USDA Agricultural Marketing Service

APPROVED

FEDERAL PURCHASE PROGRAM SPECIFICATION (FPPS) FOR FRESH CHILLED, BONELESS BEEF FOR FURTHER PROCESSING INTO FULLY COOKED ITEMS

Agricultural Marketing Service (AMS)
Livestock, Poultry, and Seed (LPS) Program
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Supersedes: FPPS BB March 2015 – Changes from previous requirements in blue

Effective: April 2016

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100   SCOPE

101   This FPPS – Boneless Beef (BB) – 2016 is for use by a contractor of the Department of Agriculture (USDA), AMS, Commodity Procurement (CP) Staff to deliver fresh-chilled (never previously frozen) boneless beef for further processing into fully cooked items.

200   APPLICABLE DOCUMENTS

210   The following documents are incorporated as part of this USDA, FPPS-BB-2016:

210.1   Quality Assessment (QA) Division Procedures Manual.

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

210.3   Applicable Supplement to AMS Master Solicitation.

300   CHECKLIST OF REQUIREMENTS

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

302   Substitution Programs - Contractors that may produce boneless beef for processing into fully cooked items for direct sales to further processors that hold QA Division substitution plans shall declare this in their technical proposal. It is the contractor's responsibility to ensure that substitutable boneless beef raw materials sold to further processors for use as substitutable product are produced and managed according to provisions outlined in Section 301.

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310   MATERIAL REQUIREMENTS FOR FRESH-CHILLED BONELESS BEEF

311   Domestic Origin and Harvest (Slaughter) Requirements – The contractor's quality control program shall be documented and have received a satisfactory onsite capability assessment by QA Division prior to supplying materials for the program. Additionally, each establishment shall be subjected to verification audits conducted by QA Division during production activities that demonstrate its adherence to the documented program. Boneless beef shall be derived from cattle harvested at establishments that comply with the following origin and harvest requirements.

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

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

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

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

316   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.

317   Residue Prevention – Harvest and production establishments shall have a HACCP system to control veterinary drug, pesticide, and environmental contaminant residues per FSIS regulations. Helpful information is available in the FSIS Compliance Guide for Residue Prevention 2013.

318   Boneless Beef Requirements

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

318.2   Handling - All boneless beef shall be maintained in excellent condition. The contractor's technical proposal shall include detailed production scheduling that addresses time and temperature controls necessary to maintain excellent condition of the boneless beef.

318.3   Boneless beef commonly referred to by the industry as XF trimmings (e.g., Beef Fat with Visible Lean) shall not be allowed as a standalone raw material source.

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

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

318.4.2   All bone, cartilage, shoulder tendon, elbow tendon, silver skin from the outside round, *sacrosciatic* ligament, opaque periosteum, serous membrane (*peritoneum*), tendinous ends of shanks, *patellar* ligament (stifle joint), *gracilis* membrane (from the inside round), *achilles* tendon, back strap and *abdominal tunic*.

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

318.6   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.

318.7   Microbial Testing – All lots of fresh chilled boneless beef shall be tested for all indicator microorganisms listed in APPENDIX B. All samples shall be sent to the AMS designated laboratory (ADL).

318.7.1   Sample Preparation and Handling - The ADL shall be responsible for supplying procedures for sample preparation, and submission. The ADL shall require contractors to submit this form as an official record with each sample. Samples submitted for boneless beef produced under a substitution plan shall be appropriately identified on the ADL sample submission form. The ADL shall also be responsible for supplying shipping supplies (including sampling bags and shipping materials), to each contractor. Contractor's technical proposal shall include and describe sample collection and preparation procedures provided by the ADL.

318.7.2   Sample Selection

318.7.2.1   For Beef Manufacturing Trimmings – The composite sample shall be selected as described within FSIS Directive 10,010.1 Revision 4 (N-60 Sections 8, 9 and NOTE).

318.7.2.2   For every lot of beef Manufacturing Trimmings, one sample shall be prepared from five different pieces of trim from five different pieces of beef product. The sample for indicator microorganisms (aerobic plate count, total coliform and generic *E. coli*) shall weigh 25 grams ± 10 percent.

318.7.2.3   Alternative sample collection methods may be used provided they are approved by AMS as equivalent to the manual excision protocols referenced in Section 319.7.2.1. The supplier's technical proposal shall include and describe any proposed alternative sample collection and preparation methods and procedures.

318.7.2.4   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.

