COMBAT RATION ADVANCED MANUFACTURING TECHNOLOGY DEMONSTRATION (CRAMTD)

"Generic Inspection-Statistical Process Control System for a Combat Ration Manufacturing Facility" Short Term Project (STP) #3

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1.0 CRAMTD Final Report STP #3 Results and Accomplishments

1.1 Introduction and Background

Up to now most quality inspection systems for combat rations focus on out of specification material but do not provide control strategies to prevent defects from occurring. New inspection systems require, however, the inclusion of Contractor Inspection Systems (CIS) and Statistical Process Control (SPC). The implementation of Computer Integrated Manufacturing (CIM) into combat ration manufacturing requires the effective control of the manufacturing process through setting of parameters at appropriate steps in the process and through the inspection of ingredients and packaging materials prior to and during processing. The overall objective of this STP is to design, develop and demonstrate a plan for automated manufacturing process controls and in-process inspection for the manufacture of combat rations such as tray pack and MRE pouches using beef stew as demonstration product.

The defined process and control plan is to be implemented in CRAMTD Phase II for production of Beef Stew in MRE pouches and Beef Chunks with Gravy in tray-pack cans at the demonstration site.

1.2 Results and Conclusions

Following a literature search, which is posted on the PFMIS BBS as a hypertext database, key processes in the manufacture of Combat Rations were characterized and their impact on overall quality defined. Included were precooking (oven and boiling water), beef yield during retort, vegetable quality following retort, starch selection, and microbial activity.

The Statistical Process Control Plan for CRAMTD was approved by DPSC and a final SPC Manual released. Also developed and released are a cookbook for Beef Chunks and Gravy in tray-packs and the on-line quality control procedures. These will serve as the basis for demonstration runs during CRAMTD Phase II. In addition to the manuals described above, computer software to assist in the preparation of the Statistical Process Control Plan was developed.

Concepts and a strategy for establishing a computer automated process/quality control system were developed. One conclusion of the examination of SPC is that production engineers need to place more effort on off-line process design in order to define a robust process. Several new concepts were examined as advanced on-line sensors. Near-infrared (NIR) was found to be a feasible technique for determining the fat content of beef chunks. A prototype high temperature moisture probe developed in the CAFT In-Line Sensors basic research program was satisfactorily tested in the Enersyst Jet Sweep Oven.

1.3 <u>Recommendations (3.3.4.5)</u>

Only a limited number of parameters which could be identified with food quality can presently be quantitatively measured for use as quality control items. Viscosity was one such item and consideration can be given to in-line viscomiters. It was recommended that a significant program be initiated to quantify qualities relevant to food manufacturing control. Such a program was initiated, "Quality Quantification and Enhancement of Combat Rations". The stated objective of that program was: "Achievement of combat ration quality enhancement necessitates defining quality, understanding the basis of quality factors, and controlling the processes used to produce combat rations. The underlying hypothesis is that the quality of food can be quantitatively described by a reasonably small set of measured characteristics and appropriate mathematical models.

The control strategies identified in STP 3, such as Statistical Process Control, should be considered and implemented and where necessary additional control strategies proposed and evaluated to ensure optimal control over the process and the product. In order to demonstrate effective inspection, tracking and control of the entire CRAMTD process, key hardware and computer software needs to be identified, acquired and implemented. On June 30, 1992 STP 12 "Implementation of Sensors and Quality Control Strategies in the Integrated Manufacturing System" was proposed and awarded on September 30, 1992.

As described in the analysis of advanced process control strategies, if a process is poorly designed or the product has low producibility, the statistical parameters included in SPC control will be of little avail toward producing the desired quality. One of the objectives of STP 20 "Dual-Use and Manufacturabilty" was proposed on May 31, 1994 as to develop a measure of the ability of a food manufacturing process to produce products within a specified maximum defective percentage. STP 20 was awarded August 31, 1994.

2.0 Program Management

STP#3 was a three-phase work activity with a review about one year into the project. The three phases had the following general objectives:

- Phase 1: Prepare Quality Control Manuals for Phase I demonstration site.
- Phase 2: Provide methodology for the preparation of SPC plans for other combat rations and provide instructional materials for the preparation of SPC plans to combat ration producers.
- Phase 3: Develop a concept and strategy for establishing a generic computer automated process/quality control system.

Detailed objectives, statement of work and CRAMTD personnel responsibilities are described in the Technical and Cost proposals for STP #3.

Following completion of STP #8 "Horizontal Form/Fill/Seal Machine". Demonstration of pouch processing including pouch qualification was assigned to STP #3.

2.1 Summary of STP Accomplishments

- The beef stew quality literature search was converted to a hypertext document and posted as an interactive document on PFMIS BBS.
- Precooking in the air impingement oven resulted in improved quality of beef chunks as compared to precooking in boiling water.
- A method was developed and evaluated for testing samples of raw beef to assess probable shrinkage during production processing.
- CRAMTD product scored higher than three commercial Beef Chunks and Gravy using Quantitative Descriptive Sensory Analysis.
- Computer tools were developed to solve for the target values of precooked beef and gravy to meet net and drain weights (STP3IE.EXE) and formulation and fill weights of sauce (SAUCE.EXE). Both programs are available for download from PFMIS BBS.
- A production run of 10,000 MRE pouches were found to have defective seal strength. Reynolds Metals identified the cause of failure as due to an adhesive layer between the foil and inner polypropylene layers.
- Under subcontract, NFPA provided HACCP draft manuals for the CRAMTD processes for both Beef stew and Beef Chunks with gravy.
- The SPC Plan for CRAMTD Tray-Pack production was approved by DPSC.
- The "Cookbook" for beef chunks with grvay describes the steps required to determine and control the production settings for each process in the production line.
- The on-line quality control procedures for producing beef chunks with gravy were determined and the control limits established.
- Version 1.0 of the Statistical Process Control Plan Preparation software was developed. Available diskettes include a copy of the approved CRAMTD Beef Chnks with Gravy Plan.
- Analysis and comparisons of SPC with the Taguchi method for quality control concluded cites the deficiency of the SPC control charts in not including the process capabilities.
- Near-infrared spectroscopy was adapted to measuring the fat content of beef chunks and also water content.
- Preliminary feasibility was demonstrated for a high temperature moisture probe for use in convection ovens.

- Twenty-six Technical Working Papers were written as part of this Short Term Project and are listed as Appendix 4.2.
- Recommended three Short Term Projects (which were funded) and a new Basic Research Program (also funded).

3.0 Short Term Project Activities

3.1 STP Phase I

The focus of Phase I was the development of the process control manuals for demonstration site production. The products identified were beef stew in MRE Pouches and beef chunks and gravy in tray-packs. In order to establish process controls, characterization of the process steps and their impact on product quality was undertaken. Qualities studied included product sensory attributes, microbial safety, military specifications, and also processing yields.

3.1.1 Off-Line Control (3.3.1.1)

The project began with a review of the scientific literature and development of a database related to quality determination, microbiological quality, and properties (such as mechanical, permeability, processing characteristics) of packaging materials for the production of beef stew with tray packs and pouches. Taguchi's techniques for quality engineering were used as a basis for designing additional analytical experiments. The results were analyzed to determine the significance of the identified process/ingredient parameters and their effects on the quality characteristics of the products.

3.1.1.1 Process Characterization and Impact on Quality

The survey of the available publications has shown that the quality of beef stew is a complex system involving attributes measurable by both sensory and instrumental methods (Technical Working Paper (TWP) #18 "Literature Review: Beef Stew Quality"). Among the sensory attributes the most important are: flavor (taste and aroma), color, and texture. Since beef stew consists of many ingredients it is important to evaluate these attributes separately for each of the components. The literature review indicated that there are no publications which took this problem into account. The literature review also showed that the quality of beef stew depends not only on the ingredients but also on the processing conditions, especially the heating methods, temperature and time. A decrease of quality can also be observed during long-term storage. In the available publications, information on the changes of the beef stew quality caused by the conditions of the processing was not found. Technical Working Paper TWP 18 was converted to a keyworded, hypertext, document and posted on the PFMIS BBS.

Four modified corn starches were evaluated for use in the beef sauce formulation. STA-O-PAQUE was found to have the best stability with regard to sauce viscosity before and after retorting and was used for future experiments (including process control).

The research on the effects of freezing beef on the quality of beef stew resulted in a Master of Science thesis by Jui-Cheng Hsu (Advisors: Professors H. Daun and D.H. Kleyn). Ms. Hsu concluded that the influence of freezing of beef on the final yield of beef in beef stew was greater than that of the precooking conditions. Freezing of beef resulted in a significant decrease of beef yield in retorted beef stew. Texture of beef was significantly affected by the freezing and precooking conditions. Beef frozen before precooking and then precooked in the air oven at 450F for 100 seconds was considered to yield the best sensory quality of beef from the standpoint of texture. Ms. Hsu's thesis has been issued as two technical working papers: "Effects of Precooking and Freezing Beef on the Quality of Beef in Retorted Beef Stew, Part I: Literature Review", J-C Hsu, Technical Working Paper TWP 26 and "Effect of Precooking and Freezing Beef on the Quality of Beef in Retorted Beef Stew, J-C Hsu, Technical Working Paper TWP 27.

The influence of precooking method (hot air impingement and boiling water) on the color, texture, flavor, and yield of precooked beef chunks and subsequent thermostabilized beef chunks with gravy was determined by both instrumental methods and quantitative descriptive sensory analysis. The literature review is contained in TWP 69 "Influence of Precooking in the Air Impingement Oven on the Quality of Thermostabilized Beef Chunks with Gravy, Part I: Literature Review". In TWP 70 "Influence of Precooking in the Air Impingement Oven on the Quality of Thermostabilized Beef Chunks and Discussion" it is reported that precooking in the air impingement oven resulted in improved quality of beef chunks with gravy as compared to precooking in boiling water in terms of darker, redder, and less yellowish color; less hardness and more juiciness; roasted-like flavor; greater yield; and a lower amount of lipid oxidation products.

Changes in the weight and firmness of carrots and peas resulting from their processing in a model starch solution in a retort pouch were determined and described in Technical Working Paper (TWP 24), "Influence of Retorting Temperature and pH of Model Starch Solutions on the Weight and Firmness of Carrots and Peas". The weight gain for peas and weight loss for carrots were strongly dependent on retorting temperature. Higher retort temperature resulted in a decreased firmness of both vegetables.

The texture of cooked vegetables can be altered by the addition of salts. Calcium salts have been used to improve texture and prevent excess softening. The texture of carrot was studied in brine processed at three different temperatures 118.3, 121.1 and 123.9° C. Processing time was adjusted at each temperature to produce three F_0 values (8,16 and 24). In TWP 105 "Effect of Thermal Processing and Calcium Chloride on the Textural Quality of Carrot in Brine", it is reported that the 123.9° C processing temperature produces firmer texture of carrot than that of 118.3° C for the same F_0 of 8. The texture of processed carrot improved by soaking in 5 mM calcium chloride prior to processing and by the addition of 5 and 10 mM calcium chloride to the brine. Sensory evaluation showed no significant changes in the acceptability of processed carrot when 10 mM calcium chloride to the brine. This indicates the possibility of adding up to 10 mM calcium chloride to the brine to improve the texture of thermally processed carrot without reducing the overall acceptability. A method was developed and evaluated for testing samples of raw beef to assess probable shrinkage during production processing. This method basically consists of cooking raw beef in boiling water for 15 minutes after which the sample is evaluated using the same test methods as are being established for the finished product beef. This evaluation procedure will also give data regarding the shrinkage of that particular lot of raw beef. Lot to lot variation in raw beef shrinkage has to be and can be compensated for by the precooking step, yielding lots of precooked beef which will shrink an identical amount during the retort process. Under this process control scheme, one can maintain target fill weights and sauce formulation in spite of lot to lot variation of raw.

Samples of Beef Chunks with Gravy, saved from July and August, 1991 experiments, were analyzed for moisture and fat content (67 samples of CRAMTD product and 16 commercial product). It was found that Beef Chunks with Gravy prepared in the CRAMTD Pilot Plant contained less moisture (67.0 vs 72%) and higher fat content (6.7 vs 3.3 %) than the commercial products (Tables 3 and 4 of TWP 35)..

Four CRAMTD (16 tray-packs) and three commercial products (9 tray-packs) were evaluated using Quantitative Descriptive Sensory Analysis (Table 5 of TWP 35). The CRAMTD product made from beef precooked in boiling water was judged as the best (overall impression: 6.4 points); second was the product precooked in the Enersyst oven (5.8 points). The lowest score was judged for commercial product, Lot AB (4.1 points). CRAMTD product made from beef precooked in the Enersyst oven had a better texture than product prepared from beef precooked in water, but both products received a much higher score than the commercial one.

3.1.1.2 Microbial Quality and Safety

Representative samples of ingredients were analyzed for total microbial count. An earlier evaluation of the microbial quality of Beef Stew and its Ingredients, August 1990, was released as Technical Working Paper TWP 17 "Evaluation of the Microbiological Quality of Beef Stew and Its Ingredients" (see also Section 3.1.2.2, On-Line Control, Microbial Quality and Safety).

No sign of spoilage was detected in processed samples of beef stew in a pouch and beef chunks with gravy in tray pack cans during the February 1992. These samples were found to be microbiologically stable after 10 months of storage at both room temperature and at 35° C.

Spores of Clostridium sporogenes PA 367 were used to evaluate the thermal process of two products: beef chunks with gravy in tray pack cans and beef stew in flexible pouches (Technical Working Paper TWP #53, "Production of Spores of Clostridium sporogenes PA 367 and Evaluation of the Safety of Thermal Process of Beef Stew in a Pouch and Beef Chunks with Gravy in Tray Pack Cans". Each container was inoculated with 2×10^4 spores. Processing times of 25 and 17 minutes for tray pack cans and pouches, respectively, were found to be sufficient to produce a microbiologically safe and stable product at 250° F.

3.1.1.3 Process Control

The military specifications of net weight and drain weight were investigated and the equations obtained to solve for target values of the amount of precooked beef and gravy to be

deposited in the tray before retorting. These target values take into account the variations of both gravy and beef filling processes. A computer program called STP3IE has been developed to show a summary of military specifications and calculate the aforementioned target values. The statistical modeling and a software session are presented in Technical Working Paper TWP 25. The program STP3IE.EXE was made available for downloading from the PFMIS BBS or it can be "test-driven" while in PFMIS BBS.

Technical Working Paper (TWP 28), "Methodology for the Estimation of Product Parameters in Beef Chunks with Gravy Formula" reviews a methodology and computer model on how to formulate the sauce and to adjust the fill weights for the two components: Beef and Sauce, based on precook yields. The computer model has been incorporated into a program SAUCE.EXE which is available upon request or can be downloaded from the PFMIS BBS.

3.1.2 <u>On-Line Control (3.3.1.2)</u>

Based upon the off-line control database and process characteristics, the characteristics of the finished product were determined and correlated to raw ingredient characteristics and processing conditions, e.g., times and temperature of retorting, formulations of ingredients, and times and temperature of cooking in the Enersyst oven. The influence of these processing parameters on proximate composition, color, textural properties, and sensory characteristics was also studied. The study of vitamins and minerals was for inferential assessment of the product quality and a minor task. On-line control techniques and sensor technologies were developed/identified to monitor the parameters of the production process and to ensure that they are within their target values. In addition, a HACCP program was used to assure product safety.

3.1.2.1 Process Characterization and Impact on Quality

A temperature of 400° F was predicted to be the most effective for precooking in the Enersyst oven. As reported in Technical Working Paper (TWP 34) "The Effects of Processing Conditions in the Enersyst Oven on Precooking Yield and Quality of Beef Chunks", that temperature allows one to obtain highly acceptable color and aroma without excessive burning of the edges of chunks.

The experiments described in Technical Working Paper (TWP 35)"Comparison Between Experimental Thermostabilized Beef Chunks with Gravy in Tray Packs and Commercial Samples" confirmed the formulas for predicting beef drained weight and gravy viscosity. An advantage of 1.3% in yield was observed for precooking in the Enersyst oven over precooking in boiling water.

Technical Working Paper (TWP36) "Observations on the Drained Weight of Beef and Viscosity of Gravy in Thermostabilized Tray Packs of Beef Chunks with Gravy" describes the influence of beef and starch levels as well as precooking yield of beef on the drained weight and gravy viscosity. At any precooking yield between 80 and 90% and with starch in the range of 26.55 to 33.67 g/tray, the minimum drained weight specification of 1530 g can be met with 2750 g of raw beef using Enersyst oven precooking or 2800 g of raw beef precooking in boiling water.

3.1.2.2 Microbial Quality and Safety

A Technical Working Paper (TWP 29) "Microbiological Quality of Ingredients of Beef Chunks with Gravy Processed in Tray Pack Cans" includes the established microbiological database for beef chunks with gravy ingredients (allowable limits). It also specifies the precooking time of beef in both the Enersyst oven and in boiling water so as to give a safe precooked beef from the microbiological viewpoint.

Beef stew and beef chunks with gravy products are categorized as low-acid food (pH>4.5). In the processing of low-acid foods, the main concern is the destruction of Clostridium botulinum. The spores of C. Sporogenes PA 3679, which have the same physiological characteristics as C. Botulinum except they are non-toxic and more heat resistant, are used instead of C. Botulinum to test the efficacy of heat treatment.

Approximately 70 MRE Beef Stew pouches were produced on November 11, 1991 to study thermostabilization. Six of these pouches were inoculated with spores of Clostridium sporogenes PA 72-142 (D250 = 1.6 min) at 104 spores/pouch. The pouches were sealed and processed at 250°F for 16 min (hold time) where a minimum F_o of 11.3 was obtained. After processing the inoculated pouches were incubated at 35°C for 10 days. The incubated samples were checked daily. After 10 days of incubation, no swelling or any sign of spoilage was noticed indicating that the thermoprocessing was adequate.

3.1.2.3 Process Control

A "cook book" manual for the design of experiments using the Taguchi method was completed, Technical Working Paper TWP 11 "Generic Inspection-Statistical Process Control System, Control System Design of Experiment: A Tutorial on Taguchi's Approach". This manual served as guidance for the design of future experiments which have as their objective the study of the effects of process parameters on the quality characteristics of the product.

A design of engineering experiments for Beef Stew Pouches, using Taguchi methods, was completed, Technical Working Paper (TWP 10) "Generic Inspection-Statistical Process Control System, Design of Experiments for Beef Stew Pouches". These experiments had as their objective establishing significant relationships between process and product variables so that process control strategies could be developed.

3.1.3 On-Line Demonstration (3.3.1.3)

At the March 25, 1992 CRAMTD Coalition Meeting (held at Arlington Virginia, a discussion of the pouch product from the form/fill/seal machine centered on the lack of product specification acceptance and the need for CRAMTD and Natick to resolve before the form/fill/seal machine can be used. CRAMTD was asked to sit down with Natick and define the work to be done.

A "Qualification Plan" for the Tiromat Form/Fill/Seal Machine included tasks both at Rutgers and at Natick. Key features of the qualification plan were 1. To produce 10,000 retorted pouches for qualifying tests, 2. Use corn starch to fill 7,500 pouches and 2,500 of ham slices, 3.

Production run tests to begin in August 1992, 4. Due to retort limitations, only 1000 pouches can be retorted per day, 5. Since the Tiromat is not being tested in this plan but only the end product, the machine does not have to run at maximum production rate but at a slower rate so that pouches can be handled more efficiently for inspection when they leave the machine. and 6. Due to testing limitations, only 100 pouches can be tested for MIL Spec compliance daily.

A qualification run (multiple lots) of the MRE pouches were produced on the Tiromat 3000. Ten thousand pouches were produced, 7500 filled with corn starch and 2500 with ham slices. The pouches passed quality control tests and specifications for residual gas, retort sterility and no delamination after retorting. However, a significant number of pouches failed the internal pressure test for good seal strength. It is believed that this is due to the weak bond strength of the film adhesive after retorting. Samples from several of our production lots were sent to Reynolds Metals for their analysis.

A meeting was held with Reynolds Metals on November 17, 1992 to identify and review the probable causes for the pouch seal inconsistency in the pouch qualification production runs. Reynolds tests indicated that the seal internal pressure failures were caused by inadequate bond strength (after retorting) between the polypropylene and the aluminum foil. Forming of the pouch did not cause pouch seal failures. Reynolds will supply pilot plant samples using three (3) different adhesives for CRAMTD to test and determine the best adhesive. Additional film for another production run of 10,000 pouches will be ordered after the selection of the best film adhesive.

A Draft Statement of Work was submitted March 22, 1993 for a new Short Term Project, STP #23 "Qualification of Retorted Food Pouches Filled and Sealed on the Horizontal Form, Fill, Seal Machine in the Combat Ration Manufacturing Facility". This Short Term Project was awarded October 1, 1993, to continue the critical Pouch Qualification effort begun under STP #3.

3.1.4 Manual Preparation (3.3.1.4)

The procedures and results developed in the off-line and on-line control areas were used to develop a draft control manual.

A meeting was held on August 8, 1990 with NFPA to discuss and define their role as consultant in the manual preparation phase. The NFPA played an important part in implementing Hazard Analysis Critical Control Points (HACCP) as part of the Process and Quality Control manual. The National Food Processors Association (NFPA) provided manuals for CRAMTD QC/HACCP for both beef stew in a pouch and beef chunks with gravy along with computer disks containing the contents of these manuals. They were reviewed for needed modifications to fit the CRAMTD project objectives.

Technical Working Papers were written on level setting strategy and inspection frequency. In Technical Working Paper (TWP) 20 "Optimal Levels of Control Factors for Products with Multiple Characteristics" the authors employ the loss function approach advocated by Yaguchi to develop a model for determining the optimal level settings. Technical Working paper (TWP 21) "Grouping and Common Diagnosis Interval for Multi-Characteristic Products" is based on Taguchi's approach to determining the optimal control parameters. The SPC plan for the CRAMTD production facility assumes a production facility which runs at an average rate of 16 trays/min or 100 pouches/min. It also assumes, for the purpose of this plan, that CRAMTD would hire the required personnel to support the production and quality control functions and that CRAMTD would support appropriate training for all personnel as identified in the SPC plan. The above assumptions produce an SPC plan, which might be hypothetical at this time, which illustrates procedures required for a production facility and serves as a demonstration SPC plan for combat ration producers who have to write their own plan.

The second draft (which addressed comments by the DPSC reviewer) SPC Plan for CRAMTD Tray-Pack production was approved by DPSC with some suggestions for improvement. The improvements are being addressed and the SPC Plan will be modified as changes to CRAMTD occur. A copy, "CRAMTD SPC Plan, Beef Chunks with Gravy in Tray-Pack" is attached as Appendix 4.3. An SPC Plan for CRAMTD MRE Pouches was also prepared but not submitted to the DPSC.

The final draft of the SPC Manual for CRAMTD was completed and released as a technical report ("Statistical Process Control for the Production of Combat Ration: CRAMTD Production Product Quality Control", TWP 44). The manual, an abridged version without the appendices, is attached as Appendix 4.4, presents a comprehensive SPC program for product quality at the CRAMTD Pilot Plant. The quality control procedures and strategies are described in detail.

The "Cookbook" for beef chunks and gravy in tray packs was completed and released as a technical working paper ("Production of Beef Chunks and Gravy in Tray Packs", TWP 47), Appendix 4.5. The "Cookbook" describes the steps required to determine and control the production settings for each process in the production line. Although based on the manufacturing facilities in the CRAMTD pilot plant, the steps can be easily adapted to different manufacturing environments or different products.

The on-line quality control procedures for producing beef chunks with gravy in tray packs are presented in "Process Control for the Production of Beef Chunks and Gravy in Tray Packs", TWP 48. All production processes and process parameters will be controlled to assure that the final product conforms to MIL-B-4230C. The control strategies were determined for each process involved and the control limits (where available) have been listed for each process parameter. An abridged version of the process control manual, without a complete set of appendices, is attached as Appendix 4.6.

3.2 STP Phase II

In the second phase, the manual preparation method was shown to be applicable to other combat ration processes and instructional material developed to assist combat ration producers in manual preparation.

3.2.1 Control Methodology, Procedures & Databases (3.3.2.1/3.3.2.2)

The MRE process line in the Green Giant plant in Leseuer was visited ,April 2, 1990, with the objective to collect information regarding SPC, CIS, and HACCP. Green Giant shared with

us their manuals which will become an important basis for our computerized manual preparation program. The Green Giant MRE program has been in existence since 1979 and has operated continually with the exception of 1989. They obtained the 1990 contract for the manufacturing of MRE Ham slices and ham omelet.

A mini symposium on statistical control was conducted on April 11, 1990 as part of the CRAMTD coalition meeting. Speakers at this symposium were Dr. Elsayed, Dr. J.G. Surak, Mr. A. Lobmeyer and Dr. T.S. Jiang.

A field trip was made to Venice Maid, Vineland, NJ on October 18,1990 to review process operating, process control and quality assurance procedures.

3.2.2 <u>Combat Ration Manual Preparation (3.3.2.3)</u>

A field trip to DPSC was made on July 6, 1990. The objectives of this meeting were to become familiar with the problems that Combat Ration manufacturers have in developing plans for SPC and CIS, and to understand with what kind of program CRAMTD could help the industry in developing these plans in order for them to be accepted by DPSC.

Pillsbury/Green Giant visited CRAMTD on October 29, 1990 during which prototype computer software for an electronic SPC Plan was demonstrated. An updated SPC Plan for MRE XI was provided by Green Giant and is being incorporated into the electronic version of the SPC Plan.

As components of a computer-based statistical process control manual preparation system: the following issues were investigated: a) usage of statistical process control charts, b) design of the information gathering process, c) on-line help facility, d) database considerations, e) user-interface, f) hypertext-based manual preparation program.

The Statistical Process Control (SPC) Plan Preparation Software (editor, compiler, viewer, and on-line help) has been completed as Version 1.0. The On-line help includes SPC-related Terminology, References, DPSC Evaluation Workbook, an Index and Plan template. TWP 23 "SPC Plan Preparation Software Requirements Specification, Version 1.0" documents the requirements specification that guided development of the software. The "product" was compiled to run under Microsoft Windows on an IBM PC (80286 with 1 Mb RAM).

Along with a User's manual, the SPC Plan Preparation Software package was distributed to key CRAMTD personnel for trial and recommendations to enhance the quality of the package. A methodology will be developed, based on using the software for preparing a Combat Ration SPC Plan.

3.3 STP Phase III

In the final phase of the program, new strategies, in-line sensors, and required hardware/software for developing generic, automated process control systems were identified.

3.3.1 <u>Hardware/Software Survey (3.3.4.1)</u>

Data acquisition, monitoring, and control architectures for quality and process control in an automated food processing system were analyzed. In TWP 59 "Data Acquisition, Monitoring, and Control Architecture for Quality Control in Batch and Continuous Process" the process operations and the quality control points along the production line are described. Also described are various architectures for measuring, monitoring, and controlling the process. Finally, the last section of the technical working paper lists attributes for sensors, interfacing hardware, and process control software.

The research teams in the "Survey for Automated Production Planning and Inventory Control Hardware and Software" (STP #5) and the "CIM Architecture" (STP #4) Projects cooperated to identify the desireable characteristics and requirements for process control and production control. The findings and specifications for sensor data requirements including lists of sensors and data acquisition devices are presented in the Final Technical Report of STP #5 (FTR 3.0) or Technical Working Paper (TWP 46) "Desireable Characteristics and Selection Attributes for Data Acquisition, Monitoring, and Control Software and Interfacing Hardware".

3.3.2 Advanced Process Control Strategy (3.3.4.2)

A comparison of Taguchi's method for quality control and conventional Statistical Process Control (SPC) techniques were evaluated and reported in TWP 58 "Quality Control Method and Economic Design - A comparative Study of Taguchi's Method and SPC". Taguchi's quality control system consists of two phases: off-line quality control and on-line quality. Examination of the causes of process variation as stated in Taguchi's on-line quality control phase shows that they are the same as the assignable causes which SPC control charts are designed to detect. Control limits of SPC control charts are usually designed according to the process statistics such as means and standard deviations. The information provided by control charts not only help monitor the process variability but also show the process tendency and shift which are important indications for the performance of the production process.

Overall, SPC as the process control method is preferred because of its practicality and direct implementation. However, SPC has a serious limitation in not including the process capability which is the focus of Taguchi's off-line Phase. If a process is poorly designed or the product has low producibility/manufacturability, the statistical parameters included in the SPC control chart will be of little avail towards producing the desired product quality.

Short Term Project (STP#20), "Dual Use Capability and Manufacturability of Combat Rations" reviewed the current approaches and then developed and validated a methodology that quantifies the producibility of a product as it relates to its design characteristics. This measure, "Producibility Index", aims to assure that newly designed products can meet both quality and cost requirements. The Final Report for STP #20 is in preparation.

Technical Working Paper "Economic Design of X-bar Control Chart Using Quadratic Loss Function", TWP 43, also defines an incentive for production engineers to place more efforts on offline process design in order to maintain a robust production process with high process capability. A typical multistage production system consists of a series of sequential processing stages. Products are produced by processing through these stages until they are finally completed at the last stage. To prevent the nonconforming products from being shipped to customers, quality inspection points are usually allocated along the production system to sort out then discard or repair the defective items. A fraction or an entire batch of production may be inspected after every production stage, or they may be inspected only after certain stages.

A new approach to allocating inspection effort has been proposed and examined, TWP 68 "Allocation of Inspection Effort in Multistage Production Systems". The approach can be summarized as follows: 1) for each stage, calculate the expected cost of discovering and discarding a defective item using the developed equation. If no expected cost is less than the penalty cost of a defective finished item, no inspection should be performed in this production system. 2) Choose the first potential inspection point. If the expected costs of discovering and discarding one defective item at the remaining subsequent stages are all greater than the penalty cost of a defective finished item, the chosen inspection point is the optimum solution and the only inspection point in the system. 3) Calculate the joint expected cost of discovering and discarding a defective item at a set of inspection points. Choose a set with the lowest expected cost.

3.3.3 <u>Product/Process Characterization (3.3.4.3)</u>

In order to demonstrate effective inspection, tracking and control of the CRAMTD process through utilization of computer integrated control strategies, Short Term Project #12 "Implementation of Sensors and Quality Control Strategies in the Integrated Manufacturing System" was proposed, awarded and carried out. Instrumentation necessary for inspection and evaluation of the incoming raw material, in-process materials and finished product were considered, as well as hardware and software necessary to track material through different processes. The first phase of the STP included a recommended "manufacturing inspection and control demonstration plan" for Government approval. Phase II focused on the acquisition of identified hardware and software while Phase III demonstrated the system as incorporated into an additional Short Term Project, STP #16 "Implementation of Integrated Manufacturing Systems". STP #12 and STP#16 along with a third, STP #14 "Engineered Systems for Materials Handling", constitute the technology development approach to CRAMTD Phase II.

3.3.4 Advanced Sensors (3.3.4.4)

3.3.4.1 Short Term Project Feasibility Studies

An NIR model 70 was leased from Trebor by the Food Science Department and was evaluated for its capabilities of on-line measurements of product attributes.

Beef was cut into chunks $(1 \times 5/8 \times 5/8")$ to fit the sample holder of a Near Infra-Red spectrometer (NIR) and used to measure the water content. The best wavelengths obtained previously for ground beef (ITR 3.8) were used to measure the water content of the chunks and the values obtained were compared with the water content of the same samples after drying in an oven at 105 C for 24 hrs. Direct spectrophotometric analysis predicted the water content of the

beef chunks within a standard error of 4.05% (average moisture content, 71.4%). The average NIR values were consistently higher than the drying oven values. This could be attributed to the way the beef chunks are held in the NIR sample holder, in which the chunks had to be slightly pressed with the sample holder cover in order to fit properly, therefore some of the water leaked out of the chunks and the NIR read this leaked water as well.

Samples of extra lean ground beef were mixed at different rates with samples of regular ground beef so as to obtain samples of beef with various fat content. Direct spectrophotometric analysis (NIR) predicted the fat content of the samples within a standard error of 2.27% over the range of 10% to 23% fat content. The fat content of beef chunks (1 X 5/8 X 5/8") was measured in the NIR using the same wavelengths as for ground beef (1600 - 1800 nm). Analysis of the results showed a standard error of prediction of 5.59% over the range of 7% to 15% fat. The higher standard error obtained with beef chunks is probably due to the physical position and location of beef chunks in the sample holder and to how much of the fat is exposed to the NIR. Grinding and mixing of meat samples would give more accurate overall sample results.

As a follow-on to the results reported in the previous Interim Technical Report concerning starch content determined using NIR prior to cooking, starch solutions containing 0 to 5.5% starch were cooked and then analyzed. Direct spectrophotometric analysis predicted the starch content after cooking within a standard error of 1.61% (comparable to the 1.48% standard error observed on solutions prior to cooking).

A prototype high temperature moisture probe based on a coated fiber optic was tested in the Enersyst Jet Sweep Oven. This device is part of the In-Line Sensors Research Project in the Center for Advanced Food Technology. Measurements were made in the fourth (final) chamber of the oven at temperatures of approximately 320 F while cycling steam off and on.

Probe response to humidity was readily measured (signal varied from 8.5 microvolt dry to 14 microvolt moist) and occurred in seconds. There may be a probe response dependence on temperature which would require sensor calibration. Research needs to be continued to optimize the probe and to integrate the optoelectronic components for field deployment. Preliminary feasibility was demonstrated and future work will depend on the control strategy proposed for the CRAMTD Precooking Process.

3.3.4.2 Quality Quantification and Enhancement of Combat Rations

It was proposed by The Center for Advanced Food Technology, Rutgers University, in mid-1992 that the quality of a food can be meaningfully described by a manageable set of measured characteristics but that such a set is not presently available. "Quality Quantification and Enhancement of Combat Rations" constituted an integrated scientific approach for the quantification of quality parameters and identification and development of the sought technologies. The faculty and staff participating in the CRAMTD program were included in the resources to be utilized in conducting this multi-year QQECR program.

A multi-phase program was proposed, and awarded (Contract DAAK60-92-C-0087), of which the first phase had as its principle goals identifying quality parameters and perceptions related to combat rations, defining the major factors which impact on those qualities and establishing the methods for measurement. The second phase consisted of research to establish the molecular, biochemical and microbiological processes occuring during manufacture and storage along with the evaluation of advanced stabilization technologies and process/product quality control.

The quality parameters and perceptions Phase began with a definition of quality factors important to the consumer of thermostabilized foods with a menu of interest to the military. The foods included a beef stew and consumer studies using descriptive analysis and multidimensional scaling to determine a comprehensive list of quality attributes. Key quality factors included were: nutritional quality, flavor, texture and color. Relative to shelf-life, additional factors examined were the effects of food-packaging materials and aspects of microbials growth.

It is anticipated that the outcome of the QQECR program will be reduced to practice in later stages of the CRAMTD program.

4.0 Appendix

- 4.5 "Production of Beef Chunks and Gravy in Tray Pack", TWP 47
- 4.6 "Process Control for the Production of Beef Chunks and Gravy in Tray Packs" (Abridged TWP 48)

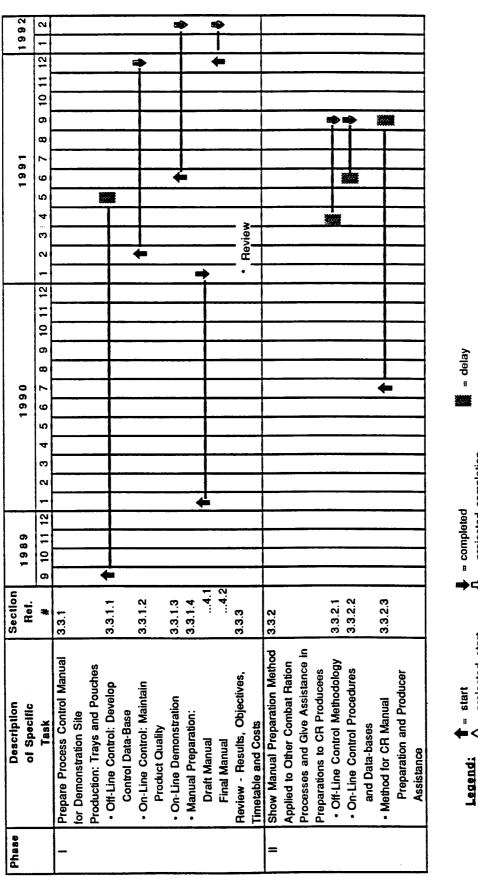
^{4.1} Figure 1 - CRAMTD FTR #3 Time and Events Milestones

^{4.2} Table of Technical Working Papers

^{4.3 &}quot;CRAMTD SPC Plan, Beef Chunks with Gravy in Tray Packs"

^{4.4 &}quot;CRAMTD Production Product Quality Control" (Abridged TWP 44)

Fig. 1 - CRAMTD Short Term Project #3 Generic Inspection-Statistical Process Control System Projected Time & Events and Milestones



T = start
L = completed
L = projected completion
L = projected completion
L = projected completion

Fig. 1 (Contrd) - CRAMTD Short Term Project #3 Generic Inspection-Statistical Process Control System Projected Time & Events and Milestones

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Description of Specific	Task	Identify Strategy, Sensors, and	Hardware/Software for Advanced	CR Process Control System	 Survey Existing Equipment, 	Hardware / Software, etc.	 Advanced Process Control 	Strategy	 Product / Process 	Characterization	 Identity Required In-Line 	Sensors: Fill Gaps	 Recommend System for Phase 	2 & Prepare Necessary STPs
Phase										•	.1		~	

Legend: $\hat{\Phi}$ = start $\hat{\Omega}$ = projected start $\hat{\Theta}$ =

completed
 projected completion

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Generic Inspection - Statistical Process Control System for Combat Ration Manufacturing Facility (STP #3)

Technical Working Paper Listing

Report #	Title	Authors	Date
TWP 10	Generic Inspection-Statistical Process Control System, Design of Experiments for Beef Stew Pouches	E.A. Elsayed, S.L. Albin, A. Chen	May 90
TWP 11	Generic Inspection-Statistical Process Control System, Control System Design of Experiments: A Tutorial on Taguchi's Approach	E.A. Elsayed, A. Chen	May 90
TWP 17	Evaluating the Microbiological Quality of Beef Stew and its Ingredients	T-C. Lee, I.M. Laham	Aug 90
TWP 18	Literature Review: Beef Stew Quality	H. Daun, D.H. Kleyn, W.B. Sznajdrowska, J- C. Hsu	Aug 90
TWP 20	Optimal Levels of Control Factors for Products with Multiple Characteristics	E.A. Elsayed, A. Chen	Feb 91
TWP 21	Grouping and Common Diagnosis Interval for Multi-Characteristic Products	E.A. Elsayed, A. Chen	Feb 91
TWP 23	SPC Plan Preparation Software Requirements Specification, Version 1.0	H.O. Lee, A. Papp III, X. Qi	Apr 91
TWP 24	Influence of Retorting Temperature and pH of Model Starch Solutions on the Weight and Firmness of Carrots and Peas	W.B. Sznajdrowska, H.B. Bruins, H. Daun, D.H. Kleyn	Jun 91
TWP 25	Manual for Software - STP31E, Analysis for Military Specifications	E.A. Elsayed, S.L. Albin, A. Chen, A. Veleber	May 91
TWP 26	Effects of Precooking and Freezing Beef on the Quality of Beef in Retorted Beef Stew, Part I: Literature Review	J-C. Hsu	May 91

TWP 27	Effects of Precooking and Freezing Beef on the Quality of Beef in Retorted Beef Stew, Part II: Results and Discussion	J-C. Hsu	May 91
TWP 28	Methodology for the Estimation of Product Parameters in 'Beef Chunks with Gravy' Formula	H.B. Bruins, W.B. Sznajdrowska, J.L. Rossen, H. Daun, D.H. Kleyn	Jul 91
TWP 29	Microbiological Quality of Ingredients of Beef Chunks with Gravy Processed in Tray Pack Cans	I.M. Laham, T-C. Lee	Oct 91
TWP 34	The Effect of Processing Conditions in the Enersyst Oven on Precooking Yield and Quality of Beef Chunks	W. Kopec, J-J. Shyr, H. Daun, D.H. Kleyn	Dec 91
TWP 35	Comparison Between Experimental Thermostabilized Beef Chunks with Gravy in Tray Packs and Commercial Samples	W. Kopec, J-J. Shyr, H. Daun, D.H. Kleyn	Dec 91
TWP 36	Observations on the Drained Weight of Beef and Viscosity of Gravy in Thermostabilized Tray Packs of Beef Chunks with Gravy	W. Kopec, J-J. Shyr, H. Daun, D.H. Kleyn	Dec 91
TWP 43	Economic Design of X Control Chart Using Quadratic Loss Function	E.A. Elsayed, A. Chen	Jan 92
TWP 44	Statistical Process Control for the Production of Combat Ration: CRAMTD Production Product Quality Control	S.L. Albin, E.A. Elsayed, A. Chen, M. Chao, S. Arshad, A. Veleber	Feb 92
TWP 47	Production of Beef Chunks and Gravy in Tray Packs	E.A. Elsayed, S.L. Albin, A. Chen	Feb 92
TWP 48	Process Control for the Production of Beef Chunks and Gravy in Tray Packs	E.A. Elsayed, S.L. Albin, A. Veleber, A. Chen	Mar 92
TWP 53	Production of Spores of Clostridium sporogenes PA 367 and Evaluation of the Safety of Thermal Process of Beef Stew in a Pouch and Beef Chunks with Gravy in Tray Pack Cans	I.M. Laham, T-C. Lee	Apr 92

TWP 58	Quality Control Method and Economic Design - A Comparative Study of Taguchi's Method and SPC	A. Chen	Aug 92
TWP 59	Data Acquisition, Monitoring, and Control Architecture for Quality Control in Batch and Continuous Process	M.B. Gursoy, M.A. Jafari, E.A. Elsayed	Sep 92
TWP 68	Allocation of Inspection Effort in Multistage Production Systems	A. Chen	Jun 93
TWP 69	Influence of Precooking in the Air Impingement Oven on the Quality of Thermostabilized Beef Chunks with Gravy, Part I: Literature Review	J-J. Shyr	Jun 93
TWP 70	Influence of Precooking in the Air Impingement Oven on the Quality of Thermostabilized Beef Chunks with Gravy, Part II: Results and Discussion	J-J Shyr	Jun 93
TWP 105	Effect of Thermal Processing and Calcium Chloride on the Textural Quality of Carrot in Brine	I.M. Laham, X. Liu, H.B. Bruins, H. Daun	Sep 95

SPC PLAN

BEEF CHUNKS WITH GRAVY MIL-B-4230B

CRAMTD PRODUCTION FACILITY

AREA 1: Policy and Scope

A. Applicability

- 1. Contractor's policy for applying SPC.
- 2. Goals and Commitments.
- 3. Alternatives to SPC that have successfully reduced/prevented production of defects.

