not limited to, QAPs developed using the following standards and codes: ASME NQA-1, ASME Boiler and Pressure Vessel Code Section III, ISO 17025, and ISO 9001. Part IV of NQA-1 provides comparisons of some other standards with NQA-1 to facilitate the evaluation of certificates. Certificates issued to standards other than NQA-1 should be evaluated to understand the differences in requirements and define actions necessary to address those differences affecting the purchase. A third party certificate issued specifying that the supplier's QAP is based on NQA-1 should be the most useful as evidence that it conforms to NQA-1.

303 Facility Survey

Evaluate the Supplier's technical quality capability, which is determined by a direct evaluation of his facilities and personnel, and the implementation of his quality assurance program.

400 BID EVALUATION

The bid evaluation should consider the following performance and schedule considerations, which have the potential to affect the procurement quality:

(a) Supplier's personnel
(b) Supplier's production capability
(c) Supplier's past performance
(d) Supplier's alternates and exceptions

500 PURCHASER/SUPPLIER COMMUNICATIONS

Depending on the complexity or scope of the item or service, the Purchaser may initiate preaward and postaward activities. These activities may take the form of meetings or other communications to establish that the Supplier understands the procurement requirements; the intent of the Purchaser in monitoring and evaluating the Supplier's performance; and the planning and manufacturing techniques, tests, inspections, and processes to be employed by the Supplier in meeting procurement requirements. When Purchaser notification points, including hold and witness points, are required, they should be identified at this time. The depth and necessity of preaward and postaward communication depend on the uniqueness, complexity, and frequency of procurement with the same Supplier, and past Supplier performance for the specific items or services covered by the procurement document.

600 CONTROL OF CHANGES IN ITEMS OR SERVICES

601 Bid Evaluation Changes

Changes agreed upon by the Purchaser and Supplier during the bid evaluation process should be incorporated into a revision of the appropriate procurement documents.

602 Control of Changes

Changes to procurement documents should be subject to the same level of controls utilized for their development, except for editorial, price, delivery, or other minor changes that do not affect technical or quality requirements.

603 In Process Control of Deviations

Supplier-generated requests for deviations, changes, or exceptions to procurement documents should be controlled in accordance with para. 702 of this Subpart. The Purchaser should evaluate the need to maintain agreement between the procurement documents, and approved Supplier and Purchaser changes.

700 PRODUCT ACCEPTANCE

Among the methods used in the nuclear industry to accept an item or service from a Supplier are source verification, receiving inspection, Supplier Certificate of Conformance, postinstallation test at the nuclear power plant site, or a combination thereof.

701 Source Verification

Acceptance by source verification may be most desirable when the item or service is one of the following:

(a) vital to plant safety
(b) difficult to verify quality characteristics after delivery
(c) complex in design, manufacture, and test

Source verification may not be necessary when the quality of the item can be verified by review of test reports, inspections upon receipt, or other means.

The source verification activities may include the following checks.

701.1 Documentation has been submitted as required and provides verification of approvals, material, applicable inspections, and tests.

701.2 Fabrication procedures and processes have been approved and complied with and the applicable qualifications, process records, and certifications are available.

701.3 Components and assemblies have been inspected, examined, and tested as required and applicable inspection, test, and certification records are available.

701.4 Nonconformances have been dispositioned as required.

701.5 Components and assemblies are cleaned, preserved, packed, and identified in accordance with specified requirements.

702 Receiving Inspection

Acceptance solely by receiving inspection should be considered only when the items or services are as follows:

(a) relatively simple or standard in design, manufacture, and test

(b) adaptable to standard or automated inspections and/or tests of the end product to verify quality characteristics after delivery

(c) such that receiving inspection does not require operations that could adversely affect the integrity, function, or cleanness of the item

703 Certificate of Conformance

In certain procurement actions that do not involve source verification by the Purchaser, the Purchaser may accept an item or service from a Supplier based on a receiving inspection and a Supplier's Certificate of Conformance stating that the specified requirements have been met. However, specific supplemental documentation, such as material certificates or reports of tests performed, may be required by procurement documents. Acceptance by this method is satisfactory when the item or service is of simple design and involves standard materials, processes, and tests. Such items may be fabricated subject to selected qualification, sample, or batch testing to establish or maintain maximum quality.

