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DEPARTMENT OF DEFENSE MILITARY HANDBOOK

GUIDELINES FOR AUDITING FOOD ESTABLISHMENTS

This handbook is for guidance. Do not cite this document as a requirement.

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FOREWORD

1. This handbook is approved for use by all Departments and Agencies of the Department of Defense.

2. This handbook cannot be cited as a requirement. If it is, the contractor does not have to comply.

3. This handbook contains guidelines for auditing manufacturing facilities.

4. Each appendix is based on controlling regulatory provisions, industry standards, or other DoD requirements.

Beneficial comments (recommendations, additions, deletions) and any pertinent data which may be of use in improving this document should be addressed to: Director, DoD Veterinary Service Activity, Office of the Surgeon General/HQDA, 5109 Leesburg Pike, Falls Church, VA 22041-3258, by using the Standardization Document Improvement Proposal (DD Form 1426) appearing at the end of this document, or by letter.

CONTENTS

1. SCOPE

1.1 Purpose. This handbook provides guidance related to conducting sanitation audits of commercial food establishments. The requirements for these audits and related DoD policy are contained in MIL-STD-3006 and AR 40-657, respectively. This handbook is based on the Current Good Manufacturing Practices (CGMP) requirements, as provided in Title 21, Code of Federal Regulations (CFR), Part 110 as basic sanitation standards for food establishments. The handbook also provides specific commodity guidance within annexes for use in the sanitation auditing process.

1.2 Application. This handbook is applicable to all establishments supplying subsistence purchased with Appropriated and Nonappropriated funds for Armed Forces use. Detailed auditing guidelines relating to specific types of food establishments are located in the Appendices of this handbook. This handbook is also applicable in military owned/leased facilities where foods are stored, utilizing Title 21 CFR, part 110, General Provisions only. Compliance with MIL-STD-3006 is mandatory for listing of plants in the Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement (Directory). Approved establishments are listed in U.S. Army Veterinary Command (VETCOM) Circular 40-1 (*Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement*) or locally approved lists. The VETCOM Home Page (located on the Web at http://domino1.hcssa.amedd.army.mil/vetcom.nsf/) includes the VETCOM Directory and links to several other related sites.

1.3 Objectives. This handbook is intended to ensure that food establishments supplying subsistence, both Continental United States (CONUS) and Outside the Continental United States (OCONUS), are in compliance with CGMPs, thus reducing the risk of transmission of foodborne disease.

1.4 Limitations. In OCONUS locations the Major Command (MACOM) Commander may supplement this document. This handbook is not used to determine an establishment's capabilities to comply with product specifications or other purchase requirements. In cases where CGMPs are provided in the CFR for specific subsistence items (i.e., acidified foods), the specific CGMPs for that item will be applied in addition to those found in Part 110. Good Manufacturing Practice (GMP) documents provided by industry and recognized by the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA) or the United States Department of Commerce (USDC), may be used in conjunction with Title 21, CFR, Part 110, with MACOM approval.

2. APPLICABLE DOCUMENTS

2.1 General. The documents listed below are not necessarily all of the documents referenced herein, but are the ones that are needed in order to fully understand the information provided by this handbook.

2.2 Government documents.

2.2.1 Standard. The following standard forms a part of this document to the extent specified herein. Unless otherwise specified, the issue of the document is as listed in the latest issue of the Department of Defense Index of Specifications and Standards (DoDISS), and supplements thereto, and are referenced for guidance only.

STANDARD

DEPARTMENT OF DEFENSE

MIL-STD-3006 Sanitation Requirements for Food Establishments

(Unless otherwise indicated, copies of the above specifications, standards, and handbooks are available from the Standardization Document Order Desk, 700 Robbins Avenue, Building 4D, Philadelphia, PA 19111-5094, http://www.dodssp.daps.mil/.)

2.2.2 Other government documents and publications. The following other Government documents and publications form a part of this handbook to the extent specified herein.

CODE OF FEDERAL REGULATIONS (CFR)

Code of Federal Regulations (CFR), Title 21, Part 110.

Title 7, Code of Federal Regulations (CFR), Agriculture.

Title 9, Code of Federal Regulations (CFR), Animals and Animal Products.

Title 21, Code of Federal Regulation (CFR), Food and Drugs.

(Application for copies should be addressed to Superintendent of Public Documents, U.S. Government Printing Office, Washington, DC 20402-0001, http://www.acess.gpo.gov/nara/cfr/index.html/.)

U.S. PUBLIC HEALTH SERVICE (USPHS)

U.S. Public Health Service (USPHS) Publication Number 229, Pasteurized Milk Ordinance (PMO)

(Application for copies should be addressed to: US Department of Health and Human Services, US Food and Drug Administration, Milk Safety Branch, HFS-626, Center for Food Safety and Applied Nutrition, 200 C Street, SW, Washington, DC 20204.)

U.S. Public Health Service (USPHS), Food and Drug Administration, Food Code, 1999

(Application for copies should be addressed to Department of Health and Human Services, Food and Drug Administration, Food Service Sanitation Branch, Washington, DC 20204. Document No. PB99-115925 available printed, on CD ROM, and on diskette from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; 1-800-553-6847; or download from web site: http://vm.cfsan.fda.gov/~dms/foodcode.html/.)

ENVIRONMENTAL PROTECTION AGENCY

Environmental Protection Agency Regulations (http://www.epa.gov/epahome/publications.htm/.)

MILITARY PUBLICATIONS

Army Regulation (AR) 25-50, Preparing and Managing Correspondence.

AR 40-5, Preventive Medicine.

AR 40-70, Department of Defense Veterinary/Medical Laboratory Food Safety and Quality Assurance Program.

AR 40-657, Veterinary/Medical Food Inspection and Laboratory Service.

(Available from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; 1-800-553-6847; or download from web site: http://www.usapa.army.mil/.)

3. DEFINITIONS

3.1 General. The definitions and interpretations of terms found in 21 CFR 110 are applicable to this handbook.

3.2 Sanitation audit. An in-depth examination of the sanitation system to determine the effectiveness and compliance with predetermined reference standards. The sanitation audit examines and evaluates the sanitation system as it applies to an overall organizational element.

3.3 Critical Defect. Condition, practice, step or procedure which: a) presents a biological, chemical or physical property that causes food to be unsafe for consumption; and/or b) the food safety hazard cannot be prevented, eliminated or reduced by a subsequent practice, step or procedure.

3.4 Major Defect. Condition, practice, step or procedure which: a) is of less food safety concern yet affects the usability of the products; and/or b) due to loss or lack of control, may become a Critical Defect.

3.5 Observation. A condition or practice that is not in accordance with the CGMP requirements, but is not a Critical or Major Defect.

3.6 Acceptable. The rating given to an establishment that complies with the requirements of the sanitary audit.

3.7 Unacceptable. The rating given to an establishment that does not comply with the requirements of the sanitary audit.

3.8 Sanitation audit rating. A rating based upon the results of the sanitation audit, scored as either “Acceptable” or “Unacceptable”.

3.9 Initial Sanitation Audit. Initial Sanitation Audit determines the sanitary status of food establishments. This audit approves or disapproves the establishment as a source for the Armed Forces. It is comprised of a complete audit of the facility, sanitary control systems and procedures employed by the establishment.

3.10 Special Sanitation Audit. Special Sanitation Audits are performed at approved establishments to decide whether the establishment will remain an approved procurement source of subsistence for the Armed Forces. This audit is performed when an establishment is rated "Unacceptable" or is suspected that the food provided by the establishment is a threat to health.

3.11 Update Sanitation Audit. An Update Sanitation Audit is a comprehensive sanitation audit performed within four years from the date of the previous Initial, Special, or Update Audit. Update Sanitation Audits are also performed when an establishment undergoes extensive remodeling, wishes approval for new items, or transfers from a local list to the Directory. The Update Sanitation Audit will be as comprehensive in detail as an Initial or Special Audit. However, an "Unacceptable" rating will result in a follow-up Special Audit. Inspectors will perform an Update Sanitation Audit when appropriate and without a request from higher headquarters.

3.12 Routine Sanitation Audit. Routine Sanitation Audits are conducted to determine the current sanitary status of an approved establishment. These audits result in the continued approval, or in notice of the possibility of removal/disapproval from the Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement, if sanitary deficiencies are not corrected.

3.13 Sanitation audit report. A written record of the results from a sanitation audit.

3.14 Corrective Action Request (CAR). A written report given to management upon completion of the sanitation audit that identifies Critical and Major Defects, requesting corrective action.

3.15 Dual-Listed establishments. Dual-Listed establishments are facilities listed in the Directory and another recognized federal listing.

3.16 Veterinary Corps Officer (VCO). The term VCO, as used in this handbook, means a graduate veterinarian serving as a commissioned officer in the U.S. Army Veterinary Corps.

3.17 Warrant Officer (WO). The term WO, as used in this handbook, means a Veterinary Services Technician, (MOS 640A) Warrant Officer.

4. GENERAL GUIDANCE

4.1 Auditing Personnel.

4.1.1 Routine Sanitation Audits/Inspections. A VCO, WO may perform Initial, Update, Special, and Routine Sanitation Audits. A qualified Noncommissioned Officer (NCO) (MOS 91R, SSG or above) may perform routine sanitary inspections (refer to AR 40-657).

4.1.2. Joint audits. Joint audits by a VCO/WO and enlisted inspector are necessary to advance training and prepare for independent enlisted personnel inspection assignments.

4.1.3. Reserve Component veterinary/Warrant Officers. Reserve Component veterinary officers and/or WO may also perform all commercial sanitation audits. The local Veterinary Commander must determine whether the Reserve Component veterinary officers/WO are fully qualified. When used, the Commander must ensure that these officers are up-to-date on changes in procedures, military standards, sanitation audit checklists, etc. Reserve Component veterinary officers/WO may perform a joint audit with active duty personnel before independent audit assignment.

4.2 Off-post caterers and civilian restaurants.

4.2.1 Inspection. Inspect these or similar off-post establishments according to paragraph 2-3 of AR 40-657. Use the Food and Drug Administration's Food Code for guidance when evaluating the methodology of commercial caterers.

4.2.2 Commercial food establishments. Commercial food establishments providing home delivery service only on a cash basis to individuals residing on a military installation are exempt from sanitation audit and Directory or local list requirements of AR 40-657. Local medical command policy will apply in these instances.

4.2.3 Dinner theaters. Directory or local listing of civilian caterers furnishing meals to a Non-Appropriated Funds (NAF) operated dinner theater on a military installation is required.

4.2.4 Unit parties. A civilian caterer furnishing meals to a military unit for a unit party or picnic (using NAF morale and welfare funds) must have sanitary approval. For one-time occasions, one-time approval is appropriate and Directory or local listing is not necessary.

4.2.5 On-post retail grocery store, restaurant, and fast-food outlets. These or similar on-post establishments are subject to military sanitary inspection and approval. However, Directory or local listing is not required. Inspectors will regard these establishments as similar to military

facilities. Retail grocery stores are subject to the same sanitary standards as military commissary stores. The veterinary service will inspect on-post retail grocery stores. Usually, the preventive medicine service is responsible for sanitary evaluation of on-post food service type establishments. AR 40-5 contains sanitary standards for food service establishments. Resale grocery items and raw materials for restaurants and/or fast-food outlets must comply with the approved source requirements of AR 40-657.

4.2.6 Mobile canteens and/or snack trucks servicing military installations. These units, when performing under a Government contract, are subject to sanitation audits and Directory or local list requirements. When the mobile unit operates as an extension of a central food preparation establishment, audit the base of operations and the mobile unit. AR 40-5 contains sanitary standards for food service operations. Resale food items and raw materials must comply with the approved source requirements of AR 40-657. The mobile units operating on-post are subject to veterinary and/or preventive medicine service audits. Coordination between veterinary and preventive medicine services is essential to establish responsibility for audits. When operating on-post permissively (without a Government contract), local command policy and requirements for audits and approval will govern. The veterinary service will coordinate with the preventive medicine service to carry out the local command policy. Whether these units are performing under a Government contract or permissively, the Veterinary Commander should maintain sanitary cognizance.

4.2.7 Privately prepared foods. Sanitation audits and Directory or local listing requirements do not apply to food prepared in military quarters or private residences for the following purposes:

(1) Direct sale to individuals.
(2) Donation to charitable organizations.
(3) Consumption at social gatherings not involving the use of Appropriated Funds (APFs) or NAFs. Local command policy will apply in these cases.
(4) Military quarters or private residences will not be approved as sources of food for purchase by APF or NAF activities. However, a food processing establishment adjacent or attached to a private residence must be completely separated by a wall or floor for approval as an acceptable source. The food-processing establishment must not be an integral part of the residence.

4.2.8 Commercial food storage warehouses. Warehouses storing or handling Government-owned perishable or semi-perishable subsistence must be Directory-listed. Commercial cold storage warehouses serving as Defense Supply Center Philadelphia (DSCP) perishable subsistence supply points or storing prepositioned war reserve material stocks will receive annual routine sanitation audits. Furnish a copy of each sanitary inspection report to the Defense Subsistence Office Chief; the contractor; and DSCP, ATTN: DSCP-HROS. Forward a copy of each Initial, Special, Update, and Unacceptable Routine sanitary inspection report to HQ VETCOM, ATTN: MCVS-FA.

4.3 Thermo processed food. Establishments furnishing thermally processed foods in hermetically sealed containers are exempt from Directory or local listing when the products are known to possess little or no potential health hazard. This exemption does not apply to

aseptically processed and packaged milk/milk products (as defined in the PMO), canned meat, poultry, or fish items; unless the appropriate recognized Federal agency inspects and lists the establishment.

4.4 Food handlers certificates. In the United States, assign defect points for failure to possess current food handlers certificates only when civil authorities require such certificates. Local medical command policy in overseas areas will govern requirements for food handlers certificates.

4.5 Change in establishment's name or ownership. When an establishment's name or ownership changes (without relocation of the plant), notify the approval authority in writing. The approval authority will make the appropriate administrative changes to the Directory or local list.

4.6 Change in establishment location (relocation). Advise the management to follow procedures for requesting an Initial Sanitation Audit.

4.7 Frequency of sanitation audits.

4.7.1 Audits. The frequency of audits will be in accordance with AR 40-657.

4.7.2 Extent and frequency of audits. The extent and frequency of sanitation audits will depend on the sanitation history of the establishment and the nature of the foods produced and handled. Frequencies may be adjusted due to frequent nonconformances, customer complaints, or identification of public health risks.

4.8 Use of documents. Appendix A, General Provisions, is the base document for scoring the establishment, and covers general sanitation requirements for all establishments. The General Provisions are used in conjunction with the appropriate product appendix located in the back of this Handbook. When a product does not have a supporting appendix, use Appendix A. In addition, supporting documents are provided for general/dairy laboratory/QC review (figures 1 and 2), dairy equipment testing (figure 3), as required. Any additional documents incorporated by reference are authorized for use.

4.8.1 Checklist. The Appendix A Checklist is comprised of different subparts and paragraphs corresponding back to the CFR (Subparts D and F within the CFR are not used). Subpart H - Hazard Analysis Critical Control Point (HACCP)/Record Keeping, does not correspond directly to the CFR. Establishments that have mandated HACCP programs, Appendix A, subpart H must be used. Establishments that do not have mandated HACCP programs are not required to meet the entire provisions of Appendix A, Subpart H. However, if a HACCP plan is in place, it will be reviewed. Each subpart has three columns; check the appropriate block as needed. On the reverse side (second page) of the Sanitation Audit Report, fully describe any defect(s) (Critical, Major and observations) corresponding to the subpart/annex used.

4.8.2 Sanitation audit rating. A sanitation audit rating is either "Acceptable" or "Unacceptable". The finding of one Critical Defect will result in an "Unacceptable" rating. Four or more Major Defect items in Appendix A will result in an "Unacceptable" rating. Each requirement in

Appendix A will only be scored once for each severity, regardless of the number of findings. Observations will not result in an "Unacceptable" rating. The cumulative effect of multiple observations indicating an out-of-control process may require an upgrade to one Major Defect, due to the increased public health significance.

5. AUDIT PROCEDURES FOR SANITATION AUDITS

5.1 Planning and initiating the sanitation audit.

5.1.1 Sanitation schedule. All sanitation audits are announced/scheduled. For Initial/Special/Update Sanitation Audit, send the Pre-audit Coordination Checklist to the establishment's representative prior to scheduling the audit. The auditor will schedule the audit, either by mail, telephonically or in person. At the time the audit is scheduled determine the type of product the establishment produces, identify those destined for sale to the governmental agencies, and ensure the establishment is operational and producing requested products on the day of the audit. Upon receipt of the Pre-audit Checklist, review for completeness and any problem areas, and re-confirm audit date. If the Pre-audit Coordination Checklist is not received, this does not preclude scheduling and conducting the audit.

5.1.2 Assemble and review all reference materials. References will include as a minimum: MIL-STD-3006, MIL-HDBK-3006 procedures, applicable appendices, reference documents, prior audits, CAR, laboratory results, etc. Check with supporting veterinary laboratory for the quality history of the company if laboratory results are not available. Reference documents will be available in the lotus notes document library.

5.2 Performance of the sanitation audit.

5.2.1 Pre-audit meeting. The Auditor will notify management immediately upon arrival. Conduct the pre-audit meeting with management. During this meeting discuss and review:

- Scope of the visit.
- Contents of the Pre-audit Coordination Checklist.
- Applicable standards.
- The plan for conducting the audit.
- Areas to be visited.
- Sequence of areas to be audited.
- Previous sanitation audits if applicable.
- Results of other agencies audits/inspections.
- Food safety program/quality plan:
  - Sanitation Standing Operating Procedures (SSOP's).
  - Pest management program.
  - HACCP plan if available.
- Requirements for laboratory analysis.
- Advise management the audit will include interviews with various plant personnel for the purpose of obtaining objective evidence.
- Request the establishment's representative is cognizant of all plant production operations.

- Pertinent rules of audit results:
  - Scoring methods (severity of defects, affect on rating of establishment and Directory listing).
- Corrective actions (immediate vs. post-audit):
  - Establish a time and location for the post-audit meeting and if necessary, the requirement for the CAR.

5.2.2 Conducting the audit. Conduct the sanitation audit in the presence of management or a designated representative. This includes all phases of the system: pre-operational sanitation, production, and post operational clean-up.

- In the pre-operational phase, focus on the effectiveness of the cleaning and sanitizing program.
- In the production phase, consider: wholesomeness of the raw product and ingredients, product flow, employee/sanitary practices throughout the process, in-line process controls, and end item protection and disposition.
- In the post-operational clean-up phase, verify the establishment's system for cleaning and sanitizing: water temperatures, chemicals, methods, etc.
- A thorough review of the laboratory program will be conducted at the end of the audit.
  - All establishments are subject to laboratory testing.
  - Auditing Laboratory/Quality Control Programs. For those establishments that have laboratories within their facility, the laboratory working paper will be completed. For those establishments that utilize independent laboratories, a review of laboratory reports will be performed.
- Additional Auditor Guidance:
  - Once initiated, the sanitation audit will be completed, regardless of deficiencies found when conducting the audit.
  - Keep the management representative fully aware of what is being observed and recorded.
  - Throughout the audit discuss positive as well as deficient conditions as they are noted.
  - Document observations and obtain objective evidence to determine compliance or noncompliance.
  - Individual major deficiencies that are corrected immediately and are not systemic may be scored as observations, if appropriate.
  - Objective evidence may be collected through interviews, examination of documents and observing activities and conditions in the establishment.
  - Physical observations, measurements and records will provide objective evidence to verify compliance or noncompliance, whether they are specifically required in the applicable appendix or not.

5.2.3 Post-audit meeting. Prior to departing the establishment, advise the food establishment of the sanitation audit results, to include:

- All defects noted, placing particular emphasis on defect(s) of public health concerns.

- Auditors will not make specific recommendations for corrective actions. However, guidelines for the steps necessary to meet the standards may be discussed.
- Prepare a separate CAR for each Critical and Major Defect.
  - Prepare and sign Part I, to include management signature, and leave the original CAR(s) with the establishment.
  - If management will not sign the CAR(s), leave an unsigned original.
- If the establishment is rated "Unacceptable" during an Initial or Special Audit, advise management of procedures for re-applying for Directory listing.
- If the establishment is rated "Unacceptable" during Routine and Update Audits, advise of the requirement for a Special Audit and potential for de-listing from the Directory.
- Advise management of any additional reports they will receive concerning the audit.
- Conclude the post-audit meeting with a positive finding (if possible) to ensure good relations are maintained between representatives of the government and industry.

6. REPORTING PROCEDURES

6.1 Reporting results of Initial, Special, and Update Sanitation Audits. Complete and distribute the following forms from this handbook:

- Sanitation Audit Report (figure 4).
  - Establishment: leave hand written copy; send final written report.
  - MACOM Veterinary Laboratory: send final written report (if applicable).
  - Veterinary Commanders and higher HQ: send final written report.
- General Provisions Checklist (see Appendix A).
  - Establishment: send final written report.
  - Veterinary Commanders and higher HQ: send final written report.
- Corrective Action Request(s) (figure 5 if required) - leave hand written copy. Final disposition completed by auditor upon receipt, retained at unit level.
- Cover Letter to Establishment (figure 6).

6.2 Reporting results of Routine Sanitation Audits. Complete and distribute the following forms from this handbook:

- Sanitation Audit Report (figure 4) - leave hand written copy.
- Corrective Action Request(s) (figure 5 if required) - leave hand written copy. Final disposition completed by auditor upon receipt.

6.3 Corrective Action Request. Any establishment receiving a major or critical deficiency should reply to a CAR. Establishments reapplying for Directory listing should also submit a CAR. The CAR should address Critical and Major Defect(s).

6.4 Sanitation Audit Report.

6.4.1 Routine audits. A Sanitation Audit Report is completed at the end of each routine audit. The front and reverse of the form will be completed without methodology.

6.4.2 Initial, Special, and Update Audits. In addition to completing the front and reverse of the Sanitation Audit Report, a detailed methodology will be completed.

- Methodology. The written methodology must contain all the information in the Production and Food Protection sections of the Pre-audit Coordination Checklist. The detailed description of the manufacturing process must accurately depict how the product is received, handled and stored throughout the process. Auditors are required to obtain or create a flow chart of the process identifying Critical Control Points (CCP) for establishments without a HACCP.

7. NOTIFICATION GUIDANCE FOR UNACCEPTABLE SANITATION AUDITS

7.1 Immediate notification. The Veterinary Commander or designated representative will immediately telephone the Directory or local list approval authority when an establishment receives an "Unacceptable" rating. The Veterinary Commander must consult the approval authority for Directory and/or local listing by phone before suspension of any deliveries. Describe any Critical Defects and current contracts (e.g., purchasing agencies, contract, or purchase order numbers, expiration dates of the contracts, items being delivered, and destinations). If the approving authority concurs with the recommendation, the Veterinary Commander or designated representative will take the applicable actions described below.

7.1.1 Unacceptable Routine or Update Sanitation Audits with delivery suspensions.

7.1.1.1 Notification. Notify the appropriate purchasing activity if the establishment is a subcontractor on a contract or an active bidder on current solicitations. Follow up all notifications in writing.

7.1.1.2 Delivery suspensions. Delivery suspensions will remain effective until completion of a Special Sanitation Audit. Special Sanitation Audits will determine approval or disapproval for continued listing in the Directory or local list.

7.1.1.3 Suspension letter. In addition to normal notification of products placed on suspension due to microbiological testing, provide a copy of the suspension letter to HQ, Army and Air Force Exchange Service (AAFES); HQ, Defense Commissary Agency (DeCA); and HQ, Defense Supply Center Philadelphia (DSCP) for the respective theater Command. Ensure that local procedures are in place to prevent the acceptance of products that have been suspended due to suspected pathogens.

7.1.1.4 Interstate Milk Shippers (IMS) List deletions. Delivery suspensions for IMS List deletions follow the policy and procedures contained in MEDCOM Regulation 40-28. The Food and Drug Administration (FDA) notifies VETCOM whenever an IMS listed dairy receives a revised rating that is less than 90. The dairy will not be re-inspected for a minimum of fifteen (15) days. During this period, the dairy plant is in a non-approved status.

7.1.2 Unacceptable Routine or Update Sanitation Audits without delivery suspension.

7.1.2.1 Official letter. Follow up the post-audit meeting with an official letter listing the sanitary deficiencies found (see Figure 6). The letter must clearly state that an auditor will perform a Special Sanitation Audit on or after a specific date. Also, explain that failure to pass this audit will result in a recommendation for the establishment's removal from the Directory or local approved list.

7.1.2.2 Purchasing agency notification. Promptly notify all purchasing activities (having a current contract with the establishment) of the impending Special Sanitation Audit. Advise the purchasing agencies of a possible supply failure if the establishment does not pass the audit. Also, notify the appropriate purchasing activities if the establishment is a subcontractor on a current contract or an active bidder on current solicitations.

7.1.2.3 State and local notification. Before conducting the Special Sanitation Audit notify the appropriate state and local health agencies and invite them to participate in the audit.

8. STANDARDIZED FORMATS AND INSTRUCTIONS FOR SANITATION AUDIT REPORT WORKING PAPERS AND LETTERS

8.1 Notification letter to the establishment of an upcoming sanitation audit. Figure 7 is a standardized format for a cover letter to the establishment informing them of the upcoming audit and requesting the information needed for the Pre-audit Checklist.

8.2 Pre-audit Coordination Checklist. Figure 8 lists the information necessary to process Initial Sanitation Audit requests and to update records prior to Special or Update Sanitation Audits.

8.3 Letter to the establishment following an Initial, Special, Update, or Unacceptable Routine Sanitation Audit. Figure 6 is a standardized format and instructions for a letter informing an establishment the results of all Initial, Special, and Update Sanitation Audits and Unacceptable Routine Sanitation Audits.

8.4 Request for removal from the directory of sanitarily approved food establishments for armed forces procurement. An establishment may be recommended for deletion or removal from a Directory or Locally Listed establishment due to other than unsanitary conditions. If an establishment has been inactive less than two years, the deletion must include a deletion request signed by the plant management (Figure 9). The auditor may omit the plant management's signed request if the plant has attained exempt status or has gone out of business and the auditor cannot contact plant management. (Refer to AR 40-657.) Use the format and instructions shown at Figure 10.

8.5 Sanitation Audit Report. Suggested format to report findings from audit. Figure 4.

8.6 Methodology format for Sanitation Audit Report. Suggested format for merge document to standardize description of methodology used by establishment. This provides the descriptive paragraph on methodology for the Sanitation Audit Report. Figure 11.

8.7 Corrective Action Request. Format used to report Major and Critical Defects found during a sanitation audit and area for response from establishment on corrective action taken. Figure 5.

8.8 Instructions for merging documents. Guidance information on merging documents to consolidate reports. Figure 12.

8.9 Recommendation for deletion of a Directory-listed establishment. Figure 10 is a standardized format and instructions for a letter recommending removal of an establishment from the Directory.

8.10 Frequencies for review of laboratory analysis. Figure 13.

8.11 General laboratory checklist. Figure 1.

8.12 Laboratory checklist for dairy products. Figure 2.

8.13 Milk plant equipment and testing working paper. Suggested format for reporting findings from testing pasteurization equipment and controls. Figure 3.