It is the Contractors goal and commitment to develop, implement and utilize advanced and robust food manufacturing systems for the production of a variety of high quality combat and civilian food products. It is also the Contractors policy and commitment to develop, implement and utilize a comprehensive quality control system to make a consistent defect free product. The quality policy is not limited to the production process but includes areas such as purchasing, shipping and receiving, employee training, preventative maintenance, sanitation, pest control, product tracing, recall procedures, etc.

The Contractor has identified process operations which are flexible and highly automated with many built in control strategies that assure the production of high quality food products. In addition, the Contractors has identified and will keep identifying areas where the implementation of SPC (Statistical Process Control) and HACCP (Hazardous Analysis of Critical Control Points) would reduce, prevent or eliminate product defects and benefit the quality of the product.

To produce defect free products, it is important to have a thorough understanding of the actual process and process interactions. Therefore, before starting actual production, engineering experiments will be conducted by the contractor, using Taguchi methods or other classical design of experiments, to establish the relationships between the process, product and finish product attributes. Also, process capability studies will be conducted to determine the capability of each unit operation. The contractor will only use processes and equipment which have the capability of producing defect free products.

Many variables can be controlled in a process, however, it is the contractor's policy to emphasize control of those variables which tend to cause product defects. Therefore, before and during production, Cause and Effect Diagrams and Pareto analysis will be used to identify potential causes for the defects. It will then be determined which process parameters should be kept under Statistical Process Control, or to which variables the emphasis of SPC should shift. SPC is a very powerful tool in the early detection of variables which tend to drift out of control and it can, therefore, minimize or prevent product defects.

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After it has been determined which parameters need to be controlled to produce a defect free product, the contractor will develop an organizational system in such a way that the technical, administrative and human factors affecting the quality of its products and services are put in place and kept under control. All such control will be oriented towards the reduction, elimination and prevention of quality defects. The Contractor's management team will take all necessary measures to ensure that this quality policy is understood, implemented and maintained.

Given this commitment to quality, the contractor intends to comply fully with the contract clauses: 52.246-E029, requiring Statistical Process Control to be implemented in highly critical areas of container integrity and critical control points of retort process schedule.

The contractor is committed to execute programs which will enhance the quality of the food products by: i)identifying and implementing new or improved control strategies, ii) identifying raw material sources which utilize SPC or equivalent programs to control their quality, iii) developing HACCP plans, iv) using Good Manufacturing and Sanitation Procedures. It is the belief of Contractor that not only should quality be designed into the product, but also that quality improvements efforts are a never ending task. Emphasis of quality improvements will be placed on those areas which are most likely to cause defects based on past or current experience. Once a quality improvement effort in a certain area is implemented and confirmed, emphasis will shift to another area. The contractor's goals regarding high quality standards will be maintained at all times and will never be compromised by high production rates.

It is the contractor's policy to identify and utilize, where appropriate, process operations which use sensors and automatic feedback loops to control process parameters, such as temperature controllers, speed controllers, load cells in gravimetric feeders, check weighers, etc. The use of feedback control loops can be seen as an alternative method of SPC.

Not in all cases can traditional SPC be used, for example the retort process will be controlled by specification limits on critical factors such as retort temperature and time, head space, fill weights and viscosity. Deviation of any of these critical factors, such as the retort temperature below the scheduled process temperature, will result in immediate action, such as reprocessing, put on hold for process authority evaluation or disposition of the product.

B. Applicable Documents: List of references used as basis for SPC Plan.

American National Standard Institute/American society for Quality Control. 1985. Z1.1-1985, Z1.2-1985 & Z1.3-1985. Guide for Quality Control charts, Control chart Method of Analyzing Data, Control Chart Method of Controlling Quality During Production.

American National Standard Institute/American society for Quality Control. 1986. Generic Guidelines for Auditing of Quality systems.

American Society for Quality Control. Statistical Process Control: A Guide for Implementation.

Quality Engineering using Robust Design. Madhav S.Phadke, AT&T Bell Laboratories, Prentice Hall.

American Society for Quality Control. Food Processing Industry Quality System Guidelines.

Quality Control Handbook, 3 ed. J.M.Juran, Mc Graw Hill 1979

Quality Improvements using S.P.C., Lawrence, S Afl

Introduction to Statistical Quality Control, Douglas C. Montgomery 2 nd edition

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AREA 2: SPC Management Structure

- A. Structure within the organization.
 - 1. Relationship of organization.
 - 2. Relationship of quality and production to overall organization.

For structure of organization see attached chart.

The QA manager and his/her staff are independent from the production process, and report directly to the VP of the contracting organization. The production staff report to the plant manager, who reports to the Vice President. The QC technicians report to the line supervisors, but have a technical (indirect) reporting relationship with the QA engineer.

- B. Delineation of SPC Responsibilities
 - 1. Who performs inspections ?
 - 2. Who records and plots data on the SPC control charts ?
 - 3. Who is responsible for identifying out of control situations?
 - 4. Who initiates corrective actions?
 - 5. Who decides upon and implements corrective actions?
 - 6. Who performs audits within the organization ?
 - 7. Who maintains control charts ?
 - 8. Who is contractor's primary, secondary, and tertiary POCs for government personnel on SPC matters?

On-line inspections are performed by the equipment operators or QC technicians. Whenever possible on-line testing will be performed by the equipment operator to encourage his/her involvement in the contractors quality control program. A QC technician preforms inspections which require specialized skills or have to be performed off-line, in the laboratory (ex: residual gas, fat, drain weight, etc).

The person who performs the inspections is also responsible for recording and plotting the data and it his/her responsibility to identify an out-of-control situation and initiate corrective action.

The implementation of the corrective action will be done by the person who performed the inspection, recorded the data and initiated the corrective action. In cases where the QC technician performs the inspection, records the data and initiates corrective actions, implementation of the corrective actions will be done by the equipment operator after the QC technician advised the operator of the out of control situation (team approach). All corrective actions will be logged on the control chart and signed off on by the person implementing the corrective action on the control chart.

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If corrective actions are inadequate, the equipment operator or QC technician will inform the line supervisor immediately who will analyze the problem, contact the appropriate resource for advise and take appropriate actions to bring the process back in control. Both the line operator/QC technician and the plant supervisor are encouraged to shut the line down if the out-of-control situation would produce defective products.

The QA engineers will conduct weekly meetings reviewing the control policy with the line supervisors, key line operators and QC technicians. The results of this meeting along with data analysis will be used to update control limits, analytical procedures and or quality control methods, etc..

Audits of the SPC strategy, implementation and execution will be initiated by the quality assurance manager. Process audits will be performed by the quality assurance engineer, while other processes will be performed by the QA manager. The QA staff is independent from the program audited. More detail of the audit will be discussed in Area 8.

Control charts will be checked by the line supervisor on a daily basis and will be kept by him/her until three years after completion of the contract.

Primary contact on SPC for Government personnel is the manager of Quality Assurance, secondary contact is the plant manager and tertiary contact is the R&D manager.

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AREA 3: SPC Training

- A. Overall Training Program
 - 1. Who will be trained?
 - 2. How much training is planned?
 - See Area 3.B.

B Types and Extent of Training:

- 1. For each position to be trained
- 2. Academic vs. On-the-Job training vs. Combination
- 3. Where will training take place

Table 1 shows the positions in a manufacturing plant, who will be trained, the training subjects, the type of training and the places and amount of training:

Personnei	Training	Туре	Place	Time
QA Manager	SPC Organization & Management	Prerequisite Prerequisite	University	Degree
	Product Contractual Requirement	Military Seminar	Outside Co.	1 Day
Eng. Manager	SPC Plan	Seminar	In-house	1 Day
Plant Manager R&D Manager	SPC Organization & Menagement	Short Course Prerequisite	Outside Co.	4 Days
	Product Contractual Requirement	Military Seminar	Outside Co.	1 Day
MRE Supervisor	SPC Plan/Military Specs.	Seminar	In-house	1 Day
Traypack Supervisor	Product Contractual Requirement	Military Seminar	Outside Co.	1 Day
	SPC	Short Course	Outside Co.	3 Days
	Better Process Control School	Short Course	Outside Co.	4 Days
QA Engineer	Management	Short Course	Outside Co.	3 Days
-	SPC Plan/Military Specs.	Seminar	In-house	1 Day
	SPC	Prerequisite	University	Degree
Operators	Process Operation	On-the-Job	Plant	1 Day
	Inspection Procedures & Methods	On-the-Job/	Plant	1 Day
	(on-line)	Seminar		
	SPC Plan/Military Specs.	Seminar	In-house	1 Day
	SPC	Seminar	In-house	1 Day
QC	SPC	Short Course	Outside Co.	4 Days
Technician	Inspection Procedures & Methods	On-the-Job/	Plant	1 Day
	(off-line)	Seminar		1
	SPC Plan/Military Specs.	Seminar	In-house	1 Day

Table 1: SPC Training

CRAMTD SPC PLAN MILE-44230E DATE: 11/15/91

For the SPC training, the contractor recommends a course, such as the <u>Statistical</u> <u>Process Control for the Food Processing Industries</u>, given at Clemson University College of Engineering. The course is an intensive three-and-one-half day short course which teaches the applications and benefits of SPC in the food processing industry. The course includes the following subjects: concept of variation, problem-solving techniques used to reduce variation (such as pareto analysis), control charts and capability studies.

The In-house course of the SPC Plan & Military Specifications is to integrate general SPC with the actual line SPC plan corresponding to Military Specifications. Production line personnel are required to receive this training so that the SPC plan can be effectively implemented in the production line. This course will be organized by the QA manager.

The On-the-Job training of Process Operation and Inspection Procedures & Methods is conducted constantly in the plant. The purpose of this training is to keep the line personnel adhering to the latest technology, to ensure that the Quality Control program is completely understood and correctly executed and to ensure that the high productivity of the line is maintained. O.J.T. programs are the responsibility of the plant manager and his/her line supervisors

The Food Safety and Inspection Service, of the Department of Agriculture, requires all operators of thermal processing systems and container closure technicians to be under the direct supervision of persons who have satisfactorily completed certain courses of instruction in thermal processing. The curricula that has been developed for The Better Process Control Schools are generally recognized as being suitable training for supervisors of thermal process and container closure operations. Both line supervisors will be required to have successfully completed this course.

The QA manager and the QA engineer should both have either a B.S. or a M.S. degree with an emphasis in Quality Assurance. The organization & management requirement for managers can be acquired by at least 2 years experience in a management position.

The contractor will request from the Defense Personnel Support Center to organize a seminar on product contractual requirements.

AREA 4: Vendor Purchase Control

- A. Are suppliers required to use SPC ?
 - 1. Which ones ?
 - 2. Which ingredients/components ?
 - 3. To what extent are supplier's policies consistent with in-house policies and procedures.
 - 4. How are vendor SPC programs approved?

The contractor will require from all of its suppliers that a quality control program (SPC or equivalent) is used to assure that all purchased materials such as packaging, raw and processed ingredients, ingredient pre-blends, finished products, processing aids, cleaning compounds, pest control materials and processing materials are defect free and within the specifications.

The contractor will also require letters of guarantee from the supplier for each ingredient. These letters have to address compliance of their products with all applicable regulations pertaining to chemical purity and/or composition, microbiological quality and extraneous materials. These letters also have to address the suppliers quality control system, its capability of meeting the required specifications and how it assures that only defect free materials are received by the contractor.

The contractor requires that the supplier has an effective quality management system in place which is equal to or exceeds the contractor's in-house policies and procedures.

Vendor's quality control programs will be audited by the quality assurance manager at regular time intervals. The audit will consist of a visit by the QA manager to the supplier's processing facility to assure compliance with GMP's and the vendor's stated quality objective. The QA manager will request historic information regarding critical product specifications. The QA manager will only approve the purchase of the vendor's materials after he/she is convinced that the vendor's quality control program is effective and reasonably precludes shipment of defective products.

- B. How are suppliers evaluated?
 - 1. What criteria are used for supplier selection?
 - 2. Supplier Audit What and how often?

All new suppliers will be evaluated based on past quality history, industry history and field inspection by the QA manager. The QA manager will only approve the purchase of raw materials from suppliers who have an acceptable quality history and who demonstrate using SPC or other methods to control their process to preclude delivery of defective ingredients.

A pre-shipment sample will be requested together with a letter of guarantee by the R&D manager to evaluate/confirm the supplier's capability to meet the specifications and to confirm that the material can be used for the production process without negative effect on the finished product quality.

The vendor will be given the status as an approved supplier after both QA and R&D have assured themselves that the new ingredient will not cause any concern maintaining the high quality standards of the contractor.

The quality of the ingredients will be audited by the Quality Assurance staff at regular time intervals. The primary audit will be the receipt inspection and random sampling and analysis of received materials by the QA engineer. The secondary audit will be a yearly evaluation of the supplier's processing facility by the QA manager, to assure continued compliance with the vendor's stated quality program.

- C. Purchase controls other than SPC.
 - 1. If methods other than SPC are used, are they documented ?
 - 2. Do purchase controls adequately assure that only conforming supplies are received ?

A letter will be required from each vendor stating the target specification of the product's critical parameter, a statement regarding the capability of the vendor's process to meet these specifications and a statement regarding the vendor's quality control program to assure that defect free materials are shipped.

The contractor might require from some suppliers, especially those who have a marginal process capability, an inspection certificate with each shipment documenting the lab results of specific quality information of that shipment.

At receipt of the raw materials, a QA person will assure that the materials received are unadulterated, supplied by the approved vendor and that critical raw material specifications are met. Once the product is found to be acceptable, it will be released from the receiving warehouse to production. Materials which do not meet the specifications or show signs of adulteration will be refused, sent back to the vendor, or disposed of.

Information regarding deviations from specifications during the primary audit will be fed back to the supplier for immediate corrective action. Serious or frequent deviations from specifications will lead to immediate disapproval of the supplier's ingredient to be used in the production process.

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AREA 5: Manufacturing controls

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- 1. How does SPC influence control?
- 2. A mechanism for feedback from SPC data evaluation to control of machines and product is delineated
- 3. Is an equipment set-up procedure used? If so, is it documented?

SPC serves as an alarm to warn plant operators of the occurrence of out-of-control products. Feedback systems are applied in SPC in order to correct the processes back to the normal status. To close the feedback loop a procedure for identifying assignable causes will be set up. Procedures consist of technical instructions (see Appendix I) such as check lists of factors affecting the process and organizational instructions such as the position and name of the individual responsible under certain circumstances.

The process of making beef chunks with gravy in tray packs consists of two cooking operations, beef precooking and gravy preparation, and a filling/seaming line followed by a retorting process. The mechanism for feedback from SPC data evaluation for the tray pack production line is shown in a diagram in the Appendix I. In the diagram, the rectangles represent the operations while the ellipses represent the inspection stations. The feedback control mechanisms linking operations and inspection stations are shown by the dashed lines with arrows. Following the diagram, timely SPC data evaluation, control charts, corrective actions and inspection stations are shown in separated tables.

Equipment set-up procedures are used and documented in Appendix II.

AREA 6: Statistical Process Control Procedures

A. Criteria for use of SPC

- 1. Which processes were chosen for SPC application and why?
- 2. Are criteria for Criticals/Majors/Minors defined?
- 3. If SPC is deemed inappropriate for a particular purpose, what actions are taken?

SPC is applied at critical production steps where the product can be measured in a timely manner. SPC helps to identify the out-of-control status which results from the unpredictable or uncontrollable factors in the process. These factors could possibly lead to the production of defective products. An out-of-control status will not occur from controllable factors since controllable factors are monitored tightly using sensors and feedback controllers. Table 2 shows the processes to which SPC is applied for the production of beef chunks and gravy, and the reasons for the application:

PROCESS	REASON FOR SPC		
Raw beef sampling inspection	Affects final fat content, connective tissue, beef chunk size, the presence of bone pieces and foreign objects.		
Precooked beef inspection	Drain weight is affected.		
Beef fill weight inspection	A certain maximum amount of beef is allowed for thermal processing in the retort and a minimum amount of beef is needed to meet drain weight specifications.		
Raw gravy ingredients sampling inspection	Raw ingredients must meet raw ingredients and microorganism specifications. Affects viscosity.		
Gravy inspections	Affects thermal processing and viscosity of finished products.		
Empty trays inspection	Checks for dents, scratches & holes to ensure hermetically sealed containers after retorting.		
Filled tray pack inspection	To ensure the net weight.		
Seaming inspection	To ensure hermetically sealed containers: proper vacuum, tray condition and seaming.		
Final product sampling inspection	Check vacuum, can condition, and variation in drain weight to ensure that finished product specifications are met.		

Table	2:	SPC	App	lications
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Projected quality problems that require SPC are taken in part from the Pareto analysis of MRE products offered to USDA from 1987 to 1989. Since the historical data of the tray pack line is not available, the following processes, which contain quality problems, were suggested by the MRE Pareto analysis (see Appendix III) and a discussion with the USDA: Seams, Drained Weight & Net Weight.

Table 3 defines the criteria for defect level:

Composite Definitions For Seriousness Classification	CRITICAL	MAJOR A	MAJOR B	MINOR
CONSUMER	Will surely cause personal injury or illness	Very unlikely to cause personal injury or illness	Will not cause injury or illness	Will not cause injury or illness
	product totally unfit for use	product unfit for use and may cause rejection by the user	product more difficult to use, e.g., removal, or will require improvisation by the user. Affects appearance neatness	appearance neatness
RELATIONS	Will offend consumer's sensibili- ties due to odor, appearance, etc.	Will likely be noticed by consumer, and will likely reduce product salability	May be noticed by some consumers, and may be an annoyance if noticed	Unlikely to be noticed by consumers, and of little concern if noticed
LOSS TO COMPANY	and will result in losses greater than value of product	and may result in losses greater than the value of the product. Will substantially reduce production yields	Unlikely to lose customers. May require product replacement. May result in loss equal to product value	Unlikely to result in loss
EFFECT ON CONFORMANCE TO GOVERNMENT RELATIONS	Fails to conform to regulations for purity, toxicity, identification	Fails to conform to regulations on weight, volume, or batch control	Minor nonconformance to regulations on weight, volume, or batch control, e.g., completeness of documentation	Conforms fully to regulations

Table 3: General Defect Level Classification

Table 4 defines seriousness rating of the various SPC process control variables in the tray pack production line:

PROCESS	PARAMETER	RATING	REASON FOR RATING
Raw Materials Inspection	Beef Chunk Size	Critical	Affects sterility of product after retorting
	Tray Integrity	Major B	May be an annoyance if noticed
Precooking	temperature residence time air velocity	Major A	May fail to conform to regulations on weight
Gravy Preparation	viscosity temperature	Critical Critical	Affects sterility of product after retorting
Filling Process	beef fill weight gravy fill weight	Critical Critical	Affects consumer safety and sterility of product after retorting
Packaging	vacuum sealing can condition	Major B Critical Critical	May cause oxidation of product May cause a non- hermetically sealed container
Retorting	pressure time temperature RPM	Major A Critical Critical Critical	May render unfit for use Affects sterility of product after retorting
Incubation	Sterility	Critical	Will surely cause personal injury or illness

 Table 4: Defect Level Classification For the Tray Pack Line

SPC will be used to measure all processes including those using sensors and computer controlled devices. SPC provides a monitoring system to ensure that the hardware controllers are working properly. For instance, the retort process is tightly monitored by a microcomputer, on the other hand, the tray's initial temperature before retort and the tray's seam conditions are monitored using control charts (See Appendix I.) Initially, the contractor uses SPC as much as possible to monitor the processes. If the process is identified to be very robust (stable) the sampling frequency can be reduced and its frequency can be estimated based on economic analysis.

B. Process Capability Studies, for each item/process

- 1. Application is fully explained
- 2. Criteria for study is explained
- 3. Contractor's definition of poor and marginal capability is explained

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- 4. Policy when capability is determined to be poor or marginal is explained/implemented
- 5. Analysis of statistical distributions, explained, complied with

Process capability studies will be performed in the following circumstances:

- 1. Production line development (off-line)
- 2. New methods or technology are applied in the process
- 3. Manufacturing environment is changed (Ex: moving, new temperature & humidity controller, etc.)

To study the process variability, in-process data is collected (as much as possible) in the pilot run of production. Then histograms and standard deviations are drawn and calculated accordingly. The following are the processes in which no product specifications are available:

- 1. Beef Precooking
- 2. Gravy Preparation
- 3. Beef Pre-weighing
- 4. Gravy Filler
- 5. Packaging

Since there are no specifications available for these in-process measures, the contractor should determine acceptable tolerance limits for the specifications which are then used to estimate the capability of the process. X-bar & R charts also allow us to study the processes without regard to specifications.

Variable data, which is collected from the final product, is studied according to the process capability ratio which compares the process variability with quality specification as a quantitative index. The following formulas, listed under each variable characteristic of the beef chunk tray pack, show how to calculate the process capability index:

- 1. Net Weight: (Avg. Spec Ind. Spec)/ 3σ
- 2. Drained Weight: (Avg. Spec Ind. Spec)/ 3σ
- 3. Fat Content: (Avg. Spec Ind. Spec)/ 3σ
- 4. Sait Content: (USL LSL)/ 6σ
- 5. Viscosity: $(USL LSL)/6\sigma$

where avg. spec. stands for the specification for the sample average and ind. spec. stands for the minimum specification for the individual sample. These two specifications can be seen as the nominal specification and the lower specification limit, respectively.

For attribute quality characteristics of the final product, p & c-bar control charts will be utilized for process capability studies. In the tray pack production line, p charts are used for sealing conditions, while c-bar charts are used for can conditions (see Appendix I.) If one output value deviates from the control limits, the process is deemed to be marginal, and if 2 or more values deviate, the process is poor.

R&D, along with the QA engineer, will conduct process capability studies on new product formulations and new equipment which they recommend. The QA engineer will conduct process capabilities on an on-going basis after the processes have been accepted.

The processes with capability index less than 1.0 will be considered a poor process because the nonconforming product will excess 0.27% under the assumption of a normally distributed process. A process with 1.0 to 1.33 of process capability index will be deemed as a marginal process while process capability index more than 1.33 will be considered a good process.

The contractor will use a new quality control approach in the total quality system: offline quality control. The contractor realizes that the role of the traditional quality control approach is to ensure the processes are working properly but not to improve the processes. A program of constant quality improvement will be in effect. Off-line experiments and robust design (Taguchi's Method) will be used to address improvements in process parameters and product design. Clearly, the priority will be to address processes showing marginal capability to meet specifications. Software packages such as StatGraphics, Quality Alert and SAS will be routinely used to analyze process capability and control chart data. QA engineers with background in probability, statistics and quality control will do the analysis which will include tests for normality, estimations of distribution parameters, design of experiments (including orthogonal arrays) and analysis of variance. The results of the analysis will be used to update the UCLs and LCLs of control charts. Furthermore, process parameters can be determined to achieve robustness through the experimental design and data analysis.

- C. Control Chart Policy (each item and process).
 - 1. Types of charts and rationale for use.
 - 2. How and when UCLs/LCLs are established.
 - 3. How, when and why are limits adjusted.

Types of charts for in-process characteristics have been summarized in Appendix I for each inspection station. The reason that they are used is to ensure that the process is performing as expected and that the final product is within its specification limits. The following table summarizes the types of control chart used for each in-process characteristic and the rationale for use:

Characteristics	Control Charts	Rationales
Precooked beef weight Beef fill weight Gravy viscosity Gravy density Salt content Tray net weight Retort Initial temp. Head space External Seam Seam sectioning Vacuum Gauge	X-bar chart & R chart	Variable Characteristic
Can surface defects	C-bar chart	Nonconformities in one product
Vacuum Seal	P-chart	Fraction of nonconforming products

UCLs and LCLs are determined by the mean and standard deviation calculated at the beginning of the production run. The QA engineers will conduct weekly meetings reviewing the control policy with the line supervisors, key line operators and QC technicians. The results of this meeting along with data analysis will be used to update the UCLs and LCLs, if needed. The reason that the limits would be adjusted is most likely because of a change in process capabilities.

- D. Criteria for Subgroup Sample Size and Frequency (each item and process).
 - 1. *Is plan fully explained?*
 - 2. Is sampling appropriate to production rate to identify variation in the process?
 - 3. Is rationale for subgroups logical?

The sample size and frequencies for each process are shown in Appendix I. The sample size is determined according to the production rate of 16 trays per minute, the types of control charts used, the particular characteristic being measured and the measurement procedure used.

In the weekly meetings conducted by the QA engineer, it will be determined if the sampling is appropriate for the production rate to identify variation in the process. If it is not, then the sampling method, sampling frequency and sample size will be adjusted.

Subgroups are always defined by production batches. In our SPC plan, two subgroups are defined in the control charts: 1) kettle batches, 2) retort load. These two subgroups are depicted in inspection station e and i respectively (refer to Appendix I).

- E. Criteria for Action
 - 1. Tests used to identify/define out-of-control processes.
 - 2. How is nonconforming product distinguished and handled? (i.e. to preclude it from being offered for acceptance.)

X-bar, c-bar, p charts and multiple checklists will be used to identify the out-of-control processes (see Appendix IV run rules). When there is an out-of-control signal, the process must be examined and then a decision will be made as to whether the process must be shut down. Refer to Appendix I for details on control charts.

Nonconforming products are classified into the following three categories:

1. Schedule Process Deviation of Retort Process

This category consists of nonconforming products caused by any parameter that affects heat transfer in retort. This includes all critical parameters such as initial temperature, viscosity, beef fill weight, and head space. The problem will be handled by consulting the process authority and then by the process authority recommending an appropriate action.

2. Incubation Test

1-2 cans per retort batch are stored at 95° for 10 days to determine if microorganisms are present in the tray. However, the can should be checked for seal defects before incubation. If a can swells, inspect the can for a seal defect. If the seam is bad the can could have been contaminated after retort. If this occurs, the same retort batch has to be entirely tested and screened out for nonconforming products. If the can swells without assignable cause (e.g. seal) then destroy the lot.

3. Finished Product Specifications

If finished products do not meet all the military specifications (but meet the above two requirements), then, isolate the lot, put it on hold, and re-sample. Release the lot if it meets acceptance criteria for double sampling plan. If it still does not meet the specifications then do one of the following: make a request for the variance of the specifications, resell it to 3rd parties, destroy the lot or, donate the lot.

F. Redundant Operations.

- 1. Are identical machines/stations delineated and controlled appropriately.
- 2. Is data stratification addressed? (How is the process defined?)

We do not have redundant operations.

G. Corrective actions/failure analysis

- 1. How are investigations handled?
- 2. Responsibilities for action addressed for: Inspectors, Operators, Supervisors, and Management.
- 3. Corrective actions/failure analysis addressed for the process.
- 4. Corrective actions addressed concerning product.

Corrective actions will be based on run rules which can be found in Appendix IV. If the run rules do not cover the particular situation the line operator and QC technician will contact the plant supervisor who will analyze the problem and develop an action plan. If the problem reoccurs, an in depth plan will be developed to analyze the problem and to develop appropriate additional run rules to deal with the situation. The following personnel (refer to Area 2.A) will be involved in this in depth study:

1. Line Operators and QC Technicians

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- 2. QA Engineer
- 3. Supervisors
- 4. Management

We shall define corrective action as creating a change in product development, production, or distribution to eliminate the risk of a quality failure. Corrective action requires periodic assessment of quality failures: by product, by failure mode, and by material suppliers. The analysis of specific failures may require the evaluation of the quality system to prevent recurring failures.

Comprehensive and well-integrated activities for achieving corrective actions are essential to a quality system. The following are nine major items for consideration in planning and implementing this important area of the quality system. Corrective actions cut across the gamut of operations within an enterprise.

- 1. Detection and documentation of problems
- 2. Quality reports leading to corrective action
 - . **Performance reporting**
 - . **Production reports**
 - . Quality reports
 - . In-process and final product inspection reports
 - . Cost reports
- 3. Evaluating the need for corrective action
 - . Routine inspection and tests
 - Customer complaints and tests
 - . Product service calls analysis
 - Warranty claims analysis
- 4. **Responsibility for corrective analysis -- organization and implementation**
- 5. Initiating corrective action, follow-up and control of corrective action
- 6. Determining the cause
 - Assessing impact
 - Designating responsibility for cause
 - Identifying variables
 - Incorporating change
- 7. Application of corrective action

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- Supplier
- . Material
- . Product
- . Process
- . Personnel
- . Field
- 8. Nonconforming product review and disposition
- 9. Recall of manufactured items product safety performance
- H. Pertinent facts to be recorded on control charts are delineated for major factors of assignable cause.

The following is a list of noise factors (assignable causes):

- 1. Raw materials
- 2. Methodology
- 3. **Personnel** (operators and QC technicians)
- 4. Equipment
- 5. Environment
- 6. Measurements

The line operator will note any incident happening on the line, such as operator change, shift change, new lot of raw materials, equipment calibration and maintenance, and environment conditions. The line operator will also record on the chart the time and the action took based on an out-of-control situation requiring an alternate but more appropriate correction than described by the run rules. He/she will note the reasons for this and note who he/she consulted for this variance in corrective action. These factors can be detected and recognized following the organizational and technical instructions when applied control charts detect an out-of-control process.

1. Type and extent of reliance on computer hardware and software used for SPC explained in plan.

Microcomputers which are implemented in the production line play the following role:

-Automatic sensing control

-Statistical process control

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- 1. SAS & StatGraphics Data analysis
- 2. Taguchi Analyst Robust design for off-line quality engineering
- 3. Quality Alert or similar software packages Control charts for on-line quality control

-Electronic database

- 1. Operational and technical instruction manual
- 2. Quality control manual
- 3. SPC plan manual
- 4. Trouble shooting manual
- 5. Product control manual
- 6. Process control manual
- 7. Sensor information manual

AREA 7: Test/Measurement Equipment Calibration and Control

A. Calibration Program

The contractor has a calibration program for each measurement and test equipment used in the SPC program. The description of a detailed calibration program for each instrument is described in the QC manual, together with the standards to be used, who is responsible to perform the job and at what frequency. The frequency and type of checks will depend on the equipment, its use/abuse and history of drift. For example, a check weigher will be checked twice a shift with a known weight by a QC technician and a set of reference weights will be checked, calibrated and certified once a year. It is the responsibility of the QA engineer to design and document the calibration procedures, to assure that the calibration program is performed on time and that it is performed according to the prescribed methods.

The following is an abstract of the calibration programs of some major pieces of equipment/instruments:

Checkweigher: The QC technician places every four hours a known weight container ten times through the checkweigher and records each of the ten readings. He/she calculates the average and range and plots data on control chart. He/she notifies the line supervisor immediately if the checkweigher is out of the control limits of the chart.

Weigh Feeder: TBD

Certified Weights: A contract will be set-up between the vendor of the weights and the contractor to check the weights at least once a year and to certify the weights for accuracy. These weights will be used as standard for in-house calibration of all weighing equipment.

Scales: All scales used in the process will be checked and when necessary recalibrated once a month with the certified weights.

Timing devices: Clocks and timers used in the retort process will be checked at the beginning of each shift against a wall mounted clock to assure that all the timing devices refer to the same time within one minute. The wall mounted clock will reflect changes in day light savings time and will be checked for accuracy twice a year.

Thermometers: The plant will have a certified Mercury and Glass Thermometer for calibration purposes. This thermometer will be recertified once a year by a recognized

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institution. The retort MIG will be checked and, if necessary, calibrated against this instrument four times a year. All other temperature measurement devices in the retort process will be checked and calibrated against the retort MIG once a month. Also, at the same time, pressure gauges in the retort process will be calibrated based on the steam pressure/temperature relationship.

Retort chart recorders: The chart recorders will be checked once a month against the MIG and be set 1°F lower than the Retort MIG as standard.

Other Chart recorders: Each temperature chart recorder will be checked every three months on accuracy and calibrated when necessary against a portable thermocouple thermometer. The thermometer is standardized against an ice bath on a quarterly basis.

Analytical measurement instruments: Salt, fat and viscosity sensors will be calibrated according to the vendor recommended schedules and methods.

B. Adjustments/corrections:

Calibration data will be plotted on a calibration control chart. The UCL and LCL of this control chart are based on the capability study of the instrument. Adjustments and corrections will be performed according to the manufacture's recommendations if the control chart indicates an out-of-control condition, based on the control chart run rules. Equipment which needs adjustments beyond the range of available adjustments will be taken out of production and repaired. Records of the calibration and adjustment activities will be recorded by the person(s) responsible for the calibration and held by the line supervisors. A cross reference of calibration checks will also be made on quality control charts which rely on the accuracy of that particular instrument.

C. Records available to government personnel for review and evaluation

Calibration records will be audited by the QA engineer at regular intervals to confirm adherence to policy, procedures and accuracy. Equipment which seems to require frequent calibration will be recommended to be replaced by instrumentation which demonstrates less drift. Records will be made available to government personnel for review and evaluation when requested.

AREA 8: Contractor Audit Program

A. Audit procedure exists:

Procedures encompass all aspects of the SPC program. (checklists included)
 Audits include objective evaluation of SPC-related practices, procedures, and instructions and conformance with the plan.
 Audit procedures include evaluations of the effectiveness of the SPC program.

Auditing the Contractors Quality Control System, under which the SPC plan resides, will be the responsibility of the QA manager. The QA manager will initiate audits at regular time intervals and include all areas of the manufacturing system, such as purchase control, process control, data analysis, personnel training, equipment calibration, record keeping, adequacy of corrective action, etc (see attached check list). The audits are designed to assure that the contractor fully complies with the contract clauses: 52.246-E029, requiring Statistical Process Control in highly critical areas of container integrity and critical control points of the retort process. The frequency of these quality audits will be increased when deficient areas are noted until they are satisfactory corrected. The process audits will be executed by the QA engineer, who will be accompanied by the line supervisor throughout the audit. Audits of management practice will be performed and evaluated by the QA manager.

The audits will be executed by the QA staff who are well trained in SPC related techniques, procedures and audits (see area 3). The QA staff is independent from the production process and will have an objective view regarding the implementation and effectiveness of the SPC plan.

The audit will address adherence to the SPC plan, accuracy of measurements, accuracy of information contained in charts, traceability of chart information, calibration information of production and measuring equipment, completeness of the files and effectiveness of the SPC procedures to correct deficiencies and general trends.

The auditor will evaluate the effectiveness of the SPC program in reducing product defects. Marginal improvement in finished product defects will result in recommendations to reevaluate the variables under control and the corrective actions which are being used.

B. Documentation of audits required.

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A report will be prepared and submitted by the QA staff on the audit results. The report will include information regarding areas which comply with the SPC plan as well as areas which are deficient. The report will recommend corrective actions to prevent reoccurrence. This report will be distributed to production supervisor(s), and all management (including copies to the President and Vice President). A review meeting will be scheduled between the management and QA staff to discuss deficiencies and to formulate corrective actions.

C. Audit Results.

1. Analyzed to identify trends/effectiveness/discrepancies.

2. Audit results discussed with responsible supervisor/management

3. Top management responsible for reviewing audit results and taking corrective actions.

The QA engineer will be asked during the audits to analyze the data for trends, effectiveness of the SPC program and discrepancies between SPC program and actual performance. Trends in data could indicate systematic behavior of personnel or equipment or lack of it. For example, if record keeping is deteriorating the defect ratio may go up at the end of each day, etc. Effectiveness of the program should be evaluated in terms of reduction and/or elimination of defect categories. Analysis for discrepancies would identify the commitment and understanding of personnel to the importance of a SPC program.

The audit report will be distributed to production supervisors, plant managers and the R&D manager. A review meeting will be scheduled between the above mentioned parties to discuss deficiencies and corrective actions. Key operating personnel will be involved in these discussions. A written corrective action plan, with a implementation time table, will be prepared by this team and distributed to the appropriate parties.

All of the manufacturing facility management will be responsible, as a team, for corrective actions based on the audit report. The President and Vice President will be informed about the recommended corrective actions and will be asked to concur with the actions recommended.

D. Corrective Action Program.

 Corrective action program requires documentation of deficiencies and action to prevent their reoccurrence.
 Documentation, handling and disposition of suspect product is required.

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If, during the audit, significant errors are found that could have led to the production of nonconforming materials, immediate action will be taken by management to identify the causes of such errors. Errors due to equipment or instrumentation failure will lead to immediate and appropriate action (adjustment, calibration, repair or replacement). Also, it will be reviewed if a preventative maintenance schedule should be developed to prevent reoccurrence. Errors due to employees not following the procedures will lead to an immediate evaluation of the capability of the employee and his/her training program. Possible actions which will be taken are retraining, additional training, reassignment or termination. Actions and decisions will be carefully documented by the responsible management team member.

If, during the audit, significant errors are found that could have led to the production of nonconforming materials, immediate action will be taken to identify and segregate the suspected lots of material. Suspected materials will be evaluated and a determination will be made either to release the product, rework the product, dispose of the product or donate the product. Actions and decisions will have to be carefully documented. Actions will also be taken to correct the problem which caused the production of nonconforming materials.

- E. Audit frequency.
 - 1. Audits periodically scheduled based on importance.
 - 2. Audit frequency adjusted according to problems encountered. (or lack of)

A complete quality audit cycle will be held at least once every six months. Audits of critical areas will be scheduled a few times within an audit cycle.

The frequency of a specific area audit will depend on the relationship between that area and historic data identifying product defects. For example, the audit of the packaging process might occur twice a month if historic data indicates that this area is the primary cause for producing nonconforming products. The frequency can be reduced once it has been established that the area is under control and corrective actions are working to prevent defects. Table 5 lists areas to be audited and the frequency of audits.

