.
- b) Lot – For the purpose of this section, a lot shall consist of boneless beef produced between “clean-ups” and that is from a single slaughterer or from a single processor.
- c) Traceability - Contractors are responsible for providing traceability of boneless beef that is derived from approved sources that comply with the above domestic origin and slaughterer requirements. They must have documentation and a program in place that verifies the source of raw materials used in each lot of product.
- d) 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 and to meet the following applicable requirements. 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 slaughter.
- e) *Objectionable Materials – All boneless beef suppliers must assure the removal of major lymph glands (prefemoral, popliteal, and prescapular), and the sciatic (ischiatric) nerve (lies medial to the outside round). For boneless beef destined to be processed and delivered as coarse ground beef, the boneless beef supplier shall also assure the removal of all bone, cartilage, and the following heavy connective tissues:*
 - (1) White fibrous – Shoulder tendon, elbow tendon, silver skin, *sacrociatic* ligament, opaque *periosteum*, *serous* membrane (*peritoneum*), tendinous ends of shanks, *gracilis* membrane, and *achilles* tendon.
 - (2) Yellow elastin – Back strap and *abdominal tunic*.
- f) Microbial Testing – All lots of fresh chilled boneless beef must be tested for all microbes listed in Appendix B. For this section, all samples will be sent to the AMS designated laboratory (ADL).
 - (1) Sample Preparation – From each lot, a composite sample will be prepared from at least 4 randomly selected samples (of approximately equal size) of boneless beef. The samples shall be ground/chopped and blended together. From the mixture, a single sample *to be submitted for analysis and a reserve sample* shall be drawn. *The ADL will be responsible for supplying all materials, protocol and methods (including sample size, handling of reserve samples, etc.) for sample preparation and submission.* Alternative sample preparation procedures, including lot size designation, will be considered within the technical proposal provided there is assurance that all specification requirements are met.
 - (2) *Testing and Results - The sample will be analyzed by the ADL for microbial levels listed in Appendix B.*
 - (a) The microbial test for all microbes, except for E. coli O157:H7, will be in accordance with the applicable test methods listed in the Compendium of

Methods for the Microbiological Examination of Foods (current edition), published by the American Public Health Association.

- (b) *The presence of E. coli O157:H7 will be determined using referenced test methods that are within or conform to the "USDA/FSIS Microbiology Laboratory Guidebook (<http://www.fsis.usda.gov/ophs/microlab/mlgbook.htm>), Chapter 5.03" for Detection, Isolation, and Identification of Escherichia coli O157:H7 and O157:NM (Nonmotile) from Meat Products, Effective Date 10/25/02.*
 - (c) *The ADL will record and plot the results on control charts and histograms for each microbial test (as illustrated in Appendix A and further defined in Appendix E). The control charts and histograms will be maintained so that process capability may be determined according to the requirements within Appendix B.*
- (3) Requirements – The capability of a boneless beef supplier to comply with microbial requirements will be based on assessment of control charts and histograms. *Test results involving all boneless beef destined for AMS ground beef purchase programs will be monitored by AMS and the boneless beef supplier to determine capability of their process according to Appendix B. The boneless beef supplier will advise the contractor of their process capability status.* Ineligible boneless beef suppliers may petition AMS to reenter the program provided corrective actions have been implemented, proven effective, and a satisfactory onsite assessment audit received from AMS.

3. Ground Beef Requirements

- a) Lot - For the purpose of this section, a lot is defined as the amount of finished ground beef produced between “clean-ups.”
- b) Traceability - Each lot of boneless beef ground for USDA must be traceable to the boneless beef microbial test results.
- c) 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 90 days from date of pack. Ground Beef, 1-pound packages shall be delivered within 30 days from date of pack.*

- d) Microbial Testing – All lots of ground beef will be tested for all microbes listed in Appendix C after final grinding and before freezing. Except, ground beef products that are irradiated will be tested for Salmonella and E. coli O157:H7 after the irradiation process, and the other microbes listed in Appendix C prior to irradiation.
- (1) Sample Preparation - From each lot, a composite sample will be prepared from at least 4 randomly selected samples (of approximately equal size) of finished ground beef. The samples shall be blended. From the mixture, a single sample *to be submitted to the AMS Laboratory for analysis and a reserve sample* shall be drawn.
 - (2) *Testing and Results - The sample will be analyzed by the AMS Laboratories for all microbes listed in Appendix C.*
 - (a) Except for E. coli O157:H7, the applicable test methods listed in the Compendium of Methods for the Microbiological Examination of Foods (current edition), published by the American Public Health Association. The results will be recorded and plotted *by the contractor* on control charts and histograms for all microorganisms as illustrated in Appendix A.
 - (b) *Testing for E. coli O157:H7 – The ground beef sample submitted to the AMS Laboratories will also be tested for the presence of E. coli O157:H7 using the referenced test methods that are within or conform to the "USDA/FSIS Microbiology Laboratory Guidebook (<http://www.fsis.usda.gov/ophs/microlab/mlgbook.htm>), Chapter 5.03" for Detection, Isolation, and Identification of Escherichia coli O157:H7 and O157:NM (Nonmotile) from Meat Products, Effective Date 10/25/02. When presence of E. coli O157:H7 is positive per 325 gram sample:*
 - (i) FSIS will be notified for final disposition of the product.
 - (ii) The contractor shall conduct a cause and effect analysis to determine the appropriate correction action necessary to eliminate the probable cause. The corrective actions must be implemented and proven effective.
 - (3) Requirements –The capability of the contractor to comply with microbial requirements will be based on assessment of control charts and histograms. Test results will be monitored by the contractor and AMS to determine acceptability of the process according to APPENDIX C. *The contractor will advise the AMS agent of their process capability status for each lot.* Ineligible contractors may petition AMS to reenter the program provided corrective actions have been implemented, proven effective, and a satisfactory onsite assessment audit by AMS has been received.

