United States Department of Agriculture

Marketing and Regulatory Programs

Agricultural Marketing Service

Specialty Crops Program

Specialty Crops Inspection Division

AIM Inspection Series

Operational Rations Inspection Manual

October 2024

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INTRODUCTION

The Operational Rations Manual, developed by the United State Department of Agriculture's Agricultural Marketing Service (USDA-AMS), is a comprehensive guide for federal and state employees within USDA, as well government agencies, contractors, and other involved in operational rations services. This manual provides guidelines and procedures for ensuring the safety, quality, and compliance of operational rations.

Compliance with the Agricultural Marketing Service (AMS) guidelines does not excuse failure to comply with the Food, Drug, and Cosmetic Act or any other applicable Federal or State laws or regulations. SCI Division of the Specialty Crops Programs (SC), AMS is responsible for grading/inspecting, audits and standardization programs of fresh and/or processed fruits and vegetables and related products. The legal authority for grading, auditing and standardization activities are the Agricultural Marketing Acts of 1936 and 1946, as amended.

Applicants may obtain inspections of any fresh and/or processed fruit and vegetable and related products for which they have a financial interest. The inspection service is voluntary and self-supporting and is offered on a fee-for-service basis.

GUIDE FOR ELECTRONIC USAGE

The AIM system of instructional manuals is available electronically in Adobe Acrobat Portable Document Format (PDF) at the following intranet address: https://usdagcc.sharepoint.com/sites/ams/AMS-SCI/SitePages/Home.aspx.

When accessed electronically, AIM materials have hyperlinks and hypertext (visible as underlined blue text) available to the PDF user. Clicking on a hyperlink takes the reader to a web site with information relating to the subject. Hypertext links the reader to a different page within the current manual, or a different manual, with information relating to the subject. For example, the hypertext in the Table of Contents allows a reader to go directly to the section of interest in the manual by clicking on the section title.

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OPERATIONAL RATIONS FEES AND CHARGES

The fee for USDA/Agricultural Marketing Service (AMS) inspection of operational rations food components will be determined according to the Fee Setting: Operational Rations Program policy. This policy defines the responsibility, goals, authority, and steps for regularly reviewing and revising fees accessed to the inspection of Operational Rations (OR) food component applicants to assure fees are adequate to recover the cost of providing Specialty Crops Inspection (SCI) Division services.

The OR fee will be an hourly rate of service and applies to Department of Defense (DoD), Defense Logistics Agency (DLA) Troop Support contracts that require contractor-paid USDA/AMS inspection of operational rations food components. This includes all types of services provided under in-plant, year-round inspection service contracts; in-plant, less-than-year-round inspection service contracts; and lot inspection or similar services for formulated and processed food components in DoD operational rations.

Operational rations include, but are not limited to:

- Meal, Ready-to-Eat (MRE) rations
- Unitized Group rations (including Polymeric Tray and Institutional Size Pouch containers)
- First Strike rations
- Long Range Patrol (LRP) rations
- Meal, Cold Weather (MCW) rations
- Tailored Operational Training Meal (TOTM)
- Modular Operational Ration Enhancement (MORE)
- MRE Wet Pack Fruits
- Wet Pack Fruits
- Spreads/ Condiments RNC
- Beverage RNC
- Water, Drinking, Emergency

The OR fee does not apply to:

- USDA grading and certification of ingredients requiring grading prior to operational rations component formulation and processing.

- USDA/AMS laboratory testing and analyses. See National Science Laboratories for additional information related to these services.

Questions relating to the operational rations fees and charges should be directed to the National Program Mission Support Operational Rations Team via scscioperationalrations@usda.gov.

As of October 1, 2024, Operational Rations fees for service are as follows:

Operational Rations Activity	Regular per hour	Overtime per hour	Holiday per hour
Lot Inspections	$91.00	$137.00	$182.00
In-plant Inspections Under Annual Contract (year-round)	$91.00	$137.00	$182.00
Additional Graders (in-plant) or Less Than Year-Round	$91.00	$137.00	$182.00
Night Differential	An additional $9.10 per hour for regularly scheduled hours between 6:00pm and 6:00am		
Processed Plant Survey	Audit Verification Services per hour rate in effect at time of service		

Charging Premium Time

Premium time such as overtime, Sunday and night differential, and holiday work shall be charged according to current SCI billing policy for processed products. See the Contracts and Agreements with Industry policy for additional guidance on premium time for Operational Rations services under a service contract.

Charging Travel Expenses

For guidance on charging travel expenses for Operational Rations services under a service contract see the Contracts and Agreements with Industry policy.

Charge travel expenses for Operational Rations services not under a service contract follow the guidance within the Travel Charge Policy. Charge for travel expenses incurred for temporary inspectors performing operational rations inspections outside of established year-round contracts. This may include travel time, tolls, and parking as applicable.

SECTION 1 – OVERVIEW OF OPERATIONAL RATIONS INSPECTION

Introduction

USDA, AMS performs in-plant inspection and lot inspection of food components used in Operational (i.e., combat) Rations for the U.S. Department of Defense (DOD), in a capacity referred to as the Government Quality Assurance Representative (GQAR). Our role is to verify that the contractor is in compliance with all contract requirements developed by DOD for the Operational Rations (OR) program. The food items are purchased by the Defense Logistics Agency (DLA) Troop Support (formerly Defense Supply Center Philadelphia).

Background information on the Operational Rations program can be found in the AIM Inspection Series, Inspection for Operational Rations Purchased by the Department of Defense.

The contract requirements and associated documents used in the procurement of Operational Rations are developed by DOD and designate USDA, AMS as the “origin” GQAR in the

processing plants where the OR component items are produced and/or packaged. These locations, where the food items are put into the primary container, are designated as "origin" locations.

An OR food component item may be procured by DOD directly from a processing plant as Government Furnished Material. On the other hand, if a producer supplies components to an assembly contractor before DOD takes ownership of the components, the production is referred to as Contractor Furnished Material or Rations National Contract. USDA, AMS provides inspection under all three methods of procurement and certifies the product in different ways depending on the contract requirements.

USDA In-Plant Inspector-in-Charge Responsibilities

Inspector-in-Charge (IIC) duties include, but are not limited to, the following:

A. Obtain the contractor's production schedule and develop a schedule for inspection activity.

B. Assign shifts for other USDA Inspectors making sure that USDA staff are present to perform pre-operational sanitation checks and present during production to verify formulation, filling, and sealing of the products, and processing of the products in accordance with the current contract requirements.

C. Set up daily sampling sheets to determine correct sampling rates for the OR products being produced.

D. Update skip-lot ledgers for both end-item skip-lot (as applicable) and analytical skip-lot (as applicable), with current day's production information and establish which lots will need to have verification inspection and/or testing performed at a later time.

- See Section 12 – Skip-Lot and Section 7 – Laboratory Testing.

E. Coordinate the pre-operational sanitation inspection with plant management and keep a list of plant personal responsible for addressing sanitation issues for all production shifts.

F. Keep the USDA Area Office informed of scheduling changes and other issues that affect the daily inspection activities.

- See Section 2 – USDA In-Plant Inspection Procedures.

USDA Inspection Staff Responsibilities

Inspector duties include, but are not limited to, the following:

Sanitation Inspections

A. Perform daily sanitation inspections and distribute the final versions of daily sanitation reports to plant management, per Sanitation Manual procedures. See Section 14 – Plant Sanitation and Integrated Pest Management.

B. When needed, coordinate sanitation issues with other regulatory agencies present in the facility, such as USDA, Food Safety Inspection Service (FSIS); and USDC, National Marine Fisheries Service.

In-Process Monitoring of Production

A. Obtain product batch sheet or use USDA in-process worksheets to document ingredient labels and code marks observed during the daily production.

B. Review the product specification and verify that the ingredients meet the requirements, such as a required certificate of analysis, a specific quality level requiring a U.S. Grade certificate, ingredients that need to be obtained from a current crop season, or the age of meat ingredients, etc.

C. Observe if the ingredients are from a domestic supplier or from a foreign source. If ingredients are from a foreign source, verify that they are on their "Master List of Ingredients from Foreign Sources." For each ingredient, the Master List will list the ingredient, the country of origin, and the product(s) in which the ingredient is used. The Master List will be updated as necessary. The Master List will be provided to the in-plant GQAR and, upon request, to DLA Troop Support Contracting Officer.[1]

D. Observe the age of ingredients and if it appears the serviceability limitations have been reached, review the contractor's list of ingredients (generic name, brand name, producer name, or supplier name in case of bulk packed plant or animal ingredients, country of origin) and the time and temperature serviceability limitations the contractor has imposed on that ingredient. Contact National Program Mission Support (NPMS) if there is an issue with an ingredient that has passed the timeframe established by the contractor.[1]

E. Perform in-process records review and record daily observations as the batching, cooking, processing, and packaging operations are taking place. Verify that the labels and markings are in accordance with the contract and specification requirements.

F. Monitor the processing records that document the time, temperature and pressure of the complete processing and cooling cycles for Class 1 through Class 5 thermostabilized products. Observe post-retort color change of ink on pouches and polymeric trays, and other indicators of appropriate processing.

G. Verify that the retort operation is supervised by a qualified person who has successfully completed the approved training in retort operations.

[1] Source: Solicitation SPE3S1-21-R-0002 Section C, page 19 of 142.

H. For thermostabilized products, monitor the incubation samples in order to verify that they are handled per current instructions.

- See Section 2 – USDA In-Plant Inspection Procedures.

USDA End-Item Verification Examinations

A. Create a folder for each lot, with applicable worksheets, to document USDA verification inspection.

B. Sample the lot during the entire production day, per USDA sampling procedures.

- See Section 11 – Sampling.

C. Review the contractor's lot submittal paperwork closely, before verification inspection begins, and verify that all required exams and tests have been performed by the contractor with conforming results, and that the product meets all specification requirements. In addition, the documentation should include disposition of all portions of the lot, including those portions which may not be offered to USDA. This is necessary for product tracking purposes to ensure that only conforming product is certified, and only certified product is shipped for DOD contracts.

D. See Section 5 – Contractor Supplied Documentation. Perform the examination of the finished product in accordance with the contract and applicable specifications. A comparison of the finished product with the approved pre-production standard (First Article, PDM, etc...) is part of the product exam process. This step is to determine if samples from the lot being inspected are equal to or better than the approved standard.

E. Certify all production that passes USDA verification exams.

- See Section 9 – Certification.

F. If a lot fails a USDA verification examination, the USDA inspector should place the lot on hold and notify the contractor, ORS, and DLA Troop Support.

- See Section 10 – Lot Failure and Hold Procedures.

Quality System Plan Activities for USDA Inspectors

USDA inspection personnel duties include, but are not limited to, the following:

A. Obtain a copy of the contractor's Quality System Plan (QSP), when applicable, and become familiar with the plan.

B. Review the contractor's proposed updates to their QSP and provide feedback to DLA Troop Support on the updates, when needed. This communication can be coordinated with SCI, ORS staff.

C. Develop a yearly QSP audit schedule (QSP-4).

D. Perform QSP audits using the frequency established in the QSP-4. QSP audits are performed during all production shifts, by the shift inspectors. This results in all inspectors participating in the QSP audits.

E. The IIC should review the QSP audits and any Corrective Action Reports (CAR), and Observation Reports before they are distributed.

F. E-mail the applicable Monthly QSP reports, CARs and Observation Reports dealing with Food Defense or Food Safety issues to individuals on the distribution list.

- See ORS SharePoint site/OR Resource Documents/OR Email Distribution Contacts and Guidance on Distribution Process (intranet link) for QSP reports for the current distribution list.
- See Section 13 – Quality System Plan Procedures for the correct distribution process.
- See ORS SharePoint site/OR Worksheets/QSP Forms and Worksheets (intranet link) for the current versions of the worksheets.

Analytical and Microbiological Testing Procedures

USDA inspection personnel duties include, but are not limited to, the following:

A. Review individual specifications to determine the test requirements.

B. Submit lots for analytical testing to the USDA, AMS Laboratories with DD Form 1222. The DD Form 1222, for all products, is found in ORS SharePoint Site/OR Worksheets/DD1222 (intranet link).

C. The alternate method for some tests is to have the USDA inspectors perform in-house testing at the contractor's facility. Certain conditions must be met for this to take place and the IIC should discuss these with the Officer-in-Charge (OIC) and ORS.

D. See Section 7 – Laboratory Testing for details on procedures.

Periodic Review and Production Standards Procedures

USDA inspection personnel duties include, but are not limited to, the following:

A. Select and submit samples for monthly reviews.

B. Select and submit samples for First Article/PDM replenishments.

- See Section 3 – Production Standards and Product Reviews.

Electronic Resources for Operational Rations

A. The Operational Rations Database (ORDB) program stores lot production information on a dedicated server. The ORDB can be accessed and updated by inspectors when their desktop USDA computer is connected to the VPN (Virtual Private Network) and AMS Network.

- See Section 6 – Operational Rations Database for details on procedures.

B. The ORS SharePoint site stores contract information and is a source for electronic documents and links to other resources, such as the attendance calendar.

C. DLA Troop Support maintains a website that provides a valuable resource for a multitude of documents associated with the Operational Rations program. The web address is: http://www.dla.mil/TroopSupport/Subsistence/Operational-rations/frozen/.

D. Inspectors should access the ORS SharePoint site at least once a week.

Contractor Responsibilities

Contractor responsibilities include, but are not limited to, the following:

A. Furnish USDA with a copy of the solicitation and the amendments to the solicitation, applicable contracts and modifications to the contract and other related documents, such as relevant Performance-based Contract Requirements, Packaging Requirement and Quality Assurance Provisions and/or Commercial Item Descriptions (CID), for the products referenced in the contract. This requirement is contained in the DLA Troop Support contract/solicitation under DLA Clause 52.246-9023, "General Inspection Requirements."

B. When required, the contractor will develop and maintain a QSP and provide the USDA Inspector with any updates to the QSP plan in a timely manner. This will allow the USDA Inspector to review the updates and provide feedback to DLA Troop Support.

C. The contractor will respond to Corrective Action Requests that are the result of findings found during USDA reviews of the Contractor's QSP.

D. The Contractor will provide to the USDA Inspector copies of invoices, USDA Grade Certificates, Certificates of Conformance (COC), Certificates of Analysis (COA) etc., covering ingredients and non-food components, when required.

- See Section 5 – Contractor Supplied Documentation.

E. The contractor will distribute the DD Form 250 (applicable to the paper version only) and/or USDA Certificate of Quality and may assist in preparation of the documents, under USDA oversight. In the case of WAWF (Wide Area Workflow), used to certify Government Furnished Material, the contractor is responsible for making the arrangements for the establishment of the inspector's electronic connection to the web-based system.

- See Section 9 – Certification.

Operational Rations Staff Responsibilities

ORS responsibilities include, but are not limited to, the following:

A. Coordinate communications between DLA Troop Support, DEVCOM-SC, the contractors, USDA inspection personnel, and supervisors to assist in resolving issues.

B. Assist, as needed, in coordinating the appropriate staffing levels of inspection personnel for OR facilities. This coordination by ORS includes communicating with the IIC, SCI Division's Field Operations, Regional Field Operations Branch, and Area Offices. In some instances, this can also include coordinating with DLA Troop Support.

C. Provide training, through Operational Rations Inspector Workshop and other means, as needed, to update and train current and new USDA inspectors on current inspection procedures.

D. Establish uniform inspection procedures and coordinate document control for Operational Rations program activities.

E. Evaluate periodic review samples submitted by USDA Inspectors and provide feedback to inspectors on packaging/container integrity and product acceptability. ORS uploads the Periodic Review Submittal Worksheets sent by USDA Inspectors to the ORS SharePoint site and each USDA review location adds their comments to the file posted on SharePoint where inspectors can view the review results.

F. Participate in DLA Troop Support/USDA joint audits, as necessary.

G. Perform the internal reviews of the USDA OR inspection activities. See Section 8 – Operational Rations In-Plant Inspection Review.

H. Manage the ORDB.

I. Provides instructions to the USDA inspectors on use of the ORDB. ORS should be contacted when new USDA Inspectors need the program installed on their computer or need to be added as users at their location. See Section 6 – Operational Rations Database.

J. Reviews results in the ORDB, for inspection trends, and periodically reports overall results to DLA Troop Support and the OR Industry.

K. Provides registration instructions for iRAPT/WAWF. See Section 9 – Certification.

USDA Supervisor Responsibilities

USDA supervisor responsibilities include, but are not limited to, the following:

A. Apply SCI Division procedures for the supervision/guidance of inspectors under their supervision.

B. Participate in DLA Troop Support/USDA joint audits, as necessary.

C. Visit and review activities at Operational Rations inspection locations and document these visits.

D. See Section 8 – Operational Rations In-Plant Inspection Review.

E. Review and initial the inspector's Self Inspection Audit on a regular basis through the year and provide feedback/guidance as needed.

F. Contact ORS personnel when questions arise, or clarifications are needed for inspection procedures involving OR inspections.

DLA Troop Support, Quality Audits & Food Defense Branch Role

Quality Audits & Food Defense Branch (FTSB) activities include, but are not limited to, the following:

A. Monitor contractor's Integrated Pest Management and Sanitation programs, and Food Defense programs.

B. Perform Operational Rations Quality systems audits of contractor's performance under contractor's QSP.

C. Manage higher level quality programs.

D. Review and determine acceptability of contractor QSP and contractor's modifications to QSP.

E. Assist in interpretation and updating of the end-item skip-lot procedures developed by DLA Troop Support.

F. Review Corrective Action Reports generated by the USDA audit of the contractor's QSP and provide guidance on any issues that may arise.

G. Review USDA QSP Monthly Reports and provide feedback to USDA on QSP audits.

H. Provide clarification and guidance to USDA when questions arise during the performance of inspection activities.

SECTION 2 – USDA IN-PLANT INSPECTION PROCEDURES

General Inspection Duties

A. It is the USDA Inspector's responsibility to verify that the contractor is in compliance with all contract requirements, including applicable specifications. Inspectors should report production issues and USDA verification exam failures to the contractor, DLA Troop Support, and SCI Division chain of command on a timely basis, and as appropriate following established procedures. See Section 10 – Lot Failure and Hold Procedures for detailed instructions.

B. The role of the USDA Inspector is to serve as the in-plant GQAR and to verify that the contractor's system and finished products meet contract requirements. To perform this verification function, the Inspector, and the Inspector's duties, must remain distinct from, and outside of, the contractor's quality assurance process. As such, the USDA Inspector should not act in a quality control/assurance function for the contractor. An Inspector's expertise and knowledge regarding contract requirements may be shared, but under no circumstances should any USDA personnel assume a role as, or be used as, a quality control/assurance representative for the contractor. The USDA Inspector monitors the contractor's system to verify that it is meeting contract requirements. To perform this function, the USDA Inspector and their involvement must remain outside of the system they are evaluating.

C. The USDA Inspector should be present during production to verify formulation of the product, monitor the production process, and confirm Good Manufacturing Practices (GMPs) are followed. The contract requires that the USDA Inspector monitor production of First Articles (production standard), even if normal production is not taking place. In contrast, initial PDM (Production Demonstration Model) production, which is produced by a firm in order to be submitted as part of a bid for a DLA contract, does not require USDA in-plant presence.

- See Section 3 – Production Standards and Product Reviews for detailed instructions for production standards.

D. The Inspector should perform sanitation inspections on a daily basis, first as a pre-operational inspection during which all equipment/utensils/facilities are inspected prior to start-up of processing operations, and afterwards on each production shift during production. Inspectors should document results and findings according to the USDA procedures found in the Sanitation Manual. During the pre- operational inspection, areas should be inspected in a logical sequence to allow plant operations to begin, to the extent possible, as soon as each area is approved. The Inspector should maintain open lines of communication with plant personnel in order to avoid unnecessary production delays once conditions have been corrected. This sanitation inspection should include monitoring of the contractor's Integrated Pest Management (IPM) program. (Note: The

presence of the USDA, Food Safety and Inspection Service inspector does not release the AMS inspector from performing sanitation inspections.)

E. Inspectors should monitor the product preparation and production areas throughout the day. This should include monitoring the ingredients used for the processing of each product. The Inspector should examine the labels, markings, U.S. Grade certificates, invoices, certificates of analysis, or other valid documents associated with the ingredients used in the formulation of the final product. If necessary, the Inspector can examine the ingredients to verify conformance to contract requirements. For example, if a contractor provides a COC indicating that an ingredient has certain characteristics required by the contract or specification, such as dice size, the Inspector may examine the ingredient to verify the COC.

F. During each production shift, the Inspector should observe, and document as needed, batching, filling, retorting, packaging, packing, and marking activities. A daily log of all areas monitored (or "inspector's rounds note sheet") can serve as a useful tool in tracking production activities and should be kept in the Inspector's file. Regarding batching, the Inspector should verify that the person(s) doing the batching are following the "batch sheet" for the day (e.g., using the correct amounts of the correct ingredients). In addition, the Inspector should verify that the day's batch sheet is the same as for the approved PDM or First Article. As in all in-plant monitoring, the Inspector should assess whether sanitary conditions and practices are in place when batching is taking place.

G. Each shift, the Inspector should verify that the retort operation is supervised by a qualified person who has successfully completed the approved training in retort operations as defined in applicable FDA and USDA/FSIS regulations. The retort supervisor does not have to be present during all retort operations; however, someone who has completed an approved retort training course must be present during all retort operations. The name(s), official position, and a copy of the approved retort training certificate of the qualified person(s) should be kept in the USDA Inspector's file.

H. The Inspector should monitor the retort records for each retort cook for completion of the specified process schedule. The Inspector must have a copy of the process schedule for each product and container size. Typical critical factors in the process schedule include, but are not limited to processing time, temperature, and pressures, net weight, headspace, etc. Inspectors should spot check retorted pouches and trays for ink color change or other heat process indicators used by the contractor to verify that the container has undergone a heat process. The retort record review performed by the USDA Inspector does not take the place of the reviews the contractor is required to perform in accordance with FDA and USDA regulation. These contractor reviews are mandatory. If the retort records are not initialed or signed and dated by the contractor's reviewer, the Inspector should withhold certification of the involved lot. Review of retort records by the USDA/AMS Inspector is for verifying contractor compliance with DLA contract requirements. Inspectors are not to sign, initial, or in any way add information to the contractor's retort records.

I. Each day, the USDA Inspector should monitor incubation of production lot samples and check the temperature of the incubation chamber(s) to verify that the temperature falls within the proper temperature ranges. The Inspector performs these steps to confirm that the contractor is executing the incubation process properly. It is the contractor's responsibility to evaluate incubation samples and determine whether incubation criteria have been met. The USDA/AMS Inspector should periodically review incubation records for ongoing incubation activities during their in-plant "rounds." In addition, the contractor should provide their documentation of successfully completed incubation for each lot the contractor offers to USDA/AMS for verification inspection. The Inspector should review records to verify that at least one sample container from each retort cook has successfully completed incubation.

J. Part of the Inspector's daily activity is the sampling and verification inspection of production lots that have passed the contractor's inspection exams. The Inspector should be familiar with all the requirements of the applicable contracts, specifications, and purchase documents.

K. The Inspector is responsible for selecting and submitting samples for analysis (salt, fat, etc.) to the USDA/AMS laboratories for verification testing or for use by USDA Inspectors performing verification testing on-site. Detailed instructions for this process can be found in the Section 7 – Laboratory Testing.

L. The IIC takes the primary role in the review and evaluation of the contractor's QSP when a QSP is required by the DLA contract. USDA inspectors should use contract requirements, guidance in Section 13 – Quality Systems Plan Procedures, and DLA Troop Support's Quality Systems Audit Workbooks I and II, as applicable, in their review of contractor's QSP plans and actual procedures.

M. All Inspectors should be familiar with the specifications, contracts, solicitations, and related documents that are applicable to the production at their assigned facility.

