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Inspection Branch Internal Quality Management System Review Procedures Guide

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BIQMS

Review Procedures Guide

This guide is specifically developed and designed by the Specialty Crops Inspection Division, Inspection Branch to assist Federal Program Managers and Officers in Charge to perform Branch Internal Quality Management System (BIQMS) Reviews.

These instructions do not establish any substantial rule not legally authorized by official SCI Division Policy. This publication supersedes any previously issued Review Procedures Guides.

October 2013

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This handbook replaces instructions dated July 1998

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INTRODUCTION

The United States Department of Agriculture, Agricultural Marketing Service, Fruit and Vegetable Programs, Specialty Crops Inspection (SCI) Division and their respective cooperators have approved the review procedures that guide the examination of the quality systems in the cooperating states. The SCI Division Branch Internal Quality Management System (BIQMS) Quality System Service Standards (QSSS) are the “specifications” or “review standards” of the BIQMS program.

The cooperators provide the majority of inspection and process reviewing services within the growing and shipping areas of their states with oversight by the SCI Division. The future of the Federal-State shipping point inspection service (FSIS) depends upon ensuring that industry will continue to use and pay for these services. SCI Division, Inspection Branch and its cooperators have agreed upon this type of reviewable quality management system to ensure that SPI core values of honesty, impartiality, and customer service are maintained in the absence of on-site Federal supervision.

A BIQMS Review is a review of the records and procedures of the cooperator made by Federal Program Managers (FPMs) who are not involved in the preparation of these records and procedures. On the basis of this examination, the reviewers obtain objective evidence to determine whether the cooperator’s records are accurate, the appropriate controls are maintained and effective, the required procedures have been followed, and whether other criteria have been satisfied as outlined in the cooperator’s manual.

The cooperator shall perform periodic management reviews and internal reviews to evaluate their quality system. This is done where there is a desire to establish a contractual relationship, or to verify within the framework of a contractual relationship that the quality system continues to meet specified requirements, and is being implemented. These reviews should be done periodically. In addition, reviews should be made when:

- significant changes have been made in functional areas, for example, reorganizations and procedures revisions;
- safety, performance or reliability of the services are suspected to be in jeopardy due to non-conformities;
- it is necessary to verify corrective actions have been taken; and
- evaluating the quality management system against the QSSS.

THE REVIEWER

Technical Expertise Needed by Reviewers

This BIQMS Review Procedures Guide has been developed for individuals who have the technical experience for inspection of fresh fruits and vegetables and “process auditing” of quality systems. Individuals must have formal classroom auditor training, and good communication skills. This guide is to assist those individuals in performing verification reviews

and other limited scope reviews of a quality management system. It includes information to make quality systems reviews as objective as possible.

The review procedure verifies that a “*quality manual*” based on the QSSS is written and approved and the quality system defined in the manual is functioning. The review team should review a copy of the cooperator’s quality manual prior to the review. The reviewer(s) should ensure that copies of the quality manual are returned to the appropriate office at the conclusion of the review. Quality manuals are not for public distribution. The contents are to be treated as CONFIDENTIAL.

The reviewers must be perceived as competent and qualified. Confidence in review results depends on the reviewer’s proficiency, judgment, and professional conduct. The reviewer’s qualifications shall meet those established by the USDA AMS SCI Division.

The review team must have the necessary technical and managerial expertise to perform the review. Ideally, the knowledge of each team member complements that of other team members. The review criteria are only guides and reviewers should understand the subject well enough to identify issues and not be misled. Reviewers must be able to expand the review in significant areas when necessary.

Knowledge of the cooperator’s organization simplifies the review planning process. This knowledge exposes the FPMs to the cooperator’s program activities. This results in better participation in discussions of regulations, quality specifications, standards and procedures in the specific areas being reviewed. Identifying discrepancies among these documents and practices will give an understanding of non-conformities which have a bearing on the quality system services.

Lead Reviewer

The lead reviewer will be pre-determined if more than one person is on the team. The lead reviewer makes all assignments, “tie breaking” decisions, leads discussion during conference, writes the review report, and presents the report, findings and ratings to the cooperator’s management. Other team members, if applicable, may be assigned some of these responsibilities, but only at the direction of the lead reviewer. Reviewers shall answer specific questions or make specific reports to management during the exit meeting.