- e) Irradiated Ground Beef - When specified by the purchaser, ground beef products to be irradiated shall comply with the additional requirements specified in APPENDIX D.
4. Meat Recovery Systems
 - a) Mechanical Separation - Beef that is mechanically separated from bone with automatic deboning systems, advanced lean (meat) recovery (AMR) systems or powered knives, will not be allowed.
 - b) Lean Finely Textured Beef - Lean beef that is processed from fat boneless beef trimmings and is finely textured is allowed provided it does not exceed 10 percent by weight of the combined finished product. The finely textured product shall be labeled "Lean Finely Textured Beef" and must comply with all the **MATERIAL** requirements for boneless beef. The contractor shall document all procedures for handling of finely textured lean beef trimmings and must use it within 60 days of the date of production. Lean finely textured beef may not be used in USDA coarse ground beef.
 5. Desinewed Beef – Must be in discernible pieces (chunks). The desinewing process must demonstrate the ability to remove heavy connective tissue in boneless beef.
 6. *Beef Patties with Soy Protein Product (SPP)* - The *SPP* will be hydrated to yield no less than 18% protein (as is basis).
 - a) Texture - The physical characteristics of SPP, in the dry form, must be either granular or textured.
 - b) Type and Combination Rate - The types of soy that may be used and combination rates shall be as set forth in Table 1.

Table 1

Types of Soy (% Protein "As is Basis")	Maximum Percent of Hydrated SPP in the Combined Finished Product
Textured Flour (50%)	15.0
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.

7. Ground Beef Patties, NTE 10% Fat – The patties shall not have any non-meat ingredients added.

C. PROCESSING

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

1. Grinding and Blending -
 - a) Ground Beef - Boneless beef shall be ground twice, with the final grind passing through a 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.
 - b) 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.
 - c) Fat Break-Outs - The grinding, blending, and packaging process shall be conducted in a manner that precludes large fat "break outs" (globs greater than 1.0 cubic inch) in the finished product.
2. Bone Collector/Extruder Systems - Except for Coarse Ground Beef, a bone collector/extruder system must be in operation to remove bone, cartilage, and heavy connective tissue during the final grind of all products. 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 lot weight basis).
3. Scoring or Waffling of Patties - Raw ground beef patties must be round and scored or waffled on both sides.
4. Metal Detection - All product shall be free of metal contaminants. Detection of stainless steel, ferrous, and non-ferrous (e.g., lead, copper, and aluminum) metals is required. The contractor's technical proposal must identify and describe the equipment, location, detection procedure, sensitivity levels, frequency of equipment validation, and corrective action procedures.

D. STATE OF REFRIGERATION

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.
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.
3. Shipping - All USDA ground beef products will not exceed 0°F at the time of shipment or delivery.

E. FAT LIMITATIONS

The contractors will establish a target average of 15 percent fat for all ground beef products except for the ground beef patties NTE 10 percent fat. 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 ground beef patties NTE 10 percent fat, the upper specification limit will be 10 percent. *Separate Statistical Process Control (SPC) assessments will be conducted on ground beef products that are 15 percent fat and the NTE 10 percent fat patties.*