704 Postinstallation Testing

Acceptance by postinstallation test is satisfactory when performed following the accomplishment of at least one of the preceding methods and when

(a) it is difficult to verify the quality characteristics of the item without it being installed and in use

(b) the item requires an integrated system checkout or test with other items to verify its quality characteristics or

(c) the item cannot demonstrate its ability to perform its intended function except when in use

705 Determining Authenticity

Measures to ensure products are authentic and reduce the risk of introducing counterfeit or fraudulent items include

(a) procedures for detection and prevention of counterfeit and fraudulent items

(b) instructing staff on the issue of counterfeit and fraudulent items and providing information on incidents of suspected counterfeit items that have been received or experienced by others

(c) purchasing items directly from the manufacturer or an authorized manufacturer's distributor/representative

(1) confirming with the manufacturer or via other independent means that the item supplier is currently authorized by the manufacturer for the scope or type of item to be provided

(2) requiring additional receipt inspection for items being procured from a source other than the item manufacturer or the manufacturer's authorized distributor/representative

(d) inspecting items upon receipt for signs of potential counterfeiting or fraud. Inspections should include the following checks for indications that the item may not be authentic:

(1) nameplates, labels, and tags for signs of alteration, which can be an indication that items may not be authentic

(2) obvious attempts at beautification

(3) evidence of hand-tool marks on fasteners and other parts of an assembly

(4) use of dissimilar parts in the same application

(5) poor fit between assembled items

(6) evidence of handmade parts

(7) software identifiers, such as version numbers that do not match

(e) processing of returned items, including the following:

(1) inspection and screening for authenticity

(2) rejecting returns of items in quantities greater than those originally purchased by the customer

(f) when an item suspected of being counterfeit or fraudulent is identified, measures including segregation and control of the suspect item as nonconforming material

SUBPART 3.1-10.1
Implementing Guidance for Part I, Requirement 10: Inspection

100 GENERAL

This Subpart provides nonmandatory guidance on the inspection, monitoring, and in-service inspection activities as specified in Requirement 10 of Part I.

(19) 200 INSPECTION AND PROCESS MONITORING

When inspection and process monitoring are used, they should be performed in a systematic manner to ensure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process.

Controls, where required, should be established and documented for the control and sequencing of these activities at established inspection points during successive stages of the conducted process or construction.

When process monitoring is used for the acceptance method it should be performed by personnel who are not directly responsible for performing the process operation consistent with Part I, Requirement 10, section 100.

300 IN-SERVICE INSPECTION

Inspection methods should be established and executed to verify that the characteristics of an item continue to remain within specified limits. Inspection methods should include evaluations of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.

SUBPART 3.1-15.1
Implementing Guidance for Part I, Requirement 15: Control of Nonconforming Items

(19)

100 GENERAL

This Subpart provides nonmandatory guidance on control of nonconforming items as specified in Part I, Requirement 15. The guidance in this Subpart is limited to nonconforming items (e.g., material, parts, or components). Figure 100 depicts a representative nonconforming item process as described in this Subpart.

Nonconforming items should be evaluated to determine the extent to which the nonconformance represents a condition adverse to quality as defined under condition adverse to quality in Part I, Introduction and described in Part III, Subpart 3.1-16.1.

200 IDENTIFICATION

Unless otherwise specified in the governing procedure or instruction, an item should no longer be considered in-process when it is presented to the entity responsible for performing independent inspection or there is no means by which the requirement(s) of the item can be met.

As maintenance consists of actions necessary to maintain or restore an item to acceptable conditions, degradations, discrepancies, and failures of an item(s) discovered during the performance of maintenance activities at an operating nuclear facility should be controlled and documented by Part II, Subpart 2.18.

201 Validation

Methods for identifying nonconforming items are identified as described in Part I, Requirement 15. Nonconforming items should be evaluated for validity by the appropriate authority(ies) under the quality program. If the basis for a nonconformance is determined to be invalid, the originator should be notified.

202 Evaluation

When a nonconforming condition is identified, prompt notifications should be made to potentially affected personnel/organizations. The seriousness of the situation should drive the urgency of the notifications. Notifications should include, as applicable and appropriate, the area work supervisor, the organization owning the item, the purchasing organization, regulatory or oversight organizations, and others who may be impacted by the nonconforming condition. Although an evaluation of extent of condition is not required by Part I, Requirement 15, Part I, Requirement 16 applies to conditions adverse to quality, including nonconforming items. See Part III, Subpart 3.1-16.1 for further guidance on extent of condition. The use of an individual item may proceed after the requirements of Part I, Requirement 15 have been satisfied; cause evaluation and corrective action as described in Part I, Requirement 16 may be conducted separately.

300 SEGREGATION

Where physical segregation is impractical or impossible, alternate methods may be used, such as electronic processes that control further processing, delivery, installation, or use of nonconforming items.

400 DISPOSITION

401 Allowable Use and Documentation of Preapproved Reject or Rework Process

Some construction, manufacturing, and fabrication activities may result in the identification of typical nonconforming items. These nonconforming items may be corrected as part of preapproved work-control processes that implement appropriate quality assurance requirements. These processes (e.g., procedures and work instructions) should include requirements for identifying, documenting, and either reworking or rejecting, as appropriate, these nonconforming items as part of the work process in a manner that permits evaluation or trending on a periodic basis. (See Part III, Subpart 3.1-16.1, para. 309 for further guidance on trend analysis.)