Personal Traits

The success of the review is largely dependent upon how reviewers present themselves. The credibility of the reviewer, the USDA and the SCI Division depends on the professional manner shown by reviewers. Reviewer selection should be made with the following attributes in mind:

- Ability to communicate in writing and orally, including choice and flow of speech, clarity of thought, and skill in listening, understanding and responding;
- Ability to plan and control an activity, with skills in organizing, initiating, observing and analyzing;
- Ability to lead, supervise, delegate, gain acceptance and accomplish objectives;

- Ability to gain cooperation between other reviewers, USDA, cooperators, and supervisors;
- Ability to reach decisions, separate facts from opinions, compile information and evidence, and compare evidence with written standards;
- Ability to administer, keep records, report, and manage budgets;
- Ability to work independently, systematically and energetically;
- Ability to acquire and use special knowledge and skills;
- Ability to adapt to changing work assignments and conditions;
- Good outward appearance and conduct;
- Intelligence, alertness, and ability to comprehend and reason;
- Stable emotions, calm, self-confident, persistent, insistent and task oriented;
- Good character, honest, reliable, constructive, helpful and diplomatic; and
- Good attitude, values, interest, work habits, initiative, carefulness, curiosity and open mindedness.

Independence and Objectivity of Reviewers

The reviewer's independence rests on the absence of conflict of interest in organizational relationships and in mental attitude with respect to the review and judgments relating to the review. The review plan should consider this since confidence in the results of the review depends upon the known and perceived independence of the reviewer.

REVIEWS AND REVIEWING

Authority to Conduct Reviews

Quality reviews should encompass all aspects of the quality system. With this in mind, the authority for conducting reviews must come from and be supported by the cooperator's upper level management. Without this authority, cooperation and the value of the quality reviews are limited.

The written policy of the cooperator and the cooperative agreement with the USDA are the most common places to find authority and support for conducting quality reviews. Support from the highest level of management is essential for quality reviews to achieve their maximum benefit. Reviews required by contract or specification mean little if the requirement is not openly supported by management policies, statements and actions.

Requirement to Maintain a Quality System

The requirement to plan and maintain a quality program is stated in the cooperative agreement. The assessment of program effectiveness will be through internal cooperator reviews as well as external (second party) USDA reviews. This requirement can be found in the QSSS and the cooperator quality manual. The FPMs are responsible for establishing and developing procedures to identify the scope of the external reviews. These review procedures should be coordinated with the cooperator's management for their concurrence and support. The reviews

will provide cooperator management with reliable information while identifying opportunities for program improvement.

Purpose of the Review

A clear definition and policy from the cooperator's upper level management as to the purpose of a quality review is critical to its success, not only to assure that senior management becomes involved, but so management's support can be relied on if an impasse is reached. This reviewing policy is established to focus program support and to provide instructions to verify on a regular basis, that each segment of the program is in compliance with the QSSS and the cooperator's quality manual. This policy should give each cooperator assurance that the program services performed are maintained at an acceptable level.

Coordinating the review plan with the organization to be reviewed is critical to ensure understanding of the purpose of the review. *The purpose of the review is not to find fault but to focus the attention of the management to areas where the program can be improved.*

Role of Internal Reviews

Internal reviews provide documentation of the effectiveness of a quality system. The USDA recognizes that the cooperator's internal reviews provide an increased assurance that consistent quality services are being provided to the industry. SCI Division, Inspection Branch reviewers should examine the cooperator's internal reviews and evaluate the corrective action taken for any non-conformity.

Definition of the Review

The review must be clearly defined and understood by both the cooperator and the reviewer. Most reviews are performed during the training and harvesting season. Both parties must understand the need to review during this time and know what the review will entail. In both internal and external reviews, the reviewer must assure that the cooperator's management understands the following:

- The scope of the review;
- When the review will be conducted and the anticipated duration;
- Who will conduct the review;
- What will be expected of the cooperator before, during, and after the review;
- Review findings are measured against the criteria found in the QSSS and the cooperator's quality manual; and
- How the review results will be used.