1. Contractor Process Assessment - The contractor shall declare the laboratory, test method and SPC charting method within their technical proposal.
 - a) Sampling and testing - The contractor will *randomly* select 4 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.
 - b) Recording results - The contractor will record and plot the results on variable data control charts and histograms (as illustrated in Appendix A and further defined in Appendix E). Control charts must have statistically derived upper and lower control limits (± 3 standard deviations from the mean). Control charts will be used to determine if the process is in statistical control. Histograms will be used to determine process capability. *Under contractor process assessment, no production lots shall be allowed delivery to USDA with average test results that are outside the upper and lower specification limits.*
 - c) Process Capability Assessment - Twenty (20) consecutive production lot results (that include the last production lot) will be plotted on histograms for capability assessment. The processor's capability (C_{pk}/C_{pu}) shall be 1 or higher.
 - d) The contractor and AMS will evaluate control charts and histograms with consecutive results (not to exceed 20) that include the last production lot.
2. *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) that are independent from those samples selected for contractor process assessment and send them to the ADL for fat analysis. The ADL will be responsible for supplying all materials, protocol and methods (including sample size, handling of reserve samples, etc.) for sample preparation and submission. After a minimum of 20 consecutive results, the ADL will plot the results on histograms and submit them to the contractor and AMS for comparison to the contractor's process assessment. The contractor shall notify the AMS agent immediately and declare what immediate corrective and preventative actions will be taken when:*
 - a) *The ADL calculated process average varies more than 1 percent from the contractor's calculated process average results, or*
 - b) *The calculated process capability (C_{pk}/C_{pu}) is less than 1 for results from either the contractor's designated laboratory or the ADL.*
3. *Continuous Improvement - Provided that the above requirements are met after the first 20 lots, on a weekly basis, the AMS agent will direct the contractor when to randomly select independent samples (each consisting of four sample units) from no more than two production lots that are sent to the ADL. The ADL will plot 20 consecutive results (always including the last recorded result) on histograms and submit them to the contractor so that they will conduct process capability assessments on each lot using 20 consecutive results). The contracting officer reserves the right to deem a supplier as unreliable for considering future contract awards when corrective or preventative actions are not adequate or effective.*

F. PATTY WEIGHT, THICKNESS, AND SHAPE

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

1. Patty weight – Target weight will be 3.0 ounces. Acceptable weight tolerance range will be 2.9 to 3.1 ounces.
2. Patty thickness – 5/16 inch (+/- 1/16).
3. Shape - Patties shall be round in shape and waffled or scored on both sides.

G. PREPARATION FOR DELIVERY

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.

1. Packaging and Packing
 - a) Fine Ground Beef (Product Code A608) – Fine ground beef must be vacuum packaged or packaged in casings and sealed. All packages shall be tamper proof. Each package 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.
 - b) Fine Ground Beef (Product Code A609) – Fine ground beef must be vacuum packaged or packaged in casings and sealed. All packages shall be tamper proof. Each package will weigh 1 pound. Forty (40) packages will be placed into each shipping container.
 - c) Fine Ground Beef-Irradiated (Product Code A579) – Fine ground beef must be vacuum packaged in a thermo formed and tamper proof 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. Consideration of the depth, width, and length of the containers shall be considered depending on the type of ionizing radiation is used.*
 - d) Coarse Ground Beef (Product Code A594) - 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.
 - e) *Ground Beef Patties (Product Codes A616, A626, and A627) - Patties must be placed into primary containers following either of the following methods. Separation material between patties is not required provided the IQF patties do not stick together at the time of shipment.*
 - (1) *Flexible Containers - Either four 10-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.*
 - (2) *Fiberboard Containers – When fiberboard primary containers are used, either four 10-pound or two 20-pound fiberboard containers will be placed into each shipping container. Patties may either be:*

- b) Shipping Containers - Commercially marked shipping containers will include the information as follows:
- (1) USDA Shield (at least 2 inches high and appearing on the top of the container or on the principle display panel).
 - (2) Contract Number.
 - (3) The product name shall include no additional disclaimers and qualifiers to the name and code listed in Table 2.
 - (4) Fat Declaration.
 - (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).



Table 2 - Shipping Container Marking Requirements

Product Name that shall appear on the label	Product Code
Ground Beef <u>1/</u>	A608
Ground Beef, 1- Pound Packages <u>2/</u>	A609
Ground Beef – Irradiated <u>1/</u>	A579
Coarse Ground Beef to be Further Processed into Cooked Items	A594
Ground Beef Patties <u>1/</u>	A626
<i>Beef Patties and SPP Patties</i> <u>1/</u> <u>3/</u>	A616
Ground Beef Patties-Irradiated <u>1/</u>	A578
Ground Beef Patties NTE 10 percent fat <u>1/</u>	A627

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

2/ UPC Shipping Container Code Required.

3/ The ingredient statement must include the identification *of the added hydrated SPP*.

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

- c) Bar Code - For shipping containers with Ground Beef, 1-Pound Packages, a Universal Product Code (U.P.C.) code and symbol will be required. A code, called Interleaved 2 of 5 (I 2/5) bar code, will appear on each shipping container in accordance with the U.P.C. guidelines published by the Uniform Code Council (UCC). A 14 digit I 2/5 bar code, which consists of the number 10715001016093, must appear on the lower corner of one side panel of each shipping container. The U.P.C. guidelines describe the requirements for the proper placement, printing, readability, and scanability for the bar coding. The complete code must be printed in machine and human readable form. The start and stop indicators must be included in the bar code symbols. Package manufacturers, printers, and film master suppliers are familiar with this symbology. The Department of Agriculture has acquired a unique manufacturer’s identification number for this application, therefore, the Contractor need not join the UCC.
5. Palletized Unit Loads – All product shall be stacked on new or well-maintained pallets and palletized with shrink wrap plastic.