(a) When a nonconformance is identified and rejected within an approved work process, the procedures or work instruction should define the type(s) of reject actions that may be conducted and the instructions for completing the rejections, e.g., items found to be nonconforming during receipt inspection.

(b) When a nonconformance is identified and reworked within the approved work process, the procedures or work instruction should define the type(s) of rework that may be conducted and the instructions for completing the rework. The work process should

document rework and evaluation of the process to the acceptance requirements. The following are examples of nonconforming items that may be corrected within the work process, provided the rework process has been approved implementing appropriate quality assurance requirements:

(1) welds with unsatisfactory inspection or nondestructive examination results to predetermined criteria that can be reworked in accordance with a preapproved welding process (e.g., in such situations as excessive undercut, undersized weld, linear indication, lack of penetration, arc strikes, or scratches)

(2) fabricated components with unacceptable dimensional inspection results that can be reworked in accordance with a preapproved work process

(3) surfaces with improper preparation for coating application identified within the process that can be recoated in accordance with a preapproved work process

(4) parts with unacceptable cleanliness inspection results that can be reworked within a preapproved work process

(5) equipment with conditions or problems identified during tests (equipment functional and preoperational testing problems) that can be corrected within the approved test plan

In cases where in-process correction fails to restore the item to the acceptance standards, the nonconforming item should be identified and processed as described in para. 402 of this Subpart.

402 Disposition Control, Documentation, and Closure

Nonconforming items that cannot be corrected as part of the preapproved reject or rework process as described in para. 401 should be documented, e.g., Nonconformance Report (NCR), Condition Report (CR), etc., and processed in accordance with Part I, Requirement 15.

Documentation of nonconforming items should include sufficient information to identify the nonconformance, disposition, and means to record completion of nonconformance disposition. Documentation should include the following information as applicable (authentication is as described in Part I, Requirement 17):

(a) Identify the nonconformance traceable to the item.

(b) Describe the nonconformance.

(c) Reference the requirement that was not met.

(d) Name the identifier and the date identified.

(e) Authenticate the validation of the nonconformance by an appropriate authority.

(f) Describe the means of segregation.

(g) Evaluate the contractual reporting requirements.

(h) Propose a disposition of the nonconformance (i.e., use-as-is, repair, rework, reject).

(i) For repair or rework dispositions, describe the work process or instructions to be performed.

(j) For a repair or use-as-is disposition, a technical justification including applicable design control measures should be developed, documented, and authenticated by the responsible organization.

(k) Approve and authenticate the disposition by the responsible organization(s).

(l) Once the item has been reworked or repaired, document and authenticate the results of the reexamined item.