N. The following is a listing of commonly required verification examinations for finished product. Generally, the contractor is required to perform the exams on all lots offered to the Government. The USDA/AMS Inspector must either (1) perform all exams to verify the compliance of the lot, or (2) when certain criteria are met, accept the contractor's conforming results, and "skip" verification inspection. See Section 12 – Skip-Lot for detailed instructions for end-item skip-lot procedures. As indicated above, the following are commonly required end-item examinations:

1. Product exam for net weight and drained weight (when applicable), and product characteristics, using the production standard (PDM or first article) as identified by the contract for comparison. For each production lot examined, a PDM or First Article is used for comparing the overall appearance and organoleptic characteristic to the current production.

2. Filled and sealed exam of pouches and polymeric trays for container integrity, in accordance with the quality assurance provisions of the applicable military

performance specification, i.e., MIL-PRF-44073 for retort pouches, and MIL-PRF-32004 for polymeric trays (some non-retort pouched items have the packaging requirements in the individual product specification). See SharePoint/OR Specifications (intranet link) to access all specifications used in the Operational Rations Program.

3. Tray/protective sleeve assembly exam, for defects listed in the military performance specification MIL-PRF-32004.

4. Filled and closed shipping container exam, for requirements in accordance with the individual product specifications. Note that this examination is not performed for all products and depends on contract and specification requirements.

   a. Under the following conditions, the USDA inspector can select samples for the Shipping Container and Marking Examination "on-line" and examine them while the lot is being produced:

      (1) Select samples from the pallet after cases have been taped and stacked on the pallet for final staging.

      (2) Do not disclose results of the USDA exam until the contractor has offered the lot to the USDA for verification examination.

      (3) Discard the results of the USDA end-item exam if the contractor fails the lot for end-item shipping container exam, reworks the lot, and reinspects it before offering it to USDA.

      (4) The contractor is aware of and in agreement with this USDA practice.

   b. The contractor may also perform this exam as the lot is being produced, if the process is documented in the contractor's accepted QSP.

5. Unit load examination, for requirements in accordance with DLA Form 3507, as applicable. Note that this examination is not performed for all products and depends on contract requirements. This examination is eligible for end-item skip-lot procedures. See Section 12 – Skip-Lot for guidance on implementing USDA end-item skip-lot procedures for unit loads.

6. Examinations for shipping container and unit load markings in accordance with DLA Form 3556, as applicable, and usually performed in conjunction with the filled and closed shipping container exam and the unit load exam (5., above). Note that this examination is not performed for all products and depends on contract and specification requirements.

O. The USDA/AMS Inspector must issue documentation for each lot they determine to be in compliance with contract requirements. This documentation is either a USDA Certificate

or a DD Form 250 (which can be an electronic version under DLA's Wide Area Workflow (WAWF), or a paper version). The contract will indicate which form of certification is correct. Certification using a USDA Certificate should be in accordance with SCI Division instructions.

P. The USDA inspector can release results of a non-conforming end-item test (exam) result to the contractor before all USDA verification exams are finalized. Notifying the contractor on a timely basis (within one day) will give the contractor an opportunity to take corrective action when subsequent lots are produced. For example, if a lot fails the filled and sealed packaging exam, the contractor could be notified of the failure even if the USDA laboratory test or incubation results are still pending.

- In some instances, DLA Troop Support has given the GQAR approval to perform specific exams prior to the lot being offered to USDA. In that scenario, the results should not be released to the contractor until the lot has been offered for USDA verification inspection. In addition, the contractor should be aware and in agreement that USDA will perform that exam prior to the lot being offered and that USDA will withhold exam results (conforming or non-conforming) until the lot is formally offered. Additionally, in these instances, if the contractor finds a need to rework the lot prior to formal offering, due to a contractor end-item exam failure, USDA will return samples and disregard the USDA results obtained from them.

Q. The USDA should provide the contractor a signed copy of the Lot Summary Worksheet after the USDA verification inspection activity is completed, and a final lot status has been established.

R. For each product produced at the facility, the Inspector should sample and submit periodic review samples (monthly or quarterly) and replenishment production standards, as needed. Details of this process can be found in Section 3 – Production Standards and Product Reviews.

S. The IIC should perform self-audits of the USDA inspection activities performed at their location, as outlined in Section 8 – Operational Rations In-Plant Inspection Review.

New Item Checklist

A New Item Checklist is a document used to track the requirements for the production of a new product at the contractor's facility. These requirements may include updated product specifications, necessary equipment, exams/tests, and required Certificates of Conformance (COCs) or Certificates of Analysis (COAs), among others. Before commencing production of a new item, the contractor must notify the inspector in advance. This allows the inspector sufficient time to utilize the New Item Checklist to gather all applicable documentation and equipment.

Once completed, the New Item Checklist is reviewed by the supervisor and ORS to ensure that all involved staff are knowledgeable about the specific requirements and that any necessary provisions are made available.

Inspectors should use this checklist to review all aspects of inspection for the product and prepare for any new procedures or equipment that may be required. Ideally, the Inspector will complete the checklist before actual production of the item begins. Upon completion, the USDA Inspector forwards the checklist to their supervisor, who then reviews it and forwards the completed document to ORS.

A blank copy of the New Item Checklist is available on SharePoint for reference.

SECTION 3 – PRODUCTION STANDARDS AND PRODUCT REVIEWS

Description of Standards Used for Product Comparison

First Article

A First Article is a pre-production standard produced by a contractor intended for the contract's production. It is generated after the contract has been awarded. During production, a USDA Inspector must be present on-site to monitor the process. The USDA Inspector and the USDA area office conduct preliminary review and approval of the First Article prior to the USDA Inspector forwarding it to the Development Command Soldier Center (DEVCOM-SC) for evaluation. The USDA Inspector utilizes the First Article submittal form SC-431 for this purpose. Subsequently, DEVCOM-SC provides DLA Troop Support with recommendations concerning their approval of the proposed standard. As soon as the panel results are accepted by DLA Troop Support, the lot is designated as the Approved First Article or production standard. For subsequent regular production runs, both the contractor and the USDA Inspector use samples from the Approved First Article for comparison with the current production. DEVCOM-SC also employs samples from its supply of this lot when conducting periodic reviews. Once the production standard has been approved by DEVCOM-SC, ship the samples to the USDA review locations.

Conditional First Article

A First Article approved by DEVCOM-SC, must be refilled with each following conforming lot to preserve its status. The First Article submission is reviewed and approved by both the USDA Inspector and the USDA area office before being forwarded to DEVCOM-SC for evaluation. The First Article Submittal Form (SC-431) is used for this purpose. After DEVCOM-SC approves the production standard, samples should be shipped to USDA review locations.

Local USDA First Article Replenishment

A Local USDA First Article replenishment lot is submitted by the USDA Inspector to DEVCOM-SC only when the remaining First Article samples needed to cover the entire 12-month period are nearly depleted. This occurs when the USDA in-plant inspectors have insufficient samples to cover intended production or when storage conditions cause product

degradation, making the samples no longer representative of the initial production standard. When submitting this sample, do not use the SC-431 First Article Submittal form; instead, use the sample submittal worksheet designed for periodic review samples. This replenishment does not require approval from the USDA area office prior to submission to DEVCOM-SC. Samples should be sent to both DEVCOM-SC and the USDA review locations.

Limited Production First Articles

DEVCOM-SC identifies approved First Articles with insufficient samples for the full year as 'Limited Production First Articles.' When these samples are running low, replenishment becomes necessary. Instead of using the SC-431 First Article Submittal form, submit these replenishment samples to DEVCOM-SC on the sample submittal worksheet typically used for periodic review samples. Designate the sample type as 'DEVCOM-SC First Article Replenishment.' Prior approval from the USDA office is not required before forwarding them to DEVCOM-SC. Remember to send samples to both DEVCOM-SC and the USDA review locations.

DEVCOM-SC First Article Replenishment

A DEVCOM-SC First Article Replenishment refers to a lot that replaces the original Approved First Article after twelve months of production. Samples from the current production, which have been inspected and passed all required tests and exams by the USDA, are sent to DEVCOM-SC by the USDA Inspector. When submitting these replenishment samples, the SC-431 First Article Submittal form is not required, and the submittal does not require review by the area office before being sent to DEVCOM-SC and USDA review locations. Instead, the worksheet used for submitting periodic review samples serves for this purpose. DEVCOM-SC evaluates these samples and provides their results to DLA Troop Support. DLA Troop Support then provides official results on the samples to the USDA and the contractor. If a lot is approved by DEVCOM-SC and accepted by DLA Troop Support, it replaces the original approved First Article (AFA) to establish the new production standard. Samples should be shipped to DEVCOM-SC and the USDA review locations together.

Product Demonstration Model

The Product Demonstration Model (PDM) serves as the standard for production, submitted by the contractor to DEVCOM-SC for evaluation. Once approved, it becomes the benchmark for future product compatibility for both USDA and the contractor. When sending periodic review samples to USDA review locations, it's important to include an approved PDM with each sample for comparison.

Initial PDM

The initial Product Demonstration Model (PDM) is a standard produced by the contractor and submitted with their bid for a solicitation to DEVCOM-SC. If approved, both USDA and the contractor will utilize it to ensure future product compatibility.
During the initial production standard process, the USDA Inspector is typically not required to be present on-site and is generally not directly involved. However, prior to submitting the lot to

DEVCOM-SC, the contractor provides USDA with samples from the PDM lot for potential future use.

Following submission, DEVCOM-SC evaluates the PDM. If approved, DLA Troop Support may award a contract specifying the approved PDM lot as the production standard for that contract cycle.

To maintain documentation, the inspector receives copies of DLA Troop Support correspondence from the contractor, establishing the identity of the PDM lot. The approved PDM lot number is then listed in the contract document, with a copy of this correspondence retained in the USDA file.

For Individual and Group PDM ration items, the 12-month period referenced in the contract/solicitation for the initial PDM begins from the date of the PDM's initial production.

- For example: Suppose an initial PDM is produced on January 10, 2023 (with a lot number of 3010), and the contract is awarded on July 10, 2023. A replenishment PDM would be needed 12 months from the production date of the initial approved PDM. This would be from production in January 2024.

Local USDA PDM Replenishment

The USDA Inspector submits a Local USDA Product Demonstration Model (PDM) replenishment lot only when they're running low on remaining PDM samples needed for the entire 12-month period. This happens if there aren't enough samples to cover planned production or if storage conditions cause product degradation, making the samples no longer representative of the initial production standard.

If DEVCOM-SC evaluates the product and approves the sample, both the Contractor and USDA can start using that product immediately as the new standard. NPMS will then forward the DEVCOM-SC results notification to the respective OR location for proper communication. Ship samples to both DEVCOM-SC and the USDA review locations together.

DEVCOM-SC PDM Replenishment

The DEVCOM-SC PDM Replenishment lot replaces the original approved PDM lot after twelve months of production. The samples are sent by the USDA Inspector to DEVCOM-SC from current production and are evaluated by DEVCOM-SC. If the lot is approved by DEVCOM-SC and accepted by DLA Troop Support, it replaces the original PDM to establish the new production standard. For the MRE products, this process does not require a written approval letter from DLA Troop Support. NPMS will forward the DEVCOM-SC results notification to the respective OR location.

Individual Rations

Individual rations, such as the MRE, FSR, ACCR, and MCW are meals designed for use by combat infantry soldiers. These rations are lightweight, flat, and flexibly packaged for easy

consumption in combat conditions. MRE retort entrees are placed in Single Serving Pouches (SSPs) and undergo heat processing, or thermostabilization, resulting in improved food quality and shorter cook cycles compared to traditional cans.

Group Rations

The Unitized Group Ration (UGR) sustains military personnel during operations with accessible organized food service facilities, especially when mobile food preparation equipment is available. Each UGR package typically contains 9 to 18 servings of ration components packaged in larger flexible pouches, polymeric trays, or metal cans.

The UGR maximizes the use of commercially available items and simplifies the process of providing high-quality food service in field environments. USDA, AMS inspection of this ration usually occurs at origin, involving entrée, side, and dessert items retorted and packaged in polymeric trays or institutional-sized pouches (ISP), bakery items packaged in polymeric trays or large, flexible pouches, and dehydrated products packaged in metal cans or ISPs.

General Requirements for All Production Standards

A. The USDA Inspector and contractor should follow the current production standard until DEVCOM-SC authorizes the new one. Once the DEVCOM-SC Replenishment is determined to be acceptable, both the contractor and the USDA Inspector should begin using the new production standard from the same approved lot.

B. When selecting a lot to replenish a production standard, the USDA Inspector should choose a conforming lot that has passed all USDA end-item verification exams, including laboratory testing. The new replenishment production lot must meet current production standard. The replenishment lot should not have been selected as the end-item skip-lot. Note: Do not submit samples of a product for periodic review if the same product is provided as a replenishment sample.

   For example, if Beef Stew lot 2234 is selected as a replenishment sample, no periodic reviews of this product will be sent during that time period. For further information on this process, refer to the Replenishment Procedures for PDMs and First Articles section.

C. The USDA Inspector will draw samples from the same lot, case, batch, cook, and sub-code.

D. Since replenishment samples are typically evaluated first and given priority over periodic review samples, it's necessary to mark the outside of the shipping container with an identification label designating these samples as such.

E. For instructions on when a new PDM or First Article is required refer to the contract and solicitation.

Specific Requirements for the First Article

A. First Article (preproduction sample) is required in accordance with the solicitation, contract, and the product specifications.

B. Coordinate with DLA Troop Support on the timing and selection of the First Article for Unitized Group Ration (UGR) contracts. The USDA Inspector should contact NPMS, who will then alert DLA Troop Support of the plan to select and submit a First Article to DEVCOM-SC.

C. The USDA Inspector will be present during production and will evaluate First Article lots in strict accordance with the contract and specification requirements.

D. The officer-in-charge will also evaluate the First Article sample in accordance with the applicable specifications. This can be done on site (at the plant) or parallel samples can be sent and evaluated at the area office.

E. The officer-in-charge must agree that the First Article is acceptable and sign the SC-431 First Article submittal.

F. Every effort should be made to expedite this process since an approved First Article is necessary before regular production can be certified.

G. After approval by the officer-in-charge or assistant officer-in-charge, the USDA Inspector will complete the First Article submittal form and attach a copy of the USDA finished product examination worksheets. These documents will be placed in the shipping container with the First Article samples to be shipped to DEVCOM-SC. When filling out the submittal form, it is important to enter the lot number and "USDA, FSIS establishment number" (for meat and poultry items) of the First Article in the block entitled "code and establishment number".

H. A copy of the USDA laboratory results should be submitted with the First Article submission if the product requires analytical and/or microbiological testing; however, do not wait to submit samples if the USDA laboratory results are not yet available. Note in the First Article submittal form's notes section that "Samples submitted prior to receipt of USDA analytical and/or microbiological test results." Results will be sent via email or fax as soon as they are available. As soon as the results are available, make sure to forward them to DEVCOM-SC.

I. The NPMS will evaluate samples and offer guidance if the officer-in-charge, assistant office-in-charge, and the inspector-in-charge cannot agree on whether the First Article is acceptable.

J. Samples should not be submitted to DEVCOM-SC unless DLA Troop Support has granted approval in the event that samples fail product examination and/or testing requirements. The inspector should retain a copy of this documentation and include it with the First article submittal form if it is granted approval. Furthermore, the inspector

must note the First Article submittal form with a reference to the DLA Troop Support approval in the remarks section.

K. The contractor may submit an independent sample to DEVCOM-SC for the purpose of obtaining a technical opinion regarding their product.

L. The First Article submittal form should be emailed to DEVCOM-SC and National Programs Mission Support. Refer to the list of contacts with Appendix IV – Operational Rations Document Email Distribution.

M. Each sample sent to USDA review locations for periodic review should include a First Article that has been approved for comparison purposes.

N. The amount of First Articles samples should be retained in accordance with the contract or solicitation by the USDA Inspector, in a secure location, for use in USDA End-item product evaluation exams.

Specific Requirements for the PDM

A. Regarding certain individual and Group Rations food components, the solicitation generally specifies the need for a PDM rather than a First Article. Refer to the contract/solicitation for description of the specific requirements for the PDM.

B. USDA is not required to be on site during production of initial PDMs.

C. A contractor (or sub-contractor) should not have more than one approved PDM for an item being produced for their military contract. A second approved PDM that has different characteristics from the original PDM is not acceptable. Any deviation from this requirement must be approved by the DLA Troop Support Contracting Officer.

D. If a new PDM is approved, the previous PDM samples should be removed from the area where PDM samples are stored. The contractor and USDA should be using samples from the same approved lot.

E. The new PDM samples should not be used until production begins for the new contract cycle and confirmation is received that DEVCOM-SC/DLA Troop Support has approved the lot as an acceptable PDM. This documentation, such as a contract with the accepted PDM lot number listed in it, should be filed in the USDA files for the duration of the contract.

F. After each PDM lot has been approved by DEVCOM-SC/DLA Troop Support, the inspector will include the approved PDM for that product when submitting periodic review samples to the appropriate USDA review locations for comparison.

G. Thirty-two PDM samples should be retained by the USDA Inspector, in a cool, dry, and secure location for use in USDA End-item product evaluation exams.

Replenishment Procedures for Annual PDMs and First Articles

A. Refer to the contract or solicitation for details on specific procedures. The USDA Inspector should select a production lot that has passed all examinations and tests, including analytical testing, when replenishment is required. A lot selected for end-item skip lot verification should not be selected as PDM replenishment or First Article replenishment. The new lot should be comparable to the current PDM or First Article.

B. The Inspector should continue to use the existing production standard until DEVCOM-SC evaluates the replenishment samples and determines that the new lot is acceptable. Once the new lot is approved, the Inspector should coordinate with the contractor to ensure that the contractor is using the same approved replenishment lot.

C. The DEVCOM-SC Replenishment or Local USDA Replenishment lot should also serve as the Periodic Review Sample for that particular period. Do not submit replenishment and periodic review samples for the same product, during the same period. This helps minimize the expenses involved when DEVCOM-SC evaluates products for DLA Troop Support. Mark the samples and indicate on the OR Sample Submittal Sheet "Periodic Review and Local USDA PDM Replenishment" or "Periodic Review and DEVCOM-SC PDM Replenishment." This procedure will allow the reviewers to evaluate one lot for both purposes. DEVCOM-SC will only distribute only one result for that particular lot.

D. The USDA Inspector must select an alternative lot of the item to submit as a replenishment lot if DEVCOM-SC rejects the replenishment lot. When making a new lot selection, it is recommended for the Inspector to consider the feedback provided by DEVCOM-SC in regard to the rejected lot.

E. For Group Rations only, if a Replenishment PDM is rejected by DEVCOM-SC, the next conforming production lot will be submitted by USDA as a Resubmittal PDM Replenishment. This follow-up Resubmittal PDM Replenishment and any subsequent Resubmittal lots cannot be shipped by the vendor without an acceptable evaluation result from DEVCOM-SC. The cut-off date for PDM Replenishments will be 18 months. After 18 months, USDA will submit a PDM sample to DEVCOM-SC as a Replacement PDM, following the PDM submittal process. The production lot that is used for the Replacement PDM submittal cannot be shipped by the manufacturer without an acceptable evaluation result from DEVCOM-SC.

F. If the sample are PDM Replenishment samples for the NPMS program, email a copy of the submittal worksheet to the list of contacts with Appendix IV- Operational Rations Document Email Distribution.

Periodic Reviews – Selection of Periodic Review Samples

A. When Periodic Review or PDM/First Article Replenishment samples are selected for submittal to the Development Command - Soldier Center (DEVCOM-SC) at Natick, MA,

they must be from conforming lots. If there is any doubt that the product compares to the currently approved Production Standard, samples will be submitted to the USDA review locations as a "Special Review" for feedback on acceptability before the lot is certified and submitted to DEVCOM-SC.

B. All Food Components inspected by USDA will be subject to periodic review sampling during the contract production period/timeframe. Refer to the DLA Letter of Instruction (LOI) for Periodic Review Submittals- Individual Rations for instructions.

C. During sample selection, inspectors should clearly identify the corresponding sample point by writing identification marks on the ration component.

- For example, if the first sample is collected at 8:00am it would be labelled "A." The second sample obtained at 12:00pm, would be labelled as "B."

- Refer to "Time Period of Periodic Review" for more information.

D. The IIC should follow the LOI instructions and use the NPMS ledger to build a calendar for periodic reviews. Use the tracking log as a template on the Operational Rations SharePoint Natick Review Sample Submittal Calendars for all locations.

E. NPMS will update the Periodic Review Submittal Worksheets when changes occur. For more details on this submitting process, please refer to "DLA Letter of Instruction for Periodic Review Submittals for Individual Rations." This document is posted on the NPMS SharePoint site under "OR Resource Documents" (intranet link).

F. Submit periodic review samples to DEVCOM-SC and USDA-Specialty Crops inspection offices as per the OR Sample Submittal Worksheet.

G. When sending samples to DEVCOM-SC, inspectors must include a printed copy of the USDA laboratory results for any required food safety tests for the lot(s).

H. This applies to all food samples submitted to review locations, including periodic reviews, First Articles, PDM replenishments, and special review samples.

I. Other test results, such as salt, fat, and calcium, should not be included. However, if the results of these tests appear on the same laboratory report, they may be included.

J. When testing bulk ingredients, inspectors should include the test results for the bulk lot from which the submitted lot was produced.

K. The list of products with food safety tests and required testing can be found here (intranet link).

Time Period of Periodic Reviews

A. If a PDM replenishment is required to be submitted during a periodic review submittal time-period, submit only the PDM replenishment sample. Resume periodic review sample submission during the food component's next scheduled time-period.

For each product, review the End-Item Skip Lot Ledger for each month and select a lot that has passed the USDA verification end-item product exam and has met all the contract requirements. Note that lots that have been skipped for USDA end-item verification examination should not be selected for periodic review. If all lots of an item produced during a submittal period are skipped, based upon USDA end-item exam skip lot procedures, a periodic review sample should not be submitted for particular submittal period, for that item.

Individual Rations Submittal Procedures

A. Individual Rations samples will be selected at three different sample points A, B, and C in a lot. These sample points should be spread out over the production lot so that they represent a cross section of production. At each sample point, four containers will be selected which, to the extent possible, share common batching, time code, retort cook, etc. If the review samples are only marked with the day code, mark the samples from each sample point using the source case or source pallet information. This will assist in follow-up in the event that issues are identified with a particular sample.

Note: It is allowable to select lots, for submittal for periodic reviews that have been skipped under Optional Contractor Testing for analytical testing. The submittal period timeframe is based upon the Julian code date of production, not when the lots are offered or certified.

1. See diagram below for Individual Rations with three sampling points:

   a. Sample Point A – 4 Like Containers

      (1) 1 container to DEVCOM-SC

      (2) 1 container to plus the current PDM to NPMS (see OR Sample Submittal Worksheet for current shipping location & DLA Letter of Instructions for Periodic Reviews)

      (3) 1 container as In-Plant Standby

      (4) 1 container plus the current PDM to USDA—Specialty Crops Inspection Area Office

   b. Sample Point B – 4 Like Containers

(1) 1 container to DEVCOM-SC

(2) 1 container plus the current PDM to NMPS (see OR Sample Submittal Worksheet for current shipping location & DLA Letter of Instructions for Periodic Reviews)

(3) 1 container as In-Plant Standby

c. Sample Point C – 4 Like Containers

(1) 1 container to DEVCOM-SC

(2) 1 container plus the current PDM to NPMS (see OR Sample Submittal Worksheet for current shipping location & DLA of Instructions

(3) 1 container as In-Plant Standby

Group Rations- Submittal Procedures

A. Required for all Polymeric Tray Items. The USDA Inspector will select eight samples of each item produced during each month of Polymeric Tray production. The eight samples will be selected from four random sampling points (A, B, C, and D) in the lot, with DEVCOM-SC receiving samples from each of these four points. The remaining samples will be distributed to the USDA review locations. These samples will be designated as Monthly Review Samples. The USDA Inspector will ship them monthly to the designated locations at the contractor's expense.