GENERAL LABORATORY CHECKLIST

Not all food plants have in-plant laboratory analysis. Some establishments routinely send products to third party laboratories for analysis, or perform no analysis on the product. If the plant has in-plant laboratory capabilities, as a minimum the following areas should be discussed and reviewed. If requirements exist for bacteriological or chemical analysis of specific type product(s) these requirements must be met, whether at in-plant laboratory or contracted facility.

1. Analysis performed as required per product reference and applicable appendix in MIL-STD -3006.
2. Analysis performed in-plant or sent to contract laboratory.
3. Other types of analysis performed (i.e. environmental sampling, additional bacteriological sampling for quality characteristics).
4. Availability of applicable reference documents for analysis performed and methods used.
5. Proficiency testing program and employee training program in place.
6. In-plant quality control program (in addition to required analysis) has established control limits and corrective action is taken when limits are exceeded.
7. If required (primarily overseas) employee health certification is current and records maintained.
   a. Tuberculosis
   b. Hepatitis A/Hepatitis A antigen
   c. Stool Exam for parasites/protozoa
   d. Enteropathogenic exam for *Salmonella*, Toxigenic E. Coli, Vibrio cholera
8. Products identified as nonconforming based on laboratory analysis should have procedures established for corrective action and records of the action taken.
9. Notes: Make any note of special circumstances not covered above, rapid kits used or other pertinent data.

FIGURE 1. General Laboratory Checklist.

DAIRY LABORATORY CHECKLIST

As a minimum the auditor should verify the required laboratory analyses for the product being produced. While not completely inclusive, this checklist synopsizes the primary laboratory requirements and is useful when visiting dairy plant laboratories. Manufactured dairy product plants may not perform all the laboratory analyses listed.

1. Appropriate references for laboratory use available and current.
   a. Standard Methods for Examination of Dairy Products._____
   b. USPHS Publication No. 229 Grade "A" PMO._____
   c. Other._____

2. Herd Health Testing (Brucellosis, Tuberculosis, other)._____

3. Employee Health and Food Handler's Certification (if required)._____

4. Raw Milk Testing - Each Producer (see PMO for details).
   a. Bacterial Count (4X each 6 Months) NMT 100,000/ml._____
   b. Somatic Cell Count (4X each 6 Months) NMT 750,000/ml._____
   c. Temperature (collection and receipt) (4X each 6 Months) 7°C/2hrs._____
   d. Drug Testing (Beta Lactam Residues)._____
   e. Added Water Test._____
   f. Chlorinated Hydrocarbon Pesticides (4X each 6 Months)._____
   g. Other Pesticides (1 each route each 6 Months)._____
   h. DMC (No clear slides allowed)._____

5. Are there means available to segregate milk destined for US Forces procurement and commingled milk with greater than (>) 300,000 cfu/ml bacterial counts?_____

6. General Laboratory Procedures.
   a. Good commercial laboratory practices employed (no mouth pipetting, proper clothing and protective environment)._____
   b. Availability of proper equipment (dilution bottles, stoppers, petri dishes, incubators, colony counters, pH meter, water bath, scales etc.)._____
   c. Distilled/de-ionized water used for dilution prep and media prep._____
   d. Media sterility control checked both am and pm._____
   e. Toxicity test for dilution and media water._____
   f. Milk plant water tested semiannually (≤ 200/100ml or HPC <500/ml, coliforms MPN <1.1/100ml)._____

FIGURE 2. Dairy Laboratory Checklist.

7. Specific Procedures for Verify.
   a. Required temperature checks for media, incubators, water baths etc._____
   b. Autoclave or otherwise sterilize media before use._____
   c. Proper dilution blanks are prepared, verified and used (99±2ml after sterilization). ___
   _____
   d. Phosphate buffer solution should be adjusted to pH 7.2._____
   e. Verify and record the media pH for each lot/batch produced prior to use. This pH should be verified at 77° F (25° C)._____
   f. Resterilization of media is not authorized._____
   g. All dairy samples must be analyzed within 36 hours of production._____
   h. Air quality control checks must be performed. These should be performed more frequently in environments where dust and non-filtered air enters the plant._____
   i. Incubator temperatures are checked and recorded twice daily._____
   j. Media overlay procedures are proper for obtaining coliform counts._____
   k. Two or more serial dilutions are prepared per sample._____
   l. Counting methods are restricted to plates exhibiting 25 - 250 colony forming units (CFU) per plate._____
   m. Plates are incubated at the proper temperature for the proper times._____

8. Antibiotic Testing.
   a. Qualitative Bacillus stearothermophilus Disk Assay performed._____
   b. Positive controls used have not expired._____
   c. No zone greater than 16mm is authorized when using the B. stearothermophilus Disk Assay method._____

9. Sharer Rapid Phosphatase Test.
   a. Performed each hour for each type/size produced._____
   b. Records are maintained for all tests performed._____
   c. Positive controls are used for each test performed._____

10. Vitamin A and D Testing (as applicable).
   a. Vitamin A: NLT 2000 IU/QT, NMT 3000 IU/QT, Recall at ≥6000 IU/QT Records reviewed._____
   b. Vitamin D: NLT 400 IU/QT, NMT 600 IU/QT, Recall at ≥800 IU/QT Records reviewed._____

11. Microbiological criteria for frozen deserts:
   a. SPC: NMT 50,000 cfu/g._____
   b. eColi: NMT 10/g (Fruits, nuts or other bulky flavors added NMT 20/g)._____

12. Corrective Action
   a. Steps taken when laboratory analysis indicates product is not conforming._____

FIGURE 2. Dairy Laboratory Checklist - Continued.

Milk Plant Equipment Working Paper					
TEST NUMBER	TEST		TEST FREQ.	TESTED	TEST RESULTS
1	Indicating Thermometers (Including Air Space) Temperature Accuracy		3 months		
2	Recording Thermometers: Temperature Accuracy		3 months		
3	Recording Thermometers: Temperature Accuracy		3 months		
4 Daily by operator	Recording Thermometers Checked against Indicating Thermometer		3 months		
5	FDD Assembly and Function				
	5.1	Leakage past valve seat	3 months		
	5.2	Operation of valve stem	3 months		
	5.3	Device assembly (microswitch), single stem	3 months		
	5.4	Device assembly (microswitch), dual stem	3 months		
	5.5	Manual Division, Parts A, B, and C	3 months	HTST ONLY	
	5.6	Response Time	3 months		
	5.7	Time Delay-Inspect	3 months		
	5.8	Time Delay-CIP	3 months		
	5.9	Time Delay-LD Flush	3 months		
6	Leak-protector, outlet, valves: leakage (Vats)		3 months		
7	Indicating Thermometers in Pipeline: Thermometric Response		3 months	HTST ONLY	
8	Recorder Controller: Thermometric Response		3 months	HTST ONLY	
9	Setting of controls: Regenerator				
	9.1	Pressure switches	3 months	HTST ONLY	
	9.2	Differential Pressure Controllers	3 months		
	9.2.1	Calibration	3 months		
	9.2.2	Interwiring-Booster Pump	3 months	HTST ONLY	
	9.2.3	Interwiring-Fdd (HTST And Aseptic)	3 months		
	9.3	Additional Interwiring			
	9.3.1	Booster pump interwired with FDD	3 months	HTST ONLY	
	9.3.2	Booster pump interwired with metering pump	3 months		
10 Daily by Operator (except HTST)	Milk-flow controls: cut-in and cut-out temperatures		3 months		

FIGURE 3. Milk Plant Equipment Working Paper.

Milk Plant Equipment Working Paper					
11	Holding Time Verification		6 months		
Adjust product time if applicable	11.1	HTST (except magnetic flow meter system)	6 months		
	11.2a	Magnetic Flow Meters	6 months	HTST ONLY	
	11.2b	Flow Alarm (HTST,HHST and Aseptic)	6 months		
	11.2c	Loss of signal/low flow alarm (HTST, HHST and Aseptic) low cut-in/cut-out	6 months		
	11.2d	Flow cut-in and cut-out	6 months		
	11.2e	Time Delay (after divert)	6 months		
	11.3	HHST Indirect Heating	6 months		
	11.4	HHST Direct Injection Heating	6 months		
	11.5	Direct Infusion Heating	3 months		
12	Controller: Sequence logic (HHST and Aseptic 12.1 or 12.2)		3 months		
13	Product pressure control switch setting (HHST and Aseptic)		3 months		
14	Injector differential pressure		3 months		
REMARKS:					
PLANT:	IDENTITY OF PASTEURIZER		LOCATION:	DATE:	AUDITOR:

FIGURE 3. Milk Plant Equipment Working Paper - Continued.

SANITATION AUDIT REPORT

Name/Address/County/Phone Number, Email and Establishment Number:	Name/Address/Phone Number of Unit Performing Audit. Auditor's Name and Email Address:
Name and Title of the Establishment's Point of Contact:	Establishment Owner:
Date of Audit:	Type of Audit (Initial) (Routine) (Update) (Special):
Product(s) for Directory Listing:	Other Product(s) Produced and Stored:

☐ Sampling is required in conjunction with this audit. If yes, final rating is pending receipt of laboratory results.

Overall Sanitation Audit Rating: ☐ **Acceptable** ☐ **Unacceptable**	Delivery Status: ☐ **Suspended** ☐ **Not Suspended**

Required Attachments:(Initial/Update/Special Only)

Findings/Methodology/CFR Checklist/Letterhead or Business Card

Other Inspection/Audit Organizations/Date/Score:

Remarks:

AUDITOR'S SIGNATURE	COMMANDER'S SIGNATURE

FIGURE 4. Sanitation Audit Report.

ANNEX:	FINDINGS
SUBPART PARA	DESCRIPTION

FIGURE 4 Sanitation Audit Report (Findings) - Continued.

ESTABLISHMENT'S NAME:	DATE:

METHODOLOGY

FIGURE 4. Sanitation Audit Report (Methodology) - Continued.

CORRECTIVE ACTION REQUEST	
AUDITED FACILITY:	POINT OF CONTACT:
PART 1	
DEFICIENCY FOUND	
AUDITOR'S SIGNATURE	MANAGEMENT'S SIGNATURE
PART 2	
ROOT CAUSE OF DEFICIENCY	
ACTION TAKEN TO CORRECT AND PREVENT REOCCURRENCE OF DEFICIENCY	
REPRESENTATIVE RESPONSIBLE TO IMPLEMENT CORRECTIVE ACTION	SIGNATURE
PART 3	
AUDITOR'S EVALUATION OF CORRECTIVE ACTION(S)	
DISPOSITION OF CORRECTIVE ACTION	FOLLOW-UP AUDIT REQUIRED
REMARKS:	
AUDITOR'S SIGNATURE:	DATE SIGNED:

FIGURE 5. Corrective Action Request.

DEPARTMENT OF THE ARMY
HEADQUARTERS, NORTHEAST DISTRICT VETERINARY COMMAND
FORT MONMOUTH, NEW JERSEY 07703-5617
«Civilian_Date_of_Writing»

REPLY TO
ATTENTION OF

Veterinary Services

«Name_Vendor»
«Address_Vendor»
«City_State_Zip_Vendor»

Gentlemen:

On «Civilian_Date_of_Inspection», «Name_Rank_Auditor» conducted an audit sanitation inspection of your establishment in accordance with Military Standard 3006. During the audit, the inspector noted the following discrepancies requiring remedial action. The inspector discussed these discrepancies with «Name_Title_Plant_Representative». The discrepancies refer to the Code of Federal Regulation, Commercial Good Manufacturing Practices.

a. «Finding1»
b. «Finding2»
c. «Finding3»
d. «Finding4»
e. «Finding5»
f. «Finding6»
g. «Finding7»
h. «Finding8»
i. «Finding9»
j. «FInding10»
k. «FInding11»

Your establishment was rated «Acceptable_Unacceptable»; therefore, we «Have_HaveNot» recommended your establishment for listing in the Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement.

(OPTIONAL PARAGRAPH) If you wish to obtain another inspection, you must request it through procurement personnel. With your request, you must include a Corrective Action Request detailing all actions taken to correct each deficiency noted during this audit.

Sincerely,
«Auditors_Name»
«Audito_Rank»
«Auditor_Title»

«Enclosures»

FIGURE 6. Cover Letter To Establishment.

DEPARTMENT OF THE ARMY
HEADQUARTERS, NORTHEAST DISTRICT VETERINARY COMMAND
FORT MONMOUTH, NEW JERSEY 07703-5617

«Date_of_Memo»

REPLY TO
ATTENTION OF

Veterinary Services

«Establishments_Name»
«Establishment_Address»
«Establishment_City_State_Zip»

«Salutation»:

It has been brought to our attention that your establishment wishes to be listed in the "Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement." In order to be listed, your establishment must undergo a sanitation audit by a member of our Command.

(Alternate). After reviewing our records, it has been determined that a/an «Update_Special» audit needs to be performed on your establishment in order to remain listed in the "Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement."

The audit will take place on «Date_of_Audit». Enclosed are reference documents that we will use to evaluate your processes. In order to receive an acceptable rating, no critical findings or no more than three (3) major findings can be annotated on the Code of Federal Regulation, Part 110, Checklist.

Enclosed you will find «Attached_Working_Papers». These are working papers that our auditor uses to prepare a methodology on how your product is processed. Please complete the enclosed checklists. Keep these working papers at your establishment and send a copy to the address listed below. Please fax directions to your facility from our audit center at «Audit_Center_Location». Our fax number is «Fax_Number».

«Name_of_Auditor» has been tasked to perform the sanitation audit of your establishment. Please feel free to contact him/her if you have any question(s) regarding this audit. «Name_of_Auditor»'s address is «Auditor_Address»; or he/she may be reached telephonically at «Auditors_Phone»

Sincerely,

«Name»
«Grade_VC»
«Title»

Enclosure(s)

FIGURE 7. Audit Notification/Letter to Vendor.

PREAUDIT COORDINATION CHECKLIST

PERSONNEL/ADMINISTRATION

1. Names of key personnel:
2. Other agencies that inspect your facility: (Include the date of inspection and the score received.)
3. Two copies of company letterhead or business card:
4. Name of individual or company that owns facility:
5. Number of employees (Full and Part Time) that work in the facility:
6. Any Federal or State establishment number(s):

FACILITIES

1. Product distribution and transportation system:
2. Age of your facility:
3. Square footage or meters of your facility: (Please include a scaled floor plan of your building).
4. Acreage of lot building is on:
5. The name of the city, county and state facility is located in:
6. Building description, i.e., material(s) used in the construction of facility:
7. Describe your waste disposal program and/or recycling:
8. Location/temperature/humidity of stored raw and finished product areas:

FIGURE 8. Preaudit Coordination Checklist.

PRODUCTION

1. Production days and hours:

2. List of products produced, list of specific products being sold to the military:

3. Approved source of raw materials:

4. Daily output produced in either weight or number of product: (i.e. 30,000 pounds of flour, 1,000 gallons of ice cream, 10,000 loaves of bread).

5. Coding method of product: (i.e. Color twist ties for bread, date of manufacturing, best if used by date). Include recommended shelf-life of product: (i.e. Ice Cream can be sold up to 90 days after manufacturing date).

FOOD PROTECTION

1. Do employees receive a medical examination before employment:

2. Describe training program and frequency:

3. Water source and required analysis:

4. Cleaning and sanitation program:

5. Integrated pest management program:

6. List of chemicals stored at the facility to include cleaning agents: (Are Hazardous Material Lists available).

7. Do you perform laboratory analysis on your product(s)? Where is it performed:

8. Does quality control program contain provisions to prevent product tampering? (Upon Receipt, Storage, Processing, Distribution.)

9. Is there a Hazard Analysis Critical Control Point Program (HACCP) in place:

10. Flow diagram of the complete process of manufacturing to include time and temperature relationships, major processing equipment and quality control (i.e. Statistical Process Control (SPC), In line Inspection Points):

FIGURE 8. Preaudit Coordination Checklist - Continued.

(Date)

SUBJECT: Request for Removal from the Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement

TO: Commander, _____ District Veterinary Command,

_____

_____

As a representative of management, I request removal of the following establishment from the *Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement*.

Name of Company: _____

Location: _____

_____

_____

This letter serves as official notification of the company's decision for removal.

_____
(Signature)

_____
(Typed/Printed Name)

_____

FIGURE 9. Vendor Request for Removal.

EXAMPLE OF A DIRECTORY OR LOCAL LIST
DELETION RECOMMENDATION

(Letterhead)

(Office Symbol) (Marks Number) (Date)

MEMORANDUM FOR (1)

SUBJECT: Recommendation for Deletion of (2)

1. We recommend deletion of subject establishment from listing in the (3), in accordance with AR 40-657.

2. (4).

3. Our point of contact is (5)

(Identify Enclosures, if any) (6)

Use with Instructions for Preparing
a Directory or Local List Deletion Recommendation

FIGURE 10. Recommendation for Deletion.

INSTRUCTIONS FOR PREPARING A
DIRECTORY OR LOCAL LIST DELETION RECOMMENDATION

(DO NOT USE THIS FORMAT IF DELETION IS FOR CAUSE - SEE AR 40-657, PARAGRAPH 2-14A.)

1. Address the recommendation FOR Commander, U.S. Army Veterinary Command, ATTN: MCVS-FA, 2050 Worth Road, Suite 5, Fort Sam Houston, TX 78234-6005; or FOR the Commander with approval authority for the local list.

2. Enter the complete name and address of the establishment as it appears in the Directory or local list.

3. Enter "Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement" or "local list of sanitarily approved food establishments," as appropriate.

4. The request must include a justification, a verification or concurrence of management, and an authority. Some possible examples follow.

   a. The USDA Meat and Poultry Inspection Directory currently lists the subject establishment as establishment number 1322. Therefore, the establishment is exempt from Directory listing in accordance with AR 40-657, paragraph 2-15.

   b. On 12 Jan 95, Mr. Johns, President, stated that the subject establishment has ceased production of all products at the present address and currently functions as a distribution point only. Therefore, the establishment is exempt from Directory listing in accordance with AR 40-657, paragraph 2-15.

   c. The subject establishment no longer produces ice cream products. The Interstate Milk Shippers (IMS) List currently lists the establishment for milk and milk products in the Jan 95 listing with a pasteurized milk compliance rating of 94 percent. Mr. Johns, plant manager, stated that ice cream production ceased on 1 Dec 95. Therefore, the establishment is exempt from Directory listing in accordance with AR 40-657, paragraph 2-15.

   d. During a routine sanitary inspection on 11 Dec 95, Mr. Smith, Vice President of subject establishment, advised the inspector that they had no desire to continue Directory listing. We enclose a request, signed by Mr. Smith, for removal from the Directory.

   e. The subject establishment has apparently gone out of business. The inspector has been unable to contact any management personnel and the building is now closed and appears to be empty.

5. Enter the name and telephone number of the point of contact.

6. Enter the appropriate signature block. The Commander should sign the memorandum. However, the inspecting officer can sign the memorandum. If the inspecting officer signs the memorandum, address the memorandum THRU the Commander to the FOR addressee.

FIGURE 10. Recommendation for Deletion - Continued.

This facility produces/stores the following item(s): «What_Plant_Produces_Stores». Its hours of operation are «Hours_of_Operation». Raw materials are received from the following approved vendors: «Raw_Materials_Received_From». Daily output for this establishment is «Daily_Output». The product is «Open_Closed_Coded» coded in the following method: «Example_Of_Coding_Method».

Employees' «Do_Do not_Receive_Physical» receive a pre-employment medical examination prior to employment. Training is provided and performed «Frequency_of_Training» in the following areas: «Training_Covers». Water for the establishment is provided by «Water_Source». There «Is_Is_Not_Sanitation_Program» a cleaning and sanitation program in place. Currently, there «Is_Is_Not_HACCP» a HACCP Program in place. «Pest_Management_Firm» surveys the area on a «Frequency_Pest_Management» basis and performs whatever service is required. The following chemicals are used and stored at the establishment: «Chemicals_Stored_At_Facility».

Laboratory services are performed «Where_Laboratory_Service_Provided_From». This establishment performs the following laboratory test(s): «Laboratory_Tests_Performed». Environmental swabbing «Environmental_Testing_Is_Is_Not_Performed» performed at this establishment.

Product flow:

Receiving

Storage

Production

Post Production Storage

Distribution

FIGURE 11. Methodology Merge Document.

FormFlow:

Creating Data: Using the Filler portion of FormFlow, open the Cover Page Form (coverpg.frp).

- File, open, select the drive, pick the form.
- Type the information into the form.
- To save information go to Data, Save As, (under format select ASCII), name the data (fill in Database File) then hit OK. Consider saving information to a disk so that you can write the exact name you saved it as on the disk cover.

Opening Data:

- To open the data you saved open the form you created the data in (see above).
- To open the information go to Data, Open Data, change the format to ASCII, and type in the exact name of the file you saved.
- If you go to Select to find the data, and if it doesn't open the data as you saved it, take off the .FIL ending to open information.

Word Merge Documents:

In order to use a merge document there has to be a data portion assigned to the document. For this example we will be using Method2doc.doc and Method2data.doc. As long as both documents are in My Documents (Win 95) or Personal (WINNT) or on a 3.5 inch disk you should have no problem. If after opening the Method2doc.doc it requests a data doc to be assigned to the form, chose the Method2data.doc.

Writing to the Merge Document: Open the Method2doc.doc (File, Open, Select a Method2doc.doc).

- Click on edit data source (icon that looks like a pad and pencil). By clicking on this icon you opened the data source of the document. This is where all the data goes into the form. (Note: All the information may not fit into a particular field you are typing into *DO NOT WORRY*) You can go back after you merge the information into a new document.
- Upon completion of entering the information into the data portion hit OK.
- Go four icons to the left of the edit data source icon to Merge to a New Document icon and click on that icon. This will create a whole new form.
- Save that new document as whatever you want to name it. Now that you have a new document you can go back in an edit the information, or add the information that did not fit into a particular field.
- When you close Word, the program will ask if you want to save the information to the merge document, select yes. (You will have to do this twice.)

FIGURE 12. Computer Guidance.

LABORATORY ANALYSIS ABRIDGED

	Sandwich	Man Dairy	Eggs	FC Produce	Ice	Seafood	Frozen Deserts	Water	Poultry	LA Foods	Meats	Fresh Dairy	Salads 4/	Bakery
Air Quality 3/	*W	Specific frequencies are listed in Figure 1. General Laboratory Checklist		*W	*W	*W	Specific frequencies are listed in Figure 1. General Laboratory Checklist	*W	*W		*W	Specific frequencies are listed in Figure 1. General Laboratory Checklist	*W	*W
pH				*D						D			*D	
Bacteriological	*M			*M	M	*M		W	*D	*A			*W	
Coliform	*M			*M	M	*M		D	*D		*D		*W	
Drugs/Antibiotics						2/			*M		*M			
E Coli	*Q			*Q				D	W		D		*W	
Foreign Material														D
Heavy metals			S		Q	2/		A						
Listeria	*Q			*Q		*M					*W		*W	
Metal detector														D
Pesticides				*M										
Potability	S		S	S	S	S		A	S	S	S		S	S
Radionucleide					4			A						
Salmonella			D	*M					D		*M		*M	
Residual Chlorine 1/			D	D					*D	D	*D			

D - Daily W - Weekly M - Monthly Q - Quarterly S - Semi annually A - Annually
4 - 4 years
* Not required but recommended. Recommendations based upon the size of facility, HACCP programs, SSOPs, raw product testing, and herd/ flock quality as applicable.
1/ Indicator test kits are acceptable.
2/ Testing is recommended for sulfites and heavy metals during receiving.
3/ Applies to those plants with in-house laboratory.
4/ Microbiological and pathogen tests vary for types of salads (e.g. Tuna, Chicken etc.)

FIGURE 13. Laboratory Analysis Frequencies Abridged.

9. NOTES.

9.1 Intended use. This handbook is intended to be used as guidance for auditing commercial food establishments.

9.2 Subject term (keyword) listing. The following terms are to [may] be used to identify this handbook during retrieval searches:

Sanitation Audit Rating
Sanitation Audit Report
Corrective Action Request
Auditing Personnel
Initial Audits
Special Audits
Update Audits
Methodology
Merge Documents
Laboratory Checklist
Recommendation for Deletion
Request for Removal
Notification
Thermally Processed Food

Custodians:

Army - MD2
Navy - SA
Air Force - 03

Preparing Activity:

Army - MD2
Project No. 89GP-0004

Review Activities:

Navy - MS, MC
DLA - SS

APPENDIX A
GENERAL PROVISIONS

A.1 SCOPE

A.1.1 Scope. This appendix contains guidelines for auditing food production facilities. The information contained herein is intended for guidance.

A.2 APPLICABLE DOCUMENTS

A.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that they must meet all specified requirements documents cited in this appendix, whether or not they are listed.

A.2.2 Government documents. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

Code of Federal Regulations (CFR), Title 21, Chapter 1, Part 110.

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

A.3 DEFINITIONS

A.3.1 Definitions. Definitions are contained in the basic handbook.

A.4 GUIDELINES

A.4.1 Checklists. Guidelines for auditing food production facilities are contained in the following checklists.

APPENDIX A

TABLE I GENERAL PROVISIONS SUBPART A - PERSONNEL 21 CFR 110		CRITICAL	MAJOR	OBSERVATION
ITEM	REQUIREMENT			
A1	Adequate disease control measures are practiced. (Sec 110.10(a)).			
A2	Employees are wearing suitable clothing. (Sec 110.10(b)).			
A3	Employees are maintaining adequate cleanliness. (Sec 110.10(b)).			
A4	Employees are washing hands thoroughly after each absence from the workstation and at any other time the hands may have become soiled or contaminated. (Sec 110.10(b)).			
A5	Employees working in the processing area are free from unsecured jewelry. (Sec 110.10(b)).			
A6	Employees are using proper gloves and maintaining them in an intact, clean, and sanitary condition. (Sec 110.10(b)).			
A7	Employees are wearing effective hair restraints. (Sec 110.10(b)).			
A8	Employees' belongings are being properly stored. (Sec 110.10(b)).			
A9	Employees are not eating food, chewing gum, drinking beverages or using tobacco where food is exposed or equipment and utensils are washed. (Sec 110.10(b)).			
A10	Precautions are taken to protect food from being contaminated by employees. (Sec 110.10(b)).			
A11	Trained personnel are available where needed to provide a level of competency necessary for production of clean and safe food. (Sec 110.10(c)).			
A12	Employees are supervised, clearly assigned their responsibilities, with competent supervisors. (Sec 110.10 (9) (d)).			