6. Total net weights per delivery unit - The delivery units for each of the respective product codes are as follows:

Product Code	Pounds Per Delivery Unit
A608, A609, A579	40,000
A626, A616, A627, A578	38,000
A594	42,000

Note: No tolerances will be allowed.

H. USDA QUALITY ASSURANCE

1. *Warranty and Complaint Resolution -*

- a) *Warranty – The contractor will warrant that the product complies with all specification requirements, technical proposal declarations, and provisions set forth in Announcement LS-10.*
- b) *Complaint Resolution – Customer complaint resolution procedures shall be included in the technical proposal. These procedures shall include: a point of contact, investigation steps, intent to cooperate with AMS, and product replacement or monetary compensation. The procedures will be used to resolve product complaints from recipient agencies or AMS.*

2. AMS Monitoring and Production Assessment -

An AMS Meat Grading and Certification Branch agent must be present during the grinding process for all USDA ground beef contracts. The AMS agent will monitor and verify the processing steps, quality assurance activities, and corrective actions to assure that all requirements outlined in the approved technical proposal are complied with. The AMS agent will be conducting the monitoring and production verification in accordance with applicable MGC instructions. Any deviations to contractual requirements will be reported to the Contracting Officer.

3. *Control of Non-Conforming Product*

The contractor must have documented procedures that assure non-conforming product is identified and controlled to prevent unintended use or delivery to USDA.

4. Checkloading -

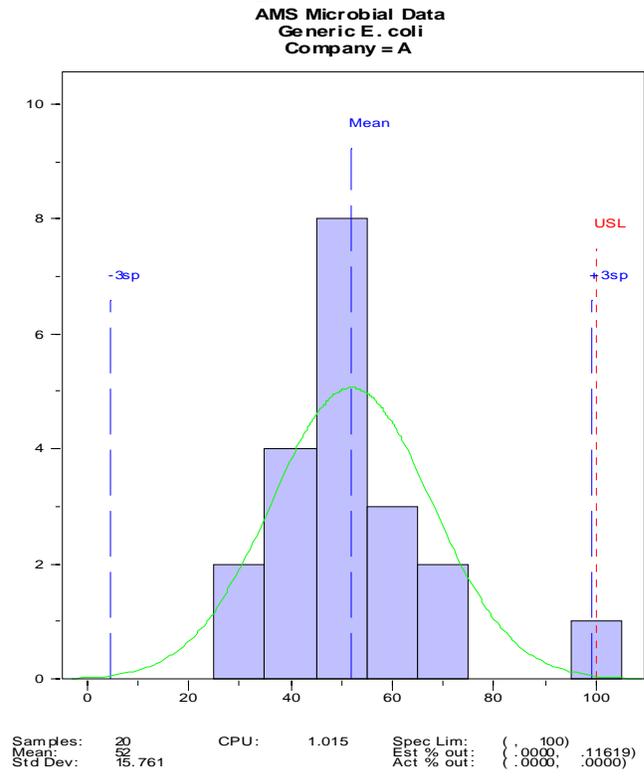
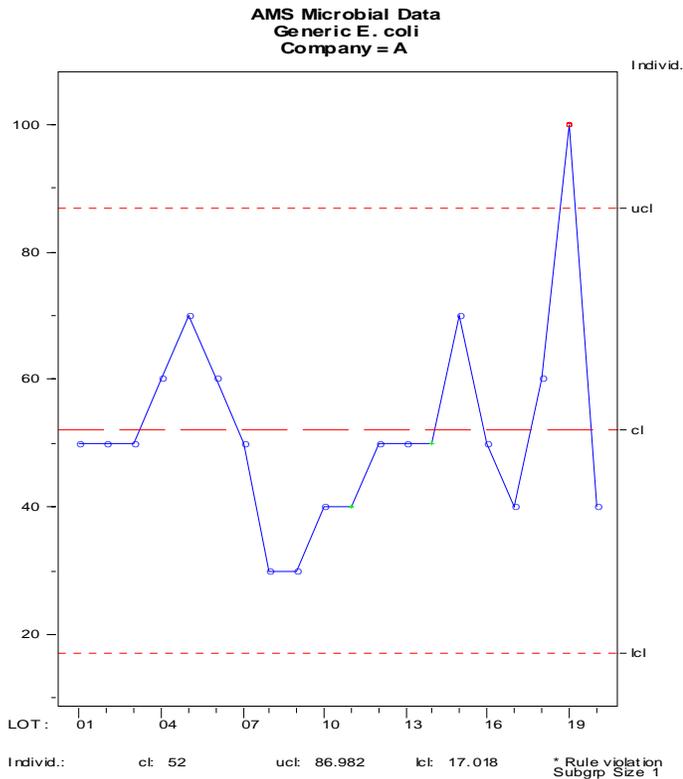
The contractor has the following checkloading options:

- a) Option 1 - At the request of the Contractor, AMS agents (on a fee basis) will checkload the product at the time of shipment and perform the following duties:
 - (1) Assure product temperature is at or below 0° F at the time of shipment.
 - (2) Conduct a final examination of condition of shipping containers that will be limited to visually scanning (without destructive sampling) the delivery unit for defects which may have occurred during handling and storage (e.g., crushed, torn, dirty, stained, etc.). All defective containers are unacceptable and must be corrected, removed or replaced, as applicable.
 - (3) Supervise the loading and sealing of each truck.
 - (4) Issue a final Acceptance Certificate, thereby allowing the Contractor to immediately submit invoice for payment to USDA. The AMS agent shall set forth on the original certificate the following:
 - (a) Contract number
 - (b) Notice-to-Deliver number
 - (c) Destination
 - (d) Name of product
 - (e) Product Code
 - (f) Production lot number(s) and the date each lot was produced along with the shipping container and primary container code(s) and the code used that provides traceability to production lot and date.
 - (g) Count of shipping containers and total net weight in each production lot.
 - (h) Total net weights per delivery unit
 - (i) Identity of conveyance (numbers and letters, seals, license, etc.) as applicable
- b) Option 2 - If the Contractor chooses to not have an AMS agent perform checkloading at the time of shipment, invoices for payment must be supported by:
 - (1) a recipient's signature on the bill of lading;
 - (2) a consignee's receipt evidencing date shipped and received; or
 - (3) other commercial receipt evidencing delivery of the product.

In all cases the information contained in the issuance of the final certificate "a through i" in the option 1 section and a statement that: "Product conforms with the TRS-GB-2004" must be included.

APPENDIX A

Example Statistical Process Control Charts and Histograms



The above control chart and histogram are examples for illustrative purposes.

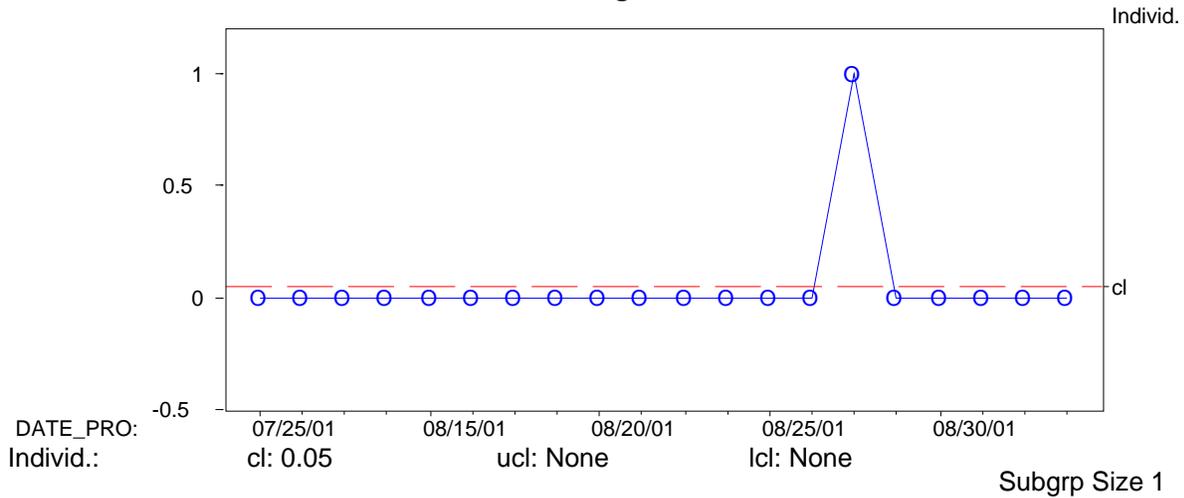
The control chart will have statistically derived upper control limits (ucl) and lower control limits (lcl) (+/- 3 times the standard deviation of the process average), and the central line (cl) value (process average, mean or x-bar). Since the subgroup size for microbial test is one (1), the calculation for standard deviation will be on individual measures.

The process capability value (C_{pk} or C_{pu}), is below the histogram chart (capability report). Since there are no lower specification limits within USDA microbial requirements and fat requirements for ground beef patties NTE 10% fat, the C_{pu} will be used. The C_{pk} will be used for fat requirements that have a lower and upper specification limit. The applicable upper specification limits (USL) along with the capability limits (+/- 3 times the standard deviation of the individual measures (+/- 3sp)) will be displayed within the histogram. USL for microbial requirements will be found in Appendix B and Appendix C. The calculation for the C_{pu}/C_{pk} for microbial and fat requirements involves two steps:

Calculation of C_{pu} with an upper specification limit only	
Step 1. The first calculation will determine the z value:	Step 2. The Z value divided by 3 will calculate the process capability (C_{pu}).
$Z \text{ value (upper)} = \frac{USL - \text{Process Average}}{\text{Standard Deviation of individual measures}}$	$C_{pu} = \frac{Z \text{ value (upper)}}{3}$
Calculation of C_{pk}	
Step 1. The first calculation will determine the min z value:	
$Z \text{ value (upper)} = \frac{USL - \text{Process Average}}{\text{Standard Deviation}}$	$Z \text{ value (lower)} = \frac{\text{Process Average} - LSL}{\text{Standard Deviation}}$
Step 2. The min Z value divided by 3 will calculate the process capability (C_{pk}).	$C_{pk} = \frac{Z \text{ value (min)}}{3}$