B. These sample points should be spread out over the production lot so that they represent a cross section of production. At each sample point, three containers will be selected which, to the extent possible, share common batching, time code, retort cook, etc. If the review samples are only marked with the day code, mark the samples from each sample point using the source case or source pallet information. This will assist in follow-up in the event that issues are identified with a particular sample.

1. Sample Point A – 3 Like Containers

a. 1 container to DEVCOM-SC

b. 1 container to NPMS (see OR Sample Submittal Worksheet for current shipping location & DLA Letter Instructions for Periodic Reviews)

c. 1 container as In-Plant Standby

2. Sample Point B – 3 Like Containers

a. 1 container to DEVCOM-SC

b. 1 container to NPMS (see OR Sample Submittal Worksheet for current shipping location & DLA Letter of Instructions for Periodic Reviews)

c. 1 container as In-Plant Standby

3. Sample Point C – 3 Like Containers

a. 1 container to DEVCOM-SC

b. 1 container to NPMS (see OR Sample Submittal Worksheet for current shipping location & DLA Letter of Instructions for Periodic Reviews)

c. 1 container as In-Plant Standby

4. Sample Point D – 3 Like Containers

a. 1 container to DEVCOM-SC

b. 1 container as In-Plant Standby

c. 1 container to USDA – Specialty Crops Inspection Area Office

Periodic Review Standby Samples

A. The "Standby Samples" must be retained until the Inspector receives DEVCOM-SC and USDA results confirming acceptability. When the conforming results are received, the samples can be returned to the contractor.

B. These samples will be used for additional review of a lot if DEVCOM-SC rejects the product during their review, or if USDA requests follow-up action.

USDA Inspector Follow-up Actions Based on DEVCOM-SC Evaluation Results for Individual Rations

For instructions on how to respond to a DEVCOM-SC rejection, refer to the DLA Letter of instruction (LOI) for Periodic Review Submittals (intranet link).

DEVCOM-SC evaluation results are forwarded to ORS for distribution to USDA inspectors and review locations.

If DEVCOM-SC "rejects" or otherwise takes exception to a Periodic Review, PDM Replenishment of First Article Replenishment, ORS will create a "Documentation of Corrective Action Request - Samples rejected by DEVCOM-SC" worksheet and post the worksheet on the ORS SharePoint site (intranet link).

A. The worksheet will be inserted as a separate "tab" in the file and the tab, identified with the lot number. Inspectors should fill out the document online.

B. If DEVCOM-SC rejects individual periodic review samples, refer to the LOI for response rejection guidelines.

C. In completing the worksheet, the Inspector-in-Charge should take the following steps:

1. Review DEVCOM-SC results with USDA personnel, as appropriate (and consider possible adjustment of future USDA organoleptic/comparability evaluations).

2. Discuss DEVCOM-SC results with the contractor. Become familiar with any actions the contractor may take to address the situation with respect to future production.

3. Perform QSP Compliance Audits on the contractor's end-item product evaluation for the next two lots produced of the item.

USDA Inspector Follow-up Actions Based on USDA Evaluation Results

A. USDA review locations will perform evaluations on periodic review samples but will no longer routinely review PDM or First Article Replenishment samples unless directed by DLA Troop Support. ORS will defer to DEVCOM-SC for feedback on Replenishment submittals.

B. The Inspector-in-Charge should review these results from the USDA review locations with USDA personnel (and consider possible adjustment of future USDA organoleptic/comparability evaluations, as appropriate) when issues are identified.

C. The Inspector-in-Charge may be asked to implement additional follow-up and/or corrective action, as needed, based on the nature of the specific finding. These USDA review results can also be used by the Inspector to inform the contractor about changes/deviations from the First Article or PDM, so adjustments can be made to ensure comparability with the production standard.

D. When USDA review locations reject a periodic review, ORS will identify the code of the sample unit and request that the USDA IIC complete a "Documentation of Corrective Action -Samples rejected by USDA."

E. ORS will add this worksheet to DEVCOM-SC Review Sample Submittal Calendars for all locations (intranet link) to track the submittal process.

Resolution Lot Status for Group Rations Rejected by DEVCOM-SC

When DEVCOM-SC rejects a lot, USDA will submit the following passing lot and will follow the guidance provided by DEVCOM-SC.

Resolution Lot Status for Individual Rations Rejected by DEVCOM-SC

Refer to LOI " Procedure for Periodic Review submittal in response to a rejection by DEVCOM-SC" (intranet link) for guidance.

Special Evaluation Samples

A special evaluation is one that USDA personnel or DEVCOM-SC may initiate for a product that raises potential concerns.

A. An Inspector-in-Charge can request that the Area Office and ORS staff provide feedback on product quality and/or packaging.

B. The Inspector-in-Charge should first notify their OIC of the purpose of the request. The OIC, and/or IIC, will then work with ORS to make the appropriate arrangements before the special evaluation samples are submitted for review.

C. Samples should be sent to the USDA review location with a review submittal sheet explaining the reason for the evaluation. The type of review should be selected as "Special Evaluation."

D. On the outside of the shipping container, label the package "Special Evaluation."

E. DLA Troop Support may request that special evaluation samples be sent to USDA review locations if there is any doubt that a lot is acceptable. This is important when DEVCOM-SC has rejected the product in a recent periodic review or replenishment submittal. Submit the samples to the USDA review locations before the lot is certified and notify the contractor that a special evaluation will be performed before certification can be completed.

Distribution of Results from USDA Review Locations

A. USDA review locations receiving periodic review samples will evaluate the samples to provide feedback to the IIC.

B. The submittal sheets sent from each OR location are uploaded to the ORS SharePoint site in a document folder called: Periodic Reviews – Active Worksheets for all Locations (intranet link). Each OR location has an excel file and within the file are multiple tabs identified with the date of each submittal. Inspectors should check this site frequently to review comments made on the various submittals. If a product is rejected at a USDA review location, a Corrective Action Response will also be added to the Submittal Calendar and ORS will notify the IIC of the reject, and when possible, provide supporting photos. The IIC will inform USDA personnel of the Corrective Action Response.

C. The USDA review locations may add their comments to the worksheet for the respective locations.

Submittal Process - Labeling and Shipment of Samples

A. Refer to ORS SharePoint site/OR Worksheets/Review Submittals (intranet link) to download the associated file to use when submitting samples for each location. These electronic worksheets are contained in Microsoft Excel spreadsheet files for each plant. For instructions on using the files, open the file and print out a copy of the instruction page found in one of the sheets. The Excel file automatically creates a list of the quantities to be sent to each location based upon the category of the submittal. The locations and addresses are built into the submittal worksheet Excel file.

B. The worksheet will populate the number of samples required once the submittal type is selected.

C. Label all submitted samples, including First Article, Natick DEVCOM-SC First Article Replenishment, Local USDA First Article Replenishment, PDM, and Natick DEVCOM-SC PDM Replenishment, individually. This can be performed by writing "PDM" or "First Article" on each sample in permanent marker. Some locations utilize applied computer-generated labels, which are applied to each pouch/box before submission.

D. It is not necessary to individually label periodic review samples.

E. When sampling the lot, make sure that permanent coding of lot information is present on all containers. DEVCOM-SC will not evaluate a product received with the lot/retort coding missing.

F. Enclose a copy of the submittal worksheet in the individual shipping container.

G. Package review samples and replenishment samples in separate boxes. It is acceptable to then place the separate boxes in a larger box for shipping. Limit the boxes to 40 pounds total, so the boxes can be handled easily.

H. Describe the contents of each shipping container on the exterior of the box. If two categories of review samples are in the same shipping container, label the outside of the box, indicating each type of sample contained in the box. Example: "Periodic review samples and DEVCOM-SC PDM replenishment samples enclosed."

I. Notify DEVCOM-SC, DLA Troop Support, and ORS when samples are being shipped by e-mailing the submittal worksheets (as Excel spreadsheet files) to the list of contacts within Appendix IV – Operational Rations Document Email Distribution.

J. Use a sturdy, clean shipping container that is the right size for the shipment and include enough durable packing material to protect the samples. Bulky boxes are difficult for DEVCOM-SC to handle. Avoid shredded paper that leaves a fine powder residue.

K. Group Rations and Individual Rations need to be submitted on separate submittal sheets. Group Rations need to be submitted each month, while Individual Rations as scheduled. Periodic Review Sample for Group Rations and Individual Rations can be sent in the

same shipping package. If sending samples of Individual Rations and Group Rations in one shipping box, place both submittal sheets in the shipping box.

Timely Submittal Process

Inspectors should submit conforming review samples within 5 working days of the final disposition of the product. If a product has an issue, ship the other samples and submit the product in the next cycle.

SECTION 4 – INSPECTION LEVELS

Switching Procedures

Responsible Authority

DLA Troop Support is designated as the "responsible authority" for determining whether switching procedures will be applied at an operational rations plant in accordance with current solicitation.

Individual Rations

The switching procedures outlined in the solicitation provides guidance on Normal, Tightened and Reduced Inspections that are applied to USDA inspection of operational rations at origin under specified conditions. See ORS SharePoint site/OR Resource Documents (intranet link) for following guidelines by DLA that should be applied.

Application

The application of switching procedures to USDA operational rations verification inspection is limited to the MRE pouch integrity examination with critical defects. The options of "tightened" and "normal" inspection are authorized; the option of "reduced" inspection is not authorized. Note: A contractor may incorporate switching procedures into their QSP and use them as described by ANSI/ASQC Z1.4, subject to acceptance by DLA Troop Support of the QSP.

MRE Pouch Integrity Examinations

A. See Section E-3-B, "Quality Assurance Provisions to be used with product packaged and/or processed in accordance with MIL-PRF-44073, Packaging of Food in Flexible Pouches", of the MRE contract for instructions on the application of switching to the inspection of MRE retorted pouches.

B. When lots that have been inspected at the tightened inspection level are entered into the ORDB, the "Level of Inspection" will be changed to indicate tightened inspection.

C. DLA Troop Support has requested notification when an individual product line goes on tightened inspection. This notification should come in the form email message to DLA Troop Support and National Programs Mission Support, via

scscioperationalrations@usda.gov.

Product offered after this lot will be inspected at the tightened inspection level for the pouch filled and sealed exam, until the product requalifies for inspection at the normal level Inspectors will make a statement on the SC-10 Notice of Hold in the section titled "Reason(s) the Above Product Fails Contract Requirements". This is issued on the lot failure prior to the start of tightened inspection.

For example, "Critical 2 Defect, Punctured Pouch".

Distribute per instructions in Notice of Hold Form (SC-10) Procedure section of the manual.

Group Rations

Switching procedures are not applicable to Group Rations and will be determined by DLA.

SECTION 5 – CONTRACTOR SUPPLIED DOCUMENTATION

This instruction outlines the procedures, as they apply to the USDA operational rations inspection program, for the review and audit of contractor inspection records and ingredient documentation that may be needed to complete certification.

Responsibilities

Contractor

The contractor is required to provide various COCs for each production lot offered to the USDA for verification inspection, as well as COCs that might cover all production for a contract. COC statements can vary between contractors, even for the same product, but all COC statements should state that the item or characteristic(s) covered meets all contract requirements. The contractor may be required to provide additional documents, such as COAs (Certificates of Analysis), U.S. Grade Certificates, and specific statements from ingredient suppliers. The contract inspection clauses found in the solicitation/contracts/specifications define these requirements for each product, and are the references used by the contractor to determine what records are required.

Government Quality Assurance Representative

When a lot is offered for USDA verification inspection, the documents provided by the contractor should be reviewed by the GQAR for completeness and accuracy. Copies of applicable documents should be retained in the Government file, after the review. The GQAR should be familiar with all the documents and in-process reviews required for each product being produced at their location. As part of the daily inspection activities, the GQAR should also verify that the contractor is meeting the requirements for the item(s) being produced by reviewing ingredient labels, performing in-process formulation reviews, and periodically auditing receipt inspection records. See Section 2 – USDA In-Plant Inspection Procedures.

Types of Documentation

Certificate of Conformance

COC is defined as a document submitted by the contractor to the GQAR stating that items, used in production for a contract, meet contract requirements. A COC should include, as appropriate:

- The contract number
- The applicable specification number
- References to any relevant modification, waiver, or amendment

A. See FAR Clause 52.246-15 Certificate of Conformance, for further guidance on the format and statement requirements.

B. Various COCs may be required for any particular contract and/or product. Some of the COCs include:

- A "Blanket" COC – this document typically addresses the requirement in a solicitation or contract for a statement from the contractor that all packaging, packing, labeling, marking, and unitization materials, used in the contract production, meet contract specifications. See Clause 52.246-9P20 Certificate of Conformance, often found in Section E of a solicitation, for a statement of this requirement.

C. In some cases, the contractor can furnish a "Blanket" COC to cover the production for an entire contract, or for each lot offered to the GQAR. If a contractor provides a single "Blanket" COC per lot, it may also address each of the specific COC statements that the product may require (see item C., above).

D. COC statements can vary between contractors, even for the same product, but all COC statements should state that the item or characteristic(s) covered meets all contract requirements. These statements may include information furnished by the supplier of the ingredients and, in such cases, this information should be included in the statement prepared by the contractor.

E. Note that a COC may be provided by a supplier. For example, the supplier of preformed pouches may provide a COC covering the performance characteristics of the pouches they supply.

F. Each lot folder should have a copy of the COCs that have been provided to the GQAR when a lot is offered for inspection.

Certificate of Conformance of components (ingredients, packaging, and packing material)

A COC of components (ingredients, packaging, and packing material) is a document provided by the supplier or contactor, certifying that the components used meets all contractually requirements. A COC should include, as appropriate:

- The requirement that is being addressed by the COC
- The identity of the ingredient, material, and/or products covered by the COC

A specific COC for certain components, ingredients, or end item characteristics the requirement for this type of COC will be specified in a product specification or the contract documentation.

Certificate of Analysis of components (ingredients, packaging, and packing material)

A COA of components (ingredients, packaging, and packing material) is defined as a document supplied by the component's manufacturer to the contractor that details the components meets all required tests/specifications. COA requirements, when they apply, are normally found in the product specification, contract/solicitation.

A component COA may cover more than one production lot and may be kept in a separate folder that is used to file all such documents for a particular product.

U.S. Grade Certificate

The requirement for a U.S. Grade Certificate for an ingredient with a specific quality level is usually found in the footnotes section of the product exam table. It will specify that a U.S. Grade Certificate is required to demonstrate that the ingredients meet those requirements. The actual requirement will usually be found in the specification.

Products with ingredients that require a U.S. Grade Certificate should not be certified if the GQAR cannot review a copy of the certificate for the production lot ingredient. The certificate must specify that the ingredient lot meets the grade requirement, as stated in the product specification.

When grades for some fresh fruits and vegetables and some grain items are specified in the contract, the GQAR should verify with their supervisor what type of certification document is acceptable. This discussion could occur during the completion of the New Item Checklist.

Other Documentation and Ingredient Requirements

Foreign Sourced Ingredients

When ingredients are from a foreign country, the contractor must have that ingredient listed on their "Master List of Ingredients from Foreign Sources". For each ingredient, the Master List shall list the ingredient, the country of origin, and the product(s) in which the ingredient is used. The Master List shall be updated as necessary. The Master List shall be provided to the in- plant GQAR and, upon request, to DLA Troop Support Contracting Officer as stated in the solicitation.

Latest Season's Crop

Some contracts or products have a requirement that the ingredients be from the latest season's crop year. This should be verified when reviewing the contractor's paperwork and during the daily formulation checks. If the GQAR determines that an ingredient is being used that does not meet the latest season's crop year requirement, the GQAR should contact their supervisor and ORS, following current procedures.

Age of Ingredients

Contractors formulating and producing end-item operational rations food items, and for each item that is manufactured, shall maintain a list of ingredients (generic name, brand name, producer name, or supplier name in case of bulk packed plant or animal ingredients, country of origin) and the time and temperature serviceability limitations the contractor will impose on each ingredient.

Each ingredient's time limitation is to be calculable using its date of pack as the starting point. A copy of this list will be made available to the Contracting Officer or to the USDA upon either's request. During product formulation/mixing the GQAR must notify the ORS team and area office if expired product is found. The ORS team and area office will provide additional guidance.

- Note: This does not modify the time and/or temperature limitations specified for ingredients in the solicitation/contract, including its technical data package and product specifications.

SECTION 6 – OPERATIONAL RATIONS DATABASE

Background Information

The ORDB is a computer-based software application used to document production activity in the Operational Rations program. Inspectors enter information and USDA inspection results for each production lot into the database. This data is used to generate numerous reports and provide information used by the USDA Inspectors, contractors, ORS, and DLA Troop Support for obtaining lot information, identifying production issues, and reviewing the quality history of each contractor.

This section provides guidance on the use of the ORDB program. The main topics are outlined below:

- Establishing an ORDB user account
- Opening the ORDB program
- ORDB training for new users
- Timeframe for entering a lot into the ORDB
- Timeframe for completing or closing-out lot information in the ORDB
- Generating worksheets and reports from the ORDB

- Updating list information in the ORDB
- Classification of "Lot Acceptance" status in the ORDB
- New reports added that generate list of products/lots with full Inspection status
- Final Lot Certification information no longer needed to be added

Establishing an ORDB User Account

In order to use the ORDB, the USDA inspector must establish an account. The user or user's supervisor must initiate the request by contacting the ORS. ORS will notify the appropriate personnel to establish the new user account in the ORDB.

Opening the ORDB Program

After ORS has established an account for the OR inspector, the user can launch the program by going to the Start menu, selecting "ORDB App" or by clicking on the ORDB icon on the desktop Fruit and Vegetable Program and clicking once on the ORDB icon.

The login is process is detailed below:

- Login name and password are no longer required. Click "login" button and select the plant name.
- Users will see a list of OR plants linked with their profile, as well as a "Test Plant" selection. The "Test Plant" option serves as a practice area. New users can submit data into the "test plant" without worrying about modifying or negatively impacting data in the ORDB for their allocated plant.
- The ORDB maintains unique records for each OR plant. The only inspectors who can access the records for a specific plant are those inspectors with ORDB logins who are assigned to the plant. This measure assists in maintaining the integrity, confidentiality, and security of ORDB records.

Timeframe for Entering and Closing a Lot into the ORDB

Inspectors should enter the lot information into the ORDB as soon as the lot is completed. If there is a USDA failure, the failure information shall be entered immediately. The failed lot information shall be updated when the final disposition is determined using the Hold lot procedures.

Generating Worksheets and Reports from the ORDB

There are numerous worksheets and reports that can be generated from the information entered into the ORDB. These reports can be used by inspectors to inform contractors of their production status. They are also used by ORS to track trends, identify issues, and in preparation for 2700 reviews.

ORS generates reports from the ORDB for DLA Troop Support throughout the year. These are reviewed by DLA Troop Support to gain information about contractors' performance. In addition, ORS presents a summary of USDA/AMS inspection results based on data in the ORDB during conferences attended by DLA Troop Support and the OR Contractors.

Inspectors should run reports on a monthly basis and review them for accuracy to ensure that the information generated is accurate.

When reviewing reports, Inspectors should cross check the reports with the lot summary worksheets, production ledgers, and hold ledgers to verify accuracy and help identify any inconsistencies.

The ORDB has additional reports that list all products/lots that were fully inspected by USDA (not acceptance based on end-item skip-lot). This report can be used to select which lots can be submitted to DEVCOM-SC as periodic reviews. ORS also uses this report to track DEVCOM-SC periodic review submittals and determine if the review submittal processes is being followed.

Updating Information Lists in the ORDB

The ORDB contains lists of product names, analytical tests, number of units per case, and product exams. These are stored in computer files within the ORDB program and appear in the drop-down lists with "grayed" fields. They cannot be changed or altered except by the ORS team.

Contact the ORS team at scscioperationalrations@usda.gov when changes or updates are needed to these lists.

Classification of "Lot Acceptance" Status in the ORDB

A. If a lot has passed all applicable USDA examinations, the lot should be closed out. In the main view, verify that the three choices have been completed correctly in the "acceptance" box.

1. Choice 1- select "Yes" if lot meets USDA/AMS Exams or "No" if the lot did not meet all contract requirements.

2. Choice 2 - select "Yes" if lot acceptance is based upon Contractor's Results End-Item Skip-Lot or N/A if lot was examined by USDA for the applicable End-Item exams.

3. Choice 3 - select "Yes" if lot acceptance is based upon Contractor's Results Analytical Skip-Lot or N/A if lot was tested for all the applicable analytical/microbiological exams.

4. To complete or close-out the lot, click the "Inspection Complete" button in the "status" box of the main view.

B. If a lot has failed to meet USDA examinations (such as product exam, packaging exam, analytical, packing, unit loads, etc.) and is accepted "as is" by DLA Troop Support with a waiver, (i.e., no change to the lot and no rework and re-inspection), Inspectors should take the following steps:

1. Enter the defect(s) into the ORDB;

2. Indicate "Waiver" as disposition (under the defect info); and

3. For Acceptance, enter "No" for Meets USDA/AMS Exams.

4. The lot does not need to be entered again into the ORDB again as a "2" submission.

C. If a lot has failed to meet the USDA examinations (such as product exam, packaging exam, analytical, packing, unit loads, etc.) and DLA Troop Support allows a retest (no change to the lot) and the lot passes the retest and DLA Troop Support accepts this result (for example, a lot is retested by the USDA laboratory for salt, and the results meet specification requirements), Inspectors should take the following steps:

1. Enter the defect into the ORDB;

2. Indicate "Reinspection" as the disposition (under the defect info);

3. If this applies to an analytical exam, mark the exam as passing (under Analytical/Micro Information); and

4. For Acceptance, enter: "Yes" for Meets USDA/AMS exams.

5. The lot does not need to be entered again into the ORDB again as a "2" submission.

D. If a lot has failed to meet USDA examinations (such as product exam, packaging exam, analytical, packing, unit loads, etc.) and, as a result of a special review, DLA Troop Support gives USDA/AMS guidance that "resets our sights" on what is acceptable, and the lot now meets (for example, DLA Troop Support/DEVCOM-SC finds broken Ravioli to be intact as long as it contains filling), Inspectors should take the following steps:

1. Do not enter the defect into the ORDB;

2. In the "Comment" field (General Lot Information) make a note that the lot was submitted for special review and found acceptable; and

3. For Acceptance, enter "Yes" for Meets USDA/Exams.

4. The lot does not need to be entered again into the ORDB again as a "2" submission.

E. If a lot has failed to meet USDA examinations (such as product exam, packaging exam, analytical, packing, unit loads, etc.) and DLA Troop Support allows a rework of the lot, which the contractor performs and then re-inspects with conforming results, Inspectors should take the following steps:

1. Enter the defect(s) into the ORDB;

2. Indicate "Reworked/reoffer" as the disposition (under the defect info);

3. For Acceptance, enter "No" for Meets USDA/AMS Exams; and

a. Enter a new lot (second submission) for the reworked lot, when it is reoffered to you for a new inspection.

b. To do this, enter the number "2" in the "submission box. This creates a unique lot identity in the ORDB and is used track lot failure rates.

c. In the "2" submission, enter in the changes that occurred since the first lot was entered and enter in the final lot disposition information.

d. Close out the number "1" and "2" submissions at the same time.

F. If a lot has failed to meet the Contractor's examinations (such as product exam, packaging exam, analytical, packing, unit loads, etc.) and DLA Troop Support has approved that the lot be offered for USDA inspection (i.e., DLA Troop Support waive the requirement that the contractor only offer conforming products), the lot can be inspected by USDA.

1. If the lot passes USDA inspections/tests, it can only be certified if DLA Troop Support has approved certification.

2. If the lot fails USDA inspection, it cannot be certified unless DLA Troop Support has waived compliance with USDA end-item inspection.

3. In the ORDB, for Acceptance, enter "No" for Meets USDA/AMS Exams.

4. The comments section may be used to add clarifying details for future reference.

The following is an example of this scenario: The contractor has a laboratory test result that does not meet the specification requirements and DLA Troop Support waives that test requirement and states that USDA does not need to test for the requirement. The lot is entered in the ORDB for acceptance as "No" for meeting USDA/AMS exams.