TABLE II GENERAL PROVISIONS SUBPART B - BUILDINGS AND FACILITIES 21 CFR 110		CRITICAL	MAJOR	OBSERVATION
ITEM	REQUIREMENT			
B1	Grounds are maintained in a condition that will protect against contamination. (Sec 110.20 (a)).			
B2	Buildings and structure are suitable in size, construction, and design to facilitate maintenance and sanitary operations. (Sec 110.20(b)).			
B3	Buildings, fixtures, utensils, and other physical facilities of the plant are maintained in a sanitary condition and in good repair. (Sec 110.20(4) & 110.35(a)).			
B4	Adequate lighting, ventilation, and screening is provided. (Sec 110.20).			
B5	Substances used for cleaning, sanitizing and pest control are approved by MACOM when required and are properly marked and stored. (Sec 110.35(b)).			
B6	Adequate measures are taken to exclude pests from processing area and to protect against contamination of foods by pests, pesticides, and/or rodenticides. (Sec 110.35(c)).			
B7	Food contact surfaces are cleaned and sanitized as frequently as necessary and are properly stored to protect against contamination of food. (Sec 110.35(d)).			
B8	The water supply is sufficient and from a sanitary source. (Sec 110.37(a)).			
B9	The plumbing is adequate in size and is adequately installed and maintained. (Sec 110.37 (b)).			
B10	Sewage and rubbish are adequately disposed of. (Sec 110.37 (c) (f)).			
B11	Adequate toilet facilities are provided for employees. (Sec 110.37 (d)).			
B12	Adequate hand-washing facilities are provided at convenient locations. (Sec 110.37 (e)).			

TABLE III GENERAL PROVISIONS SUBPART C - EQUIPMENT AND UTENSILS 21 CFR 110		CRITICAL	MAJOR	OBSERVATION
ITEM	REQUIREMENT			
C1	All pieces of equipment and utensils are adequately cleanable. (Sec 110.40(a)).			
C2	Food contact surfaces are corrosion resistant and made of nontoxic materials. (Sec 110.40(a)).			
C3	Seams on food-contact surfaces are smoothly bonded or maintained so as to minimize the growth of microorganisms. (Sec 110.40(b)).			
C4	Surfaces of equipment, other than food contact surfaces, maintained in the food handling area, are constructed so they can be kept in a clean condition. (Sec 110.40(c)).			
C5	Holding, conveying and manufacturing systems are designed and constructed so that they can be maintained in an appropriate sanitary condition. (Sec 110.40(d)).			
C6	Adequate indicating thermometers, temperature-measuring devices, temperature-recording devices, and temperature controls are in place. (Sec 110.40(c)).			
C7	Instruments and controls used for measuring pH, water activity, or other conditions are accurate and adequate in number. (Sec 110.40(d)).			
C8	Compressed air or other gases that are mechanically introduced into food or used to clean food-contact surfaces are free of indirect food additives. (Sec 110.40(g)).			
C9	Equipment lubrication does not contaminate the product; only food grade lubricants are used in the food zone. (Sec 110.40(a)).			

TABLE IV GENERAL PROVISIONS SUBPART E - RAW MATERIALS AND OPERATIONS 21 CFR 110		CRITICAL	MAJOR	OBSERVATION
ITEM	REQUIREMENT			
E1	Raw materials and other ingredients are purchased from an approved source, protected from contamination and adulteration (intentional or otherwise) at all times. (Sec 110.80(a)).			
E2	Manufacturing operations are conducted under conditions and controls necessary to minimize the potential growth of microorganisms or contamination (intentional or otherwise) of foods. (Sec 110.80(a)).			
E3	Foods are maintained under conditions during warehousing and distribution, that will protect the food item and its container against physical, chemical, and microbial contamination (intentional or otherwise) as well as against deterioration. (Sec 110.93).			
E4	Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible food contamination. (Sec 110.80).			
E5	Methods to exclude physical contaminants are established and monitored (metal detector, visual screening, sieves). (Sec 110.80).			

TABLE V GENERAL PROVISIONS SUBPART G - DEFECT ACTIONS LEVELS 21 CFR 110		CRITICAL	MAJOR	OBSERVATION
ITEM	REQUIREMENT			
G1	Defect action levels are in compliance. (Sec 110.110 (a)-(e)).			

NOTE: See appendices for detailed information concerning defects for this subpart.

TABLE VI GENERAL PROVISIONS SUBPART H - HAZARD ANALYSIS and RECORD KEEPING		CRITICAL	MAJOR	OBSERVATION
ITEM	REQUIREMENT			
H1	Hazard analysis is performed, for all stages of production.			
H2	A Hazard Analysis Critical Control Point (HACCP) plan is written and implemented for each kind of product produced.			
H3	HACCP plan contains food safety hazards, critical control points, critical limits, monitoring procedures, corrective action plans, verification procedures and record keeping system.			
H4	Corrective action plan is followed or deviant product segregated.			
H5	Corrective actions are fully documented.			
H6	Records include all required information.			
H7	Records are reviewed, signed and dated as required.			
H8	Records are retained as required and are available and subject to public disclosure limitations.			
H9	Reviews are performed as required.			
H10	Overall verification is performed by a trained individual annually or as a process change is made and when the HACCP plan is modified.			
H11	Sanitation control and monitoring is performed and documented with sufficient frequency to ensure compliance with Current Good Manufacturing Practices (CGMP) checklists as listed in Part 110.			

Note: Reference to the controlling 21 CFR 110 sections are identified in parentheses in Table I through V above.

APPENDIX B
BAKERY

B.1 SCOPE

B.1.1 Scope. This appendix contains guidelines for auditing bakery facilities. The information contained herein is intended for guidance.

B.2 APPLICABLE DOCUMENTS

B.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that they must meet all specified requirements documents cited in this appendix, whether or not they are listed.

B.2.2 Non-government publications. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents which are DoD adopted, are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

BAKING INDUSTRY SANITATION STANDARDS COMMITTEE

Sanitation Standards for the Design and Construction of Bakery Equipment and Machinery, January 1994

(Application for copies should be addressed to the Baking Industry Sanitation Standards Committee, 401 N. Michigan Avenue, Chicago, IL 60611, e-mail: bakesan@aol.com.)

B.3 DEFINITIONS

B.3.1 Definitions. Definitions are contained in the basic handbook.

B.4 GUIDELINES

B.4.1 General. Upon arrival at the establishment remove all jewelry (i.e. watch, ring, etc.). Also be sure there are no extraneous items sticking out of your smock pocket that can drop off into the product during the inspection. Prior to or directly after the tour of the plant, walk completely around the facility looking for rodent/insect harborages and the ability for these pests to enter the establishment. Go up onto the roof of the establishment, and look for low-lying areas where water can pool. This is normally where leaks will occur. While on the roof be sure all vent covers are in place.

Recommended flow of tour. It is always beneficial to follow the flow of the product; however, some establishments might not want you to go from the dirty portion of their facility into the clean. Again, this is only a suggestion. Be sure to work out all details of the audit with

management in the pre-audit meeting. Depending on whether a bakery gets bulk deliveries, or sacks of flour will make a difference. Bulk deliveries can be railed or trucked in. If there is an unloading bay of some type at these establishments, be sure the product is protected during off-loading, and that piping is capped upon completion of the off-loading process. The bulk flour may, at this time, go through a sieve prior to being pumped into a silo. Ask if the establishment is testing any of their raw ingredients (i.e. ash testing for flour). Also, find out if the establishment is using any dairy products, egg products, liquid sugars etc. Be cognizant of any hazards these items can bring. Establishments using bagged flour should be using pre-sifted flour. If they are not, be alert to the possibility of an insect problem.

The mixing area should be next in the product flow. It can either be completely automated, or ingredients metered out and added by dumping into the mixer. If there is a formulation room be sure the product is protected until it is dumped into the mixer. (All ingredients should be covered when not in use.) After mixing, the dough may sit in troughs to rest. Be sure product is protected. Dough may then go into a proofer where it can rise. Proofers are hot, humid boxes whose environment is conducive to mold growth. (Dough would have been formed prior to entering the proof box.)

The dough is then formed and baked. Although baking is usually at high heat 500° F (260° C), be aware that the interior of the product never gets that hot. So, if mold is a problem in the establishment, it can be a problem in the finished product. The center of the item never reaches the temperature that the exterior of the product reaches. After exiting the oven there are no other kill steps; therefore, auditors should increase their vigilance looking for possible ways the product can be contaminated.

The product is usually cooled at this time by sitting on racks, or traveling along a conveyor with fans, or other cooling instrument blowing on the product. Fans should be clean and there should be no over-head contamination.

The product then goes through a slicer. (Be aware of where the metal detection device(s) fit into the flow of the process. Some establishments have them prior to slicing. If this is the case, there is the potential that the knife blade of the slicer may break off in the product, thus physically adulterating the end item.) After the metal detection device, product is packaged. (Many bakeries do this process by hand, so employees should have proper hand protection and hand washing sinks should be present in this area.)

B.4.2 Checklist. Guidelines for auditing bakery facilities are contained in the following checklist:

APPENDIX B

BAKERY CHECKLIST Baking Industry Sanitation Standards	
APPENDIX A PARAGRAPH	REQUIREMENT
C1	Where equipment passes through walls, ceilings or floors, sufficient clearance is provided between the equipment and the wall, ceiling or floor, and the opening is finished to permit cleaning, or the equipment is sealed to the adjoining surface. (A6).
C5	Product chutes at floor level are installed so that the rim is a minimum of 100mm (4 inches) above floor level. Such chutes are provided with overlapping covers. (A13).
C4	Pans used to collect spillage or drip are readily accessible or readily removable, and are large enough to catch all spillage or drips. Also, fixed pans used to collect liquid spillage or drip are readily accessible, have drains, and are pitched to ensure complete drainage away from the product zone. (A14).
C5	Liquid ingredient inlet pipes, valves and fittings are of sanitary take-apart type, unless designed for in-place cleaning, and are pitched for self-draining, back to the point where the line is continuously filled. (A21).
B2	A concrete curb is built around all floor-mounted washing equipment to confine leakage. (A27).
C5	Vents on equipment for handling and storing dry ingredients are protected against entry of foreign material, and are provided with readily removable filters to exclude particles of 5 microns or larger. (1-4.1.3).
C5	Screw conveyor housings are hinged or removable so that the area around the helical flights can be cleaned from the outside. Sufficient clearance is provided between the bottom of the screw housing and the floor to permit sufficient exposure of the screw for cleaning. The screw housings are dust-tight and readily accessible. (1-4.1.8).
C5	Straight run surfaces of pneumatic conveyors, valves and rotary feeders are smooth and readily accessible or removable, except that piping, tubing, valves or feeders which are self-purging are exempt from the requirements for accessibility. (1-4.3.1).
C8	The air supply for blowers or compressors is filtered to exclude particles of 5 microns or larger. (1-4.3.4).
E2	Dry product handling includes a sifter. (1-4.4.1).
C8	Separate conveying air systems are provided before and after an atmospheric sifter in the system. (1-4.4.2).
C1	A removable flexible connection is provided between the inlet to the hopper and the product delivery equipment. (1-4.5.1).
C5	Discharge piping and unloading hoses are equipped with caps. (1-4.8.3).
C5	Bearings are outside the product zone and are sealed or self-lubricated; and design and construction are such that lubricant cannot leak, drip or be forced into the product zone. (2-4.2.6).

BAKERY CHECKLIST - Continued.

C1	Flexible tubing is transparent or translucent. Nozzles are readily removable. (5-4.1.3).
C1	Pumps, valves, pipe fittings, including those used to insert thermometers and pressure gauge bulbs, are of the sanitary take-apart type and are readily accessible or removable. (5-4.1.10).
C5	Stationary mixer bowls drain completely. Close-coupled sanitary drain valves which are accessible or removable are provided. (6-4.2.11).
C1	The system for lubricating dough-contact surfaces, as distinct from the means of mechanical lubrication, has a reservoir readily accessible or removable for cleaning. Distribution lines, valves and pumps are removable for cleaning, or so designed as to permit Cleaning In Place (CIP). (8-4.2.6).
E2	Proofing cloths are smooth, except they may be of absorbent material, but are readily removable for laundering. An extra set of proofing cloths are provided. (16-4.1.1).
C5	Pumping, piping, valves and fittings used to dispense or convey frying fats, batter, glaze, icing, jellies and fillings are of sanitary take-apart type at least equal to 3A standards, and are accessible for inspection and cleaning. (16-4.1.16).
C1	The icing and/or glazing reservoir return is readily accessible and self-draining. (32-4.1.1).
C5	Drip or catch pans are provided under all product transfer points, as well as under cleaning attachments, and are readily removable. (32-4.1.6).
C4	Drip or catch pans are provided between overhead trolleys and product zone, on suspended monorail type cooler. (33-4.2.5).

NOTE: Reference to the controlling Baking Industry Sanitation Standards Committee are identified in parentheses.

APPENDIX C
MANUFACTURED DAIRY PRODUCTS

C.1 SCOPE

C.1.1 Scope. This appendix contains guidelines for auditing manufactured dairy products facilities. The information contained herein is intended for guidance.

C.2 APPLICABLE DOCUMENTS

C.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that they must meet all specified requirements documents cited in this appendix, whether or not they are listed.

C.2.2 Government publications. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

Code of Federal Regulations (CFR), Title 7, Chapter 1, Part 58.

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

National Institute of Standards and Technology, Handbook 44

(Application for copies should be addressed to National Institute of Standards and Technology, 110 Bureau Drive, Gaithersburg, MD 20899-0001, http://www.nist.gov/.)

C.2.3 Non-government publications. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents which are DoD adopted, are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)

ANSI/ASHRAE 52.1-1992 Gravimetric and Dust Spot Procedures for Testing Air Cleaning Devices Used in General Ventilation for Removing Particulate Matter

(Application for copies should be addressed to American National Standards Institute, 11 West 42nd Street, New York, NY 10036, http://www.ansi.org/.)

C.3 DEFINITIONS

C.3.1 Definitions. Definitions are contained in the basic handbook.

C.4 GUIDELINES

C.4.1 General.

Making natural cheese is an art, not just a process. Removing most of the milk solids from the milk by coagulating with rennet or a bacterial culture, the curd is separated from the whey by heating, then drained and pressed. Both milk and cream may be used to make different varieties of cheese, and often times, skim milk is used. It is important to know and document the type of milk used in the process to understand the distinctive flavors, body and texture of the end product. The basic steps in cheese making include:

(a) Preparation of the milk or cream used based on type
(b) Method used for coagulating
(c) Cutting, cooking and forming the curd
(d) Type of culture used
(e) Salting
(f) Ripening conditions

After the cheese is formed and shaped, usually it is coated with a wax or wrapped and then aged for a specific period of time, depending on the sharpness desired. Cheese is then classified into four primary varieties: Very Hard, Hard, Semi-soft or Soft.

Basic terms used in cheese making:

Cured: Flavor and texture characteristics are determined by the time enzymes and/or microorganisms are allowed to develop. The terms Mild, Medium or Sharp indicate ripening time and the expected flavor characteristic of the product. Mild cheese is cured for 2-3 months, softness and mild flavor. Medium cheese is cured for up to 6 months, mellow and smooth textured with a slightly nutty flavor. This is stronger than mild cheese. Sharp or "Aged" cheese is cured over 6 months, has a rich full bodied (strong) flavor.

Natural cheese: This cheese is the natural solids or casein portion of milk curd separated from whey, treated with organisms to impart flavor and cured over time.

Pasteurized process cheese: This cheese is a blend of fresh and already aged natural cheese. The aged cheese has been shredded, mixed with emulsifiers and then heated. Pasteurization halts the ripening process and the heat allows the cheeses to blend smoothly, creating uniform body,

flavor and texture. Blends may have one or more varieties of natural cheese and may also contain vegetable or meat (i.e. Jalapeno, Monterey Jack).

Pasteurized process cheese food: This cheese is prepared much the same as processed cheese except that it contains less cheese and more nonfat milk or whey solids and water. Cheese food has higher moisture content and lower milk fat.

Pasteurized process cheese spread: Cheese spread is made in the same manner as processed cheese food except that it contains less milk fat and has slightly higher moisture content.

Unripened fresh cheese: This cheese is not cured, thereby imparting a slight bland flavor. These cheeses are Cottage cheese, Cream cheese and Neufchatel cheese. The differences in Cream cheese and Neufchatel cheese are that Neufchatel contains less fat and more moisture. Both are made from milk and cream mixtures, pasteurized and coagulated with a lactic acid starter culture.

Common cheese varieties:

(a) Blue cheese - a semi-soft, made with whole milk; marbled with blue-green mold, white in color and spicy flavor.
(b) Brick - a semi-soft, made with whole milk; light yellow to orange color, shaped like a brick.
(c) Camembert - a semi-soft, made with whole milk; has and edible white crust, creamy yellow cheese interior and mild flavor.
(d) Cheddar (American) - a hard cheese made with whole milk; white to orange color, various shapes and wheel sizes; may be with a rind or without; mild to sharp aging.
(e) Colby - a hard cheese made with whole milk but slightly softer than Cheddar. Light yellow to orange in color; usually cylindrical with mild flavor.
(f) Cottage - a soft, creamy cheese made from skim milk; moist with large or small curds throughout. This is a white cheese, packaged in cups or tubs and slightly acidic in flavor.
(g) Cream - a soft cheese made from cream and whole milk. This cheese is white and usually packaged in foil blocks or in small tubs. The flavor is mild and slightly acidic.
(h) Edam - a hard type cheese, but softer than Cheddar and made from partly skimmed milk. Edam has a creamy yellow color and most often found in red wax coated blocks or small balls or wheels. This is a mild flavored cheese.
(i) Farmers (Pressed Pot) - a soft cheese made from partly skimmed milk. A white cheese, Farmers is a dry Cottage cheese pressed into paper packages. This is a mild flavored cheese.
(j) Gorgonzola - a semi-soft cheese made from whole milk. This cheese has a light tan color on the surface and light yellow interior. Similar to Blue cheese, this variety has blue-green mold marbling, a spicy flavor and usually is packaged in cylindrical shapes.
(k) Gouda - a hard cheese made from partly skimmed milk, but softer than Cheddar. A creamy yellow colored cheese, Gouda normally is packaged in red wax and round, yet flat. This cheese is very similar to Edam.

(l) Limburger - a soft cheese made with whole or partly skimmed milk. Limburger has a creamy white consistency with a highly aromatic property and robust flavor. This cheese is usually packaged in rectangular bricks.
(m) Monterey Jack - a semi-soft cheese made from whole milk. This is a creamy white colored cheese packaged in wheels or in rectangular bricks.
(n) Mozzarella - a semi-soft cheese made from whole or partly skimmed milk. Another creamy white cheese, with mild and delicate flavor. Usually packaged in rectangular or spherical wheels.
(o) Muenster - a semi-soft cheese made from whole milk. This cheese has a yellow, tan or white surface with a creamy white interior. This may be found packaged in small wheels or blocks, has a mild to mellow type flavor that varies between a Brick and Limburger cheese.
(p) Neufchatel - a soft cheese made from whole milk. White in color, this mild cheese is very similar to Cream cheese and packaged in small foil bricks or tubs.
(q) Parmesan - a hard cheese designed for grating made from partly skimmed milk. A light yellow cheese, Parmesan is covered with a brown or black coating. In bulk, this cheese is usually cylindrical with a very sharp flavor.
(r) Provolone - a hard cheese made from whole milk. This light golden brown cheese has a shiny surface and is tied (bound) with cord. The interior of the cheese is yellow-white; usually smoked and packaged in salami style shapes and packages.
(s) Ricotta - a soft cheese made from whey and whole or skim milk, or whole or partly skimmed milk. This cheese may be moist and packaged in containers or tubs. Some varieties are dried for grating purposes. A bland flavor is expected, but often also referred to as semi-sweet.
(t) Romano - a hard grating type cheese made from partly skimmed milk. This cheese has a black coating and usually is packaged cylindrically with flat ends. Romano is a sharp flavored cheese.
(u) Swiss - a hard cheese made from partly skimmed milk. This cheese is rindless in blocks and comes with a rind in large wheels. This cheese has a mild, sweet nutty flavor.

Storage and shelf-life: Cured cheese will keep well in refrigerated storage for long periods of time. The longer in storage, the sharper the flavor may become. The recommended storage temperature for cheese is 40° F (4° C). Natural cheese may develop mold spots which can be easily removed without damage to the cheese. Should the mold penetrate to the deep crevices of the cheese, the entire wheel or block may have to be discarded. Mold is desirable in some cheeses, such as Blue cheese, where the strong flavor originates. Pasteurized process cheese should always be refrigerated after opening. Most cheese may be stored in the freezer for short periods not exceeding two (2) months. Some varieties of cheese do not freeze well and will crumble after thawing. Pasteurized processed cheese can be stored in frozen conditions for up to four (4) months. Frozen storage of cheese should not exceed one pound block sizes and must be tightly wrapped to prevent drying.

Public health and cheese processing: The incidence of food-borne illness related to cheese is very small. Most often noted is the cheese processing and errors in manufacturing that contributed to the contamination of the product. Post pasteurization contamination of the cheese is an area of great concern in the cheese manufacturing operations.

Variety cross comparison of soft cheeses:

(a) Alouette: Boursin.
(b) Boursault: Boursin, Brillat-Savarin, Caprice des Dieux, St. Andre or Excelsior.
(c) Boursin: Boursault or Alouette.
(d) Brie: Camembert, Paglietta, Limburger.
(e) Brillat-Savarin: see Boursault.
(f) Brinza: Feta cheese is a good comparison. Armenian cheese.
(g) California Chevre: Chevre.
(h) Camembert: Brie, Paglietta, Limburger.
(i) Caprini: Chevre.
(j) Carre de l'Est: Camembert or Brie.
(k) Chaource: Camembert or Brie.
(l) Chevre: Montrachet, Mascarpone or Feta.
(m) Coulommiers: Camembert or Brie.
(n) Feta: Shevre, Ricotta, Queso Fresco, or Romano
(o) Gorgonzola: Roquefort, Stilton or Sago Blue cheese.
(p) Hand: Mainz, Harz, or Limburger.
(q) Harz: Mainz, Hand, Limburger, Mariolles, Livarot, Brick or Liederkrantz.
(r) Maytag Blue: any other blue-veined cheese.
(s) Paglietta: Camembert or Brie.
(t) Petit-Suisse: Boursin or Camembert.
(u) Pont l'Eveque: Camembert.
(v) Queso Anejo: Feta or Queso Fresco (Mexican).
(w) Ricotta Salata: (Italian) Feta.
(x) Robiola: Mix equal parts Ricotta and Mascarpone, or Taleggio.
(y) Stracchino (Crescenza): Taleggio (unripened version of Stracchino).
(z) Taleggio: Stracchino (ripened version of Taleggio) or Fontina.
(aa) Teleme: Brie.

Variety cross comparison of semi-soft cheeses:

(a) Asadero (Queso Asadero): Muenster, Jack or Mozzarella.
(b) Beaumont: Reblochon, Havarti, or Port du Salut.
(c) Bel paese: Fontina, Gouda, Samsoe, Brick, Jack, Meunster or Mozzarella.
(d) Bleu de Bresse: Roquefort.
(e) Blue cheese: Gorgonzola.
(f) Brick: Lagerkaese, Liederkranz, Bel Paese, Limburger.
(g) Caciocavallo: Provolone, Scarmorza, or Mozzarella.
(h) Cantal: Monterey Jack.
(i) Danish Blue: Roquefort.
(j) Esrom: Havarti, Tilsit, Port Salut or Saint Paulin.
(k) Excelsior: Boursault or Brillat-Savarin.
(l) Farmer's cheese: Jack or Muenster.
(m) Gouda: Edam, Samsoe, Bel Paese, Jack, Muenster.

(n) Haloumi: Mozzarella.
(o) Havarti: Tilsit, Esrom or Port Salut.
(p) Jack: Montery Jack, Sonoma Jack - Muenster, Gouda, Bel Paese or Samsoe.
(q) Lagerkaese: Brick or Limburger.
(r) Laguiole: Monterey Jack.
(s) Livarot: Maroilles, Limburger, Harz, Mainz, Hand, Brick, or Liderkranz.
(t) Morbier: any other semi-soft cheese.
(u) Mozzarella: Scarmorza, Cacciocavallo, string cheese, Queso Blanco, Provolone.
(v) Muenster: Jack, Brick, Port du Salut, Bel Paese.
(w) Oka: any other semi-soft cheese.
(x) Oregon Blue: other blue-veined cheese.
(y) Pipo Crem': other blue-veined cheese.
(z) Port Salut: Saint Paulin, Esrom, Havarti, Jack, Muenster, Brick, Bel Paese.
(aa) Provolone: Cacciocavallo, Scamoraza, Mozzarella.
(bb) Queso Blanco: Mozzarella, Meunster.
(cc) Reblochon: Beaumont, Esrom, Beaufort, Tomme, Raclette, Port Salut or Fontina.
(dd) Ricotta, solid: buffalo-milk Mozzarella.
(ee) Roquefort: Gorgonzola, Stilton.
(ff) Saint Paulin: Port Salut, Esrom or Havarti.
(gg) Samsoe: Gouda or Bel Paese.
(hh) Sarmorza: Mozzarella, Cacciocavallo, or Provolone.
(ii) String cheese: Mozzarella.
(jj) Syrian cheese: Jack or Muenster.
(kk) Tilsit: havarti, Esrom or Port Salut.
(ll) Tomme: Reblochon, Beaufort or Gruyere.

Variety cross comparison of semi-firm (hard) cheeses:

(a) Abondance: Fontina or Appenzell.
(b) American: Cheddar, Colby, Longhorn or Tallamook
(c) Appenzell: Emmentaler, Gruyere, Raclette, or Fontina.
(d) Asiago: any other semi-firm cheese.
(e) Beaufort: Emmenthal, Gruyere, Tomme or Reblochon.
(f) Caerphilly: Cheddar.
(g) Cantal: Cheddar, Gruyere or Monterey Jack.
(h) Cheddar: Colby, Tillamook, Cheshire, American.
(i) Chesire: Cheddar.
(j) Colby: Cheddar, Tillamook, American.
(k) Comte: Emmentaler.
(l) Coon: Cheddar.
(m) Danbo: Samsoe or Cheddar.
(n) Derby: Cheddar.
(o) Derby Sage: Vermont Sage.
(p) Double Gloucester: Cheddar.

C.4.2 Checklists. Guidelines for auditing manufactured dairy products facilities are contained in the following checklists:

APPENDIX C

MANUFACTURED DAIRY PRODUCTS CHECKLIST CFR Title 7, Chapter 1, Part 58	
APPENDIX A PARAGRAPH	REQUIREMENT
E2	Graded product is marked, labeled, and handled in accordance with Part 58.
B2, B3	Building and facilities are maintained for laboratory, starter rooms, grading rooms, etc. in accordance with 58.126.
C5	All CIP systems, weighing and receiving tanks comply with 3-A accepted practices in accordance with 58.128.
C7, C8	If applicable, all can washers, associated water and steam lines are equipped and maintained for proper temperature and pressure controls. Steam pressure is not less than 80 lbs and the final rinse is an automatically controlled system, and does not exceed 140º F (60° C). (58.128 (c)).
C7, H6	All scales comply with the National Institute of Standards and Technology Handbook 44 (latest version) and are accurate to the specifications of 58.128 (m).
E1, E4, H6	Raw milk conforms to basic quality and classification specifications of 58.132 - 133 and is tested at the frequencies required, and records are maintained in accordance with 58.134 - 139.
C5	Receiving, holding, and processing of milk and cream and the manufacturing, handling, packaging, storing, and delivery of dairy products is in accordance with Part 58.
H8	Records are maintained for all required tests and analyses in accordance with 58.148.
C5	Sanitary seal assemblies are removable on all agitators, pumps, and vats, and are inspected at regular intervals and kept clean. (58.146 (a)).
E4, H6	Packaging room atmosphere is practically free from mold and verified in accordance with 58.151.
E1	Salt is free flowing, white, refined sodium chloride, and meets the requirements of Food Chemical Code 58.
E1	Color, if used, is annatto or other color approved by US FDA. (58.329).
B2, B4, H6	A separate starter room or properly designed starter tanks with satisfactory air movement is provided. The air supply is filtered to 90% efficiency in accordance with ASHRAE Synthetic Dust Arrestance Test. (58.406).
E4, H6	Mold counts for make rooms are not more than 15 colonies per plate/15 minutes. (58.407).
B2	Brine room is separately constructed with minimum corrosion. (58.408).
B2	Adequate shelving, air circulation, temperature and humidity control is provided and maintained in drying rooms. (58.409) (cheese plants only).
B2	Separate rooms are provided for packaging and boxing; maintained at proper temperature to prevent sweating prior to paraffining. (58.410) (cheese plants only).