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

318.7.3   Testing and Results

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

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

318.7.3.3   The ADL shall record results of all indicator microorganisms' analysis in a format that can be easily captured and analyzed.

318.7.3.4   The ADL shall record all results on spreadsheets and calculate the process capability (CPU) for indicator organism tests performed on production lots as outlined in Section 319.7.4.

318.7.3.5   Any lot that exceeds the critical limit criteria of APPENDIX B shall not be delivered to USDA.

318.7.4   Statistical Process Capability – The statistical process capability of a boneless beef contractor to comply with microbial requirements shall be based on the assessment of calculated process capability (CPU) derived from the individual combo test results representing one 2,000 pound combo lot randomly selected by the ADL from every five consecutive individual 2,000 pound combo lots produced each production day. In the event that a production day concludes with less than five consecutive individual 2,000 pound combo lots, a randomly selected test result shall be utilized from one of the remaining lots. The spreadsheets shall be maintained so that process capability assessment on the 20 lots can be determined as described within APPENDIX B. Test results involving all

boneless beef offered for testing for AMS purchase programs shall be monitored by AMS and the contractor, to determine individual lot acceptance and/or capability of the contractor's process according to APPENDIX B. Ineligible boneless beef contractors may re-enter the program under conditional status provided corrective actions have been submitted for review and approved, implemented and a satisfactory onsite corrective action audit by QA Division has been conducted. Upon notification by the FSCS Division that the plan has adequately addressed the issues that resulted in the ineligible status determination, the boneless beef contractor may re-enter the program under conditional status.

318.7.5   Contractor's Responsibility - The contractor shall 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 QA Division 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 re-enter the program under conditional status provided corrective actions have been submitted for review and have been deemed approved, implemented and a satisfactory onsite corrective action audit by QA Division has been conducted. Upon notification by the FSCS Division that the plan has adequately addressed the issues that resulted in the ineligible status determination the boneless beef contractor may re-enter the program under conditional status.

318.7.6   Supplier requests to remove samples from AMS testing shall be submitted and approved by FSCS Division prior to sample removal from ADL testing.

318.8   Lots of boneless beef tested for indicator microorganisms only (as described in Section 318.7) shall not be diverted for use in ground beef products for delivery to USDA under FPPS-GB or for Type II under FPPS-CGB.

320   STATE OF REFRIGERATION

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

330   FAT LIMITATIONS

331   Requirements - The contractor shall establish a target average of 15 percent fat of all boneless beef destined for USDA. The upper and lower specifications limits shall 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 shall not be shipped to USDA.

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

333   Documentation - The contractor shall declare within its technical proposal:

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

333.2   The laboratory and a test method,

333.3   Data management and storage of fat results,

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

334   Assessment by AMS - AMS reserves the right to:

334.1   Check production records of the recipient where the contractor's boneless beef is further processed;

334.2   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

334.3   Deem a contractor unreliable for failure to comply with the above requirements.

340   PACKAGING AND PACKING

341   The contractor's technical proposal and process shall 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 shall have procedures for verifying the net weight of shipping containers.

342   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 covered so that the container arrives at the destination intact.

343   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.

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

344.1   The following statement: "Complies with FPPS-BB-2016 - Boneless Beef for Further Processing into Fully Cooked Items":

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

344.3   USDA Shield (at least 2 inches high).

344.4   Purchase Order Number.

344.5   Fat Declaration.

344.6   The appropriate material number listed in the table below for each of the items:

Item	Material Number
Boneless Beef Combo, Fresh	100155
Boneless Beef Combo, Grass Fed, Fresh	110091

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

345   Total net weights per delivery unit - The delivery unit shall be 40,000 pounds.

346   Sealing - All products shall be delivered to AMS assigned destinations under seal with tamper proof, tamper resistant, serially numbered, high security seals that meet the American Society for Testing and Materials Standard (ASTM) F 1157-04 and/or the International Organization for Standards (ISO) 17712-2010 as required under the Master Solicitation. Seals shall be $\geq \frac{1}{8}$th inch diameter cable, high-security bolt, or equivalent.

400   CONTROL OF NON-CONFORMING PRODUCT

401   The contractor shall include a plan and supporting documentation to assure that non-conforming product is not delivered under USDA contracts. The plan shall address 1) control and segregation of non-conforming product, 2) removal of any USDA markings, and 3) disposition of non-conforming product, including documentation of final disposition (e.g., diverted to cooked product or destroyed).