G. Final Lot Certification information no longer needs to be entered in the ORDB. This information should still be recorded in the "Lot Summary" worksheet in the event that this information is needed.

SECTION 7 – LABORATORY TESTING

USDA/AMS Laboratory Testing - General Information

A. Analytical (i.e., chemical or nutrient) and microbiological requirements for items are contained in the product specifications. Testing for analytical requirements may include, but is not limited to, testing for: salt content, fat content, moisture content, protein, vitamins, water activity, Brix, pH, etc. Testing for microbiological requirements may include, but is not limited to, testing for Salmonella, E. coli, Aflatoxin, Standard Plate Count, etc.

B. All lots must meet analytical and microbiological requirements in the specification and contract.

C. There are two procedures applicable to laboratory testing: (1) Optional Contractor Testing and (2) USDA acceptance testing. One or the other will apply.

1. Under optional contractor testing, the contractor tests every lot, and USDA "verifies" the reliability of the contractor's results by testing a portion of the lots using a skip-lot procedure. This procedure is specified in DLA Troop Support Contract Clause 52.246-9024, "Alternative Inspection Requirements for Selected Items (Nov 2011) DLAD." This document is posted on the ORS SharePoint site/OR Resource Documents (intranet link). When this clause is referenced in the contract, this procedure is applicable and required for analytical testing. A contractor must obtain approval from the contracting officer to use another procedure for analytical testing.

2. Under USDA acceptance testing, USDA tests every lot. The contractor may test each lot for their quality assurance purposes; however, this testing by the contractor is not required. USDA acceptance testing is required for pathogen testing (e.g., Salmonella), and is in place for all microbiological testing. Any exceptions to this must be approved by DLA Troop Support and verified through the OIC and ORS.

D. When submitting samples to the USDA laboratory for testing, Inspectors should include a completed DD Form 1222 "Request for and Results of Test" with the samples.

E. When the contractor and USDA are both testing for the same analytical requirements, the test methods may vary between the two parties. The USDA laboratory must perform all Government testing using one of the test methods listed in the product specification. These method(s) should be detailed on the laboratory submittal document (DD Form 1222). Under Optional Contractor Testing, the contractor may use a test method not

listed in the specification; however, the method the contractor uses should provide reliable results.

F. When more than one specification is referenced for a product, such as when a Commercial Item Description (CID) and Quality Assurance Provision are both referenced for a product, the Quality Assurance Provision normally takes precedence over the CID when determining what tests to perform and what quantitative limits to apply for the item being tested. The USDA Inspector should ask for guidance from the OIC when the test method is not clear for a new product, a change in the specification has occurred, or at any time clarifications are needed.

G. Under certain conditions, the contractor may wish to have USDA perform all or part of the testing or analysis of end items and/or component material. As indicated in C 1. (above), if DLA Troop Support clause 52.246-9024 is applicable, the contractor must seek approval to use USDA acceptance testing in place of optional contractor testing for analytical requirements.

H. USDA acceptance testing is mandatory for each production lot when microbiological testing is required by the specification. Optional contractor testing procedures can be used for all other tests except in a few instances (which are generally food safety-related) as indicated in the specification or contract. For example, USDA tests each lot of pouch tuna for mercury and histamine. Similarly, USDA tests each lot of shelf stable sandwiches for water activity, pH, and oxygen.

I. Inspectors should review the specifications and complete a “New Item Checklist” when a new product is added to the Operational Rations program. This will help identify any new or unique testing requirements the item may have.

J. Contact information for the USDA, AMS laboratories can be found on the internet at https://www.ams.usda.gov/services/lab-testing/nsl

Optional Contractor Testing of Food Components

A. Optional Contractor Testing allows for reduced rates of government verification testing based on skip-lot procedures. The contractor will test every lot.

B. The Optional Contractor Testing procedures can be found in the Technical Data Package (TDP) section of each solicitation, currently DLA Troop Support clause 52.246-9024. It is the intent of the government to exercise Optional Contractor Testing whenever possible.

C. Initially, under Optional Contractor Testing, lot by lot testing will be performed by USDA on products produced by a new contractor. For established contractors, if USDA has not inspected the item produced by the contractor within the previous 120 days, the same skip-lot procedures need to be followed as for a new contractor until the contractor’s reliability has been re-established for that product and test.\

D. Once the contractor has tested and passed 3 consecutive lots, and USDA has also tested and passed the same 3 consecutive lots, the contractor's testing system is considered reliable for the product and test. Note that the USDA Inspector may begin skip-lot procedures after submitting the third consecutive lot to the USDA laboratory even though conforming contractor and USDA results for all three consecutive lots may not have been received yet. It is necessary, however, that the Inspector receive conforming results from the USDA laboratory for the first three lots before he or she can certify a lot based on the contractor's test results.

E. Skip-lot verification will be done by randomly selecting one lot in six consecutive lots presented for inspection of a specific item. The sampling procedure under skip-lot places the succeeding lots not chosen for inspection back into the universe available for subsequent inspection. For instance, starting with a group of six lots (i.e., 1-6), the Inspector will randomly select one of them for inspection. If lot 4 were selected, the next lot would be selected from lots 5, 6, 7, 8, 9, and 10. If lot 8 were chosen at random, the next selection would be from lots 9, 10, 11, 12, 13, and 14, and so on. See SharePoint/ OR Resource Documents/Analytical Skip Lot - Examples on interrupting skip-lot when test failure occurs, dated 07/21/2010 (intranet link).

F. Normally, product will be accepted or rejected on the basis of contractor's results when the contractor's testing system is in a reliable status. However, Inspectors should postpone certification until they receive conforming USDA results for lots submitted to the USDA laboratory.

G. For each production lot, the Inspector will obtain from the contractor a report showing the results of test(s) performed by the contractor. The report will have the typed name and title of the laboratory official and the signature of that person.

H. In addition, a certification statement as described in DLA Troop Support Clause 52.246-9024, will also be affixed to the test report, and distributed to the USDA Inspector. This statement can be incorporated into a blanket certification statement offered with each conforming lot.

I. When the contractor's test results and USDA laboratory test results (if tested by USDA) indicate compliance and all other requirements of the contract are met, the USDA Inspector can sign and issue the applicable inspection documents (DD Form 250 or government certificate). The USDA Inspector can certify a lot based on conforming contractor test results if the contractor is reliable and the lot has been skipped for USDA verification testing.

J. The Inspector should draw a full set of laboratory samples on all lots produced that are intended for Operational Rations use, even when lots are not submitted for verification testing. This provides the opportunity for any lot to undergo verification testing and avoids any indication in advance as which lots will be skipped, and which will be tested by the USDA laboratory.

K. Samples from skipped lots can be returned to the contractor once the contractor provides their test results to the USDA Inspector.

L. A USDA skip-lot ledger for analytical testing is required to track all products and production lots at the facility. This ledger should be kept confidential so that the contractor is not informed in advance which lots will be skipped. Examples of skip-lot ledgers for analytical testing can be found on the ORS SharePoint site/OR Worksheets/Skip Lot Ledger Examples (intranet link).

M. The USDA laboratory will furnish the results of its analysis to the USDA inspectors specified on the DD Form 1222. These laboratory results sometimes arrive before the contractor provides their test results to the USDA Inspector. The USDA laboratory and the USDA Inspector should not release the USDA test results to the contractor until the contractor provides their test results. Any exception to this requires advance approval from the Defense Supply Center Philadelphia (DLA Troop Support) Contracting Officer. (Note that the contractor will receive by mail a hard copy of the USDA/AMS test results along with a bill from the USDA/AMS laboratory; however, this information generally arrives after the contractor results are available and timing is generally not an issue.)

N. No statement is required in the remarks area of DD Form 250 or the USDA Certificate if the testing is performed by the USDA laboratory as well as the contractor. Otherwise, the following statement should be included on the USDA Certificate. "Acceptance based in part on Contractor Test Results in accordance with analytical skip-lot procedures." No statement is required on the DD Form 250

Procedures for Submitting Samples to the USDA Laboratories

A. An electronic version of DD Form 1222, in the form of an Excel spreadsheet, has been developed for most products to assist in preparing the submittal form. These spreadsheets can be found in on the ORS SharePoint site/OR Worksheets/DD1222 (intranet link).

B. Inspectors should check with their OIC and ORS if any questions exist as to which USDA laboratory samples should be sent.

C. For each submittal of samples, the Inspectors should assign a sample number to the set of samples represented on the DD Form 1222. The sample number should be entered in block 6 of the DD Form 1222. The sample number format should be the three-letter product code, followed by a number. The number would start with "1" at the beginning of the calendar year and run consecutively, for the specific product, for a one-year period. For example, "MPP1" could be used for the first lot of MRE Mashed Potatoes submitted for a calendar year and "MPP12" could be used for the 12th lot of MRE Mashed Potatoes submitted for the same calendar year.

D. When a change to the DD Form 1222 is necessary, due to a change in test methods, or a change in the allowable range for results, etc., the Inspector will include, with the submitted DD Form 1222, a copy of the solicitation, amendment, contract, or

modification that contains the changes to the requirements for the analysis, and highlight the changed areas on the DD Form 1222. This will assist the USDA laboratory personnel in ensuring that the specified procedures and tolerances are applied.

E. The USDA Inspector should confirm that the current specification is listed in the DD Form 1222. If the specification has been updated and the DD Form 1222 has been modified accordingly since the last submittal for a specific product, it is recommended that the Inspector highlight the updated information on the DD Form 1222 submittal form. This is a courtesy to the laboratory and helps ensure that the change is acknowledged.

F. Products with specifications that require individual testing of each sample unit should have some marking on each individual sample unit to establish the timeframe the sample was packaged or cased. In the event of a test failure, this code/marking can be used to assist the contractor in establishing when the failing sample was produced. If the sample already has a time code printed on the pouch, no further identification is necessary. If the markings on the individual samples do not identify the production time, the USDA Inspector should mark the pouch with a case code or pallet code or other designation that can assist in establishing the location from which the sample was selected from within the lot.

G. For those products for which each sample is tested individually, the DD Form 1222 should have the following statement in Section B of the DD Form 1222: "The USDA laboratory should document the individual pouch code identification and corresponding test results for samples that are individually tested." Inspectors should record the time codes (or other identifiers used to identify each individual sample unit) in Section B of the DD Form 1222. A copy of the completed DD Form 1222 should be kept with the USDA Inspector's files for those products that have samples that are individually tested.

H. It is not necessary to include the individual sample coding information for samples which will be combined and tested as a composite; however, Inspectors may do so if they choose.

I. If the Inspector has a question about the test method being used by the USDA laboratory, he or she should contact their OIC and ORS for guidance. This contact will be used to initiate discussion to ensure that the appropriate test methods are used.

J. Inspectors should refer to the product specification for information on sampling rates for test samples. If sampling rates are not specified, Inspectors should refer to USDA sampling procedures; however, Inspectors should verify sampling rates with their OIC and ORS if sampling rates for test samples are not clearly stated in the specification.

K. Some specifications list tests that USDA and the contractor are only required to perform on the first production lot of a contract cycle. In such cases, once conforming results are obtained, the USDA will simply verify that the formulation has not changed from the formulation that resulted in conforming results. If the formula is changed or a new contract starts, the Inspector should submit another set of samples to the USDA

laboratory for analysis. In addition, the contractor should provide the USDA Inspector with a Certificate of Analysis providing test results from the new formula. The contractor should also provide a copy of the new formulation. The USDA Inspector will monitor subsequent production to verify compliance with the new formulation. A unique DD Form 1222 has been developed when requesting these initial "first lot only" tests.

L. Lots selected as Replenishment Production Standards (i.e., First Articles or Product Demonstration Models (PDM)) will always be contractor and Government tested for compliance with all analytical requirements.

M. When microbiological tests are requested on a DD Form 1222 submittal form, email the DD Form 1222 (as Excel spreadsheet files) to the list of contacts within Appendix IV-Operational Rations Document Email Distribution.

Procedures for Shipment of Samples

A. USDA Inspectors are not allowed to ship samples until the contractor has submitted the lot submittal package documentation to the inspector. The exception is with the written authorization of the contracting officer.

NOTE: The contractor's lot submittal package must include the documentation of all inspections results required by the contractor. The results must show conformance to all applicable contractual requirements.

B. All sample to be submitted to the USDA National Science Laboratory for testing will be drawn by USDA personnel. USDA personnel will package the samples in boxes and always maintain them under USDA control.

C. The USDA Inspector will personally transfer the boxes to the shipping company representative. The use of security strips for sample integrity is required and the serial numbers of the tapes should be listed on the DD Form 1222.

D. Inspectors should send samples by overnight delivery using the USDA SCI Division shipping account. Inspectors should notify the USDA National Science Laboratory in advance, if it is necessary to submit a large number of samples, or if arrivals at the laboratory need to be scheduled for a weekend.

E. Contractors can request early Government inspection on a product-by-product basis. When authorized by the contracting officer, the contractor will communicate to the Government Quality Assurance Representative (GQAR) (i.e., USDA inspector) in writing when the early government inspection lot is available to the GQAR for sampling, and shipping to the USDA National Science Laboratory. Refer to Appendix VII – DLA MRE Solicitation Attachment 6-Request For Early Government Inspection for complete details on DLA contractor requirements regarding early Government inspection.

Laboratory Stand-by Samples

A. For all lots of products that require laboratory testing, Inspectors should either draw stand-by samples when selecting samples for laboratory testing or ensure that they have access to the lot for later sampling, if needed. Such samples could be needed in the event of loss or damage to samples, or if retesting is required.

B. Stand-by samples for laboratory testing should be drawn at the next higher sample size.

C. Selection of stand-by samples (or access to the source lot for sampling) is required for lots which are tested by USDA and also for lots which may ultimately be skipped.

D. Draw the stand-by samples at the same time and/or from the same location (e.g., the same case) as the test samples to be sent to the laboratory.

E. Return the stand-by samples to the contractor after testing is completed and conforming results are received.

F. Stand-by samples of failing lots should be retained until it is determined that they will not be needed.

G. Stand-by samples will be submitted for testing for the following reasons:

1. Original samples lost in mail.

2. Original samples received at laboratory in poor condition.

3. Possible error in analysis and USDA determines that retesting should be performed.

4. Contractor/subcontractor requests a waiver on a failing lot and the DLA Troop Support Contracting Officer requests testing of stand-by samples for additional information regarding the waiver request. (Coordinated through ORS.)

H. Inspectors should not submit stand-by samples at the contractor/subcontractor's request. Any request to submit stand-by samples must be pre-approved by DLA Troop Support. Inspectors should notify their OIC and ORS before proceeding.

Procedures to Follow for Contractor Laboratory Analytical Test Failures

A. If a lot fails the contractor's end-item testing for an analytical requirement and the contractor reworks the lot to remove the portion of the lot that does not meet requirements, the lot must be completely re-sampled and re-tested by the contractor at the next higher sample rate. The contractor will only need to re-test for the analytical exam that had the failed value(s).

B. When the contractor goes to the next higher sample size for analytical testing (due to a contractor test failure), the USDA sample size for testing should similarly increase. This may require additional sampling. Also, if the USDA Inspector has submitted a lot to the USDA laboratory for testing, and the contractor has a test failure for that lot, the Inspector should notify the lab to try to prevent the lab from performing the test for which the contractor had a failure. The USDA Inspector will need to select and submit new samples to the laboratory for the test that the contractor failed. This will occur after the contractor has reworked, re-sampled, and re-tested the lot, and has provided the inspector with conforming results from the re-test.

C. Note that, under Optional Contractor Testing, the USDA Inspector can certify a lot as conforming if (1) the lot fails a contractor's test; (2) the contractor's test results after rework are conforming, and (3) the lot was not selected for analytical verification by USDA.

Procedures to Follow for USDA Laboratory Analytical Test Failures

A. When the USDA laboratory determines that a test result does not meet requirements, the failing value is normally preceded by an asterisk on the laboratory report. The USDA inspector should review all results carefully to check the conformance of each test result. Inspectors should issue a Notice of Hold for lots which fail USDA laboratory testing.

B. Inspectors should notify their OIC and ORS if a failing test result on a USDA laboratory report is not marked with an asterisk. ORS will advise the laboratory and discuss laboratory procedures. ORS will assist in confirming the test failure with the USDA laboratory. Once confirmed, the Inspector should issue a Notice of Hold for the failing lot.

C. The following steps are procedures for handling analytical failures when an item is on skip-lot testing under Optional Contractor Testing (DLA Troop Support Clause 52.246-9024).

D. When a product passes the contractor's test(s) and the USDA laboratory has failing results, the Inspector will place the lot on hold. Refer to the instructions in Section 10 – Lot Failure and Hold Procedures for placing lots on hold.

E. The Inspector will submit samples for verification testing on the next three consecutive lots produced of the item, for the specific test that was found to be nonconforming.

F. If multiple tests are performed on the product, those which did not fail can remain on skip-lot testing.

G. Testing of consecutive lots by the government will continue until such time as the contractor's reliability is again established for the specific test(s). Reliability can be established after three consecutive lots have conforming USDA results for the test in question.

H. If a lot fails USDA testing, Inspectors should withhold certification of subsequent lots of the item offered until conforming USDA test results are received for the lots. This procedure should remain in place until conforming USDA results are received for three consecutive lots. Once these are received, the inspector can begin certifying lots based on the contractor's test results for the test and product in question.

I. A contractor qualifies for resuming skip-lot for a test which failed USDA testing once three subsequent and consecutive lots are tested by USDA and found to be conforming for the test that failed the USDA laboratory.

Procedures to Follow for Microbiological Test Failures (i.e., Positive Test Results), including Presumptive Positives

A. Retesting/reinspection/rework of product that tested positive for food borne pathogens (salmonella, etc.) is not authorized.

B. If a product tests positive (or above allowable limits) for a microbiological criterion, the contractor is responsible for taking steps to identify the source of the contamination. (If the source can be identified, it simplifies the next steps of identifying any potentially affected product(s) and appropriate corrective actions.)

C. Inspectors should take the following steps upon receipt of a positive test result for a microbiological criterion. Items C.1, C.3, and D. below are also the applicable steps for a "Presumptive Positive" result for a food borne pathogen, such as salmonella. (A Presumptive Positive result means that an organism has been found in the test sample which may be the pathogen being tested for, or it may be another organism which causes a positive response in the test media. The lab must take additional steps to determine whether the sample contains the pathogenic organism or another organism. Once these additional steps are taken, and the lab provides its final report, ORS staff can advise the OIC and inspection personnel as to appropriate next steps. ORS will base this guidance on discussions with DLA Troop Support and other sources, which may include FDA or FSIS.

1. Notify the contractor, OIC, ORS, and DLA Troop Support.

2. Issue a Notice of Hold for the lot.

3. Coordinate with the OIC and ORS for specific instructions before certifying or performing organoleptic examinations for any additional lots or products.

D. ORS and the OIC will coordinate with DLA Troop Support to determine appropriate steps, which may include suspension of organoleptic examination of products and suspension of certification of products until adequate assurances are in place that products are not affected by possible contamination.

E. DLA Troop Support may request that the contractor provide information regarding plant, equipment, and production conditions; personnel; ingredients; sanitation; and other associated conditions in order to assess the potential extent of possible contamination.

F. Inspectors should be aware that positive microbiological results may have an impact on a wide range of plant activities, products, and production. The specifics of what may be affected will be assessed on a case-by-case basis by DLA Troop Support, USDA, the contractor, and regulatory agencies, as necessary, to determine appropriate actions.

G. Inspectors may be asked to assist DLA Troop Support in gathering necessary information to help determine, to the extent possible, the source of contamination and potential impact on products.

H. Areas of concern, which could affect other lots and products, include, but are not limited to, common ingredients, common equipment, or common personnel; proximity during production; storage; and shipment.

I. Inspectors should resume inspection and certification activities only when so advised by the OIC and ORS.

J. Under the Memorandum of Understanding between AMS and FDA, when SCI Division provides in-plant inspection, SCI Division is required to report to FDA any adulterated product that is found in the course of inspection that is not under SCI Division control. SCI Division will also report to FDA any positive results for a food borne pathogen.

Shipment of Lots

A. Contractors should ship product from the processing facility to the assembly facility only after USDA certification has been completed. This applies to Rations National Contract, and Contractor Furnished Material, and Government Furnished Material. Any exception to this requires advance approval from DLA Troop Support's Contracting Officer. In addition, the in-plant USDA Inspector should be notified of any such approved exceptions. See SharePoint/OR Resource Documents/Guidance for Testing, Certification of Shipments of Operational Rations Components (intranet link).

B. If a contractor is given approval by DLA Troop Support to ship a product at their own risk prior to receiving USDA test results, USDA/AMS certification for the product will only occur after all required contractor inspections and documentation have been received and determined to be acceptable by the USDA/AMS in-plant Inspector and after all required Government verification inspections and/or testing have been completed and are conforming.

C. If a contractor is given approval by DLA Troop Support to ship a product at their own risk prior to receiving Government test results, and the results are later found to be nonconforming, the USDA Inspector needs to report the failure to the contractor, DLA Troop Support, ORS, and the OIC.

Determining Sample Size for Tests Specified in a Commercial Item Description

A. The following procedures should be used for determining sample size for those rations covered by CIDs that do not contain a sampling rate for analytical and/or microbiological testing. Note that, in certain instances, the sample rate for testing may be in a Quality Assurance Provision associated with the CID.

B. When a sampling rate is not provided in a CID nor in a Quality Assurance Provision for the CID, Inspectors should use the following table to determine the number of samples to select and submit for laboratory testing.

Sample Size for Salient Characteristics	Sample Size for Laboratory Testing
3	1
6	2
13	3
21	4
29	5
38	6

C. All samples tested must conform with contract requirements. If one or more samples fail testing, the lot will be rejected.

D. The sample size for salient characteristics will be the sample size for the performance of the product examination as specified by the military contract. If this sample size (i.e., the sample size called for by the military contract) falls between two of the established values listed under "Sample Size for Salient Characteristics" in the table above, go to the next higher established value in the table and use the corresponding sample size for the number of sample units to select for testing.

For example, if the sample size from the military contract for the performance of the product examination is 20, use the established sample size of 21 in the table, resulting in a sample size of 4 for analytical or microbiological testing.

E. Test results will be reported in the same units as are used for the requirements. For example, if the requirements in the specification state that a percentage must be greater than 0.05%, the test results will be reported to the nearest 0.01%.

F. In the event of conflicting procedures, the contract requirements (specification, technical data package, etc.) will take precedence over these guidelines. The above guidelines in Part A above are intended to give inspection guidance in the absence of any other instructions.

SECTION 8 – OPERATIONAL RATIONS IN-PLANT INSPECTION REVIEW

The delivery of uniform and accurate inspection service is essential for maintaining the integrity of the Operational Rations (OR) inspection program. OR In-plant Reviews are one of the tools SCI Division uses to verify specific OR policies and procedures are followed properly. OR In-Plant Reviews are in addition to SCI Supervisory Reviews of Agricultural Commodity Graders that are also performed at OR in-plant locations.

To ensure a balanced level of oversight, OR in-plant reviews are conducted at the headquarters level by National Programs Mission Support Specialists (Team) and at the local level by Area Office Officers-in-Charge.

National Programs Mission Support (NPMS) In-Plant Reviews

These reviews are performed by NPMS Agricultural Marketing Specialists or designees approved by the Associate Director of National Programs Mission support.

A. NPMS In-Plant Internal Reviews are conducted annually each calendar year at Operational Rations plant locations. The frequency of the review process may be modified in concurrence with the Associate Director of NPMS depending on the extent of controls necessary to ensure operational procedures and processes are working as intended.

B. The NMPS reviewer will notify the plant Inspector-in-Charge (IIC) and the Officer-in-Charge (OIC) of the scheduled date of the review. During the review, the NPMS reviewer will work closely with the IIC and other inspectors to observe and evaluate procedures, review documentation, interview personnel, and assess facility operations. SCI Division supervisors responsible for the facility are also encouraged to participate. At the conclusion of the review, the NMPS reviewer will conduct an exit briefing with the IIC and, if possible, the supervisor to discuss any findings, observations, and corrective actions as needed.