MANUFACTURED DAIRY PRODUCTS CHECKLIST - Continued.

B2	Separate rooms are provided for preparation of bulk cheese to be cut and wrapped into smaller packages. Air movement is outward moving. (58.413) (cheese plants only).
C6	Bulk starter vats are equipped with tight fitting lids and have adequate temperature controls and indicating/recording devices. (58.414).
C1, C2, C3	Vats, tanks, and drain tables are constructed of 16 gauge steel or equally corrosion resistant metal, properly pitched, welded, and fitted with sanitary outlets and valves for maintenance of heat to the lines. Auto curd makers, cyclone separators, conveying systems, and curd fillers are properly constructed and maintained.
C1	Mechanical agitators, shields, shafts, hubs, blades, forks, and stirrers are in accordance with 3-A Accepted Standards.
C1, C8	Automatic salters meet the specific requirements (salting method, design, and steam quality) of 58.418 (cheese plants only).
B4	Hoop and barrel washing equipment is vented to the outside. (cheese plants only).
C1, C2, C3	All hand utensils, knives, racks, shovels, scoops, paddles, strainers and other miscellaneous equipment meets 3A Sanitary Standards. Wires in curd knives are stainless steel, tight, and replaced as necessary. (58.419).
C1	Reuse of single service press cloths is prohibited. (58.421) (cheese plants only).
E2	Brine tanks, vacuumizers, and monorail systems do not contribute to the contamination of the product. (58.422, 423, and 424).
C7, E2	Cheese wax is kept clean. Paraffin tanks are of adequate size, fitted with wooden racks, and have heat controls and an indicating thermometer. (58.427) (cheese plants only).
E1, H6	Hydrogen peroxide, catalase, cheese cultures, and calcium chloride comply with the specifications of 58.431, 432, and 433.
E1	Rennet, pepsin, and other milk clotting/flavor enzymes meet the requirements of 58.436.
E4	Each vat and representative sample of finished product is analyzed for milk fat, moisture, and weight/volume control.
E2	Based on the variety of products produced, the stated quality, identity, and analytical requirements of Part 58 are met.

NOTE: Reference to the controlling CFR Title 7, Chapter 1, Part 58 sections are identified in text or parentheses above.

APPENDIX D
FLUID DAIRY

D.1 SCOPE

D.1.1 Scope. This appendix contains guidelines for auditing fluid dairy facilities. The information contained herein is intended for guidance.

D.2 APPLICABLE DOCUMENTS

D.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that they must meet all specified requirements documents cited in this appendix, whether or not they are listed.

D.2.2 Government documents. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

U.S. Public Health Service Publication 229 Grade "A" Pasteurized Milk Ordnance (PMO), 1997 Revision

(Application for copies should be addressed to U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Milk Safety Branch, 200 C Street SW, Washington, DC 20204.)

CODE OF FEDERAL REGULATIONS (CFR)

Code of Federal Regulations (CFR), Title 21, Part 173.

(Application for copies should be addressed to Superintendent of Public Documents, U.S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

D.3 DEFINITIONS.

D.3.1 Definitions. Definitions are contained in the basic handbook.

D.4 GUIDELINES

D.4.1 General. Vat Pasteurization Systems. The following are areas that need to be evaluated when determining if the vat pasteurization systems meets PMO standards 16p(A):

- Outlet Valves -
  - Constructed of solid stainless steel.
  - Leak protector type - designed to prevent leakage past the valve body.
  - Leak detector groove - at least 3/16 inch in width and 3/32 inch in depth.
  - Stop - required to ensure complete closure during operation.
  - Outlet - close coupled to prevent the accumulation of non-pasteurized milk when closed.
  - All valves must be kept closed during - filling, heating, and holding periods.
- Covers -
  - Designed to prevent the entrance of surface contamination.
  - Openings must have raised lips and the covers must overlap.
  - Pipes, agitator shafts, thermometer, etc. must have aprons that divert condensation.
- Agitators –
  - Must insure each particle of milk is heated (not to exceed 1° F (0.5° C)) between two product locations in the vat).
  - Agitator shaft opening must be large enough to allow shaft removal and cleaning.
- Indicating and Recording Thermometer –
  - Compared to each other daily and results recorded on the recording chart.
  - Recording thermometer does not read higher than the indicating thermometer.
  - Should not read less than the pasteurization temperature throughout the holding time.
- Airspace Heater and Thermometer -
  - Air space thermometer bulb 1 inch/25 millimeters or more above product during processing.
  - Record the airspace temperature on the recording thermometer chart each batch.
- Recording Chart (retained for three months) –
  - Date.
  - Number and location of recorder when more than one is used.
  - Extent of holding time including filling and emptying times.
  - Reading of airspace thermometer, within the holding period, at a given time and reference point.
  - Reading of indicating thermometer, within the holding period, at a given time and reference point.
  - Quarterly, the initials of the regulatory agency opposite the required readings of the indicating and airspace thermometers.
  - Quarterly, time and accuracy of the recorder, as determined by the regulatory agency.
  - Amount and name of product represented by batch or run.
  - Any unusual occurrences.
  - Signature or initials of the operator.
  - Name of plant.

- General –
  - If at any time during pasteurization the process is interrupted, the timing process must be restarted.
  - No ingredients are added during pasteurizing.
  - At no time during or after pasteurization may piping be attached to the vat that is also attached to a line or vessel containing raw milk or any other contaminating substance.

High Heat Short Time (HHST) Pasteurization Systems. The following are areas that need to be evaluated when determining if the HHST pasteurization systems meets PMO standards 16p(B):

- Constant Level Supply Tank (Balance Tank) –
  - Overflow level below the lowest level of raw milk in the regenerator.
  - All re-circulation lines, divert lines, and leak detect lines must have an air gap.
  - NLT twice the size of the line coming into the balance tank.
- Flow Promoting Devices –
  - Must be located upstream from the holding tube unless a vacuum breaker is installed between the end of the holding tube and the flow promoting device.
  - Air break must rise NLT 30 cm/1 ft higher than any raw milk downstream from the balance tank.
  - Flow promoting device controlling the holding time is connected to the metering pump and sealed.
  - When a homogenizer is used as the timing pump it will be sealed (see specific requirements).
  - Metering or timing pump; positive displacement type or comply with the magnetic flow meter system.
  - Manual switches for pumps that produce flow through the holding tube must be wired so they only operate when the milk is above pasteurization temperature.
  - Booster pump must shutdown in divert flow.
- Plate Heat Exchanger (Regen) –
  - Designed to be self-draining back to the balance tank during shutdown.
  - Designed so that the pasteurized product is under higher pressure than raw milk and other mediums in the system.
  - Gauges installed at the raw milk/medium inlet and pasteurized product outlet.
  - If 1 psi differential is not maintained system diverts, inter-wired with the flow diversion device.
- Design of pressure gauges (pressure differential gauges installed and a scale NMT 13.8 kPa/2 lbs per sq inch on the working scale NMT 138 kPa/20 lbs per sq inch per 25.4 ml/inch).
- Holding Tube –
  - Diameter of 17.8 cm/7 inches or less and free of fittings.
  - Continuous upward slope NLT 2.1 cm per meter/0.25 inches per foot.
  - No devices installed that can alter the holding time.
  - No portion of the holding tube may be heated, wrapped, or otherwise enclosed.
  - High viscosity products; holding time is calculated at twice the length required (laminar flow).

  - When steam injection is used a pressure indicator/pressure switch is required.
  - (pressure below 69 kPa/10 psi the system will divert, inter-wired with flow diversion device.)
- Indicating and Recording Thermometers –
  - Indicating thermometer is located as near as possible to the recording thermometer (indicating thermometer is first in the line).
  - The two thermometers are compared daily by the plant operator and recorded.
  - Recording thermometer does not read higher than indicating thermometer.
  - Recording thermometer inter-wired with the flow diversion device.
  - For specific thermometer scale, accuracy, etc., see Appendix H of the PMO.
- Flow Diversion Device –
  - Located NMT 46 cm/18 inches downstream from the recording thermometer.
  - Designed and installed so that when power is lost the system diverts (spring closure).
  - Leak escape installed on the forward flow side of the valve seat (no back pressure).
  - Leak escape installed between two valve seats or two portions of the same seat (back pressure).
  - When the leak escape line goes to the balance tank; an air break at the end and a sight glass in the line.
  - Leak detect line is self-draining.
  - Inter-wired with the booster pump.
- Recording Chart (retained for three months) –
  - Date.
  - Number or location of recorder, when more than one is used.
  - Reading of indicating thermometer, within the holding period.
  - Quarterly, the initials of the regulatory agency opposite the reading of the indicating thermometer.
  - Record of the time during which the flow diversion device is in the forward flow position.
  - Cut-in and cut-out temperature recorded daily at the beginning of the run (initialed quarterly by the regulatory agency).
  - Quarterly, time accuracy of the recorder.
  - Amount and name of pasteurized product represented by the chart.
  - Record of unusual occurrences.
  - Signature or initials of the operator.
  - Name of plant.

HHST and Aseptic Pasteurization Systems. The following are areas that need to be evaluated when determining if the HHST and Aseptic pasteurization systems meets PMO standards 16p(C):

- Constant Level Supply Tank (Balance Tank) –
  - All re-circulation lines, divert lines, and leak detect lines must be have an air gap.
  - NLT twice the size of the line coming into the balance tank

- Flow Promoting Devices –
  - Must be located upstream from the holding tube unless a vacuum breaker is installed between the end of the holding tube and the flow promoting device.
  - * The requirement for an air break rising NLT 30 cm/1 ft above the highest raw milk downstream from the balance tank may be eliminated if a differential pressure controller is used. And all product contact surfaces between the holding tube and the diversion device are held at or above pasteurization temperature for at least the required pasteurization time.
  - Flow promoting device controlling the holding time is connected to the metering pump and sealed.
  - When a homogenizer is used as the timing pump it will be sealed (see specific requirements).
  - Metering or timing pump; positive displacement type or comply with the magnetic flow meter system.
  - Manual switches for pumps that produce flow through the holding tube must be wired so they only operate when the milk is above pasteurization temperature.
  - * Booster pump can run during divert flow.
- Plate Heat Exchanger (Regen) –
  - Designed to be self-draining back to the balance tank during shutdown.
  - Designed so that the pasteurized product is under higher pressure than raw milk and other mediums in the system.
  - Gauges at the raw milk/medium inlet and pasteurized product outlet.
  - If 1 psi differential is not maintained system diverts, inter-wired with the flow diversion device.
  - * Design of pressure gauges (pressure differential gauges installed and a scale NMT 13.8 kPa/2 lbs per sq inch on the working scale NMT 138 kPa/20 lbs per sq inch per 25.4 ml/inch).
  - * Raw product booster pump may be permitted to run in divert flow if the metering pump is operating.
- Holding Tube –
  - Diameter of 17.8 cm/7 inches or less and free of fittings.
  - Have a continuous upward slope NLT 2.1 cm per meter/0.25 inches per foot.
  - No devices installed that can alter the holding time.
  - No portion of the holding tube may be heated, wrapped, or otherwise enclosed.
  - * High viscosity products; holding time is calculated at twice the length required (laminar flow).
  - * Holding time must be calculated rather than measured.
  - * When forward flow can be maintained with less than 518 kPa/75 psi pressure the holding tube is equipped with a pressure limit indicator/pressure switch (to ensure product remains in liquid state).
  - Inter-wired with the flow diversion device.
  - * Steam injection process requires a differential pressure indicator across the injector (inter-wired with the flow diversion device to divert if pressure is less than 69 kPa/10 psi).

- Indicating and Recording Thermometers –
  - Each aseptic system has at least one mercury-in-glass thermometer or equivalent.
  - Indicating thermometer is located as near as possible to the recording thermometer.
  - Indicating thermometer is first in the line.
  - The two thermometers' readings are compared daily by the plant operator and recorded (recording thermometer does not read higher than the indicating thermometer).
  - Recording thermometer inter-wired with the flow diversion device.
  - For specific thermometer scale, accuracy, etc. see Appendix H of the PMO.
- Flow Diversion Device –
  - Located NMT 46 cm/18 inches downstream from the recording thermometer.
  - Designed and installed so that when power is lost the system diverts (spring closure).
  - Leak escape installed on the forward flow side of the valve seat (no back pressure).
  - Leak escape installed between two valve seats or two portions of the same seat (back pressure).
  - If leak escape goes to the balance tank an air break at the end and a sight glass in the line is required.
  - Leak detect line is self-draining.
  - Inter-wired with the booster pump.
- Recording chart (retained for three months) –
  - Date.
  - Number or location of recorder, when more than one is used.
  - Reading of indicating thermometer, within the holding period.
  - Quarterly, the initials of the regulatory agency opposite the reading of the indicating thermometer.
  - * Record of the time during which the flow diversion device is in the forward flow position.
  - Quarterly, time accuracy of the recorder.
  - Amount and name of pasteurized product represented by the chart.
  - Record of unusual occurrences.
  - Signature or initials of the operator.
  - Name of plant.
  - * NMT 1 working day after processing, a member of management reviews, signs or initials, and dates the recording thermometer chart.
- General –
  - If heating by direct addition of steam, the steam boiler is equipped with a de-aerator.
  - * All product surfaces from the holding tube to the flow diversion device must be at pasteurization temperature for the required time to get into forward flow.
  - * Vacuum breaker not required after the pasteurization side of the regen.

Note:
* Indicates issues only related to HHST and aseptic systems.

D.4.2. Sources of manufactured and processed diary products. Establishments listed in the "Dairy Plants Surveyed and Approved for USDA Grading Service" may serve as sources of

manufactured or processed dairy products as listed by product code. Those operations denoted with "P" codes (packaging and processing) must be Directory-listed when providing ungraded manufactured or processed dairy products. When veterinary or medical personnel inspect "P" coded establishments providing ungraded products, the inspector must verify the source of raw materials being processed and packaged. (This publication is on the Web at http://www.ams.usda.gov/dairy/dypubs.htm/.)

D.4.3. Sources of milk and milk products. Establishments listed in the "Sanitation Compliance and Enforcement Rating of Interstate Milk Shippers (IMS) List" may serve as sources (as listed) of milk and milk products. Listing in another approved source document is mandatory to serve as a source of other milk and milk products and/or frozen dessert items. In addition, the IMS List must include establishments producing both fresh milk products and frozen desserts before military sanitary inspection for frozen desserts. If the IMS List does not include the facility, the inspector must cover both processing operations. If the Food and Drug Administration (FDA) removes a Directory of local listed frozen dessert establishment from the IMS List, the Commander will recommend the establishment for removal from the Directory or local list. A commercial establishment previously listed in the IMS List and delisted for cause, or initially disapproved for listing, will not be inspected for listing in the Directory. Verify the status of the establishment by calling the State Grade A Milk Sanitation Regulatory official. (This publication is on the Web at http://vm.cfsan.fda.gov/~ear/mlist.html/.)

D.4.4. Commercial dairies located outside the United States.

- Dairy plants outside of the United States will not be approved if they do not provide public health protection equivalent to the U.S. Public Health Service Pasteurized Milk Ordinance (PMO)/3-A Sanitary Standards.
- Dairy farm inspections are not required in Australia and New Zealand. Both countries are free of Bovine Brucellosis and Tuberculosis and have good farm inspection programs.

D.4.5 Deviations from the PMO: The following are issues that may be encountered in dairy plants were the PMO is normally not applied (primarily overseas). The deviations discussed below are intended to meet the food safety concerns of the PMO even though they do not meet the PMO exactly. No deviation can be accepted automatically and must be evaluated as it relates to the entire process and the final product. The auditor must ensure that authorized deviations do not (at the point of the change or elsewhere in the system) violate the intent of the PMO. At first glance a deviation from the PMO in one area may seem harmless, however most systems are highly interactive, and an unacceptable effect may result elsewhere in the system.

D.4.5.1 Issue: As part of the dairy plant audit, the raw milk source must be evaluated.

Deviations: The approval of the raw milk source(s) will be based on a review of the host nation farm inspection program, herd health issues, testing of the raw milk supplies, etc. Antibiotics require special mention here. Traditional residue tests are only sensitive for penicillin and its relatives because those have been the only drugs approved in most western countries. However, aminoglycosides, macrolids, and other potentially dangerous classes of drugs are often the drugs of choice in developing countries. They are usually cheaper and more effective. Currently, the

Charm II system is recommended for the detection of chloramphenicol, kanamycin, and other prohibited antibiotic residues. PenZyme and Delvo tests are not sensitive enough to detect therapeutic levels of these drugs. Similarly, insecticide use is a concern. DDT and other dangerous organochlorides are in daily use in much of the developing world. Farm visits are a good opportunity to check for prohibited antibiotics and pesticides, but most overseas dairies buy from a milk shed. In most cases, this practice will prohibit the approval of a dairy who packages milk procured from a shed or collective because it is impossible to verify farm practices. Australia and New Zealand are exceptions because farm practices are tightly regulated by skilled, independent auditors. After it has been determined that all the raw milk is coming from a country/area that has been deemed acceptable, then the dairy plant can be audited.

D.4.5.2 Issue: The highest level of raw milk in the constant level must be lower than the lowest point of raw milk in the regenerator. The regenerator must be set up so that the raw milk in the regenerator drains freely back to the raw milk constant level tank during shutdown (holes drilled in the bottoms of the plates).

Deviations: The entire regeneration system must be Cleaned-In-Place (CIP) in the event of a shutdown for any reason, prior to resuming processing (going into forward flow).

D.4.5.3. Issue: All lines (such as re-circulation lines) that go from the pasteurized side of the system to the non-pasteurized side must have a physical break to ensure raw milk is not pulled back in the system on the pasteurized side. For example, re-circulation lines that run from the pasteurized side of the system to constant level tank can allow raw product to be sucked into the pasteurized system. This can occur if the re-circulation line is not cut off above the overflow on the constant level tank and there is a drop in pressure on the pasteurized side of the system.

Deviation: Re-circulation line (and other such lines) can have a hole drilled in them at a level above the overflow on the constant level tank. The hole must be of adequate size as to ensure product is not drawn back into the pasteurized side of the system should a pressure drop occur on the pasteurized side of the system.

D.4.5.4. Issue: The flow diversion valve should not be more than 46 centimeter (18 inches) down stream from the recording thermometer.

Deviation: When the flow diversion valve is more than 46 centimeters down stream from the recording thermometer, the system must have a delay sufficient enough to ensure all sub-legal product is past the flow divert valve prior to the valve going into forward flow. The time delay must be part of the routine testing of the system. In addition, the minimum temperature (cut-out) should be raised by 4° F (2° C) to ensure proper temperature for pasteurization. The time delay does not apply to the valve going into divert flow, the PMO standard of not more than 1 second stands.

D.4.5.5. Issue: The PMO does not authorize the use of computers as a sole means of operating public health controls on pasteurization system.

Deviation: All public health controls on the pasteurization system will be required to be hardwired and tested as indicated in the PMO. However, the computer can be used to operate the pasteurization system using more restrictive settings. This would allow the computer to control the system prior to hardwired controls taking place. The hardwired controls will need to be tested per the PMO.

D.4.5.6. Issue: The majority of the tests required by the PMO are to be performed every three months.

Deviation: In areas where Veterinary Auditors are not assigned/located, quarterly testing may not be possible. Dairy plants are required to have their own PMO equivalent test equipment. And a minimum of one employee must be trained in performing the PMO tests. That person(s) will perform the tests (if a Veterinary Auditor is not available) when there is a change in equipment or procedures that effect a portion of the process that would normally be sealed by a regulatory agency. They may also test the equipment if there is a three-month period when a Veterinary Auditor is unable to perform the testing. However, at a minimum Veterinary Auditor will perform or assist in the performance of the testing every other three-month period. It is highly recommended that more than one person per dairy plant be trained in performing the PMO tests. Only those dairy personnel trained and approved will be authorized to test equipment in the absence of a Veterinary Auditor.

D.4.5.7. Issue: Anytime there is a change to the pasteurizing system that effects a portion of the equipment that would normally be sealed, that portion of the system must be tested prior to further processing. This is not possible in locations where a Veterinary Auditor is not readily available.

Deviation: Equipment will not be sealed, however, dairies will be required to test their own equipment in accordance with the PMO, if there are changes to the system. The testing must be done by a trained/approved plant employee and prior to any further processing. All equipment changed, adjustments made, and the testing results (to include the name of the person performing the test) will be full documented. This information will be made available to the Veterinary Auditor during the next audit.

D.4.5.8. Issue: On a daily basis the plant operator is required to compare the recording thermometer to the indicating thermometer and check the cut-in and the cut-out temperatures. The results are to be written on the recording thermometer chart along with the initial of the plant operator that performed the checks. For systems without a recording thermometer that can be written on, this may not be possible.

Deviation: If the recording thermometer chart can not be written on at the time of the checks, a log with all the necessary information may be used. This may be the case with computer operated systems where the information prints out at a different location. However, the log must be compared to the printout (recorded information) and the printout signed by a supervisor prior to the product being release.

D.4.5.9. Issue: The holding tube is designed so that no sections of pipe can be left out resulting in a shortened holding time. And the holding tube does not have a device in any portion of it that permits a shortened holding time. For dairies that process several types of products on the same pasteurizer, changing the holding tube length may be necessary.

Deviation: If the holding tube is designed so that the length or diameter can be changed, the system must be tested using all holding tube options. Plant management must demonstrate a method of controlling the type of holding tube used for every process/product. For holding tubes with devices in them that can alter the holding time, a method such as hardwiring the device to the controller program must be in place and tested.

D.4.6 Checklist. Guidelines for auditing fluid dairy facilities are contained in the following checklist.

APPENDIX D

FLUID DAIRY CHECKLIST USPHS Publication 229 (PMO) and CFR Title 21, Part 173	
APPENDIX A PARAGRAPH	REQUIREMENT
E1	Milk originates from herds accredited tuberculosis-free, brucellosis-free, and from countries/regions determined to be acceptable. (Sec. 8).
B7, H6	A system of tagging or recording tanker trucks that have been cleaned and sanitized is established and maintained for 15 days. (Sec. 7, Item 12p).
E1	Upon arrival, raw milk and/or raw products for pasteurization complies with bacteriological, chemical and temperature standards of Sec. 7, Table 1.
E4	Raw milk and milk products are screened for drug residue. (Sec. 6).
E2	Raw milk and milk products are held at 45° F (7° C) until processed. (Sec. 7, Item 17p).
C3	Welded portions of food contact surfaces are smooth and free from pits, cracks, or inclusions. (Sec. 7, Item 10p).
C2	All milk contact surfaces of multi-use containers and equipment are constructed of American Iron and Steel Institute (AISI) 300 series stainless steel or other non-corrosive material as described in the Pasteurized Milk Ordinance (PMO). (Sec. 7, Item 11p).
C5	Equipment is designed to protect against surface and overhead contamination. (Sec. 7).
B7	Storage tanks are cleaned when emptied and are emptied at least every 72 hours. (Sec. 7, Item 12p).
C7	Storage tanks used to store raw milk or heat-treated milk products are equipped with a 7 day temperature recording device. (Sec. 7, Item 12p).
C5	Equipment complies with the sanitary design and construction standards of the PMO. (Sec. 7).
E2	The overflow of the top rim of the constant level raw milk tank is lower than the lowest milk level in the regenerator. (See High Heat Short Time (HHST) exception) (Sec. 7, Item 16p(D)).
E2	Raw milk in the regenerator drains back to the constant-level tank. (Sec. 7, Item 16p(D)).
E2	The pasteurized side of the regenerator is always under higher pressure than the raw side. (Sec. 7, Item 16p(D)).
E2	An atmosphere break exists at least 30.48 centimeters above the raw milk. (See HHST exception) (Sec. 7, Item 16p(D)).
E2	There is no flow promoting device between the regenerator and the air-break. (Sec. 7, Item 16p(D)).
E2	There is no pump between the raw milk inlet to regenerator and the raw milk supply tank. (See HHST exception) (Sec. 7, Item 16p(D)).

FLUID DAIRY CHECKLIST - Continued.

E2	The holding tube slope in the direction of flow is at least 2.1 centimeters per meter (0.25 inches per foot). (Sec. 7, Item 16p(B)).
E2	The holding tube is designed so that no deviations can be made to the flow rate or holding time. (Sec. 7, Item 16p(B)).
E2	The flow control sensor (Recording Thermometer) is not more than 46 centimeters (18 inches) up stream from the control device. (Sec. 7, Item 16p(B)).
E2	The indicating and recorder thermometers are properly located. (Sec. 7, Item 16p(B)).
E2	The flow diversion devices are properly installed and functioning. (Sec. 7, Items 16p(B)(C)).
E2	The flow promoting devices are properly located and of the proper speed, displacement, and capacity. (Sec. 7, Item 16p(F)).
E2	Pasteurized milk is not strained or filtered except through a perforated metal strainer. (Sec. 7, Item 15p(A)).
E2	Manual valves meet PMO standards (stop/leak grove/close coupled). (Sec. 7, Item 16p(A)).
E2	Pasteurization equipment and controls testing is performed in accordance with the PMO. (Appendix I).
H8	Pasteurization recording charts are maintained on file at the processing plant. (Sec. 7, Item 16p(E)).
C7	Thermometers meet requirements. (Sec. 7, Item 16p(A) & 16p(B), Appendix H).
E2	Air space heating is accomplished when required for Batch Pasteurization. (Sec. 7, Item 16p(A)).
E2, H8	Recording charts are complete and maintained. (Sec. 7).
C8	Culinary steam is in accordance with PMO. (Sec. 7, Item 16p(B)).
B8	Boiler water additives comply with 21 CFR 173.310.
C8	Air under pressure is in accordance with 3-A Accepted Practices. (Appendix H).
E2	There is no cross-connection or direct contamination of pasteurized milk or milk product. (USPHS Publication 229).
B6, C5	All openings, including valves, pipes, milk tanker trucks, etc. are capped or otherwise protected. (Sec. 7, Item 15p(A)).
E5	Filling lines are equipped with a device capable of detecting, in each container before filling, volatile organic contaminants. The device is interconnected so that the system will not operate unless the detection device is operational. (Sec. 7, Item 12p).
E2, E5	Recirculated cooling water is protected from contamination. (Appendix G).
E4	Recirculated cooling water is tested once per six-month period. (Appendix G).
C7	Clean-In-Place (CIP) systems are in compliance with PMO. CIP systems have a recording device installed in the return solution line or other appropriate area to record the temperature and time at which the line or equipment is exposed to cleaning and sanitizing solution (retained for 3 months) (Sec. 7, Item 12p).