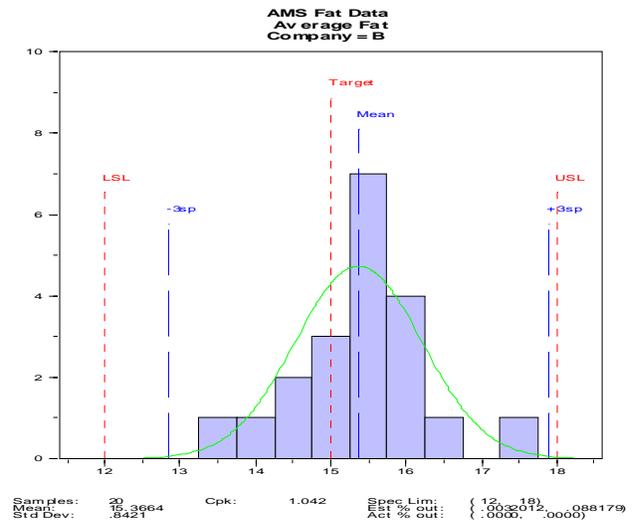
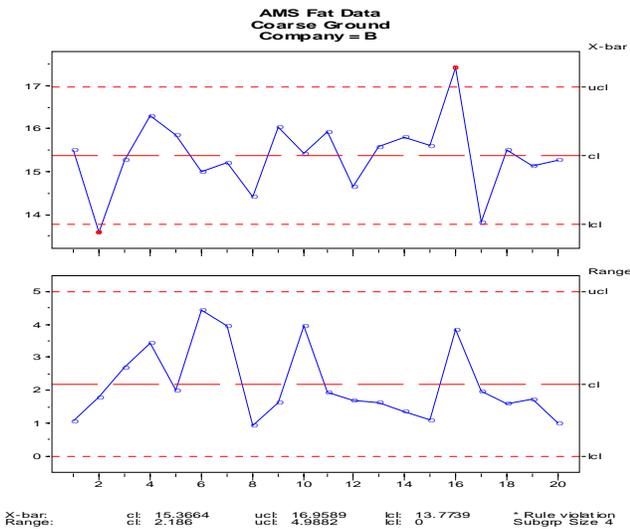
Control Chart

AMS Microbial Data SY 2001- 2002 Salmonella 1 = Positive, 0 = Negative



The central line (cl) in the above control chart indicates the incidence of positive *Salmonella* results (5.0%). The results are plotted with the positive results for *Salmonella* as 1 and negative results as 0.

The charts below are illustrative of the x-bar and range control chart and the histogram that shall be used for analysis of fat test results.



APPENDIX B

AMS BONELESS BEEF PROCESS REQUIREMENTS FLOW CHART

Quality Control Program – Prior to supplying boneless beef destined for USDA, the documented quality control program as described within the technical proposal must be approved by AMS. AMS will audit the program.

Process Assessment Status - A process assessment involves sampling and testing of 20 consecutive lots of boneless beef for USDA ground beef. Boneless meat may be processed into ground beef destined for USDA prior to receipt of test results. However, when results for *Salmonella* and *E. coli* O157:H7 are positive, such production lots of ground beef will not be allowed delivery to USDA.

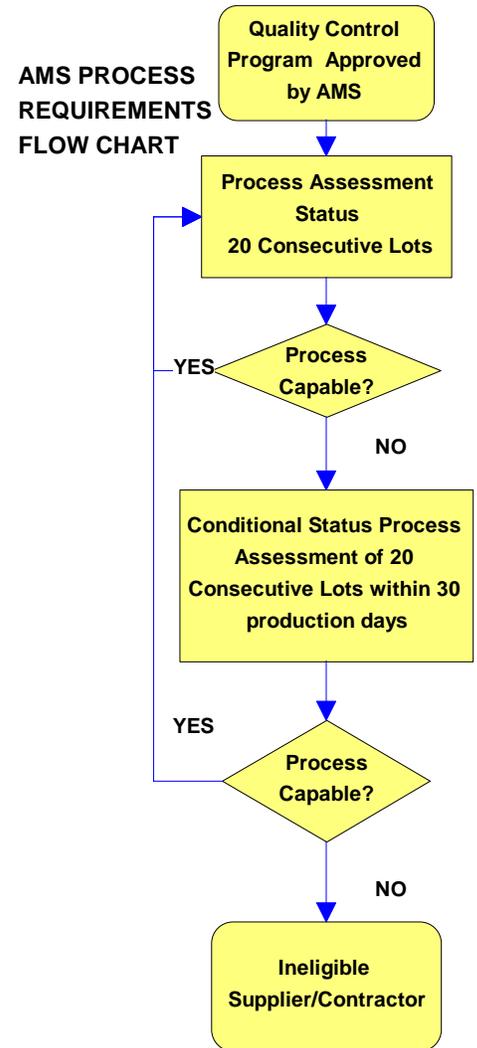
Process Capable? – Results of twenty (20) consecutive lots (which will include the last recorded result) will be used to determine the process capability value (C_{pu}) and central limit value (cl). Test results will be plotted on control charts and histograms (See APPENDIX A). A process is not capable when:

- The Cl and C_{pu} values do not meet the levels specified in the table below;
- Two (2) or more results exceed the critical limits in the table below; or
- The C_{pu} value after 2 or more results is negative.