C. The Operational Rations In-Plant Inspection Review (Appendix VIII) report will document findings, observations, products, and compliance with OR related inspection procedures.

D. The SC-550 Operational Rations (OR) In-Plant Inspection Survey Corrective Action Request (CAR) will be used in conjunction with the Operational Rations In-Plant Inspection Review report to document non-conformances discovered during the review. Instructions for completing the CAR are found within the form.

- Reviewer will track, follow-up and verify effectiveness of corrective actions taken.
- Non-conformances of a serious nature will be immediately elevated to the attention of the Regional Branch Chief or Associate Director of Field Operations.

E. The Operational Rations In-Plant Inspection Review report and SC-550 OR In-Plant Inspection Survey CAR will be distributed within 20 working days of the conclusion of the review to:

- NPMS Operational Rations Support via scscioperationalrations@usda.gov
- OR Plant IIC
- Area Office OIC
- Regional Operations Branch Chief and Assistant Branch Chief

F. The Area Office OIC will coordinate with the NPMS reviewer regarding non-conformances listed on the SC-550 OR In-Plant Inspection Survey CAR within 15 days of receipt of the report. Responses, if needed, will use the CAR and should be distributed to the recipients listed above. The OIC may be utilized to conduct a follow-up site visit to confirm corrective actions are complete and will report observations to the reviewer to close out the CAR.

Area Office In-Plant Reviews

These reviews are performed by the Area Office Officer-in-Charge or designee supervisor.

A. The reviewer will conduct a review of inspection activities for each OR in-plant location within their jurisdiction at a minimum of one per calendar year. These reviews may coincide with periodic supervisory reviews of ACGs assigned to the facility. These reviews are in addition to the NPMS In-Plant reviews.

B. The SC-398 Field Office Review Report will be used to document the Area Office in-plant review findings, observations, and compliance related to OR related inspection procedures.

C. The distribution of the SC-398 will be as stated within the Federal Field Office and Federal-State Cooperative Market Field Office Review policy, and in addition, a copy to NPMS Operational Rations Support via scscioperationalrations@usda.gov

Inspector-In-Charge (IIC) Internal Reviews

The Operational Rations IIC will conduct periodic internal reviews of the USDA OR inspection procedures at their location. The IIC will review different portions of the ongoing USDA inspection procedures at different times over the course of the year. The Operational Rations In-Plant Inspection Review (Appendix VIII) can be used as a guide for the areas reviewed during the year. Observations as needed may be noted on the report. Operational Rations In-Plant Inspection Review reports completed for the purposes of internal reviews will be designated as "Internal Review Only" on the summary page and be kept on file within the office for review during the annual NPMS Operational Rations In-Plant Inspection Review.

SECTION 9 – CERTIFICATION

General

This instruction outlines certification requirements and procedures that should be followed to certify Operational Rations production. Inspectors should follow the general procedures found in the Certification Manual and in addition, follow the specific requirements that are found within the Operational Rations Program.

The USDA Inspector who signs the certification document is directly responsible for ensuring that the document is accurate, complete, and adequate. The inspector entering the data or signing the certificate or form is not necessarily the one who has inspected the material for quality, packaging, unit load, etc. It must be emphasized that everyone from the person who prints or types the report to the Officer-in-Charge and supervisors who are responsible for reviewing the work of inspectors shares in the responsibility for the accuracy and adequacy of all inspection certificates.

USDA/AMS certification should not take place until all required contractor inspections and documentation have been completed and reviewed for acceptability. The contractor is required to perform or have an acceptable outside testing service perform all examinations and tests required by the contract.

USDA will normally perform the same examinations and tests to verify contract compliance before certification can be completed. As the contractor builds a quality history, some of the USDA examinations may be skipped under end-item and/or analytical skip-lot procedures, resulting in certification based, in part, on the contractor's examination and/or test results.

If a lot fails to meet contract requirements, in some instances certification can still proceed if/when DLA Troop Support provides guidance to USDA allowing for the certification. In those instances, the lots are accepted based upon DLA Troop Support waivers, with the applicable comments associated with the waiver included in the certification document.

A certificate ledger must be maintained by the USDA Inspector, showing the dates the certificates are issued along with other pertinent information. See the General Procedures Manual, or the procedures to follow when certificates are issued under an in-plant assignment.

Certification of Government Furnished Material Lots

Government Furnished Material items are certified by USDA using a web-based DOD electronic invoicing system called Invoicing, Receipt, Acceptance and Property Transfer (iRAPT) (formerly known as WAWF). This system has replaced the printed DD Form 250. The printed DD Form 250 can still be used for certifying Government Furnished Material in situations when the electronic system is not available, and DLA Troop Support has approved the use. This form is found on the ORS SharePoint site under Documents/iRAPT Instructions. (The DLA Troop Support Subsistence Inspection Manual 4155.6 is also posted at this SharePoint location and provides detailed information for completing a DD Form 250.)

Invoicing, Receipt, Acceptance and Property Transfer

A. In order to use iRAPT, the user must establish an iRAPT account.

B. To begin the process of establishing an account, the user or user's supervisor must initiate the request by contacting ORS. The registration process is performed on- line in collaboration with ORS and DLA iRAPT team guidance. Before the process begins, the user must create and provide ORS the following information: Full name, User ID (must be 8-letter word), email address (official email address) and phone number.

C. This information will be sent to DLA iRAPT team by ORS. DLA iRAPT team will use this information to initiate and allow the registration process by adding the user to the DLA iRAPT security profile (PKI exemption table).

D. ORS will receive an email alert that DLA iRAPT team has completed the user's profile registration with some additional instructions for the user to proceed with registration. ORS will forward the information with additional instructions to the user to begin the registration.

E. ORS will provide the additional support necessary to complete the registration process.

F. Once registration in iRAPT has been completed, the user can access the "online" Software User's Manual (SUM) found on the iRAPT website.

G. Once registration in iRAPT has been completed, the user can access the "online" SUM found on the iRAPT website.

H. The iRAPT website address is: https://wawf.eb.mil/.

I. To become familiar with WAWF iRAPT, it is recommended that the user also access the web-based training site and mirror image test site.

Instructions for USDA Inspectors Completing Information in iRAPT

A. Verify the lot/product meets all contract requirements and then perform the following steps in iRAPT.

1. Access the iRAPT website login page, enter User ID and Password and press login button on login page, and then click on "Government."

2. Click on Inspection Folder.

B. The next screen is the Search Criteria Inspection Folder entry form. Enter the following information:

1. **DODAAC:** Click drop down window and highlight the correct code (example: S0507A). (Note: the acronym DODAAC stands for "Department of Defense Activity Address Code.") This code uniquely identifies a DOD unit, activity, or organization that has the authority to requisition and/or receive material.)

2. **Contract Number:** Type in contract number provided by contractor (Example: SPM3S106DZ11 (Do not use dashes))

3. **Delivery Order:** Type in the delivery order provided by the contractor (Example: 0005).

4. **Shipment Number:** Type in shipment number provided by contractor (Example: CVT0016Z). Click the Submit button.

C. The next screen will be the Inspection folder for S0507A. This screen will list the matching report requested in the previous step.

1. Click on the shipment number (Example: CVT0016Z). This will load the matching Receiving Report in the right pane of the screen.

2. Verify that the product description, National Stock Number (NSN), and quantity match the inspected quantity.

3. Print information from the Receiving Report. To do this, click the print button at the bottom of the screen, click OK, and then click the print icon on the title bar.

D. If the USDA inspected ration components failed to meet contract requirements, and the USDA inspector gets written documentation from the DLA Contracting Officer (KO) indicating acceptance of the product for shipment, a comment to that effect for the lot should be added in the iRAPT entry by using the Comments section.

1. Check the box next to CQA (Contract Quality Assurance)

2. Click on the date field and select the ship date from the calendar icon. This will enter the date in the required format.

3. Click the signature button. A dialog box (iRAPT Password Confirmation) will appear. Enter your password and click continue.

4. Click OK. The next window will indicate if the Receiving Report was successfully entered.

E. "Send more e-mail Notifications" will appear on the screen. The names you add will appear in table form when you complete this and all future iRAPT certifications. These e- mail notifications may include the IIC and in-plant USDA inspectors (for verification that iRAPT transactions have been entered and sent) as well as receiving personnel at the assembly contractor's location.

1. After adding addresses for additional e-mails, click return.

2. You have the option of logging out or accessing another shipping order by clicking on the appropriate box.

3. A confirmation of Receiving Report e-mail (sent from cscassing@csd.disa.mil) will be sent to the inspector who completed the Receiving Report as well as to all e-mail addresses added by the inspector.

F. File all Receiving Reports with other shipping paperwork as required.

Contractor Responsibilities with Respect to iRAPT

Include (but are not limited to):

- Entering shipment information correctly with all lot numbers, product names and quantities with the associated Contract Number, the Department of Defense Activity Address Code (DODAAC), Delivery Order and shipment number.

- Furnishing USDA personnel with associated documentation (e.g., bills of lading, shipping roster, etc.)

USDA Responsibilities with Respect to iRAPT

Include (but are not limited to):

- Verifying the lot/product meets all contract requirements.

- Verifying that the information entered by the contractor in iRAPT is correct, and then performing the steps in iRAPT to complete certification.

- Advising the contractor if iRAPT information is incorrect. The contractor should revise WAWF and return to USDA for verification.

Instructions for Completing DD Form 250

A. Note: If iRAPT is not accessible, the contractor may complete a paper copy of DD Form 250, as long as DLA Troop Support concurs with this change. The form can be found on the ORS SharePoint site at OR Worksheets/iRAPT (intranet link).

B. Review for accuracy the contract number, line item number(s), NSN, and description of the product.

C. Check the container codes against the inspection records. The codes on the DD Form 250 must be those codes inspected and must meet the contract requirements. If there are

too many codes for the space, the list can be continued in Block 23 or on a DD Form 250 Continuation Sheet.

D. Verify that the number of cases per code is on the DD Form 250 (usually in Block 17, Quantity Shipped/Received). The USDA inspector will verify by means of a running tally in the USDA inspection records that the number of cases certified on all DD Form 250's do not exceed the total number of cases inspected and accepted for those codes. The inspector will not sign a DD Form 250 if the total case count exceeds the amount inspected.

E. USDA inspectors should complete the following area to indicate that the certified materials meet contract requirements. Most contracts require Government inspection at origin and acceptance at destination.

F. Under "A. Origin" in Block 21: make an "X" in the CQA square;

1. Sign and date the DD Form 250 in the space provided;

2. Under the signature, write "USDA" and the name and code of the USDA Area Office; and sign the continuation sheet, if included.

G. The date of the DD Form 250 will be the date of the last USDA examination or inspection of the certified product.

1. Check the "ACCEPTANCE of listed items" square under "A. ORIGIN" but do not sign in block 21 under "B. DESTINATION."

2. Present the signed DD Form 250 to the contractor and retain one copy in the USDA file.

H. If the USDA inspected ration components fail to meet contract requirements, the contractor may contact the DLA Troop Support's Contracting Office (KO) to request acceptance. If the USDA inspector gets written documentation from the KO indicating acceptance of the product, the DD Form 250 can be signed by USDA with a written statement in Block 23 documenting the situation. The following provides an example of a format that can be used for a written statement:

"Chicken with Feta Cheese and Tomato, lot 2321A fails contract requirements account low drained weight. Waiver granted and shipment authorized by (name-title), DLA Troop Support, per letter dated (date)."

I. If one or more lot(s) being certified has had one or more USDA end-item examinations skipped, a statement worded substantially as follows should be added to block 23 of the DD Form 250:

"Acceptance of Lot (product name and lot number), is based in part on contractor's inspection results in accordance with end-item skip-lot procedures."

Please note that a similar statement should not be used on the DD Form 250 when one or more analytical tests have been skipped under Optional Contractor Testing.

J. See the DLA Troop Support Subsistence Inspection Manual 4155.6 (posted at the ORS SharePoint site location under "Documents/WAWF Instructions") for detailed information for completing a DD Form 250 and for correcting DD Form 250s.

K. The contractor is responsible for preparing a corrected DD Form 250 if, because of errors or omissions, it is necessary to correct it after distribution has been made. A revised or new DD Form 250 will be generated by correcting the original master or preparing a new DD Form 250 containing identical data as the original DD Form 250 (plus corrections) and distributing the corrected form. The words "CORRECTED DD Form 250" will be typed in the upper left-hand corner of the form.

L. Corrections of entries in Blocks 19 or 20 will be made as follows:

1. Circle the error and place the corrected information in the same block. If space is limited, enter the corrected information in Block 16, referencing the error page and block. Enter omissions in Block 16, referencing omission page and block. Examples of errors may include incorrect line-item descriptions or quantities.

2. The words, "CORRECTIONS HAVE BEEN VERIFIED," will be entered on page 1, Block 23. After reviewing and verifying the corrections, the authorized Government representative will date and sign immediately below the statement.

Certification of Contractor Furnished Material or Rations National Contract Lots

General

A. Certification of Contractor Furnished Material or Rations National Contract items are normally certified on the SC-66 or SC-146 Certificate forms (including electronic versions when implemented), as appropriate.

B. See the AMS Forms Catalog (intranet link) for examples of blank SC-66 and SC-146 forms.

C. Examples of completed OR Certificates can be found on the ORS SharePoint site/OR Worksheets/USDA Grade Certificate Examples SC-66 and SC-146 (intranet link).

D. The following are examples of the applicable statement(s) that may be included in SC-66 USDA Certificates, depending on the inspection results and whether any examination or inspection has been skipped.

1. When USDA performs all examinations (analytical, microbiological, and end-item) and the lot was found to meet all contract requirements, the following statement should appear in the "Remarks" section.

"Product meets requirements of contract number (contract no.)." Place a footnote indicator such as "1/" in the "U.S. Grade" column to reference this statement in the Remarks section as it applies to a lot(s).

2. When USDA does not perform some analytical, microbiological or end-item verification exams due to applicable skip-lot procedures and the lot was found to meet all contract requirements, one of the following statements should appear in the "Remarks" section, with a footnote indicator such as "2/" in the "U.S. Grade" column, to reference this statement as it applies to a lot(s).

   "Lot meets requirements of contract number (contract no.)." Acceptance of lot based in part on contractor's inspection results in accordance with End-Item Skip-Lot procedures.

   "Product meets requirements of contract number (contract no.)." Acceptance of lot based in part on contractor's inspection results in accordance with Analytical Skip-Lot procedures.

   "Product meets requirements of contract number (contract no.)." Acceptance of lots based in part on contractor's inspection results in accordance with End-Item Skip-Lot procedures and Analytical Skip-Lot procedures.

3. If a lot fails a contract requirement but was accepted via a waiver granted by DLA Troop Support, a statement similar to the one below should appear in the "Remarks" section with a footnote indicator such as "3/" in the "U.S. Grade" column, to reference this statement as it applies to a lot.

   "Product fails requirements of contract number (contract no.) account (reason of failure). Acceptance and shipment authorized by (name of person signing waiver), with a letter, email, etc., from DLA Troop Support on (date of waiver)."

E. The SC-146 should have similar statements, depending on the inspection results and whether any examinations or inspections have been skipped. The statements are placed in the "Grade" section of the document, since only one lot is certified on each certificate.

F. If all testing and end-item exams are performed by USDA, do not issue a certificate until all USDA results are completed and found to be conforming.

Distribution of Certificates

Original Signed Copy – Contractor

Copy of Original - Local USDA file

Tracking Contractors Completion of Delivery Orders and Line Items

A. USDA is not required to keep a "shipment tracking log" to verify completion of delivery orders and individual line items for Government Furnished Material product. Shipment tracking is the contractor's responsibility and USDA is not responsible for notifying the contractor if/when issues arise.

B. The USDA inspector's responsibility is to review contractor-supplied information in WAWF for accuracy with respect to the lot identity, quantities, inspection status, and related content. If/when information is incorrect, the inspector should inform the contractor and approve the corrected version.

C. The USDA inspector should record shipments in the lot summary worksheet created for each lot and enter that data into the ORDB.

D. When the USDA inspector performs the unit load exam, the inspector should verify case count when the product is staged for shipment.

E. If the inspector observes that a production lot is being shipped to more than two assembly locations, the inspector should notify the contractor to determine whether there has been approval from the contracting officer for these shipments. (Contract requirements generally restrict shipments of single lots to no more than two assembly locations.)

SECTION 10 – LOT FAILURE AND HOLD PROCEDURES

General Guidance for Lot Failures

A. In the course of the inspection of operational rations, a lot may fail to meet contract requirements for one or more reasons. In these cases, it is mandatory that the lot identity and integrity be clearly maintained and that established procedures be followed. Various scenarios are outlined below to describe the correct procedures to follow when lots fail to meet contract requirements. In all cases, the contractor should provide documentation, with details of rework activity, to the GQAR when a lot is offered for USDA inspection which has failed either the contractor's end-item inspection or an earlier USDA end-item inspection. The GQAR must evaluate any previously selected official samples, to ensure that they continue to represent the lot that is offered. (Note that in this section, the terms "GQAR" and "USDA inspector" are generally used interchangeably.)

B. If a contractor identifies production issues with a lot or fails a lot during their end-item inspection, they can rework the lot before offering it to USDA unless certain conditions are found in the lot that require advance DLA Troop Support notification and approval. The contractor should inform the GQAR of any such rework plans. See Part C below for further instructions.

C. Section E of the contract provides information detailing the circumstances when DLA Troop Support's permission is required for rework approval. It currently states that reworks due to the following conditions must be approved by the Contracting Officer:

1. Insect or rodent infestation/contamination

2. Food safety or foreign material

3. Critical pouch defects - thermostabilized pouches (unless the lot is 100% reworked)

4. Second time rework
5. Nonconformance's noted during the Government end item verification inspection

6. Swollen pouches, when a possible food safety issue is involved

7. Failure to meet the two-hour maximum time between pouch sealing and start of retort process (for retort pouches)

In addition, the USDA Area Office and NPMS ORS must also be informed of the condition and can assist in coordination and review of the rework plan. Note that rework approval from the Contracting Officer is required in these cases, regardless of whether the condition was identified during the contractor's inspections or by the USDA verification inspection. See Part C below for further instructions.

Process for Lots which Fail Initial Contractor's Exams

A. The contractor may take any of the following steps when a lot fails their initial end item exam:

1. Rework the lot (unless the failure reason is identified in C 1-7 above)

2. Withdraw the lot (dispose of it or sell it on the commercial market)

3. Request a waiver from DLA Troop Support for acceptance of the failing lot

B. If the contractor chooses to rework the lot, the contractor is required to reinspect the reworked lot for the examination which failed initially, at the next higher sample size. If the lot passes the contractor's exam, they can then offer the lot to the GQAR with all associated documentation (including details of rework activity). The GQAR is required to also inspect the lot at the next higher sample size. Whenever a contractor reworks a lot, the USDA inspector must determine whether the USDA samples represent the reworked lot. Inspectors should take the necessary steps to return previously selected samples and obtain new samples to ensure that the samples to be examined represent the reworked lot.

C. If the contractor withdraws the lot, the USDA inspector will return all samples from this lot to the contractor and indicate on paperwork and in the ORDB that the lot was withdrawn.

D. If DLA Troop Support grants a waiver and accepts the failing lot, the contractor can offer the lot to the GQAR with all associated documentation (including details of DLA Troop Support waiver).

E. The procedure for USDA verification inspection of contractor-failed lots is as follows:

1. The GQAR will review the contractor's associated documentation presented with the offered lot. This documentation must include records of end-item examinations, as well as any reworks and DLA Troop Support waivers.
2. The GQAR will perform the Government verification examinations, moving to the next higher sample size as appropriate, for any contractor-failed examination.

3. If a lot fails a contractor's initial analytical examination, and the contractor reworks the lot, resamples the lot at the next higher sample size, and obtains conforming results, the lot can be offered to the USDA for verification testing. If the product is under analytical skip-lot testing, the GQAR can skip the lot if it is designated as a skipped lot, or it can be selected as a lot for verification testing. This will depend on the GQAR's random skip-lot selection process. If the contractor does not follow all the steps indicated above, they will need to obtain approval for acceptance of lot from DLA Troop Support.

Process for Lots which Fail USDA Verification Inspection and/or Need DLA Troop Support Approval for Rework

A. When a lot fails a USDA inspection for any reason, or if a lot fails the contractor's or USDA's inspection for any of the reasons listed in General Guidelines for Lot Failures, Part C, above, the entire lot is placed on hold. The contractor has the following options when notified of a failing lot:

1. Withdraw the lot (dispose of it or, if it is commercially acceptable, divert it to commercial channels);

2. Request a waiver from DLA Troop Support for acceptance of the failing lot;

3. Request permission from DLA Troop Support to rework the failing lot. This request for rework should follow the requirements in the Inspection and Acceptance Requirements, Section E, of the contract (it should address the mandatory elements listed there, as well as have a reasonable chance of eliminating the defect); or

4. Perform a 100% rework of the failed lot, for the specific cases specified in Section E of the contract that allow for this. Some current examples include:

a. Lots that fail either the contractor's or USDA's initial filled and sealed, internal pressure, or seal strength exams for critical packaging defects. This applies for both MRE thermostabilized pouch products and thermostabilized polymeric tray products.

b. Lots that fail the USDA's initial filled and sealed, internal pressure, or seal strength exams for major pouch defects. This applies to some non-thermostabilized MRE Contractor Furnished Material items, if stated in Section E of the contract document.

B. DLA Troop Support may provide guidance to USDA for procedures to follow when reinspecting a reworked or failed lot. This guidance may be included in DLA Troop Support's response to a contractor's request for a waiver or acceptance of a failing lot.

General Guidance for Lot Rework and USDA Inspection

A. The contractor should not rework the lot until the rework plan has been approved by DLA Troop Support, as appropriate.

B. The contractor's rework activities must be done at a time and location that allow monitoring by the GQAR.

C. Rework of a lot must be done in a timely manner, as established by the contract. For example, MRE contracts require contractors to perform reworks within 30 days of the date of initial rejection.

D. After the rework, the contractor is required to reinspect the lot for the failed exam at the next higher sample size.

E. If the reworked lot passes the contractor's examinations, it may be offered to USDA for verification inspection. The contractor will provide USDA with their rework and reinspection results.

F. When the lot is re-offered, the USDA should perform the specific exam which initially failed the original USDA verification examination. USDA should also consider additional exams that might need to be performed due to the possible effect of the rework activity on the lot. For example, if the lot was reworked for residual gas by floating all pouches in a water bath, it would be necessary to also perform the filled and sealed examination on the lot since the integrity of the pouches could have been affected by the rework. The USDA examination, performed to verify that the lot no longer fails, should utilize the next higher sample size.

G. The USDA inspector should document the results of the 2nd USDA inspection on a new worksheet and summarize the results on the USDA Lot Summary Worksheet. The documents resulting from a rework inspection should be attached to the original USDA worksheets. In addition, there should be cross-references between the worksheets documenting the initial failure results and second inspection results. The final documentation should be self-explanatory and allow an individual unfamiliar with the lot history to be able to determine what took place. Pages should be numbered 1 of 2, 2 of 2, etc. Also, see instructions for ORDB lot entry for submittals 1, 2, etc. See Section 6 – Operational Rations Database.

General Guidance for Placing Lots on Hold

A. USDA SC-10 Notice of Hold and SC-11 Hold Tags are used to identify and monitor the movement and disposition of lots which have failed USDA inspection, or that have been identified with defects listed in Section A, No. 3. These forms can be found on the AMS Forms Catalog.

B. See Notice of Hold Form (SC-10) Procedure for specific instructions for completing and distributing the Notice of Hold, SC-10. See Hold Tag (SC-11) Procedure for specific instructions for completing and using Hold Tags, SC-11.

C. A "Hold" should be maintained to document all product placed on hold.

D. Refer to Section 7 – Laboratory Testing for additional specific procedures to follow for Microbiological Test Failures (i.e., positive findings).