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AREAS TO BE AUDITED	FREQUENCY OF AUDITS
Statistical Control	4 times a year
Sampling Procedures	4 times a year
Corrective Actions	4 times a year
Defective Product Handling	4 times a year
Equipment Calibration	4 times a year
Purchase Control	Twice a year
Personnel Training	Twice a year
Record Keeping	Twice a year
Instruction Manual	Twice a year

Table 5: Areas to be Audited and Frequency of Audits

F. Auditors are properly trained/evaluated.

The auditor will be sufficiently experienced in all phases and aspects of a SPC audit and will be trained by a qualified and acknowledged institution or professional association. See area 3 for more details

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AREA 9 SPC Records

- A. Records are developed for:
 - . Supplier Evaluation Form
 - . Vehicle Inspection Report
 - . Raw Ingredient Receiving Log
 - . Packaging Material Receiving Log
 - . Raw Beef Inspection Form
 - . Raw Material Inspection Report
 - . Meat Precook Processing Log
 - . Sauce Formula Batch Sheet
 - . Visual Seam Examination Form
 - . Seam Quality Control Form
 - . Critical Factor Monitoring Form
 - . Retort Processing Log
 - . Record of Incubation
 - . Finish Product Examination Form
 - . Packaging Report
 - . Packaging Data Sheet for Trays
 - . Product Failure Report Form
 - . Hold Summary Log
 - . Shipping Record
 - . Pest Control Report
 - . Sanitation Check List
 - . SPC Audit and Review Check List
 - . Cause and Effect Diagram for Seams
 - . Cause and Effect Diagram for Drained Weight
 - . Cause and Effect Diagram for Net Weight

See Appendix V for the actual forms.

B. Control Charts Maintained for:

- 1. Each characteristic identified in the plan
- 2. Data recorded and plotted at each sampling interval
- 3. Procedures require documentation of corrective actions on control charts
- . Precook Beef Control Chart
- . Gravy Viscosity Control Chart
- . Gravy Salt Content Control Chart
- . **Pre-weighing Process Control Chart**
- . Can Surface Defect Control Chart

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- External Seam Control Chart
- Seam Sectioning Control Chart
- Filled Tray Pack Checklist
- Seam Teardown & Internal Control Chart
- . Vacuum Gauge Control Chart
- . Initial Temperature Control Chart
- . Surface Defect Control Chart after Retort
- Finish Product Examination Form

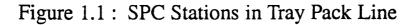
See Appendix V for the actual charts.

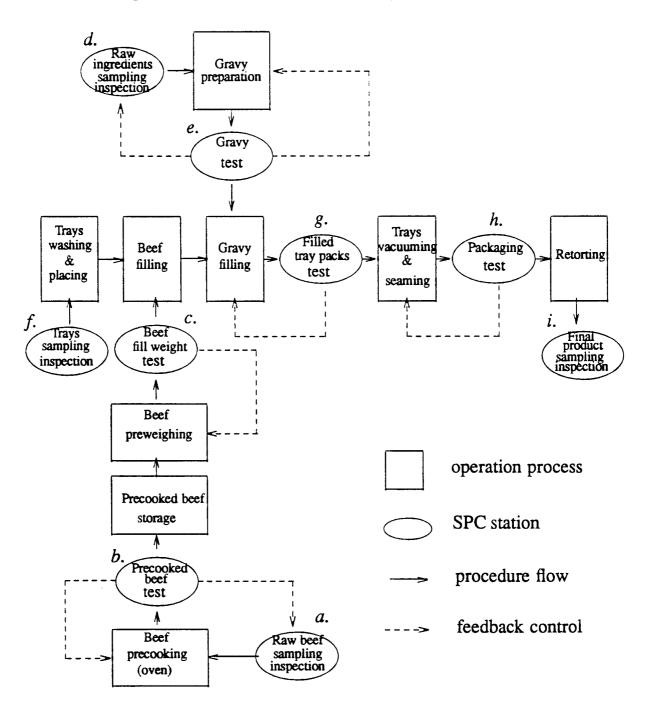
- C. Retention period and review
 - 1. All control charts retained for 3 years after completion of the contract
 - 2. All records will be made available for government review upon request

All control charts will be retained for 3 years after completion of the contract by the line supervisor. They will be made available for government review upon request.

APPENDIX I

INSPECTION STATIONS AND FEEDBACK CONTROL MECHANISMS





Station a Raw Beef Sampling SPC Station					
Characteristics	Control Method	Sample Size	Corrective Action		
Foreign Color					
Foreign Odor					
Foreign Material					
Drained Wt.					
Cube Size	MIL-STD-105E Sampling Plan	Special Inspection Level S-4	accept/reject		
Surface Fat					
Connective Tissue					
Bone Pieces					
Microbiology Quality					

Station b Precooked Beef SPC Station						
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action		
Weight Loss of Beef	x Chart & R Chart			1. Check the oven 2. Re-check the raw beef		
Precooked Beef Texture	Checklist			same as above		
Foreign Material	Checklist			same as above		
Foreign Odor	Checklist	4 samples of 5 lb beef	1/2 hr (480 trays)	same as above		
Foreign Color	Checklist			same as above		
excessive heating	Checklist			same as above		
beef chunks mushy	Checklist			Check the oven		
Incident Note	Comments	-	-	 Operater change Shift change New lot of raw beef Conditions Last calibration others 		

Station c Precooked Beef Fill Weight SPC Station						
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action		
Net wt. of precooked beef/tray	x Chart & R Chart	4 trays		Check the weigher		
Foreign Material	Checklist		1 hr (960 trays)	Check the evironment		
Foreign Odor	Checklist			same as above		
Foreign Color	Checklist			same as above		
Incident Note	Comments	-	-	 Operator change Shift change New weigher Conditions Last calibration Others 		

Station d						
Raw Ingredients Sampling SPC Station						
Characteristics Control Method Lot Size Corrective Action						
Raw Ingredients Certification - shipping lot accept/reject						

	Station e Gravy SPC Station											
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action								
Gravy Viscosity	x Chart & R Chart			 Check raw ingredients Check the kettles Check the formula of gravy 								
Gravy Density	x & R Charts			same as above								
Gravy Lumpy	Checklist			same as above								
Salt Content	x Chart & R Chart	4 samples	1/2 hr. (every kettle)	 Check raw ingredients Check the formula of gravy 								
Foreign Material	Checklist											1. Check raw ingredients 2. Check the environment
Foreign Odor	Checklist			same as above								
Foreign Color	Checklist			same as above								
Incident Note	Comments	-	-	 Operator change Shift change New lot of raw ingredients Conditions Last maintenance of kettles Others 								

Characteristics	Control Method	Sample Size	Corrective Action
Can Dimension			
Flange Dimension	MIL-STD-105E Sampling Plan	Special Inspection Level S-4	accept/reject
Dents			

Station g Filled Tray Packs SPC Station						
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action		
Net Weight of Cans	x Chart	whole lot	continuous automatic measurement	 Check the weighing scale Check the gravy filler Add or extract gravy 		
Gravy Splashes on Edges	Checklist			Check the filler		
Foreign Material	Checklist	16 trays			Check the environment	
Foreign Odor	Checklist				Check the environment	
Foreign Color	Checklist		10 5-	Check the environment		
Scored Tray	Checklist		lo trays	1/2 hr	Check the conveyor	
Crushed Tray	Checklist					Check the conveyor
Holed Tray	Checklist				Check the conveyor	
Corroded Tray	Checklist			Check the conveyor		
Incident Note	Comments	-	-	 Operator change Shift change Last adjustment Conditions Last maintenance of filler Others 		

Station h					
		Seaming SPC S	tation		
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action	
Surface Defects of Can (dents, abrasions & cuts)	C Chart & R Chart				
Scored Tray	Checklist				
Crushed Tray	Checklist	8 trays			
Holed Tray	Checklist		1 hr (960 trays)	Check seamer & conveyor	
Corroded Tray	Checklist				
Burst	Checklist				
Rupture	Checklist				
Overfill	Checklist				
Vacuum Seal	p-chart	100	2 hr (1920 trays)	Check seamer	
Initial Temp. for Retort	x chart & R Chart		Retort Batch (240 trays)	Check Environment	
Head Space	x Chart & R Chart	1 trays		1. Check filling processes 2. Check checkweigher	
External Seam Measurement (length and thickness)	x Chart & R Chart	4 trays*	1 hr (960 trays)	Check seamer	
Seam Teardown & Internal (cover & hook, pressure ridge & tightness)	x Chart & R Chart	2 trays*	1 hr (960 trays)	Check seamer	
Seam Sectioning (length, overlap, body & hook length)	x Chart & R Chart	2 trays*	1 hr (960 trays)	Check seamer	
Vacuum Gauge	x & R Chart	4 trays	1/2 hr	Check seamer	
Incident Note	Comments.	-		 Operator change Shift change New lot of lids Conditions Last calibration of gauge Others 	

* Approximately 4 retort batches are run every hour, so 4 trays will be accumulated each hour by performing the tests of initial temperature for retort and head space. All four of these trays will be used to perform the External Seam Measurement, and then, of those same 4 trays, 2 will be used for the Seam Teardown & Internal test, and the other 2 will be used for Seam Sectioning test.

Station i Finished Product Inspection after Retorting					
a		-			
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action	
Surface Defects of Can (dents, abrasions & cuts)	c Chart & R Chart			Check the retorter	
Scored Tray	Checklist		Retort Batch	Check the retorter	
Crushed Tray	Checklist	4 trays		Check the retorter	
Holed Tray	Checklist			Check the retorter	
Corroded Tray	Checklist			Check the retorter	
Incident Note	Comments	-	-	 Operator change Shift change Conditions Last calibration of retorter Others 	
Finished Product Sampling Inspection after 24 hour storage (a sample size of 1 from every retort batch - 8 from 2 hrs. production)					
Characteristics	Control Method	Sample Size	Sampling Interval	Action	
Net Weight	x & R Charts				
Drain Weight	x & R Charts				
Viscosity	x & R Charts				
Beef Texture					
Chunk Dimensions					
Connective Tissue		4 from 8 trays	2 hrs. production	Review Charts & Checklists	
Bone Fragments	Checklists				
Gravy Texture & Color	Checklists				
Foreign Color					
Foreign Odor					
Foreign Material					
Salt Content	x & R Charts	1 6	2 hm modeuties	Review Charts & Checklists	
Fat Content	x & R Charts	4 from 8 trays	2 hrs. prodcution	Review Charls & Checkhists	
		Incubation To	est		
Characteristic	Method	Sample Size	Sampling Interval	Corrective Action	
Microorganism Growth	Stored at 95°F for 10 days	2 trays	Retort Batch	 Check the retort process Check the seaming process 	

SPC TECHNICAL INSTRUCTION FOR BEEF CHUNK TRAY-PACK LINE

In-Process SPC Station

The stations that are characterized as in-process are those ranging from the precooking of the beef to the filling of the trays with beef and gravy. The first station discussed will be the Precooked Beef SPC station, station b on Figure 1.1. At this station, precooked yield, which determines how much beef should be placed in the trays, will be calculated. The next station, Precooked Beef Net Weight SPC station, labeled c on Figure 1.1, is a check to see if the beef in the trays meets net weight requirements. Station e, Gravy SPC station, checks gravy viscosity, texture, salt content, and density for sensory results and also checks for net weight. The last station of in-process SPC stations is Filled Tray SPC station, station g on Figure 1.1, which monitors the gravy filling process. Following are descriptions of procedures, goals, and control actions of these stations.

Precooked Beef SPC Station

The precooking process plays a very crucial role in the production line because the effects of this process determine quality characteristics of the finished product, such as, drained weight, gravy viscosity, and sensory results. Precooked beef yield is an important in-process characteristic that determines the amount of precooked beef and gravy needed for each tray to meet the drained and net weight requirements. Every 1/2 hour the inspector will take 4 samples of 5 lbs of raw beef and place them separately on the oven conveyor. The 4 samples should be weighed 10 minutes after removal from the oven. The 10 minutes delay of measurement is to ensure the measuring consistency since the weight of precooked beef will vary by time. The delay of measurement can be chosen other than 10 minutes for the inspection convenience. However, the delay of weight measurement after the precooking process should be consistent with the delay used in the off-line experiments where the settings of the precooking process were determined. The inspector will record the weight data at the appropriate spots on the \bar{x} and R chart form [Figure 5.1] and then the average of these 4 data points will be the point on the control charts for that time period. Precooked beef yield can be calculated using the following formula:

Precooked Beef Yield =
$$\frac{\text{Precooked Beef Weight}}{5} \times 100\%$$

Foreign odor, color and material can result during residence in the oven and should be visually inspected for when weighing the four samples. Excessive heating can also result by inappropriate cooking. Observations should be noted on the checklist following the \bar{x} and R charts on the form [Figure 5.1.] Any incident occurring in the plant regarding the precooking process such as operator change, shift change, new lot of raw beef, oven maintenance and calibration should be noted on the control chart form. If problems are indicated in the \bar{x} and R control charts, the following conditions should be investigated accordingly:

- 1. Oven Conditions
 - conveyor controller
 - temperature controllers in chamber 2 & 3
 - temperatures in chamber 1 & 4
 - air blowers in chamber 2 & 3
 - steamers in chamber 1, 2, 3 & 4
- 2. Raw Beef Quality
 - surface fat
 - texture
 - bone pieces
 - connective tissue

When foreign odor, color and material are found, the process should be shut down and the environment conditions should be check immediately including the following particulars:

- raw beef for contamination

- oven for contamination
- ambient temperature
- ambient humidity
- Plant sanitary conditions
- operator hygiene

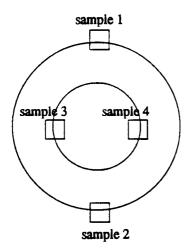
Precooked Beef Fill Weight SPC Station

The precooked beef is preweighed before it is placed into the trays. In order to ensure the weighing process is working properly, a second calibrated weigher will be used to confirm the results of first weigher (in Precooked Beef Preweighing process). Precooked beef is weighed according to the calculated filled weight for each tray can. Every hour (960 trays) 4 tray samples of precooked beef are taken and weighed. The data will be recorded on an \bar{x} and R chart form [Figure 5.2.] Foreign odor, material, and color, (which can result from transport and storage) should be checked for while weighing the samples. Any incident occurring in the plant regarding the weighing process such as operator change, shift change, and weigher maintenance and calibration should be noted on the control chart form. If problems are found in the \bar{x} and R charts the weigher should be checked for accuracy or damage. Again, when foreign odor, color and material are found, the process should be stopped immediately and check the followings:

- precooked beef for contamination
- containers for contamination
- ambient temperature
- ambient humidity
- plant sanitary conditions
- operator hygiene

GRAVY SPC STATION

The objective of this SPC station is to ensure good sensory results and to meet the net weight requirements. Gravy viscosity, texture and salt content will affect the sensory results while the density of gravy will affect the amount of gravy to be deposited in each tray by Raque filler. 4 samples of gravy are taken every kettle (1/2 hour) to measure viscosity, density and salt content. The samples should be taken fairly from locations in the kettle. The following locations are suggested:



Data of viscosity, density and salt content will be recorded on \overline{x} and R control chart forms [Figures 5.3-5]. The inspector should also lookout for lumpy gravy, foreign color, foreign material, and foreign odor that could arise during the cooking process. Any observations should be recorded on the checklist. Incidents in the plant regarding the process such as operator change, shift change, new lot of starch and weigher maintenance and calibration should be noted on the control chart form. If any problems are exhibited in the viscosity, density or salt content control charts the following conditions should be investigated:

- 1. Ingredients Quality
 - starch
 - salt

- 2. Gravy Formula
 - starch to water ratio
 - proportion of ingredients

The environment conditions should be checked after the process is stopped due to the exhibition of foreign odor, color and material:

- ingredients for contamination
- kettles for contamination
- ambient temperature
- ambient humidity
- plant sanitary conditions
- operator hygiene

Filled Tray SPC Station

The main objective of this station is to monitor the gravy filling process using the Raque filler. The Raque filler adds a volume of gravy to a tray in which a preweighed portion of beef has already been placed and checked (precooked beef fill weight SPC station) By observing this process, nonconforming trays will be diverted from the production line and gravy can be added or extracted from trays as needed to meet the net weight specifications. The net weight of the filled can will be measured continuously with a check-weigher. A recorder will be connected to the check-weigher and automatically record data on an \bar{x} and R chart to monitor the process. In addition to the net weight the inspector at this station will take a sample size of 16 trays every half hour and check for the following attributes:

- Gravy splashes on edges
- Foreign Material
- Foreign Odor

— Foreign Color

- Scored, Crushed, Holed, or Corroded tray

Gravy splashes on the edges (sloshing) of the tray can be caused by malfunctioning of the Raque filler and/or from an inappropriate texture of the gravy. Sloshing will not allow the tray to be seamed properly and microorganism growth will result in the seam. Foreign materials, odors, and color can result from change of environment during the transport of the trays through the line and during the gravy filling process. Tray damage can also occur while the tray is in transport. A note should be made on the checklist [Figure 5.6] if any of the above incidents occur. Any unusual incidents such as operator change, shift change, last adjustment, conditions, last maintenance of filler, etc. should also be noted on the form. If any problems are indicated by the \bar{x} and R charts the inspector should perform one or more of the following corrective actions as deemed appropriate:

- 1. Examine the check-weighing system (see Appendix II)
- 2.

self-check

— weight module

— zone module

— production settings

- 3. Examine the Raque filler (see Appendix III) position and function of electric eyes
 - position of dispensing head
 - pump speed
 - filled weight
 - dispensing valve
 - dispensing piston speed.
 - air line lubrication

— gravy density and temperature

When foreign odor, material or color are found, the production environment should be checked meticulously including the following factors:

- gravy transport pipe for contamination
- raque filler for contamination
- ambient temperature
- ambient humidity
- plant sanitary conditions
- operator hygiene

Trays can be damaged when moving along the conveyor and track which can result in scoring, crushing, or holing. Corrosion can result from environmental conditions such as humidity and temperature. Thus, these attributes are important factors to check.

It should be noted that the examinations at this station are quick and visual only with an emphasis of looking out for major problems.

Seaming and Final Product SPC Stations

This section contains two SPC stations, Seaming and Final Product SPC stations. The first station, seaming SPC station is station h on Figure 1.1. This station examines traypack condition and vacuum seal. Other required tests at this station include the tests of input conditions to the retort process: traypack initial temperature and head space, and tests of 3 types of seam characteristics: external seam measurement, seam teardown & internal, and seam sectioning. The seaming SPC station is located after the seaming process but before retort. The second station described in this section is the final product SPC station after retort process(station i on Figure 1.1). The test procedures in this station can be divided into three categories. The first category is of can condition, which is a check for travpack defects after the packs have gone through the retorter. These trays are inspected every retort batch, which is taken to be every 240 trays. The second category deals with sampling inspection (after 24 hour storage.) This type of inspection includes Net Weight, Drained Weight, Viscosity of Gravy, Total Salt Content, and Total Fat Content. Finally, the last category is the Incubation Test for microorganism growth. All these tests will be performed after seaming but before retort. The procedures, goals, and control actions pertaining to the seaming and final product SPC stations follow.

Seaming SPC Station

The main concern of this SPC station is to ensure safe tray packages as any minor defect can cause microorganism growth and failure of the retort process. At this station, the four objectives will be to check surface defects of the can, check the input conditions of retort process, check the seams of the can and check the vacuum seal.

The first objective of the examination of surface defects is essential to ensure that the final product will meet specifications. Surface defects of the tray can result from transport on the conveyor during seaming. These defects (scratches, dents, and abrasions) will be recorded on a \overline{c} chart [Figure 6.1] from a sample size of 8 every hour (960 trays.) The inspector will circle defects on the can with a red marker, count the number of circles and record the number at the appropriate spot on the control chart form. The average of the eight measurements will be recorded as the point on the \overline{c} chart for that time period. While checking these same trays the inspector should note on the checklist any major problems that will not allow the tray to move down the line such as scoring, holing, crushing, corrosion, burst, rupture, and overfill. The seamer should be checked if there are any types of problems exhibited by the eight tray sample.

Two tests, initial temperature for retort and head space, must be performed before checking traypack seams. Both of these tests will have a sample size of 1 tray for every retort batch (240 trays) and both can be done using the same tray. First, the test of initial temperature for retort will be done. The purpose of this test is to determine the temperature of the coldest traypack entering retort which will be the first traypack of every batch. The temperature should be above a minimum temperature that has been set for the thermal process. The inspector will cut open the traypack, mix the contents of the traypack and then determine the coldest component of the mixture. If the beef is packed straight from the oven, the gravy may be colder. However, the more common case is of hot gravy is added to beef cubes taken from the refrigerator, so the beef is the colder component. The procedure for checking the beef cubes is to put a thermocouple in the five largest cubes and take the minimum of the five readings. This minimum value should be greater than the minimum temperature requirement which is a minimum input condition set for a specified retort process. The reading will be also recorded on a x control chart [Figure 6.2.]

The tray that has been inspected for initial temperature for retort will then be used to check head space. Head Space is defined to be the distance between the lid and the surface of the liquid (gravy of beef stew). This is net head space, but as the lid is slightly lower than the edges of the traypack, we will have to measure gross head space, the distance from the top edges of the traypack to the liquid. Head Space needs to be measured because it affects heat transfer by determining how much the liquid will be moving during transport of the tray through the retorter. The procedure consists of puncturing a hole in the middle of the lid and then placing a straightedge across the top of the traypack. Using an appropriate measuring device the inspector will measure the distance from the straightedge to the liquid. This reading will be compared to a minimum value which has yet to be determined as a minimum input condition for a specified retort process. The reading will be also recorded on a x control

chart [Figure 6.3.]

Approximately 4 retort batches are run every hour, so 4 trays will be accumulated each hour by performing the above 2 tests (initial temperature and head space.) All four of these trays will be used to perform the External Seam Measurement, and then, of those same 4 trays, 2 will be used for the Seam Teardown & Internal test, and the other 2 will be used for Seam Sectioning since the trays used for seam teardown & internal test can not be used again for seam sectioning test. These are the three types of seam tests and all will be performed every hour. These tests are required to ensure that all trays are in good condition before retort and that less traypacks will be rejected after retort. For each of the seam tests, initial data of twelve points for each tray will be recorded on the Seam Quality Control Form of which there is an example on the following page. The twelve points from which this data is obtained are depicted on a diagram on the form. The worst of these data points (highest or lowest value depending on the test) is the number that is recorded on the control charts for that time period.

The first seam test is External Seam Measurement which is a measure of the length and thickness of the seams on the outside of the tray. (See Appendix IV and refer to *Inspection Plan for Traypacks* for the procedure to perform this test.) Each measurement reading will be recorded on the \bar{x} and R charts for length and thickness (there are separate control charts for each). [Figure 6.4 and Appendix I, Figure 6.5.]

Seam Teardown and Internal testing (cover and hook, pressure ridge, & tightness) is the second type of seam test. (See Appendix IV and refer to *Closures For Metal Containers and Inspection Plan for Traypacks.*) Again, the readings will be recorded on separate \bar{x} and R charts for each characteristic. [Figures 6.6 and Appendix I, Figure 6.7-6.8.]

The third and last type of seam test is Seam Sectioning (length, overlap, body, and hook length) (see Appendix IV and refer to *Inspection Plan for Traypacks* for procedure). The readings will be recorded on separate \bar{x} and R charts for each characteristic [Figure 6.9 and Appendix I, Figures 6.10-6.12].

The corrective action to be taken for any of these three seam tests (and also the initial temperature test) is to check the seamer. Of course any incidents such as operator change, shift change, new lot of lids, conditions, last calibration of gauge, etc. should be recorded on the forms.

The last objective of this station is to check the vacuum seal. This is very important as a faulty seal affects heat penetration and food condition. The vacuum seal itself will be tested by placing a straight edge on top of the tray and checking to see if there is a visual gap. It is important that the lid be bulging inward. Defects (traypacks with outward bulges) from a sample of 100 trays every 2 hours (1920 trays) will be noted on a p-chart [Figure 6.13].

The vacuum gauge is a device that measures the vacuum of the sealed tray, and its test will be done with a sample size of 4 every 1/2 hour and the data will be recorded on \bar{x} and R charts [Figure 6.14]. The procedure to perform this test is to puncture the traypack in the top side corner with the gauge itself. The gauge will then give a reading that should be noted for each tray. The average reading obtained from the four trays will be the point on the control chart for that time period. There is also a vacuum gauge on the seamer that should be monitored to see if it remains on the setting of 20 which represents the vacuum pressure. The corrective action to be taken for these tests is to check the seamer and its environment.

If any problems are indicated by the External Seam Measurement, Seam Teardown & Internal Measurement, and Seam Sectioning control charts, the first items to be checked are the followings attributes of seamer conditions (refer to *Manual for Yaguchi Seamer*):

- 1. Seaming chuck
 - Check the periphery for damage
 - Check the periphery for wear
- 2. Seaming roll
 - Check the groove wear
 - Check the roll for damage
 - Check the roll bearing for damage
 - Check the roll washers for wear and make sure that the roll is at a proper height.

- 3. Model cam roll
 - Check the outer diameter for wear
 - Check the roll bearing for damage
 - Check the model cam roll for wear
- 4. Model cam
 - Check the cam groove for wear
 - check the corner area R for uneven wear

5. Knockout pad

- Check the pad for deformation or damage
- Check the knockout shank for damage
- 6. Cams
 - Check the oil level of oil fillers
 - Check the cam groove for wear
 - Check the cam roll and pin for wear
- 7. Spring
 - Check the springs for damage
 - Check the springs if they come off
- 8. Cover feed wickets
 - Check the wickets for damage done during installation
 - Check the wickets for deformation or warping
- 9. Lubrication system
 - Check the lubricating pump
 - Note the oil level
 - Check the oil pipe for damage
 - Check the oil pipe for damage

- Make sure that all terminal parts are properly lubricated

Second, dimensions need to be checked because when the can and flange dimensions are not within tolerances the seamer will not place the lid properly and cause defective seams. These defective seams will result in an out-ofcontrol signal on the control charts. Dents that arise during tray transportation can affect the tray dimensions and also cause problems during seaming.

Third, lids need to be examined for warping, compounding, denting, and deviation of dimensions. These attributes can cause faulty seams which will also result in an out-of-control signal on the control charts.

Fourth, following conveyors and their synchronization controllers should be checked because the tray position when entering the seamer may be out of place due to conveyor inconsistencies (refer to Revised Automation Control Strategy For Tray Pack Filling/Sealing Line):

- Discharge Conveyor
- Phasing conveyor
- Reject Tray Conveyor
- Filling Conveyor
- Spacing Conveyor

Last, filling conditions need to be checked. This includes examining for overfilling and sloshing. Overfilling and sloshing of gravy is caused by two factors, the gravy filler and conveyor speed. Both these items should be examined.

Problems concerning can surface defects indicated by the \overline{c} chart and checklist should be investigated by first checking the transport system of the trays. Then, the seamer should be examined because defects can result during movement of trays in the seaming process.

Final Product SPC Station

The procedures at this SPC station will be divided into three categories: can condition test (immediately after retort), sampling inspection (after 24 hour storage), and incubation test. At this station the condition of the can will again be checked. Surface defects (which of the can which can be caused by transport and the retorting process) will be monitored using a \bar{c} chart (Figure 6.15) from a sample size of 4 every retort batch. The inspector will circle defects such as dents, cuts, and abrasions, with a red marker, then he/she will count the number of circles and record them at the appropriate spot on the control chart form. The average of these 4 measurements will be recorded as the point on the \bar{c} chart for that time period. While checking these same trays the inspector should note on the checklist portion of the control chart form any major problems that will not allow the tray to move on, such as scoring, holing, crushing, and corrosion. The control chart results will be compared with the surface defect control chart form the previous station.

Net weight, drained weight, viscosity of gravy, total salt content, and total fat content will be checked in lab procedures (see Appendix V) 24 hours after removal of trays from the retorter. This will be done using a sample size of 1 from every retort batch (240 trays) such that average of 8 trays will be sampled from 2 hours production. One set of 4 trays from these 8 samples will be used for salt content and fat content tests while a the other 4 trays will be used for the other tests. The data will be recorded on \bar{x} and R control charts (Figures 6.16-17 and Appendix I, Figure 6.18-6.20). Other characteristics which will be monitored by checklists are: Beef Texture, Chunk Dimensions, Connective Tissue, Bone Fragments, Gravy Texture and Color and Foreign Odor, Color and Material. Any incidents such as operator change, shift change, conditions, last calibration of retorter, and others should be recorded on the checklist form. Incubation tests will be also conducted by sampling 1-2 cans from each retort batch and store them at 95 °F for 10 days to determine if microorganisms are present in the trays.

Nonconforming products from the final product tests are classified into the three categories and corrective actions will be taken accordingly:

1. Schedule Process Deviation Of Retort Process

This category consists of nonconforming products caused by any parameter that affects heat transfer in retort. This includes all critical parameters such as initial temperature, viscosity, beef fill weight, and head space. The problem will be handled by consulting the process authority and then the process authority recommending an appropriate action (either reprocessing or destroying the product.)

2. Incubation Test

The can should be checked for seam defects before incubation. If a can swells, inspect the can for a seal defect. If the seam is bad it was probably contaminated after retort. If this occurs, the same retort batch has to be entirely tested and screened out for nonconforming products. If the can swells without another cause (e.g. seal) then destroy the lot.

3. Finished Product Specifications

If finished products do not meet one of the military specifications (but meet the above two requirements), then, isolate the lot, put it on hold and re-sample. Release the lot if it meets acceptance criteria for double sampling plan. If it still does not meet the specifications then do one of the following: make a request for the variance of the specifications, resell it to third parties, destroy the lot, or donate the lot.

Appendix II

SETUP PROCEDURES

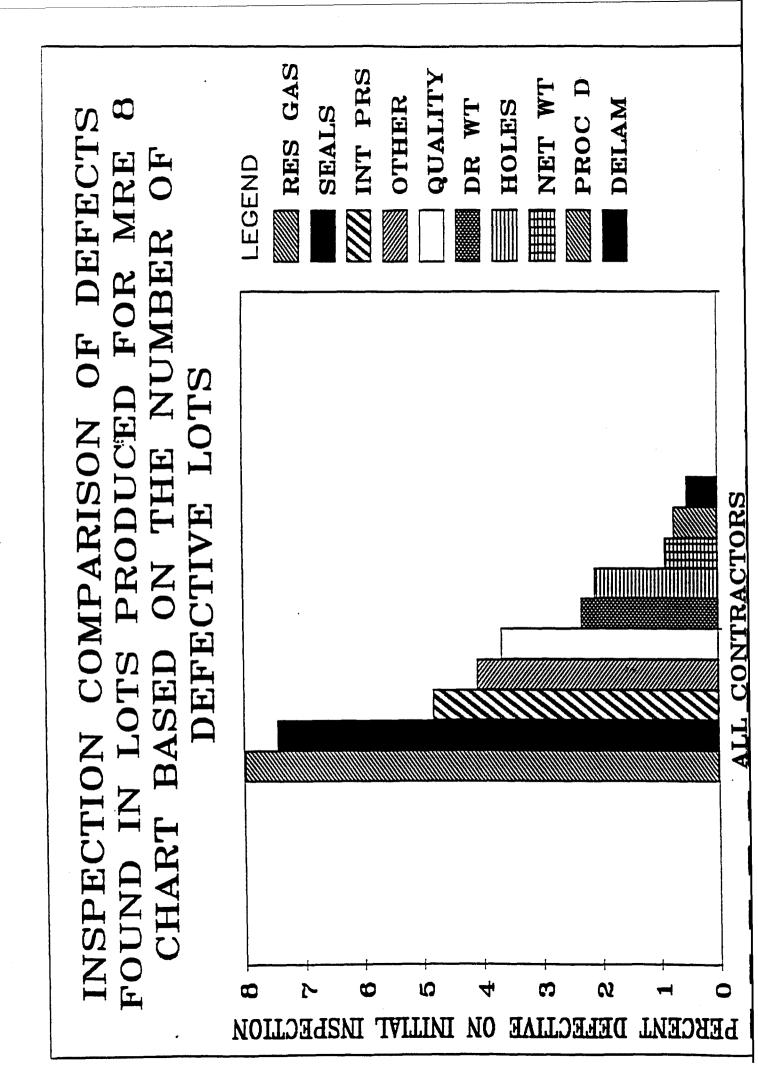
Set up Procedures

- 1. Beef Precooking
 - A preliminary run of the oven should be done prior to production.
 - Check and calibrate the controllers of oven and make sure the control parameters attain the desired levels (to be obtained from experimental results). Following is the checklist for the conditions of the oven:
 - . conveyor speed
 - . heat source selection (for chambers 2 & 3)
 - . temperature (for chambers 2 & 3)
 - . steam application (for chambers 1,2,3 & 4)
 - . rate of air flow (for chambers 2 & 3)
 - . pattern of air impingement (for chambers 2 & 3)
 - Check the availability of storage room in the refrigerator
- 2. Gravy Preparation
 - Be sure that the beef broth collected from the beef precooking is ready.
 - Check the conditions of two kettles for the slurry and the emulsion
 - . temperature
 - . agitation
 - . formula of ingredients (percent by weight)
 - Check and calibrate the test equipment of gravy viscosity
- 3. Filling Operation
 - Check and calibrate the preweighing equipment of precooked beef chunks.

- Check and calibrate the volumetric piston filler of gravy.
- Have a preliminary run of the Raque filler.
- Check and calibrate Mwe conveyor speed.
- Assure the ingredients are ready for filling.
- Assure the trays are washed and placed properly.
- Check and calibrate the equipment such as check weighing system and seamer.
- 4. Seaming Process
 - Have a preliminary run to check the seam (complete seam teardown test.)
 - Check and calibrate the vacuum.
- 5. Retorting
 - Check the steam, air and water supply pressure.
 - Make sure that the retort program corresponds with the scheduled process.
 - Preheat the water in a storage vessel.

APPENDIX III

MRE PARETO ANALYSIS



APPENDIX IV

RUN RULES

IDENTIFYING OUT OF CONTROL PROCESSES

The following events indicate that the process is out of control:

- 1. Single point is outside of control limits. The chance of finding a single point that far from the mean is so slim that we are surprised at finding a value there. Thus a point outside the limits certainly merits investigation for its cause.
- 2. More than 50% of the values are on one side of the mean. The mean, by its definition, implies that half the values are larger and half are smaller. A major difference with that is suspicious and should be indicative that *something* is happening to the process.
- 3. A run of 6 points occurs. A run is a set of ascending or descending points. It is closely related to a long-term trend. A point is counted in a run if it continues increasing (decreasing) in the same direction as the previous point. Normal variation is supposed to be random. Six consecutive increasing or decreasing points is not likely to occur. Therefore, it is worth investigating.
- 4. A pattern or cycle regularly recurs. Again, the normal variation that is always present in a process is random. If a pattern or cycle emerges, then it is quite possible that the variation is not random.
- 5. Obvious short trends with adjustments. Rather than fixing the process, sometimes the process is merely adjusted everytime there appears to be a change. The overadjustment of the process can cause as much as twice the variation normally expected.
- 6. A percentage of values other than 68% within one sigma limits. Either too many points too close to the mean or not enough points close to the mean indicates that something abnormal may be happening to the process.
- 7. A percentage of values other than 95% within the two sigma limits. Either too many points too close to the mean or, more likely, too many points too far away from the mean indicates that something unusual is happening. In both this an the preceding suggested criteria, the percentages 68 and 95 are a suggested guideline. If the actual count gives a percentage of 65, this is probably close enough not to raise any undue concern. Remember, it is an overall trend we are looking for.
- 8. Three consecutive points between two an three sigma limits. The likelihood of three consecutive points that far from the mean is very small. When that situation occurs, it should be investigated.

Sometimes the pattern that emerges is indicative that the process is totally unstable. Immediate steps should be taken to bring the process into control before any steps are taken to improve it.

COMBAT RATION ADVANCED MANUFACTURING TECHNOLOGY DEMONSTRATION (CRAMTD)

Statistical Process Control for the Production of Combat Ration: CRAMTD Production Product Quality Control Technical Working Paper (TWP) 44

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1. INTRODUCTION

1

The report presents a comprehensive SPC program for product quality for the Rutgers University Pilot Plant CRAMTD production process. The report describes in greater details the quality control procedures and strategies for the production of beef chunks and gravy in tray packs. Moreover, we briefly present the SPC program for MRE pouch production through a discussion of the differences and similarities between the tray pack and pouch lines. The purpose of the report is to help other food processors making similar products with similar production processes to initiate SPC in their own plants.

The outline of the production steps for beef chunks and gravy in tray packs is as follows: The beef is precooked in an Enersyst oven and then preweighed into packets. At the same time, gravy is prepared in kettles. In the filling line, the beef and gravy are assembled into the tray packs. The tray packs are then seamed and retorted.

There are nine SPC stations that have been designed for this production process. Three control the incoming raw materials: beef, gravy ingredients and trays. Four control in-process product. Two control final product: one for the final food product and one for the final package.

Each SPC station has special objectives. The incoming material stations assure good quality raw material, track vendor performance, and determine production parameters. The objective of the in-process stations is to track precooking and filling operations and stop production of bad product. The final product stations detect bad product, monitor packaging operations, and prepare for customer acceptance sampling.

For each of the nine SPC stations, this report describes in detail the procedures that are needed to control the production process. For each SPC station, the report specifies: (1) measurement tools and protocols; (2) sampling intervals and sizes; (3) statistical decision making tools such as control charts and acceptance sampling plans; (4) checklists for process and product observations; and (5) procedures for corrective actions. The report gives sample forms and charts for data collection.

The purpose of the SPC stations is to monitor production, that is, to insure that the

processes are working properly and to prevent bad product from being made. In the past, quality control in the food industry has focussed on inspection to separate bad product from good product. We emphasize that the inspection and data collection described in this report address the goal of monitoring production rather than separating bad from good product.

As an example, we now briefly describe the components of the SPC stations that monitor the weighing operation for the precooked beef. This is a critical production step because the beef is the most expensive ingredient and the weight of beef put into the tray affects the final production specifications on drain weight and net weight and on gravy viscosity. The amount of beef also impacts the packaging and retorting steps. At this SPC station, the precooked beef is removed from its packet and weighed again on a scale, separate from the one used in production. We recommend sampling four packets each hour, that is, four packets per 960 based on a production rate of sixteen tray packs per hour.

Continuing with the example, the decision making tools are X and R statistical control charts for weight means and ranges. Sample charts are included in the report. The charts have space for the operator to record raw data, calculate mean and range, and graphs on which to plot the sample information. The charts include checklists for product observations such as foreign color, odor or material. The charts include checklists for process observations such as dates of scale calibrations and unusual events such as power failures.

When the control chart indicates there is a problem in the weighing operation corrective actions must be taken. The charts are designed to alert the users to the existence of special, important causes of problems; these are called assignable causes in the language of SPC. In any operation there is a "natural" variability. The charts call attention to variability beyond this amount. In the example of the SPC station for weighing precooked beef, the corrective actions include checking the production and SPC scales and checking operator training. If there is a contamination problem, the actions include immediately stopping production and then searching for the source of the problem.

The recommendations in this report for SPC stations are intended to serve as a starting point. As operators, line supervisors, and plant managers gain experience with SPC the forms, charts, control limits, checklists, and corrective actions will be continually improved. Also, as plant procedures and machinery change the SPC plan must change as well.

Companies in the food processing industry and in other industries from electronics to automobiles have used SPC to contribute to their success in higher quality, lower costs, and greater customer satisfaction. The considerable commitment and work required to implement SPC pays. If a company uses a better grade of beef, the quality of the beef chunks in gravy will improve and so will the cost. If a company implements SPC, the quality of the product will improve and the costs should ultimately be reduced.

Finally, SPC must be part of a larger program by a food manufacturer to implement a Total Quality Management System. Such a program includes a host of efforts including employee involvement, vendor relations, HACCP programs, off-line quality control, continuous improvement, and concurrent engineering. The success of these programs rests on the commitment and leadership of the company.

The report is organized as follows: Section 2 describes the production process. Section 3 introduces SPC and control charts. Section 4 contains the SPC programs for the three incoming raw material SPC stations. Section 5 gives the SPC programs for the four inprocess SPC stations and section 6 gives the SPC programs for the two final product SPC stations. Section 7 summarizes the SPC stations. There are 5 appendices.

2. DESCRIPTION OF PROCESSES

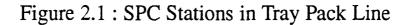
The process of making beef chunks with gravy in tray packs consists of two cooking operations and a filling/sealing line followed by a retorting process. The two cooking operations are the beef precooking and the gravy preparation. The flow diagram of the process is shown in Figure 2.1. In this figure, the rectangles represent the operations while the recommended SPC stations represented by ellipses. A report on Production of Beef Chunks and Gravy in Tray Packs will focus on the operations particularly. In this report, however, we will focus only on the SPC stations given an assumption that the line will run at 16 trays/min. The assumption of 16 trays/min. production rate is a goal that was set by calculating 80% of the seamer's full capacity.