FLUID DAIRY CHECKLIST - Continued.

H6, H7, H8, H9	Record of CIP cleaning process is maintained for recirculated cleaning systems. (Sec. 7, Item 12p).
C7	During processing, pipelines and equipment used to conduct milk are effectively separated from cleaning and sanitizing solutions (see the PMO for methods). (Sec. 7, Item 15p(B)).
B3	Plants where containers are manually cleaned have a two compartment sink and a steam cabinet to sanitize containers or a three compartment sink if a chemical sanitizer is used. (Sec. 7, Item 12p).
E4, H8	Pasteurized milk and/or milk products comply with bacteriological, chemical and temperature standards of Sec. 7. Results are recorded and records maintained. (Sec. 7, and Table 1.)
E2	Pasteurized milk and milk products are cooled to 45° F (7° C) and maintained at that temperature. (Sec. 7, Item 17p)
E4, H8	Residual bacteria counts for multi-use and single-service containers meet the standards listed in the PMO. Results are recorded and records maintained. (Sec. 7, Item 12p).
E1	Packaged milk and milk products which have physically left the premises or processing plant are not repasteurized for Grade A use (see the exception) (Sec. 7, Item 15p(A)).
B5	Poisonous or toxic materials are not stored in any room where milk or milk products are received, processed, pasteurized or stored. (Sec. 7, Item 15p(A)).
B5	Only approved rodenticides and insecticides are used. (Sec. 7, Item 15p(A)).

NOTE: Cited reference documents for the above are U.S. Public Health Service Publication 229 and 21 CFR 173.

APPENDIX E
EGGS

E.1 SCOPE

E.1.1 Scope. This appendix contains guidelines for auditing egg processing facilities. The information contained herein is intended for guidance.

E.2 APPLICABLE DOCUMENTS

E.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that they must meet all specified requirements documents cited in this appendix, whether or not they are listed.

E.2.2 Government documents. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

Code of Federal Regulations (CFR), Title 7, Chapter 1, Parts 56 and 59.

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

E.3 DEFINITIONS

E.3.1 Definitions. Definitions are contained in the basic handbook.

E.4 GUIDELINES

E.4.1 General. Unnecessary handling at the farm, during transportation or processing and poor packaging procedures can reduce the natural protection of the shell and provide entry sites for bacteria. Packaging plants must provide effective methods to screen eggs so that damaged eggs are removed.

Lowering the temperature of the egg and maintaining that temperature should start at the farm. Ideally eggs should be held at ambient temperatures between 40º F-50º F (4º C-10º C) at 70-80% humidity. The distance from the farm to the packaging plant will influence the extent of cooling necessary at the farm before subsequent transportation.

Effective cleaning of eggs during washing has the following important components that must be considered: wash water temperature, water quality characteristics (i.e. hardness and pH), detergent type and concentration, and defoamer. Wash water must be potable and should be added to continuously maintain a constant overflow rate. Chlorine or quaternary ammonium sanitizing compounds may be part of the replacement water provided they are compatible with the detergent. Iron content of the water may influence the growth of bacteria when the egg membrane is penetrated. Consequently, wash water may contain no more than 2-ppm iron. Ideally, a 10-11 pH of the wash water should be maintained.

USDA regulations require that wash water temperature be at 90º F (32º C) or higher, or at least 20º F (-7º C) warmer than the highest egg temperature (which ever is greater). Cooler water temperatures may create conditions that would draw water through the porous eggshell, contaminating the egg contents. Wash water must be changed every four hours or more often if needed to maintain sanitary conditions. According to USDA regulations the eggs cannot be immersed at any time.

After washing, the eggs are rinsed with hot water and then dried utilizing ambient air. The eggs may then be oiled using clean edible oil. The process should be continuous to limit the exposure of the eggs to ambient temperatures outside the preferred temperature zones. Rapid placement back into storage coolers is vital to maintaining a high quality product.

Packaging equipment should be designed in such a way as to minimize damage to the egg.

E.4.2 Checklist. Guidelines for auditing egg processing facilities are contained in the following checklist.

APPENDIX E

EGGS CHECKLIST CFR Title 7, Chapter 1, Part 56	
APPENDIX A PARAGRAPH	REQUIREMENT
E3	Grading and packing rooms are kept reasonably clean during grading and packaging operations, and are thoroughly cleaned at the end of each day. (56.76, para (a) (2)).
B4	The egg grading or candling area is adequately darkened to make possible the accurate quality determination of the candled appearance of eggs. There are no other light sources or reflections of light that interfere with, or prohibit accurate quality determination of eggs in the grading or candling area. Other light sources and equipment or facilities are provided to permit the detection and removal of stained or dirty eggs, or other undergrade eggs. (56.76, para (b) (1) & (2)).
E3	The cooler room has refrigeration facilities capable of reducing within 24 hours and holding the maximum volume of eggs handled to 45° F (7° C) or below. Accurate thermometers are provided. (56.76, para (c) (1)).
E3	Eggs with excess moisture on the shell are not shell protected (oil processed). (56.76, para (d) (1)).
E3	Oil having any off odor, or that is obviously contaminated, is not used in shell egg protection. (56.76, para (d) (2)).
E1	Processing oil that has been previously used and which has become contaminated is filtered and heated at 180° F (82° C) for 3 minutes prior to use. (56.76, para (d) (3)).
C4, E2	Shell egg processing equipment is washed, rinsed and treated with a bactericidal agent each time the oil is removed. It is preferable to filter and heat treat processing oil and clean processing equipment daily when in use. (56.76, para (d) (4)).
E2	The temperature of the wash water is maintained at 90° F (32° C) or higher, and is at least 20° F (-6° C) warmer than the temperature of the eggs to be washed. These temperatures are maintained throughout the cleaning cycle. (56.76, para (e) (2)).
E2	Replacement water is added continuously to the wash water of washers to maintain a continuous overflow. Iodine sanitizing rinse is not used as part of the replacement water. (56.76, para (e) (5)).
E4, H6	An analysis of the iron content of the water supply, stated in parts per million, is performed. When the iron content exceeds 2 parts per million (ppm), equipment is provided to correct the excess iron content. If the water source is changed, new tests are performed. (56.76, para (e) (6)).

EGGS CHECKLIST - Continued.

E2, E4, H6	The washing and drying operation is continuous and is completed as rapidly as possible. Eggs are not allowed to stand or soak in water. Immersion washers are not used. (56.76, para (e) (8)).
E2, E4	Washed eggs are spray-rinsed with water having a temperature equal to, or warmer than, the temperature of the wash water, and containing an approved sanitizer of not less than 50 ppm nor more than 200 ppm of available chlorine or its equivalent. Alternate procedures, in lieu of a sanitizer rinse, are approved by the FDA or MACOM. (56.76, para (e) (10)).
E2	During any rest period, eggs are removed from the washing and rinsing area of the egg washer and from the scanning area whenever there is a buildup of heat. (56.76, para (e) (12)).

NOTE: Reference to the controlling CFR Title 7, Chapter 1, Part 56 sections are identified in parentheses.

APPENDIX F
FROZEN DESSERTS

F.1 SCOPE

F.1.1 Scope. This appendix contains guidelines for auditing frozen dessert production facilities. The information contained herein is intended for guidance.

F.2 APPLICABLE DOCUMENTS

F.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that they must meet all specified requirements documents cited in this appendix, whether or not they are listed.

F.2.2 Government documents. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

Frozen Dessert Processing Guidelines, 1st Edition, October 1989, U. S. Department of Health and Human Services, Food and Drug Administration.

(Application for copies should be addressed to U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Milk Safety Branch, 200 C Street SW, Washington, DC 20204.)

CODE OF FEDERAL REGULATIONS (CFR)

Code of Federal Regulations (CFR), Title 21, Part 135

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

F.3 DEFINITIONS

F.3.1 Definitions. Definitions are contained in the basic handbook.

F.4 GUIDELINES

F.4.1 General. Of utmost importance in a frozen dessert plant is where the mix is made. Some facilities purchase mix from another establishment and it is trucked over the road to their establishment. If the mix goes over the road, it should be re-pasteurized prior to it being used. If the facility is not re-pasteurizing the product, this may be a finding of significant public health importance.

For the purpose of this audit, break down the plant tour as raw (prior to pasteurization), pasteurized, and finished product.

Raw: Everything prior to the divert value is considered raw. Milk (ice cream is not considered Grade A) is trucked into the establishment. There should be a protect bay where the raw milk is unloaded. Tankers have to be vented to prevent them from collapsing; ensure there is a filter or screen on top of the tanker when it is off loading (to protect the product). Some tests that may be performed in the raw unloading area are Standard Plate Count (SPC) or Direct Microscopic Clump Counts (DMCC), Freezing Point, Antibiotics, and Somatic Cell Count. The acceptable levels for Non-Grade A are higher. Raw milk should be pumped into raw silos and be kept at a temperature around 40° F (4° C) for not more than 72 hours. Verify the time and temperature by reviewing the recorder controller charts. Also, verify silo Clean In-Place (CIP) cleaning by these charts. Ask how the silos are vented, whether the vent is on top of the silo or at eye level. There can also be a port at the top of the silo, just ask if there are any other openings. Also establish if they are separating the fat out of the milk and storing that in a separate silo. They will reintroduce the fat into the mix to satisfy recipes. All added ingredients (except for bulky ingredients) should be added prior to pasteurization. Bulky ingredient added after pasteurization should be tested to make sure the establishment is not contaminating their product post pasteurization.

After pasteurization comes the filling process. Some establishments might store pasteurized product in a silo, prior to filling. This silo holding pasteurized product has to be in a separate area of the plant away from the raw silos. Product will be chilled to the consistency of a soft serve product prior to filling. Different fillers are used for the different size containers. The product could be used in the creation of novelty items (ice cream sandwiches, ice cream bars, etc.). Ensure the product is shielded against contamination during the entire filling process. After the filling process the product should be sent immediately to a blast freezer.

Perform a tour around the plant to determine rodent/insect harborages and entryways into the establishment. Go onto the establishment's roof looking for low-lying areas where water can pool. Pooling water can cause leaks into the establishment. While on the roof look up to the silos to see if there are any ports on the top.

Points of interest: Find out how much re-work is incorporated back into the product. Also where the rework is stored and at what temperature it is stored. Review recorder controller charts to see if there were any interruptions during the pasteurization process (if product went through diverted flow). If a product went through diverted flow see if there is an explanation on the recorder controller. Check recorder controller charts also for the CIP process. Make sure divert valves pulsed during CIP process. A proper CIP process should take between 90 to 120

minutes (there is no mandated time). Higher coliform counts in the product could be tied back to poor sanitation, or improper CIPing of the pasteurizer.

F.4.2 Checklists. Guidelines for auditing frozen dessert production facilities are contained in the following checklists.

APPENDIX F

FROZEN DESSERTS CHECKLIST TABLE I - GENERAL CONSIDERATIONS Frozen Dessert Processing Guidelines	
APPENDIX A PARAGRAPH	REQUIREMENT
E2, H6	Raw milk, low fat milk, skim or cream which was heated above 45º F (7° C), but below 160º F (71° C) for separation, is used in frozen dessert if: 1) It was heated only once for pasteurization, 2) After separation, it was immediately cooled to below 45º F (7° C), 3) No more than 3 days have elapsed between separation and shipment to the frozen dessert plant, or 4) If it is heated above 125º F (51° C), it meets 30,000 Standard Plate Count and 10 coliform at plant of shipment, 100 coliform at plant of receipt. (Page 4).
C5	Adequate physical breaks to the atmosphere (at least as large as the piping diameter) are provided in order to eliminate cross-connections, and are verifiable by walk-through with installation drawings. (Page 9).
E2	All openings into product or onto sanitized product-contact surfaces are capped, closed, or adequately protected. (Page 9).
C4	Fill line connections are made to tank fittings, and tank lids are not propped open during filling. (Page 9).
C4	Absorbent items such as rags and sponges are not used in the plant environment, and separate brushes are used for product and non-product surfaces. (Page 10).
B7	All containers, utensils, and equipment are cleaned and sanitized at least once during each day they are used; storage tanks are emptied and cleaned at least every 72 hours. (Page 11).
B7	Piping equipment and containers used to process or package aseptically processed frozen dessert mix beyond the final heat-treatment process are sterilized before any aseptically processed product is packaged. (Page 11).
E2	Pasteurized mix is frozen, dried, packaged, or shipped within 72 hours of being pasteurized. (Page 12).
C1	All openings in covers of tanks, vats, separators, etc. are protected by raised edges or other means to prevent the entrance of surface drainage. (Page 13).
C1	There are no threads used in contact with milk, milk products, frozen desserts, or frozen dessert mixes except where needed for functional and safety reasons, such as clarifiers, pumps, and separators. (Page 14).
B2	The following areas are separate from one another: 1) the tank truck receiving area, 2) the processing area, 3) the can or case wash areas, 4) the dry storage areas, 5) the packaging area. (Page 16).

FROZEN DESSERTS CHECKLIST
TABLE I - GENERAL CONSIDERATIONS - Continued.

E2	All milk, milk products, frozen dessert mix, liquid eggs, and dairy ingredients are maintained at 45º F (7° C) or below. Products in coolers are stored at temperatures under 45º F (7° C). (Page 17).

NOTE: Page numbers cited in parentheses apply to the controlling Frozen Dessert Processing Guidelines.

FROZEN DESSERTS CHECKLIST

TABLE II - PLANT SYSTEMS

Frozen Dessert Processing Guidelines

APPENDIX A PARAGRAPH	REQUIREMENT
E2	Pressurizing air processing systems which incorporate air directly into the product, such as freezers, air blows, and air agitating systems, are properly designed to reduce potential contamination. They are equipped with filters and sanitary check valves. (Page 25).
B8, H6	Where steam is used to provide heat for vat or HHST processes, the water source for the boiler is identified as potable and is in compliance with CFR, Title 21. (Page 27).
E4, H6	The recirculating cooling water (sweetwater) and recirculating glycol and water mixtures are tested at least every six months and are free of coliforms and listeria. (Page 28).
B4	Outside air entering the facility is filtered and free of condensates. (Page 29).

NOTE: Page numbers cited in parentheses apply to the controlling Frozen Dessert Processing Guidelines

FROZEN DESSERTS CHECKLIST TABLE III - SPECIFIC PLANT OPERATIONS Frozen Dessert Processing Guidelines 21 CFR 135	
APPENDIX A PARAGRAPH	REQUIREMENT
E2	Dusty, raw ingredient blending operations which create powdery conditions are located away from pasteurized product areas. (Page 32).
E2	Products are pasteurized in accordance with the time/temperature tables listed in the Frozen Dessert Processing Guide. (Page 33).
E2	Pasteurization is in accordance with the methods explained in the Frozen Dessert Processing Guide. (Pages 32 through 67).
E1	Mix shipped in bulk tank trucks to another location is repasteurized at that plant prior to freezing and packaging. (Page 68).
E2	All dairy products, eggs, egg products, cocoa products, emulsifiers, stabilizers, liquid sweeteners and dry sugar are added prior to pasteurization. (Page 69).
E2	All reconstitution or recombination of dry, powdered, or condensed ingredients with water is done prior to pasteurization. (Page 69).
E2, H6	Ingredients which may be added after pasteurization are limited to those flavoring and coloring ingredients which are: 1) subjected to prior heat treatment sufficient to destroy pathogenic microorganisms, 2) of 0.85% water activity or less, 3) of pH less than 4.7, 4) roasted nuts added at the freezer, 5) contain high alcohol content, 6) bacterial cultures, 7) fruits and vegetables added at the freezer, and 8) subjected to any process which will assure that the ingredient is free of pathogenic microorganisms. (Page 69).
E4	A plant quality assurance program is in place to assure that the fresh fruit and vegetable products are of high quality and do not contaminate the dairy product. (Page 69).
C1	To prevent contamination, lids of tub and canister-type containers for frozen desserts are designed to overlap the tub or container to be overwrapped. (Page 70).
E2	If defoamers are used, they do not return product or foam to the filler bowl. (Page 70).
B7	Transfer pumps, and ripple pumps are broken down, inspected, and cleaned after each use and sanitized prior to startup. (Page 71).
B7	Pails used for rework or adding flavors are cleaned after each use and sanitized prior to reusing. (Page 71).
C8	The air supply in the freezer is properly filtered. (Page 71).
E2	A bright distinctive food color is added to the brine used on novelty sticks if the brine is calcium carbonate, in order to detect leakage onto the finished product. (Page 72).
B3	When a stainless steel chute is used to convey product (novelty) to the wrapper after extraction, the chute is cleaned at least every four hours during the production run. (Page 72).

FROZEN DESSERTS CHECKLIST
TABLE III - SPECIFIC PLANT OPERATIONS - Continued.

E2	Water used to glaze product to help prevent sticking to the paper wrapper is pasteurized or treated to lower the pH. Water dips have a continuous over-flow to minimize product accumulation throughout the product run. (Page 73).
C1	There is a physical break between pasteurized product for repasteurization when the product is loaded in a raw product receiving area, with particular attention being paid to product and CIP connections, so that raw product in lines and tanks is never directly connected to any line which extends back to the pasteurized product lines or tanks. A physical break is required. (Page 68).
C1	Adequate drip deflectors are provided at each filler valve. (Page 70).
C1	Tanks used for holding cooling media are adequately protected and are coliform and pathogen free. (Page 70).
E1	For reclaiming operations, only product which has not left the plant premises is reclaimed. (Page 74).
C1	Woven wire strainers are not used to remove bulky ingredients. (Page 74).
E1	Reworked product, such as ice cream, which is retained in buckets during startup while overrun is stabilized, is kept to a minimum. If this product is to be recycled back into product, it is properly protected and repasteurized. (Page 75).
E4, H6	Microbiological criteria for end items are not more than 50,000 cfu/g Standard Plate Count; not more than 10 coliform/g; and not more than 20 coliform/g for fruits, nuts, or other bulky flavors. (21 CFR 135).
E2	Hardening is performed immediately after mix is containerized. Rapid freezing is recommended from 0º F (-18° C) to -15º F (-26º C). (21 CFR 135).

NOTE: Page numbers cited in parentheses apply to the controlling Frozen Dessert Processing Guidelines or 21 CFR 135.

APPENDIX G
ICE

G.1 SCOPE

G.1.1 Scope. This appendix contains guidelines for auditing ice production facilities. The information contained herein is intended for guidance.

G.2 APPLICABLE DOCUMENTS

G.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that they must meet all specified requirements documents cited in this appendix, whether or not they are listed.

G.2.2 Government documents. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

U.S. ENVIRONMENTAL PROTECTION AGENCY DRINKING WATER REGULATIONS

(Application for copies should be addressed to the National Service Center for Environmental Publications, P.O. Box 42419, Cincinnati, OH 45242-2419, (800) 490-9198, http://www.epa.gov/ncepihom/Catalog/EPA811F95002C.html/.)

U.S. DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, PUBLIC HEALTH SERVICE

Sanitary Standard for Manufactured Ice, 1964, Recommendations of the Public Health Service Relating to Manufacture, Processing, Storage, and Transportation

(Application for copies should be addressed to U.S. Department of Health, Education and Welfare, Public Health Service, Food and Drug Administration, Food Service Sanitation Branch, Washington, DC 20204.)

G.2.3 Non-government publications. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents which are DoD adopted, are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

INTERNATIONAL PACKAGED ICE ASSOCIATION

Sanitary Standard for Packaged Ice

(Application for copies should be addressed to the International Packaged Ice Association, P.O. Box 1199, Tampa, FL 33601.)

G.3 DEFINITIONS

G.3.1 Definitions. Definitions are contained in the basic handbook.

G.4 GUIDELINES

G.4.1 General.

Consider the following guidelines when performing an audit on an Ice Establishment:

Potable water is the main concern. Where is the water supply coming from? If it is from a well system, how is the water treated?

Once a potable water system is contaminated by the inadvertent action of a user, the foreign or toxic material can be distributed throughout the facility's potable plumbing system and adjacent premises connected to the same supply. Watch cross-connections. They are actual or potential links between the potable water supply and source of contamination (sewage, chemicals, gas, etc.). A cross-connection can be any temporary or permanent direct connection, by-pass arrangement, jumper connections, removable sections, swivel or change-over devices that connect potable and non-potable systems together.

Watch for back-siphonage. This is a backflow that occurs when the pressure in the water supply drops below zero (less than atmospheric pressure or negative head pressure) and the adjacent nonpotable source is “sucked” or siphoned into the potable supply. There are several backflow devices available, become familiar with several. Air gaps (or physical air gap, “air break”) are the most desirable method of backflow prevention. An air gap is an unobstructed, vertical air space that separates a potable from a nonpotable system.

Physical adulterants are a large concern. Check on overhead areas for peeling paint, rusty pipes, and lubricant from processing chains. Make sure the overhead lights have protective shields or shatter proof bulbs. Watch for any toxic lubricants, chemicals, fuels, metal fragments, sanitizers, etc. that might contaminate the ice.

Air and water filters need to be changed often. Galvanized surfaces, solder, and corrosive-resistant surfaces are a concern. If the pH is less than 6.5, and the establishment has galvanized surfaces, additional testing for potable water, core water, and ice samples should be tested for heavy metals.

Filters, setting tanks and contact surfaces should be sanitized as often as necessary to assure a bacteria free product.

Review laboratory sampling, the correct testing frequency, especially for coliforms.

When dipping wells are used, ice will not come in direct contact of water in the dipping wells. When canvas covers are used, there has to be a single-service lining. Watch for dirty core in block ice.

There should be a separate room used for processing and packaging of ice for human consumption. There should be no handling of finished product with bare hands.

Finished product should be protected against cross contamination during storage and shipping.

G.4.2 Checklist. Guidelines for auditing ice production facilities are contained in the following checklist.

APPENDIX G

ICE PLANT CHECKLIST INTERNATIONAL PACKAGED ICE ASSOCIATION Sanitary Standard for Packaged Ice	
APPENDIX A PARAGRAPH	REQUIREMENT
E4, H6	Bacteriological tests of the finished ice are conducted monthly, chemical and physical tests annually, and radiological tests every four (4) years, to ensure that ice manufactured for human consumption or for the refrigeration of food products complies with U.S. Environmental Protection Agency Drinking Water Regulations. (Section 7, para 5).
E4, H6	Random samples of ice produced in the plant are tested by an approved laboratory at least monthly for fecal and/or total coliform organisms and Heterotrophic Plate Count (HPC). Total coliform is not greater than 2.2 organisms/100 ml. using the Most Probable Number (MPN) method and not greater than 1 organism/100 ml. using the Membrane Filtration (MF) method. The HPC does not exceed 500 colonies/ml. Records of these tests are maintained for two (2) years. (Section 7, para 6).
E4, H6	A testing program has been implemented to obtain background information on the chemical and microbiological of the brine solution as it relates to leaking cans and the subsequent contamination of the product. Such data reflects the presence of any refrigeration defrosting chemicals, such as ethylene or propylene glycol (if used in the plant), lead (Pb), cadmium (Cd), zinc (Zn), chromium (Cr), and nitrate (NO_2). On a quarterly basis, the finished products (varying product types and packages) are randomly sampled and analyzed for ethylene or propylene glycol (if applicable) and chlorides (Cl). Reports of analyses are maintained for two years. (Section 7, para 7 & 8).
E3	Packaged ice products are tightly sealed and clearly labeled to show the name, manufacturer, location of processing plant, date code, and net weight. (Section 8, para 3).
E2	Filtering equipment is designed to protect ice from contamination and is subject to periodic treatment and cleaning. (Section 6, para 1)
E2	Freezing tank covers of acceptable materials are designed and constructed to protect ice containers from splash, drip, and other contamination; are easily cleanable and are kept clean and in good repair. Such covers are equipped with rings or similar devices when hooks are used for pulling. Can or tank covers, and the ledges of sides of the tank upon which the cover rests, are cleaned as often as necessary to keep them in sanitary condition. (Section 6, para 4).

ICE PLANT CHECKLIST - Continued.

C8	Air used for water agitation is filtered or otherwise treated to remove dust, dirt, insects, and extraneous material. Filters are placed upstream of the compressor and are easily removable for cleaning or replacement. The compressor used to supply air for water agitation is designed to deliver oil-free air. (Section 6, para 8 & 9).
C2	Air lines and core or sucking (vacuum) devices are used as needed to produce ice free of rust or other foreign materials. (Section 6, para 11).
A6	Hands do not come into direct contact with the ice at any time during manufacturing, processing, packaging, and storage. (Section 7, para 1).
E3	All frozen unpackaged ice blocks intended for sale for human consumption or for refrigeration of food products are washed thoroughly with potable water. Ice manufactured for industrial purposes is handled and stored separately from ice intended for human consumption. (Section 7, para 2).
B10	Water used for washing or rinsing is not reused and is disposed of as liquid waste. (Section 7, para 3).
B7	All equipment used to store or deliver water, or in contact with ice in the freezing process, is regularly sanitized. (Section 7, para 4).

NOTE: Cited reference document for the above is Sanitary Standard for Packaged Ice.

APPENDIX H
SEAFOOD

H.1 SCOPE

H.1.1 Scope. This appendix contains guidelines for auditing seafood production facilities. The information contained herein is intended for guidance.

H.2 APPLICABLE DOCUMENTS

H.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that they must meet all specified requirements documents cited in this appendix, whether or not they are listed.

H.2.2 Government documents. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

Code of Federal Regulations (CFR), Title 21, Part 123 and Part 172.

Code of Federal Regulations (CFR), Title 50, Subchapter G, Part 260

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

FDA Fish and Fishery Products Hazards & Controls Guide (JAN 98).

(Available on-line at: http://vm.cfsan.fda.gov/~dms/haccp-2a.html. Single copies of this Guide may be obtained as long as supplies form the FDA district offices and from: U.S. Food and Drug Administration, Office of Seafood, 200 C St., SW, Washington, D.C. 20204, 202-418-3133. Multiple copies may be obtained from: National Technical Information Service, U.S. Department of Commerce, 703-487-4650. This guide is also available electronically at: http://www.fda.gov/. Select "foods;" then select "seafood;" then select "HACCP.")

H.2.3 Non-government publications. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents which are DoD adopted, are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

Cured, Salted and Smoked Fish Establishments Good Manufacturing Practices. An Association of Food and Drug Officials Model Code adopted June 1991, revised June 1997

(Application for copies should be addressed to Association of Food and Drug Officials, 2250 Kingston, Suite 311, York, PA 17402, (717) 757-2888, http://www.healthfinder.gov/text/orgs/hr0316.htm/.)

H.3 DEFINITIONS

H.3.1 Definitions. Definitions are contained in the basic handbook.

