DEPARTMENT OF THE ARMY
UNITED STATES ARMY PUBLIC HEALTH COMMAND
ARMY INSTITUTE PUBLIC HEALTH VETERINARY SERVICES

OPERATIONAL RATIONS INSPECTION PROCEDURE (OPRATS IP02)
01 March 2013

Quality Assurance Terms, Definitions and References

1.0 **PURPOSE**: To promote the use of common words and phrases pertaining to quality assurance programs which will improve the clarity of communications and to provide a list of references for the interpretation of the quality assurance mission and functions.

2.0 **SCOPE**: This procedure provides a standardized interpretation of quality assurance terms and definitions to be applied to the operational rations procurement quality assurance mission, and provides a mandatory list of reference materials to be kept at all inspection branches. This list of references is supplemental to contractually referenced documents.

3.0 **DEFINITIONS**:

3.1 ACR. Assembly-based Contract Requirement. DLA quality assurance requirements for the assembly and inspection of operational ration components.

3.2 Acceptable Quality Level (AQL). The maximum percentage or proportion of variant units in a lot or batch that, for the purpose of acceptance sampling, can be considered satisfactory as a process average.

3.3 Acceptance. The act of an authorized Government representative by which the Government, for itself or as agent of another, assumes ownership of existing and identified supplies tendered, or approves specific services rendered, as partial or complete performance of the contract on the part of the contractor.

3.4 Acceptance Number. The maximum number of defects or defective units in the sample that will permit acceptance of the inspection lot or batch.

3.5 Attribute. A characteristic or property which is appraised in terms of whether it does or does not exist (e.g. go or no-go, pass or fail) with respect to a given requirement.

3.6 Assignable Cause. The reason found for an uncommon variation of a process, usually initially identified by an out-of control situation on a control chart.

3.7 Calibration. Comparison of two instruments or measuring devices, one of which is a standard of known accuracy traceable to national standards, to detect, correlate, report, or eliminate by adjustment any discrepancy in accuracy of the instrument or measuring device being compared with the standard.

3.8 Cause and Effect Diagram. A chart used to determine the cause of a problem by identifying all possible causes to each category of a process (e.g. personnel, machinery, environment, methods, supplies, etc.) and by investigation and elimination, identifying the root cause.

3.9 Certificate of Analysis. A certificate which is issued by a testing agency, which lists the results of specific analytical testing.

3.10 Certificate of Conformance. A contractor's written statement, when authorized by contract, which certifies that supplies or services comply with the contract requirements.

3.11 Control Chart. A graphic representation of data used to detect, identify and analyze variation in a given characteristic, process or product. This statistical tool can be used in problem solving as an indication of whether the system is in or out of control, as determined by computing control limits.

3.12 Control Limits. Statistical limits that establish the maximum variation beyond which action must be taken to investigate and when feasible correct the cause(s) of nonconformance. Control limits are developed using standard statistical methods and based on documented process history.

3.13 Control Point. A point, step or procedure in a system where conformance to contractual requirements can be controlled.

3.14 Conveyance Inspection. Inspection of subsistence conveyance both on receipt and prior to shipment.

3.15 Corrective Action. Changes to processes, work instructions, workmanship, training, inspections, tests, procedures, specifications, equipment, facilities or material that result in preventing, minimizing or eliminating nonconformances.

3.16 Critical Control Point (CCP). A point, step or procedure in a system at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels.

3.17 Cyclic Inspection. A surveillance inspection performed on a routine scheduled basis.

3.18 Defect. Any nonconforming unit of product with specified requirements or any state or condition of nonconformance to requirements.

3.19 Defective. A unit of product which contains one or more defects.

3.20 Defects Per Hundred Units. The number of defects per hundred units of any given quantity of units of product is one hundred times the number of defects contained therein (one or more defects being possible in any unit of product) divided by the total number of units of product, i.e.:

$$\frac{\text{Number of Defect} \times 100}{\text{Number of Units}}$$

3.21 Deviation. (1) A specific written authorization, granted prior to manufacture of an item, to depart from a particular requirement(s) of an item's current approved configuration documentation for a specific number of units or a specified period of time.

(2) The difference or distance of an individual observation or data value from the center point (often the mean) of the data set distribution.

3.22 First Article. Samples of potential “new” items, to be added to rations, in which a contractor submits to NATICK for evaluation of analytical requirements, physical requirements, microbial requirements, and/or performance requirements.