Notice of Hold Form (SC-10) Procedure

A. When a product is placed on hold, the USDA inspector will fill out the top portion (Section I) of the SC-10 Notice of Hold and distribute it with a copy of the worksheets or laboratory results which document the lot failure (for example, the applicable exam worksheet).

B. In the "Defect Summary" area in Section I of the SC-10, only list the defect(s) that directly contributed to the lot failure. It is not necessary to list all defects observed during the examinations.

C. Inspector names on the electronic version should be followed by /s/ to indicate that the original paper copy was signed by the inspector.

D. When individual product lines go on tightened inspection for the retort pouch filled and seal examination, special notation is required on the SC-10. See Inspectors Handbook Section 6, Inspection Levels, Section I, Part C, line 3 for more information. See also the reference in Section E, Part E-3-A-2 in the Technical Data Package for the current MRE contract.

Electronic distribution (e-mail or fax) is the preferred method for distribution of the Notice of Hold form and the additional associated documents. The contractor representative(s) should be the primary contact and the additional contacts should be included as Ccs when distributing the documents in an electronic format.

Distribution of Notice of Hold and copies of the worksheet(s) documenting the lot failure should be as follows:

- Original signed paper copy to plant management. (This can be provided electronically if the plant prefers an electronic copy.)

- The distribution list can be found within Appendix IV- Operational Rations Document Email Distribution.

The contractor will complete Section II of the SC-10 and return a copy to the inspector. This will show that the contractor is aware of the failure and will describe the action the contractor plans to take to deal with the situation. The USDA Inspector should not enter information in Section II - PLANT ACTION, since this area is reserved for the contractor's response. When the final disposition of the lot on hold has been determined, the USDA inspector will complete Section III "DISPOSITION" of the SC-10. The final, completed hold form will be distributed following the original distribution.

Inspectors should annotate the DD 250 or USDA Certificate when acceptance of a lot is based on a waiver granted by the DLA Troop Support contracting officer. The annotation should identify the waiver and contracting officer. Contact the USDA Area Office for guidance to determine the correct procedure.

Hold Tag (SC-11) Procedure

A. USDA Hold Tags (SC-11) are used to identify and monitor the movement of lots which have failed USDA inspection, or that have been identified with defects listed in Section A, No. 3.

B. The Area Office will furnish Hold Tags, which are sequentially numbered. Only officially issued USDA Hold Tags (Form SC-11) should be used to identify product placed on hold by the GQAR.

C. The inspector will advise plant management each time USDA Hold Tags are used. This will prevent any misunderstanding between management and inspection personnel.

D. Lots that do not meet contract requirements should be tagged with a minimum of one Hold Tag per lot. In some circumstances, numerous tags will be needed to properly identify and control a production lot. The USDA inspector will determine the number of Hold Tags needed to ensure effective identification of the lot on hold.

E. Hold Tags will be affixed directly to shipping case(s). They will not be attached to shrink wrap or other material used to wrap cases on a pallet.

F. The properly completed Hold Tags will remain attached to the product on hold until final disposition is made on the lot. The tags should not be removed by unauthorized individuals. Plant management is responsible for assuring that Hold Tags are not lost or thrown away while attached to the lot.

G. Once a lot has been released, the Hold Tags are to be removed by the USDA Inspector, attached to the SC-10, and filed with the USDA records.

Reinspection Guidance - Next Higher Sample Size

A. DLA Troop Support will often indicate the sample size to be applied to a reinspected lot in the DLA Troop Support rework approval. The default instructions, in the absence of any other stated instruction, is to move to the next higher sample size, using ANSI/ASQC Z1.4 "Sampling Procedures and Tables for Inspection by Attributes".

B. Examples:

1. A reworked lot of a retorted pouch product, initially examined at a 200 sample size for the filled and sealed examination, would be re-inspected at a 315 sample size by both the contractor and USDA.
2. A reworked lot of a bakery component item, initially examined at a sample size of 8 pouches for internal pressure, would be re-inspected at a sample size of 13 pouches by both the contractor and USDA.

C. Polymeric tray products are handled differently, based on specific instructions from DLA Troop Support.

1. If a lot of polymeric tray products is initially inspected at a sample size of 200 trays, for the filled and sealed exam, any re-inspections will also be at the 200 tray sample size.

2. If the polymeric tray production lot is normally inspected at the reduced sample size, for example 80 trays, the re-inspection sample size would return to the sample rate of 200 trays for both the Contractor's and the USDA's filled and sealed examinations.

3. The thermostabilized polymeric tray program also has unique inspection procedures that allow for use of a non-destructive burst test (NDBT) exam to test trays with visual defects that would normally result in a lot failure. In this application, the NDBT is used to verify whether a visual defect is scoreable. MIL-PRF-32004B provides guidance on use of the NDBT, and DLA Troop Support has allowed for contractor testing of visually defective trays using the NDBT. If no test failures result, the lot can be offered to USDA for verification inspection without DLA Troop Support approval. Documentation of this NDBT testing should be included with the contractor's lot submittal paperwork. The contractor should have their procedures for using the NDBT stated in their QSP (Quality System Plan).

SECTION 11 – SAMPLING

Representative Samples

The accuracy of an inspection depends upon how well the samples represent the lot. An examination of the contents of every container in a lot is one way to ascertain the quality of a lot. This, however, is not feasible in the inspection of processed food for quality due to the large

number of containers in most lots and the destructive nature of most examinations. For efficiency and practicality, sampling must be confined to a manageable and comparatively small number of samples which, when drawn at random, will usually reflect a sufficient and reliable estimate of the quality of the lot.

The inspector will determine the number of containers to be drawn from each sampled case (and the containers' relative positions in the cases) before beginning to sample. Sampling will not be restricted to the top or bottom layers or to the corners of the cases. The best samples are those which have been randomly selected and which represent all of the various positions in the shipping cases.

Selection of Random Samples

The following may be used in the selection of random samples:

- Sampling Manual
- Condition of Food Container Manual
- Any random sampling procedure accepted by the SCI Division

Sampling Point

On-line sampling or stationary lot sampling may be used depending upon the production process and the availability of product for representative sampling.

On-line Sampling

Samples for end-item examinations will be selected after the pouch has been placed in the carton (when applicable) or the tray has been placed in the protective sleeve. All samples will be selected from sealed cases. It is important that samples are selected after the contractor has completed all in-process quality assurance measures.

Stationary Lot Sampling

The USDA inspector selects samples from the palletized lot after production is completed. The entire lot must be made available for sampling.

Maximum Sample Units per Case

Inspectors should use as guidance the following excerpt from the U.S. Standards for Condition of Foods Containers, Title 7, Code of Federal Regulations, Part 42.105(e):

Maximum sample units per case. If the lot is cased, predetermine the number of containers to draw from each sampled case as well as the position within the case. Do not restrict the sampling to the top or bottom layers or to the corners. The best sample is one selected from all the various positions in the shipping case. It is desirable but not mandatory to limit the number of sample units to a single container from any one case. Multiple sample units may be taken from a single case but not in excess of the following plan:

A. When containers are packed 12 or less to a case, draw a maximum of 6 sample units from any one case; and

B. When containers are packed more than 12 to a case but not more than 60, draw a maximum of 12 sample units from any one case; and

C. When containers are packed more than 60 to a case but not more than 250, draw a maximum of 16 sample units from any one case; and

D. When containers are packed more than 250 in a case, draw a maximum of 24 sample units from any one case."

Identity of Sample Units

Under some circumstances, such as sampling for certain analytical tests, the time stamp (or subcode) on a sample, or the time or location when/where a sample unit was drawn can have significance and should be identified by the inspector when obtaining samples. The time stamp (or subcode) on a sample or the sampling time, the case marking, or pallet number are sometimes used to identify samples within a lot. For example, if samples are to be sent to the USDA laboratory for testing, the sample identity should be recorded on the DD1222 form when individual sample testing is required. (On the other hand, if the samples are combined by the USDA laboratory into a composite and tested as a composite, it is generally not necessary to record individual sample information about each individual sample unit on the DD1222.) See Section 7 – Laboratory Testing.

- If individual samples do not have a time stamp (or subcode) to identify the sampling point, group the samples taken at each sampling time by placing them in individual plastic bags or use some other method to maintain the identity of the sampling timeframe. Record the sampling time or other reference on the plastic bag but not on individual samples that will be returned to the contractor for inclusion in the final lot.

- Note that DLA Troop Support and contractors may use sample unit identification information to assist in the rework approval process and possible segregation of a lot, in the event that a lot fails a laboratory test. For other USDA end-item verification exams, the sample unit time stamp (or subcode) or the time or location that a sample unit was drawn from a lot can be useful information for the contractor in the event of a lot failure. When available, the identity of sample units (such as a sample unit's time stamp or subcode) should be recorded on the USDA worksheet used to document the USDA end-item examination.

Sampling Guidelines

A. USDA samples will be selected by USDA inspectors.

B. USDA on-line sampling will be performed in such a manner that it is not "predictable" to contractor personnel. This eliminates opportunities for manipulation of product quality on the production line such that samples drawn are not representative of the lot.

C. Sampling may be "proportional," also called "representative" or "stratified" or "segmented." Under this approach, a lot is broken into parts (e.g., subcodes or time periods) and a proportionate number of samples are randomly selected from each part (i.e., from each subcode or time period). This approach ensures that samples are drawn from each segment or "strata" of production. For example, if 200 retort pouch samples are to be drawn from a lot of 20,000 pouches which was processed in 5 retort "cooks," the inspector could choose to select 40 pouches randomly from each of the five retort cooks, for a total of 200 pouches.

D. Contract documents and specifications specify the sampling plan for each exam.

E. Virtually all exams required under military contracts in the Operational Rations program use sampling plans in ANSI/ASQC Z1.4-2003: "American National Standard - Sampling Procedures and Tables for Inspection by Attributes." This is the 2003 version of this document. Note that some inspection documents may refer to "ANSI/ASQC Z1.4-1993." This is the 1993 version of this document. There are some limited changes between these two versions; however, there are no changes to the values in the tables in the documents which are the primary references for inspectors for sampling and inspection purposes.

F. The Performance-based Contract Requirement document or other specification will provide requirements for the end-item exam including Sampling Plan (Single or Double), Inspection Level, and Acceptable Quality Level (AQL). If the document does not specify a single or double sampling plan, the default selection is a single sampling plan. For more information on these topics, see the following sections in ANSI/ASQC Z1.4-2003:

- Section 4 "Acceptable Quality Level (AQL),"
- Section 9 "Sampling Plans," and
- Section 10 "Determination of Acceptability."

G. The Inspector should "plug" requirements and lot size into tables in ANSI/ASQC Z1.4 to obtain the sample sizes and accept and reject numbers for the particular sample size.

H. End-item exams cannot be performed before the entire lot has been produced and all samples have been selected. Additionally, USDA end-item exams are performed after the contractor has offered the lot for USDA verification inspection. (Note there are two exceptions: under some circumstances, USDA may perform end-item shipping case exam prior to the lot being offered to USDA for verification. This should be coordinated with the Officer-in-Charge. In addition, USDA generally submits samples for USDA analytical testing prior to the lot being offered to USDA for verification inspection. In each of these instances, USDA results for the exam or test are not released to the

contractor until after the contractor has offered the lot to USDA and provided the contractor's conforming results for the exam or test.)

I. Samples must be representative of the lot being offered for verification inspection. If USDA selects samples for a lot on-line, and the contractor reworks the lot such that portions are removed or the lot otherwise changes, the USDA samples must be evaluated to determine whether they continue to accurately represent the reworked lot. Generally, samples must be returned to the contractor so they can be included in the rework process. USDA then selects a new set of samples from the new lot, once the contractor has completed all of their quality assurance measures.

Sample Integrity and Security

It is necessary to preserve the integrity of the samples selected for inspection. Adequate steps should be taken in order to prevent the samples from being tampered with by non-USDA personnel.

A. The inspector can arrange with the plant to have a secure place to store samples that are under their control. If the storage area for "officially sampled" samples does not provide adequate security, the inspector should place the samples in shipping cases, seal the cases, and attach USDA tamper-proof tape to the top and bottom closure areas. See the Sampling Manual.

B. Alternatively, the in-plant inspector at an Operational Rations plant can write their name or initials with permanent marker across the closure tape on the top and bottom of the case in such a manner that tampering with the closure would be evident. This procedure is limited to sample storage at Operational Rations plants under in-plant inspection.

C. In addition, inspectors should only use this option when it is necessary due to limited storage resources and after the IIC has determined that it provides adequate sample security. IICs should contact their OIC and ORS if they have any concerns regarding this procedure or for additional review and guidance.

Priority of Inspection

Under in-plant inspection conditions, the USDA inspector may draw USDA samples for residual gas, internal pressure, pouch/tray filled and sealed examination, product evaluation, analytical testing, and other examinations during production.

Samples drawn by USDA can be used for multiple end-item examinations if the initial and preceding examinations do not affect the samples with respect to subsequent examinations. Example: Samples which have been used for one-item examination for net weight may subsequently be used for end-item examination for internal pressure.

SECTION 12 – SKIP-LOT

This section provides instructions for inspectors implementing end-item skip lot procedures for inspection of operational ration items. These instructions provide means for uniform

implementation of end-item skip lot procedures in accordance with the Department of Defense-Defense Logistics Agency (DLA Troop Support) skip lot requirements. The DLA Troop Support skip lot requirements are referenced by the operational rations contracts and consist of two sub-programs, one addressing examinations and one addressing tests. The skip lot end-item inspection requirements for Government end-item verification inspections pertaining to **examinations** are found in Appendix V - Procedures for Alternative Skip-Lot End-Item Inspection Requirements for Government End-Item Verification Inspections for Operational Rations. The skip-lot end-item inspection requirements for Government end-item verification inspections pertaining to **tests** are found in Appendix VI – 9024 Alternative Inspection Requirements for Selected Items (OCT 2020). These DLA Troop Support skip lot requirements establish the basic requirements and protocols for implementing a Government end-item skip lot. The following SCI Operational Rations procedures are to be applied in support of the DLA Troop Support skip lot requirements.

Background

DLA Troop Support introduced "higher level quality" requirements in operational rations contracts in 1989 during Meal, Ready-to-Eat (MRE) procurement cycle number 9 (MRE 9). These requirements called for contractors to develop and adhere to a written plan for ensuring that they produced and offered conforming product to the Government. These plans were originally called "Contractor Inspection System" (CIS) plans. In most cases, contractors were also required to develop and adhere to a Statistical Process Control plan. Requirements for these two documents were later combined in what DLA Troop Support has termed the QSP.

In addition, starting with MRE 9 for MRE items (and later for tray pack cans), contractors were required to perform all end-item exams indicated in the applicable military specification(s). Under the higher level quality requirements, items produced under an acceptable plan and which pass the contractor's end-item inspection are then offered to SCI Division for end-item inspection. This SCI Division inspection is seen by DLA Troop Support as a "verification" inspection.

As such, SCI Division end-item inspection is a way of verifying that the contractor's system (including the contractor's end-item inspection) is performing properly, and the contractor is offering conforming product to the Government.

End-item skip lot inspection by SCI Division allows a decrease in the amount of "verification" inspection performed by the Government. End-item skip lot allows the Government to rely on a contractor's end-item inspection in lieu of SCI Division end-item inspection as long as certain conditions are met and the Government has adequate assurances that the contractor's results are reliable. By implementing end-item skip lot inspection, DLA Troop Support is (1) acknowledging good contractor performance by allowing decreased verification inspection; and (2) allowing Government inspection resources (i.e., SCI Division inspection) to focus on and monitor the effectiveness of a contractor's implementation of their QSP. This increase in monitoring of the QSP is intended to promote improvements during production, which could reduce production of nonconforming product and result in both improved quality and savings for the Government.

Scope

USDA end-item skip lot procedures contained in this section are applicable to all operational rations items inspected by SCI Division for DLA Troop Support when the following conditions are met:

- Contractor has an accepted quality system plan;
- Contractor is performing in a satisfactory manner under the QSP; and
- Quality history for item(s) meet all criteria in DLA Troop Support skip-lot guidelines

Note that implementation of end-item skip lot verification procedures may not be approved or may be discontinued after implementation if it is determined that use of end-item skip lot is not in the best interest of the Government.

Preparing for USDA End-Item Skip Lot Procedures

SCI Division in-plant inspectors should follow the steps below in preparation for implementing USDA End-Item Skip Lot:

A. Read, become familiar with, and apply the DLA Troop Support guidelines for end-item skip lot procedures. The DLA Troop Support skip lot guidelines describe the responsibilities of USDA, DLA Troop Support, and contractors with respect to end-item skip lot verification inspection.

B. Verify that the appropriate contractor personnel are familiar with the protocol and requirements established in the DLA Troop Support skip lot guidelines. There are several specific actions the contractor must take under end-item skip lot.

C. Determine whether the contractor's QSP is acceptable (per DLA Troop Support) and whether the contractor is following it in a satisfactory manner (per DLA Troop Support compliance audits, and USDA/AMS in-plant compliance audits). If the QSP is acceptable and the contractor is following it in a satisfactory manner, the USDA/AMS inspector should follow the steps, below, to implement end-item skip lot procedures.

Implementing USDA End-Item Skip Lot Procedures

A. SCI Division in-plant inspectors will follow the steps below to implement USDA End-Item Skip Lot:

1. Using the requirements contained in Appendix V - Procedures for Alternative Skip-Lot End-Item Inspection Requirements for Government End-Item Verification Inspections for Operational Rations. To identify products (if any) which qualify for application of end-item skip lot procedures.

   Products packaged in flexible pouches subject to pouch integrity examinations that include critical category defects DO NOT qualify for skip-lot inspection for filled and sealed examination.

NOTE: Internal pressure testing is a test, ineligible for this skip-lot program if (1) unequivocally designated as a critical test or (2) the component subject to internal pressure testing is also a component that is packaged in a flexible pouch and that has defect descriptions categorized as critical as a part of the product's end-item pouch integrity examination (ex. filled and sealed exam).

2. DLA has determined to classify internal pressure, residual gas, pH, brix, seal strength, etc. as tests, and therefore subject to the requirements of Appendix VI – 9024 Alternative Inspection Requirements for Selected Items (OCT 2020). To qualify for skip lot, requires testing three consecutive lots. If the three lots conform to requirements, then initiate skip lot of 1 in 6. To requalify if there is a failure, test and accept 3 consecutive lots.

3. Because internal pressure is categorized as a test, the skip lot program containing the cited Part I, D of Appendix V - Procedures for Alternative Skip-Lot End-Item Inspection Requirements for Government End-Item Verification Inspections for Operational Rations, is not applicable for use with internal pressure testing.

For example, products that are packaged in flexible pouches that have critical defects listed in MIL-PRF-44073 (PERFORMANCE SPECIFICATION-PACKAGING OF FOOD IN FLEXIBLE POUCHES) Table II – Filled, sealed and thermal processed pouch defects, do not qualify for skip lot inspection - see below.

TABLE II. Filled, Sealed, and Thermally Processed Pouch Defects

Category				Defect
Critical	Major A	Major B	Minor	
1				Swollen pouch.
2				Tear, cut, hole, or if a multi-layered laminate is used, abrasion through one or more layers in the pouch material or leakage through any seal.
3				Fold over wrinkle extending into the seal such that the closure seal is reduced to less than 1/16inch for heat seals or less than 1.0 mm for ultrasonic seals.
4				Presence of entrapped matter (for example, product, moisture, grease, etc.) that reduces the closure seal to less than 1/16 inch for heat seals or less than 1.0 mm for ultrasonic seals.

When products do not have critical defects listed on Table II – Filled, sealed and thermal processed pouch defects and or other product specifications (ex. CIDs, MIL-PRF- 44073, PKG&QAPs, MIL-DTL-32347) internal pressure testing is a test eligible to qualify for skip lot inspection in accordance with DLA Provision 9024.

Note: Because Table I product examination and its constituent sub-exams (ex. drained weights, net weights, composition) is not a test; the skip-lot eligibility requirements cited in DLA Provision 9024, such as 3 consecutive lots, do not apply.

B. Notify the contractor of the products selected for end-item skip lot procedures.

C. Apply end-item skip lot procedures independently from analytical skip lot procedures. Skip lot status for end-item inspections will have no effect on a product's skip lot status for analytical testing, and vice versa.

D. Prepare a separate end-item skip lot tracking log for each product selected for end-item skip lot procedures. See examples of the end-item skip lot tracking log posted on SharePoint/ORS/OR Worksheets/Skip-lot Ledger Examples (intranet link).

E. Make a list showing the lot numbers and dates of initial USDA inspection for the 10 consecutively offered conforming lots which qualify the product for end-item skip lot procedures. File this list with the initial end-item skip lot tracking log. (Note that the skip lot tracking log may be used for recording the 10 consecutively offered lots.)

Selecting Lots for USDA End-Item Verification Inspection

For each item selected for end-item skip lot, use the following procedures:

A. Use the random number generating device (e.g., six-sided die) to select which of the next four/six lots offered by the contractor will be selected for USDA end-item examination. (If a six-sided die is used, re-roll the die if "5" or "6" come up.)

B. Note in the end-item skip lot tracking log which lot will be subjected to USDA end-item inspection.

C. As an example, assume that lot number 0100 is selected for USDA end-item inspection. Beginning with the next lot offered after 0100, use the random number generator to select which lot, of the next four/six lots offered, to subject to USDA end-item inspection. Continue with this procedure as long as the product qualifies for end-item skip lot inspection.

D. Notify DLA Troop Support of USDA end-item failures.

E. The contractor should not have advance knowledge of the lot(s) selected for USDA end-item inspection. As a result, the skip lot tracking log should be maintained in an area that is not accessed by contractor personnel.

F. As long as all qualifying exams for an item remain under end-item skip lot, all exams can be skipped at the same interval. However, if one or more exams fail USDA end-item inspection, they must be treated independently from the exams which passed. Consider the following scenarios:

- Scenario 1: Assume Mexican Rice is in skip lot State 2. (See the DLA Troop Support guidelines for discussion of State 2.) If Mexican Rice lot 0100 is selected for USDA end-item verification, and all qualifying exams are under skip lot, the USDA inspector should perform all of the required end-item exams on lot 0100 and then use the random lot section device to determine which of the next 4/6 lots offered to inspect.

- Scenario 2: If one or more end-items exams performed by USDA on lot 0100 are nonconforming, each of these exams must be performed by USDA on every subsequent lot offered of Mexican Rice until each exam requalifies for end-item skip lot. (See the DLA Troop Support guidelines for requalification requirements) For the conforming exams performed on lot 0100, skip lot selection procedures should remain in place. It is important to note that under this scenario, some exams for Mexican Rice will be on skip lot and others will be under 100% inspection until they requalify for skip lot. When an exam requalifies for skip lot, the inspector may place it into the same "skip" pattern being used for other exams on skip lot.

Documentation Requirements for USDA End-Item Skip Lot

Contractor Responsibilities

The contractor must provide USDA with documentation (e.g., completed scoresheets) indicating that the contractor has performed all end-item examinations, and the lot has passed these examinations.

The following records must be provided by the contractor for USDA review:

- The contractor's records for applicable in-process examinations for the lot offered;
- The retort records for the lot offered;
- The formula for the current production standard (First Article or PDM); and
- Formulation/batching records for the individual lot offered.

USDA Responsibilities

For those lots skipped by USDA, the contractor's complete documentation for each end-item examination (including those examinations skipped by USDA) must be included in the USDA records for the lot.

USDA Lot Summary Worksheet:

- For each lot of production offered for USDA inspection, the USDA inspector should maintain a Lot Summary Worksheet. See OR Worksheets/Lot Summary Worksheets (intranet link). This cover page will list each of the required end-item examinations and will indicate the status of each exam (passed/failed/skipped).

- The USDA Lot Summary Worksheet for lots which meet contract requirements and for which one or more USDA end-item examination(s) have been skipped should include a statement worded substantially as follows:

  Acceptance of Lot 0112 Vegetable Crackers is based in part on contractor's inspection results in accordance with end-item skip lot procedures.

Certification of Lots

See Section 9 – Certification for certification guidelines.