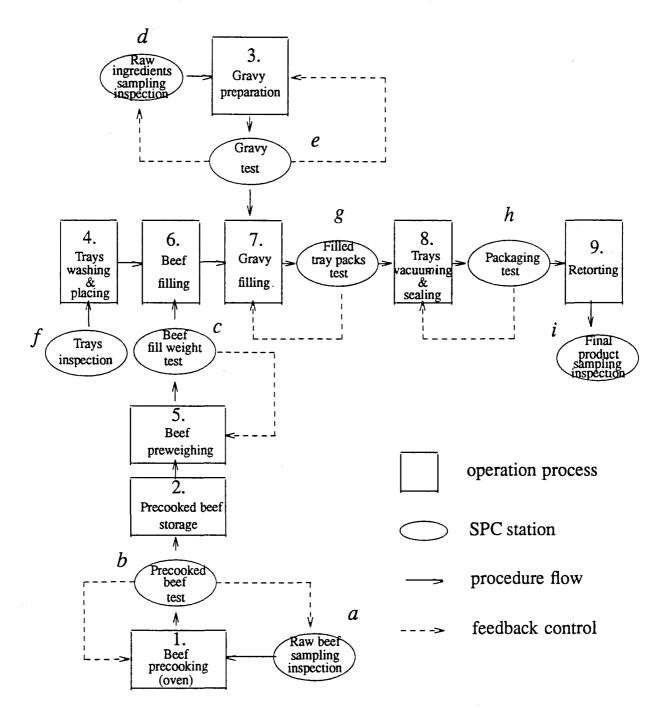
In this section, we will briefly describe the production procedures of each operation as noted by the number in the Figure 2.1.

2.1 PRECOOKING

Precooking is done for two important reasons. First, this initial cooking kills microorganisms present in the beef and, therefore, lets the beef be stored safely for a period of time before the actual cooking process. Second, precooking quickly hardens the beef cubes in order to facilitate its handling during different cooking processes.

The precooking process in the Enersyst Oven is done by placing the beef cubes on a conveyor which moves through an oven manufactured by Enersyst Development Center. The oven has four chambers. The parameters of each chamber can be controlled. Chamber 1 is a steam zone that is used to precondition the meat. Chambers 2 and 3 are identical. Each of these two chambers is equipped with two heaters, a steamer, and an air blower to cook the meat under a programmed condition. Chamber 4 is a passive equilibration zone used to condition the meat after cooking. The beef cubes are moved sequentially through each chamber to complete the precooking process.





2.2 STORAGE OF PRECOOKED BEEF

The precooked beef shall be maintained in the temperature range of 28°F to 40°F for not more than 48 hours from the time of cooking to the time of filling into tray packs. Cooling is not necessary if filling occurs immediately after cooking.

2.3 GRAVY PREPARATION

The process of gravy preparation consists of two cooking kettles: one is for the slurry and the other for the emulsion. A slurry is made by mixing the starch, vegetable oil and water. An emulsion is made by mixing mushrooms, tomato paste soup stock, onion powder, salt, sugar, lecithin, pepper, celery seed, garlic powder, bayleaves, allspice, and nutmeg. The emulsion shall be heated to a boil with continuous, vigorous agitation to attain maximum emulsification of the rendered fat. The final mixture is formed by uniformly mixing the slurry and the emulsion in a certain ration. The prepared gravy shall be held in the temperature range of 150°F to 180°F at all times prior to filling and shall be used within 4 hours after cooking.

2.4 TRAYS WASHING & PLACING

Trays shall be denested, washed and placed on the power conveyor that transports the clean trays to the filling area.

2.5 BEEF PREWEIGHING

Before filling the precooked beef into the trays a certain amount of beef for each tray should be preweighed. A mathematical model has been developed to determine the target filled weight of the gravy and precooked beef for given a precooked beef yield and process variability.

2.6 BEEF FILLING PROCESS

The precooked beef cubes are preweighed and stored in separate containers until needed

for the filling operations. The beef cubes are placed manually into the tray.

2.7 GRAVY FILLING

Gravy is deposited in the tray with a volumetric piston filler (Raque filler.) The trays are then weighed before transporting them for packaging and retorting. A checkweighing system will be used to examine the net weight of each filled tray. A minimum net weight requirement from military specifications (104 oz.) is the lower limit of this checkweigher control while a maximum net weight requirement to insure a proper retort process is the upper control limits. If the net weight of a tray falls outside of these limits, then this tray will be automatically diverted from the production line.

2.8 TRAYS VACUUMING & SEAMING

After the weight checking, acceptable trays are transported along the seamer conveyor. Before the seaming process, a photoelectric sensor alerts the operators that the tray ingredients are above the lid line to prevent placement of the lid for seaming.

Lids are denested before they are seamed on the tray. The seaming operation shall be done under a vacuum established by a processing authority so as to ensure proper vacuum. The sealed tray packs are transported to a buffer area and wait for the retorting process. Each filled and sealed tray pack shall be in the retort process within 2 hours after seaming.

2.9 RETORT PROCESS

The filled and sealed tray packs shall be thermostabilized by retorting until a sterilization value (F_0) of not less than 6 has been achieved. The temperature, time, and RPM of agitation of retort are the controllable factors in this process. A scheduled process of these parameters has to be properly determined.

3. INTRODUCTION TO SPC AND CONTROL CHARTS

The main instrument of SPC is the control chart. This report recommends many control charts to monitor the steps in the production of beef chunks in gravy. The goal of this section is to describe the basic principals underlying the construction and use of control charts to control production processes.

We begin by describing sample control charts for monitoring the weighing of the precooked beef shown in Figure 3.1. The control charts are part of the form in Figure 5.1 which also includes space to record data and a checklist of process and product observations.

There are two control charts in Figure 3.1 to monitor this production step: the \overline{x} -Chart to monitor the process mean; and the R-Chart to monitor the process range. At each sampling time, four packets are reweighed on a scale separate from the production scale. The sample average and range are computed and then plotted on the \overline{x} -Chart and R-Chart. The control charts show how the sample averages and ranges vary over time.

Let us now consider the \overline{x} -Chart. The line in the center is called the center line and the two other lines are called the upper and lower control limits. When a sample average falls outside the control limits, corrective action must be taken. A sample point outside the control limits indicates that an "assignable cause" is at work and the production process must be fixed before production continues. The R-chart also has center line and control limits. Again, the production process must be stopped when a sample range falls outside the control limits.

A trained operator is the person who is responsible for the collection and plotting of the control chart data. The charts should be reviewed by line supervisors and plant engineers routinely. Even with no sample averages outside the control limits, the charts can show important trends in the production process. The charts also keep operators informed about the behavior of the process on the previous shift.

Control Charts for Precooked Beef Fill Weight

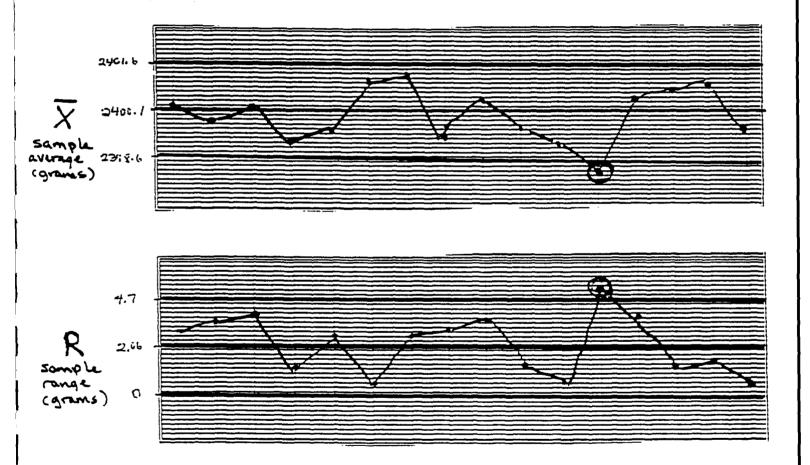


Figure 3.1 X and R Charts for Statistical Process Control

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We now describe how to obtain the center line and upper and lower control limits. The most important concept is to recognize that these are not specification limits. The control limits are obtained by collecting data from the production process and identifying the "natural" average and variation in the sample data. The control limits do not come from the customers specifications. The technical details of how to calculate the center line and the control limits can be found in many texts and handbooks including Montgomery (1985).

Control limits must be recalculated as the production process changes. A new maintenance procedure, a new technology, or a new operator training program can change the output of the process. Thus the control limits must be updated periodically.

There are several types of control charts in addition to the X-Chart and R-Chart. Another type of chart used in this report is the C-Chart for controlling number of defects. The sample measurement is the number of defects in the sample.

There are numerous computer packages available for running a control chart system. Each year, a list of commercially available systems is given in the March issue of the magazine Quality Progress. Before embarking on a computer implementation of SPC, however, it is universally recognized that the operators and supervisors must be comfortable with a manual system. We note that some computer systems include data acquisition elements allowing the computer to make measurements using sensors and then plot the data automatically.

An additional important feature of control charts is that they provide data on the capability of the production process. For example, if a new product with different specifications is proposed, one may analyze the control chart data to determine if the current process could make the new product.

4. INCOMING RAW MATERIAL SPC STATIONS

The incoming materials include raw beef, trays and ingredients for making the gravy. The materials are inspected at the SPC stations in Figure 2.1 labeled a, f, and d, respectively. The raw beef is inspected for foreign odor, color, and material; drain weight; cube size; surface fat; connective tissue and cartilage; bones; and microbiological quality. The trays are inspected for tray and flange dimensions and dents. The gravy ingredients such as salt, starch, etc. are not directly inspected. The quality of these materials is controlled with a purchase control program which requires letters of guarantee from the supplier for each ingredient. Suppliers are also required to establish an effective quality control program to assure the quality of purchased materials. The quality of the ingredients will be audited by the quality assurance staff according to the quality guarantee letters submitted by vendors. Information regarding the quality deviation from the specifications will be fed back to the supplier for immediate corrective action.

4.1 RAW BEEF SAMPLING INSPECTION

The raw beef sampling inspection is divided into three phases. In phase I a sample of raw beef is obtained and inspected for foreign odor color and material. If the sample is found acceptable, then phase II is initiated. A sample of raw beef is boiled under laboratory conditions according to a protocol we describe later. The laboratory cooking procedure is designed to simulate the normal production process. The precooked beef is then inspected for cube size, surface fat, connective tissue and cartilage, and bones. The lot is acceptable if the sample passes this inspection. The third phase determines the yield of the beef (amount of shrinkage) after the lab oratory precooking. This information is used later to determine precooking time in production. The third phase of inspection is not an acceptance/rejection criteria.

The raw beef sampling inspection plans are developed following the criteria and standards of MIL-STD-105E. Special inspection level S-4 of Single Sampling is adopted. The sample size and critical acceptance numbers are determined based on three factors: level

of inspection - normal, tightened and reduced; the lot size; and the criticality of the defect. We now discuss these three factors.

Level of Inspection: The three inspection levels are normal, tightened, and reduced. As the level of inspection goes from reduced to normal to tightened the required sample size increases.

We begin inspecting the first lot of raw beef under normal inspection. If two out of five consecutive lots are rejected, we move to tightened inspection. If ten consecutive lots are accepted we move to reduced inspection. When five consecutive lots have been accepted under tightened inspection we resume normal inspection. If there is any lot rejected under the reduced inspection, normal inspection is resumed. If there are ten consecutive lots inspected under the Tightened Inspection Action, the inspection process should be discontinued. At this time, the suppliers of raw beef should be notified so that they can take actions to improve the quality of the incoming raw beef.

A record of the sequence of inspection levels is kept in order to decide what Inspection Action should be adopted for the subsequent lots. This information is also helpful in supporting vendor relations. A form, Inspection Action Sheet (Appendix I, Figure 4.1), is given to record this information.

Lot size: The sample size for inspection also depends on lot size. In general, the sample size increases under the same level of inspection as the lot size increases.

Criticality of the Defect: AQL or acceptable quality level is a defect rate that is associated with each product characteristics. For critical characteristics the AQL will be very low. Foreign odor, color or material, and microbiological defects are classified as "critical." The AQL level for these is 0.01%. All the other categories are classified as "major" and the AQL level is 1.0%.

Tables 4.1 and 4.2 display the required sample size and acceptance/rejection numbers given level of inspection, lot size and AQL. For example, suppose lot size is 1000; we are using normal inspection; and the product characteristic is major (AQL = 1%) then the

required sample size is 20 units. Accept the lot if there are 0 defects; reject the lot if there is 1 defect.

Sample Size vs. Lot Size (Major Defect) [Ac/Re] under AQL=1%				
Lot Size	Sample Size [Ac/Re]			
Lot Size	Normal	Tightened	Reduced	
501-1200	20[0/1]	20[0/1]	8[0/1]	
1201-3200	32[1/2]	32[1/2]	13[0/2]*	
3201-10000	32[1/2]	32[1/2]	13[0/2]*	
10001-35000	50[1/2]	50[1/2]	20[0/2]*	
35001-150000	80[2/3]	80[1/2]	32[1/3]*	
150001-500000	80[2/3]	80[1/2]	32[1/3]*	
500001-over	125[3/4]	125[2/3]	50[1/4]*	
			1	

Table 4.1: Single Sampling Plan: Special Inspection Level S-4 (AQL=1%)

* If the number of accepted samples falls between acceptable level and rejected level, it is suggested to accept the lot but reinstate the inspection level to *Normal*

Sample Size vs. Lot Size (Critical Defect) [Ac/Re] under AQL=1%				
I at Sina	Sample Size [Ac/Re]			
Lot Size	Normal	Tightened	Reduced	
501-1200	20[0/1]	20[0/1]	8[0/1]	
1201-3200	32[0/1]	32[0/1]	13[0/1]*	
3201-10000	32[0/1]	32[0/1]	13[0/1]*	
10001-35000	50[0/1]	50[0/1]	20[0/1]*	
35001-150000	80[0/1]	80[0/1]	32[0/1]*	
150001-500000	80[0/1]	80[0/1]	32[0/1]*	
500001-over	125[0/1]	125[0/1]	50[0/1]*	

Table 4.2: Single Sampling Plan: Special Inspection Level S-4 (AQL=0.01%)

* If the number of accepted samples falls between acceptable level and rejected level, it is suggested to accept the lot but reinstate the inspection level to *Normal*

We now discuss the sampling and inspection procedure. First the inspector randomly selects boxes from the lot. From each box randomly select two types of samples: (1) one pound of raw beef for tests of foreign color, odor, material; drain weight; cube size; surface fat; connective tissue and cartilage; and bones and (2) 50 grams of raw beef for the test of microbiological quality. Note that the total number of type 1 and type 2 samples obtained should meet the required sample size specified in Table 4.1 (AQL=1%) and Table 4.2 (AQL=0.01%).

It is essential that the samples be obtained in a random manner from each box so that the samples fairly represent the average quality and cube size of the beef contained in each selected box. If the sample taken from the top of the box cannot represent the average quality and cube size of the beef in the box, special steps should be taken to ensure the fair representation of the sample taken. It is through the fair representation of the sample taken can we fairly evaluate the general quality of the arriving lot of raw beef to decide whether to accept or reject the raw beef.

The two groups of samples obtained should be put into containers already numbered so that the results of different tests of inspection could be properly recorded on different forms provided. For the first group of one pound samples, the inspector should begin with weighing the beef sample in each container and record the net weight of the beef sample for each container on Figure 4.2 (Appendix I.)

First we describe the inspection of the one pound samples. This inspection of raw material is based on the specifications for the end product (refer to MIL-B-44230B - Military Specification: Beef Chunks with Gravy, Thermostabilized, Tray Pack and FP INSP.PROC./T- B44230 - finished product inspection procedure].

The first step is to boil the sample beef in water so that the sample beef bears the same characteristics as beef prepared under the normal process. The standard boiling procedure specifying the size of pot to be used, the amount of water to be boiled as well as the time needed for the boiling process should be followed. The boiled beef sample will be a close representation of the end product of the beef prepared under normal process.

The first test of sample beef inspection is to check for foreign color, odor and material. There should be no foreign odor such as, but not limited to, burnt, scorched, stale, sour, rancid or moldy. There should be no foreign color. There should be no foreign material such as, but not limited to, dirt, insect parts, hair, wood, glass, or metal. The described defects, if found, on a yes/no basis, are critical defects. The inspector should record such defects, if found, on Figure 4.3 (Appendix I.)

The second step is to measure the drain weight of the beef samples. Drain weight of beef sample is not a defect criteria. The measurement is needed to estimate and evaluate how much weight is left during the preparation process. The inspector should record the drain weight and the drain weight in percentage of total weight for each sample on Figure 4.4 (Appendix I.)

The third test of sample beef inspection is to check the size of beef cubes. Defect is specified as more than 50% of the beef cubes measuring less than 1/2 inch or greater than 1/2 inch in any dimension. For test purpose, a gauge (to be developed) measuring 1/2 inch in

width and 1-1/2 inch in length. The inspector should apply the gauge to measure the size of the beef cubes. When a beef cube fits the gauge, that is, the shortest side of the beef cube is greater or equals to the short side of the gauge and the longest side of the beef cube is smaller than or equals to the long side of the gauge, it is laid aside as the "regular size" beef cube. If the longest side of the beef cube is greater than the long side of the gauge or the shortest side of the beef cube is shorter than the short side of the gauge, such beef cube should be classified as "irregular." The inspector should then weigh all the regular size beef cubes and compare the weight with the net weight of the beef sample. If the weight of the regular size beef cubes is less than 50% of the net weight, it is considered a major defect. The weight of the regular size beef cubes, the percentage of such weight versus the net weight, and defect, if found, should be recorded on Figure 4.6 (Appendix I.)

The fourth test of beef sample inspection is to measure the surface fat of beef cubes. A ruler should be applied to measure the surface fat of the beef cubes. If the surface fat of any beef cube is thicker than 1/8 inch, it is classified as a major defect. The inspector should record the total number of beef cubes with surface fat thicker than 1/8 inch as well as defect, if found, on Figure 4.8 (Appendix I.)

The fifth test of beef sample inspection is to measure the connective tissue and cartilage. The inspector should cut all the connective tissue and cartilage from each beef cube. Then the inspector should weigh all the connective tissue and cartilage thus obtained. Since a major defect is specified as more than 2 ounces of connective tissue and cartilage contained in one can of finished product (50 ounces), we conclude that no more than 4% of the net weight of the beef sample should be connective tissue and cartilage. The inspector should record the total weight of connective tissue and cartilage, the percentage of the total weight of connective tissue and cartilage, the percentage of the total weight of connective tissue and cartilage, the percentage of the total weight of connective tissue and cartilage. The inspector should (Appendix I.)

The next test of the beef sample inspection is to measure the size of bones found in beef cubes. The inspector should first remove all the bones from the beef cubes. A ruler is applied to measure the size of bones. A major defect is specified as any bone found with size greater than 0.3 inch in any dimension. The inspector should record the total number of bones with size greater than 0.3 inch in any dimension and defect, if found, on Figure 4.12

(Appendix I.)

We now discuss the microbiological inspection of the second type of samples consisting of 50 grams each. (Refer to Lee & Abraham - General SPC procedure area 6.) The method applied to raw sample beef for determining the microbiological quality is the Aerobic Plate Count (APC). This method is adopted to indicate the level of microorganisms in a product. The materials and equipments needed to perform this test include: (1) petri dishes containing plate count agar or tray pack soy agar; (2) dilution tubes with rubber stoppers containing 9 ml tryptic soy broth; (3) dilution bottles containing 450ml 0.1% peptone diluent; (4) sterile pipets, 1, 5, and 10 ml, graduated in 0.1 ml units; (5) blender; (6) balance; (7) colony counter and tally register; and (8) incubator, 35 ± 1 °C.

Aseptically, the inspector should weigh the 50g sample obtained for microbiological quality test and place it into a sterile blending jar. If samples are frozen, it is preferable not to thaw it. If the entire sample weighs less than 50 g, weigh portion equivalent to one-half of sample and add amount of diluent required to make 10-1 dilution. Total volume in blender must cover the blades completely. Blend the sample for two minutes. Chilled diluent is recommended. The inspector should be cautious so to avoid and prevent excessive heating.

Prepare decimal dilutions of 10-2, 10-3, 10-4 and others as appropriate, of sample homogenate, by adding 1 ml of previous dilution to 9 ml of sterile diluent in a tube. Pipet 0.1 ml of each dilution on a petri plate and smear it on the surface. Duplicate plates should be made from each dilution. Incubate all the plates at 35 C for 48 + hours.

At the end of the incubation period, count duplicate plates in suitable range (25 - 250 colonies), using colony counter and tally register; record results per dilution plate counted. Compute average count per gram, and report as Colony Forming Units per Gram (CFU/g). Round off counts to 2 significant figures only.

CFU/g =Number of colonies on a plate×dilution×10*

* Multiplied by 10, since 0.1 ml of the dilution was plated on a plate.

The average CFU/g should be compared with the established standards (limits) for the tested beef. The lot in which the beef sample was taken from will be accepted if CFU/g is smaller or equals to the standard. If CFU/g is greater than the standard, it is categorized as a critical defect. The inspector should record the CFU/g as well as defect, if found, on Figure 4.14 (Appendix I.)

The inspector should then summarize the defects found under each sample test for all samples and record on Figure 4.16 (Appendix I.) Compare the data summary with specifications provided in Table 4.1 and decide whether the arrived lot should be accepted or rejected.

Finally, the inspector should plot the following charts so that the average quality of the raw beef of each arriving lot is shown. The charts to be plotted are: (1) The average percentage of drain weight over net weight of beef sample and range on Figure 4.5 (Appendix I); (2) the average percentage of weight of regular size cube over net weight of beef sample and range on Figure 4.7 (Appendix I); (3) the average number beef cubes with surface fat defect per pound on Figure 4.9 (Appendix I); (4) the average percentage of weight of connective tissue and cartilage over net weight of beef sample and range on Figure 4.11 (Appendix I); (5) the average number of bones (0.3 inches or more) per pound on Figure 4.13 (Appendix I); and (6) the average CFU/g and range on Figure 4.15 (appendix I.)

4.2 TRAY INSPECTION STATION

The tray sampling inspection plan is developed following the criteria and standards of MIL-STD-105E. Special inspection level S-4 of Single Sampling is adopted. The sample size is determined by the lot size as well as the inspection action taken. A total of three categories of characteristics such as can dimension; flange dimension; and dents should be inspected. Whether a lot of tray will be accepted or rejected depends on whether defects are found and/or how many defects are found under the tray sampling inspection (refer to MIL-1-45208A).

All the three categories to be inspected that include can dimension, flange dimension and dents are classified as "critical," that is, if defects are found, they are critical defects. The suggested Average Quality Level (AQL) is 0.01%. The selected AQL is tight because these defects may result in serious sealing quality defects.

The purpose of the tray inspection at this station is to ensure that the trays and covers delivered not only meet the specifications but also are of no surface defects that may result in sealing defects. The procedure to decide the Inspection Action to be taken is the same as that of the raw beef sampling inspection. A record of the Inspection Action adopted for each lot of trays is kept in order to decide what Inspection Action should be adopted for the subsequent lots as well as whether the suppliers should be notified to improve the quality of the trays. The inspector should note down the Inspection Action adopted for each lot on the Figure 4.17 (Appendix I.)

The inspector should take one tray from each randomly selected box from the arriving lot. Note that the samples obtained should meet the number of the sample size specified in Table 4.1.

The first test of sample tray inspection is to check can dimension. (Specifications of can dimension to be filled in.) Defect is specified as dimensions of the can in any way do not meet the specifications. The inspector should apply a ruler as well as a micrometer to measure the dimensions of the can. The inspector should record defects, if found, on Figure 4.18 (Appendix I.) The inspector should then calculate and record the percentage of defected trays on Figure 4.18 (Appendix I) and plot Figure 4.19 (Appendix I.) with the result.

The second test of sample tray inspection is to check flange dimension. (Specifications of flange dimension to be filled in.) Defect is specified as dimension of flange does not in any way meet the specifications. The inspector should apply a ruler as well as a micrometer to measure the dimensions of the flange. The inspector should record defects, if found, on Figure 4.20 (Appendix I.) The inspector should then calculate and record the percentage of defected trays on Figure 4.20 (Appendix I) and plot Figure 4.21 (Appendix I.) with the result.

The third test of sample tray inspection is to check for dents. Defect is specified as any kind of existence of dents on the surface of the trays. The inspector should visually inspect the trays for dents. Defects, if found, should be recorded on Figure 4.22 (Appendix I.) The inspector should then calculate and record the percentage of defected trays on Figure 4.22 (Appendix I) and plot Figure 4.23 (Appendix I) with the result.

The inspector should then summarize the total number of defects of can dimension, flange dimension and dents from Figures 4.18, 4.20 and 4.22 on Figure 4.24 (Appendix I.) Together with the known (1) defect type, (2) number of samples, and (3) inspection action taken, the inspector will discover the Ac/Re condition and make Ac/Re decision of the lot.

4.3 RAW INGREDIENTS SAMPLING INSPECTION

The raw ingredients sampling inspection plan is developed following the CRAMTD-SPC Plan. The suppliers are required to use a quality control program to assure that all materials purchased are defect free and within agreed upon specifications. The contractor will require for each ingredient a letter of guarantee from the supplier. These letters have to address compliance of their products with all applicable regulations pertaining to chemical purity and/or composition, microbiological quality and extraneous materials. The letter has to address also the suppliers quality control system and it's capability of meeting the required specifications and how it assures that only defect free materials are received by the contractor.

Vendors quality control programs will be audited by the Quality Assurance manager at regular time intervals. The audit will consist out of a visit by the QA manager to the suppliers processing facility to assure compliance with GMP's and the vendors stated quality objective. The QA manager will only approve the purchase of the vendors materials after he/she is convinced that the vendors quality control program is effective and reasonably precludes shipment of defective product.

All new suppliers will be evaluated based on past quality history, industry history and field inspection by the QA manager. The QA manager will only approve the purchase of raw

materials from suppliers who have an acceptable quality history and demonstrate using SPC or other methods to control their process to preclude delivery of defective ingredients.

A pre-shipment sample will be requested together with a letter of guarantee by the manager of R&D to evaluate/confirm the suppliers capability to meet the specifications and to confirm that the material can be used for the production process without negative effect on the finish product quality.

The vendor will be given the status as approved supplier after both QA and R&D have assured themselves that the new ingredient will not cause any concern regarding maintaining the high quality standard of the contractor.

The quality of the ingredients will be audited by the quality assurance staff at regular time intervals. Primary audit will be the receipt inspection and random sampling and analysis of received materials by the QA engineer. Secondary audit will be a yearly evaluation of the suppliers processing facility by the QA manager to assure continued compliance with the vendors stated quality program.

A letter will be required from each vendor stating the target specification of the product critical parameter, a statement regarding the capability of the vendors process to meet these specifications and a statement regarding the vendors quality control program to assure that defect free materials are shipped.

The contractor might require from some suppliers, especially those who have a marginal process capability, an inspection certificate with each shipment, documenting the lab results of specific quality information of that shipment.

At receipt of the raw materials, a QC person will assure that the materials received are unadulterated and supplied by the approved vendor and that critical raw material specifications are met. Once the product is found to be acceptable, it will be released from the receiving warehouse to production. Materials which did not meet the specifications or show signs of adulteration will be refused, send back to the vendor, or disposed. Information regarding deviation from specification during the primary audit will be fed back to the supplier for immediate corrective action. Serious or frequent deviation from specification will lead to immediate disapproval of the suppliers ingredient to be used in the production process.

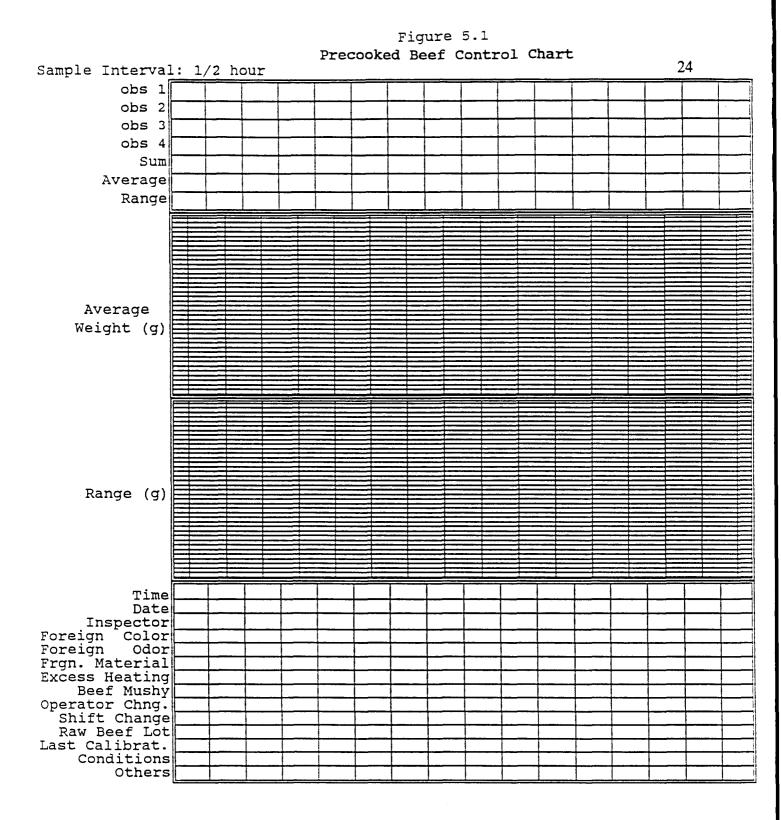
5. IN-PROCESS SPC STATIONS

The stations that are characterized as in-process are those ranging from the precooking of the beef to the filling of the trays with beef and gravy. The first station discussed will be the Precooked Beef SPC station, station b on Figure 2.1. At this station, precooked yield, which determines how much beef should be placed in the trays, will be calculated. The next station, Precooked Beef Net Weight SPC station, labeled c on Figure 2.1, is a check to see if the beef in the trays meets net weight requirements. Station e, Gravy SPC station, checks gravy viscosity, texture, salt content, and density for sensory results and also checks for net weight. The last station of in-process SPC stations is Filled Tray SPC station, station g on Figure 2.1, which monitors the gravy filling process. Following are descriptions of procedures, goals, and control actions of these stations.

5.1 PRECOOKED BEEF SPC STATION

The precooking process plays a very crucial role in the production line because the effects of this process determine quality characteristics of the finished product, such as, drained weight, gravy viscosity, and sensory results. Precooked beef yield is an important in-process characteristic that determines the amount of precooked beef and gravy needed for each tray to meet the drained and net weight requirements. Every 1/2 hour the inspector will take 4 samples of 5 lbs of raw beef and place them separately on the oven conveyor. The 4 samples should be weighed 10 minutes after removal from the oven. The 10 minutes delay of measurement is to ensure the measuring consistency since the weight of precooked beef will vary by time. The delay of measurement can be chosen other than 10 minutes for the inspection convenience. However, the delay of weight measurement after the precooking process should be consistent with the delay used in the off-line experiments where the settings of the precooking process were determined. The inspector will record the weight data at the appropriate spots on the \bar{x} and R chart form [Figure 5.1] and then the average of these 4 data points will be the point on the control charts for that time period. Precooked beef yield can be calculated using the following formula:

Precooked Beef Yield = $\frac{\text{Precooked Beef Weight}}{5} \times 100\%$



Foreign odor, color and material can result during residence in the oven and should be visually inspected for when weighing the four samples. Excessive heating can also result by inappropriate cooking. Observations should be noted on the checklist following the \bar{x} and R charts on the form [Figure 5.1.] Any incident occurring in the plant regarding the precooking process such as operator change, shift change, new lot of raw beef, oven maintenance and calibration should be noted on the control chart form. If problems are indicated in the \bar{x} and R control charts, the following conditions should be investigated accordingly:

- 1. Oven Conditions
 - conveyor controller
 - temperature controllers in chamber 2 & 3
 - temperatures in chamber 1 & 4
 - air blowers in chamber 2 & 3
 - steamers in chamber 1, 2, 3 & 4
- 2. Raw Beef Quality
 - surface fat
 - texture
 - bone pieces
 - connective tissue

When foreign odor, color and material are found, the process should be shut down and the environment conditions should be check immediately including the following particulars:

- raw beef for contamination

- oven for contamination
- ambient temperature
- ambient humidity
- Plant sanitary conditions
- operator hygiene

5.2 PRECOOKED BEEF FILL WEIGHT SPC STATION

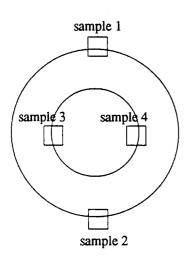
The precooked beef is preweighed before it is placed into the trays. In order to ensure the weighing process is working properly, a second calibrated weigher will be used to confirm the results of first weigher (in Precooked Beef Preweighing process). Precooked beef is weighed according to the calculated filled weight for each tray can. Every hour (960 trays) 4 tray samples of precooked beef are taken and weighed. The data will be recorded on an \overline{x} and R chart form [Figure 5.2.] Foreign odor, material, and color, (which can result from transport and storage) should be checked for while weighing the samples. Any incident occurring in the plant regarding the weighing process such as operator change, shift change, and weigher maintenance and calibration should be noted on the control chart form. If problems are found in the \overline{x} and R charts the weigher should be checked for accuracy or damage. Again, when foreign odor, color and material are found, the process should be stopped immediately and check the followings:

- precooked beef for contamination
- containers for contamination
- ambient temperature
- ambient humidity
- plant sanitary conditions

— operator hygiene

5.3 GRAVY SPC STATION

The objective of this SPC station is to ensure good sensory results and to meet the net weight requirements. Gravy viscosity, texture and salt content will affect the sensory results while the density of gravy will affect the amount of gravy to be deposited in each tray by Raque filler. 4 samples of gravy are taken every kettle (1/2 hour) to measure viscosity, density and salt content. The samples should be taken fairly from locations in the kettle. The following locations are suggested:

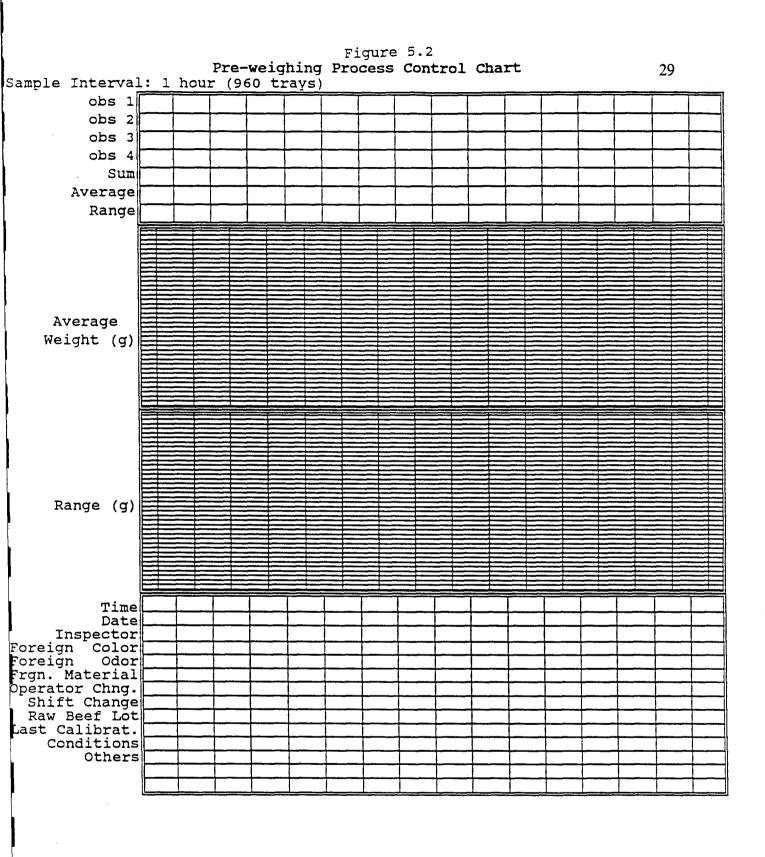


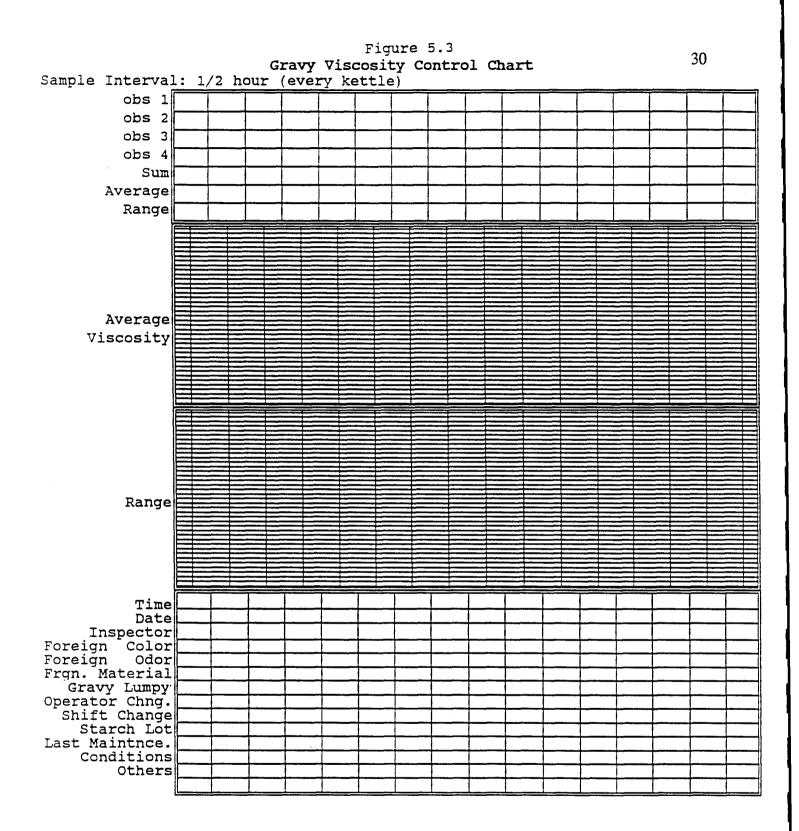
Data of viscosity, density and salt content will be recorded on \overline{x} and R control chart forms [Figures 5.3-5]. The inspector should also lookout for lumpy gravy, foreign color, foreign material, and foreign odor that could arise during the cooking process. Any observations should be recorded on the checklist. Incidents in the plant regarding the process such as operator change, shift change, new lot of starch and weigher maintenance and calibration should be noted on the control chart form. If any problems are exhibited in the viscosity, density or salt content control charts the following conditions should be investigated:

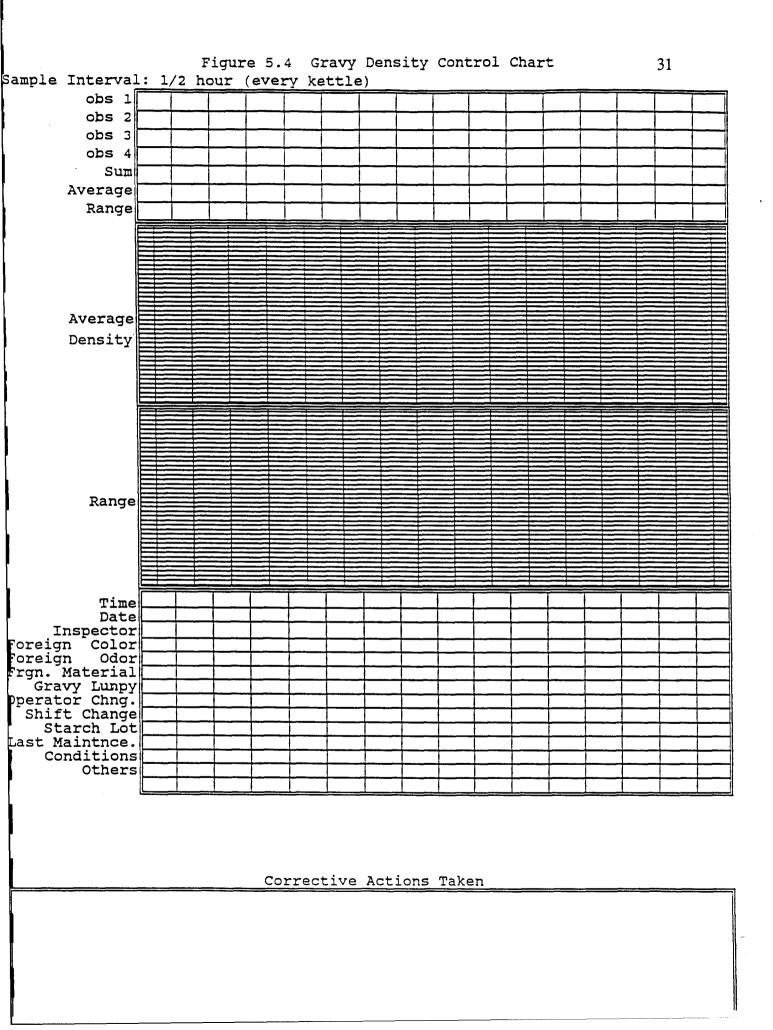
- 1. Ingredients Quality
 - starch
 - salt
- 2. Gravy Formula
 - starch to water ratio
 - proportion of ingredients

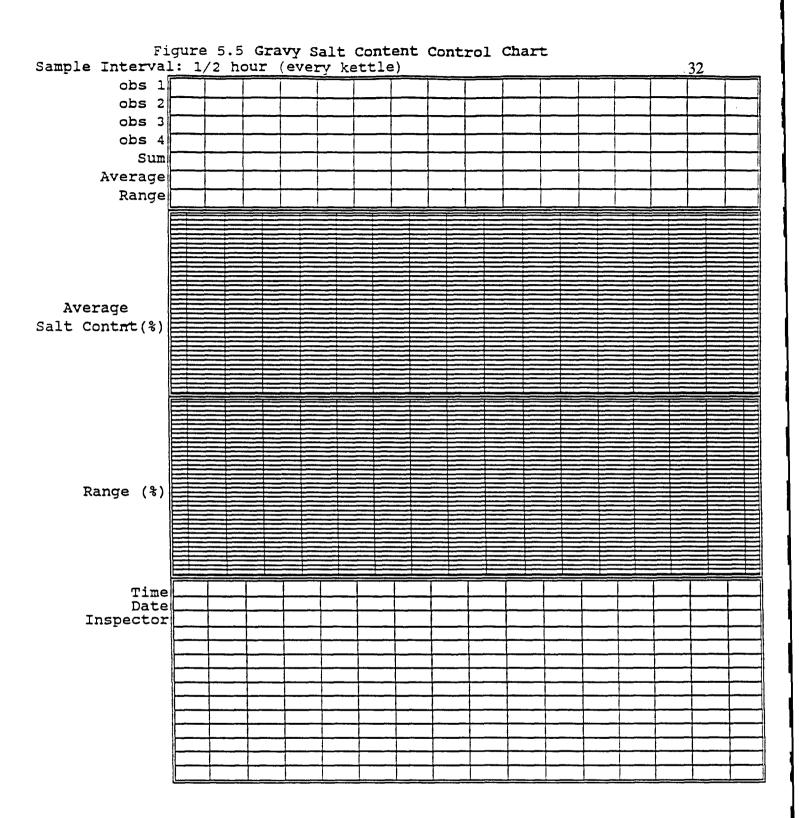
The environment conditions should be checked after the process is stopped due to the exhibition of foreign odor, color and material:

- ingredients for contamination
- kettles for contamination
- ambient temperature
- ambient humidity
- plant sanitary conditions
- operator hygiene









5.4 FILLED TRAY SPC STATION

The main objective of this station is to monitor the gravy filling process using the Raque filler. The Raque filler adds a volume of gravy to a tray in which a preweighed portion of beef has already been placed and checked (precooked beef fill weight SPC station) By observing this process, nonconforming trays will be diverted from the production line and gravy can be added or extracted from trays as needed to meet the net weight specifications. The net weight of the filled can will be measured continuously with a check-weigher. A recorder will be connected to the check-weigher and automatically record data on an \overline{x} and R chart to monitor the process. In addition to the net weight the inspector at this station will take a sample size of 16 trays every half hour and check for the following attributes:

- Gravy splashes on edges
- Foreign Material
- Foreign Odor
- Foreign Color
- Scored, Crushed, Holed, or Corroded tray

Gravy splashes on the edges (sloshing) of the tray can be caused by malfunctioning of the Raque filler and/or from an inappropriate texture of the gravy. Sloshing will not allow the tray to be seamed properly and microorganism growth will result in the seam. Foreign materials, odors, and color can result from change of environment during the transport of the trays through the line and during the gravy filling process. Tray damage can also occur while the tray is in transport. A note should be made on the checklist [Figure 5.6] if any of the above incidents occur. Any unusual incidents such as operator change, shift change, last adjustment, conditions, last maintenance of filler, etc. should also be noted on the form. If any problems are indicated by the \bar{x} and R charts the inspector should perform one or more of the following corrective actions as deemed appropriate:

- 1. Examine the check-weighing system (see Appendix II)
 - self-check
 - weight module
 - zone module
 - production settings
- 2. Examine the Raque filler (see Appendix III) position and function of electric eyes
 - position of dispensing head
 - pump speed
 - filled weight
 - dispensing valve
 - dispensing piston speed.
 - air line lubrication
 - gravy density and temperature

Figure 5.6

Filled Tray Packs Checklist

Sample Interval: 1/2 hour

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Τ											
[
Τ	T			Τ											
Τ	T	Γ			Τ	Γ	Τ	T	T						Γ
	T		T	T	T				Γ						
Τ	T	T		Τ	Τ	Τ	Γ					Γ			
T	1				T				1			—		1	1
					1 2 1.										