Therefore, the planning phase should include the reviewer's preparation of an agenda notifying the cooperator of these considerations.

Procedures, Specifications and Contract Requirements

A review should start with an objective and thorough review of applicable requirements in the cooperator's quality manual, procedural manuals, work instructions, contract specifications and regulations. Any cooperator-generated specifications or other requirements that identify operational needs outside the cooperator's normal, inspection or process auditing services provided under agreement with the SCI Division Inspection Branch should be identified. These should be used in the review planning and preparation phase if applicable.

History

An effective way to evaluate the expected usefulness of procedures and to develop a review plan is to review a cooperator's performance history. A thorough understanding of the history is important to the planning and development of the review checklist. Service integrity should be reviewed, and areas that could have an impact on industry acceptance of the program's services should be specifically added to the scope of the review. This includes verification of corrective actions, industry satisfaction, appeals and re-inspections, statistics, etc. Depending on the service, any and all of these may apply. Former problem areas need to be evaluated to ensure that the corrective action was effective in preventing further similar occurrences.

The reviewer should be aware that bias and pre-judgment can occur when, in planning the review, the focus is on the former problem areas and corrective actions.

Verification of Service Integrity

A verification review is performed to verify the adequacy of services provided by the cooperator. Any non-conformity found should lead to improvements to meet employee and industry expectations more reliably. The primary purpose of documenting non-conformities during a review is to identify services that can be improved. A verification review is performed when specific areas of concern are identified or when reliability needs to be confirmed. This type of review should occur at various times during the service activity. First and middle level managers should cooperate to avoid unnecessary conflicts. This cooperative support is a positive step in any review and the success will depend on how these managers view the review function.

When to Review

The quality management system should identify non-conformities as early as possible through the timely reviews. This early detection allows management to implement corrective action before non-conformities actually affect delivery of services. It should also prevent recurrence of the non-conformity.

The frequency of reviews is determined by the complexity and scope of a particular cooperator's program. Larger and more complex programs may require more reviews in order to provide full confidence that all parts of a program are being serviced adequately. Review frequency is also influenced by the number of commodities inspected, process auditing services provided and the number of offices a cooperator has under its program. The quality, frequency and findings of the cooperator's internal reviews should also influence the number of reviews performed by SCI Division Inspection Branch reviewers.

All cooperators shall be treated equally, proportionate to the complexity and scope of the particular program.

Special Concerns

Quality systems require internal reviews, especially when service problems or customer complaints are encountered. Often these concerns can be documented by a well-planned review. The problem areas could be detected from records control, excessive rejections in receiving inspections, a reduction in productivity, personnel problems or industry concerns. These reviews normally receive maximum visibility and usually are directed by upper management. Caution should be taken to avoid overly frequent reviews in the same area as this could lead to the review function losing the sense of urgency and cooperation from middle management.

Establishment of Tentative Review Schedule

Federal Program Managers shall make a tentative review schedule for each cooperator's program based on the types of services provided under USDA oversight, the number of commodities, when the commodities are in season, and the location and number of offices within the program. There should be a minimum of one BIQMS review annually for each different segment of a cooperator's the program. Reviews for a specific segment of the program could be considered "targeted" in the respect that the FPMs may identify a narrower review scope of "PLI procedures," or "equipment," for example. In these cases, the subject area is targeted in order to determine how a cooperator controls that area throughout their program

Reviews should be scheduled to cause the least amount of disruption to both the reviewer and the service delivery. Production schedules, vacations, unusually heavy workloads, etc., should be considered. Establishing a tentative time agreeable to the cooperator can help foster a good relationship with the cooperator. However, sometimes reviews must be performed during busy production and servicing times. Even then they should be planned to cause as little disruption as necessary.

Opportunities for Improvement

A review generally encompasses every aspect of the service provided by the cooperator and industry acceptance of that service. One objective of the review is to determine if the program has kept up with advancements made within the industry. A review of a specific operation within the program (i.e., limited scope review) is a prime example of an evaluation that may identify opportunities for improvement.