3.23 Flow Chart. A pictorial representation of a single process, from beginning to end, showing all steps of the process.

3.24 Histogram. A type of bar graph used to show the distribution of groups of data.

3.25 Inspection. The examination and testing of supplies and services to determine whether they conform to specified requirements.

3.26 Mean. The average or expected value of a number of observations.

3.27 Measuring and Test Equipment (M&TE). All devices used to measure, gage, test, inspect, diagnose, or otherwise examine materials, supplies and equipment to determine compliance with technical requirements.

3.28 Median. The middle value identified when the values are arrayed in numerical order. It is the value which has half of the observations above it and half of the observations below it.

3.29 Mode. The value in a group of observations which occurs the most frequently.

3.30 One Hundred Percent Inspection. Inspection in which specified characteristics of each unit of product are examined or tested to determine conformance with requirements.

3.31 Pareto Chart. A type of bar chart used in problem solving to identify the area(s) which require immediate attention. Characteristics are represented by descending bars according to the frequency of occurrence, with the underlying principal being that 20% of the characteristics account for 80% of the overall problem.

3.32 Percent Defective. The percent defective of any given quantity of units of product is one hundred times the number of defective units of product contained therein divided by the total number of products, i.e.:

$$\frac{\text{Number of Defectives} \times 100}{\text{Number of Units Inspected}}$$

3.33 PCR. Performance-based Contract Requirement. DLA quality assurance requirements for the production and inspection of operational ration components.

3.34 PDM. Product Demonstration Model. Samples which a contractor submits to NATICK for evaluation of analytical requirements, physical requirements, microbial requirements, and/or performance requirements.

3.35 Pre-award survey. An evaluation of a prospective contractor's capability to perform under the terms of a proposed contract.

3.36 Probability. The number of times an event can be assumed to occur based on the past occurrences of the event over a specified number of possible cases.

3.37 Probability of acceptance. That percentage of inspection lots expected to be accepted when the lots are subjected to a specified sampling plan.

3.38 Process. A repeatable set of tasks or activities designed to add value to the output of a product or service for a customer.

3.39 Process average. The average percent defective or average number of defects per hundred units of product submitted by the supplier for original inspection. Original inspection is the first inspection of a particular quantity of product as distinguished from the inspection of product which has been resubmitted after prior rejection.

3.40 Process capability. A statistical evaluation of a process to determine its ability to produce output within specification limits.

3.41 Product quality review. An action by the Government to determine that the quality of supplies or services accepted by the Government do, in fact, comply with specified requirements.

3.42 Process Capability. The composite of all attributes or characteristics, including performance, of an item or product that bear on its ability to satisfy stated or implied needs.

3.43 Quality assurance (QA). A planned and systematic pattern of all actions necessary to provide adequate confidence that management and technical planning and controls are adequate to:

a. Establish correct technical requirements for design and manufacturing.

b. Create products and services that conform to the established technical requirements.

3.44 Quality assurance representative (QAR). The individual directly charged with performance of the Government contract quality assurance function at a contractor facility.

3.45 Quality audit. A systematic and independent examination and evaluation to determine whether quality activities and results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

3.45.1 Process audit. An analysis of elements of a process and appraisal of completeness, correctness of conditions, and probable effectiveness.

3.45.2 Product audit. A quantitative assessment of conformance to required product characteristics. Product quality audits usually involve an inspection operation, but these are carried out independently of the routine inspection and assessment activities.

3.46 Quality system audit. A documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the quality system are suitable and have been developed, documented, and effectively implemented in accordance with specified requirements.

3.47 Random sample. A sample selected in such a way that each unit of the population has an equal chance of being selected.

3.48 Range. The difference between the largest and smallest values in a group of observations.

3.49 Rejection number. The minimum number of defects or defective units in the sample that will cause rejection of the lot represented by the sample.

3.50 Request for Waiver (RFW). A written request from the contractor to the contracting officer requesting that an item be accepted with a known variation from the specified requirements.

3.51 Resubmitted lot. A lot which has been rejected, subjected to either examination or testing for the purpose of removing all defective units which may or may not be reworked or replaced, and submitted again for acceptance.

3.52 Rework. A procedure applied to a nonconformance that will completely eliminate it and result in a characteristic that completely conforms to contract requirements.