H.4 GUIDELINES

Additional guidance for the hazards associated with fish and fish products, to include risk assessment and HACCP plans, are found in the FDA's Fish and Fishery Products Hazards & Controls Guide, January 1998.

H.4.1 General.

ACIDIFIED, FERMENTED, AND SALTED FISH AND FISHERY PRODUCTS

Process establishment. Except where finished product water phase salt, pH, or water activity analysis is the monitoring procedure, the adequacy of the pickling/brining/ formulation process should be established by a scientific study. It should be designed to ensure: a water phase salt level in the loin muscle of at least 5%; a pH in the loin muscle of 5.0 or below; a water activity in the loin muscle of 0.97 or below; or a combination of salt, pH, and/or water activity in the loin muscle that, when combined, prevent the growth of *C. botulinum* type E and nonproteolytic types B and F (established by scientific study). Expert knowledge of pickling/brining/ formulation processes is required to establish such a process. Education or experience or both can provide such knowledge. Establishment of pickling/brining/formulation processes requires access to adequate facilities and the application of recognized methods. In some instances, pickling/brining/formulation studies will be required to establish minimum processes. In other instances, literature establishing minimum processes is available. Characteristics of the process and/or product that affect the ability of the established minimum pickling/brining/formulation process should be taken into consideration in the process establishment. A record of the process establishment should be maintained.

Critical aspects of processes. Critical aspects of pickling, brining, or formulation processes may include:

- Brine/acid strength;
- Brine/acid to fish ratio;
- Brining/pickling time;
- Brine/acid temperature;
- Thickness, texture, fat content, quality, and species of fish;

- Water phase salt, pH, and/or water activity of the finished product;
- Accuracy of thermometers, recorder thermometer charts, high temperature alarms, maximum indicating thermometers, and/or digital data loggers; and
- Accuracy of other monitoring and timing instruments.

BATTERED FISH AND FISHERY PRODUCTS

Potential food safety hazard. *S. aureus* toxin formation in hydrated batter mixes can cause consumer illness. This toxin in particular is a concern because heating steps that may be performed by the processor or the consumer cannot destroy the toxin. Pathogens other than *S. aureus,* are, in many cases, less likely to grow in hydrated batter mixes, and are likely to be killed by the heating steps that follow.

Control measures. *S. aureus* can enter the process on raw materials. It can also be introduced into foods during processing from unclean hands and insanitary utensils and equipment. The hazard develops when a batter mix is exposed to temperatures favorable for *S. aureus* growth for sufficient time to permit toxin development. *S. aureus* will grow at temperatures as low as 44.6º F (7º C) and at a water activity as low as 0.83. However, toxin formation is not likely at temperatures lower than 50º F (10º C). For this reason, toxin formation can be controlled by minimizing exposure of hydrated batter mixes to temperatures above 50º F (10º C). Exposure times greater than 12 h for temperatures between 50º F (10º C) and 70º F (21.1º C) could result in toxin formation. Exposure times greater than 3 h for temperatures above 70º F (21.1º C) could also result in toxin formation.

FDA guidelines.

- Hydrated batter mix temperatures should not exceed 50º F (10º C) for more than 12 h, cumulatively; and
- Hydrated batter mix temperatures should not exceed 70º F (21.1º C) for more than 3 h, cumulatively.

Critical aspects of processes. Critical aspects of battered fish and fishery product processes may include:

- Temperature of the hydrated batter;
- Length of time the hydrated batter has been held at temperatures above 50º F (10º C);
- Accuracy of thermometers, recorder thermometer charts, high temperature alarms, maximum indicating thermometers, and/or digital data loggers; and
- Accuracy of other monitoring and timing instruments.

COOKED FISH AND FISHERY PRODUCTS

Potential food safety hazard. Pathogen survival through a cook step can cause consumer illness. Cooking is a relatively severe heat treatment, usually performed before the product is placed in the finished product container. Cooking procedures are often established to develop the desirable sensory attributes characteristic of cooked fish and fishery products, not specifically to

eliminate pathogens. An important consequence of thorough cooking is the destruction of vegetative cells of pathogens (or reduction to an acceptable level) that may have been introduced in the process by the raw materials or by processing that occurs before the cook step. Cooking processes are not usually designed to eliminate spores of pathogens.

Undercooking may allow the survival of pathogens leading to several unintentional but potentially hazardous conditions: 1) direct contamination of a ready-to-eat product with pathogens, 2) elimination of other less heat resistant microorganisms that, if present, may suppress pathogen growth or cause spoilage prior to significant pathogen growth, and 3) thermal conditioning of pathogens and increasing their heat resistance to any subsequent cooking or reheating step. It is also possible for a sublethal heating step to trigger bacterial spores to germinate, producing vegetative cells that are more hazardous than spores, but also far more vulnerable to subsequent reheating.

Control measures. Generally, after cooking, fishery products are referred to as cooked, ready-to-eat. Examples of cooked, ready-to-eat products are: crabmeat, lobster meat, crayfish meat, cooked shrimp, surimi-based analog products, seafood salads, and hot-smoked fish. Controlling pathogen survival through the cook step is accomplished by:

- Scientifically establishing a cooking process that will eliminate pathogens or reduce their numbers to acceptable levels; and
- Designing and operating the cooking equipment so that every unit of product receives at least the established minimum process.

A thorough hazard analysis is important when evaluating a thermal process. In some cases, a cooking or heating step will not present a potential health hazard even if it is sublethal to pathogens. Examples include a blanching step to inactivate enzymes and a pan-fry operation to set the breading on products to be fully cooked by the consumer.

FDA guidelines. FDA's recommendations for cooking fish and fishery products to destroy organisms of public health concern in food service, retail food stores, and food vending operations include:

- Raw fish and foods containing raw fish are cooked to heat all parts of the food to 145° F (63° C) or above for 15 s.
- Comminuted fish and foods containing comminuted fish are cooked to heat all parts of the food to 155° F (68° C) for 15 s.
- Stuffed fish or stuffing containing fish are cooked to heat all parts of the food to 165° F (74° C) for 15 s.

FDA guidelines for cooling cooked fish and fishery products:

- Cooked products should generally be cooled from 140° F (60° C) to 70° F (21.1° C) or below within 2 h and to 40° F (4° C) or below within another 4 h.

DRIED FISH AND FISHERY PRODUCTS

Potential food safety hazard. Pathogen growth in the finished product as a result of inadequate drying of fishery products can cause consumer illness. Examples of dried fish products include salmon jerky, octopus chips, dried shrimp, and stockfish. The drying operation used in the production of smoked or smoke-flavored fish is not designed to result in a finished product water activity of 0.85 or below.

Control measures. Dried foods are usually considered shelf stable and are, therefore, often stored and distributed at ambient temperatures. The characteristic of dried foods that makes them shelf stable is their low water activity (a_w). Water activity is the measure of the amount of water in a food that is available for the growth of microorganisms, including pathogens. A water activity of 0.85 or below will prevent the growth of pathogens such as *C. botulinum*, and toxin production from *S. aureus*. *S. aureus* grows at a lower water activity than other pathogens (growth above a_w of 0.83, toxin production above a_w of 0.85), and should, therefore, be considered the target pathogen for drying.

Pathogen growth is not a concern in dried products that are stored, distributed, displayed, and sold frozen, and are so labeled. These products need not meet the control measures outlined in this chapter since in this case drying is not critical to product safety. Similarly, drying may not be critical to the safety of dried products that are stored refrigerated, since refrigeration may be sufficient to prevent pathogen growth.

FDA guidelines.

- Finished product has a water activity of 0.85 or less.
- Because spores of *C. botulinum* are known to be present in the viscera of fish, any product that will be preserved using salt, drying, pickling, or fermentation must be eviscerated prior to processing. Without evisceration, toxin formation is possible during the process. Small fish, less than 5 inches (12.7 cm) in length, that are processed in a manner that prevents toxin formation, and that reach a water phase salt content of 10%, a water activity of below 0.85, or a pH of 4.6 or less are exempt from the evisceration requirement.

Process establishment. Except where finished product water activity analysis is the monitoring procedure, the adequacy of the drying/dehydration unit operation should be established by a scientific study. It should be designed to ensure the production of a shelf stable product with a water activity of <0.85. Expert knowledge of drying process calculations and the dynamics of mass transfer in processing equipment is required to establish such a drying process. Education or experience or both can provide such knowledge. Establishment of drying processes requires access to adequate facilities and the application of recognized methods. The drying equipment must be designed, operated, and maintained to deliver the established drying process to every unit of product. In some instances, drying studies will be required to establish the minimum process. In other instances, existing literature or federal, state or local regulations establish minimum processes or adequacy of equipment. Characteristics of the process, product, and/or equipment that affect the ability of the established minimum drying process should be taken into

consideration in the process establishment. A record of the process established should be maintained by the processor.

Critical aspects of processes. Critical aspects of drying processes may include:

- Drying time;
- Input/output air temperature, humidity, and velocity;
- Dry and wet bulb temperatures at dryer inlet and outlet;
- Flesh thickness;
- Accuracy of thermometers, recorder thermometer charts, high temperature alarms, maximum indicating thermometers, and/or digital data loggers; and
- Accuracy of other monitoring and timing instruments.

SMOKED FISH AND FISHERY PRODUCTS

Potential food safety hazard. *C. botulinum* toxin formation can result in consumer illness and death. *C. botulinum* produces a potent toxin when it grows which can cause death by preventing breathing. It is one of the most poisonous naturally occurring substances known. The toxin can be destroyed by heat (e.g., boiling for 10 min). There are 2 major groups of *C. botulinum*, the proteolytic group (i.e., those that break down proteins) and the nonproteolytic group (i.e., those that do not break down proteins). The proteolytic group includes *C. botulinum* type A and some of types B and F. The nonproteolytic group includes *C. botulinum* type E and some of types B and F. *C. botulinum* is able to produce spores. In this state the pathogen is very resistant to heat. The spores of the proteolytic group are much more resistant to heat than are those of the nonproteolytic group. The vegetative cells of all types are easily killed by heat. Temperature abuse occurs when product is exposed to temperatures favorable for *C. botulinum* growth for sufficient time to result in toxin formation.

Packaging conditions that exclude oxygen (e.g., vacuum packaging) favor the growth of *C. botulinum*, because oxygen is toxic to the pathogen. Vacuum packaging inhibits the growth of many spoilage bacteria, which increases the shelf life of the product. The safety concern with these products is the increased potential for the formation of *C. botulinum* toxin before spoilage makes the product unacceptable to consumers. Both smoked and raw products in vacuum packaging and other reduced oxygen packaging require strict refrigeration (or frozen storage conditions) throughout distribution.

C. botulinum forms toxin more rapidly at higher temperatures than at lower temperatures. The minimum temperature for growth of *C. botulinum* type E and nonproteolytic types B and F is 38° F (3° C). For type A and proteolytic types B and F, the minimum temperature for growth is 50° F (10° C). As the shelf life of refrigerated foods is increased, more time is available for *C. botulinum* growth and toxin formation. As storage temperatures increase, the time required for toxin formation is significantly shortened. Processors should expect that at some point during storage, distribution, display, or consumer handling of refrigerated foods, proper refrigeration temperatures will not be maintained (especially for the nonproteolytic group). Surveys of retail display cases indicate that temperatures of 45-50° F (7-10° C) are not uncommon. Surveys of home refrigerators indicate that temperatures can exceed 50° F (10° C).

Sources of C. botulinum. *C. botulinum* can enter the process on raw materials. The spores of *C. botulinum* are very common in nature. They have been found in the gills and viscera of finfish, crabs, and shellfish. *C. botulinum* type E is the most common form found in freshwater and marine environments. Types A and B are generally found on land, but may also be occasionally found in water. It should be assumed that *C. botulinum* will be present in any raw fishery product, particularly in the viscera.

Control measures. There are at least 3 steps to control *C. botulinum* in smoked and smoke-flavored fishery products:

- Controlling the amount of salt or preservatives, such as sodium nitrite, in the finished product, in combination with other barriers, such as heat damage and competitive bacteria, sufficient to prevent the growth of *C. botulinum* type E and nonproteolytic types B and F;
- Managing the amount of time that food is exposed to temperatures that are favorable for *C. botulinum* growth and toxin formation during processing and storage; and
- Controlling the growth of *C. botulinum* type A and proteolytic types B and F in the finished product with refrigerated storage.

Achieving the proper concentration of salt and/or nitrite in the flesh of salted, smoked, and smoke-flavored fish is necessary to prevent the formation of toxin by *C. botulinum* type E and nonproteolytic types B and F during storage and distribution. In salted fish, the salt concentration alone is responsible for this inhibition. In smoked and smoke-flavored fish, salt works along with smoke and any nitrites that are added to prevent toxin formation by *C. botulinum* type E and nonproteolytic B and F. (Note: nitrites may only be used in salmon, sable, shad, chubs, and tuna - 21 CFR 172.175 and 21 CFR 172.177.) In hot-smoked products, heat damage to the spores of *C. botulinum* type E and nonproteolytic types B and F also helps prevent toxin formation. In these products control of the heating process is critical to the safety of the finished product. It is important to note, however, that this same heating process also reduces the numbers of naturally occurring spoilage organisms. The spoilage organisms would otherwise have competed with, and inhibited the growth of, *C. botulinum*.

In cold-smoked fish, it is important that the product does not receive so much heat that the number of spoilage organisms are significantly reduced. This is true because spoilage organisms must be present to inhibit the growth and toxin formation of *C. botulinum* type E and nonproteolytic types B and F. This inhibition is important in cold-smoked fish because the heat applied during this process is not adequate to weaken the *C. botulinum* spores. Control of the temperature during the cold-smoking process is, therefore, critical to the safety of the finished product.

The interplay of these inhibitory effects (salt, temperature, smoke, and nitrite) is complex. Control of the brining or dry salting process is clearly critical to ensure that there is sufficient salt in the finished product. However, preventing *C. botulinum* type E (and nonproteolytic types B and F) toxin production is made even more complex by the fact that adequate salt levels are not usually achieved during brining. Proper drying is also critical in order to achieve the finished

product water phase salt level (the concentration of salt in the water portion of the fish flesh) needed to inhibit the growth and toxin formation of *C. botulinum*. Processors should ordinarily restrict brining, dry salting, and smoking loads to single species and to fish of approximately uniform size. This minimizes the complexity of controlling the operation.

Salt levels alone in some salted products may be adequate to prevent toxin formation by *C. botulinum* type A and proteolytic types B and F. However, even the combination of inhibitory effects that are present in smoked and smoke-flavored fish are not adequate to prevent the growth of type A and proteolytic types B and F. Strict refrigeration control must be maintained to prevent the growth of *C. botulinum* type A and proteolytic types B and F in these products (FDA, 1998).

FDA guidelines.
Smoker temperature (cold smoking):

- For cold-smoked fish and fishery products, the smoker temperature must not exceed 90º F (32º C) (FDA, 1998).

Internal fish temperature (hot smoking):

- For hot-smoked fish and fishery products, the internal temperature of the fish must be maintained at or above 145º F (63º C) throughout the fish for at least 30 min.

Water phase salt:

- For air packaged smoked fish or smoked-flavored fish, not less than 2.5% water phase salt in the loin muscle; and
- For vacuum or modified atmosphere packaged smoked fish or smoke-flavored fish, not less than 3.5% water phase salt in the loin muscle, or, where permitted, the combination of 3.0% water phase salt in the loin muscle and 100-200 ppm nitrite (21 CFR 172.175; 21 CFR 172.177).

Temperature control during processing:

- The product must not be exposed to temperatures above 50º F (10º C) for more than 12 h nor to temperatures above 70º F (21º C) for more than 4 h, excluding time above 140º F (60º C).

Temperature control during in-process and finished product storage:

- The product must not be exposed to temperatures above 50º F (10º C), which may be assured by:
- A maximum cooler temperature of 50º F (10º C); and/or
- The presence of sufficient cooling media (e.g., adequate ice to completely surround the product).

Temperature control at receipt of smoked and smoke-flavored fishery products for storage or further processing:

- The product must not be exposed during transportation to temperatures above 50º F (10º C), which may be assured by:
- A maximum refrigerated container temperature of 50º F (10º C) throughout transit; or
- The presence of sufficient cooling media (e.g., adequate ice to completely surround the product) upon receipt.

VACUUM AND MODIFIED ATMOSPHERE PACKAGED FISH AND FISHERY PRODUCTS

Potential food safety hazard. Packaging conditions that exclude oxygen (e.g., vacuum packaging and other reduced oxygen packaging) favor the growth of *C. botulinum*, because oxygen is toxic to the pathogen. Vacuum packaging inhibits the growth of many spoilage bacteria, which increases the shelf life of the product. The safety concern with these products is the increased potential for the formation of *C. botulinum* toxin before spoilage makes the product unacceptable to consumers.

C. botulinum forms toxin more rapidly at higher temperatures than at lower temperatures. The minimum temperature for growth of *C. botulinum* type E and nonproteolytic types B and F is 38º F (3º C). For type A and proteolytic types B and F, the minimum temperature for growth is 50º F (10º C). As the shelf life of refrigerated foods is increased, more time is available for *C. botulinum* growth and toxin formation. As storage temperatures increase, the time required for toxin formation is significantly shortened. Processors should expect that at some point during storage, distribution, display, or consumer handling of refrigerated foods, proper refrigeration temperatures will not be maintained (especially for the nonproteolytic group). Surveys of retail display cases indicate that temperatures of 45-50º F (7-10º C) are not uncommon. Surveys of home refrigerators indicate that temperatures can exceed 50º F (10º C).

Control measures. Both smoked and raw products in vacuum packaging and other reduced oxygen packaging require strict refrigeration (or frozen storage conditions) throughout distribution.

FDA guidelines.
Vacuum packaged raw and cooked fish and fishery products:

- A maximum temperature of 40º F (4º C) for finished product coolers and for trucks or other carriers throughout transportation; or
- Sufficient ice or other cooling media to fully cover containers at all times during storage and distribution.

Vacuum packaged smoked fish and fishery products:

- A maximum temperature of 50º F (10º C) for finished product coolers and for trucks or other carriers throughout transportation; or

- Sufficient ice or other cooling media to fully cover containers at all times during storage and distribution.

H.4.2 Checklist. Guidelines for auditing seafood production facilities are contained in the following checklist.

APPENDIX H

SEAFOOD CHECKLIST Cured, Salted and Smoked Fish Establishments Good Manufacturing Practices CFR, Title 21, Parts 123 and 172	
APPENDIX A PARAGRAPH	REQUIREMENTS
B2	Processing rooms are separated/segregated to eliminate contamination. (Cured, Salted and Smoked Fish Establishments Good Manufacturing Practices (FGMP), 2.1 (a)).
E2	Equipment and utensils used in the handling of raw or frozen fish portions are not used in the handling, transport, or packaging of product after it has entered the smoking chamber or used in the handling of finished product. (FGMP, 2.2 (b)).
E2	Sanitary zones are established around areas in which processed fish is handled/stored. (FGMP, 2.2 (c)).
E1	Containers used to convey, brine, or store fish are not nested (stacked) while they contain fish or otherwise handled during processing or storage in a manner conducive to direct or indirect contamination of their contents. (FGMP, 3.1 (b)).
C6	Each smoking chamber is equipped with a temperature monitoring device so installed as to indicate accurately at all times the internal temperature of the fish within the smoking chamber. (FGMP, 3.1 (g)).
E2	Equipment and utensils are marked in some way to ensure that equipment and utensils used to handle raw fish are not used to handle product that has entered the smoking chamber, or used in the handling of finished product. (FGMP, 3.1 (I)).
E1	Imported fish or fishery products are obtained from approved sources. (Section 56.76, para (d) (4)) (21 CFR 123.12).
E1	Fresh and frozen fish received are inspected and adequately washed before processing. (FGMP, Sec. 4.1 (a)).
E3	Fresh fish, except those immediately processed, are iced or otherwise refrigerated to an internal temperature of 38° F (3° C) or below upon receipt and are maintained at that temperature until fish are to be processed. (FGMP, 4.1 (c)).
E3	All fish received in a frozen state are thawed promptly and processed, or stored at a temperature which will maintain it in a frozen state. (FGMP, 4.1 (d)).
E2	After thawing, fish are washed thoroughly with a vigorous potable water spray or a continuous water flow system. When thawing and brining occur concurrently, the fish are washed in this same fashion following the thawing and brining. (FGMP, 4.1 (f)).
E2	All fish are free of viscera prior to processing (see reference document for exceptions). (FGMP, 4.1 (g)).

SEAFOOD CHECKLIST - Continued.

E2	The evisceration of fish is conducted in a segregated or separate processing room. The evisceration is performed with minimal disturbance of the intestinal tract contents, and the fish, including the body cavity, is washed thoroughly with a vigorous spray or a continuous water flow system following evisceration. (FGMP, 4.1 (h)).
E4, H6	All processed fish are produced pursuant to the process as established by a competent processing authority. (FGMP, 4.2 (b)).
E3	All processed fish are distributed and sold in a manner that ensures that the internal temperature is maintained at 38° F (3° C) or below (see reference for exceptions). (FGMP, 4.2 (d)).
E2	The vacuum packaging or modified atmosphere packaging of processed fish is conducted only within the facilities of the manufacturer. (FGMP, 4.2 (e)).
E4	Processed fish to be vacuum packaged or modified atmosphere packaged are chemically analyzed for water phase, salt, and for nitrate and other additives when used, with sufficient frequency to ensure conformance with finished product specification requirements. (FGMP, 4.2 (f)).
A10	The finished product is handled only with clean, sanitized hands, gloves or utensils. Manual manipulation of the product is kept to a minimum. (FGMP, 4.4 (a)).
E3	Shipping containers, retail packages and shipping records relating to processed fish are appropriately labeled in accordance with the perishable nature of the product. (FGMP, 4.4 (c)).
E3	Each container of processed fish is legibly marked or labeled with an identifying code and required identification. (FGMP, 4.4 (d)).
E2, H6	Brining operations are performed IAW the appropriate time and temperature parameters. (FGMP, 5.1 (a)).
E2	For dry salting, the fish are returned to a refrigerated area of 38° F (3° C) or lower immediately after the application of the salt. (FGMP, 5.1 (b)).
E2	Different species of fish are not mixed in the same brine tank. (FGMP, 5.1 (c)).
E2, E4, H6	Brines are not reused without an adequate process available to return the brine to an acceptable microbiological level. (FGMP, 5.1 (d)).
E2	Fish are rinsed with fresh potable water after brining, except for fish which have been injected with brine. (FGMP, 5.1 (e)).
E2	Drying of a product to be cold smoked is carried out in a refrigerated area of 38° F (3° C) or below. (FGMP, 5.1 (f)).
E3, H6	The use of sodium nitrite is permitted with those species of fish allowed by regulation. (FGMP, 5.1 (g)). (21 CFR 172.175 and 172.177).
E3	Fish are of relatively uniform size and weight and arranged without overcrowding or touching each other within the smokehouse oven. (FGMP, 5.2 (a)).
E2	Liquid smoke, generated smoke, or a combination of liquid smoke and generated smoke are applied to all surfaces of the product at the appropriate times. (FGMP, 5.2 (b)).

SEAFOOD CHECKLIST - Continued.

C6	Hot processed smoked fish is produced by a controlled process that utilizes a temperature monitoring system to assure that all products reach the required temperature. (FGMP, 5.3 (a)).
E2, H6	For hot processed smoked fish to be air packaged, a controlled process is used to heat the fish. (FGMP, 5.3 (b)).
E2, H6	For hot processed smoked fish to be vacuum or modified atmosphere packaged, a controlled process is used to heat the fish. (FGMP, 5.3 (c)).
C6, H6	Cold processed smoked fish are produced by a controlled process that utilizes a temperature monitoring system assuring all products do not exceed process temperatures in accordance with authorized methods. (FGMP, 5.4 (a)).
E2, E4, H6	For cold processed smoked fish to be air packaged, fish that have brine contain not less than 2.5 percent water phase salt in the loin muscle of the finished product. (FGMP, 5.4 (b)).
E2, E4, H6	For cold processed smoked fish to be vacuum or modified atmosphere packaged, fish that have been brined contain not less than 3.5 percent water phase salt in the loin muscle of the finished product, or a combination of 3.0 percent water phase salt in the loin muscle of the finished product and not less than 100 nor more than 200 parts per million of sodium nitrite. (FGMP, 5.4 (c)).
E3	The finished products are properly cooled to 70° F (21° C) within 2 hours and further cooled to 38° F (3° C) within an additional 4 hours. Finished products are then maintained at 38° F (3° C). (FGMP, 5.5).
H8	Records are kept of every transaction involving the sale and distribution of processed fish. (FGMP, 4.3 (a)).
H6	Fish processing records are legibly written in English and identify the processing procedures, the product processed, process time, temperature, and the results of the chemical examination, together with the identifying lot code, the number of containers per coding interval, the size of the containers coded, and the year, day, and period when each lot was packed. (FGMP, 4.3 (b)).
H8	Records are maintained for the chemical examination of the finished product for the purpose of validating the water phased salt and sodium nitrite requirements. (FGMP, 4.3 (c)).
H8	All records relative to the scheduled process used to produce processed fish or smoked fish are readily available to government inspection personnel. (FGMP, 4.3 (d)).
H8	Records of refrigerated and/or frozen products, the general adequacy of equipment, process used, or results of scientific studies and evaluations, are retained for the amount of time specified in 21 CFR 123.9.

NOTE: Reference to the controlling sections of the FGMP and of 21 CFR 123 and 172 are identified in parentheses.

APPENDIX K
BOTTLED WATER/SOFT DRINK

K.1 SCOPE

K.1.1 Scope. This appendix contains guidelines for bottled water/soft drink processing facilities. The information contained herein is intended for guidance.

K.2 APPLICABLE DOCUMENTS

K.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that they must meet all specified requirements documents cited in this Appendix, whether or not they are listed.

K.2.2 Government documents. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

Code of Federal Regulations (CFR), Title 21, Parts 129 and 165

Code of Federal Regulations (CFR), Title 40, Part 141, Subparts C, E, and F.

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

K.3 DEFINITIONS

K.3.1 Definitions. Definitions are contained in the basic handbook.

K.4 GUIDELINES

K.4.1 General. Bottled water is water that is intended for human consumption and is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents. Bottled water may be used as an ingredient in beverages (e.g. diluted juices, flavored bottled waters). Products labeled as “carbonated water,” “filtered water,” “seltzer water,” “soda water,” “sparkling water”, and “tonic water” although audited under the requirements of Appendix K, MIL-STD-3006 do not comply with the description of bottled water under 21 CFR 165.110.

When auditing a bottled water/soft drink facility, key points to verify are:

a. Source of water is from an approved source (e.g. artesian well, natural spring, community water source, etc.).
b. Type of treatment utilized to process water prior to the bottling operation. This may include processes such as: distillation, ion-exchange, filtration (sand filters or other filtration devices) ultraviolet treatment, ozone treatment, reverse osmosis, carbonation, mineral addition, and syrup addition. Processes such as coloration, mixing and addition of syrups and addition of carbon dioxide for carbonation are performed under good manufacturing procedures.
c. Filling, capping, or sealing operations.
d. Cleaning and sanitizing processes.
e. Process controls to include microbiologic, physical, and chemical evaluation methods.