Opertor Change	
Shift Change	
Adjustment of Filler	
Maintenance of Filler	
Conditions	
Others	

Corrective Actions Taken

Inspector:

Time:

Date:

i

C

When foreign odor, material or color are found, the production environment should be checked meticulously including the following factors:

- gravy transport pipe for contamination
- raque filler for contamination
- ambient temperature
- ambient humidity
- plant sanitary conditions
- operator hygiene

Trays can be damaged when moving along the conveyor and track which can result in scoring, crushing, or holing. Corrosion can result from environmental conditions such as humidity and temperature. Thus, these attributes are important factors to check.

It should be noted that the examinations at this station are quick and visual only with an emphasis of looking out for major problems.

6. SEAMING AND FINAL PRODUCT SPC STATIONS

This section contains two SPC stations, Seaming and Final Product SPC stations. The first station, seaming SPC station is station h on Figure 2.1. This station examines tray pack condition and vacuum seal. Other required tests at this station include the tests of input conditions to the retort process: tray pack initial temperature and head space, and tests of 3 types of seam characteristics: external seam measurement, seam teardown & internal, and seam sectioning. The seaming SPC station is located after the seaming process but before retort. The second station described in this section is the final product SPC station after retort process(station i on Figure 2.1). The test procedures in this station can be divided into three categories. The first category is of can condition, which is a check for tray pack defects after the packs have gone through the retorter. These trays are inspected every retort batch, which is taken to be every 240 trays. The second category deals with sampling inspection (after 24 hour storage.) This type of inspection includes Net Weight, Drained Weight, Viscosity of Gravy, Total Salt Content, and Total Fat Content. Finally, the last category is the Incubation Test for microorganism growth. All these tests will be performed after seaming but before retort. The procedures, goals, and control actions pertaining to the seaming and final product SPC stations follow.

6.1 SEAMING SPC STATION

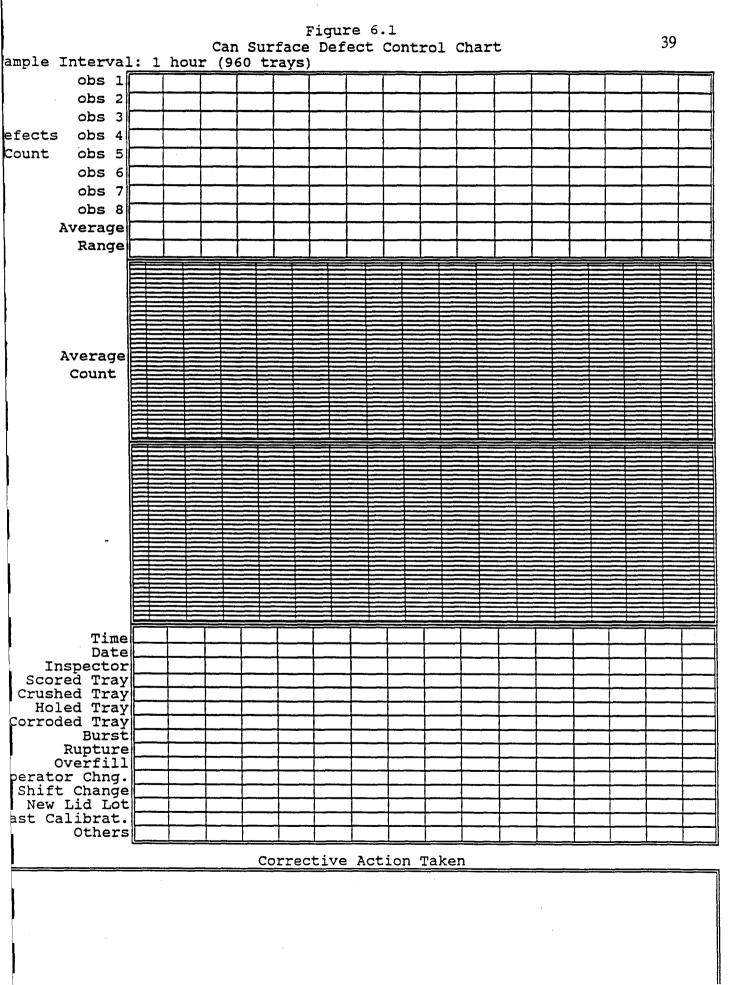
The main concern of this SPC station is to ensure safe tray packages as any minor defect can cause microorganism growth and failure of the retort process. At this station, the four objectives will be to check surface defects of the can, check the input conditions of retort process, check the seams of the can and check the vacuum seal.

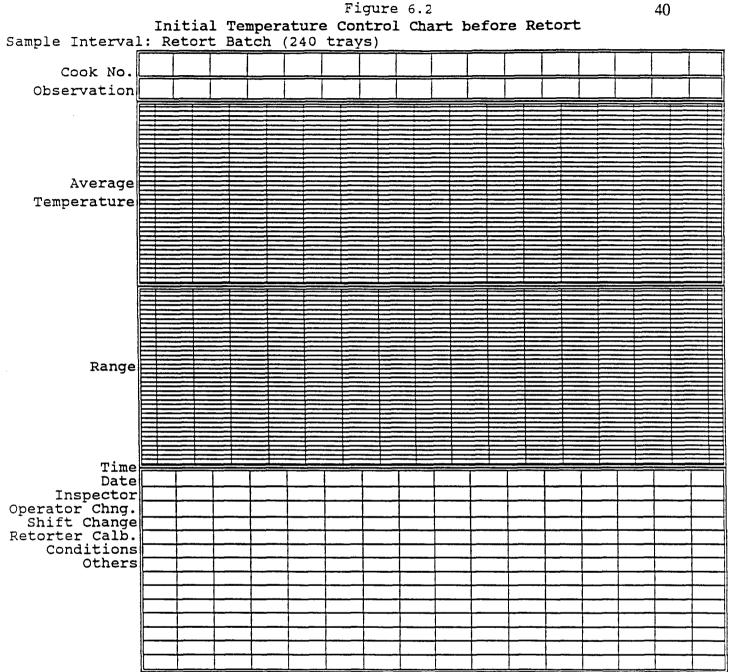
The first objective of the examination of surface defects is essential to ensure that the final product will meet specifications. Surface defects of the tray can result from transport on the conveyor during seaming. These defects (scratches, dents, and abrasions) will be recorded on a \overline{c} chart [Figure 6.1] from a sample size of 8 every hour (960 trays.) The inspector will circle defects on the can with a red marker, count the number of circles and record the number at the appropriate spot on the control chart form. The average of the eight

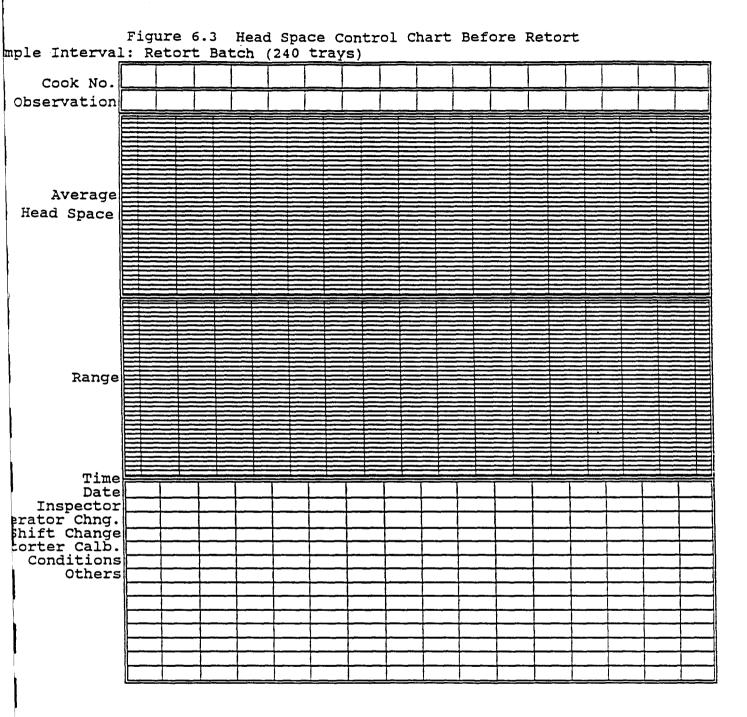
measurements will be recorded as the point on the \bar{c} chart for that time period. While checking these same trays the inspector should note on the checklist any major problems that will not allow the tray to move down the line such as scoring, holing, crushing, corrosion, burst, rupture, and overfill. The seamer should be checked if there are any types of problems exhibited by the eight tray sample.

Two tests, initial temperature for retort and head space, must be performed before checking tray pack seams. Both of these tests will have a sample size of 1 tray for every retort batch (240 trays) and both can be done using the same tray. First, the test of initial temperature for retort will be done. The purpose of this test is to determine the temperature of the coldest tray pack entering retort which will be the first tray pack of every batch. The temperature should be above a minimum temperature that has been set for the thermal process. The inspector will cut open the tray pack, mix the contents of the tray pack and then determine the coldest component of the mixture. If the beef is packed straight from the oven, the gravy may be colder. However, the more common case is of hot gravy is added to beef cubes taken from the refrigerator, so the beef is the colder component. The procedure for checking the beef cubes is to put a thermocouple in the five largest cubes and take the minimum of the five readings. This minimum value should be greater than the minimum temperature requirement which is a minimum input condition set for a specified retort process. The reading will be also recorded on a x control chart [Figure 6.2.]

The tray that has been inspected for initial temperature for retort will then be used to check head space. Head Space is defined to be the distance between the lid and the surface of the liquid (gravy of beef stew). This is net head space, but as the lid is slightly lower than the edges of the tray pack, we will have to measure gross head space, the distance from the top edges of the tray pack to the liquid. Head Space needs to be measured because it affects heat transfer by determining how much the liquid will be moving during transport of the tray through the retorter. The procedure consists of puncturing a hole in the middle of the lid and then placing a straightedge across the top of the tray pack. Using an appropriate measuring device the inspector will measure the distance from the straightedge to the liquid. This reading will be compared to a minimum value which has yet to be determined as a minimum input condition for a specified retort process. The reading will be also recorded on a x control chart [Figure 6.3.]





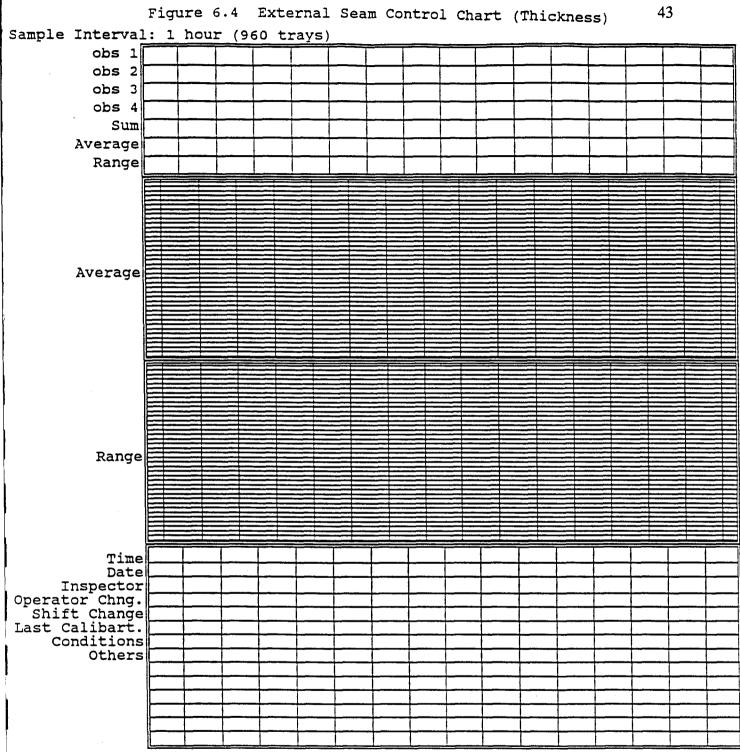


Approximately 4 retort batches are run every hour, so 4 trays will be accumulated each hour by performing the above 2 tests (initial temperature and head space.) All four of these trays will be used to perform the External Seam Measurement, and then, of those same 4 trays, 2 will be used for the Seam Teardown & Internal test, and the other 2 will be used for Seam Sectioning since the trays used for seam teardown & internal test can not be used again for seam sectioning test. These are the three types of seam tests and all will be performed every hour. These tests are required to ensure that all trays are in good condition before retort and that less tray packs will be rejected after retort. For each of the seam tests, initial data of twelve points for each tray will be recorded on the Seam Quality Control Form (see Appendix IV: Figure 11). The twelve points from which this data is obtained are depicted on a diagram on the form. The worst of these data points (highest or lowest value depending on the test) is the number that is recorded on the control charts for that time period.

The first seam test is External Seam Measurement which is a measure of the length and thickness of the seams on the outside of the tray. (See Appendix IV *Traycan Evaluation Guide* and refer to *Inspection Plan for Traypacks* for the procedure to perform this test.) Each measurement reading will be recorded on the \overline{x} and R charts for length and thickness (there are separate control charts for each). [Figure 6.4 and Appendix I, Figure 6.5.]

Seam Teardown and Internal testing (cover and hook, pressure ridge, & tightness) is the second type of seam test. (See Appendix IV and refer to *Inspection Plan for Traypacks.*) Again, the readings will be recorded on separate \bar{x} and R charts for each characteristic. [Figures 6.6 and Appendix I, Figure 6.7-6.8.]

The third and last type of seam test is Seam Sectioning (length, overlap, body, and hook length) (see Appendix IV and refer to *Inspection Plan for Traypacks* for procedure). The readings will be recorded on separate \bar{x} and R charts for each characteristic [Figure 6.9 and Appendix I, Figures 6.10-6.12].



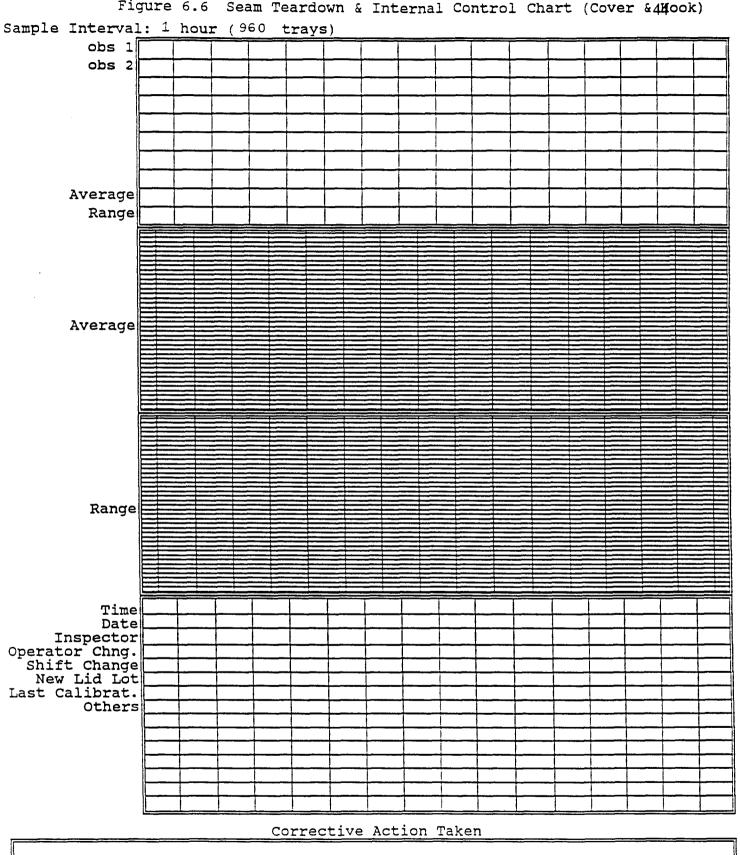
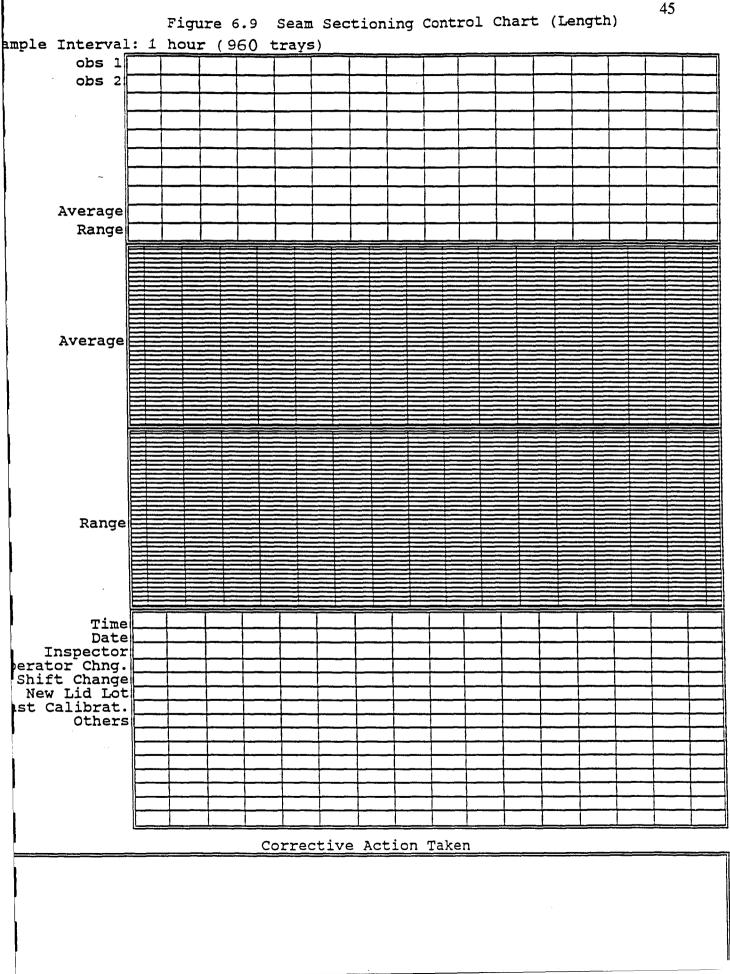


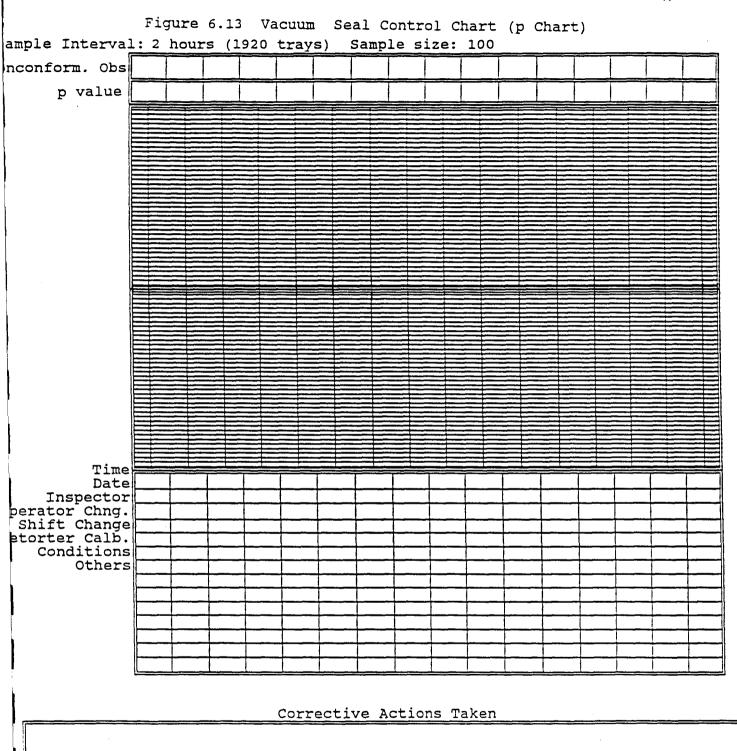
Figure 6.6 Seam Teardown & Internal Control Chart (Cover &4#ook)

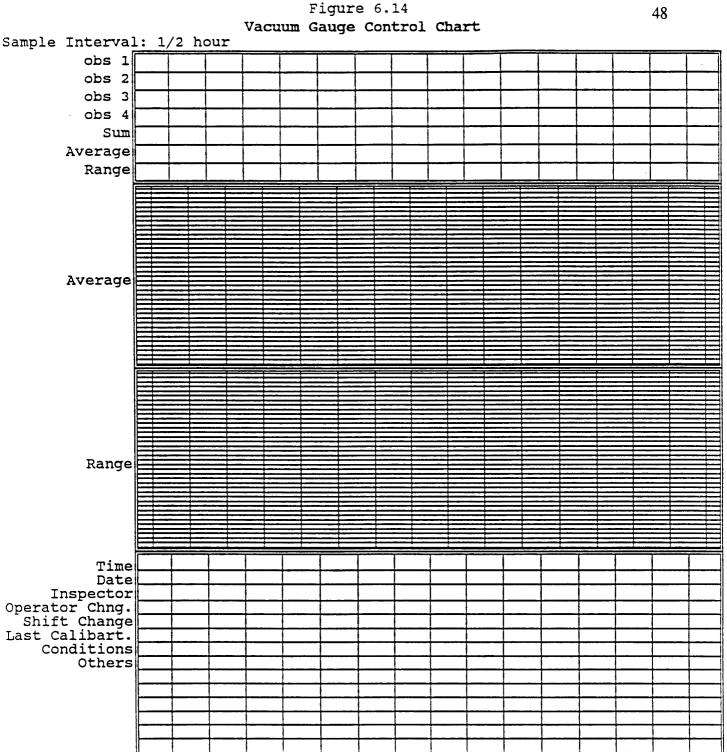


The corrective action to be taken for any of these three seam tests (and also the initial temperature test) is to check the seamer. Of course any incidents such as operator change, shift change, new lot of lids, conditions, last calibration of gauge, etc. should be recorded on the forms.

The last objective of this station is to check the vacuum seal. This is very important as a faulty seal affects heat penetration and food condition. The vacuum seal itself will be tested by placing a straight edge on top of the tray and checking to see if there is a visual gap. It is important that the lid be bulging inward. Defects (tray packs with outward bulges) from a sample of 100 trays every 2 hours (1920 trays) will be noted on a p-chart [Figure 6.13].

The vacuum gauge is a device that measures the vacuum of the sealed tray, and its test will be done with a sample size of 4 every 1/2 hour and the data will be recorded on \overline{x} and R charts [Figure 6.14]. The procedure to perform this test is to puncture the tray pack in the top side corner with the gauge itself. The gauge will then give a reading that should be noted for each tray. The average reading obtained from the four trays will be the point on the control chart for that time period. There is also a vacuum gauge on the seamer that should be monitored to see if it remains on the setting of 20 which represents the vacuum pressure. The corrective action to be taken for these tests is to check the seamer and its environment.





If any problems are indicated by the External Seam Measurement, Seam Teardown & Internal Measurement, and Seam Sectioning control charts, the first items to be checked are the followings attributes of seamer conditions (refer to *Manual for Yaguchi Seamer*):

- 1. Seaming chuck
 - Check the periphery for damage
 - Check the periphery for wear
- 2. Seaming roll
 - Check the groove wear
 - Check the roll for damage
 - Check the roll bearing for damage
 - Check the roll washers for wear and make sure that the roll is at a proper height.
- 3. Model cam roll
 - Check the outer diameter for wear
 - Check the roll bearing for damage
 - Check the model cam roll for wear
- 4. Model cam
 - Check the cam groove for wear
 - check the corner area R for uneven wear
- 5. Knockout pad
 - Check the pad for deformation or damage
 - Check the knockout shank for damage
- 6. Cams

- Check the oil level of oil fillers
- Check the cam groove for wear
- Check the cam roll and pin for wear
- 7. Spring
 - Check the springs for damage
 - Check the springs if they come off
- 8. Cover feed wickets
 - Check the wickets for damage done during installation
 - Check the wickets for deformation or warping

9. Lubrication system

- Check the lubricating pump
- Note the oil level
- Check the oil pipe for damage
- Check the oil pipe for damage
- Make sure that all terminal parts are properly lubricated

Second, dimensions need to be checked because when the can and flange dimensions are not within tolerances the seamer will not place the lid properly and cause defective seams. These defective seams will result in an out-of-control signal on the control charts. Dents that arise during tray transportation can affect the tray dimensions and also cause problems during seaming.

Third, lids need to be examined for warping, compounding, denting, and deviation of dimensions. These attributes can cause faulty seams which will also result in an out-of-control signal on the control charts.

Fourth, following conveyors and their synchronization controllers should be checked because the tray position when entering the seamer may be out of place due to conveyor inconsistencies (refer to *Revised Automation Control Strategy For Tray Pack Filling/Sealing Line*):

- Discharge Conveyor
- Phasing conveyor
- Reject Tray Conveyor
- Filling Conveyor
- Spacing Conveyor

Last, filling conditions need to be checked. This includes examining for overfilling and sloshing. Overfilling and sloshing of gravy is caused by two factors, the gravy filler and conveyor speed. Both these items should be examined.

Problems concerning can surface defects indicated by the \overline{c} chart and checklist should be investigated by first checking the transport system of the trays. Then, the seamer should be examined because defects can result during movement of trays in the seaming process.

6.2 FINAL PRODUCT SPC STATION

The procedures at this SPC station will be divided into three categories: can condition test (immediately after retort), sampling inspection (after 24 hour storage), and incubation test. At this station the condition of the can will again be checked. Surface defects (which of the can which can be caused by transport and the retorting process) will be monitored using a \overline{c} chart [Figure 6.15] from a sample size of 4 every retort batch. The inspector will circle defects such as dents, cuts, and abrasions, with a red marker, then he/she will count the number of circles and record them at the appropriate spot on the control chart form. The average of these 4 measurements will be recorded as the point on the \overline{c} chart for that time period. While checking these same trays the inspector should note on the checklist portion of the control chart form any major problems that will not allow the tray to move on, such as scoring, holing, crushing, and corrosion. The control chart results will be compared with the surface defect control chart from the previous station.

Net weight, drained weight, viscosity of gravy, total salt content, and total fat content will be checked in lab procedures (see Appendix V) 24 hours after removal of trays from the retorter. This will be done using a sample size of 1 from every retort batch (240 trays) such that average of 8 trays will be sampled from 2 hours production. One set of 4 trays from these 8 samples will be used for salt content and fat content tests while a the other 4 trays will be used for the other tests. The data will be recorded on \bar{x} and R control charts [Figures 6.16-17 and Appendix I, Figure 6.18-6.20]. Other characteristics which will be monitored by checklists are: Beef Texture, Chunk Dimensions, Connective Tissue, Bone Fragments, Gravy Texture and Color and Foreign Odor, Color and Material. Any incidents such as operator change, shift change, conditions, last calibration of retorter, and others should be recorded on the checklist form. Incubation tests will be also conducted by sampling 1-2 cans from each retort batch and store them at 95 °F for 10 days to determine if microorganisms are present in the trays. Nonconforming products from the final product tests are classified into the three categories and corrective actions will be taken accordingly:

1. Schedule Process Deviation Of Retort Process

This category consists of nonconforming products caused by any parameter that affects heat transfer in retort. This includes all critical parameters such as initial temperature, viscosity, beef fill weight, and head space. The problem will be handled by consulting the process authority and then the process authority recommending an appropriate action (either reprocessing or destroying the product.)

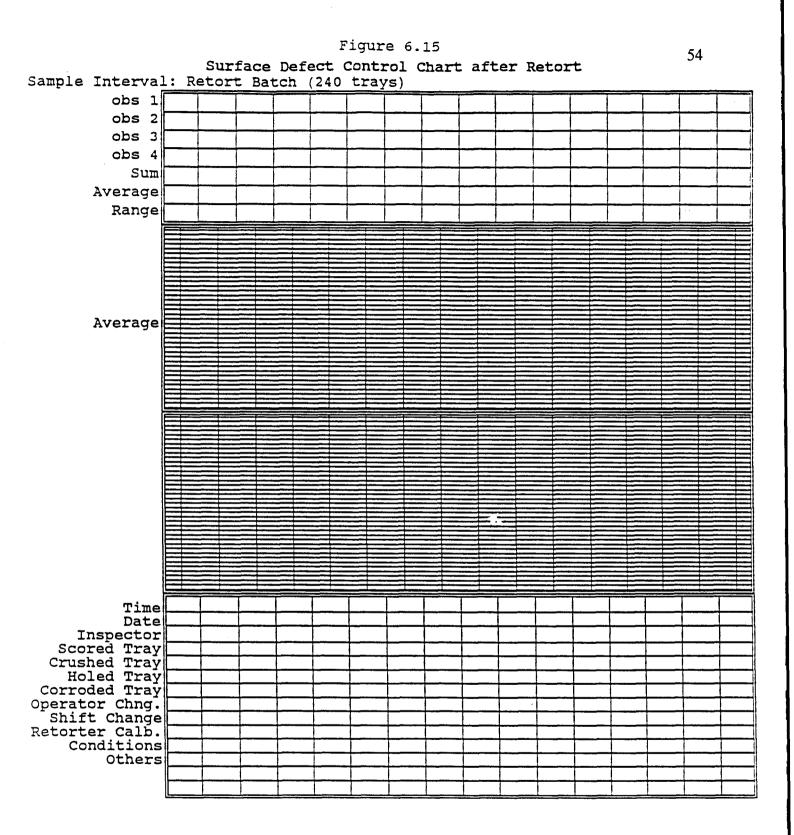
2. Incubation Test

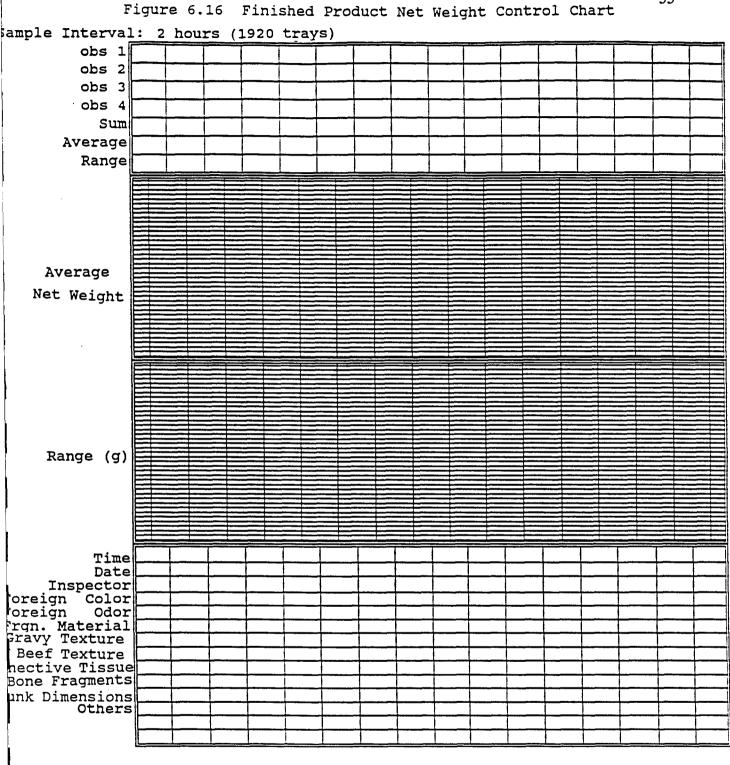
The can should be checked for seam defects before incubation. If a can swells, inspect the can for a seal defect. If the seam is bad it was probably contaminated after retort. If this occurs, the same retort batch has to be entirely tested and screened out for nonconforming

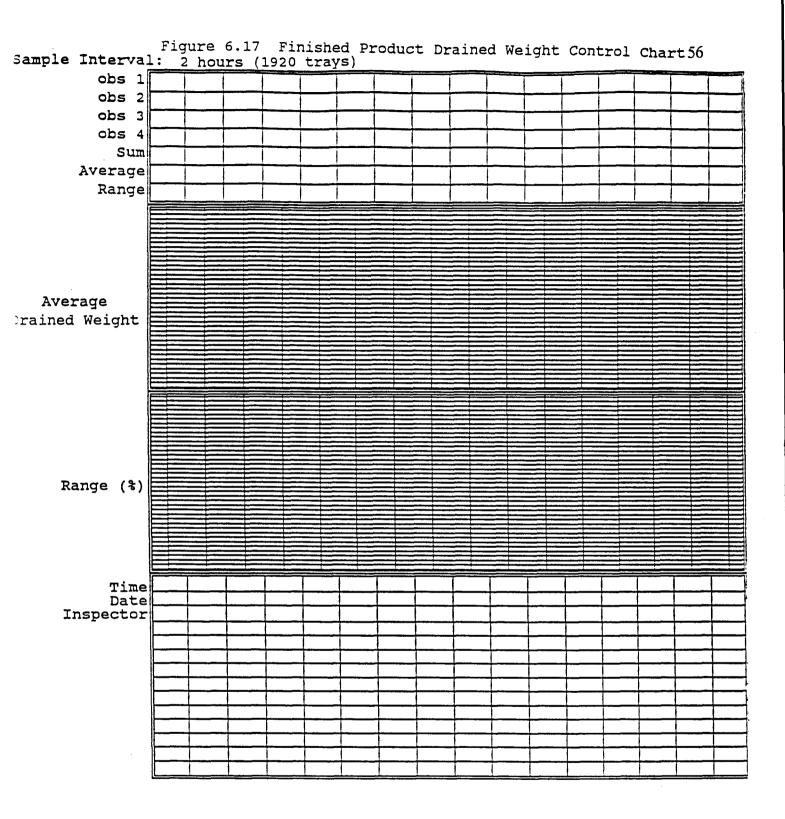
products. If the can swells without another cause (e.g. seal) then destroy the lot.

3. Finished Product Specifications

If finished products do not meet one of the military specifications (but meet the above two requirements), then, isolate the lot, put it on hold and re-sample. Release the lot if it meets acceptance criteria for double sampling plan. If it still does not meet the specifications then do one of the following: make a request for the variance of the specifications, resell it to third parties, destroy the lot, or donate the lot.







7. SUMMARY OF SPC STATIONS FOR TRAY PACK PRODUCTION LINE

This section presents a summary of all nine SPC stations in table form. The tables describe the characteristics to be inspected in the first column. Following columns differ for each station but generally the control method, sample size, sampling interval, and corrective actions are given. The control methods are of three types: control charts (\bar{x} , \bar{c} , etc.), acceptance sampling plans, and checklists. Also listed on the tables are suitable comments that should be noted for each station on its respective charts. At all stations, an emphasis is placed on inspecting for foreign odor, foreign color, and foreign material because any of these characteristics may arise anywhere along the line during transport and handling of the tray packs. The following tables present the main points of each SPC station at a glance as noted by the alphabetic letter in Figure 2.1.