3.53 Sample. One or more units of product drawn from a lot or batch. Each unit is selected randomly.

3.54 Sample size. The number of units of product selected to be a part of a sample.

3.55 Sampling plan. A plan which indicates the number of units of product from each lot which are to be inspected and the criteria for determining the acceptability if the lot. A sampling plan includes a sample size, acceptance number and rejection number.

3.56 Scatter diagram. A graph which is used to study the relationship between two or more variables. Data points of each variable are plotted to determine the strength of the relationship, but the identity of a cause is not determined.

3.57 Scrap. Nonconforming material that is not suitable for its intended purpose and which cannot be economically reworked or cannot be repaired in a manner acceptable to the Government.

3.58 Screening inspection. Inspection in which each item of product is inspected for designated characteristics and all defective items are removed.

3.59 Skip lot inspection. A sampling technique which provides for the acceptance of a lot without verification of its quality characteristics or compliance to contractual requirements.

3.60 Specification. A document intended primarily for use in procurement, which clearly and accurately describes the essential and technical requirements for items, materials and services, including the procedures by which it will be determined that the requirements have been met.

3.61 Statistical Process Control. The application of statistical techniques to the control of processes and quality. These techniques include the use of frequency distributions, measures of central tendency and dispersion, control charts, acceptance sampling, regression analysis, etc.

3.62 Senior Quality Assurance Representative (SQAR). The senior (civilian and/or military) inspector assigned to a ration assembly plant.

3.63 Traceability. The ability to trace the history, application, or location of an item or activity and like items or activities by means of recorded identification. Generally, the ability to identify the assembled lots and location of those lots which contain a particular component.

3.64 Variable. A quantity that may assume any one of a number of values. A measurable quantity.

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4.0 **REFERENCES**:

4.1 The following references which contain further definitions and valuable information regarding quality assurance functions will be maintained at each inspection site:

4.1.1 TM 38-400 (DLA Troop Support M 4145.12), Joint Service Manual (JSM) For Storage and Materials Handling

4.1.2 AR 25-400-2, The Army Records Information Management System, (ARIMS)

4.1.3 AR 40-657, Veterinary/Medical Food Safety, Quality Assurance, and Laboratory Service

4.1.4 AR 40-660, DoD Hazardous Food and Nonprescription Drug Recall System

4.1.5 MEDCOM Regulation 40-28, United States Army Veterinary Command Policies and Procedures

4.1.6 MEDCOM Pamphlet 40-13, United States Army Veterinary Command Guidelines and Procedures

4.1.7 USAPHC Circular 40-1, Directory of Sanitarily Approved Sources for Armed Forces Procurement

4.1.8 FED STD 595, Federal Standard Colors

4.1.9 MIL STD 109, Quality Assurance Terms and Definitions

4.1.10 MIL STD 3006C, Sanitation Requirements for Food Establishments

4.1.11 MIL STD 904, Detection, Identification, and Prevention of Pest Infestation of Subsistence

4.1.12 DLA Troop Support Manual 4155.2 D, Quality Assurance Program for

DLA ICPs 4.1.13 DLA Troop Support Manual 4155.21, Quality Assurance

Program Instructions for DLAICPs

4.1.14 DLA Troop Support HDBK 8200.1, Defense In-Plant Quality Assurance Program

4.1.15 DLA Troop Support HDBK 4155.2, Inspection of Composite Rations w/ All Appendices

4.1.16 DLA Troop Support M 4155.6, Number 101.1, DLA Troop Support Subsistence Manual Inspection Manual

4.1.17 DLA Troop Support Manual 4155.35, Subsistence Test Evaluation

4.1.18 ANSI/ASQ Z1.4-2003, Sampling Procedures and Tables for Inspection by Attributes

4.1.19 Natick Pam 30-25, 8th Edition, Operational Rations of the Department of Defense

5.0 **PROCEDURES**:

5.1 Unique terms and definitions which require standardization or inclusion in this procedure will be submitted to the Operational Rations Section.

5.2 Periodic review of references will be made to determine the necessity of adding required publications to the above list. Suggested additions will be submitted to the Operational Rations Section.

5.3 If a section does not have one of the required references, an immediate request will be sent to the Operational Rations Section.

6.0 **RECORDS, REPORTS AND FORMS**:

None.