Reviews may reveal that procedural processes need to be evaluated. Sometimes a cooperator's inspection or process auditing program cannot be understood due to lack of instructions. Other times too many procedures address the same subject and confuse the issue. Cooperators understand the economics of their operation, so when a more economical method can be suggested through a review report, its value to the cooperator will be recognized and management support will increase.

Observations during the review which are not considered serious enough for immediate attention, should be recorded on the review report under the "General Comments" or

“Observations that may lead to Non-Conformities” sections and be discussed during the exit meeting. This should result in program improvement. Reviewers should use caution not to use the “General Comments” section to the extent that it detracts from the central purpose and scope of the review.

TYPES OF REVIEWS

Internal Reviews

The internal reviews are conducted by the cooperator to verify whether the various elements in their quality system are implemented effectively and are achieving the quality objectives as defined by management. It is especially important to assure that the services provided are being maintained to meet USDA requirements and that the services meet or exceed levels as outlined in the cooperator’s quality manual.

Reviews are performed in accordance with the cooperator’s quality manual which establishes the frequency of the reviews. This frequency is based on the status and importance of the activity being reviewed. Therefore, in areas where problems exist, or in areas which are more critical to the quality of the services provided, more frequent reviews are likely to be carried out. In addition these reviews are performed when specific program needs are identified. Even though past reviews may indicate an acceptable service delivery, future reviews should be scheduled because people, places and situations affecting a cooperator’s operation change over time.

Four factors are essential for any review system to be effective.

1. The cooperator must select and assign trained competent quality systems personnel to review each segment of their program functions.
2. The review must be performed against defined and documented criteria such as the QSSS, the cooperator’s quality manual, program instructions, a customer’s contract and/or other formal requirements. Without a clear set of defined criteria, variability and subjectivity will be introduced into the process as each review may be influenced by the biases and personal work experience of the reviewer.
3. Clear, accurate and complete review records must be maintained. Details of these records will include: the scope of the quality system that was examined; positive observations and negative findings; and verification that effective corrective actions were implemented to deal with the root cause of problems (if/when non-conformances are identified).
4. A report of the review must be sent to management.

The review plan for an internal review should include a complete review of recent non-conformity reports and corrective actions as well as review of facilities, equipment, and personnel training that are within the scope of the review.

Cooperator Management Review

An internal management review program is vital to assure cooperator management that its program is accomplishing their quality objectives and maintaining the services delivered to industries they serve. This type of review should be conducted upon initial implementation of a quality system, process, or procedure, and periodically thereafter. Lower level supervisory visits should be reviewed by management to assure adherence to the cooperator's quality manual.

The dynamics of change is constant. Cooperators need to prepare themselves for any adverse effects of change. Management decisions may be made to address changes. A regularly scheduled internal verification review of their quality program keeps management abreast of the following possible circumstances:

- Licensees may become lax in procedural rules and regulations.
- Licensees may transfer or quit, putting less experienced people into a position, sometimes without adequate training.
- Licensees may develop more efficient methods and training without documentation.
- Changes in specifications may not always be communicated effectively.
- Shortcuts may be taken.

External Reviews

An external review is performed by the FPMs on a cooperator's program to evaluate the quality of services provided on behalf of USDA, as outlined in the quality manuals. This requirement is based on the QSSS.

Initial Review

An initial review affords the opportunity to identify strengths and weaknesses of a service, process, or product. This review is then used to initiate improvements aimed at assuring the future integrity of the program. The initial review also establishes a baseline that may be used to evaluate and measure future progress. Planning should be thorough and include all functions or elements of the quality system, and should be performed as early as possible. This can apply to both internal cooperator reviews as well as external USDA BIQMS reviews.

Preseason Reviews

The preseason review should be performed before program services begin. Planned inspection or other service (process reviewing) requirements, if appropriate at this time, should be made to assure that all aspects of the program have been considered.

An advantage of the preseason review is that there is an opportunity to review personnel needs, calibration systems and measurement and test equipment prior to performing the service. The preseason reviews often show that equipment and personnel needs are met, however they must be evaluated periodically to assure continuous quality service is provided.