Station a Raw Beef Sampling SPC Station							
Characteristics	Control Method	Sample Size	Corrective Action				
Foreign Color							
Foreign Odor							
Foreign Material							
Drained Wt.							
Cube Size	MIL-STD-105E Sampling Plan	Special Inspection Level S-4	accept/reject				
Surface Fat							
Connective Tissue							
Bone Pieces							
Microbiology Quality	1						

Station b Precooked Beef SPC Station							
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action			
Weight Loss of Beef	x Chart & R Chart			 Check the oven Re-check the raw beef 			
Precooked Beef Texture	e Checklist			same as above			
Foreign Material	Checklist	4 of 5 lb beef	1/2 hr (480 trays)	same as above			
Foreign Odor	Checklist			same as above			
Foreign Color	Checklist			same as above			
excessive heating	Checklist			same as above			
beef chunks mushy	Checklist			Check the oven			
Incident Note	Comments	-	-	 Operator change Shift change New lot of raw beef Conditions Last calibration others 			

Station c Precooked Beef Fill Weight SPC Station							
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action			
Net wt. of precooked beef/tray	x Chart & R Chart			Check the weigher			
Foreign Material	Checklist	4 trays	1 hr (960 trays)	Check the environment			
Foreign Odor	Checklist			same as above			
Foreign Color	Checklist			same as above			
Incident Note	Comments	-	-	 Operator change Shift change New weigher Conditions Last calibration Others 			

.

Raw In	Station d gredients Sampling	SPC Station			
Characteristics	Control Method	Lot Size	Corrective Action		
Raw Ingredients Certification - shipping lot accept/reject					

Station e Gravy SPC Station					
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action	
Gravy Viscosity	x Chart & R Chart			 Check raw ingredients Check the kettles Check the formula of gravy 	
Gravy Density	x & R Charts			same as above	
Gravy Lumpy	Checklist			same as above	
Salt Content	x Chart & R Chart	4 samples	1/2 hr. (every kettle)	 Check raw ingredients Check the formula of gravy 	
Foreign Material	Checklist			 Check raw ingredients Check the environment 	
Foreign Odor	Checklist			same as above	
Foreign Color	Checklist			same as above	
Incident Note	Comments	-	-	 Operator change Shift change New lot of raw ingredients Conditions Last maintenance of kettles Others 	

	Static Trays SPC		
Characteristics	Control Method	Sample Size	Corrective Action
Can Dimension			
Flange Dimension	MIL-STD-105E Sampling Plan	Special Inspection Level S-4	accept/reject
Dents			

	Fille	Station g d Tray Packs SP	C Station			
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action		
Net Weight of Cans	x Chart	whole lot	continuous automatic measurement	 Check the weighing scale Check the gravy filler Add or extract gravy 		
Gravy Splashes on Edges	Checklist			Check the filler		
Foreign Material	Checklist	- 16 trays			Check the environment	
Foreign Odor	Checklist					Check the environment
Foreign Color	Checklist			101	Check the environment	
Scored Tray	Checklist		1/2 hr	Check the conveyor		
Crushed Tray	Checklist			Check the conveyor		
Holed Tray	Checklist			Check the conveyor		
Corroded Tray	Checklist			Check the conveyor		
Incident Note	Comments	-	-	 Operator change Shift change Last adjustment Conditions Last maintenance of filler Others 		

		Station h Seaming SPC S	ation		
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action	
Surface Defects of Can (dents, abrasions & cuts)	C Chart & R Chart				
Scored Tray	Checklist				
Crushed Tray	Checklist				
Holed Tray	Checklist	8 trays	1 hr (960 trays)	Check seamer & conveyor	
Corroded Tray	Checklist				
Burst	Checklist	1			
Rupture	Checklist				
Overfill	Checklist	1			
Vacuum Seal	p-chart	100	2 hr (1920 trays)	Check seamer	
Initial Temp. for Retort	x chart & R Chart				Check Environment
Head Space	x Chart & R Chart	1 trays	Retort Batch (240 trays)	 Check filling processes Check checkweigher 	
External Seam Measurement (length and thickness)	x Chart & R Chart	4 trays*	1 hr (960 trays)	Check seamer	
Seam Teardown & Internal (cover & hook, pressure ridge & tightness)	x Chart & R Chart	2 trays*	1 hr (960 trays)	Check seamer	
Seam Sectioning (length, overlap, body & hook length)	x Chart & R Chart	2 trays*	1 hr (960 trays)	Check seamer	
Vacuum Gauge	x & R Chart	4 trays	1/2 hr	Check seamer	
Incident Note	Comments	-	-	 Operator change Shift change New lot of lids Conditions Last calibration of gauge Others 	

* Approximately 4 retort batches are run every hour, so 4 trays will be accumulated each hour by performing the tests of initial temperature for retort and head space. All four of these trays will be used to perform the External Seam Measurement, and then, of those same 4 trays, 2 will be used for the Seam Teardown & Internal test, and the other 2 will be used for Seam Sectioning test.

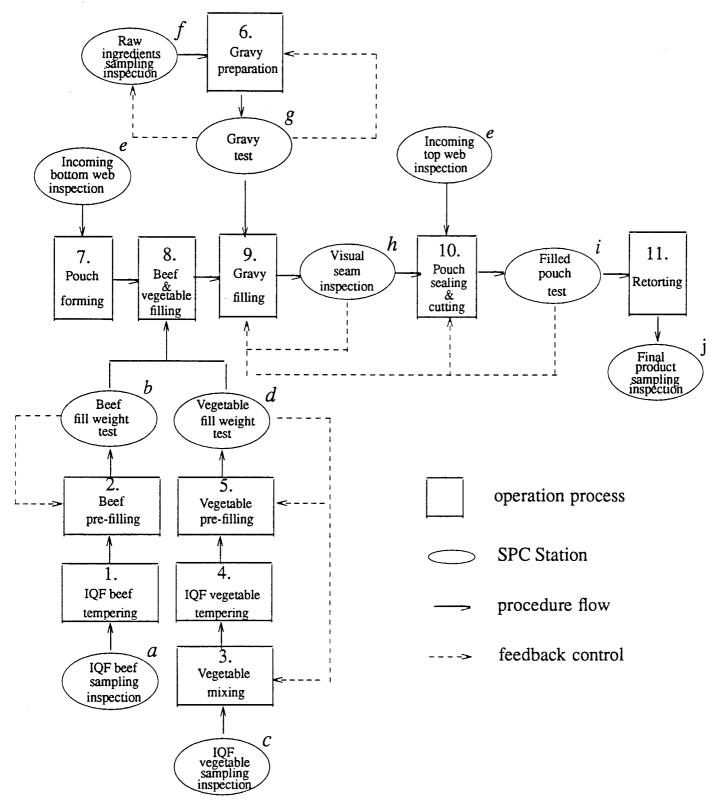
		Station i				
	Finished	Product Inspection	n after Retorting	r		
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action		
Surface Defects of Can	c Chart	4 trays Retort Batch				Check the retorter
(dents, abrasions & cuts)	& R Chart					
Scored Tray	Checklist		Datart Datab	Check the retorter		
Crushed Tray	Checklist	- uays	Keiget Baten	Check the retorter		
Holed Tray	Checklist			Check the retorter		
Corroded Tray	Checklist			Check the retorter		
Incident Note	Comments	-	-	 Operator change Shift change Conditions Last calibration of retort Others 		
			ion after 24 hour stora			
(a)	sample size of 1 from	m every retort bate	ch - 8 from 2 hrs. prod	uction)		
Characteristics	Control Method	Sample Size	Sampling Interval	Action		
Net Weight	x & R Charts					
Drain Weight	$\overline{\mathbf{x}}$ & R Charts					
Viscosity						
	x & R Charts					
Beef Texture	x & R Charts					
······································	x & R Charts					
Beef Texture	x & R Charts	4 from 8 trays	2 hrs. production	Review Charts & Checklist		
Beef Texture Chunk Dimensions		4 from 8 trays	2 hrs. production	Review Charts & Checklist		
Beef Texture Chunk Dimensions Connective Tissue	x & R Charts Checklists	4 from 8 trays	2 hrs. production	Review Charts & Checklist		
Beef Texture Chunk Dimensions Connective Tissue Bone Fragments		4 from 8 trays	2 hrs. production	Review Charts & Checklist		
Beef Texture Chunk Dimensions Connective Tissue Bone Fragments Gravy Texture & Color		4 from 8 trays	2 hrs. production	Review Charts & Checklist		
Beef Texture Chunk Dimensions Connective Tissue Bone Fragments Gravy Texture & Color Foreign Color		4 from 8 trays	2 hrs. production	Review Charts & Checklist		
Beef Texture Chunk Dimensions Connective Tissue Bone Fragments Gravy Texture & Color Foreign Color Foreign Odor						
Beef Texture Chunk Dimensions Connective Tissue Bone Fragments Gravy Texture & Color Foreign Color Foreign Odor Foreign Material	Checklists	4 from 8 trays 4 from 8 trays	2 hrs. production 2 hrs. production	Review Charts & Checklist Review Charts & Checklist		
Beef TextureChunk DimensionsConnective TissueBone FragmentsGravy Texture & ColorForeign ColorForeign OdorForeign MaterialSalt Content	Checklists		2 hrs. production			
Beef TextureChunk DimensionsConnective TissueBone FragmentsGravy Texture & ColorForeign ColorForeign OdorForeign MaterialSalt Content	Checklists	4 from 8 trays	2 hrs. production			

8. SPC STRATEGIES FOR MRE POUCH LINE

The previous sections have presented a detailed SPC program for traypack production process. The Meal-Read-to-Eat (MRE) pouch line is similar to the traypack line. In this section, we briefly describe the production process and proposed SPC stations for the MRE pouch line. The concise description of control strategies is also presented in table form for each SPC station.

The outline of the production steps for the MRE pouches is as follows (refer to Level 1 Automation Control Strategy for Horizontal Forming/Filling/Sealing Machine): The IQF precooked beef and IQF frozen vegetable are tempered prior to the filling process. At the same time, the gravy is cooked in kettles before transported to the filling/packaging line. The filling/packaging line consists of bottom film forming, pouch filling, and sealing processes. In the bottom film forming station the lower mold assembly is raised until a vacuum can draw the web film into the mold for a time period such that the web film is formed into pouch bottom. When the forming is complete, the mold is lowered and the formed open pouches are advanced to a filling area. The filling area consists of beef volumetric filler, vegetables volumetric filler, and cup dumping assembly. Empty cups are first moved to beef filling area where calculated amount of beef is deposited into the cups. The cups are then moved to the vegetable filling area and are filled with calculated amount of mixed vegetables. Cups filled with beef and vegetables finally reach the dumping area where beef and vegetables are dumped into open pouches. Pouches filled with beef and vegetables are then transported to gravy filling area where a volumetric filler deposits certain amount of gravy into the pouches. The package sealing station following the filling station is where the loaded bottom film and top film are heat-sealed together to form the final package. Pouches are then separated and trimmed in the separation station before transported to be retorted. A flow diagram describing the above process is shown in Figure 8.1.

Figure 8.1: SPC Stations for MRE Pouch Line



Unlike the tray packs, MRE pouches contain vegetable ingredients in addition to the beef and gravy. Therefore, an incoming vegetable inspection station is added while receiving the raw material from vendors. An SPC station for testing the fill weight of vegetable is also added to ensure that the vegetable drained weights of finished products will meet the military specification. Incoming precooked beef and frozen vegetable are tempered and do not need to be cooked before the filling process. Thus, the SPC station for testing the precooked beef quality shown in the traypack line is not present for the pouch line. Besides, net weights of pouches can not be checked in-process as indicated in traypack line because the loaded open pouches are not separated until they are sealed and cut. Consequently, we move the pouch net weight test to the station after the sealing/cutting process. According to MIL-I-45208A and MIL-P-44073, the packaging quality characteristics of MRE pouches are different from those of tray packs. We outline the packaging quality characteristics and the surface defects of concern for MRE pouches as follows:

- Delaminations
- Leakages
- Abrasions/Silver
- Tears/Cuts
- Residual Gas
- Internal Pressure
- Seal width
- --- Nonvisible Leaks
- Seal Strength

Except the differences described above, the rest of the SPC stations for pouch line are designed in the way similar to those for traypack line (refer to MIL-B-44059C and MIL-B-44230B). There are ten SPC stations for the MRE pouch production. Four control the incoming raw materials: beef, gravy ingredients, vegetable ingredients and web film. Four control in-process products. Two control final products: one for the sealed pouches and one for the sealed and retorted pouches. These ten SPC stations are summarized in table form.

The tables describe the characteristics to be inspected, the control charts or sampling plans to be used, the sampling strategies and the suggested corrective actions to be taken while the process is found out-of-control. The following tables present the main points of each SPC station as noted by the alphabetic letter shown in Figure 8.1.

	Station IQF Beef Samplin		
Characteristics	Control Method	Sample Size	Corrective Action
Certification	-	-	accept/reject
Foreign Color			
Foreign Odor			
Foreign Material			
Drained Wt.			
Cube Size	MIL-STD-105E Sampling Plan	Special Inspection Level S-4	accept/reject
Surface Fat			
Connective Tissue			
Bone Pieces			
Microbiology Quality			

Station b Beef Fill Weight Inspection						
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action		
Net wt. of beef per pouch	x Chart & R Chart			Check the filler		
Foreign Material	Checklist	8 pouches	8 pouches	8 pouches	s 1/2 hr (3060 pouches)	
Foreign Odor	Checklist			Check the environment		
Foreign Color	Checklist					
Incident Note	Comments	-	-	 Operator change Shift change New weigher Conditions Last calibration Others 		

	Statio IQF Vegetable Sar		<u> </u>
Characteristics	Control Method	Sample Size	Corrective Action
Certification	-	-	accept/reject
Foreign Color			
Foreign Odor	MI STD 1055 Someline Disp	Special Inspection Level 6.4	
Foreign Material	MIL-STD-105E Sampling Plan	Special Inspection Level S-4	accept/reject
Moisture			

.

	Vegetz	Station d able Fill Weight	Inspection		
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action	
Net wt. of vegetable per pouch	x Chart & R Chart				
Ratio of combination	x & R Chart	8 pouches			
Foreign Material	Checklist		1/2 hr (3060 pouches)	Check the weigher	
Foreign Odor	Checklist				
Foreign Color	Checklist				
Incident Note	Comments	-	-	 Operator change Shift change New weigher Conditions Last calibration Others 	

	Station e Incoming Web Inspection (*	Top & Bottom)	
Characteristics	Control Method	Sample Size	Corrective Action
Abrasions/Silver			
Delaminations			
Tears/Cuts		Inspection Level S-2	
Leakages			
Foil Bond Strength	MIL-STD-105E Sampling Plan		accept/reject
Poluolefin Thickness			
Aluminum Foil			
Polyester Thickness		Inspection Level S-1	
Certification			

Station f Raw Ingredients Sampling Inspection					
Characteristics Control Method Lot Size Corrective Action					
Raw Ingredients Certification	-	shipping lot	accept/reject		

Station g Gravy Inspection				
Characteristics	Control Method	Corrective Action		
Gravy Viscosity	x Chart & R Chart			 Check raw ingredients Check the kettles Check the formula of gravy
Gravy Density	x & R Charts			same as above
Gravy Lumpy	Checklist			same as above
Salt Content	x Chart & R Chart	4 samples	1/2 hr. (every kettle)	 Check raw ingredients Check the formula of gravy
Foreign Material	Checklist			 Check raw ingredients Check the environment
Foreign Odor	Checklist			same as above
Foreign Color	Checklist	1		same as above
Incident Note	Comments	-	-	 Operator change Shift change New lot of raw ingredients Conditions Last maintenance of kettles Others

Station h Visual Seam Inspection					
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action	
Contamination on Pouch Edges	Checklist	Visual Inspection	continuous	 Check the fillers Check the environment 	
Foreign Material					
Foreign Odor				Check the environment	
Foreign Color					
Incident Note	Comments	-	-	 Operator change Shift change New weigher Conditions Last calibration Others 	

		Statio Sealing and Cut		
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action
Net Weight of Pouch	x Chart & R Chart		8 pouches 1/2 hr (3060 pouches)	
Foreign Material		8 pouches		Check gravy filler
Foreign Odor	Checklist			
Foreign Color				
Surface Defects on Pouch 1. Abrasions/Silver 2. Delaminations 3. Tears/Cuts 4. Leakages	c Chart			Check sealer & conveyor
Initial Temp. for Retort	x & R chart	2 pouches	Retort Batch (1500 pouches)	Check Environment
Residual Gas	x Chart & R Chart		2 3 1/2 hr (3060 pouches)	 Check filling processes Check time & vacuum
Internal Pressure	x & R Chart	4 pouches		Check sealer
Seal Width	x & R chart			Check Sealer
Nonvisible Leaks	c Chart			Check sealer
Seal Strength	x & R Chart	4 pouches	1/2 hr (3060 pouches)	Check sealer
Incident Note	Comments	-	-	 Operator change Shift change New lot of lids Conditions Last calibration of gaug Others

		Station j		
	Finished P	roduct Inspectio	n after Retorting	
Characteristics	Control Method	Sample Size	Sampling Interval	Corrective Action
Surface Defects of Pouch 1. Abrasions/Silver 2. Delaminations 3. Tears/Cuts 4. Leakages	c Chart	4 pouches	Retort Batch	Check the retorter
Incident Note			- ion after 24 hour stor	-
(a s	ample size of 1 from	every retort bat	ch - 8 from 2 hrs. proc	duction)
Characteristics	Control Method	Sample Size	Sampling Interval	Action
Net Weight	x & R Charts			
Beef Drain Weight	x & R Charts			
Vegetable Drain Wt.	x & R Charts			
Viscosity	x & R Charts			
Beef Texture		-		
Vegetable Texture				
Chunk Dimensions		4 from 8	2 hrs. production	Review Charts & Checklists
Connective Tissue				
Bone Fragments	Checklists			
Gravy Texture & Color				
Foreign Color				
Foreign Odor				
Foreign Material				
Salt Content	x & R Charts	4.6		Review Charts & Checklists
Fat Content	x & R Charts	4 from 8	2 hrs. production	Review Charts & Checkhists
Incubation Test				
Characteristic	Method	Sample Size	Sampling Interval	Corrective Action
Microorganism Growth	Stored at 95°F for 10 days	2	Retort Batch	 Check the retort process Check the searning process

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COMBAT RATION ADVANCED MANUFACTURING TECHNOLOGY DEMONSTRATION (CRAMTD)

Production of Beef Chunks and Gravy in Tray Pack Technical Working Paper (TWP) 47

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PRODUCTION OF BEEF CHUNKS AND GRAVY IN TRAY PACKS

1

OBJECTIVE

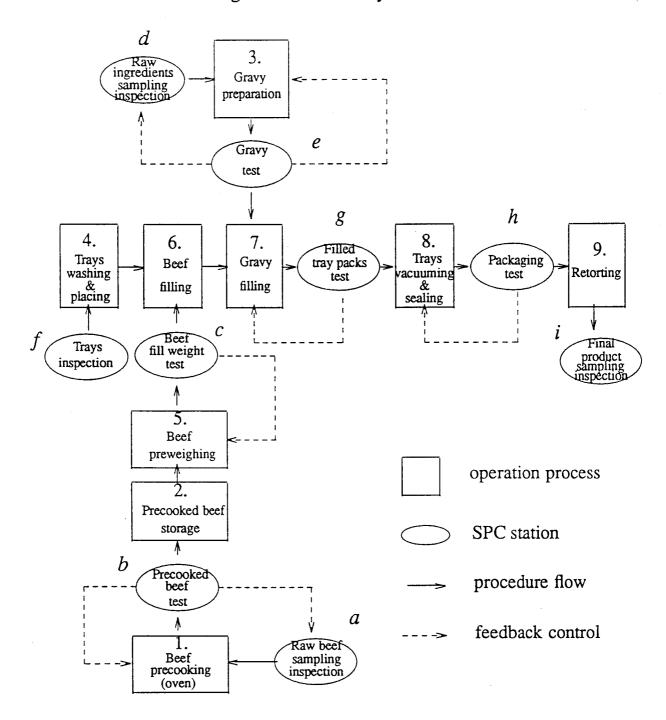
The objective of this report is to present the procedures for preparing production of beef chunk tray packs that meet MIL-B-4230B requirements. These procedures describe the steps required to determine and control the production settings for each process in the production line. It should be noted that all the steps provided in this report are based on the research investigation conducted on manufacturing facilities in CRAMTD pilot plant. However, the steps can be easily adapted or revised for different manufacturing environment or different types of products.

1. INTRODUCTION

This report focuses on the processes involved in the production line of beef and gravy in tray packs. There are two types of beef that can be used for the tray pack production by contractors: raw beef cubes and diced IQF precooked beef cubes. We assume the raw beef is used for the production in this report. Nevertheless, the steps in the report are still valid when diced IQF precooked beef is used instead. The main difference when using raw beef is the precooking process which must be performed when contractors choose raw beef cubes as production raw material. The precooking can be done by either using boiling water or in an oven. Both methods will be explained later in this report.

The process of making beef chunks with gravy in tray packs consists of two cooking operations: beef precooking and gravy preparation, and a filling/packaging line followed by a retort process. A flow diagram of the processes is shown in Figure 1.1. In this figure, the rectangles represent the operations while the recommended inspection stations are represented by ellipses. In this report, however, we will focus only on the operations (inspection stations are discussed in a separate technical report). We will first present the procedure to examine the raw beef received from vendors and then the control strategies and preparation procedures for each process will be demonstrated as noted by their numbers in Figure 1.1.

Figure 1.1: The Tray Pack Line



The production steps are developed in such a way to ensure that the microbiological control and the military specifications are met. The microbiological control is to ensure that the microbial count at every production process is within a safe limit. The product's acceptance depends on whether it meets the military specifications or not. Therefore, the steps for determining the production target values such as tolerance of precooking yield, fill weights of beef and gravy and the formulation of making gravy are developed to ensure that the final specifications are satisfied. Finally, we present the run rules for retort operation before products are removed from the production line for end-item inspections.

2. RAW BEEF EXAMINATION

The quality of raw beef plays a very crucial role in the production process. A purchase control program should be implemented prior to the production. This purchase control program will be described in a report on Statistical Process Control. Essentially, a new lot of raw beef will be sampled and inspected to determine if the lot will be accepted or rejected. Contractor's R&D department is assigned to establish control rules for searching raw material sources and defining raw beef specifications. The following elements should be included:

- a) Determine the critical quality attributes of the meat
- b) Methods to check the quality attributes
- c) Establish raw material specifications
- d) Identify a vendor who can deliver a product under these specifications
- e) Develop a process which is capable of producing finished product within specifications using this raw material
- f) Establish adequate vendor control program to assure that the shipped beef meets the agreed specifications
- g) Establish an acceptance inspection sampling plan to assure that the vendor indeed ships the beef conforming to the specifications

Quality attributes, such as overall beef shrinkage, fat content, bone pieces, and cube dimensions, will be checked in a acceptance sampling plan. The beef quality should be checked after the beef is cooked. A small scale experiment simulating the cooking processes in the production line is recommended for the raw beef examinations. A simple cooking (boiling) test, however, is suggested for contractors when the experiment is not considered economic. After the small scale experiment or the simple cooking test is conducted, the quality attributes can be measured accordingly. The acceptance sampling plan then is utilized to determine if the lot of beef should be accepted. Once the lot is accepted, the raw beef will be stored in the freezer until precooking.

A very important purpose of the small experiments or tests, in addition to the quality tests, is to determine the mean and standard deviations of the overall shrinkage after precooking and retorting. Our experience is that the overall beef shrinkage is independent of the cooking methods. Once the contractor knows the potential shrinkage (yield) of a raw beef lot, the contractor can precook the beef to a certain degree such that a steady shrinkage during the retort process can be expected. These values, means and standard deviations of overall shrinkage and shrinkage during retort process, will be used later in the settings of precooking process estimating the amount of beef and gravy needed such that

all production units will meet the drain and net weight requirements.

There are two methods of precooking: using boiling water and using the Enersyst oven. Since we will describe the two methods of precooking, we will accordingly explain the small scale experiments for each method. We first describe the boiling water method and then follow it with appropriate changes when using the Enersyst oven.

2.1 EXPERIMENTS FOR THE BOILING WATER METHOD

In addition to the acceptance sampling plan for receiving incoming raw beef, every new lot of raw beef received from a certified vendor should be sampled and then used to conduct the experiments as follows:

- a) Samples of the beef lot are removed from freezer immediately prior to running of experiments.
- b) Samples are preweighed and stored in a freezer.
- c) Samples are precooked in boiling water.
- d) It is then weighed after 10 minutes (or a predetermined time length similar to the one to be used in actual production.) The precooking yield is calculated.
- e) Trays are filled with precooked beef.
- f) A calculated amount of gravy is added to filled trays.

- g) Trays are placed on line to be vacuum sealed.
- h) Sealed trays are retorted. Retorting yield is calculated and then multiplied by the precooking yield to determine total drain weight yield.
- Calculate the mean and standard deviation of the drained weight.

2.2 EXPERIMENTS FOR THE ENERSYST OVEN METHOD

The process is the same as above with the exception of the following step concerning the precooking parameters:

- c) Place the beef chunks on the conveyor and set the following oven parameters, suggested parameters are in parenthesis:
 - . Belt Speed (8%)
 - . Temperature
 - zone 2 (475°F)
 - zone 3 (475°F)
 - . Air speed (6000 ft/min)
 - . Jet height -(1.5")
 - . Air proportion (75% / 25%)
 - . Steam (only zone one is applied)

* the values shown in the parenthesis are suggested only.

Contractors should use similar values to those used in the Actual production settings.

2.3 TESTS USING BOILING WATER

As mentioned earlier, our experience shows that the overall beef shrinkage is independent of the precooking methods. In other words, contractors can simply conduct a cooking process in boiling water instead of the small full scale experiments. The cooking procedure is described as following:

- a) Sample a small amount of raw beef (sample size is determined by contractors); weights of the samples are referred as "original weights" in later calculation.
- b) Immerse the raw beef samples in boiled water for at least15 minutes (fully cooked).
- c) Weigh the cooked beef samples and then calculate the overall yields by dividing them by the original weights.
- d) Calculate the mean and standard deviation of the overall yields.

After these small scale experiments (cooking tests) are completed and overall means and standard deviations are calculated, the data obtained can then be used to determine production target values (calculated by mathematical models described in the Section of BEEF PREWEIGHING.)

3. PRECOOKING

Precooking (operation 1, as indicated in Figure 1.1) is done for three important reasons. First, this initial cooking lowers the level of microorganisms present in the beef and, therefore, lets the beef be stored safely for a period of time before the actual cooking process. Second, precooking quickly hardens and shrinks the beef cubes in order to facilitate its handling during filling and packaging processes. Third, the proper precooking process may result in better sensory products. The two methods for precooking raw beef are in boiling water and in the Enersyst oven. The precooking process capability is studied in terms of military requirements of gravy viscosity and beef drained weight.

We first look at how the precooking process influence the beef drained weight of finished products. In order to meet the military specification of drained weight, each tray will be filled with a calculated amount of precooked beef following the beef precooking process. The filled weight of precooked beef for each tray is a fixed setting during the production and is calculated according to the overall shrinkage and the shrinkage caused by the precooking. As mentioned before, the overall beef shrinkage after precooking and retort processes is quite consistent and independent of the cooking process. Therefore, when the shrinkage during the precooking process is more or less than expected, the final drained weight after retort will vary. In the section of Beef Preweighing, we will present a statistical methodology to determine the target fill weight of precooked beef in terms of the overall yield, the precooking yield and the overall production line variability.

3.1 In-Process Control

The precooking process also affects the gravy viscosity. The broth yielded from beef during the retort process will contribute moisture to the gravy and lower the viscosity. Thus, the greater yield of beef during the precooking process results in lower yield of beef during retort process and greater contribution of broth so that the gravy viscosity becomes lower. Because different precooking yields require different target fill weights of precooked beef and gravy and dictate different gravy formulas, we present a methodology for determining the in-process tolerance range of beef precooking yield such that the robustness of precooking process assure minimum adjustments of the filling gravy formula while still meeting military process and specifications.

According to our experiments (see Section 5: GRAVY PREPARATION), we found the relationship (valid for Sta-O-Paque

starch) between the gravy viscosity and water-to-starch ratio as
follows (also refer to CRAMTD Technical Working Paper #28):

 $Visc=187502400 \times WS^{-3.1001}$ (1.1)

where

Visc : gravy viscosity of finished product
WS : water-to-starch ratio

The water-to-starch ratio can be expressed as:

 $WS = \frac{M_t}{W_s}$

where

 M_t : total weight of gravy moisture of finished product

 W_s : weight of starch prepared for one tray

The total weight of gravy moisture of finished product can be calculated based on the moisture content of each individual component:

 $M_t = M_b + M_i + M_s + W_w$

where

M_b : weight of juice released from beef during retorting

*M*_i : weight of moisture of flavor ingredients

M_s : weight of starch moisture

 W_{ω} : weight of water in gravy prepared for one tray

The weight of water in gravy per tray can be express as follows:

 $W_w = GFW - W_i - W_s$

where

GFW : gravy fill weight
W, : weight of flavor ingredients per tray

We assume that the beef juice has the same effect on viscosity dilution as water does. We also assume the beef juice produced during the retort process is equal to the difference between Beef Fill Weight (BFW) and Beef Drained Weight (BDW):

 M_{b} =BFW-BDW

From experiments, we found that the moisture content of starch is 2.28%, i.e;

 $M_s = 0.0228 \times W_s$

Experimental results also showed that the moisture content of flavor ingredients is 43.8%. The weight of flavor ingredients in the gravy per tray is held constant (290 grams/tray) according to MIL-B-4230B:

W_i =290 grams/tray

Therefore, the weight of the moisture contributed by the flavor ingredient will be also constant ($M_i=127$ grams/tray). Thus, we can rewrite the calculation of the total gravy moisture as follows:

$$M_t = WS \times W_s = BFW - BDW + GFW - W_s - 290 + 0.0228W_s + 127$$
$$\leftarrow M_b - - \leftarrow M_i - - - - M_s - - - - W_w$$

Rewrite the above equation. We can obtain:

$$WS = \frac{BFW - BDW + GFW - 163}{W_s} - 0.9772$$

The Net Weight (NW) of one tray equals to the addition of beef fill weight and gravy fill weight, so the following two equations can be obtained:

$$WS = \frac{NW - BDW - 163}{W_s} - 0.9772 \qquad (1.2)$$

and

$$W_{s} = \frac{NW - BDW - 163}{WS + 0.9772}$$
(1.3)

The tolerance range of the gravy viscosity is [1300, 3550] cp according to military specifications. Therefore, we choose the center point of the range (2425 cp) as our target value of the gravy viscosity. Given the target value, we can calculate the target water-to-starch ratio from Equation (1.1).

$$WS^{*} = \left(\frac{2425}{187502400}\right)^{-\frac{1}{3\cdot 1001}} = 37.74$$

where

WS* : the target value of water-to-starch ratio

We then calculate the target weight of starch from Equation (1.3):

$$W_{s}^{*} = \frac{NW^{*} - BDW^{*} - 163}{37.74 + 0.9772}$$
(1.4)

where

W^{*}_s : the target weight of starch
NW^{*} : the target net weight of finished product
BDW^{*} : the target drained weight of beef

The target net and drained weights of finished product are determined in terms of the military specifications and the overall production variability (see Section of BEEF PREWEIGHING.) The target weight of starch, the target net weight and the target drained weight are three production parameters that need to be determined prior to the production. Suppose the settings of the precooking process are set to attain a specific target value of precooking yield. With the variability of precooking process, the precooking yield will deviate from the target value and result in a deviation of final drained weight from its target value. The relationship among the target drained weight and actual drained weight can be expressed as follows:

$$BDW=BDW^* \times \frac{Y_p^*}{Y_p}$$

where

 Y_p : the actual precooking yield Y_p^* : the target precooking yield

Substituting the actual drained weight into Equation (1.2), we can obtain the actual water-to-starch ratio as follows:

$$WS = \frac{NW^* - \frac{BDW^* \times Y_p^*}{Y_p} - 163}{W_s^*} - 0.9772 \qquad (1.5)$$

where NW', BDW', Y_p , and W_s are determined prior to production (see Sections of GRAVY PREPARATION and BEEF PREWEIGHING) and the settings of processes are set accordingly. The objective of our calculation is to determine the tolerance range of precooking yield such that the production settings do not need to be changed and the military requirements of gravy viscosity is still met. From Equation (1.1) and (1.5), we can obtain the lower limit of the precooking yield through the following equation given the upper specification limit of gravy viscosity (3550 cp):

$$\frac{NW^* - \frac{BDW^* \times Y_p^*}{Y_p^1} - 163}{W_s^*} = -0.9772 = \left(\frac{3550}{187502400}\right)^{-\frac{1}{3.1001}}$$

where

 Y_p^1 : lower tolerable deviation of precooking yield

Similarly, the upper limit of the precooking yield can be obtained using the following equation (given a lower specification of gravy iscosity (1300 cP)):

$$\frac{NW^* - \frac{BDW^* \times Y_p^*}{Y_p^u} - 163}{W_s^*} = -0.9772 = \left(\frac{1300}{187502400}\right)^{-\frac{1}{3.1001}}$$

where

 Y_p^u : the upper tolerable deviation of precooking yield

The above calculation for the tolerable range of precooking yield can be used by process engineers to estimate the process capability in regard to finished product viscosity. It should be noted that the variability of precooking process also affects the final drained weight of beef but there is only a lower limit for military drained weight requirement so that one can always increase the fill weight of precooked beef to meet the drained weight requirement regardless of the process variability. The military requirement for gravy viscosity has upper and lower bounds. Therefore, the variability of precooking yield should be restricted in order to yield conformed gravy viscosity accordingly.

Example:

Assume the target net weight and target drained weight are selected to be 3015 grams and 1550 grams, respectively (see the Section of BEEF PREWEIGHING.) From Equation (1.4), one can calculate the target weight of starch (W, \cdot) which is the amount of starch prepared for the gravy cooking and will be held constant during the production:

$$W_s^* = \frac{3015 - 1550 - 163}{37.74 + 0.9772} = 33.63 (g/tray)$$

Suppose the settings of the precooking process attain a precooking yield of 85% (Y_p =85). The lower tolerable limit of precooking yield can be calculated as follows:

$$\frac{3015 - \frac{1550 \times 85}{Y_p^{l}} - 163}{33.63} - 0.9772 = \left(\frac{3550}{187502400}\right)^{-\frac{1}{3.1001}}$$
$$Y_p^{l} = 77.65(\%)$$

Similarly, the upper tolerable limit of precooking yield can be obtained:

$$\frac{3015 - \frac{1550 \times 85}{Y_p^u} - 163}{33.63} - 0.9772 = \left(\frac{1300}{187502400}\right)^{-\frac{1}{3.1001}}$$

Thus, the in-process tolerance range for the precooking yield can be found as [77.65%, 100%]. To achieve process capability index greater than 1, process engineers should control the standard deviation of precooking yield to be less than 2.45 %. The process capability index can be calculated using the following formula: Process Capability Index = $\frac{\Delta}{3\pi}$

where

Δ : the tolerable deviation from the target value

o : the process standard deviation

After the target value of the standard deviation for the precooking yield is determined, process engineers should compare it with the actual measured standard deviation and then improve the process until the target standard deviation is achieved. It also should be noted that the target net and drained weights could be adjusted after the capability of precooking process is improved and then the above calculation should be repeated to find the new target standard deviation of precooking yield. The calculation and adjustment of target weights may need to be reiterated until the standard deviation of precooking yield meet the calculated target.

Following the methodology of determining the in-process specification and attaining an acceptable process capability for the precooking process, we present the microbiological control strategy for the precooking process.

3.2 Microbiological Control

Precooking, in general, reduces the microbial loads on beef

and enable it to be stored for a longer period of time. Although the microbial load is too low after precooking immediately, it usually builds up and increases by time during refrigeration. This, in turn, causes spoilage and undesirable changes in the beef characteristics.

First, we explain the methodology for determining the microbiological quality of the beef chunks in gravy.

The method applied for determining the microbiological quality of the beef chunks in gravy ingredients is the Aerobic Plate Count (APC). This method is intended to indicate the level of microorganisms in each ingredient. The conventional plate count method for examining food ingredients is outlined below:

- Materials and Equipment:

- Petri dishes containing plate count agar or tryptic soy agar.
- Dilution tubes with rubber stoppers containing 9 ml tryptic soy broth.
- Dilution bottles containing 450 ml 0.1% peptone diluent.
- Sterile pipets, 1, 5, an 10 ml, graduated in 0.1 ml units.
- Blender.
- Balance.
- Colony counter and tally register.

- Incubator, $35 \pm 1^{\circ}$ C.

- Preparation of Sample:

Aseptically, weigh 50 \pm 0.1 g sample and place it into a sterile blending jar. If entire sample weighs less than 50 g, weigh portion equivalent to one-half of sample and add amount of diluent require to make 10⁻¹ dilution. Total volume in blender must cover the blades completely.

Blend the sample for 2 min. Caution should be exercised during blending to avoid or prevent excessive heating, therefore, chilled diluent is recommended.

- Plating Procedure:

Prepare decimal dilutions of 10^{-2} , 10^{-3} , 10^{-4} and others as appropriate, of sample homogenate, by adding 1 ml of previous dilution to 9 ml of sterile diluent in a tube.

Pipet 0.1 ml of each dilution on a petri plate and smear it on the surface. Duplicate plates should be made from each dilution. Incubate all the plates at 35° C for 48 ± 2 hours.

- Counting and Calculation:

At the end of the incubation period, count duplicate plates in suitable range (25 - 250 colonies), using colony counter and tally register; record results per dilution plate counted. Compute average count per g, and report as colony forming units per g (CFU/g). Round off counts to 2 significant figures only.

CFU/g sample = Number of colonies on a plate X dilution X 10*
 * Multiplied by 10, since 0.1 ml of the dilution was
 plated on a plate.

The average CFU/g should be compared with the established standards (limits) for the tested samples. The lot in which samples were taken from will be accepted or rejected according to those standards.

3.2.1 Precooking in Boiling Water

The precooking of the beef in boiling water is done by immersing the beef into the water for a certain time period. To prepare for this precooking process the following equipment should be checked and outfitted for use:

- kettle
- steam pipe
- agitator

- steam gauge
- drain spout

In boiling water, precooking time and the ratio of beef to water in the cooking kettle play an important role in reducing the number of microorganisms on beef. The allowable limits of microbial count per gram of beef precooked in boiling water and refrigerated at 5°C for 24 and 48 hrs are shown in Table 3.1. The count in refrigerated beef should not exceed these limits. Any lot of refrigerated beef with a count beyond these limits should be excluded from production due to the undesirable changes in color, smell, texture, etc. caused by the high number of microorganisms, and the effect of these changes on the quality and safety of the finished product.

Table 3.1 The Allowable Limits of Total Microbial Count on Precooked (Boiling Water) and Refrigerated Beef.

Precooking Time	Total Count	CFU/g, After	Refrigeration
Precooking lime		24 Hours	48 Hours
1 min 0 sec 1 min	n 30 sec.	5.0 X 10 ⁴	5.0 X 10 ⁵
1 min 31 sec 2 m:	in 30 sec.	5.0 X 104	5.0 X 10 ⁵
2 min 31 sec 3 m:	in 30 sec.	5.0 X 104	5.0 X 10 ⁵
3 min 31 sec 4 m	in 30 sec.	1.0 X 104	5.0 X 10 ⁵

3.2.2 Precooking in the Enersyst Oven

The precooking process in the Enersyst Oven is done by placing the beef cubes on a conveyor which moves through an oven manufactured by Enersyst Development Center. The oven has four The parameters of each chamber can be controlled. chambers. Chamber 1 is a steam zone that is used to precondition the meat. Chambers 2 and 3 are identical. Each of these two chambers is equipped with two heaters, a steamer, and an air blower to cook the meat under a programmed condition. Chamber 4 is a passive equilibration zone used to condition the meat after cooking. The beef cubes are moved sequentially through each chamber to complete the precooking process. The beef broth collected from in chambers 2 & 3 is used to make the gravy. We summarize the parameters of each chamber as follows:

Chamber 1

- time

- steam (on/off)

Chambers 2 & 3

- time
- temperature
- steam (on/off)
- rate of air flow
- pattern of air impingement

Chamber 4

- time

- steam (on/off)

Again, the settings must allow an adequate level of precooking in order to permit storage for up to 48 hours without bacteria growth reaching an unsafe level.

In Enersyst Oven, precooking time is not the only factor affecting the microbial load on precooked beef. Other factors do contribute as well to the total count. These factors include the temperature of zones 2 and 3, belt speed, air speed, jet height and steam.

The allowable limits of microbial count per gram of beef precooked in Enersyst Oven and refrigerated at 5°C for 24 and 48 hrs are shown in Table 3.2. The count in refrigerated beef should not exceed these limits. Any lot of refrigerated beef with a count beyond these limits should be excluded from production due to the undesirable changes caused by the high number of microorganisms.