500   QUALITY ASSURANCE

510   Warranty and Complaint Resolution

511   Warranty – The contractor shall guarantee that the product complies with all specification requirements, technical proposal declarations, and provisions set forth in the Master Solicitation.

512   Complaint Resolution – Customer complaint resolution procedures shall be included in the technical proposal. These procedures shall include: a point of contact, investigation steps, intent to cooperate with AMS, and product replacement or monetary compensation. The procedures shall be used to resolve product complaints from recipient agencies or AMS.

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

520.1   Purchase Order Number/Purchase Order Line Item Number;

520.2   Sales Order Number/Sales Order Line Item Number;

520.3   Destination of shipment;

520.4   Name of Product and applicable Material Number;

520.5   Shipping Date;

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

520.7   Count of shipping containers and total projected net weight in each production lot;

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

520.9   Contractor certification that product conforms with the applicable specification (FPPS-BB-2016);

520.10   Count and projected net weight verified and;

520.11   Signature of company official responsible for checkloading.

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APPENDIX A

DATA ENTRY AND PROCESS CAPABILITY VALUE

Data Entry

The ADL shall record microbiological test results on spreadsheets and make those spreadsheets readily available to AMS and its contractors/suppliers. Quantitative (plate count) results shall be expressed as colony forming units (CFU) per gram or per ml reflecting the original sample measurement. Test results shall be entered as a whole number (i.e., no decimal places, no preceding < (less than) symbol).

The ADL shall provide the calculated process capability values (CPU, 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) shall be calculated by the ADL. CPU shall be used for microbiological tests, given these requirements only have an upper specification limit. Cpk shall be used for fat testing requirements that have an upper and lower specification limit (see **Section 332**). The upper specification limits (USL) for microbiological requirements are in APPENDIX B. The calculations for CPU and Cpk are as follows:

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

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 shall have received a satisfactory onsite capability assessment by QA Division. AMS shall audit and monitor the program. The quality control program shall specifically address management of microbial data to comply with the AMS Process Requirements Flow Chart and the following descriptions.

Process Assessment Status - A process assessment involves sampling and testing of 20 consecutive lots (which shall include the last recorded result as defined within APPENDIX C) of boneless beef (see **Section 319.7.4**) destined for USDA contracts for the organisms listed within the table below.

Process Capable? – Flow chart decision step that involves test results for up to 20 consecutive lots (which shall include the last recorded result) recorded in spreadsheets, where the process capability (CPU) value is calculated (See APPENDIX A) for evaluation. A process that is not capable shall be declared to the FSCS Division immediately when results are known and shall result in switching from **process assessment** status to **conditional status** or switching from **conditional status** to **ineligible status** when:

➢ The CPU values do not meet the levels specified in the table below;

➢ Two results exceed any of the critical limits in the table below; * or

➢ After 2 or more results, the CPU value is negative.*

    *Immediate action shall be taken prior to completion of 20 lots.

AMS PROCESS REQUIREMENTS FLOW CHART

Conditional Status –To regain **process capable** status, the boneless beef contractor shall notify the FSCS Division that the process is not capable, and then have 20 consecutive results that meet the **'Process Capable'** criteria within 60 calendar days or in accordance with a production schedule pre-approved by the FSCS Division. Change in status begins after a cause and effect analysis has been performed and corrective actions have been implemented. The boneless beef contractor may also declare itself ineligible at any time.
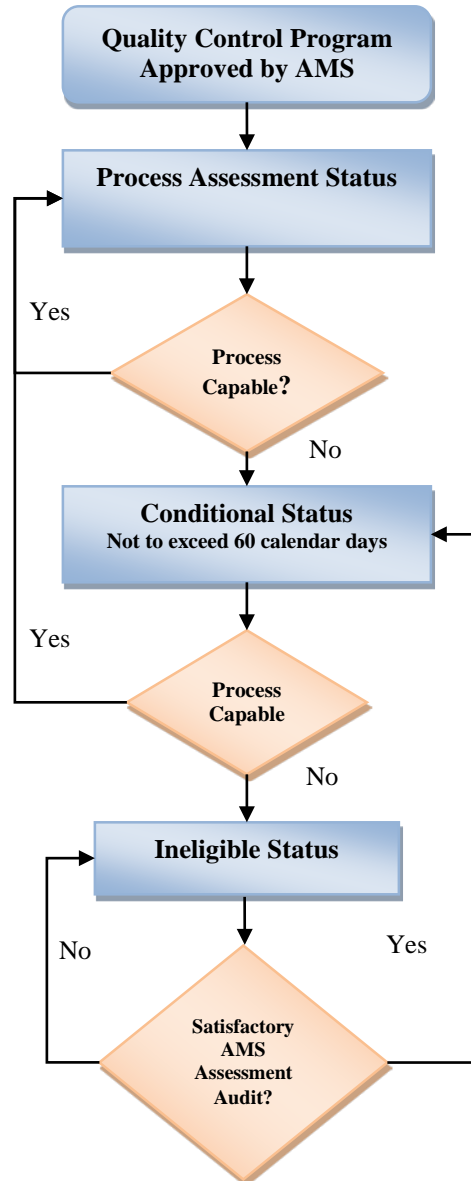
Ineligible Supplier/Contractor – An ineligible boneless beef contractor shall not be allowed to supply boneless beef to USDA until a cause and effect analysis has been performed and corrective actions have been submitted to AMS for review and approved, implemented and a satisfactory AMS assessment audit has been completed. Once satisfactorily becoming eligible, subsequent production shall be under **Conditional Status.** The AMS FSCS Division reserves the right to declare a boneless beef contractor **ineligible** at any time.