Unscheduled Reviews

Reviews should be planned and coordinated in advance when possible but there are situations that may require unscheduled reviews. In most cases, an reviewer can find a non-conformity if one exists. In the case of suspected wrongdoing, if prior notification could allow

the opportunity to hide the “real information,” significantly jeopardizing the reliability of the review judgment, then the review should be unscheduled.

Unscheduled reviews are usually sensitive and require a great deal of diplomacy. This type of review may be necessary if intentional unethical or illegal practices or procedure violations are suspected. This type of review should be used sparingly as the “got you” kind of interface it may produce could cause many hard feelings.

External and Internal Process Verification

Process verification is achieved through the cooperator’s internal supervisory checks and by external BIQMS reviews performed by FPMs. These reviews consist of observing the product and observing the licensee performing the service to determine if their actions are in compliance with the specified requirements. Observations should include conditions such as work site, rules as applied to industry employees, safety regulations, use of current specifications, etc. The review should determine if inspectors require special training, education, experience, or certification.

Verification Reviews

Verification reviews are generally scheduled. Review frequencies should be varied from one review to the next so as not to develop a predictable pattern. Cooperators may be contacted to get information pertaining to their service delivery schedule. If the reviewer arrives to perform a review and there is no activity, the scope of the review can be limited, for example, to records review. This is an option that should be used sparingly.

PERFORMING THE REVIEW

Review Plan

The scope of the review must be determined and if necessary, narrowed to a specific area. The reviewer must research data and develop an organized checklist. The Review should be planned so that it is organized and follows a systematic review path.

The development of the checklist is a part of the review planning process. If standardized checklists are used the reviewer may develop follow-up questions that apply to the specific scope of the review. The source from which each question or item on the checklist is derived should be identified. A note can be made that the item is from procedures, regulations, contract requirements, or quality objectives, etc. This adds credibility and is useful in referencing non-conformity reports.

A sampling plan that ensures effective representation must be based on the services provided as well as knowledge of previous reviews and the corrective actions or current problems. When the cooperator has implemented preventive actions as the result of a review, the adequacy of those actions should be evaluated. It is vital that reviewers be aware of preventive actions taken so they may prepare for the current review criteria.

An integral element of the review planning is an awareness of a possible need for follow-up. The reviewer should allot sufficient time at a future date to perform a follow-up review regarding any findings made during the current review.

Contractual Requirements

Two key elements to understanding review requirements are the cooperator's contract review process and the communication of the contract requirements to internal and external parties. When contracts or requests for service specify certain information, the internal review system must address those items. The internal reviews should determine whether or not the cooperator's employees have complied with the services required or requested in the "contract/request for service" or "application for service". The reviewer must recognize the requirements of the contract. Non-conformities in contract services during a review should be corrected with a great sense of urgency; otherwise the potential for loss can be considerable.

Opening Meeting

Every review must have an opening meeting regardless of the type or scope of the review. At a minimum, the opening meeting will be attended by the reviewer and a representative of the cooperator. Additional management personnel and representatives may be invited to attend by the cooperator. Occasionally the opening meeting may be by telephone.

The meeting should be scheduled in advance and upper level management should be notified. The meeting is useful in affirming the type and scope of the review to be performed, the expected duration of the review, what facilities will be reviewed and what the reviewers' needs are. The opening meeting times and persons present must be documented in the review report.

The Review

Reviewers must know their particular assignment as well as the products and program areas being reviewed. Each concern or issue identified during a review should be confirmed before leaving the area where it was detected. The responsible supervisor of the affected area should give confirmation as to the non-conformity. During the review, the reviewer should observe the program and document any observations or findings that may be contrary to the quality management system. Positive observations of processes and procedures should also be noted. Any notes or other documentation will become part of the review working papers. The cooperator's management should be notified if the review process leads outside of the predetermined scope of the review.