Operational Rations Database

The instructions for the required documentation of USDA end-item skip lot status in the ORDB are posted on ORS SharePoint site. See Section 6 – Operational Rations Database.

SECTION 13 – QUALITY SYSTEM PLAN PROCEDURES

This section outlines the responsibilities of the contractor, DLA Troop Support and USDA that are associated with the QSP, as described in Section E of the OR solicitations. Additional information in this section details the process of reviewing the contractor's QSP documents, the DLA Troop Support compliance audit process, and the procedures for the USDA evaluation of the contractor's QSP and the associated documents used by USDA Inspectors in the compliance audit process.

Background

Operational Rations contractors are required to have a QSP if Higher Level Quality Requirements are specified in their solicitation/contract. Each contractor's QSP has a general layout that addresses the thirteen elements outlined in Section E of the Technical Data Package of the Solicitation. The initial QSP document is evaluated by the Quality System Audit Team (composed of DLA Troop Support-FTSB staff) and rated as acceptable if/when the document meets the requirements outlined in the solicitation.

Responsibilities

Contractor Responsibilities

Contractor responsibilities with respect to the Higher Level Quality Requirements include, but are not limited to:

A. Design, document, distribute, and implement a QSP which meets the requirements outlined in Section E of the applicable solicitation.

B. Submit the initial QSP to DLA Troop Support-FTSB, through the Contracting Officer, for review no later than the time of bid submittal, to determine if the QSP meets the requirements.

C. Prior to the initiation of production, provide one copy of the QSP to ORS, the USDA Area Office and hand deliver a copy to the USDA IIC at the contractor's location.

D. Keep the QSP up to date; ensuring that it accurately reflects the firm's actual practices.

E. Produce the products covered by the QSP in accordance with the procedures stated in the QSP.

F. Notify DLA Troop Support with a carbon copy to USDA in writing of changes or updates to the plan. (See the Technical Data Package in the applicable Solicitation/Contract for additional details on notification steps.)

G. If/when a CAR is issued by DLA Troop Support or the USDA IIC, respond to the CAR in a timely manner.

DLA Troop Support Responsibilities

DLA Troop Support Responsibilities include:

A. Prepare solicitations/contracts that include all applicable requirements.

B. Review the contractor's QSP and revised QSP submittals and notify both the contractor and USDA of the acceptance or non-acceptance of the plan. Provide current copies of DLA Quality Systems Audit Workbook I (Documented Quality Systems Plan Evaluation Guideline) and Workbook II (Compliance Audit Guidelines) to USDA.

C. Conduct Joint DLA Troop Support/USDA audits of the contractor's quality system and distribute reports of these audits to the contractor and to USDA.

D. Review monthly QSP Reports submitted by USDA which summarize USDA evaluations/internal audit activity.

E. Review CARs submitted by USDA, provide guidance if/when needed on the associated issue, and review the close-out of each CAR.

F. Review Observation Reports submitted by USDA in response to Food Defense observations, contact the contractor, when needed, and determine actions that may be required to address observations.

USDA Responsibilities

Specific responsibilities of USDA personnel with respect to the Higher Level Quality Requirements of the solicitation/contract include, but are not limited to:

A. Review the contractor's written QSP and/or QSP revisions and provide comments and recommendations regarding the plan to DLA Troop Support-FTSB within 20 days of receipt of the QSP/revision. Copies of any comments should be provided to the OIC and ORS.

B. Conduct evaluations (called "QSP audits") of the contractor's execution of their QSP throughout the life of the contract.

C. Document the QSP audits performed by USDA and distribute the documentation as described in this section.

D. When requested by DLA Troop Support, USDA will also:

1. Provide support for DSCP/USDA Joint Audits, which may include active participation.

2. Verify adequacy of contractor's corrective action activities initiated in response to Joint Audit findings.

3. When requested by DLA Troop Support, verify that a contractor has taken corrective action to address an observed Food Defense issue.

Review of the Contractor's Written QSP

Contractors are required to revise their QSP when necessary to keep the documented plan up to date and to ensure the document reflects the actual procedures in place in the processing facility. The contractor must submit the changes and associated documents to DLA Troop Support for review and acceptance and also provide a copy to the USDA Inspector-in-Charge at the same time. The in-plant USDA inspector reviews the changes and provides feedback to DLA Troop Support. The in-plant USDA inspector may accept implementation of changes to the QSP and consider them sufficient for production, unless specifically rejected by DLA Troop Support after submittal. Final acceptance or non-acceptance of QSP revisions is decided by DLA Troop Support. (See the Technical Data Package in the applicable Solicitation/Contract for additional details on QSP notification, implementation, and acceptance steps.)

Quality System Compliance Audits by DLA Troop Support

The purpose of the DLA Troop Support compliance audit is to verify implementation and compliance to the documented QSP and to other requirements of the contract, and to assess the effectiveness of the contractor's quality system. The evaluation process includes review and verification of historical records, procedures, instructions, and practices used by company personnel. DLA Troop Support notifies the contractor of a pending compliance quality system audit at the production facility. The audit is based on the QSP on file at DLA Troop Support. If a company has made QSP updates that have not been submitted to the GQAR and DLA Troop Support-FTSB, and these updates have been implemented as QSP changes/revisions without government review and approval, they will be classified as a finding during the audit. The primary documents used by DLA Troop Support during a compliance audit are DLA Quality Systems Audit Workbooks I and II (see definitions in index).

USDA Evaluation of the Contractor's Performance of QSP Procedures

USDA is responsible for conducting evaluations of the contractor's QSP throughout the life of the contract. This is accomplished by evaluating the contractor's actual quality assurance procedures for compliance with their written QSP and documenting the results on a USDA compliance audit worksheet. The audits should include direct observation of the quality assurance procedures contractor personnel are performing and the corresponding documentation used by the contractor. This may also include activities performed by contractor's administrative personnel involved in purchasing, contract review, etc. Before auditing a contractor's QSP, the USDA Inspectors should become familiar with the contractor's QSP and the DLA Troop Support Workbooks used to perform the DLA Troop Support Compliance Audits. At the beginning of each calendar year, the USDA Inspector should develop a plan for performing QSP audits by completing an Annual Audit Frequency Plan (USDA worksheet QSP-4). The completed QSP-4 maps out a proposed audit schedule for each of the audit areas. All periods of production and contractor operations are subject to audits. In addition, USDA inspectors may choose to perform an audit at a time not included in the schedule. The following are some examples of possible reasons to perform an unscheduled audit:

- An observance of questionable practices in the contractor's quality system, prompting a special audit of that area.

- The receipt of marginal or non-acceptable review results from DEVCOM-SC for a specific product, prompting an audit of the contractor's end item comparability exam for the next two lots offered of that product.

- Upon auditing one process, the auditor observes a deficiency that may stem from a related issue and determines that an additional audit may be required to fully evaluate the issue.

- A lot fails to pass a USDA end-item exam which has passed the contractor's end-item exam.

USDA Compliance Audit Documents

The USDA in-plant inspector has five main documents that are used to plan, document and follow-up on the USDA auditing activities. See Appendix I – Glossary for a definition of the documents described below. These five documents are located on the ORS SharePoint site under OR Worksheets/QSP Forms/Worksheets (intranet link). The current list of contacts associated with the distribution of these documents can be found within Appendix IV – Operational Rations Document Email Distribution.

- QSP-1 Compliance Audit Worksheet
- QSP-2 Monthly QSP Report (Continuous or non-continuous production)
- QSP-3 Corrective Action Report
- QSP-4 Annual Audit Frequency Plan (Continuous or intermittent production)
- QSP-5 Observation Report

Steps for Completing a Compliance Audit Worksheet – QSP-1

The USDA in-plant inspector will use the QSP-1 to document their compliance audit activity. In the top portion of the QSP-1 document, the reviewer should pay close attention to the area where the "specific procedure or process audited" is described. Provide enough detail so that another inspector, who did not perform the audit can tell precisely what area was audited. This helps establish the specific scope of the audit activity. For example, a specific description such as "Observed product exam and use of production standard" is preferable to a general statement, such as "Audited End-Item Inspection."

Steps for Completing a Monthly Report – QSP-2

At the end of each month, the USDA IIC will complete a QSP-2 to summarize the audits USDA has performed that month. The QSP-2 lists the minimum audit frequency for each of the required areas of the QSP and is based upon the QSP-4 schedule. The IIC will document the date of each audit, the specific procedures or processes evaluated and if the audit found the contractor's activity to be compliant. A proposed date for the next planned audit for the specific QSP area should also be documented. In the remarks section, include information about any CAR or Observation Reports issued during that month. It is not necessary to include lot production information on the report.

Steps for Completing a Corrective Action Request – CAR

If, while conducting a Compliance Audit, the USDA inspector observes a quality assurance procedure that does not conform to the contractor's written QSP or to the contract requirements, the inspector must investigate further. If it is determined that a non-conformance has been identified, the Inspector will report it as a "finding" and notify the contractor using the Corrective Action Request (CAR)(SC-550) commonly referred to as a "CAR." The CAR tells the contractor what non-conformance the inspector found and includes the requirement in the QSP or contract that was not being followed. The CAR also requires the contractor to provide a description of their corrective action to address the non-conformance.

Note: That there may be instances when a minor non-conformance may not be significant enough to require a CAR.

In completing the CAR, the inspector must establish a due date for the contractor's corrective action. The timeframe for the contractor's corrective action and response is determined by the severity of the finding. A USDA inspector can establish the timeframe based on their experience and judgment. If a finding involves a situation that allows, or has the potential to allow, non-conforming product to be produced, immediate notification to the contractor would be required. If a finding involves a departure from the QSP that would likely have little bearing on the effective production of a conforming product, timely notification to the contractor is required. In all cases, the time frame designated by USDA for the contractor's corrective action and written response should be appropriate for the severity of the finding. The process for completing a CAR is as follows:

A. The USDA inspector will document the finding using the appropriate blocks of the CAR. The CARs generated during a calendar year will be sequentially numbered, beginning with "CAR" followed by the 3-letter contractor's name code, the year, and then sequentially numbered, e.g., CAR ABC 2012-01, CAR ABC 2012-02, CAR ABC 2012-03 etc.

B. The contractor will receive a digital copy of the CAR from the USDA inspector.

C. The contractor must complete the portion of the CAR describing the cause of the deficiency and contractor's planned corrective action (Section II-CAR Response). The contractor must then return the CAR to the inspector within the time specified.

D. The USDA inspector will evaluate the contractor's written response to the finding, provide any necessary comments, and then forward it to ORS for evaluation. The inspector should refrain from marking the corrective action plan as "Acceptable" until it receives approval from ORS. Additionally, the inspector will coordinate with ORS to determine whether and when a follow-up audit is required.

E. If a follow-up audit is required, the USDA inspector will use the CAR to document the audit and submit to ORS to determine whether the corrective action plan is acceptable.

F. If an inadequate or untimely corrective action response occurs, the inspector will make immediate distribution of the partially completed CAR using the same distribution list as above.

G. Once a CAR is completed with the corrective action found to be acceptable, the inspector will make full distribution of the form.

Steps for Completing an Annual Audit Frequency Plan – QSP-4

The "Evaluation Frequency" for USDA audits established in the QSP-4 provides a baseline for audit frequencies; however, it does not prevent inspectors from being able to audit areas more often, depending on the circumstances. Audit frequencies are split into the following two groups

depending on whether the production operation is "continuous" or "intermittent" as described below.

Continuous Production Audit Plan

For those facilities where production occurs on a continuous basis (usually producing more than five days per month), the audits are performed at the "normal frequency" rate, as indicated in the QSP-4.

Inspectors should complete the QSP-4 and distribute it in January to cover the January to December calendar year.

Intermittent Production Audit Plan

Facilities designated by ORS as intermittent production locations (usually producing five days or less per month), are audited at the "intermittent" rate indicated in the QSP-4. OICs and IICs should coordinate with ORS to determine when a facility is considered "intermittent."

Inspectors at these locations should distribute the completed QSP-4 within 30 days of the first production cycle of the calendar year.

Steps for Completing an Observation Report – QSP-5

During a compliance audit, the USDA inspector may observe a system weakness which is not necessarily a deviation from a requirement, but which may impede the effectiveness of the contractor's QSP. This system weakness would be classified as an observation and can be documented using a QSP-5. Additionally, an inspector may observe what he or she determines to be a minor non-conformance and use the QSP-5 to document it. An observation does not require a documented response from the contractor, but a contractor can choose to provide a response. A second use of the QSP-5 Observation Report is to document a Food Defense issue. Finally, a third use for an Observation Report is as a means for an auditor to communicate recognition of noteworthy contractor practices. The process for completing a QSP-5 is described as follows:

Minor Non-conformance

A. The USDA inspector will document the observation using the appropriate blocks of the QSP-5. The report generated during a calendar year will be sequentially numbered in the same format as the CAR.

B. The USDA inspector will give the contractor a copy of the QSP-5 as part of the notification of the observation.

C. It is important to note that if a "minor non-conformance" (which prompts a QSP-5) is found to be recurring, it may be appropriate to elevate the USDA response to the level of a CAR which requires documented contractor corrective action and includes notification to DLA Troop Support.

D. Inspectors should consider the nature and severity of a non-conformance, and contractor's past performance (e.g., has the non-conformance occurred before?) when determining whether to issue an Observation Report or a CAR. In general, if a non-conformance is a failure to follow direct QSP or contractual requirements, it should be documented using a QSP-3 CAR.

Food Defense Issue

A. The QSP-5 is also used to document an observed Food Defense issue in an OR facility. The purpose is to bring the issue to the attention of the contractor, DLA Troop Support, USDA Supervisors, and ORS, without divulging sensitive information.

B. The following steps must be followed when a Food Defense issue is identified:

1. At the time of the Food Defense-related observation, the inspector will notify the appropriate plant representative responsible for the Food Defense measure not being followed, so appropriate corrective action can be taken.

2. The inspector will verbally notify their supervisor of the Food Defense observation within one working day. The supervisor will then verbally notify ORS of the observation.

3. The USDA IIC will complete and distribute the QSP-5 within one working day. The written description of the observation should only identify the area in which the Food Defense issue was found (see DLA Troop Support Food Defense Checklist for definitions of area terms – found on ORS SharePoint site/OR Resource Documents) (intranet link). The areas are:

   a. Personnel

   b. Security of Perimeter, Buildings, Docks, & Receiving/Shipping Areas

   c. Receipt Inspection

   d. Warehousing and Storage

   e. Production Areas

   f. Emergency Procedures

   g. Subcontractors/suppliers

   No further details should be documented in writing (e-mails or reports). For example, a description of a Food Defense issue could be: "Food Defense issue identified in production area."

4. ORS will contact DLA Troop Support -FTSB and bring the observation to their attention.

5. DLA Troop Support -FTSB will take appropriate action as deemed necessary. This may include an immediate request for the contractor to take corrective action, a follow up on the Food Defense issue during their next audit, or other steps.

6. DLA Troop Support -FTSB may request that the IIC provide assistance in the verification of corrective actions.

Positive Feedback

A. The QSP-5 can be used to provide the contractor a document that identifies employees performing QSP activities in an exceptional manner.

B. The QSP-5 can also be used to identify an improvement in the contractor's QSP that as has resulted in improved product quality or direct/indirect savings to DLA Troop Support.

SECTION 14 – PLANT SANITATION AND INTEGRATED PEST MANAGEMENT

General Information

The Contractor is responsible for maintaining and addressing sanitary conditions in the plant. Two DLA Troop Support documents, Contractor Sanitation Program – Operational Rations, Applicable to All Operational Rations, November 2015; and IPM Program Requirements for Operational Rations, Applicable to All Operational Rations Facilities, November 2017, establish the requirements for most OR contracts. See ORS SharePoint/OR Resource Documents (intranet link) to view these documents. These documents, in addition to the Good Manufacturing Practices (21 CFR 110); provide the basis for the sanitary conditions that are expected at the OR production facilities.

In addition, if the Contractor is producing a dairy, meat, poultry, or seafood commodity, other sanitation requirements may apply. For example, a facility that produces a dairy product must be an AMS, Dairy Programs approved facility, which necessitates an AMS, Dairy Programs plant survey and, possibly, participation in the Salmonella Surveillance Program. For those facilities producing seafood products, the Good Manufacturing Practices, as stated in 21 CFR 123, apply; and for those which produce meat or poultry products, applicable USDA, FSIS regulations, including 9 CFR 416, apply.

If the plant produces items that contain meat and/or poultry, the FSIS Inspector(s) assigned to the facility may also perform sanitation inspections, as well as periodic audits of plant conditions, procedures, and documentation. The USDA/AMS Inspector will perform sanitation inspections in addition to inspections/audits which may be performed by the USDA/FSIS Inspector. In a seafood facility, during the timeframe an Operational Rations product is being produced and

USDC National Marine Fisheries Inspectors are also present, both agencies combine sanitation inspection results in a shared document that is distributed to the contractor.

The USDA/AMS Inspector will perform pre-operational (pre-op) and routine sanitation inspections in accordance with Sanitation Manual when the plant is scheduled to produce items under OR contract(s). These sanitation inspections will include review of the current conditions in the facility to determine if they meet the requirements as stated above.

Most OR contracts require a contractor to have an approved QSP, which will include reference to the contractor's sanitation and pest management control procedures. The USDA Inspector should be familiar with these procedures. Inspectors should report any deficiencies noted during the daily sanitation pre-op or routine sanitation inspections, using the instructions in this section and AIM Inspection Series, Sanitation Manual. In addition, if the Inspector observes that the facility has failed to adhere to a sanitation-related QSP procedure or documentation requirement, the Inspector should report it as part of a QSP audit.

Documentation of Sanitation Inspections

Inspectors will follow the procedures in AIM Inspection Series, Sanitation Manual for documenting and reporting the results of sanitation inspections. Inspectors will use the Sanitation Score Sheet for Operational Rations Processing Plants (SC-416-9) (intranet link) to generate a report that will document inspection results and any deficiencies, as they are observed. Inspectors should ensure that the final sanitation score sheet for a day is accurate and clearly written. The score sheet should reflect the current status of sanitation deficiencies, with documentation of close outs, as they occur. If a deficiency is not resolved on the initial day that it is noted, the deficiency should be carried over to the next day's sanitation score sheet, with final closure indicated on the latest applicable score sheet.

Distribution of the sanitation score sheet is according to Sanitation Manual. Inspectors will distribute the final copy of the sanitation score sheet to plant management. This may be done electronically as long as a signed copy is placed in the USDA file and the Contractor finds this form of distribution acceptable. Inspectors should coordinate with appropriate plant management to ensure that the distribution of the report allows for effective communication and timely corrective action, if/when needed.

At facilities producing meat and/or poultry items, the USDA/AMS IIC should coordinate with the USDA/FSIS Inspector to determine when to provide a copy of a sanitation score sheet to the USDA/FSIS Inspector. The IIC should discuss significant sanitation issues with the USDA/FSIS Inspector. This coordination will help keep all parties aware and informed of what was found and the timeframe(s) established for correction.

If the Inspector notifies their supervisor of unsatisfactory sanitation conditions, the supervisor should notify a member of the ORS staff. ORS will communicate the information to DLA Troop Support, as appropriate.

Inspection and Safety Guidelines

When performing a sanitation inspection, Inspectors should use a flashlight with a plastic (non-breakable) lens cover that provides a strong beam of light for illuminating low light areas. This will facilitate the inspection of areas that have poor visibility or certain interior or enclosed areas. Using the added light source can be especially helpful when observing the interior of kettles, pipes, pumps, and filler hoppers; underneath filling equipment; behind pallets; and in cooler and freezer areas.

Inspectors must follow all lock-out and tag-out procedures in place at a facility. If, in the course of a sanitation inspection, the Inspector determines that disassembly of equipment is necessary, the Inspector must have this disassembly performed by the appropriate plant personnel. Similarly, any re-assembly must be performed by the appropriate plant personnel. Inspectors should not place hands or any body part within the confines of operating equipment.

During the sanitation tour, Inspectors may need to wash and sanitize their hands before performing different portions of the inspection, in order to avoid contamination of clean equipment and surface areas. Inspectors should wear proper head covering (e.g., approved hair net and beard net), a USDA bump cap, and appropriate clothing. At some locations, Inspectors are also required to wear a lab coat over existing clothing. Hairnets and lab coats are usually furnished by the Contractor. The lab coat should be removed before entering a restroom area, to avoid cross-contamination. Inspectors should take appropriate steps to ensure that clothing and lab coats are kept clean and well maintained.

Pre-Operational Sanitation Inspection

On each day of production, before production starts, the Inspector will perform a pre-operational sanitation inspection that includes all applicable areas of the production facility. Any sanitation deficiencies observed should be brought to the attention of responsible plant personnel, at the time of the inspection tour, so that corrections can be made. A plant representative may accompany the Inspector during the pre-operational sanitation inspection. This can facilitate timely correction of deficiencies and attention to potential problems.

The USDA/AMS Inspector should plan the pre-op inspection tour to allow sufficient time to complete the sanitation inspection before production start-up. Once a specific area is inspected, and found to be in acceptable condition for production, that area can used for processing activities as long as additional clean-up in adjacent areas does not contaminate the approved area. If requested by the plant, Inspectors can give priority to areas deemed critical for the start-up of operations. Such areas could include ingredient preparation rooms, batching rooms, cooking areas, and container filling areas. Two of the last areas to be inspected might be the restrooms and the warehouse. These areas can be checked once all production areas have been inspected. This sequence can help minimize delays in production start-up.

Inspectors should not begin the pre-operational inspection tour until the plant indicates which areas are ready to be inspected. In this way, the Inspector will avoid the possibility of checking equipment that is not ready for inspection or that has not been cleaned.

Inspectors should be familiar with the plant's equipment and operations and should perform a thorough pre-operational sanitation check of all appropriate areas, which include, but are not limited to, the following:

- Blending areas and equipment
- Cooking areas and equipment
- Filling and sealing areas and equipment
- Processing areas and equipment
- Packaging and packing areas and equipment
- Pipe connections and clamps
- Drains and filler nozzles
- Pipes and other equipment suspended high above floor-level
- Ceiling surfaces in the kitchen and processing areas

Pieces of equipment that are pre-assembled (such as pipes, filler nozzles, and pumps) are to be disassembled by plant personnel to allow the Inspector the access he or she needs for appropriate inspection.

Routine Sanitation Inspections

During production, the Inspector will perform at least one routine sanitation inspection per shift and record the information on the sanitation score sheet for that day. This inspection should include of a tour of the processing areas to monitor the plant sanitation and housekeeping activities. Inspectors should include close attention to areas where exposed product is stored temporarily during the production day. Floors, walls, and ceiling areas should be monitored for debris build-up, standing water, and condensation. Inspectors should inform plant management of any deficiencies in a timely manner and document when the deficiency was observed, who was notified, and when corrections occurred, on the current day's sanitation score sheet.

Integrated Pest Management

Inspectors will observe and document issues/deficiencies relating to the Integrated Pest Management program (IPM) as part of the USDA sanitation inspection. In addition, Inspectors should monitor a facility's compliance to their IPM procedures, as part their audits of the plant's QSP.

The Contractor is responsible for complying with all IPM requirements, as stated in the contract/solicitation. Most contractors will obtain the services of an outside pest control company, who will perform many of the necessary maintenance duties called for by the IPM. Some of the types of controls that an inspector might see in an OR facility are insect pheromone traps, insect electrocution devices, and various bird and rodent control measures. The locations of all traps and devices will be plotted on a facility map by the Contractor – a copy of this map should be made available to the Inspector.

The Contractor and/or pest control personnel will monitor the traps and devices and document findings, in accordance with their IPM. If the Contractor is unable to identify an insect, they

may ask the USDA/AMS Inspector to submit it to DLA Troop Support for identification (the Contractor is responsible for providing necessary packaging and sampling supplies and covering shipment costs for these submittals). Prior approval from DLA Troop Support is needed before any specimens are sent. A DD Form 1222 (Request for and Results of Tests) is used to submit specimens to DLA Troop Support.