AMS MICROBIAL REQUIREMENTS FOR BONELESS 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**
E. coli	100 / gram	500 / gram	**CPU ≥ 1**

GLOSSARY OF TERMS

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

Figure *1*
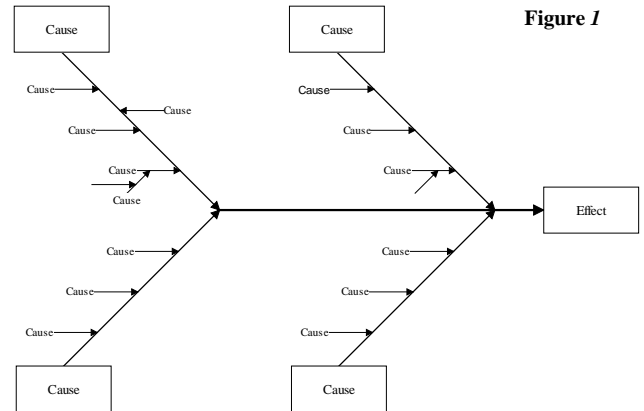
"Cleanup to cleanup" - Part of a HACCP program that the establishment has in place to support statistically distinguishing one portion of production from another. Production destined for USDA contracts is to be commenced on clean equipment. However, "cleanup to cleanup" without other supporting documentation 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

Figure *2*

results may be plotted on control charts featuring average and range of the fat test results (See Figure 2).

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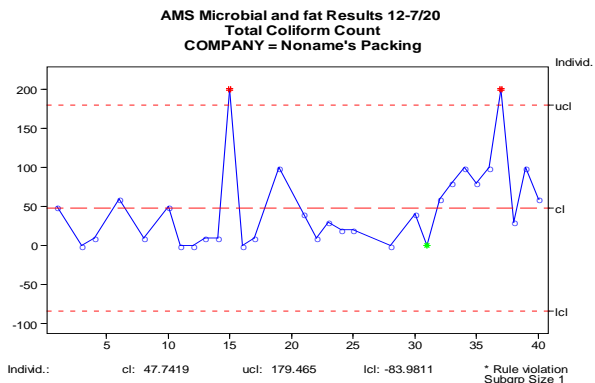**Cpk** – Process Capability Value (Cpk) is a capability analysis index used to determine if a process can meet specification limits. A Cpk value of 1 indicates that the process is producing at least 99.73% within the specification limit. Cpk values of 1 for many organizations have become the minimum 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 shall 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).

Figure *3*

Excellent Condition - All product shall be in excellent condition (e.g., exposed lean and fat surfaces shall be of a color and bloom normally associated with the class, grade, and cut of meat and typical of meat which has been properly stored and handled). Cut surfaces and naturally exposed lean surfaces shall show no more than slight darkening or discoloration due to dehydration, aging, and/or microbial activity. The fat shall show no more than very slight discoloration due to oxidation or microbial activity. No odors foreign to fresh meat shall be present. Changes in color and odors characteristically associated with vacuum packaged meat in excellent condition shall be acceptable. Also, product shall show no evidence of mishandling. Beef shall be maintained in excellent condition through processing, storage, and transit.

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).