K.4.2 Checklist. Guidelines for auditing bottled water/soft drink processing facilities are contained in the following checklist.

APPENDIX K

BOTTLED WATER/SOFT DRINK CHECKLIST CFR Title 21, Parts 129 and 165	
APPENDIX A PARAGRAPH	REQUIREMENT
B2	The bottling room is separated from the other plant operations or storage areas by tight walls, ceilings, self-closing doors, and size of conveyor opening. (129.20 (a)).
B4	Adequate ventilation is provided to minimize odors, noxious fumes, or vapors; and condensate in processing, bottling, container washing and sanitizing rooms. Ventilation equipment is clean. (129.20 (c)).
E2	Product in process in other than sealed piping systems under pressure is protected from back-siphonage and other sources of contamination. (129.20 (b)).
B2	Bottle washing and sanitizing are in an enclosed room and are positioned so as to minimize post-sanitization contamination. (129.20 (d)).
B2	Processing, washing, and storage rooms are not directly connected to room(s) used for domestic household purposes. (129.20(e)).
E1, H6	Product water supply is from an approved, properly located, protected, operated, and accessible source. The water is of safe, sanitary quality, and conforms at all times to applicable laws and regulations. Operations water meets the same requirements. (129.35 (a)).
E4, H6	Source waters are analyzed annually for chemical and physical parameters; and once every four years for radiological parameters. Source waters, other than municipal sources, are analyzed weekly for microbiological quality. (129.35 (a)).
B7	Product water contact surfaces (utensils, pipes, equipment, etc.) are clean and are adequately sanitized daily. (129.37 (a)).
B7	Product water contact surfaces (utensils, pipes, equipment, etc.) are maintained free of scale, oxidation, and other residue. The presence of any unsanitary condition is corrected immediately. (129.37 (a)).
E3	Containers, caps, or seals are purchased and stored in sanitary closures (original containers) in a clean, dry place. They are examined before use and are handled, dispensed and used in a sanitary manner. They are washed, rinsed, and sanitized as needed. (129.37 (c)).
E2	Filling, capping, closing, sealing, and packaging are done in a sanitary manner. (129.37 (d)).
E3	Storage tanks are closed to exclude all foreign matter. Filtered vents are provided. Filters are readily cleanable or have replaceable elements. (129.40 (a))
H6, H8	Treatment methods accomplish their intended purpose. Records are maintained to show type and date of treatments and physical inspections of equipment. Conditions found, performance and effectiveness are noted. (129.80 (a)).

BOTTLED WATER/SOFT DRINK CHECKLIST - Continued.

E2	Treatment equipment processes and substances are used which preclude contamination or adulteration of the product. (129.80 (a)).
E4, H6	Product water samples are taken after processing, prior to bottling, to assure uniformity and effectiveness of the treatment process. Methods of analysis are approved by the government agency having jurisdiction. (129.80 (a)).
E2	All unsanitary or defective containers are reprocessed or rendered unusable and discarded. Multi-service primary containers are cleaned, sanitized, and inspected immediately prior to being filled, capped, and sealed. (129.80 (b)).
H6	Mechanical washers are inspected. Records of physical maintenance, inspections, conditions found, and performance of the mechanical washer, are maintained by the plant. (129.80 (b)).
E3	Multi-service shipping cases are maintained to assure that they will not contaminate primary containers or the product. (129.80 (b)).
H11	For sanitizing operations: Records are maintained concerning the concentration of sanitizing agents and the amount of time the agents were in contact with surfaces being sanitized. (129.80 (c) and (d)).
E2	Each unit package is identified by a production code. The code identifies the particular batch or segment of a continuous run, and the production date. (129.80 (e)).
H6, H8	Records are maintained of product type, volume produced, date produced, lot code used, and distribution to wholesale and retail outlets. (129.80 (e)).
E1	Containers and closures are nontoxic and comply with FDA standards. (129.80 (f)).
E2	Filling, capping, and sealing are monitored. Filled containers are visually or electronically inspected. (129.80 (f)).
E4, H6	A swab and/or rinse bacterial count is performed quarterly on four containers and closures immediately prior to filling the containers. (129.80 (f)).
E4, H6	Representative bacteriological samples are taken once per week of each type of product water produced during a day's production. (129.80 (g)) (165.110).
E4, H6	Representative chemical, physical, and radiological samples are analyzed once a year for each product water. (129.80 (g)) (165.110).
E4, H6	Records are maintained of sampling date, type of product, production code, and results of each analysis. (129.80 (h)).
H8	All records are retained for two years. Current certificates or notifications of approval authority for source and supply of product and operations water are on file. (129.80 (h)).

NOTE: Reference to the controlling 21 CFR 129 and 21 CFR 165 sections are identified in parentheses.

APPENDIX L
OFF POST CATERERS AND CIVILIAN RESTAURANTS

L.1 SCOPE

L.1.1 Scope. This appendix contains guidelines for auditing off post caterers and civilian restaurant facilities. The information contained herein is intended for guidance.

L.2 APPLICABLE DOCUMENTS

L.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that they must meet all specified requirements documents cited in this appendix, whether or not they are listed.

L.2.2 Government documents. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

Food Code 1999

(Application for copies should be addressed to U.S. Department of Health and Human Services, Food and Drug Administration, Food Service Sanitation Branch, Washington, DC 20204. Document No. PB99-115925 available printed, on CD ROM, or on diskette from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; 1-800-553-6847); or download from web site: http://vm.cfsan.fda.gov/~dms/foodcode.html/.)

L.3 DEFINITIONS.

L.3.1 Definitions. Definitions are contained in the basic handbook.

L.4 GUIDELINES

L.4.1 General. This standard is written for CONUS and overseas. The reference for the checklist is the "Food Code" U.S. Public Health Service, Food and Drug Administration. The definitions found in Part 1-2 of the "Food Code" apply. Disregard the automatic critical defects identified in the "Food Code." Consider the entire public health risk when evaluating defects in catering and restaurant facilities. Do not use the forms provided in the "Food Code." For auditing the normal Good Manufacturing Practices, use Appendix A.

Temperature evaluations must be made during these audits. It is recommended that you take two calibrated thermometers with you when performing an inspection at a catering or restaurant facility. Your appearance is important. Be sure to take a clean over-garment to wear over your street cloths. Always wear a head cover when walking through the facility. Before beginning the audit, wash your hands and continue to wash your hands each time after you touch equipment or foods during the audit. The primary areas to check are the dining area (if applicable), salad bar, cooking area, preparation area, coolers/freezers, dry storage, and waste area. These facilities may vary from a single room to multi-complex food preparation areas with many rooms.

The primary purpose of the audit is to ensure the customer is receiving a safe, unadulterated, and honestly presented product. Special consideration needs to be placed on Potentially Hazardous Foods (PHF). PHF's includes an animal food (a food of animal origin) that is raw or heat-treated; a food of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified in the "Food Code."

L.4.2 Checklist. Guidelines for auditing off post caterers and civilian restaurant facilities are contained in the following checklist.

APPENDIX L

OFF POST CATERERS AND CIVILIAN RESTAURANTS CHECKLIST Food Code	
APPENDIX A PARAGRAPH	REQUIREMENT
E1	Food prepared in a private home is not used or offered for human consumption in a food establishment. (3-201.11).
E1, E2	If game animals are used they have been commercially raised for food, are processed under a regulatory inspection program, and in accordance with applicable meat and poultry laws. (3-201.17).
E2	A food employee does not use a utensil more than once to taste food that is to be sold or served. (3-301.12).
A10	Food is protected from cross contamination by separation, packaging, cleaning, or other means. (3-302.11).
E3	Food items are stored in their original containers or are identified with their common name on working containers. (3-302.12).
E1	Pasteurized eggs or egg products are substituted for raw shell eggs in applicable foods, with exceptions as noted in the reference. (3-302.13).
E1	Prepared foods do not contain unapproved additives. (3-302.14).
E2	Raw fruits and vegetables are thoroughly washed/disinfected prior to processing, with exceptions as noted in the reference. (3-302.15).
E1	Ice used as an external cooler is not used as food. (3-303.11).
E2	During pauses in food preparation or dispensing, food preparation and dispensing utensils are stored in a manner to inhibit/reduce contamination. (3-304.12).
A6	If used, single-use gloves are used for only one task. Slash-resistant gloves and cloth gloves are used in an appropriate manner. (3-304.15).
E3	During preparation, unpackaged food is protected from environmental sources of contamination. (3-305.14).
E2	Raw animal foods comply with cooking requirements listed in the Food Code. (3-401.11/12).
E2	Fruits and vegetables that are cooked for hot holding are cooked to a temperature of 140° F (60° C). (3-401.13).
E2	Raw, raw-marinated, partially cooked, or marinated-partially cooked fish other than molluscan shellfish are frozen throughout to a temperature of either -4° F (-20° C) or below for 168 hours (7 days) in a freezer, or -31° F (-35° C) or below for 15 hours in a blast freezer, with exceptions as noted in the reference. Records are created and retained as specified, with exceptions as noted in the reference. (3-402.11/12).

OFF POST CATERERS AND CIVILIAN RESTAURANTS CHECKLIST - Continued.

E2	Potentially hazardous food (PHF) that is cooked, cooled, and reheated for hot holding is reheated so that all parts of the food reach a temperature of at least 165° F (74° C) for 15 seconds, with exceptions as noted in the reference. (3-403.11).
E2	Reheating for hot holding is done to ensure the food is between 41° F (5° C) or 140° F (60° C) and 165° F (74° C) for not more than 2 hours. (3-404.11)
E2	Frozen PHF is slacked under refrigeration below 41° F (5° C) with exceptions as noted in the reference. (3-501.12).
E2	Frozen PHF is thawed under proper refrigeration; proper running water technique; proper cooking techniques; and for proper time periods. (3-305.13).
E2	Cooked PHF is cooled utilizing proper time temperature requirements, and proper cooling methods, with exceptions as noted in the reference. (3-501.14/15).
E2	PHF is maintained in accordance with proper hot and cold holding procedures. (3-501.16).
E3	Ready-to-Eat PHF prepared and held refrigerated for more than 24 hours is clearly marked at the time of preparation with appropriate date marking, with exceptions as noted in the reference. (3-501.17).
E2	A food establishment obtains a variance from the regulatory authority when specialized processing methods are employed. (3-502.11).
C7	Food temperature measuring devices with glass stems or sensors are encased in shatterproof coatings. (4-201.12) .
C6, C7	Temperature measuring devices are properly designed, located and easily readable. (4-203.12).
C7	Warewashing machines are equipped with proper temperature and pressure indicating devices. (4-203.13 & 4-204.115).

NOTE: Cited reference document for the above is the Food Code.

APPENDIX M
SLAUGHTER AND FABRICATION OF FRESH MEAT PRODUCTS IN OVERSEAS AREAS

M.1 SCOPE

M.1.1 Scope. This appendix contains guidelines for auditing of slaughter and fresh meat products fabrication facilities in overseas areas. The information contained herein is intended for guidance.

M.2 APPLICABLE DOCUMENTS

M.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that they must meet all specified requirements documents cited in this appendix, whether or not they are listed.

M.2.2 Government documents. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

Code of Federal Regulations (CFR), Title 9, Parts 53, 54, 71, 72, 75, 110, 307, 308, 309, 310, and 313.

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

M.3 DEFINITIONS.

M.3.1 Definitions. Definitions are contained in the basic handbook.

M.4 GUIDELINES

M.4.1 General. This guideline has been written for military procurement overseas. Therefore, it is extremely important that an auditor know about the herd health in the region the livestock are coming from. It is not unusual in today's meat production business to ship livestock from one major region to another. Livestock destined for food production must be tested and/or certified as Tuberculoses and Brucellosis free. Animals must also be free of the following diseases: equine piroplasmosis, bovine piroplasmosis, splenetic fever, swine erysipelas, bluetongue, anthrax, chlamydiosis, Newcastles disease, or poultry diseases caused by *Salmonella* enteritidis, African swine fever, hog cholera, Teschen disease, European fowl pest, contagious equine

metritis, vesicular exanthemal or screwworms, Foot-and-Mouth disease, Pleuropneumonia, Rinderpest, Scrapie and Infectious Anemia. No animals infested with ticks or exposed to severe tick infestation should be rendered for food or human consumption. Auditors must be knowledgeable of the signs and symptoms of the medical conditions listed above in order to ensure wholesome meat products are consumed. Regional Public Health Officials should be able to provide one with their region's status concerning herd health; therefore, good communications should be maintained between overseas health authorities and the Army Veterinary Service.

NOTE: Tuberculosis may be determined by intradermal tuberculin test or other applicable diagnostic procedure. Facilities found to be tuberculosis infected must be disinfected immediately. Disinfection may be with sodium orthophenylphenate at one pound per 12 gallons of water; and applied at 60° F (16° C) or higher. If the ambient temperature is less than 60° F (16° C), the solution must be heated to 120° F (49° C).

Ante-mortem inspections are performed on each animal prior to slaughter for the purpose of eliminating those unfit for the preparation of food. Competent ante-mortem inspection gives the only assurance that unfit animals will not enter the slaughter facility (abattoir). It should be assumed that some livestock providers intentionally send sick animals to the abattoir. Many conditions develop during transit, in the holding pens, or at the stunning area that may render an animal less than fit for entry into the abattoir. These conditions are covered in 9 CFR 313, "Humane Slaughter of Livestock." Auditors should be familiar with these requirements. Auditors must also keep in mind that the standards written in 9 CFR 313 were intended for practices in the United States and that many countries overseas may not have similar standards. If an auditor identifies a normal practice taking place in an overseas plant that does not comply with the CFR requirements; it must be brought to the attention of the plant management. If there is clear resistance to change based on cultural differences, the auditor should not get involved in an argument. The auditor should carefully review the host country's methods and make a decision for deviation based on the wholesomeness of the end item.

Many diseased and otherwise unfit conditions affecting animals are not detectable on ante-mortem examination. Therefore, a post-mortem examination of the carcass and viscera of each animal passed for slaughter is examined to eliminate it or any part of it if diseased or otherwise unfit. Some overseas areas may have alternative methods for performing post-mortem examinations. In these cases, a Veterinary Corp Officer must determine if the alternative methods are adequate (equivalent). In any case, the auditor must be familiar with the basic required post-mortem examinations to include: examination of the lymph glands, viscera (lungs, heart, liver and paunch), and carcass.

The slaughter line is a dangerous area to work around. Auditors should have their own clean knee high rubber boots, adequate outer clothing, and a good fitting hard hat. Never enter the slaughter area directly from the holding pens without first washing your boots. Inspect yourself before entering the slaughtering area to ensure you are clean. Take special care around mechanical hide pullers. It is not unusual for chains to come loose during the pulling motion and create a dangerous situation. Check disinfecting units during slow-downs or breaks so that you don't interfere with the workers. Stay clear of electrical stimulation devices, you are working in

a wet area and possibility of an electrical problem does exist. Under no conditions should the auditor enter the stunning box.

Most modern facilities will have an overhead rail system but many developing countries may still use the cradle method. The cradle method is slow and often results in excessive contamination from the hide if care is not taken while dehiding the carcass. If the cradle method is used, ensure that the gut buggy does not cross-contaminate to the carcass. Also, pay special attention to the water being used to wash the floor. In an effort to make the facility look cleaner, workers will often continuously wash the floor with high pressure hoses while the carcass is still in the cradle. The washing often results in an increased amount of splash contamination. Also, pay special attention during the hoisting of the carcass. Ensure that the anterior of the carcass does not drag on the floor during the hoisting process.

The overhead rail is the most common system used today for beef slaughter. The normal steps are as follows: (this information may be used for describing the methodology) Stunning, Shackling, Sticking, Bleeding, Head Skinning, Foot Skinning, Leg Breaking, Ripping, Rimming Over, Rumping, Hide Pulling, Breast Sawing, Eviscerating, Tail Sawing, Scribing/Splitting, Trimming, Inspection, Washing, and Chilling. Recommended maximum times from the stunning-box to the bleeding is twenty minutes and from the stunning to the cooler is sixty minutes. The deepest part of the carcass should reach 40° F (4° C) within 48 hours. The above time recommendations include saved parts (hearts, tongues, livers, etc.). As a general rule, all equipment, tools, surfaces contacted by animal tissue should be rinsed and disinfected prior to coming in contact with the next animal. Examples include brisket splitting, tools, knives, gut buggies, tables, hooks, rodding tools, splitting saws, and chains.

The principle objective for slaughtering animals is that they are humanely slaughtered and processed in such a manner as to minimize potential contamination.

Meat fabrication only includes meats that have been cut (even to individual cuts) and chilled. Comminuted meats, hearts, livers and kidneys will be included in the category of fabrication, even though some textbooks may not include them. Meat fabrication does not include meats that have additives (i.e., smoke, cure) added to them or have been made into a sausage. This standard does not include meat processing. All fabrication rooms must be equipped with an adequate number of disinfection units (sometimes referred to as sanitizers). The temperature of the product should never exceed 40° F (4° C). Meat that is not boned must be fabricated in an adequately chilled room and must immediately be chilled. Prior to each day's production, a pre-operational sanitary inspection must be performed (by either an auditor or acceptable company representative).

This portion was written to acquaint you with livestock (meat) slaughtering and fabrication. It was not intended for use with poultry. You will find numerous variations of slaughtering and dressing procedures throughout the world. One major change over the last ten years has been the final rinse. Many areas use an organic acid while others may use steam. Anytime you identify a variation or deviation from the normal procedures, contact your Veterinary Officer for advice. The final determination should be based on the wholesomeness of the finished product and not solely on the fact that it is not mentioned or allowed in the Code of Federal Regulations. The

Code of Federal Regulations should be viewed as the basic requirement but exceptions may be made after professional consideration by proper medical authorities.

M.4.2 Checklists. Guidelines for auditing of slaughter and fresh meat products fabrication facilities in overseas areas are contained in the following checklist.

APPENDIX M

CHECKLIST SLAUGHTER AND FABRICATION OF FRESH MEAT PRODUCTS IN OVERSEAS AREAS SUBPART A - ANTE-MORTEM (UNLOADING RAMPS TO STUNNING AREA) CFR Title 9, Parts 53, 54, 71, 72, 75, 110, 307, 308, 309, 310, and 313	
APPENDIX A PARAGRAPH	REQUIREMENT
A1, E1	Livestock originate from an approved region. Food production animals are free of communicable disease. Animals from a quarantine region are processed in that region. (9 CFR 71/72/75/53/54).
E1	Handling of livestock from the unloading ramps to the stunning area is done in a humane manner. (9 CFR 313).
B2	Pens, chutes and alleys are paved, drained and supplied with adequate hose connections for cleanup purposes. (9 CFR 307.2).
E2	Livestock entering the facility receive an adequate ante-mortem inspection on the day of and before slaughter and are properly segregated when required. (9 CFR 309.1/2).
B2	Satisfactory pens, equipment, lighting, and assistants are available for conducting ante-mortem inspection and for separating, marking and holding apart passed livestock from livestock which has been identified as suspect or condemned. (9 CFR 307.2).
B2	When holding pens of an establishment are located in a public stockyard, such pens are regarded as part of the premises of that establishment. (9 CFR 309.1).
B2	Holding and shackling pens are located outside of or effectively separated from the slaughtering department. (9 CFR 307).
E1	Animals have access to water in all holding pens and if held longer than 24 hours, feed is provided. (9 CFR 313.2).
E1	Seriously crippled animals, "downers," are identified as suspects and properly disposed of. (9 CFR 309.2).
E1	Livestock found to be dead or in a dying condition on the premises of an establishment are identified as condemned and disposed of. (9 CFR 309.3).
E1	Any swine having a temperature of 106° F (41° C) or higher and any cattle, sheep, goats, horses, mules, or other equines having a temperature of 105° F (40° C) or higher are identified as condemned. (9 CFR 309.3)
B2	Floors of livestock pens, ramps, and driveways are constructed and maintained as to provide good footing for livestock. (9 CFR 313.1).
E1	Humane methods of slaughter are applied within an appropriate stunning area. (9 CFR 313).
E1	Animals are adequately stunned prior to being shackled, hoisted, thrown, cast, or cut (bleeding). (9 CFR 313.2).

CHECKLIST SLAUGHTER AND FABRICATION OF FRESH MEAT PRODUCTS IN OVERSEAS AREAS SUBPART B - POST-MORTEM CFR Title 9, Parts 53, 54, 71, 72, 75, 110, 307, 308, 309, 310, and 313	
APPENDIX A PARAGRAPH	REQUIREMENT
E2	A careful post-mortem examination and inspection is made of carcasses and parts of all livestock slaughtered. (9 CFR 310.1).
E2	The head, tail, tongue, thymus gland, and all viscera of each slaughtered animal are handled in such a manner as to identify them with the rest of the carcass and as being derived from the particular animal involved, until the post-mortem examination of the carcass and parts thereof has been completed. (9 CFR 310.2).
E2	Identification devices (i.e., ear tags) are removed from the animal's hide or ear by an establishment's employee and are placed in a clear plastic bag and affixed to the corresponding carcass. (9 CFR 310.2).
E2	Each carcass, including all detached organs and other parts, in which any lesion or condition is found that might render the meat or any part unfit for food purposes, or otherwise adulterated, and which, for that reason, would require a subsequent inspection, is retained. All parts are retained until an approved authorized veterinary final inspection has been completed. Retained carcasses are not washed or trimmed unless authorized by veterinary official. (9 CFR 310.3).
E2	Each carcass or part which is found on final inspection to be unsound, unhealthful, unwholesome, or otherwise adulterated is conspicuously marked. (9 CFR 310.5).
E2	Spermatic cords and pizzles are removed from all carcasses. Preputial diverticuli are removed from hog carcasses. (9 CFR 310.7).
E2	When a carcass is to be dressed with the skin left on, the skin is thoroughly washed and cleaned before any incision is made for the purpose of removing any part thereof or evisceration. (9 CFR 310.10).
E2	All hair, scurf, dirt, hoofs and claws are removed from hog carcasses, and the carcasses are thoroughly washed and cleaned before any incision is made for inspection or evisceration. (9 CFR 310.11).
E2	The sternum of each carcass is split and abdominal and thoracic viscera is removed at the time of slaughter in order to allow proper inspection. (9 CFR 310.12).
E2	Carcasses found before evisceration to be affected with anthrax are not eviscerated but are retained, condemned, and immediately tanked and the complete working area is cleaned immediately and disinfected. (9 CFR 310.9).
E2	The kidney capsule is opened to expose the kidneys for the purpose of inspection. (9 CFR 310.19).

SLAUGHTER AND FABRICATION
OF FRESH MEAT PRODUCTS IN OVERSEAS AREAS
SUBPART B - POST-MORTEM - Continued.

E2	If the hide is penetrated by electrodes during electrical stimulation, the penetrated tissue is trimmed. Disinfection of electrodes between each hide-on carcass stimulation is not required. (9 CFR 308.16).
E2	Partially skinned carcasses are not stimulated. (9 CFR 308.16).
B7	For hide-off stimulation, the carcass contact surfaces of equipment are disinfected between carcasses. (9 CFR 308.16).
E2	Carcass contamination of edible tissue by stomach contents, feces and/or urine is unacceptable. To prevent this contamination, any of the following are used prior to electrical stimulation: (9 CFR 308.16). a. Leave the sphincter muscles intact. b. Cut the rectum (scalp the bung) and the urethra free from surrounding tissue and securely tie each off. c. Partially open the mid-line and/or slay the brisket to reduce pressure on the visceral organs. d. Any other pressure-relieving or discharge-restricting alternative acceptable to the chief veterinary inspector. e. Rod (separate the esophagus from the surrounding tissue) and tie it off.
E2	When only a portion of a carcass is to be condemned on account of slight bruises, either the bruised portion is removed immediately and disposed of, or the carcass is promptly placed in a retaining room and kept until chilled, and the bruised portion is then removed and disposed of. (9 CFR 308.16).
C1	Tables, benches, and other equipment on which post-mortem inspection is to be performed, are of such design, material, and construction as to enable inspectors to conduct their inspection in a ready, efficient and clean manner. (9 CFR 307.2).

SLAUGHTER AND FABRICATION
OF FRESH MEAT PRODUCTS IN OVERSEAS AREAS
SUBPART B - POST-MORTEM - Continued.

E2	Cases, Carcasses, organs, and other parts are handled in a sanitary manner to prevent contamination (adulteration) with fecal material, urine, bile, hair, dirt, or foreign matter; however, if contamination occurs, it is promptly removed in a manner satisfactory to the inspector. (9 CFR 310.18). Specific preventive measures include: a. Knives are immediately disinfected after contamination (i.e., after sticking, head removal, following the initial cut through the hide/skin, after removal of an abscess, bruise or contamination). b. No water is placed onto a carcass until the entire hide has been removed and the carcass inspection has been performed. c. Manual hide removal begins at the hind leg and proceeds downward allowing the hide to be laid back away from the flesh. d. The final wash is begun at the highest point of the carcass and works downward. e. No portion of the forequarters comes in contact with eviscerating/inspection tables. f. Overhead rails are free of flaking rust or grease. g. Carcasses do not come in contact with walls, pillars, dividers or other features that will result in cross-contamination. h. Adequate separation is provided between offal rooms and product areas. i. Pressurized water used to wash down equipment and facilities is only used when carcasses are not in the location (to avoid splash contamination). j. Ventilation is provided at the location of a mechanical hide puller. k. Condensation does not drip onto carcasses. l. Carcasses are washed immediately after the final inspection and prior to being placed into a cooler. m. The floor area (dry landing) within the stunning box is maintained in a reasonably dry condition.

CHECKLIST SLAUGHTER AND FABRICATION OF FRESH MEAT PRODUCTS IN OVERSEAS AREAS SUBPART C - SLAUGHTER AND FABRICATION CFR Title 9, Parts 53, 54, 71, 72, 75, 110, 307, 308, 309, 310, and 313	
APPENDIX A PARAGRAPH	REQUIREMENT
B8	Nonpotable water is permitted only in those parts of the establishment where no edible product is handled or prepared and then only for limited purposes such as on ammonia condensers not connected with potable water supply. (9 CFR 308.3).
B8	Nonpotable water is not permitted for washing floors, areas, or equipment involved in trucking materials to and from edible product departments nor is it permitted in hog scalding vats, dehairing machines, or vapor lines serving edible product rendering equipment, or for cleanup of shackling pens, bleeding areas, or runways within the slaughtering department. (9 CFR 308.3).
B9	In all cases, nonpotable water lines are clearly identified. (9 CFR 308.3).
B8	If hot water is used for cleaning, it is not at a temperature of less than 180° F (82° C). (9 CFR 308.3).
B2	Rails are located so as to prevent product from coming in contact with posts, walls, and other fixed parts of the building, barrels, boxes, etc. (9 CFR 308.3).
A4	Butchers and others who dress or handle diseased carcasses or parts cleanse their hands with liquid soap and hot water, and rinse them in clear water, before handling or dressing other parts. (9 CFR 308.8).
B7	Implements used in dressing diseased carcasses are thoroughly cleansed with hot water having a minimum temperature of 180° F (82° C) or approved disinfectant. (9 CFR 308.8).
B3	The rooms and compartments in which any product is prepared or handled are free from dust and from odors from dressing and toilet rooms, catch basins, hide cellars, casing rooms, inedible tank and fertilizer rooms, and livestock pens. (9 CFR 308.3).
A10	Such practices as spitting on whetstones; spitting on the floor; placing skewers, tags, or knives in the mouth; inflating lungs or casings with air from the mouth are prohibited. (9 CFR 308.8).
C7, B5	Disinfecting units are maintained above 180° F (82° C) and are adequately located. Chemical disinfectants may be used during production when approved by the MACOM Veterinarian. (9 CFR 308.3).
C1	Cutting boards and tables are solid, clean and sanitary. (9 CFR 308.7).
A1	Employees showing evidence of a communicable disease or affected with boils, sores, or infected wounds do not handle or prepare any product. (9 CFR 308.14).