Conditional Status – Boneless beef production lots with test results that exceed any Critical Limits listed in the table below may not be used in ground beef that is delivered to USDA. To regain process assessment status, the boneless beef supplier and/or the contractor must have 20 consecutive results that meet the C_{pu} and cl levels within 60 calendar days.

Process Capable? - While in Conditional Status – The supplier will be deemed ineligible when the process is not capable.

Ineligible Supplier/Contractor – An Ineligible Boneless Beef Supplier will not be allowed to supply boneless beef to any USDA contracted grinding facilities until corrective actions have been implemented, proven effective, and a satisfactory AMS assessment audit has been completed.



AMS MICROBIAL REQUIREMENTS FOR BONELESS BEEF

Microbial Test	Upper Specification Limits	Critical Limits	Cl or C_{pu} Value
Standard Plate Count	100,000/gram	500,000/gram	$C_{pu} \geq 1$
Total <i>Coliforms</i>	500/gram	2,500/gram	$C_{pu} \geq 1$
<i>E. coli</i>	100/gram	1,000/gram	$C_{pu} \geq 1$
<i>Salmonella</i>		Positive Results/25 grams	$Cl \leq 0.05$
<i>E. coli</i> O157:H7		Positive Results/325 grams	$Cl \leq 0.05$

APPENDIX C

AMS 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 technical proposal must be approved. AMS will audit and monitor the program.

Process Assessment Status - A process assessment involves sampling and testing of 20 consecutive lots of ground beef destined for USDA contracts for Standard Plate Count, Total *Coliforms*, *E. coli*, Coagulase Positive *Staphylococci*, *Salmonella* and *E. coli* O157:H7. *Production lots of ground beef will not be allowed delivery to USDA when results for Salmonella or E. coli O157:H7 are positive or the critical limits are exceeded for Standard Plate Count, Total Coliforms, or E. coli. When the upper specification limits are exceeded for Coagulase Positive Staphylococci, a reserve sample shall be submitted to the laboratory for testing. If the results for the reserve sample exceed the critical limits for Coagulase Positive Staphylococci, the production lot will not be allowed delivery to USDA.*

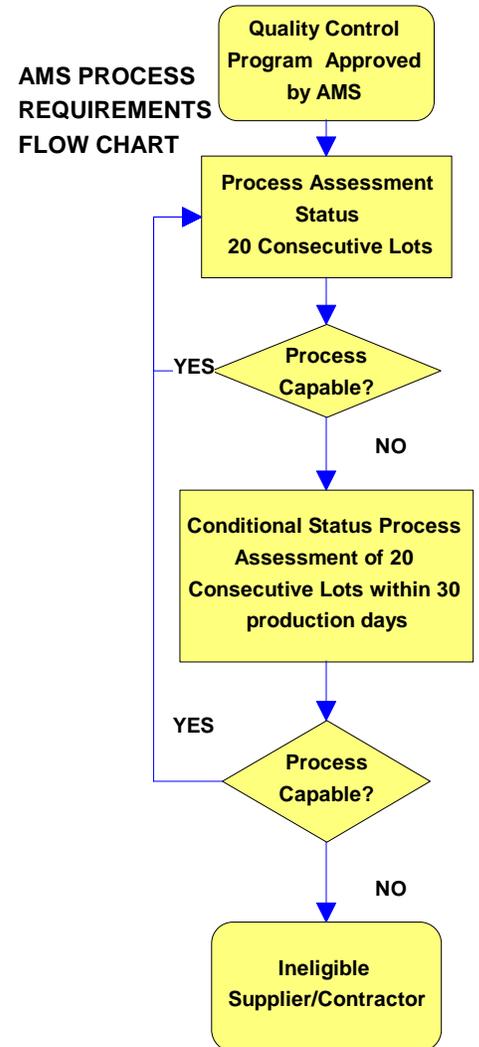
Process Capable? – Results of twenty (20) consecutive lots (which will include the last recorded result) will be used to determine the process capability value (C_{pu}) and central limit value (cl). Test results will be plotted on control charts and histograms (See APPENDIX A). A process is not capable when:

- The C_{pu} values do not meet the levels specified in the table below;
- Two (2) or more results exceed the critical limits for Standard Plate Count, Total *Coliforms*, or *E. coli* in the table below;
- The C_{pu} value after 2 or more results is negative; or
- The Cl values do not meet the levels specified in the table below for *Salmonella* and *E. coli* O157:H7.