Exit Meeting

Every review must have an exit meeting attended by the reviewer and a management representative. The exit meeting allows the cooperator's management to understand and ask questions concerning review observations and findings. If management wishes to rebut findings they should be allowed time during the exit meeting. The reviewer should be prepared to justify any findings or non-conformities with a rating standard from one of the cooperator's documents or the QSSS. The cooperator may present information that satisfies the findings or non-conformities of the review. A successful exit meeting results in the management being in a position to begin corrective action, if needed. Information brought up during this meeting may

also affect the formal written report. The time and attendees of the exit meeting must be documented.

Written Report

The product of a review is a written report. While the format of the report may vary, it should follow the USDA SCI Division procedure for conducting reviews. The report should include the cooperator's responses to the findings and incorporate them into a final summary for distribution. The value of such an approach is that it provides cooperator management with corrective and preventive actions along with review findings. Regardless of the format used, the review report should identify who has responsibility for an action and should provide a date requiring a response plan for corrective and preventive actions.

The review report and any non-conformity reports should be transmitted to the SCI Division Inspection Branch, Federal-State Inspection Management Section when the review is complete. An electronic or a hard copy of the review report should be given or transmitted to the cooperator's representative as soon as possible after the conclusion of the review. The FPMs shall maintain a file of review reports with original signatures. The file should include all the review working papers.

Corrective Action

The primary purpose of the review is to verify compliance, or when non-conformities of the program are noted, to require corrective action. When criteria are identified as needing correction, the reviewer should document the findings and the related criteria on a non-conformity report (NCR). The corrective action should be proposed by the cooperator on a corrective action report (CAR). The reports may be combined on one page. It is appropriate to request in the review report that a formal corrective action plan be prepared by the cooperator describing the cause of the problem(s), the actions that will be taken, who will take them, and when the action will be effective.

An appropriate corrective action plan corrects the specific non-conformity, identifies the root cause of the non-conformity, and schedules the action to prevent a recurrence. *Correcting a specific non-conformity may be easy; identifying the root cause is often difficult.* Successful identification of the root cause increases the likelihood that a corrective action will prevent recurrence of a non-conformance. The corrective action plan submitted by the cooperator will be evaluated by the FPMs and SCI Division Inspection Branch.

Follow-Up Reviews

The need for a follow-up review is determined after submission and acceptance of a corrective action plan. This must always be included in the review schedule. Not allowing time for follow-up reviews creates a hardship for the reviewer and hinders the value of future reviews.

A non-conformance will require follow-up to verify the corrective action's effectiveness and adequacy. Records must reflect follow-up on non-conformities particularly when the cooperator is subject to external reviews.

If the planning for the next verification review incorporates checks on previous non-conformities or findings, then a specific follow-up review may not be necessary. However, with some shipping seasons so short, follow-up should be planned and completed within 5 days so the reviewer can confirm whether or not the corrective action was put in place and effective prior to the season ending.

Review Close-Out

There is a tendency to consider the review complete when the review report is issued. However, the review is not complete until the reviewer is confident that the actions needed to correct the non-conformities have been implemented and are effective. Therefore, review close-out should take place only after documentation of appropriate follow-up action.

QUALITY REVIEWING TERMS, DEFINITIONS AND STANDARDS

ANSI/ASQC Q90, Quality Management and Quality Assurance Standards
ANSI/ASQC Q1, Generic Guidelines for Reviewing Quality Systems
ANSI/ASQC A3, Quality Systems Terminology
ANSI N45.2.10-1973, Quality Assurance Terms and Definitions
CAN3-Q395-81, Quality Reviews
ISO 8402 (1987), Quality Vocabulary

Assessment	An estimate or determination of significance, importance or value of something.
Cooperator	An organization to be reviewed.
Certification	The procedure and action, by a duly authorized body, of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with applicable requirements.
Characteristic	A property that helps to identify or to differentiate between entities and that can be described or measured to determine conformance or non conformance to requirements.
Client	The person or organization requesting the review. Depending on the circumstances, the client may be the reviewing organization, the cooperator, or a third party.
Compliance	An affirmative indication or judgment that the supplier of a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements.
Conformance Conformity	An affirmative indication or judgment that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirement.
Contractor	Any organization under contract to furnish items or services; a vendor, supplier, subcontractor, fabricator, and sub-tier levels of these, where appropriate.
Convention	A customary practice, rule or method.
Corrective action	Action taken to eliminate the root cause(s) and symptom(s) of an existing undesirable deviation or non-conformity to prevent recurrence.
Critical Control Point	A point or operation, beyond which if not controlled, non-conforming services will be produced.