Figure *4*

Histograms – The histogram shows a pictorial representation of the frequency of distribution of microbial test results over time. Sometimes referred to as process capability charts, histograms compare the distribution of the test results with AMS specification requirements. Use histograms along with control charts to better understand process capability (See Figure 3).
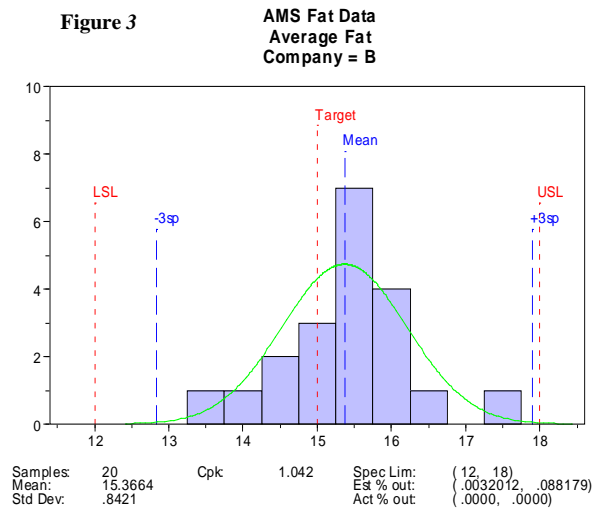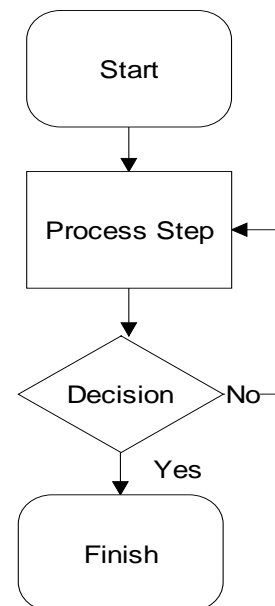
Pareto Diagrams – The Pareto diagram ranks the importance of different non-conformities. Typically, non-conformities are measured against frequency of occurrence. The Pareto analysis is helpful in identifying and justifying which problems shall need to be solved first (see Figure 5).
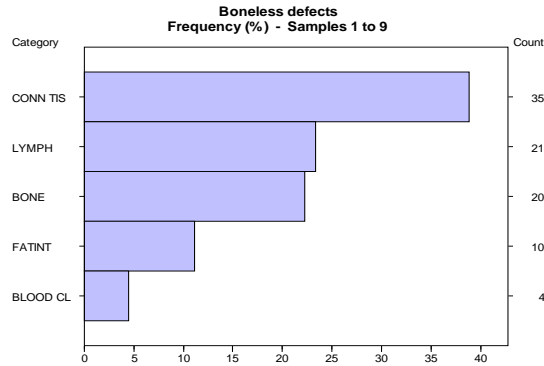
Process – For the purpose of this specification, a single process involves the input of a raw material on a production line with a value added activity resulting in a output that can is be further processed or meet a customer's need. A complex process involves output being another processes input. The production of ground beef is a complex process.

Boneless defects
Frequency (%) - Samples 1 to 9

Category		Count
CONN TIS		35
LYMPH		21
BONE		20
FATINT		10
BLOOD CL		4

0   5   10   15   20   25   30   35   40

Figure 5

Process Capability Assessment on 20 consecutive lots – For the purpose of this specification, process capability assessments are conducted on data results from each lot for fat and microbial requirements. A process assessment involves sampling and testing of 20 consecutive lots (which always includes the last recorded result). Information from each lot shall be evaluated with information from the preceding 19 lots (i.e., while in process assessment of the first 20 lots, the process was found to be capable, then assessment shall continue on lot numbers 2-21). This has often been referred to as a 'Rolling 20'. This assessment takes into account process variations that may be attributed to product, management, sources, and time (see Figure 6).

Figure 6

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 |
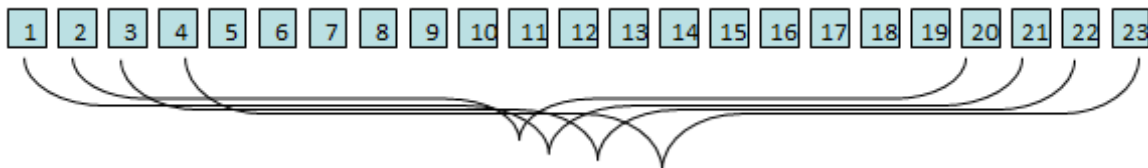
Random Sampling – A process of selecting a sample from a lot whereby each unit in the lot has an equal chance of being selected and is representative of the lot's production.

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 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 FPPS-BB. The specification limits reflect customer needs (See Figure 3).