Conditional Status – Ground beef with test results exceeding the critical limit for Standard Plate Count, Total *Coliforms*, or *E. coli* will not be allowed delivery to USDA. To regain process assessment status, the contractor must have 20 consecutive results that meet the C_{pu} and cl levels within 60 calendar days.

Process Capable? - While in Conditional Status – The contractor will be deemed ineligible when the process is not capable.

Ineligible Supplier/Contractor – An ineligible Ground Beef Contractor will not be allowed to supply ground beef products under USDA contracts until corrective actions have been implemented, proven effective, and a satisfactory AMS assessment audit has been completed.



AMS MICROBIAL REQUIREMENTS FOR GROUND BEEF

Microbial Test	Upper Specification Limits	Critical Limits	Cl or C_{pu} Value
Standard Plate Count	100,000/gram	500,000/gram	$C_{pu} \geq 1$
Total <i>Coliforms</i>	500/gram	2,500/gram	$C_{pu} \geq 1$
<i>E. coli</i>	100/gram	1,000/gram	$C_{pu} \geq 1$
Coagulase Positive <i>Staphylococci</i>	500/gram	N/A	N/A
<i>Salmonella</i>		Positive Results/25 grams	$Cl \leq 0.05$
<i>E. coli</i> O157:H7		Positive Results/325 grams	$Cl \leq 0.05$

APPENDIX D

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, E. coli, and Coagulase Positive Staphylococci after final grinding and before freezing and tested for Salmonella and E. coli O157:H7 after completion of the irradiation process.

APPENDIX E

Glossary of Terms

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.

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

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 1).

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

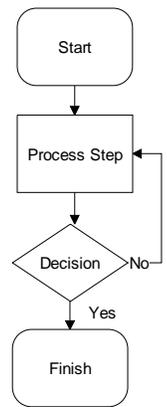
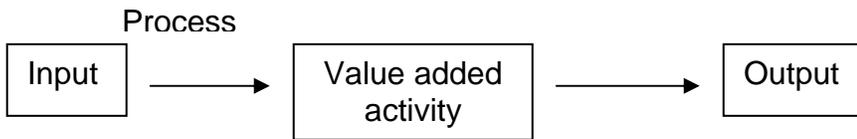


Figure 1

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 2)

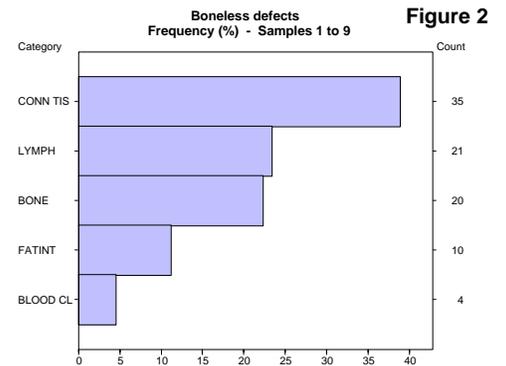


Figure 2

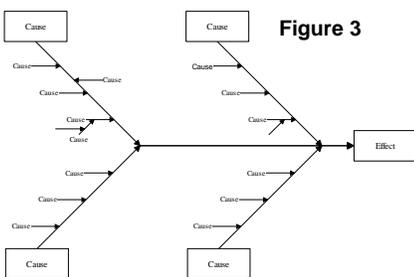
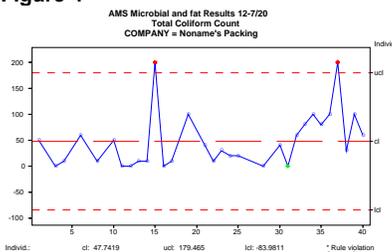


Figure 3

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 3)

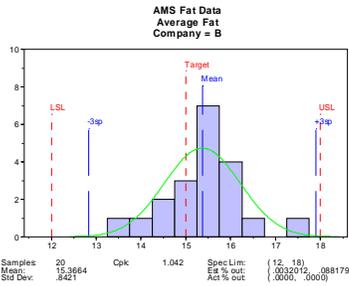
Figure 4



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. We recommend microbial test results be plotted on control charts for individual measurements with moving range and fat test results be plotted on control charts featuring average and range of the fat test results (See Figure 4).

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.

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 5).



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 5).

Figure 5

C_{pk} – Process Capability Value (C_{pk}) is a capability analysis index used to determine if a process can meet specification limits. A C_{pk} value of 1 indicates that the process is producing at least 99.73% within the specification limit. C_{pk} values of 1 for many organizations have become the minimum requirement. However, the larger the C_{pk} values the better. C_{pk} 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 C_{pk} will not involve relating the process average with a lower specification limit.

C_{pu} - Process Capability Value (C_{pu}) is the same as C_{pk} except that there is no lower specification limit. The process performance index is correctly known as a Centered Process Capability Upper Specification Limit only (C_{pu}) (See Figure 5).

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.

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.