Deviation	A non-conformance or departure of a characteristic from specified product, process, or systems requirements.
Finding	A conclusion of importance based on observation(s).
Follow-up review	A review, the purpose and scope of which is limited to verifying that corrective action has been accomplished as scheduled and determining that the action prevented recurrence effectively.
Guidelines	Documented instructions that are considered good practice but are not mandatory.
Independence	Freedom from bias and external influences.
Inspection	Activities such as measuring, examining, testing, and gauging one or more characteristics of a product or service and comparing these to specified requirements to determine conformity.
Internal review	A formal evaluation by top management of the status and adequacy of the quality system in relation to the quality policy and new objectives resulting from changing circumstances.
Non Conformance Non Conformity	The non-fulfillment of specified requirements.
Objective evidence	Verifiable qualitative or quantitative observations, information, records, or statements of fact pertaining to the quality of an item or service or to the existence and implementation of a quality system element.
Observation	An item of objective evidence found during a review.
Procedure	A document that specifies the way to perform an activity.
Process quality review	An analysis of elements of a process and appraisal of completeness, correctness of conditions, and probable effectiveness.
Product quality system	A quantitative assessment of conformance to required characteristics.
Qualification	The status given to an entity or person when the fulfillment of specified requirements has been demonstrated; the process of obtaining that status.
Quality	All the features and characteristics of a product or service that bear on its ability to satisfy stated or implemented needs.
Quality assurance	All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy specified requirements for quality.
Quality review	A systematic and independent examination and evaluation to determine whether quality activities and results comply with planned procedures and whether these procedures are implemented effectively and are suitable to achieve objectives.
Quality control	The operational techniques and activities that are used to fulfill requirements for quality.

Quality documents	Documents that form part of a cooperator's quality system, including manuals, written procedures, organizational charts, work instructions, plans, designs, drawings, specifications, test methods, job descriptions, pre-printed forms, tags, labels, and all kinds of records related to the quality system.
Quality management	The aspect of the overall management function that determines and implements the quality policy.
Quality manual	A document stating the quality policy, quality system, and quality practices of an organization. A document produced by a cooperator to describe the quality system in operation that satisfies the specifications of the quality assurance system.
Quality plan	A document setting out the specific quality practices, resources, and activities relevant to a particular product, process, service, contract or project.
Quality policy	The overall intentions and direction of an organization regarding quality, as formally expressed by top management.
Quality surveillance	The continuing monitoring verification of the status of procedures, methods, conditions, products, processes and services and the analysis of records in relation to stated references to ensure that requirements for quality are being met.
Quality system	The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.
Quality system review	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.
Record	Any written or printed findings or results pertaining to design, inspection, testing, reviewing, surveying, reviewing or other observations related to the quality system.
Review	A planned, independent, and documented assessment to determine whether agreed-upon requirements are being met. An review.
Review program	The organizational structure, commitment, and documented methods used to plan and perform reviews.
Review standard	The authentic description of essential characteristics of reviews that reflects current thought and practice.
Review team	The group of individuals conducting a review under the direction of a team leader.
Reviewer	The individual who carries out the review. A person who is trained and designated to perform reviews of documented quality assurance systems. An reviewer.

Reviewing organization	A unit or function that carries out reviews through its employees. This organization may be a department of the cooperator, a client, or an independent third party.
Survey	An examination for some specific purpose; to inspect or consider carefully; to review in detail. (Note: some authorities use the words “review” and “survey” interchangeably. “Review” implies the existence of some agreed-upon criteria against which the plans and execution can be checked. “Survey” implies the inclusion of matters not covered by agreed-upon criteria.)
Testing	A means of determining an item’s capability to meet specified requirements by subjecting the item to a set of physical, chemical, environmental or operating actions and conditions.
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.
Verification	The act of reviewing, inspecting, testing, checking, or otherwise establishing and documenting whether items, processes, services, or documents conform to specified requirements.