For analysis of the total microbial count on precooked beef, refer to the procedure described in the section of **Precooking in Boiling Water**.

Table 3.2	The Allowa	ble Limits	of	Total	Microbial	Count	on
	Precooked	(Enersyst O	ven)	and F	Refrigerate	d Beef	•

		Total Count Refrigerati	CFU/g, After on For
Precooking Time	Temp/°F in Zones 2 & 3	24 Hours	48 Hours
3 min 30 sec 4 min 30 sec.	465 - 475	5.0 X 104	5.0 X 10 ⁵
4 min 31 sec 6 min 0 sec.	515 - 525	5.0 X 10 ⁴	5.0 X 10 ⁵
6 min 1 sec 7 min 30 sec.	455 - 465	1.0 X 10 ⁴	5.0 X 10 ⁵
7 min 31 sec 9 min 0 sec.	390 - 415	1.0 X 104	5.0 X 10 ⁵

4. STORAGE OF PRECOOKED BEEF

The precooked beef shall be maintained in the temperature range of 28°F to 40°F for not more than 48 hours from the time of cooking to the time of filling into tray packs (operation 2, as indicated in Figure 1.1.) Cooling is not necessary if filling occurs immediately after cooking. The refrigerator for storing precooked beef should be properly maintained to prevent any possibility of microorganism growth in the precooked beef.

5. GRAVY PREPARATION

The process of gravy preparation consists of two cooking kettles: one is for the slurry and the other is for the emulsion. A slurry is made by mixing the broth (collected from the beef precooking if possible), starch, vegetable oil and water. An emulsion is made by mixing mushrooms, tomato paste soup stock, onion powder, salt, sugar, lecithin, pepper, celery seed, garlic powder, bayleaves, allspice, and nutmeg. The emulsion shall be heated to the boil temperature with continuous and vigorous agitation to attain maximum emulsification of the rendered fat. The final mixture is formed by uniformly mixing the slurry and the emulsion. The prepared gravy shall be held in the temperature range of 150°F to 180°F at all times prior to filling and shall be used within 4 hours after cooking.

Before starting this process an equipment check should be done for the following apparatus:

- kettle
- agitator
- stirrer
- steam pipe
- steam gauge
- pressure regulator
- drain spout.

5.1 Gravy Formulation

A gravy formula obtained through experiments designed for different settings of precooking process needs to be devised to ensure that the amount of gravy filled into the trays will meet viscosity and salt content specifications with a given precooking process and precook yield range.

The experimental design for determining the gravy formula required a range of products with different "precooking" yields of beef. Eight levels of precooking yields were selected from 62% to 86%. Example of calculations needed to determine the anticipated beef juice loss for the case of 86% yield is outlined in this paragraph. Calculations were performed to estimate the beef fill weight based on an assumed 52.5% processing meat yield and required meat drained weight of 1565 g (calc. 1 and 2, also see Section of BEEF The sauce fill weight was calculated by taking the difference PREWEIGHING). between the required net weight of 3015 g (see Section of BEEF PREWEIGHING) for each can and the meat fill weight (calc. 3). The anticipated beef juice loss during the retort process was calculated as a difference between beef fill weight and required drained weight (calc. 4). The results of the calculations for each designed level of precooking yield (samples A - H) are The sauce formula used for these experiments is listed shown in Table 5.1. in Table 5.2. It was based on the required flavor ingredients concentration for sample "E" and remained the same for all samples (A-H).

Example of the calculation for sample code "A" (precooking yield: 86%)

retort yield = 0.525/0.86 = 0.61	(1)
<pre>beef fill weight: 1565/0.61 = 2564 g/tray</pre>	(2)
<pre>sauce fill weight: 3015-2564 = 451 g/tray</pre>	(3)
beef juice loss : 2564-1565 = 999 g/tray	(4)

Table	5.1	Calculated	fill	weights	per	trav	pack	can
	.				DCT.			Cuii

Sample	Assumed Beef Precooking Yield [%]	Fill Weight [g]	Sauce Fill Weight [g]	Estimated Beef Juice Loss [g]
A	86	2564	451	999
В	82	2444	571	879
с	78	2325	690	760
D	74	2206	809	641
Е	71.75	2139	876	574
F	70	2087	928	522
G	66	1967	1048	402
H	62	1848	1167	283

Table 5.2 Sauce Formula required for sample E. Concentration (%)

Broth and water	62.67	
Mushrooms	10.93	
Starch	4.21	
Vegetable oil	6.43	
Tomato paste	5.14	
Soup Stock	4.50	
Onion Powder	3.22	
Salt	1.61	
Sugar	0.64	
Lecithin	0.32	
Pepper	0.15	
Celery seed	0.06	
Garlic Powder	0.04	
Bayleaves	0.03	
Allspice	0.03	
Nutmeg	0.01	
-		
	100	

The finished product was evaluated according to the Military Inspection Procedures for "Beef Chunks with Gravy" (MIL-B-44230A). In particular, the viscosity was measured by Brookfield Viscometer (spindle #3, 10 rpm, 500 ml, @ 27°C). The moisture content of gravy and its ingredients were measured in a forced convection oven (sample size 2-3 gram, drying time 23 hrs @ 102°C).

The gravy fraction of the samples was analyzed for moisture content and viscosity. The water to starch ratio was calculated based on the analytical measurement of moisture content. The results of this analysis are given in Table 5.3.

Table 5.		cosity and W ction of the s		rch Ratio of retorting).	gravy
Sample Code	Gravy Weight ¹ [g/tray]	Moisture of Gravy ² [%]	Starch Quantity [g/tray]	Water/Starch Ratio ³ [-]	Gravy Visc. [CP]
A	1450	93.90	18.9	72.0	343
В	1450	92.07	23.9	55.9	710
С	1450	90.13	28.9	45.2	1322
D	1450	89.20	33.9	38.2	2312
E	1450	88.58	36.7	35.0	3003
F	1450	88.02	38.9	32.8	3763
G	1450	86.25	44.0	28.4	5827
Н	1450	83.90	48.9	24.9	9113

¹Gravy weight is equal to sauce fill weight and added water

²Results represent an average of three analytical measurements

³Water/Starch ratio: Gravy weight * Moisture of Gravy / Starch quantity

The experimental data presented in Table 5.3 (Water to Starch ratio vs Gravy Viscosity) were subjected to statistical analysis in order to identify the "best-fit" curve. Six functions were tested (linear, polynomial-second order, exponential, power, hyperbolic and logarithmic).

The highest correlation coefficient as well as the F-value of the Fisher test were found for the power function. The calculated parameters of this function are:

 $y = 1.875 \times 10^8 \times x^{-3.1}$

or

 $x = 466.2 * y^{-0.3225}$

Where

y: finished product viscosity [cp]

x : ratio water/starch

The graphical representation of the function is illustrated in Figure 5.1. Based on this function the gravy viscosity can be predicted as a function of the water/starch ratio in the finished product.

VISCOSITY [cP] Thousands х WATER/STARCH RATIO [-] X - EXPERIMENTAL DATA

FIGURE 5.1. FINISHED PRODUCT VISCOSITY AS INFLUENCED BY WATER/STARCH RAT

Table 5.4 shows data of the moisture content of the various ingredients in the sauce formula. The moisture of mushrooms was determined by analytical methods, the moisture of the other ingredients is based on the manufacturers specification sheets.

Table 5.4 Raw Material Moisture Data (%)

Mushrooms	94.07
Tomato Past	74.00
Vegetable Oil	0.02
Starch1	0.50
Meat Stock	5.00
Onion Powder	4.50
Salt	0.01
Sugar	0.03
Lecithin	1.00
Pepper	12.00
Celery Seed	10.00
Garlic Powder	6.75
Bay Leaves	7.00
All Spice	8.00
Nutmeg	8.00

Table 5.5 shows the recommended fill levels and required finished product specifications of Beef Chunks with Gravy (MIL-B-44230B).

Table 5.5 Military Suggested Product Preparation

Recommended fill ratios:	(%)
Precooked Beef	62.5
Sauce	37.5

Table 5.6 lists the Military Specification for the sauce components in Beef Chunks with Gravy. To obtain a certain flavor in the finished product, each can should contain a constant quantity of flavor ingredients. The sauce formula consists of broth and water, starch and 14 flavor ingredients. Those 14 ingredients should be kept constant on a weight per tray basis, because they directly impact the flavor of the gravy. Based on Military Specification (concentration of ingredients in sauce formula and sauce fill weight per can), the required quantity of each ingredient per can was calculated. The results of the calculation are shown in Table 5.6. According to these data each tray pack can should receive 290 grams of "flavor" ingredients, the remaining components are broth and water and starch. The ratio of these two last ingredients, together with the juices derived from the beef, influence significantly the viscosity of the gravy in the finished product.

	Table 5.6	Military	Suggested	Sauce	Formula	
· · · · · · · · · · · · · · · · · · ·	Broth and Mushrooms Starch Vegetable Tomato pas Soup Stock Onion Powe Salt Sugar Lecithin Pepper Celery see Garlic Pow Bay leaves Allspice	water oil ste der	Conc. (%) 69.00 8.50 5.25 5.00 4.00 3.50 2.50 1.25 0.50 0.25 0.12 0.05 0.03 0.02 0.02		g/Tray 777.57 95.79 59.16 56.35 45.08 39.44 28.17 14.09 5.63 2.82 1.35 0.56 0.34 0.23 0.23	
	Nutmeg		0.01 == == ===		0.11	:
	2			1	======== L127.00	:

Microbiological Control 5.2

The microbial loads of gravy ingredients must be controlled in order to contain the number of microorganisms in the finished gravy, and therefore, in the tray cans.

The heat applied during gravy preparation reduces the number of microorganisms significantly on the ingredients. One of the parameters which plays an important role in the efficiency of thermal process is the initial number of microorganisms in the product before processing. A lower number of microorganisms in the gravy will result in a lower number of microorganisms in the product before processing, and therefore, a lower initial number and a higher thermal destruction efficiency.

The allowable limits of the total microbial count per gram of certain gravy ingredients are shown in Table 5.7. The count in such ingredients should not exceed these limits. Any lot with a total count beyond the limit should not be used for production.

For analysis of the total microbial count on gravy ingredients, refer to the procedure described in the section 3.2.

Table 5.7	The	Allowable	Limits	of	the	Total	Microbial
	Coun	t on Gravy	Ingredi	ents	•		

<u>Ingredients</u>	<u>Total Count CFU/g</u>
Frozen mushrooms	5.0 X 10 ⁵
Onion powder	1.0 X 10 ⁶
Garlic powder	1.0 X 10 ⁶
Black pepper	1.0 X 10 ⁶
Ground allspice	1.0 X 10 ⁶
Ground bay leaves	1.0 X 10 ⁶
Ground celery seeds	1.0 X 10 ⁶
Ground nutmeg	1.0 X 10 ⁶
Modified starch	1.0 X 104

6. BEEF PREWEIGHING

Before filling the precooked beef into the trays a certain amount of beef needed for each tray should be preweighed (operation 5, as indicated in Figure 1.1.) A mathematical model has been developed to determine the target fill weight of the gravy and precooked beef for given a precooked beef yield and process variability. The target fill weights of gravy and precooked beef are determined by the target net weight, target drained weight, anticipated overall beef yield, and precooking yield of beef. The relationship can be expressed as follows:

$$BFW=BDW^*\times \frac{Y_p^*}{Y_t^*}$$

where

BFW	:	beef fill weight
BDW*	:	the target drained weight of beef
Y_p^*	:	the target precooking yield of beef
Y_t^*	:	the anticipated overall beef yield

and

 $GFW = NW^* - BFW$

where

GFW : gravy fill weight
NW* : target net weight

We now explain how the target net and drained weights are determined:

Net Weight

MIL-B-44230B requirements: Average net weight \geq 3005 grams (106 oz), individual net weights \geq 2948 grams (104 oz).

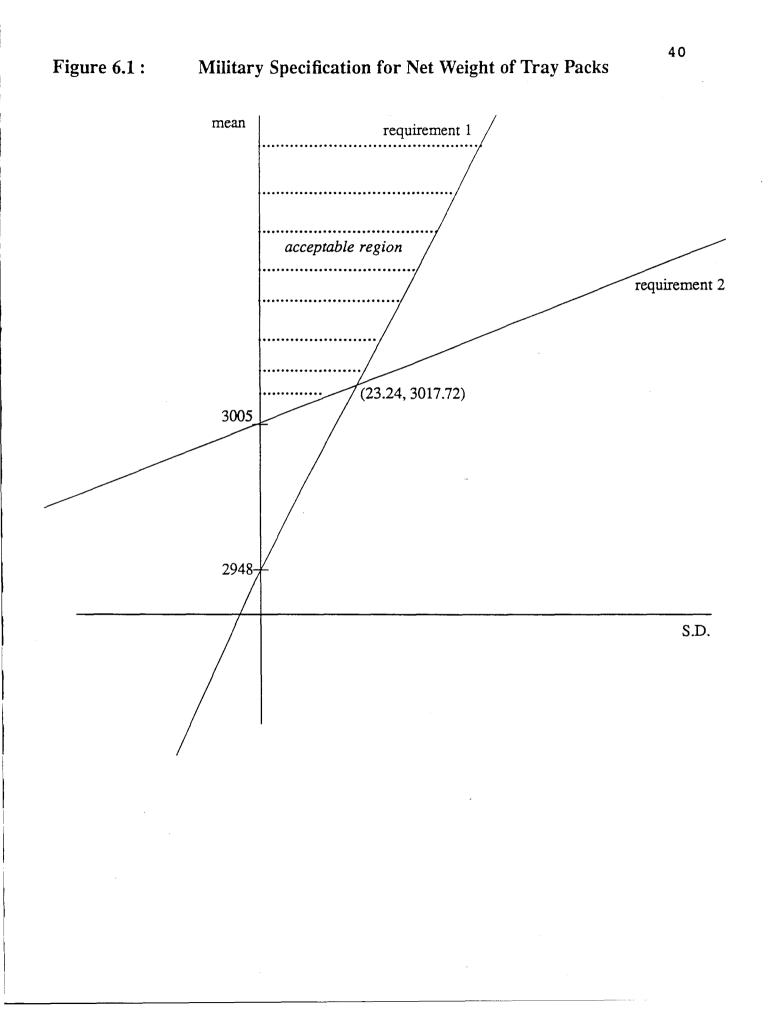
Statistically, we have obtained the target value, in terms of the military specifications, for the net weight, given the standard deviation (σ). From the military specifications, the following are the two requirements for the net weight in order to have the probability of the products meet the military specifications equal to 0.9975. We are assuming that the process is normally distributed.

1.
$$\mu \ge 2948+3\sigma$$

2. $\mu \ge 3005+3\frac{\sigma}{\sqrt{30}}$

where μ is the mean of the net weight and 30 is the sample size used to obtain the average net weight. Figure 6.1 is a graph of the two requirements. According to Figure 6.1:

1. For
$$\sigma \ge 23.24$$
, $\mu \ge 2948+3\sigma$
2. For $\sigma < 23.24$, $\mu \ge 3005+3\frac{\sigma}{\sqrt{30}}$



In other words, if the standard deviation of the filling process (beef and gravy) is less than 23.24, the mean value of the filling weight should be greater than

$$3005+3\frac{\sigma}{\sqrt{30}}$$

If the standard deviation of the filling process (beef and gravy) is greater than 23.24, the mean value of the filling weight should be greater than

$2948 + 3\sigma$

For instance, the experimental results of the net weight show that the standard deviation (σ) is 18.6, therefore, the target value of the net weight (μ) should be at least 3015.

Drained Weight

MIL-B-44230B requirements: average drained weight \geq 1529.82 grams (54 oz), individual drained weight \geq 1416.5 grams (50 oz). Similar to the net weight, the following are the military requirements for the drained weight of the tray packs in terms of statistical analysis:

where μ is the mean of the drained weight and 8 is the sample size

1. $\mu \ge 1416.5+3\sigma$ 2. $\mu \ge 1529.8+3\frac{\sigma}{\sqrt{8}}$

used to obtain the average net weight. Figure 6.2 is a graph of the two requirements. According to Figure 6.2

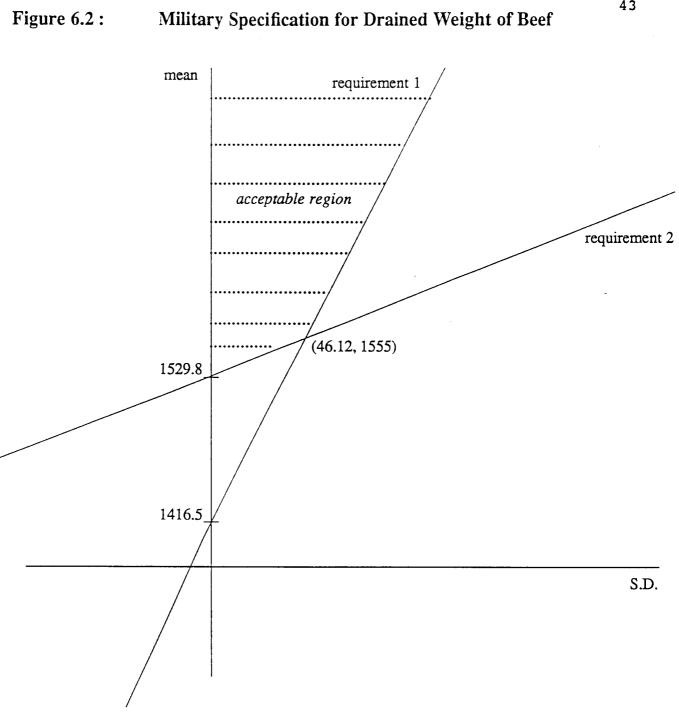
1. For
$$\sigma \ge 58.42$$
, $\mu \ge 1416.5+3\sigma$
2. For $\sigma < 58.42$, $\mu \ge 1529.8+3\frac{\sigma}{\sqrt{8}}$

In other words, if the standard deviation of the drained weight obtained is less than 58.42, the mean value of the drained weight should be greater than

$$1529.8+3\frac{\sigma}{\sqrt{8}}$$

If the standard deviation of the drained weight obtained is greater than 58.42, the mean value of the drained weight should be greater than

The target net and drained weights are essentially determined by the overall production line variation and military requirements and are two critical production target values. Given these two values, other production settings such as tolerance of precooking yield and gravy formula can then be determined (see Sections of PRECOOKING and GRAVY PREPARATION).



7. FILLING PROCESSES

The precooked beef cubes are preweighed and stored in separate containers until needed for the filling operations (operation 6, Figure 1.1.) The beef cubes are placed manually into the tray. Prior to starting this process the conveyor belt must be checked and calibrated if necessary.

Gravy is deposited in the tray with a volumetric piston filler (Raque filler, operation 7, Figure 1.1.) The trays are then weighed before transporting them for packaging and retorting. A checkweighing system will be used to examine the net weight of each filled tray. A minimum net weight requirement from military specifications (104 oz.) is the lower limit of this checkweigher control while a maximum net weight requirement to insure a proper retort process is the upper control limits. If the net weight of a tray falls outside of these limits, then this tray will be automatically diverted from the production line.

The microbiological quality and the total microbial count of combined beef chunks and gravy is a direct result of several factors; the initial count on gravy ingredients, the count on gravy after preparation, the count on precooked beef, and the time and temperature both the prepared gravy and precooked beef are held before filling and processing.

The number of microorganisms in combined beef chunk and gravy has an effect on the thermal process. A higher number of microorganisms requires a longer time to achieve the specified lethality at certain temperature in order to ensure commercial sterility of the product. Therefore, it is important to analyze and to set a microbial limit of the combined beef and gravy in order to standardize the thermal process.

The total microbial count on combined beef chunks and gravy should not exceed

$1.0 \times 10^{5} cfu/g.$

If the total microbial count of combined beef chunk and gravy exceeds these limits, the thermal process should be adjusted so as to avoid any spoilage due to underprocessing of the product.

For analysis of the total microbial count refer to the procedure described in the section of **PRECOOKING**.

8. TRAYS VACUUMING & SEAMING

After the weight checking, acceptable trays are transported along the seamer conveyor. Before the seaming process, a photoelectric sensor alerts the operators that the tray ingredients are above the lid line to prevent placement of the lid for seaming. Lids are denested before they are seamed on the tray. The seaming operation shall be done under a vacuum established by a processing authority so as to ensure proper vacuum.

The sealed tray packs are transported to a buffer area and wait for the retorting process. Each filled and sealed tray pack shall be in the retort process within 2 hours after seaming.

9. RETORT PROCESS

The filled and sealed tray packs shall be thermostabilized by retorting until a sterilization value (F_0) of not less than 6 has been achieved. The temperature, time, come-up time and RPM of agitation of retort are the controllable retort factors in this process. Other factors which can affect the heat transfer rate during retoring can be identified as additional critical factors; examples of these factors are: initial product temperature, product viscosity, beef cube size, headspace, and beef fill weight. A scheduled process would identify which of these parameters are critical and has to be properly monitored. The following are two uses of retort in the production environment and for R&D purposes.

First, products can be made on a production basis with a scheduled process following USDA Canning Regulation Part 318. The retort operator is responsible to assure that the scheduled process is followed and that critical process parameters are within the ranges identified in the scheduled process. Two retorted containers of each batch should be placed in an incubator for ten days. Container swelling in the incubator might indicate under processed product and will lead to an immediate hold on the product and an evaluation by a recognized process authority of all process data. Observed deviations of the process or product variables beyond the ranges identified in the scheduled process have to be brought immediately to the attention of his/her supervisor, regardless of the incubation test results. Product produced under a process deviation should be put on hold the deviation has to be reviewed by a recognized process authority according to USDA regulation 318.308 before the product can be released, reworked or destroyed. The product is being considered commercial sterile when the scheduled process has been applied and all critical parameters were held within the identified ranges, and no container swells were noticed during incubation.

Second, the retort can be used for R&D experiments to evaluate different process conditions and/or product variables. The retort operator is responsible for maintaining accurate records regarding the retort conditions and identified critical product parameters. We recommend that each retort batch contains at least three containers with thermocouple to perform a heat penetration study. The Ellab data logging system is capable of performing online lethality calculations and this data should be used to estimate the appropriate retort sterilization time. However, it should be realized that heat penetration studies on limited product samples can not guarantee that all product is sterile. Therefore, we suggest that each R&D staff signs a release form, indicating that they understand that the product might not be commercially sterile and that therefore the product can't be used for any type of consumer test. Because the product is not commercial sterile, all R&D products are to be stored under refrigerated conditions at

all times.

To ensure that the product in R&D experiments are exposed to a reasonably heat process, the following guidelines are developed for the retort operation. <u>However, these guidelines will</u> <u>not necessarily lead to commercially sterile products.</u>

1) Only one product variable can be retorted at a time

2) Each retort load/product variable should have at least three containers with thermocouple.

3) Each of these containers should have at least one thermocouple in the cold spot of the container. Initial studies on the half steam table tray with "beef chunks with gravy" indicate that the cold spot is located in the geometric center of the can. However formulation and process changes might influence the exact location of the cold spot and it therefore is recommended to locate a second thermocouple in the corner of the half steam table tray (2" from the sides).

4) In "beef chunks with gravy", the tip of the thermocouple should be imbedded in the center of a beef cube. The cube should be secured to the thermocouple with the aid of a rubber disk and cheese cloth. The beef cube used for this test should represent the biggest beef cube in the lot of beef used for the experiment.

5) The weight of the container should be measured before and after the retort process. Significant weight loss or gain indicates a non hermetically sealed container and heat penetration data from this container might be erroneous and should be discarded.

6) The cans with thermocouple should be opened after retorting to assure that the beef cube stayed on the thermocouple. Data from thermocouple which lost its beef during the retort operation should be discarded.

7) Written records should be obtained or generated regarding the critical process parameters. The preliminary list of critical parameters for "beef chunks with gravy" are:

Fill weight beef
Fill weight sauce
Largest beef cube size
Sauce viscosity
Precook yield
Type of precook
Lowest product temperature (IT)
Head space can
Vacuum level during seaming
Utility conditions (steam and water pressure)

Retort conditions (program times, temperatures, pressure)

In addition to the above data, the following records should be collected:

Taylor chart recording (temperature and pressure) Strip chart recording (rpm) Retort process alarm print out Heat penetration data (hard copy and computer file)

8) To ensure that the product is exposed to a reasonable heat process, We recommend that the product be heated until an F_0 > 8 has been measured on the slowest thermocouple of the three containers. Cooling can start after this lethality has been reached. Note: this guideline might lead to variable cook times for identical formulated products.

9) All retorted products should be marked with the retort run number and should be placed in the refrigerator immediately after processing and should be stored at all times at this temperature until the analysis is complete.

10) Products no longer needed should be removed from the refrigerator. The containers should be opened and product should be removed before discarding.

11) All process data and heat penetration data should be submitted for evaluation immediately after completion of the retort run.

12) R&D products are intended for research studies only and at no time should product be used for consumer testing. A release form has to be signed by the other personnel that he/she understands that the product might not be sterile, before R&D staff can release the product to the personnel.

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COMBAT RATION ADVANCED MANUFACTURING TECHNOLOGY DEMONSTRATION (CRAMTD)

Process Control for the Production of Beef Chunks and Gravy in Tray Packs Technical Working Paper (TWP) 48

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OBJECTIVE

This manual presents on-line quality control procedures for the production of beef chunks with gravy in tray packs. All production processes and process parameters will be controlled, which will assure that the final product conforms to MIL-B-423OC requirements. We determine the control strategies for each process involved and list the control limits (when determined) for each process parameter.

INTRODUCTION

Process control is defined as a set of activities to be performed to ensure that the parameters of the process are maintained at the predetermined values which result in the production of non-defective products. A robust process is one in which the uncontrollable noise factors in a process, such as environment (humidity, temperature....) do not significantly affect the final product. This can be achieved by monitoring and controlling the controllable factors.

Final product quality will remain consistent if the process parameters that significantly affect the output are kept at their predetermined values. Since it is very difficult to maintain process parameters at their values, they should be monitored and controlled so that they are kept within a tolerance range that will produce a product of acceptable quality. Deviations of the parameters from their targets or set values will be adjusted via feedback (or feed forward) control systems. The processes to be controlled are those needed to produce beef chunks and gravy in tray packs. The specifications of the final product are shown in Table 1.

1

Variable Characteristic	Specifications
Net weight of individual can	≥ 104 grams
Average net weight	≥ 106 grams
Drain weight of individual can	≥ 50 grams
Average Drain weight	≥ 54 grams
Viscosity of gravy	[1300.3550] centipoise
Individual fat content	≤ 9.0%
Average fat content	≤ 7.0%
Surface fat on beef chunks	\leq 1/8 inch in thickness
Individual salt content	[0.5.1.3] %
Can condition	USS for food container
Labeling	MIL-L-1497
Can closure	21 CFR. Part 113, Subpart D 9 CFR. Part 318, Subpart G
Total wt. of cartilage, tendons	≤ 2 ounces
Presence of bone piece	≤ 0.3 inch
Dimensions of beef chunks	≥ 50% in [0.5,1.5] inch

Table 1: Final Product Specifications

If process control is not tightly monitored, the final products will tend to have more defects, thereby increasing the economic losses due to rejected products. Ensuring that process parameters are within the predetermined values will reduce the total variability in the product characteristics. Variations in the product characteristics due to noise will still be present in the final product, but its effect will be minimized by using process control. For example by controlling the process parameters in the Enersyst oven (used for precooking), such as the temperature, the belt speed and the air velocity, the variation of the precooked beef yield will be minimized and accordingly the variation of the final drain weight will be reduced.

A list of sensors that will monitor the process parameters will be provided in a separate report.

ON-LINE PROCESSES

The production process of manufacturing the beef chunks with gravy tray pack line consists of the following processes: Beef precooking, precooked beef storage, gravy preparation, trays washing and placing, beef filling, gravy filling, trays vacuuming and sealing, and retorting. A diagram of the processes and their respective inspection stations is shown in Appendix I. In this figure the rectangles depict the production processes while the ellipses depict the inspection stations. The specifications of the final product are shown in Table 1. The following is an overview of each production process:

- <u>Beef precooking</u> The beef chunks are precooked in the Enersyst Oven to obtain a predetermined yield.
- Precooked beef storage The beef chunks can either be filled immediately after precooking or they can be stored in a refrigerator. If they are stored, their temperature must remain between 28-40°F. The time lag between precooking the beef chunks and the filling of the beef chunks should not exceed 48 hours.
- <u>Gravy preparation</u> The military specifications require that the gravy temperature should be kept between 150-180°F. The time lag between the making of the gravy and the depositing of the gravy in the trays should not exceed 4 hours.
- 4. <u>Trays washing & Placing</u> Each tray should be washed and dried before it is placed on the tray pack conveyor belt.
- 5. <u>Beef filling</u> A volumetric beef filler will be used to deposit the predetermined amount of beef into the tray pack. The target value can be determined by using a mathematical model which calculates the target value using the following parameters: the meat precooked yield, the total desired yield after retorting and the standard deviation of the filling process.
- 6. <u>Gravy filling</u> A volumetric filler will be used to deposit the gravy into the trays. The target value of the gravy volume is calculated by the same mathematical model used to calculate the target value of the beef weight.

3

- 7. Trays vacuuming and sealing Lids are placed on the trays and then the trays are vacuum sealed.
- <u>Retorting</u> The tray packs are thermostabilized in the retort until the sterilization value of F_o=6 has been reached.

In order to meet the specifications of the final product, the parameters of the processes must be maintained within predetermined specifications limits. These limits have been determined by conducting experiments for which the effect of process parameters on the product quality has been investigated. We now present each process, its parameters, and methods for controlling them.

PRECOOKING

Precooking is done by placing the beef chunks on a conveyor belt in an oven manufactured by the Enersyst Development Center. (Requirements of the beef are shown in Appendix IV). The oven is currently being used in the pilot plant and consists of four chambers, which can be expanded as production requires. Chamber 1 is a steam zone that is used to precondition the beef. Chambers 2 and 3 are identically equipped with electric heaters. steam, and an air blower. Chamber 4 is a passive equilibration zone which is not utilized in this particular line. The beef is moved through each chamber by a conveyor to complete the precooking process. The controllable factors during this process are as follows:

- All Chambers conveyor speed
- Chamber 1 steam (on/off)
- Chambers 2 & 3 temperature
 - steam (on/off)
 - rate of air flow
 - pattern of air flow
 - jet height above conveyor belt
- Chamber 4 steam (on/off)

The controllable process parameters in the Enersyst Oven are presently controlled by a Programmable Logic Controller (PLC). Research is currently being done on a redundant central control system (software and hardware) that will monitor the process parameters. The system will have an external sensors with built-in alarm points for parameter deviations. If a parameter deviates, steps will be taken to remedy the situation for each process parameter. Control charts, see Appendix I, will also be kept by the operators for these parameters. It is recommended to do a preliminary run to obtain data for the standard deviations of the process parameters so that the control limits can be calculated (target value $\pm 3\sigma$), and to obtain the process capability index.

In addition to the above control methods, parameter deviations can be reduced by performing daily, weekly and monthly maintenance, which is outlined in the Enersyst Oven Manual in Appendix II. The process parameters of the Enersyst oven are the following:

1. Residence Time

The residence time is defined as the amount of time the beef is precooked in the Enersyst Oven. The amount of time, which can vary from 5-10 minutes, will depend on the desired precooked yield. A plot of the relationship between the precooked beef yield, temperature and time is shown in Appendix III. The diagonal lines reference the yield and the horizontal lines reference the time.

The residence time is dependent on the belt speed. If the residence time deviates from its control limits, the following corrective actions must be taken:

- A. Check the original settings of the belt speed.
- B. Check the belt for an object causing a belt jam.
- C. Check the encoder wheel and optical pickup. There should be approximately 0.006 inches between the end of the pickup and the encoder wheel (about the thickness of a piece of paper).
- D. Check if the conveyor belt tension is too tight. There are springs on one set of rollers to compensate for the differential thermal expansion between the frame and the belt.
- E. Have an electrician run voltage checks.

2. <u>Temperature</u>

The optimal temperature in zones 2 & 3 of the Enersyst oven is 400° F. In order to maintain this temperature, the temperature should be set at 410° F. Upper and lower specification limits on the oven temperature are $\pm 10^{\circ}$ F.

A built-in feedback control system to control the temperature is in place in the Enersyst oven. When the temperature reaches 5°F above the target temperature, the electrical heat source is turned off, and when the temperature falls 5°F below the target temperature, it is turned back on.

Currently the oven operates on electrical heat, but it is also capable of running on gas heat or a combination of the two. The advantages of using gas heat are the following:

- Gas can preheat the oven very quickly while it takes electrical heat about 40 60 minutes to initially heat the oven to 400°F.
- B. Gas is more economical than electricity.
- C. When both gas and electricity are used
 - One can be used as a backup heat
 - Temperature can be more easily fine tuned to its setting.

If the Temperature falls outside the control limits, the following steps must be taken:

- A. Turn off the oven.
- B. Call an electrician, who should use electronic diagnostics to trouble shoot the probable causes which are either defective wiring/coils, or a defective staging relay.

3. Air Velocity

The recommended air velocity is 6000 ft/min. Upper and lower specification limits are not determined. but it is preferable to have the air velocity higher than 6000 ft/min. If the air velocity deviates from the lower control limit, the following corrective actions must be taken:

- A. The bearings should be checked for lubrication. They should be lubricated every 8-10 hours. (This is part of normal preventive maintenance and should be done between each shift).
- B. The electrical wiring should be checked by an electrician.

4. Humidity

Humidity exists in the first chamber when steam is applied. The humidity generated from steam application affects the heat transfer, and ideally, it should be kept constant. Currently, there no sensor available to measure humidity at temperatures above 300°F, but research is being done to develop a humidity sensor that will operate at higher temperatures. Humidity is affected by the pressure and temperature of the steam, and its parameters such as the speed and the amount of the steam. No research has been conducted to study the effect of humidity on the precook yield.

5. Air proportion and jet height

These are manually set at fixed points, so they do not need to be monitored.

Table 2 lists miscellaneous problems with the Enersyst Oven and their remedies:

Problems	Probable Causes	Remedies					
Nuisance shutdowns	-Safety air switch not set properly -Insufficient blower speed	-Reset switches so they are stable when actuated. "borderline settings will make the system sensitive -Increase speed					
Noisy recirculating fan drives	-Loose belt -Dry or worn out bearing	-Adjust(without overtightening) -Check, lube or replace					
Recirculating motor trips off on overload	-Defective motor -Motor bearings need lubrication or replacement -Blower shaft bearing dry/worn out	-Check or replace -Replace -Replace					

Table 2

GRAVY PREPARATION

The steps to prepare the gravy are the following:

- 1. Weight the proper amounts of the gravy ingredients as specified. The ingredients are water, mushrooms, starch, vegetable oil, tomato paste, soup stock, onion powder, salt, sugar, lecithin, black pepper, celery seed, garlic powder, bay leaves, allspice, nutmeg and prebiended spice and seasoning mixture. Requirements of the ingredients can be found in Appendix IV.
- 2. Grind the mushrooms into a pasty consistency.
- 3. Preweigh the starch, vegetable oil and water.
- 4. Prepare the slurry from starch, vegetable oil and water.
- 5. Preweigh all of the remaining ingredients.
- 6. Mix and heat all of the ingredients (except the slurry) together in a blender kettle.
- 7. When the mixture boils, add the slurry. Then shut down the steam into the kettle and control the temperature between 150°F and 180°F.
- 8. Mark the volume of the gravy in the kettle (this mark will be used to check for evaporation). Examples of how to mark the volume are the following: 1) mark inside the kettle the level of the gravy, 2) put a stick in the kettle and mark how deep it submerges into the gravy or 3) use a sensor.
- 9. Mix the gravy until the ingredients are mixed uniformly.
- 10. If the volume of the gravy decreases below the premarked mark (due to evaporation), add water to compensate for evaporation to the mark.

Research is currently being done for a computer system (hardware and software) to control the process parameters. If either the temperature, density, or the pH level of the gravy deviate from their tolerance ranges, the hardware/software system will sound a signal and the process will be inspected for assignable causes. The following is a description of these process parameters:

1. Temperature

The temperature of the gravy, according to the military specifications, must be between 150°F-180°F during filling. Currently, the heat source of the kettle is controlled by steam. A thermostat will be used to regulate the temperature. If the temperature is too low, the thermostat will signal for the steam to be turned on; if the temperature is too high, the steam will be signaled to be turned off. If the

temperature deviates from its tolerance range, then either the sensor or the kettle must be checked by an electrician.

2. Density

Density is an important parameter since it affects the amount of gravy pumped by the Raque Filler into the tray pack. Since the Raque Filler is a volumetric filler, the amount of gravy being filled will change as the density changes.

Density can be measured either by using a sensor, or a line worker (technician or quality control inspector) can measure it off line by measuring the mass and volume (density = mass/volume).

The density of the gravy is dependant on precise preweighing of the ingredients. If all the ingredients are measured correctly, then there is only one cause for the density to deviate from its tolerance range. If the density is too high, it could be due to water evaporation. If the kettle has not had any gravy pumped from it to the Raque Filler, then water should be added to bring the volume to the predetermined volume. If gravy has been pumped to the filler, water should be added to the gravy until the desired density is obtained.

The target value and the specification limits of the density have not been established.

3. <u>pH</u>

pH, which may affect sensory results. is not considered to be a critical parameter. pH has been proven to affect the final yield of beef in past experiments for products other than beef chunks with gravy. This has not been proven for the beef chunks with gravy line yet.

If all the ingredients are measured precisely, then pH should remain within its tolerance range. If the pH is found to be out the range, then the cause would be that the tomato paste (or other ingredients) were preweighed incorrectly and the batch should be rejected.

The target value and specification limits of the pH have not been determined yet.

The pH level should be greater than 4.6. An upper specification limit has not been established.

4. Flow Rate

The flow rate from the kettle to the filler will be monitored using a flowmeter. This parameter will be monitored since it will affect the volume of gravy that is deposited into each tray.

FILLING PROCESS

The subprocess are tray washing and placing, gravy filling, beef filling and check weighing/diverting. See Appendix V for a flow diagram of the filling process. Presently, a Raque volumetric filler is being used to pump the gravy, which may be replaced by an Oden pump filler. The beef filling process, which is currently done manually, will be performed by a Solbern volumetric filler. The following describes each individual process:

TRAY WASHING AND PLACING

Presently, these processes are done manually, but may be automated in the future. The denesting process is the process of removing the trays from their boxes and disposing of their protective paper. Then the trays must be washed, since during manufacturing they acquire an oil residue. The last process is a tray flip, which will be necessary if the process is to be automated.

GRAVY FILLING

The two fillers being considered are the Raque filler and the Oden filler.

A. Raque Filler

The Raque filler is a volumetric filler, which pumps a preset amount of gravy into each tray. Before production, the Raque filler must be calibrated to pump the predetermined volume of gravy.

The Raque gravy filler is equipped with a photo sensor which senses the beginning of the tray when it passes under the filler nozzle. Once the tray is detected, a preset amount of gravy is released into the tray. The amount of gravy and beef deposited is checked as the tray passes through the check weigher/ diverter. If the amount deposited is not within its control limits then the tray is diverted. The line will automatically stop when the diverter storage area becomes full. The Raque filler should then be inspected.

Sanitation and preventive maintenance procedures are outlined in the Raque Filler Manual in Appendix VI.

B. Oden Filler

The Oden filler consists of the following (see Appendix V for a diagram):

- Three accurate pumps, which have a flexible nozzle arrangement. The volume of gravy that will be pumped into each tray, and its speed will be individually and digitally preprogrammed into the control system. See Appendix V for a diagram of how the gravy is pumped.
- A 30 gallon hopper, which feeds gravy through its bottom, so that air is never introduced into the system.
- An ultrasonic level sensor, which senses the amount of gravy in the hopper. Since this is not a mechanical system, it will never break down.
- A tray sensor which will is either a photo sensor or a proximity sensor.

The Oden filler needs to be calibrated only once, and it will stay calibrated as long as the filler remains clean. Preventive maintenance needs to be done on the pumps only. The pumps, which can be detached from the shaft with special tools, are cleaned by submersing them in water. The covers of the filler can be removed for cleaning. The hopper and the hoses need to be detached and then washed out.