SLAUGHTER AND FABRICATION
OF FRESH MEAT PRODUCTS IN OVERSEAS AREAS
SUBPART C - SLAUGHTER AND FABRICATION - Continued.

A2	Aprons, frocks, and other outer clothing worn by persons who handle product are clean and are changed each day. (9 CFR 308.8).
C1	Scabbards are constructed of a smooth impervious material. (9 CFR 309.1).
E-2	Fabrication rooms are maintained at 50° F (10° C)
E2	Fresh meat does not exceed 45° F (7° C) during storage or fabrication. If hot boning is in place, the production takes place in a room that is maintained at 50° F (10° C) and the finished product is immediately chilled. (21 CFR 110.80).

NOTE: Cited reference documents for the above are 9 CFR 53, 54, 71, 72, 75, 110, 307, 308, 309, 310, and 313.

APPENDIX N
DRY DAIRY PRODUCTS

N.1 SCOPE

N.1.1 Scope. This appendix contains guidelines for auditing dry dairy products facilities. The information contained herein is intended for guidance.

N.2 APPLICABLE DOCUMENTS

N.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that they must meet all specified requirements documents cited in this appendix, whether or not they are listed.

N.2.2 Government documents. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

U.S. Public Health Service Publication 229 Grade “A” Pasteurized Milk Ordnance, 1997 Revision

(Application for copies should be addressed to U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Milk Safety Branch, 200 C Street SW, Washington, DC 20204.)

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

National Institute of Standards and Technology, Handbook 44

(Application for copies should be addressed to National Institute of Standards and Technology, 110 Bureau Drive, Gaithersburg, MD 20899-0001, http://www.nist.gov/.)

CODE OF FEDERAL REGULATIONS (CFR)

Code of Federal Regulations (CFR), Title 21, Part 173.

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

N.2.3 Non-government publications. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of the documents which are DoD adopted are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)

ANSI/ASHRAE 52.1-1992 - Gravimetric and Dust Spot Procedures for Testing Air Cleaning Devices Used in General Ventilation for Removing Particulate Matter

(Application for copies should be addressed to American National Standards Institute, 11 West 42nd Street, New York, NY 10036, http://www.ansi.org/.)

N.3 DEFINITIONS.

N.3.1 Definitions. Definitions are contained in the basic handbook.

N.4 GUIDELINES

N.4.1 General. Pasteurization Systems. The pasteurization requirements detailed in the fluid dairy Appendix of this handbook apply to dry milk production. These standards must be met prior to the plant being evaluated for dry milk production. In most cases the process will be a continuous one.

Dry Milk Processing. Some primary factors to be evaluated when auditing the drying portion of milk processing is identified below. These factors should not be considered all inclusive.

- Evaluate the source and nature of the water supply and any subsequent treatment.
- Be alert for careless handling of powdered ingredients (vitamins, flavors, etc.) which may contribute to product contamination.
- Obtain sources of Vitamins A & D and other optional ingredients.
- Condensed milk should be held at 45° F (7° C) or less, but it can be held up to 1 hour at 45° F - 135° F (7° C - 57° C) or two hours at 135° F - 165° F (57° C - 74° C).
- All whey for condensing is maintained at a temperature of 45° F (7° C) or less; or 145° F (63° C) or greater until processed.
- Condensed whey is cooled during the crystallization process to 45° F (7° C) or less within 18 hours of condensing.
- All pasteurized milk and milk products, pasteurized whey and condensed milk products except those to be immediately dried, are cooled immediately in approved equipment to a temperature of 45° F (7° C) or less.
- If surge tanks or balance tanks are used between the evaporator and the drier, such tanks hold the product at a temperature of 150° F (66° C) or more, or are completely cleaned at

a minimum of once every 4 hours of operation or less. Exception: acid type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below.

- Evaluate equipment construction characteristics for assurance that static accumulations are controlled, particularly in fluid milk drying and conveying equipment, sifters, rollers, drum, sanitizers.
- Determine if equipment is constructed and maintained to protect the product from dust and environmental contamination.
- Equipment used for the manufacture of dried dairy products should not be used in drying other products unless effectively cleaned and sanitized prior to the drying of the dairy products.
- Preheaters and hotwells should be fitted with tight covers when in use.
- Spray dryers should be a continuous discharge type, easily cleanable and should be cleaned and inspected at least daily.
- Rollers and collectors should be located in a room separated from other operations to
- prevent airborne contamination.
- Conveying equipment such as augur ends, bucket elevators, etc., should be cleaned at least daily to prevent accumulation of static material.
- Sifter screens should be easily removable and maintained in a clean condition.
- Evaluate air filtration system and determine the air-flow throughout the plant. Consider the following:
  - The quality and source of intake air.
  - Is the air recycled, filtered? How? Are the filters reusable or disposable?
  - Air for cooling powder may pass over refrigerated coils and pick up dust or powder contaminants.
  - Proximity of air exhaust to air intake.
  - Air temperature at critical points, i.e., entering and leaving drying chamber.
  - Potential for plumbing back-flow. For example, can water used to produce vacuum be back siphoned into the plant's water supply?
- Plant air supply systems should provide clean, adequately filtered air for all post-pasteurization processing rooms in which the finished product is exposed to the air, i.e. instantizing and packaging rooms.
- Clean, adequately filtered air should be supplied to product dryers, product coolers, dry product handling equipment and instantizing equipment. The air supply system should be maintained in a clean, sanitary, and efficient operating condition including changing or cleaning of filters as often as necessary. Filters should be tightly fitted or sealed in frames to avoid air by-pass.
- Plant forced air intakes should be properly located to prevent the entrance of airborne contaminants.
- Air exhausts from buildings or equipment should be so constructed as to prevent back-flow of air or material when not operating.
- If the air for cooling powder is mechanically cooled, refrigeration units should be maintained in a clean condition.
- Be alert for condensate formation throughout the plant and for optimum moisture and temperature conditions conducive to *Salmonella* growth in static material.

- Evaluate the handling and treatment of the condenser cooling water. Small amounts may be drawn into the systems during operation. If cooling water is circulated over a cooling tower, evaluate the potential for *Salmonella* and other bacterial contamination.
- Cooling water utilizing a cooling tower may not be used directly for cooling of product in a plate heat exchanger or other mechanical system where product may be contaminated.
- Condensing water for evaporator must be from a safe source unless the evaporator is constructed and operated to preclude contamination of such equipment or its contents by condensing water; or by water used to produce vacuum.
- Examine the inspection, sampling and cleanout ports on the evaporator for buildup of static material and avenues for airborne contaminants.
- Evaluate product flow through the plant and determine whether there is unnecessary product movement between areas which may increase the likelihood of cross-contamination.
- Observe procedure for incorporating Vitamin A & D and other optional ingredients into the product. Review the volume control records on the use of vitamins. Compare the usage with products produced. Review the records of vitamin testing if products produced are vitamin fortified.
- Observe and evaluate the packaging operation to determine:
  - The suitability of finished product containers.
  - Storage of unused containers.
  - Container cleaning, if applicable.
- Evaluate the safeguards and precautions in the filling and packaging areas to avoid product contamination, i.e., the method of final weight adjustment and the sanitary handling of packaging containers at this point.
- Topping off to obtain proper net weight should be conducted in a sanitary manner using clean utensils and equipment and using fresh dry milk which is protected from airborne contamination.
- The contents of damaged containers of dry milk should be reconstituted, re-pasteurized, and processed if intended for food use and if no visible extraneous material was introduced into the product.
- Determine quality control specifications for raw materials, i.e., bacterial load, antibiotics, pesticides, butterfat, sediment, etc.
- Evaluate sampling, test procedures and results of incoming raw milk, pasteurized milk, base powder, and other ingredients.
- Ascertain scope of *Salmonella* testing of water supply, and the air supply, at critical processing points, in the plant environment, and in finished products.
- Determine the qualifications of laboratory personnel, adequacy of laboratory equipment, and record keeping procedures.
- Determine if production lots are quarantined until completion of finished product analysis.
- Observe employee habits and dress, particularly, use of special clothing while handling or contacting in-process materials and equipment surfaces that contact the product.
- Evaluate cleaning methods (CIP, vacuum, compressed air, etc.) for all raw ingredient, in-process, and dried milk contact equipment, i.e., pumps, valves, tanks, lines, belts, conveyors, air filtering bags, packaging machines, etc.

- Observe scheduled plant and equipment cleanup including plant start-up and shut down procedures. The evaluation should consider the following:
  - Separate cleaning equipment should be used exclusively for the drying system and should be stored properly.
  - Frequency of cleaning.
  - Equipment suitability, including smooth impervious construction, easily accessible for cleaning, etc.
  - Degree of employee supervision.
- Determine the identity, strength, and use of sanitizing agents. Proper use requires flushing these agents from the system.
- Verify that box dryer(s) are being sanitized as described in the PMO.
- Determine the disposition of powder and dust collected during plant cleanup.
- Milk powder recovered from bag collectors and other places in the instantizing process (other than "fines" which are recirculated) may be fed back into the system, but, unless rehydrated and pasteurized prior to recycling, this may be a source of bacterial build-up and recontamination.
- Sifter tailings should not be used for food purposes and should be disposed of in a manner that would preclude contamination of plant facilities or finished products.

N.4.2. Nonfat Dry Milk (NFDM) power used as an ingredient for further processing. NFDM powder from any source is acceptable for use as an ingredient for frozen desserts and recombined dairy products if:

a. It is produced in a state of the United States, or
b. The source is listed in the Directory, or
c. It has been imported into a state of the 50 United States, and
   (1) Each lot is accompanied by an official Government report from the country of origin stating that the lot has been tested and found free of *Salmonella*, or
   (2) A certified laboratory has tested each lot and found each lot free of *Salmonella*. When using this alternative, collect and submit samples of NFDM for testing as follows: Despite the lot size, aseptically select eight 100-gram samples. The testing laboratory will prepare two 400-gram composites from each set of eight samples received. The inspector should consider the presence of *Salmonella* in either sample of the lot represented as sufficient reason to reject that lot. Discontinue use of NFDM from that source unless subsequent lots are determined *Salmonella*-free before use.

N.4.3 Checklist. Guidelines for auditing dry dairy products facilities are contained in the following checklist.

APPENDIX N

DRY DAIRY PRODUCTS CHECKLIST USPHS Publication 229 and CFR Title 21, Part 173	
APPENDIX A PARAGRAPH	REQUIREMENT
E1	Milk originates from herds accredited Tuberculosis-free, Brucellosis-free, and is from countries/regions determined to be acceptable. (PMO, Sec. 8).
E1	The source of water, vitamins, flavorings, etc. meets standards. (Sec. 7, Item 7p and Appendices A, G and K).
B7 & H6	A system of tagging or recording tanker trucks that have been cleaned and sanitized is established and maintained for 15 days (Sec. 7, Item 12p).
E1	Upon arrival, raw milk and/or raw products for pasteurization complies with bacteriological, chemical and temperature standards of Sec. 7, Table 1.
E4	Raw milk and milk products are screened for drug residue. (Sec. 6 and Table 1).
E2	Raw milk and milk products are held at 45° F (7° C) until processed. (Sec. 7, Item 17p).
E2	Condensed milk is held at 45° F (7° C) or less. (Sec. 7, Item 17p)
E2	Whey for condensing is maintained at 45° F (7° C) or less; or 145° F (63° C) or greater until processed. (Sec. 7, Item 17p and Table 1).
E2	Condensed whey is cooled during the crystallization process to 45° F (7° C) or less within 18 hours of condensing. (Sec. 7, Item 17p and Table 1).
E2	If the surge tanks or balance tanks are used between the evaporator and the drier, such tanks hold the product at 150° F (66° C) or above, or are cleaned at least once every 4 hours of operation (see exception for acid type whey or pH factor). (Sec. 7, Item 17p).
C3	Welded portions of food contact surfaces are smooth and free from pits, cracks, or inclusions. (Sec. 7, Item 10p).
C2	All milk contact surfaces of multi-use containers and equipment are constructed of American Iron and Steel Institute (AISI) 300 series stainless steel or other non-corrosive material as described in the PMO. (Sec. 7, Item 11p).
C5	Equipment is designed to protect against surface and overhead contamination. (Sec. 7, Item 11p).
B7	Raw milk storage tanks are cleaned when emptied and should be emptied at least every 72 hours. (Sec. 7, Item 12p).
C7	Storage tanks used to store raw milk or heat-treated milk products are equipped with a 7 day temperature recording device. (Sec. 7, Item 12p).
C5	Pasteurizing equipment complies with the sanitary design and construction standards of the PMO. (Sec. 7, Item 11p).
E2	Pasteurization equipment and controls testing is performed in accordance with the PMO. (Appendix F).

DRY DAIRY PRODUCTS CHECKLIST - Continued.

H8	Pasteurization recording charts are maintained on file at the processing plant. (Sec. 7, Item 16p(E)).
C7	Thermometers meet requirements. (Sec.7, Item 16p(A) & 16p(B), Appendix E).
E2, H8	Recording Charts are complete and maintained. (Sec. 7, Item 16p).
C4	Equipment is constructed to ensure static accumulations are limited. (Sec. 7, Item 11p).
B2	Rollers and collectors are located in a room separate from other operations to prevent airborne contamination. (Sec. 7, Item 5p).
C1	Conveying equipment is cleaned at least daily. (Sec. 7, Item 12p).
C1	Sifter screens are easily removed and kept clean. (Sec. 7, Item 12p).
C5	The plant air filtration system meets requirements. (Sec. 7, Item 4p).
E2	Cooling water used in a cooling tower is not used where it will come in direct contact with products (cooling products). (Sec. 7, Item 7p).
E2	Safeguards are in place to preclude the contamination of finished products during filling. (Sec. 7, Item 18p).
E2	The topping off of containers to obtain the proper weight is done in a sanitary manner. (Sec. 7, Items 15p and 18p).
E1	Ingredients from damaged containers are reprocessed prior to being repackaged. (Sec. 7, Item 15p).
C8	Culinary steam is in accordance with PMO. (Sec. 7, Item 16p(B).
B8	Boiler water additives comply with 21 CFR 173.310.
C8	Air under pressure is in accordance with 3-A Accepted Practices. (Appendix C).
E2	There are no cross-connection or direct contamination of pasteurized milk or milk product. (Sec. 7, Item 15p).
B6, C5	All openings, including valves, pipes, milk tanker trucks, etc. are capped or otherwise protected. (Sec. 7, Item 15p(A)).
E2, E5	Re-circulated cooling water is protected from contamination. (Sec. 7, Item 7p).
E4	Re-circulated cooling water is tested once per six-month period. (Appendix D and Appendix G).
C7	Clean-in-place (CIP) systems are in compliance with PMO. CIP systems have a recording device installed in the return solution line or other appropriate area to record the temperature and time which the line or equipment is exposed to cleaning and sanitizing solution (retained for 3 months). (Sec. 7, Item 12p).
H6, H7, H8, H9	Record of CIP cleaning process is maintained for recirculated cleaning systems. (Sec. 7, Item 12p).
B3	Plants where containers are manually cleaned have a two compartment sink and a steam cabinet to sanitize containers or a three compartment sink if a chemical sanitizer is used. (Sec. 7, Item 12p).

DRY DAIRY PRODUCTS CHECKLIST - Continued.

E4, H8	Pasteurized milk and/or milk products comply with bacteriological, chemical and temperature standards of Sec. 7. This is recorded and records maintained. (Sec. 7, and Table 1).
E4, H8	Residual bacteria counts for multi-use and single-service containers meet the standards listed in the PMO. This is recorded and records maintained. (Sec. 7, Item 12p).
B5	Poisonous or toxic materials are not stored in any room where milk or milk products are received, processed, pasteurized or stored. (Sec. 7, Item 15p(A)).
B5	Only approved rodenticides and insecticides are used. (Sec. 7, Item 15p(A)).
A10	Employee habits and dress, particularly the use of special clothing while handling or in contact with products or product contact surfaces, is appropriate. (Sec. 7, Item 20p).

NOTE: Cited reference documents for the above are USPHS Publication 229 and 21 CFR 173.

APPENDIX P
FRESH-CUT PRODUCE

P.1 SCOPE

P.1.1 Scope. This appendix contains guidelines for auditing fresh-cut produce facilities. The information contained herein is intended for guidance.

P.2 APPLICABLE DOCUMENTS

P.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that they must meet all specified requirements documents cited in this appendix, whether or not they are listed.

P.2.2 Government documents. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

Code of Federal Regulations (CFR), Title 21, Part 110.

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Guidance for Industry, Oct. 98, U. S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN).

(Application for copies should be addressed to Food Safety Initiative Staff, HFS-32, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 200 C Street S.W. Washington, DC 20204, http://www.foodsafety.gov/~dms/prodguide.html/.)

P.2.3 Non-government publications. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents which are DoD adopted, are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

Food Safety Guidelines for the Fresh-Cut Produce Industry, 1996, Third Edition, International Fresh-Cut Produce Association

Assessment of the Risk of Botulism Contributed by Modified Atmosphere Packaging of Fresh-Cut Produce, 1993, A Report Prepared by the International Fresh-Cut Produce Association

(Application for copies of the two documents above should be addressed to International Fresh-cut Produce Association, 1600 Duke Street, Suite 440, Alexandria, VA 22314, http://www.fresh-cuts.org/publications1329/publications.htm/.)

Fresh Cut Produce Handling Guidelines, 1997, International Fresh-Cut Produce Association and Produce Marketing Association

(Application for copies of this document should be addressed to International Fresh-cut Produce Association, 1600 Duke Street, Suite 440, Alexandria, VA 22314 http://www.fresh-cuts.org/publications1329/publications.htm/, or Produce Marketing Association, P.O. Box 6036, Newark, DE 19714.)

Voluntary Food Safety Guidelines for Fresh Produce, Voluntary Guidelines for Minimizing Microbial Contamination in Fresh Produce, 1997, International Fresh-Cut Produce Association (IFPA) and Western Growers Association (WGA).

(Application for copies of this document should be addressed to International Fresh-cut Produce Association, 1600 Duke Street, Suite 440, Alexandria, VA 22314 http://www.fresh-cuts.org/publications1329/publications.htm, or Western Growers Association, 17620 Fitch Street, Irvine, CA 92614.)

Postharvest Chlorination - Basic Properties and Key Points for Effective Distribution, 1997

(Application for copies should be addressed to University of California, Davis, Dept. of Vegetable Crops, Div. Of Agriculture and Natural Resources, Attn: Trevor Suslow, Extension Specialist, One Shields Avenue, Davis, CA 95616, http://anrcatalog.ucdavis.edu/specials.ihtml/.)

P.3 DEFINITIONS

P.3.1 Definitions. Definitions are contained in the basic handbook.

P.4 GUIDELINES

P.4.1 General. The following factors should be considered for different units of operation in a fresh produce processing plant.

Receiving. Incoming produce can be the source of microbiological, physical, and chemical hazards. Some of the responsibility of controlling the hazards can be pushed back to the growers, such as pesticide certification. The plant should have a good supplier certification program. Periodic microbiological testing of raw produce can help evaluate the supplier.

The most common hazard associated with raw produce is foreign objects, mainly metal objects. Inspection procedures must be established to inspect incoming produce for these hazards.

Storage. Temperature, product rotation, GMP of the storage area, and pest control are critical factors to look at in the storage facilities of fresh-cut produce.

Processing. Measures must be taken to prevent cross contamination and other hazards throughout the different points of production. Some of the most important critical control points in processing are:

- Trim/Core Operation. Employee hygiene to prevent microbiological contamination and foreign object control to prevent staples, wood slivers, etc. This area should be separate from other areas of processing to prevent cross contamination between raw and finished products.
- Cutting. Equipment sanitation (blade cleaning and sanitizing).
- Washing. Chlorination (ppm, pH, temperature), equipment sanitation, chemical residue from cleaning chemicals. Water is one of the key elements in the quality of processed fresh-cut produce. The source and quality of water must be considered. Three parameters should be controlled in washing the fresh-cut produce:
  - Quantity of water used: 5-10 L/kg of product.
  - Temperature of water: 40º F (4º C) to cool the product.
  - Concentration of active chlorine: 100 mg/L.

In regards to chlorine, the FDA allows the use of sodium hypochlorite (bleach), calcium hypochlorite and gas chlorine to wash fresh-cut vegetables, followed by a potable rinse. Liquid chlorine is most widely used in the industry.

- Drying. Sanitation of direct contact equipment.
- Packaging. Metal detection, tamper-proof tape, equipment hygiene.
- Finished Product Sampling program. Microbiological testing, chemical residue (chlorine), code dating, temperatures.

Distribution. Temperature and sanitation of delivery vehicles.

P.4.2 Checklist. Guidelines for auditing fresh-cut produce facilities are contained in the following checklist.

APPENDIX P

FRESH-CUT PRODUCE CHECKLIST

CFR Title 21, Part 110

Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables

Food Safety Guidelines for
the Fresh-Cut Produce Industry

Postharvest Chlorination -
Basic Properties and Key Points for Effective Distribution

Fresh Cut Produce Handling Guidelines

IFPA/WGA Voluntary Food Safety Guidelines
for Fresh Produce

Assessment of the Risk of Botulism Contributed by Modified Atmosphere Packaging of Fresh-Cut Produce

APPENDIX A PARAGRAPH	REQUIREMENT
E2	Trimming, coring, cutting and culling operations are performed in a sanitary manner. (21 CFR 110.35, 110.37, 110.40).
E2, E4, H6	Wash water chlorine level parameter is established and monitored at 100 - 150 ppm total chlorine or 2 - 7 ppm free chlorine; max 200 ppm. (Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Food Safety Guidelines for the Fresh-Cut Produce Industry).
E4, H6	Wash water pH level parameter is established and monitored at 6.0 - 7.0. (Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Food Safety Guidelines for the Fresh-Cut Produce Industry).
E2, H6	Wash water temperature range is established and monitored at 33° F - 36° F (18° C - 20° C) higher temperature than the product, to preclude pressure differential. (Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Food Safety Guidelines for the Fresh-Cut Produce Industry).
E2, H6	Product contact time is established and monitored (dump tank, submersion, sprayer, flume, hydrocooler method). (Food Safety Guidelines for Fresh-Cut Produce Industry; Postharvest Chlorination - Basic Properties and Key Points for Effective Distribution.)
E2, H6	Water recirculation method is established and monitored (filtration, displacement, replacement). (Food Safety Guidelines for the Fresh-Cut Produce Industry; Postharvest Chlorination - Basic Properties and Key Points for Effective Disinfection).

FRESH-CUT PRODUCE CHECKLIST - Continued.

E2	Only approved treatment process water additive(s) are used. (Food Safety Guidelines for the Fresh-Cut Produce Industry).
E4	Alternative method of disinfecting treatment process water (ozone, chlorine dioxide, ultraviolet treatment) is effectively performed. (Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Food Safety Guidelines for the Fresh-Cut Produce Industry; Postharvest Chlorination - Basic Properties and Key Points for Effective Distribution).
E2, H6	Dewatering, centrifugation, or drying method is established and monitored for effectiveness. (Food Safety Guidelines for the Fresh-Cut Produce Industry).
E5, H6	Method(s) to exclude physical contaminants are established and monitored (metal detector, visual screening, sieves). (Food Safety Guidelines for the Fresh-Cut Produce Industry).
E2	Holding time throughout the entire process, especially post-wash and prior to packaging (weighing, transporting, collecting), is minimized. (Handling Guidelines for Fresh Cut Produce; IFPA/WGA Voluntary Food Safety Guidelines for Fresh Produce).
E2, H6	Packaging materials are made of approved material, are gas-permeable and preclude packaging migration, the entrance of foreign materials, spoilage prior to toxin production and avoid anaerobic respiration. (Food Safety Guidelines for the Fresh-Cut Produce Industry; IFPA/WGA Voluntary Food Safety Guidelines for Fresh Produce).
E2, H6	Parameters for modified atmosphere(s) packaging are established and monitored (e.g. 2 - 8% oxygen/5 - 15% carbon dioxide). (Food Safety Guidelines for the Fresh-Cut Produce Industry; Assessment of the Risk of Botulism Contributed by Modified Atmosphere Packaging of Fresh-Cut Produce).
E4, H8	Product testing protocol(s) are established and performed, and results are available (E. Coli, Listeria monocytogenes). (Food Safety Guidelines for the Fresh-Cut Produce Industry).

NOTE: Reference to the controlling documents are identified in parentheses.

STANDARDIZATION DOCUMENT IMPROVEMENT PROPOSAL

INSTRUCTIONS

1. The preparing activity must complete blocks 1, 2, 3, and 8. In block 1, both the document number and revision letter should be given.

2. The submitter of this form must complete blocks 4, 5, 6, and 7, and send them to preparing activity.

3. The preparing activity must provide a reply within 30 days from receipt of the form.

NOTE: This form may not be used to request copies of documents, nor to request waivers, or clarification of requirements on current contracts. Comments submitted on this form do not constitute or imply authorization to waive any portion of the referenced document(s) or to amend contractual requirements.

I RECOMMEND A CHANGE	1. DOCUMENT NUMBER MIL-HDBK-3006	2. DOCUMENT DATE *(YYYYMMDD)* 20000820

3. DOCUMENT TITLE
GUIDELINES FOR AUDITING FOOD ESTABLISHMENTS

4. NATURE OF CHANGE *(Identify paragraph number and include proposed rewrite, if possible. Attach extra sheets as needed)*

5. REASON FOR RECOMMENDATION

6. SUBMITTER

a. NAME *(Last, First, MI)*	b. ORGANIZATION	
c. ADDRESS *(Include ZIP Code)*	d. TELEPHONE *(Include Area Code)* (1) Commercial (2) DSN *If applicable*	7. DATE SUBMITTED *(YYYYMMDD)*

8. PREPARING ACTIVITY

a. NAME COL S. Severin	b. TELEPHONE *(Include Area Code)* (1) Commercial (703) 681-3056 (2) DSN 761-3056
c. ADDRESS *(Include ZIP Code)* Director, DoD Veterinary Service Activity Office of the Surgeon General/HQDA 5109 Leesburg Pike Falls Church, VA 22041-3258	IF YOU DO NOT RECEIVE A REPLY WITHIN 45 DAYS, CONTACT: Defense Standardization Program Office (DLSC-LM) 8725 John J. Kingman Road, Suite 2533, Fort Belvoir, VA 22060-6221 Telephone (703) 767-6888 DSN 427-6888