If insect activity is observed within contractor facilities by the GQAR during the course of contract operations, exclusive of pheromone traps and electrocution devices, the GQAR will immediately notify the contractor verbally and confirm this in writing, A copy of the written report will simultaneously be emailed to the Contracting Officer, DLA Troop Support-FTS, supervisor, and ORS. The contractor must take immediate action and submit a written corrective plan (including specimen identification by the Contractor's Pest Management Company or Qualified Pest Management personnel) within 5 working days to the Contracting Officer and DLA Troop Support-FTS IPM requirement.

The Sanitation Scoresheet for Operational Ration Processing Plants (SC-416-9) (intranet link) and the Operational Rations In-Plant Inspection Survey Corrective Action Request (CAR) will be used in documenting the insect activity and distributed in accordance with the Appendix IV - Operational Rations Document Email Distribution.

A. The contractor must complete the portion of the CAR describing the cause of the deficiency and contractor's planned corrective action (Section II-CAR Response). The contractor must then return the CAR to the inspector within the time specified.

B. The USDA inspector will evaluate the contractor's written response to the finding, provide any necessary comments, and then forward it to ORS for evaluation. The corrective action plan should not be marked as "Acceptable" by the inspector until the DLA Troop Support entomologist, via ORS, grants approval. Additionally, the inspector will coordinate with ORS to determine whether and when a follow-up audit is required.

C. If a follow-up audit is required, the USDA inspector will use the CAR to document the audit and submit to ORS to determine whether the corrective action plan is acceptable.

D. If an inadequate or untimely corrective action response occurs, the inspector will make immediate distribution of the partially completed CAR using the same distribution list as above.

E. Once a CAR is completed with the corrective action found to be acceptable, the inspector forwards the CAR to ORS to complete Section IV and returns to the inspector for final full distribution of the form.

Plant Survey

An annual Plant Survey is required for Operational Rations facilities under USDA/AMS in-plant inspection. This includes facilities producing meat, poultry, or dairy items. Supervisors should apply the instruction in Section 3 of the Sanitation Manual. The Plant Survey can be accessed by Supervisors on Lotus Notes.

Quality System Plan Audits of Sanitation and IPM Procedures

Sanitation procedures and IPM fall under QSP Section IX. (Regulatory Controls). Planned audits of this section of the QSP are conducted by USDA/AMS at least 3 to 6 times per year. An inspector may review compliance with any particular procedure, including correct documentation and completion of procedures by appropriate personnel. The Inspector should document a nonconformance noted during a QSP audit on a Corrective Action Report, as instructed in Section 13 – Quality System Plan Procedures unless immediate correction is needed because of a GMP concern. If the observed nonconformance has created a GMP sanitation deficiency, the Inspector must document the issue following the sanitation procedures in this section. A future QSP audit may be planned to verify compliance with associated QSP procedures.

APPENDIX I – GLOSSARY

The following definitions apply to SCI Division procedures relating to operational rations inspection.

Contractor Furnished Materials (CFM): Material purchased by assemblers for integration into final, assembled rations, such as Meal, Ready-to-Eat (MRE) or First Strike Ration.

Compliance: An indication or judgment that a product or service meets the requirements of the relevant specification or regulation.

Compliance Audit: A systematic, independent, and documented process by which USDA personnel obtain audit evidence and evaluate it objectively to determine adherence to the contractor's written QSP.

Conformance: The fulfillment of a requirement.

Continual Improvement: Recurring activity to increase the ability to fulfill requirements.

Corrective Action Report (CAR): A report format used by government auditors to document (1) audit findings; (2) contractor's response to findings; (3) auditor's assessment of response; and (4) auditor's follow-up assessment (if required). This report has been designated as the QSP3.

Deficiency: See Finding.

DLA Troop Support-FTSB: Acronym for the Quality Audits & Food Defense Branch

DODAAC: The Department of Defense Activity Address Code (DODAAC) is a six position code that uniquely identifies a unit, activity, or organization that has the authority to requisition and/or receive material. The first position designates the particular Service/Agency element of ownership.

Finding: A determination made by an auditor that a requirement is not being met; also known as a non-conformance or a deficiency. A finding is substantiated by objective evidence such as, but not limited to, observations, documents, etc. The severity of a finding is determined by the degree to which it affects the process or end-item. A finding is documented using a Corrective Action Report (QSP3) and requires contractor corrective action.

Food Defense: The protection of food products from intentional adulteration by biological, chemical, physical, or radiological agents.

Government Furnished Material (GFM): Material purchased from contractors by DLA Troop Support for delivery to assembly plants or receiving depots.

Higher Level Quality Requirements: Criteria developed by DLA Troop Support and included in most operational rations contracts requiring contractors to develop and adhere to an accepted, written QSP in order to ensure production of conforming product.

ISO: The official title for the International Organization for Standardization.

Manufacturing Process Controls and In-Process Inspections (MPC): An outline of contractor responsibilities designed to ensure that all manufacturing operations are carried out under controlled conditions. MPC is contained in Defense Logistics Agency Regulation (DLAR) clause 52.246-9001, which is included in Section E of certain solicitations.

Non-conformance: See Finding.

Objective Evidence: The data supporting the existence of something. It may be obtained through observation, measurement, test, or other means.

Observation: A statement of fact made as part of the audit process and substantiated by objective evidence. Generally, a comment made by an auditor when he or she detects a system weakness which is not necessarily a deviation from a requirement, but which may impede the effectiveness of the contractor's QSP. An observation may also be made by an auditor to communicate recognition of noteworthy contractor practices. An observation is documented using an Observation Report (QSP5) and does not require contractor corrective action.

Operational Ration: Food specifically produced to feed military personnel when supply lines are contested. Examples: Meal, Ready-to-Eat (MRE); Polymeric Tray; Meal, Cold Weather (MCW); UGR; etc.

Plan Review: A procedure to analyze and evaluate a written QSP, to determine compliance with the Higher Level Quality Requirements.

Quality Systems Plan (QSP): A contractor's documentation and implementation of a quality system meant to ensure that product conforms to specified requirements. The written plan will include the quality system procedures, will outline the documentation used, and will meet, or exceed, the requirements of ISO 9001.

Rations National Contract (RNC): DLA Troop Support contract under which ration food components are purchased by assemblers for integration into final, assembled rations, such as Meal, Ready-to-Eat (MRE) or First Strike Ration (FSR). The contracts for producers of RNC materials are awarded by DLA Troop Support for a fixed cost amount and certified by USDA on the SC-66 or SC-146 Certificate forms.

Statistical Process Controls (SPC): A system of statistical audit procedures which, when performed properly, will identify control parameters to effect desired production performance.

Workbook I: Quality Systems Audit Workbook I, developed by the DLA Troop Support-FTSB Systems Audit Team to assist in the review and assessment of a contractor's written QSP. This document in posted on the ORS SharePoint site/OR Worksheets/QSP Worksheets and Reference Documents (intranet link).

Workbook II: Quality Systems Audit Workbook II, developed by the DLA Troop Support-FTSB Systems Audit Team to assist in the audit and documentation of a contractor's QSP

compliance through direct observation of the contractor's quality assurance procedures. The workbook is primarily used by the DLA Troop Support /USDA Joint Audit Team, when performing an annual audit of a contractor's system. The workbook and is not available for widespread distribution. Contract a ORS staff member to request a copy.

APPENDIX II – REFERENCE MATERIAL/TOOLS

ANSI/ASQC M1-1987, American National Standard for Calibration Systems

ANSI/ASQC Z1.4, Sampling Procedures and Tables for Inspection by Attributes

DLAR clause 52.246-9001, Manufacturing Process Controls and In-Process Inspections (MPC)

DLA Troop Support Quality Systems Audit Workbook I, Documented Quality Systems Plans (QSP) Evaluation Guideline

DLA Troop Support Quality Systems Audit Workbook II, Compliance Audit Guideline

ISO 9001, Quality Management Systems - Requirements

ISO 19011, Guidelines for Quality and/or Environmental Management Systems Auditing

ISO 10012, Measurement Management Systems -- Requirements for Measurement Processes and Measuring Equipment

Military Solicitations, Section E-1-A-1, Higher Level Quality Requirements - Documented Quality Systems Plan (QSP)

Military Solicitations, Section E-1-A-3, Quality Assurance Provision, Statistical Process Controls, DSCP-H-94-001

APPENDIX III – COMMONLY USED ABBREVIATIONS

Acronym	Meaning
AMS	Agricultural Marketing Service
CID	Commercial Item Description
COA	Certificates of Analysis
COC	Certificates of Conformance
CAR	Corrective Action Reports
DEVCOM-SC	Development Command- Soldier Center
DLA	Defense Logistics Agency
DOD	U.S. Department of Defense
FSIS	Food Safety Inspection Service
FTSB	Quality Audits & Food Defense Branch
GQAR	Government Quality Assurance Representative
IIC	Inspector-in-Charge
iRAPT	Invoicing, Receipt, Acceptance, and Property Transfer
NPMS	National Program Mission Support
MRE	Meal, Ready-to-Eat
OIC	Officer-in-Charge
OR	Operational Rations
ORDB	Operational Rations Database
PDM	Production Demonstration Model
QSP	Quality System Plan
SCI	Specialty Crops Inspection Division
UGR	Unitized Group Ration
USDA	United States Department of Agriculture
WAWF	Wide Area Work Flow

APPENDIX IV – OPERATIONAL RATIONS DOCUMENT EMAIL DISTRIBUTION

Electronic version of Operational Rations Document Email Distribution (intranet link)

The current document email distribution can be found via the internet link above. These email addresses are for distributing Operational Rations (OR) service documents to the Defense Logistics Agency (DLA), Natick Combat Feeding Division, National Science Laboratory (NSL), and the United States Army Research Institute of Environmental Medicine (USARIEM). In addition, check with the Officer-in-Charge if a copy to Area Office management is also required.

APPENDIX V – PROCEDURES FOR ALTERNATIVE SKIP-LOT END-ITEM INSPECTION REQUIREMENTS FOR GOVERNMENT END-ITEM VERIFICATION INSPECTIONS FOR OPERATIONAL RATIONS

Electronic version of Procedures for Alternative Skip-Lot End-Item Inspection Requirements for Government End-Item Verification Inspections for Operational Rations.

PROCEDURES FOR ALTERNATIVE SKIP-LOT END-ITEM INSPECTION REQUIREMENTS FOR GOVERNMENT END-ITEM VERIFICATION INSPECTIONS FOR OPERATIONAL RATIONS

I. **GENERAL:** These Alternative End-Item Inspection guidelines were developed using the guidance of ASQ/ANSI S1, *An Attribute Skip-Lot Sampling Program* (with modifications), and the general requirements cited in operational rations contracts. These procedures apply to Government end-item verification inspections only. It is the intent of the Government to rely on the contractor/subcontractor's examination inspection results and minimize Government end-item verification inspection. All requests for clarification/ interpretation of the procedures cited herein shall be directed to the Contracting Officer, DLA Troop Support. NOTE: For the purposes of this program, the definition of inspection includes examinations only.

A. **End-item Inspection Requirement:** All operational rations contractors/ subcontractors performing under the higher level contract quality requirements are required to perform or have performed by their suppliers, contractually required component or end-item examination inspection in accordance with the contract and its technical specifications and technical requirements documents containing contractually required quality assurance provisions, unless in-process inspection results are authorized by the Contracting Officer for use as a substitute for contractor/subcontractor end-item verification inspection. NOTE: Substitute in-process contractor/subcontractor end-item conformance verification is not authorized for use by the contractor/subcontractor for the purposes of initially qualifying for, or requalifying for, State 3 Government skip-lot end-item verification inspection.

B. There are three basic states for skip-lot inspection:

1 **State 1: Lot-by-lot inspection.** This is the starting point for skip-lot inspection.

2 **State 2: Skip-lot inspection.** When the contractor/subcontractor and the product qualify for skip lot inspection, with the approval from DLA Troop Support-FTRC, the program switches to State 2.

3 **State 3: Skip-lot interrupt.** Skip-lot inspection may be temporarily interrupted, under circumstances described below, resulting in a transfer to State 3.

C. **Products/Characteristics Eligible for Skip-lot Inspection:** Skip-lot procedures are applied to a product's characteristics examinations on a product by product basis. Each individual type of product (identifiable by its NSN) is composed of categorically independent parts, principally in the form of packaging characteristics and product characteristics inherent to a product, which are measurable by their respective filled and sealed and product examinations. A product's approval for Government skip-lot inspection, in addition to the necessity of meeting pre-

APPENDIX VI – 9024 ALTERNATIVE INSPECTION REQUIREMENTS FOR SELECTED ITEMS (OCT 2020)

Electronic Version of 9024 Alternative Inspection Requirements for Selected Items (OCT 2020)

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED: SPE3S1-21-R-0002	PAGE 61 OF 142 PAGES

9024 Alternative Inspection Requirements for Selected Items (OCT 2020)

Physical, microbiological, and analytical tests not eligible for the application of this provision include, but are not limited to, those tests used to identify critical package integrity defects (internal pressure), any pH, water activity, oxygen content tests of food safety concern (identified as critical control point in producer's HACCP or HARPC), and tests for histamine, methylmercury, aflatoxin, *Listeria monocytogenes, Salmonella,* and *Escherichia coli*.

(a) Optional Contractor Testing.
To expedite shipment, the Contractor has the option to perform, or have performed by an independent laboratory, contractually-required tests of end items or component material not specified by the U.S. Standards of Grade. The inspector for the Government having jurisdiction over ascertaining compliance may permit shipment, provided all other requirements of the contract are met. The designated Government inspector will select random samples of each lot of end items or component material for verification testing until the Contractor's testing system is determined reliable in accordance with paragraph (c) of this clause. It is the intent of the Government to rely on Contractor test results to the maximum extent practicable and minimize Government verification testing.

(b) Compliance of Product.
Acceptance of material as complying with required characteristics shall be based on the Contractor test results; provided that Government verification indicates the Contractor's testing system is reliable, in accordance with paragraph (c) of this clause, as to each of the required characteristics. If the Contractor's test system is determined to be unreliable, product compliance will be determined based solely on Government test results. In the event the Government detects any irregularities in the Contractor's testing system, the designated Government inspector may withhold approval until Government test results indicate products conform to contract requirements. For Operational Rations component items (ex: FSR, MCW, MOD, MRE component items), if Government laboratory test results show that product is nonconforming, the product shall be withheld from final assembly and subject to return and replacement by the component Contractor, even if previously approved by the Government inspector.

(c) Reliability Conditions.
(1)The contractor's testing system will be considered reliable as long as its test results are determined to be conforming and to be comparable to government test results. Unless a government agency having jurisdiction has inspected the item produced at the contractor's plant within the previous 120 days and determined the item to be reliable, and unless otherwise specified in this contract, for each different type of end item presented for inspection, in order to establish test system reliability, the inspector will select, for verification testing, random samples of the first three end item lots offered. If the results of the three tests indicate product conformance, the test system will be considered reliable. As long as the contractor's testing system is reliable, the government inspector will sample product for verification testing on a skip-lot basis. Skip-lot verification is done by random selection of samples from not less than one lot in six consecutive lots presented for inspection. The sampling procedure under skip-lot places the succeeding lots not chosen for inspection back into the universe available for subsequent inspection. (For instance, starting with a group of six lots (i.e., 1-6), one lot is randomly selected for inspection. If lot 4 is selected, the next samples will be selected from lots 5, 6, 7, 8, 9, or 10. If lot 8 is selected, the next samples will be selected from lots 9, 10, 11, 12, 13, or 14; and so on.)
(2) Contractor's testing system shall be considered unreliable when (i) the Government verification results indicate product nonconformance to contract requirements; and (ii) a significant disparity exists between Government laboratory results and Contractor test results. When a Contractor's testing system is determined to be unreliable, compliance testing will revert to the Government, and all items shall be inspected by the Government prior to shipment.
(3) Contractor's testing system will be considered doubtful when (i) a significant disparity exists between Government laboratory results and Contractor test results; (ii) the Government test results indicate significant lypoorer quality than the Contractor's; and (iii) the Government laboratory test results do not indicate product nonconformance to a statistically significant degree. When the Contractor's testing system is considered doubtful, verification testing will be performed on each lot produced; however, the Government will continue to permit the Contractor to ship based on its own test results.
(4) Contractor testing system reliability will be determined by applying recognized statistical tests to the Contractor's and Government's test results. These determinations shall be accomplished by the DLA Troop Support, Directorate of Subsistence, 700 Robbins Avenue, Philadelphia, Pennsylvania 19111-5092.
(5) The Contracting Officer will notify the Contractor of any change in reliability status. Notification will include details of the statistical determinations and test results used in reliability studies.

(d) Procedures. When the Contractor elects to perform testing, the following shall apply:
(1)Reporting of Contractor's Results. Test reports for each lot of end item and components shall be submitted in the format contained in this clause by the Contractor in an original and one copy to the designated Government inspector. When requested by DLA Troop Support, the inspector will forward one completed copy to DLA Troop Support FTSC.

APPENDIX VII – DLA MRE SOLICITATION ATTACHMENT 6 – REQUEST FOR EARLY GOVERNMENT INSPECTION

Electronic version of Attachment 6 - Request for Early Government Inspection

Attachment 6 – REQUEST FOR EARLY GOVERNMENT INSPECTION

It is the intent of the Contracting Officer, when and if deemed appropriate by the Contracting Officer, to issue written authorization to Government inspection activities for the purpose of performing early Government inspection when requested by the contractor. This request guide identifies information required from the contractor and concurrences by contractor to conditions by which the Contracting Officer shall render his decision. It is the intent of the Contracting Officer to receive petitions for written authorization and to issue written authorization for early Government inspection to Government inspection activities on a product by product basis, not on a lot by lot approach. However, point (B,2), below, is to be [illegible]d on a lot by lot basis.

A. List the products and inspections for which Contracting Officer authoriz[illegible] early Government inspection is being requested:

(1) The contractor shall list by individual product (i.e., by nam[illegible]d NSN) those products for which the contractor is requesting early GQAR/Lab inspection p[illegible]formance.

(2) The contractor shall identify those inspection[illegible]ms and/or tests for which the contractor is requesting early Government inspection perf[illegible]mance and shall indicate which inspections are requested for which products.

B. Conditions of early Government inspection requiring contractor concurrence:

(1) All lots for which the Contracting Officer authorizes early Government inspection shall be sampled by the GQAR. The contractor shall be responsible for communicating to the GQAR when each early Government inspection lot is available to the GQAR for sampling, using a system comprehended by all involved parties.

(2) For each lot that the contractor wants forwarded by the GQAR to be early Government inspected, the contractor shall submit to the GQAR, in writing, a signed and dated document, requesting that the GQAR commence shipment of each lot's test samples to the contractually designated laboratory. The request must identify by lot number(s) the specific lot(s) to be shipped by the GQAR.

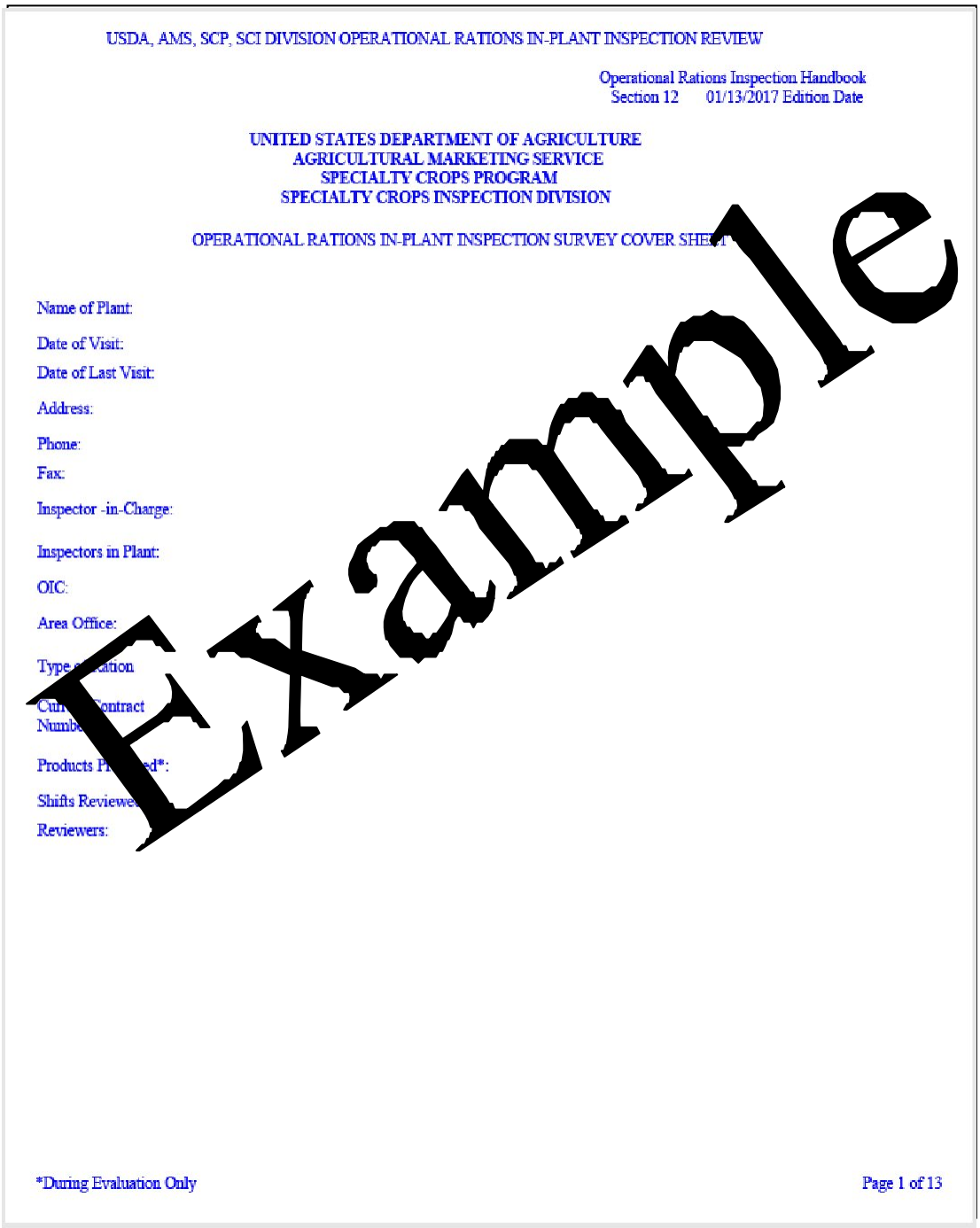
(3) The contractor concurs that once laboratory samples are shipped to the USDA National Science Laboratory (NSL), or other contractually designated laboratory, the lot shall be considered as having been offered to the Government, the performance of all applicable tests shall not be interrupted, and the lot inspection results cannot be expunged from the inspection record of lots offered for government inspection.

(4) The contractor concurs that once requested of the Contracting Officer and sanctioned by the Contracting Officer, the inspection results are final and conclusive.

(5) The contractor concurs that GQAR/Lab inspection results are not to be shared with the contractor until such time as the contractor presents, to the GQAR, documentation of conforming product. However, DLA does require that the GQAR, upon the GQAR's receipt of any positive

APPENDIX VIII – OPERATIONAL RATIONS IN-PLANT INSPECTION REVIEW

Electronic version of Operational Rations In-Plant Inspection Review



USDA, AMS, SCP, SCI DIVISION OPERATIONAL RATIONS IN-PLANT INSPECTION REVIEW

Operational Rations Inspection Handbook
Section 12 01/13/2017 Edition Date

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
SPECIALTY CROPS PROGRAM
SPECIALTY CROPS INSPECTION DIVISION

OPERATIONAL RATIONS IN-PLANT INSPECTION SURVEY COVER SHEET

Name of Plant:

Date of Visit:

Date of Last Visit:

Address:

Phone:

Fax:

Inspector -in-Charge:

Inspectors in Plant:

OIC:

Area Office:

Type ...cation

Cur... Contract Numb...

Products P... ...ed*:

Shifts Reviewe...

Reviewers:

*During Evaluation Only

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