The Oden filler is equipped with a sensor which will alarm if the level of the gravy is too high or too low. If the amount of gravy in the filler is too low a sensor will ask for more gravy to be deposited into the filler. If the condition is not resolved within a set time, the line will be stopped. If there is too much gravy in the filler the sensor will stop the infeed of gravy. If the problem is not remedied, the line will be stopped.

BEEF FILLING

The beef filler is a Solbern volumetric filler which is designed to accurately fill the beef into the tray packs. The Solbern filler contains a big drum that rotates and mixes the beef. The beef is then individually dropped into cups, tilted to a specific angle, on a vibrating conveyor belt. The cups are tilted to determine the fill volume. The vibrating conveyor belt shakes the cups while they are being continually filled. This feature produces a uniform product bulk density inside the cups, therefore assuring that the beef fill weight is accurate (see Appendix V).

The beef filler also has the option of having a check weigher/diverter for the individual cups of beef. A description is given below.

After the cups are filled they proceed to and are loaded into the automatic cup dumper. This dumper is equipped with a sensor which will not allow a cup to dump the beef if there is not a tray under the cup. The cups are first turned upside-down with a plate over the opening. Second, a piston pushes the cup off the plate so that the beef falls into the tray. Third, the cup is turned right-side-up.

The main problem that can arise with the beef filler is over/under weight filling into the tray pack. The following is a list of corrective actions to remedy the problem:

- Check the volume of the transfer cup. The cup contains rings which adjust the depth of the cup.
- Check the tilt angle of the cup.
- Check the vibration amplitude and frequency.

The parameters in the above list are currently controlled by a mechanical system.

The Solbern Filler is equipped with a sensor that will alarm if the level of beef becomes too high or too low. If the amount of beef in the filler is too low a sensor will ask for more beef to be deposited into the filler. If the condition is not resolved within a set time, the line will be stopped. If there is too much beef in the filler the sensor will stop the infeed of beef. If the problem is not remedied, the line will be stopped.

CHECK WEIGHING/DIVERTING

The check weigher/diverter is located after the beef and gravy filling, and there is an option to have another one during the beef filling which would record the weight of individual cups.

The check weigher/diverter automatically records the weight of each tray. If a tray does not meet minimum weight specifications it will be rejected (diverted off of the line). The check weigher/diverter, which is located after the beef and gravy filling, also contains a mound detector. The mound detector rejects the tray if the beef and/or gravy is mounded such that the placement of the lid would prevent proper seaming.

The check weigher should be checked and calibrated at regular intervals to ensure that it is working properly. This could be done by taking trays off of the line at set time intervals, weighing them on an operational scale, and comparing results. If the check weigher fails to operate properly, the line should be stopped and first the settings entered into the control unit should be checked. Second, the following components should be inspected: (See Appendix VII for a more detailed explanation)

1. The weight module, which is the check weigher's "master computer".

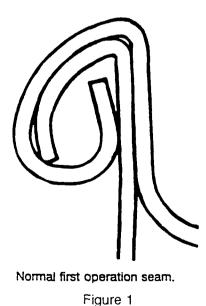
2. The zone module, which controls the diverting process.

The operation of the mounded detector can be monitored visually. If the mound detector fails to detect when the beef and/or gravy is too high for placement of the lid, the operator should notice this before the lid is placed on the tray. Once the operator observes mounding at the seamer, he/she should check if the cause is the mound detector. If it is, the line should be stopped, and the detector should be inspected/adjusted.

SEAMING PROCESS

The Yaguchi Seamer motor is controlled by the Programmable Logic Controller (PLC). This motor regulates the Yaguchi seamer, the seamer conveyor and the lid dispenser. The speed of the Yaguchi seamer is used as a reference speed for the Fenner Control System (FCS). The FCS controls and coordinates the conveyor speeds of the entire tray pack line. Once the seam speed is set the FCS automatically coordinates the speeds of the following: the filling conveyor, the vibrating conveyor, the check weigher and the diverter. If there is a problem with the coordination of these subsystems, then the control panel should be checked for an error display.

The seaming process itself consists of the following: first, lid placement on the tray pack and, second, seaming by the Yaguchi seamer. Once the tray pack is conveyed into the seamer, a chuck plate descents onto the lid and the tray pack is vacuum sealed. After this is completed, the seaming of the lid to the can begins, in which 6 rollers revolve around the can and individually rotate. Three of the rollers begin the first operation which preform the initial seam. The remaining 3 rollers perform the second operation which finishes the seaming process. Figures 1 and 2 show the first and second operations.



Normal second operation. Figure 2

The parameter of the seamer is the vacuum gauge, which is to be set at 10cmHg, will be monitored on a control chart (see Appendix I). If the vacuum deviates beyond acceptable limits, the vacuum should either be increased or decreased.

If tray pack seam dimensions deviate from their specifications, some or all of the following should be done to detect the cause of the problem.

- 1. Check that the rollers are rotating.
- 2. Open the seamer, run it manually and examine the process for any faulty operations.
- 3. Determine and mark the sections of the lid that will be seamed by each individual roller. Since the seaming process involves two operations, each section will have been seamed initially by a first operation roller and lastly by the second operation roller.
- 4. A high speed camera can be used to analyze the operations of the seamer. Before the camera is implemented, each roller should be painted a different color so that they can be distinguished from each other.

Inspection procedures, which are outlined in the Yaguchi Seamer Manual, can be found in Appendix VIII.

The specifications for the seam are given by the tray manufacturer which currently is Central States Can

Co. The following are the seam specifications:

DESCRIPTION	SET-UP	OPERATIONAL
1 st Operation Seam Thickness	0.080 +/- 0.005	0.080 +/- 0.005
2 nd Operation Seam Thickness	0.056 +/- 0.003	0.056 +/- 0.005
Finished Seam Height	0.120 +/- 0.005	0.120 +/- 0.008
Bodyhook Length	0.075 +/- 0.005	0.075 +/- 0.010
Coverhook Length	0.062 Oper. Min.	Same
Overlap	0.035 Oper Min.	Same
Cover Tightness Rating	90%	70% Min.

For a details on tray seam inspection, see the Product Control Manual.

In the event of a can jam in the seamer, the following inspections must preformed:

- Visual tray pack inspection
- External measurements of the seam
- Seam teardown and internal measurements
- Seam sectioning and direct internal measurements

These procedures are explained further in Appendix IX.

Inspection and preventive maintenance should be done on a regular basis. The seamer should be lubricated every shift.

RETORTING

1. <u>Temperature</u>

The thermostabilization process is based on heat penetration studies at 250°F and the process schedule is based on this temperature. Alternate schedules will be filed for 249. 248. 247. 246 and 245 F. The scheduled process time is based on the Ball calculation with a 42% credit towards come up time, which is the time it takes the temperature to reach its target value. The target value during production will be set at 1 or 2°F higher that the schedule being run. depending on the temperature controller capability. If the temperature falls below 250°F, the trays must be retorted on an alternate appropriate schedule. If the temperature exceeds 250°F the time of retort remains the same. The reason for this is that lethality = 6 minutes must be reached at all times: the product should be retorted at 250°F for 6 minutes, or retorted for an equivalent time for temperatures less than 250°F. If the temperature exceeds 250°F, the retort time must be extended to kill the micro-organisms.

The retort currently being utilized is supplied by Stock, which comes equipped with the sensors that are required by the FDA and the military specifications to measure and record temperature. These are the following:

- Mercury in glass (MIG) thermometer Required by 21 CFR, part 113 (FDA) and 9 CFR, part 318 (USDA). This
 measures the retort water temperature, which must be checked at least once during the retort process.
- Chart recorder Required by 21 CFR. part 113 (FDA) and 9 CFR, part 318 (USDA). This records the retort temperature in a continuous mode. If the temperature falls below 250°F, the time of retorting must be extended according to a filed alternate schedule process.
- RTD sensor thermocouple a temperature feedback system. It opens/closes a steam valve to adjust the temperature when needed.

2. Pressure

The Stock Retort also is equipped with a Strain Gauge Transducer to monitor the pressure. It checks the pressure in the storage drum and adjusts the pressure by opening and closing the steam valve during the hold phase. The target value for the pressure is 2.0 bars, and the upper and lower specification limits are ± 1 psi. The pressure will be

increased or decreased up and down during the process to match the pressure inside the container as close as possible. Too high or too low of an override pressure can cause danger to the container and cause nonhermetically sealed containers.

3. Rotations per Minute (RPM)

The target value for the RPM is 10, which will vary within 1/2 RPM. This variation is acceptable. Rotation of the retort is a critical factor for the heat transfer and has to be measured at least once during the process. The Stock Retort provides an electronic sensor to monitor the pressure and a built-in chart recorder.

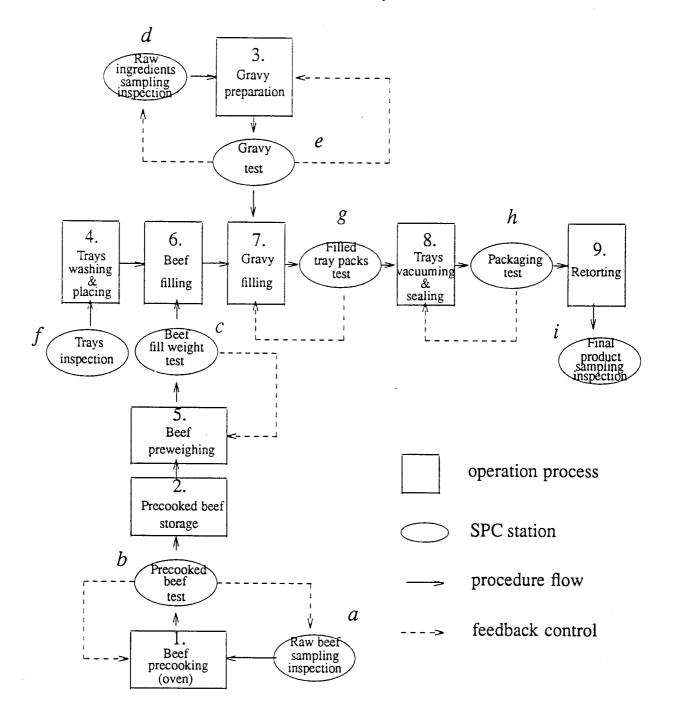
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APPENDIX I PRODUCTION PROCESSES INSPECTION STATIONS AND

CONTROL CHARTS

SPC Stations in Tray Pack Line

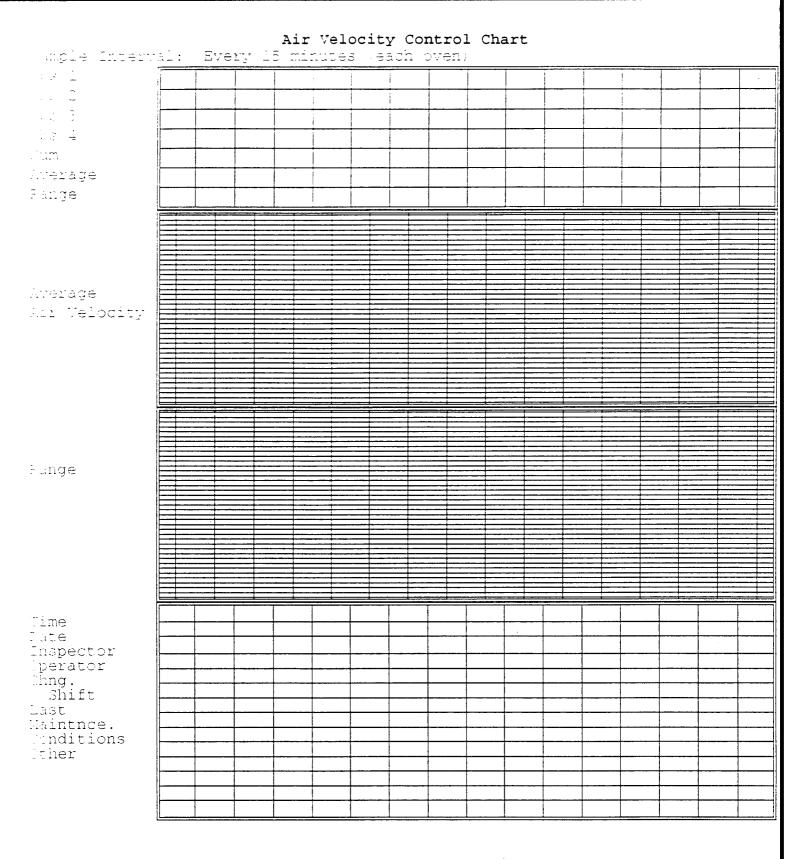


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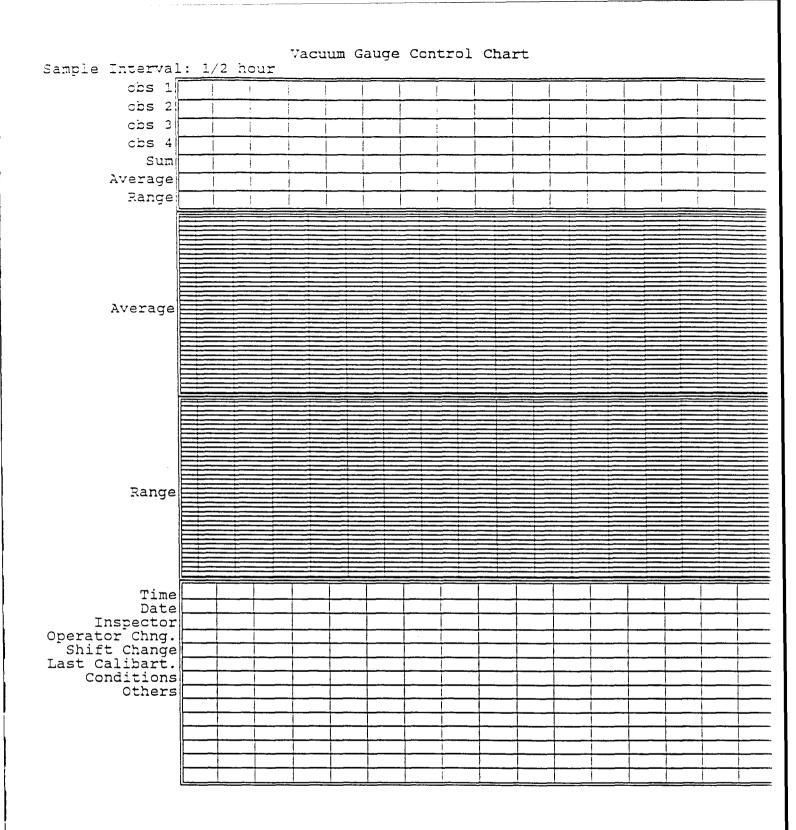
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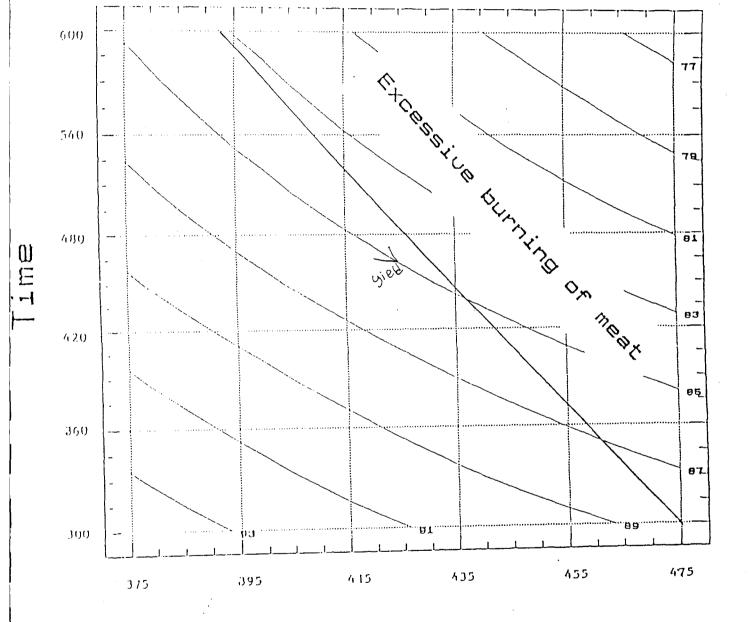
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APPENDIX III GRAPH OF PRECOOKED YIELD VS. TEMPERATURE

VS. TIME

Temperature



Yield us Temperature & Time

APPENDIX IX

INSPECTION PLAN FOR TRAYCANS

INSPECTION PLAN FOR TRAYCANS

Kit L. Yam, Ph.D. Panos N. Giannakakos, Ph.D.

Packaging Laboratory Food Science Department Cook College Rutgers University

1 INTRODUCTION

- 1.1 This plan is written for the expressed purpose of complying with MIL-I-45208A and assuring the quality of foodstuffs offered for sale to the Department of Defence.
- 1.2 The plan identifies guidelines and inspection criteria used to access the quality of the traycan from the can supplier through the finished product offered for sale.
- 1.3 Within the plan is a description of what indicators are monitored, when, and how often, with a specific Inspection Procedure (IP). Within each IP is detailed information on conducting the check, accept/reject criteria or guidelines and reference to specific Lab or Test Procedure (LP or TP respectively) which may reference in-turn to specific EQuipment (EQ) which equipment is calibrated according to specific Calibration Procedure (CP).

2 RESPONSIBILITIES

2.1 The plan provides for document control as well as auditing procedures to ensure the plan is implemented correctly.

3 VENDOR QUALIFICATION

- 3.1 Purchase requirements are conveyed to the vendors through the issuance of a Packaging Material Specification (PMS).
- 3.2 Vendors are then required to supply a MATERIAL INFORMATION AND CONTINUING GUARANTEE FORM. This form will act as a "certificate of conformance" guaranteeing that the materials provided will continue to be supplied as originally evaluated.

4 INCOMING MATERIAL

4.1 TRAYCAN BODY AND LID INSPECTION

4.1.1 Load inspection

- 4.1.1.1 Each load of Traycan bodies and lids are checked to insure proper documentation and for damage resulting from shipment following procedures outlined in IP-21.
- 4.1.1.2 This inspection does not require calibratable equipment.
- 4.1.1.3 In the event the documents are wrong, or damage is found, the MRE supervisor will be notified, and procedures will be followed as outlined in IP-21.

4.1.2 Thickness, coating and visual inspection

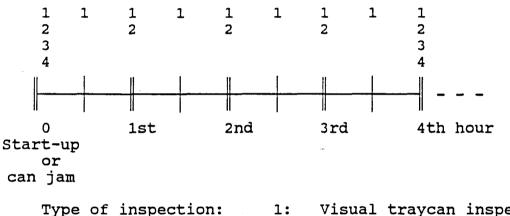
- 4.1.2.1 Each load of traycans is tested for thickness. In lieu of testing, determination of compliance to thickness requirements may be ascertained by examination of vendor records, invoices, or other valid documents.
- 4.1.2.2 If such documents do not exist then the traycan bodies and lids shall be tested following procedures outlined in IP-21.
- 4.1.2.3 Each load of traycans are checked visually for coating imperfections as well as container or lid defects as outlined in IP-21.
- 4.1.2.4 This check requires no calibratable equipment.
- 4.1.2.5 In the event that thickness or external defects are found to be non-complying, the MRE supervisor will be notified, and procedures will be followed as outlined in IP-21.

Inspection Plan for Traycans

5 IN-PROCESS CONTROLS

5.1 TRAYCAN INSPECTION

- 5.1.0.1 Traycans are monitored through out the production in accordance with the following time schedule. These inspections are conducted by the Q.A. Line Inspector and records are maintained in the Q.A. lab. The Traycan Supervisor is solely responsible to judge, from the inspection results, the soundness and integrity of the double seam, and whether a shut-down or corrective actions are required.
- 5.1.0.2 Time schedule for different inspection types (4 hour cycle):



1: Visual traycan inspection 2: External seam measurements

- 3: Seam teardown and
- internal measurements
 4: Seam sectioning and
 direct internal

measurements

5.1.1 <u>Visual traycan inspection</u>

- 5.1.1.1 Every thirty minutes or immediately after can jam two traycan containers are removed from the seamer out-going line to be visually inspected for container and seam defects as outlined in IP-22.
- 5.1.1.2 This evaluation is conducted by the Line Inspectors and the type and number of defects are recorded on form LS72 and C6520.
- 5.1.1.3 This inspection requires no calibratable equipment.
- 5.1.1.4 In the event that defects are found to be non-complying,

the Traycan Supervisor will be notified, and procedures will be followed as outlined in IP-22.

5.1.2 External measurements of seam

- 5.1.2.1 Every 1 hour or immediately after can jam, the two traycan containers removed for visual inspection are to be used for external seam measurements as outlined in IP-23. This evaluation is conducted by the Line Inspectors and the type and number of defects are recorded on form LS72 and C6520.
- 5.1.2.2 The inspection is conducted according to procedures outlined in LP-22 using a Seam Micrometer (EQ-21) which is calibrated every time before a test according to CP-21. These records are maintained by the Q.A. technician and are located in the Q.A. lab.
- 5.1.2.3 In the event that defects are found to be non-complying, the Traycan Supervisor will be notified, and procedures will be followed as outlined in IP-23.

5.1.3 Seam teardown and internal measurements

- 5.1.3.1 Every 4 hours or immediately after can jam, one of the two traycans removed for visual and external seam measurements, is to be used for a seam teardown and internal measurements as outlined in IP-24. This evaluation is conducted by the Line Inspectors and the type and number of defects are recorded on form LS72 and C6520.
- 5.1.3.2 The inspection is conducted according to procedures outlined in LP-23 using a Seam Micrometer (EQ-21) which is calibrated every time before a test according to CP-21. These records are maintained by the Q.A. technician and are located in the Q.A. lab.
- 5.1.3.3 In the event that defects are found to be non-complying, the Traycan Supervisor will be notified, and procedures will be followed as outlined in IP-24.

5.1.4 Seam sectioning and direct internal measurements

5.1.4.1 Every 4 hours or immediately after can jam, the second of the two traycans removed for visual and external seam measurements, is to be used for a seam sectioning and direct internal measurements as outlined in IP-25. This evaluation is conducted by the Line Inspectors and the type and number of defects are recorded on form [] and [].

- 5.1.4.2 The inspection is conducted according to procedures outlined in LP-24 using a Seam Saw (EQ-25) and a Seam Projector (EQ-26) which is calibrated every time before a test according to CP-21. These records are maintained by the Q.A. technician and are located in the Q.A. lab.
- 5.1.4.3 In the event that defects are found to be non-complying, the Traycan Supervisor will be notified, and procedures will be followed as outlined in IP-25.
- 6 RETORT PROCESS
- 7 FINISHED PRODUCT
- 7.1 TRAYCAN EXAMINATION
- 7.1.1 <u>Traycan condition examination</u>
- 7.1.1.1 Examination of filled and sealed traycans shall be in accordance with the Traycan Evaluation Guide of the U.S Army Natick and the U.S. Standards for Condition of Food Containers except that inspection for labeling shall be as specified in 7.1.3.
- 7.1.1.2 Each finished lot is visually examined for external defects in accordance with IP-26. This evaluation is conducted by the Q.A. technician and records are maintained in the Q.A. lab.
- 7.1.1.3 This inspection does not require calibratable equipment.
- 7.1.1.4 In the event that defects are found to be non-complying, the Traycan Supervisor will be notified, and procedures will be followed as outlined in IP-26.

7.1.2 <u>Traycan closure examination</u>

- 7.1.2.0.1 Can closure shall be examined visually and by teardowns in accordance with the can manufacturer's requirement, the 21 CFR, Part 113, Subpart D, or the 9 CFR, Part 318, Subpart G, as applicable, and the Traycan Evaluation Guide of the U.S Army Natick.
- 7.1.2.1 Visual seam inspection
- 7.1.2.1.1 Traycan containers are visually inspected for seam defects as outlined in IP-22.

- 7.1.2.1.2 This evaluation is conducted by the Line Inspectors and the type and number of defects are recorded on form LS72 and C6520.
- 7.1.2.1.3 This inspection requires no calibratable equipment.
- 7.1.2.1.4 In the event that defects are found to be non-complying, the Traycan Supervisor will be notified, and procedures will be followed as outlined in IP-22.

7.1.2.2 External measurements of seam

- 7.1.2.2.1 Traycan containers removed for visual inspection are to be used for external seam measurements as outlined in IP-23. This evaluation is conducted by the Line Inspectors and the type and number of defects are recorded on form LS72 and C6520.
- 7.1.2.2.2 The inspection is conducted according to procedures outlined in LP-22 using a Seam Micrometer (EQ-21) which is calibrated every time before a test according to CP-21. These records are maintained by the Q.A. technician and are located in the Q.A. lab.
- 7.1.2.2.3 In the event that defects are found to be non-complying, the Traycan Supervisor will be notified, and procedures will be followed as outlined in IP-23.
- 7.1.2.3 Seam teardown and internal measurements
- 7.1.2.3.1 Half of the traycans removed for visual and external seam measurements, are to be used for a seam teardown and internal measurements as outlined in IP-24. This evaluation is conducted by the Line Inspectors and the type and number of defects are recorded on form LS72 and C6520.
- 7.1.2.3.2 The inspection is conducted according to procedures outlined in LP-23 using a Seam Micrometer (EQ-21) which is calibrated every time before a test according to CP-21. These records are maintained by the Q.A. technician and are located in the Q.A. lab.
- 7.1.2.3.3 In the event that defects are found to be non-complying, the Traycan Supervisor will be notified, and procedures will be followed as outlined in IP-24.
- 7.1.2.4 Seam sectioning and direct internal measurements

- 7.1.2.4.1 The other half of the traycans removed for visual and external seam measurements, are to be used for a seam sectioning and direct internal measurements as outlined in IP-25. This evaluation is conducted by the Line Inspectors and the type and number of defects are recorded on form [] and [].
- 7.1.2.4.2 The inspection is conducted according to procedures outlined in LP-24 using a Seam Saw (EQ-25) and a Seam Projector (EQ-26) which is calibrated every time before a test according to CP-21. These records are maintained by the Q.A. technician and are located in the Q.A. lab.
- 7.1.2.4.3 In the event that defects are found to be non-complying, the Traycan Supervisor will be notified, and procedures will be followed as outlined in IP-25.
- 7.1.3 Traycan label examination
- 7.1.3.1 Labels shall be examined for defects in accordance with MIL-L-1497.
- 7.1.4 <u>Vacuum examination</u>
- 7.1.4.1 Each load of traycans are examined for vacuum retention as outlined in IP-27.
- 7.1.4.2 This check requires no calibratable equipment.
- 7.1.4.3 In the event the vacuum retention is found to be noncomplying, the MRE supervisor will be notified, and procedures will be followed as outlined in IP-27.

8 TRAINING

- 8.1 All new employees receive a period of training which consists of the following topics:
 - 1. Employment Policy
 - 2. Safety & Sanitation
 - 3. SPC Concepts/Control Charts
 - 4. Job Specific Training
- 9 DOCUMENT CONTROL
- 10 EQUIPMENT CALIBRATION
- 10.1 EQUIPMENT IDENTIFICATION
- 10.2 FREQUENCY

-- page 7 --

- 10.3 PROCEDURES
- 10.4 RECORDS
- 10.5 CORRECTIVE ACTION
- 10.6 AUDITING AND REVIEW

INSPECTION PROCEDURE - 21

IP-21

TITLE:	TRAYCAN	BODY A	ND LID	INSPECTION	AND TESTING	
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Approved by				<u> </u>		
Q.A. Manage	er			·····		

- 21.1 <u>Load inspection</u>
- 21.1.1 Bill of lading should be checked against the load to insure accuracy of shipment quantity and number of lot numbers in shipment.
- 21.1.2 Upon delivery of traycan, the receiving clerk, Q.A. technician or MRE supervisor should check each shipment for signs of damage, abuse or infestation and proper documentation. Damage includes, but is not limited to, unsanitary conditions, holes in the cases or crushed or dented cases. Any damage should be documented on Receiving Form SF2909 and the drivers signature obtained.
- 21.1.3 Each shipment must be accompanied by a Certificate of Compliance (COC) from the manufacturer stating that this item complies with internal and external coating requirements for this item.
- 21.1.4 Receiving Form SF2909 is to be delivered to Q.A. lab. A copy of the manufacturers COC should be supplied to the Government Inspector in Charge.
- 21.1.5 Each shipment must also be accompanied by a Certificate of Specifications from the manufacturer stating base weight as well as nominal thickness. If such document does not exist then the traycan containers should be checked for thickness following procedures outlined below, otherwise continue test procedures in paragraph 21.3.
- 21.2 <u>Testing for thickness</u>
- 21.2.1 The Q.A. technician, selects randomly two traycan bodies and two lids from each of the lots received.

- 21.2.2 Traycan bodies and lids are tested for thickness according to LP-21. Any non conformance is classified as a major defect and the traycan lot shall be rejected.
- 21.3 <u>Visual inspection</u>
- 21.3.1 The Q.A. technician determines sample size separately for the traycan bodies and lids from Tables I & IIA of Mil-STD-105. Sample size is determined from the quantity of traycan bodies and lids received, inspection level S-3, and AQL of 0.5 percent defective.
- 21.3.2 Traycan lids and bodies are visually inspected for possible interior and exterior defects. Defects are listed, but are not limited to those, on Tables 1 and 2.
- 21.3.3 Defects are documented on form LS59 and accept/reject criteria are based on inspection level S-3, AQL of 0.5 percent defective.

Table 1. Traycan lid defects (adapted from "Traycan Evaluation Guide", U.S. Army Natick) 21.3.4

Defect Type	Alternate terminology
Scrap-In-Die	scored (depending on severity) scored fracture
Faulty Sealing	excess compound incomplete compound voids in compounds
Faulty Coating	faulty finish incomplete coating
Damaged Coating	scratched (inside/outside) damaged finish
Double End	double component double lid
Damaged Curl	dented curl
Compound Smear	

Table 2. Traycan body defects (adapted from "Traycan Evaluation Guide", U.S. Army Natick) 21.3.5

Defect Type	Alternate terminology
Damaged Coating	scratched (inside/outside) damaged finish
Flange Damage	dented/bent flange turned back flange
Delaminated Plate (metal plate flaw)	
Wrinkled Body	
Scrap-In-Die	die cut

Gray Spot

INSPECTION	PRO	DCEDURE -	22			IP-22
TITLE:	IN	PROCESS,	VISUAL	TRAYCAN	INSPECTION	÷
					Initial	Date
Submitted b	⊳у_					
Approved by	Z _					
Q.A. Manage	er _					

- 22.1 Each traycan is visually inspected for container profile defects and double seam defects. Defects include, but are not limited to, seam irregularities, malformations, and abnormalities.
- 22.2 Lead Person records type and number of defects found on Form LS72 and C6520 before returning product for rework.
- 22.3 The Traycan Supervisor is solely responsible to evaluate, from the inspection results, the soundness and integrity of the double seam, and whether a shut-down of the traycan line and/or corrective actions are required.
- 22.4 Defective traycans are immediately opened by the Lead Person or under the Lead Persons direction in the filling area and produce is transferred to the filling station.

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INSPECTION PROCEDURE - 23

- 23.1 External double-seam measurements are taken from each traycan according to LP-22 using the Seam Micrometer (EQ-21). Measurements include seam length and seam thickness.
- 23.2 Lead Person records type and number of defects found on Form LS72 and C6520 before returning product for rework.
- 23.3 The Traycan Supervisor is solely responsible to evaluate, from the inspection results, the soundness and integrity of the double seam, and whether a shut-down of the traycan line and/or corrective actions are required.
- 23.4 Defective traycans are immediately opened by the Lead Person or under the Lead Persons direction in the filling area and produce is transferred to the filling station.

IP-23

INSPECTION PRO	CEDURE - 24	IP-24
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TITLE: IN PROCESS, SEAM TEARDOWN AND INTERNAL MEASUREMENTS

	Initial	Date
Submitted by		
Approved by		
Q.A. Manager		

- 24.1 Seam teardown and internal double-seam measurements are taken from a traycan according to LP-23 using the Seam Micrometer (EQ-21). Measurements include cover and body hook, pressure ridge inspection, and seam tightness rating.
- 24.2 Lead Person records type and number of defects found on Form LS72 and C6520 before returning product for rework.
- 24.3 The Traycan Supervisor is solely responsible to evaluate, from the inspection results, the soundness and integrity of the double seam, and whether a shut-down of the traycan line and/or corrective actions are required.
- 24.4 Defective traycans are immediately opened by the Lead Person or under the Lead Persons direction in the filling area and produce is transferred to the filling station.

INSPECTION	PROCEDURE - 25 IP-25						
TITLE:	IN PROCESS, MEASUREMENTS	SEAM	SECTIONING	AND	DIRECT	INTERNAL	
			Int	itial	D	ate	
Submitted 1	by						
Approved by	У		·····				
Q.A. Manage	er						

- 25.1 Seam sectioning and direct internal double-seam measurements are taken from a traycan according to LP-24 using the Seam Saw (EQ-25) and the Seam Projector (EQ-26). Measurements include seam length, overlap, the body, and cover hook length.
- 25.2 Lead Person records type and number of defects found on Form LS72 and C6520 before returning product for rework.
- 25.3 The Traycan Supervisor is solely responsible to evaluate, from the inspection results, the soundness and integrity of the double seam, and whether a shut-down of the traycan line and/or corrective actions are required.
- 25.4 Defective traycans are immediately opened by the Lead Person or under the Lead Persons direction in the filling area and produce is transferred to the filling station.

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INSPECTION PROCEDURE - 26

TITLE:

IP-26

	Initial	Date
Submitted by		
Approved by		
Q.A. Manager		

FINISHED PRODUCT, TRAYCAN CONDITION EXAMINATION

- 26.1 Each traycan lot is examined separately. The Q.A. technician, determines sample size for each lot from Tables I & IIA of Mil-STD-105. Sample size is determined from the quantity in a lot, inspection level S-3, and AQL of 0.5 percent defective.
- 26.2 Traycans are visually inspected for possible interior and exterior defects. Defects are listed, but are not limited to those, on Tables 3 and 4.
- 26.3 Defects are documented on form LS59 and accept/reject criteria are based on inspection level S-3, AQL of 0.5 percent defective.

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Defect Type	Alternate terminology
Panelling	excessive vacuum buckle
Peaked traycan	buckling peaking
Flipper	overfill
Soft swell	
Hard swell	
Blown traycan	burst rupture leaker

26.5 Table 4. Traycan physical abuse defects (adapted from "Traycan Evaluation Guide", U.S. Army Natick)

Defect Type	<u>Alternate terminology</u>
Dent	seam dent
Abrasion	cable marks score marks
Cut seam	cable cut torn seam abrasion cut
Crushed	split burst
Holed	punctured slashed or gashed
Scored	score fracture cut can scrap-in-die fracture
Corrosion	rust (external) pitted gray spot (internal)

INSPECTION PROCEDURE - 27

IP-27

TITLE:	FINISHED	PRODUCT,	TRAYCAN	VACUUM	EXAMINATION
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	Initial	Date
Submitted by		
Approved by		
Q.A. Manager		·

- 27.1 Each traycan lot is examined separately. The sample size is 50 traycans.
- 27.2 Traycans are examined for vacuum retention according to LP-25.
- 27.3 Defects are documented on form LS59 and any nonconformance is a major defect and the lot shall be rejected.

LAB PROC	EDURE - 21		LP-21
TITLE:	TRAYCAN THICKNESS	TEST	
		Initial	Date
Submitte	d by		
Approved	by		
Q.A. Mana	ager		

- 21.1 The Digital Micrometer (EQ-22) is calibrated daily before use by the Q.A. Technician by closing the moveable shaft onto the stationary anvil (zero position) and zeroing the display. If this cannot be done notify the Inspection Technician.
- 21.2 Each traycan body or lid is measured for thickness four times at each of twelve points around the periphery (see figure 1) using the Digital Micrometer (EQ-22). Document the thickness measurements on the form [].
- 21.3 For each traycan body or lid calculate average values for each point and document the results on the form [].
- 21.4 Calculate from all the points, on a traycan body or lid, average values and sample standard deviation. Document the results on the form []. Map these results no the same form.

LAB PROCEDURE - 22 LP-22

TITLE: TRAYCAN SEAM EXTERNAL MEASUREMENTS

	Initial	Date
Submitted by	<u></u>	
Approved by		
Q.A. Manager		

- 22.1 Each traycan is measured for seam length and thickness four times at each of twelve points around the periphery (see figure 2) using the Seam Micrometer (EQ-21).
- 22.2 Check the Seam Micrometer (EQ-21) daily before use as follows: close the moveable shaft onto the stationary anvil (zero position). The zero graduation mark on the rotatable barrel should match exactly with the index line on the stationary body member. If zero graduation mark is more than one-half a division (space) from the index line, an adjustment to the micrometer is required; notify the Inspection Technician.
- 22.3 Measure the seam length by holding the flat surface of the micrometer against the traycan body as shown in Figure 12. Document the thickness measurements on the form [].
- 22.4 Figure 12. Seam length measurement
- 22.5 Measure the seam thickness by balancing the micrometer with the index finger immediately above the seam until the anvil assumes the same angle as the taper of the countersink (chuck wall angle), as shown in Figure 13. Document the thickness measurements on the form [].
- 22.6 Figure 13. Seam length measurement
- 22.7 For each traycan calculate average values for each point and document the results on the form [].
- 22.8 Calculate from all the points on a traycan body or lid average values and sample standard deviation and document the results on the form []. Map these results on the same form.

LAB PROCED	URE - 23		_LP-23
TITLE:	SEAM TEARDOWN AND INTERNAL M	EASUREMENTS	
		Initial	Date
Submitted 1	oy		
Approved by	Υ		
Q.A. Manage	er		
23.1	Cut out a circle (approximat center of the traycan bott opener (EQ-23).		
23.2	Remove and discard the produc Wash the traycan with deterg		
23.3	At the lid of the traycan (approximately 2" diameter) corner with the sanitar approximately 3/8" from the Figure 16A.	from the radi y can opener	ius of the (EQ-23),
23.4	Figure 16. Removing traycan	lid	
23.5	Cut through the double seam	using the nipper	cs (EQ-24).
23.6	Remove the remainder of the 24) as shown in Figure 16B.	lid using the ni	ippers (EQ-
23.7	Remove the stripped part of t with the nippers. Take care body hook.		
23.8	Measure the cover hook length (EQ-21). Document the result		
23.9	Measure the body hook length (EQ-21). Document the result		
23.10	Inspect for the pressure rid on the inside of the traycan i double seam as shown in Figur on the form [].	body near the bo	ttom of the
23.11	Figure 21. Pressure Ridge		

23.12 Inspect the inside of the cover hook and assess the seam tightness in terms of the tightness rating. Document the results on the form [].

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LP-24

LAB PROCEDURE - 24

TITLE:	SEAM SECTIONING AND DIRECT	INTERNAL MEASURE	MENTS
		Initial	Date
Submitted 1	oy		
Approved by	I		
Q.A. Manage	er		
24.1	Cut out a circle (approxima center of the traycan bott opener (EQ-23).		
24.2	Remove and discard the produ Wash the traycan with deterg		
24.3	Cut sections of the seam using the double-bladed Seam Saw (EQ-25) at the 12 designated locations shown on the Quality Control Form [].		
24.4	Polish the seam section wire emery cloth, and position or		
24.5	Project the double-seam and instrument to directly meas overlap, the body, and cover results on the form [].	sure the seam 1	ength, the

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LAB PROCEDUR	E - 25	i	······································		LP-25
TITLE: V	ACUUM	RETENTION	EXAMINATION		
				Initial	Date
Submitted by					
Approved by					
Q.A. Manager					

- 25.1 Traycans are allowed to cool to 75° ± 5°F, held for at least 24 hours after sealing.
- 25.2 To examine, lay a straight edge in the center of the lid along the length of the traky pack. Both ends of the straight edge shall touch the lid at the inside edge of the double seam. There shall be a visible gap between the straight edge and the lid for the entire distance of the label panel.
- 25.3 Using a shorter straight edge, the same procedure shall be used across the width, in the center of the traycan.
- 25.4 When examining a ribbed lid, only lay the straight edge between the two center ribs along the length of the traycan.

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EQUIPMENT LIST

<u>EQ #</u>	NAME	LOCATION
EQ-21	Seam Micrometer	Pilot Plant
EQ-22	Digital Micrometer	413 Packaging Lab
EQ-23	Sanitary Can Opener	Pilot Plant
EQ-24	Nippers	Pilot Plant
EQ- 25	Seam Saw	Pilot Plant
EQ-26	Seam Projector	Pilot Plant

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