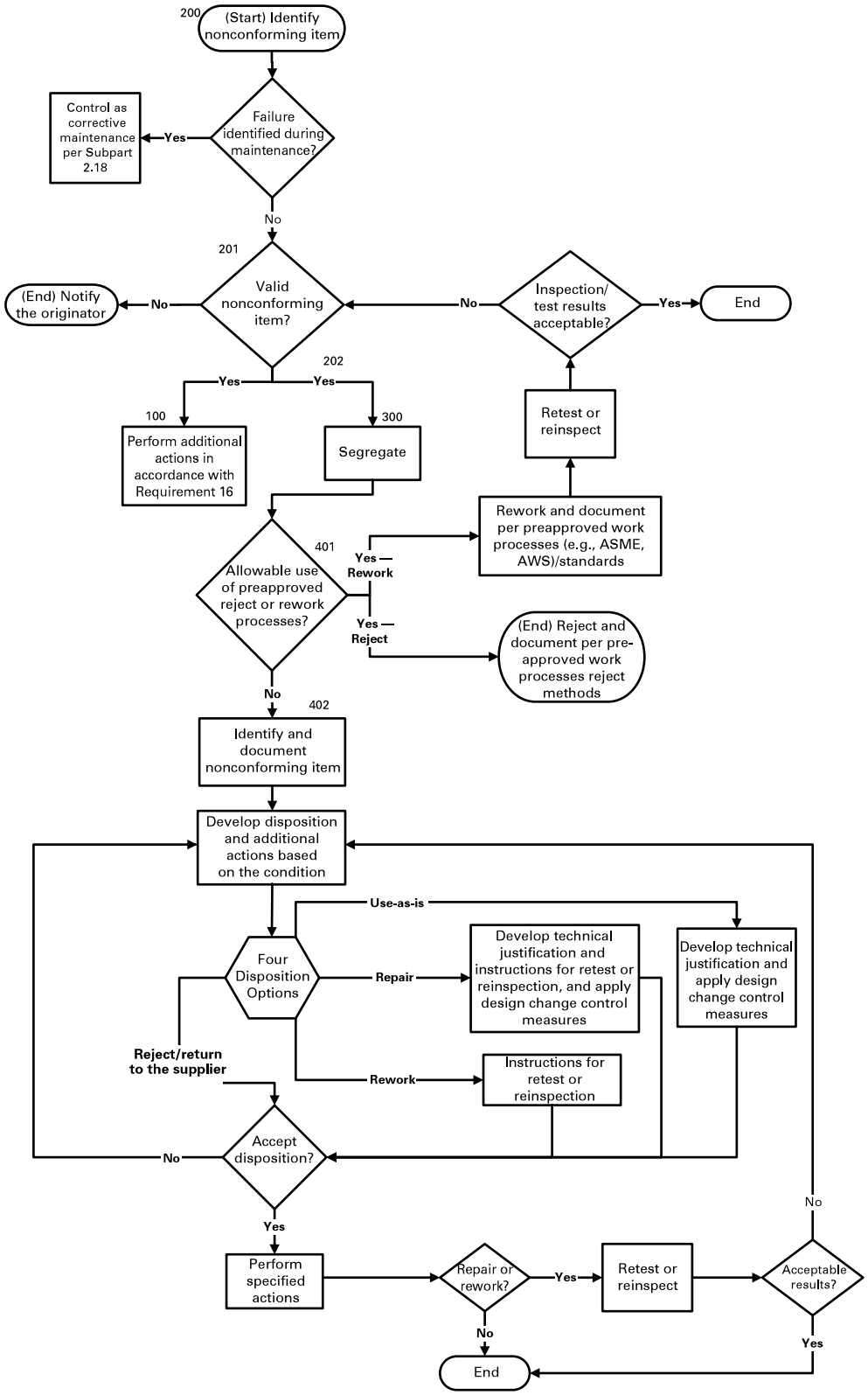
(m) For use-as-is or repair dispositions, update and authenticate appropriate records, e.g., as built drawings and design documents.

(n) Authenticate the verification of closure activities.

Once the authentication of a valid nonconformance is documented, the document should be controlled and protected.

(19)

Figure 100 Nonconforming Item Process Chart



SUBPART 3.1-16.1
Implementing Guidance for Part I, Requirement 16: Corrective Action

100 GENERAL

This Subpart provides nonmandatory guidance on corrective action as specified in Requirement 16 of Part I. While conditions adverse to quality are required to be identified promptly and corrected as soon as practicable, Requirement 16 also calls for a response to conditions adverse to quality appropriate to their significance.

(19) 200 CORRECTIVE ACTION

Corrective action should be integrated into all aspects of the quality assurance program. It consists of the following basic elements:

(a) identification and documentation
(b) significance classification
(c) report to management
(d) determination of extent of condition
(e) cause determination
(f) corrections
(g) follow-up
(h) effectiveness review
(i) closure
(j) trend analysis

Corrective action activities should be documented in a manner that permits the review, verification of implementation, and verification of effectiveness of these activities.

(19) 300 BASIC CORRECTIVE ACTION ELEMENTS

This section provides additional guidance on the basic elements of corrective action processes. Figure 300 depicts a representative corrective action process as described in sections 300 and 400 of this Subpart.

301 Identification and Documentation

Conditions adverse to quality (see definition in Introduction) should be promptly identified, documented, and corrected.

Where conditions adverse to quality have been identified, the extent to which other items and activities may be affected should be evaluated so that appropriate action may be taken, including measures to control any affected work in process, if necessary.

The extent of the condition may be identified by internal or external organizations and may include documentation resulting from audits, inspections, tests, design reviews, individual observations, operational events, maintenance activities, and other information that could indicate conditions adverse to quality.

302 Classification

302.1 Criteria for classifying conditions and trends adverse to quality as to significance should be established and, as a minimum, as conditions adverse to quality and significant conditions adverse to quality. Classifying the conditions should consider the following:

(a) impact on health and safety of the public, workers, or the environment

(b) impact on reliability, availability, or maintainability, or safety function of the equipment or facility

(c) impact and likelihood of not meeting regulatory requirements

(d) repetition of specific conditions adverse to quality and the consequence of recurrence, as well as the relationship or similarity between different adverse conditions and causes

(e) the extent to which the adverse condition or cause may apply to and impact other items or activities beyond the specific occurrence or work in progress

302.2 Conditions adverse to quality identified under para. 301 of this Subpart should be classified according to significance using the established criteria. Examples of conditions that may be significant under certain conditions include

(a) deficiencies in design, manufacturing, construction, testing, or process requiring substantial rework, repair, or replacement

(b) damage to a structure, system, component, or facility requiring substantial rework, repairs, or replacement

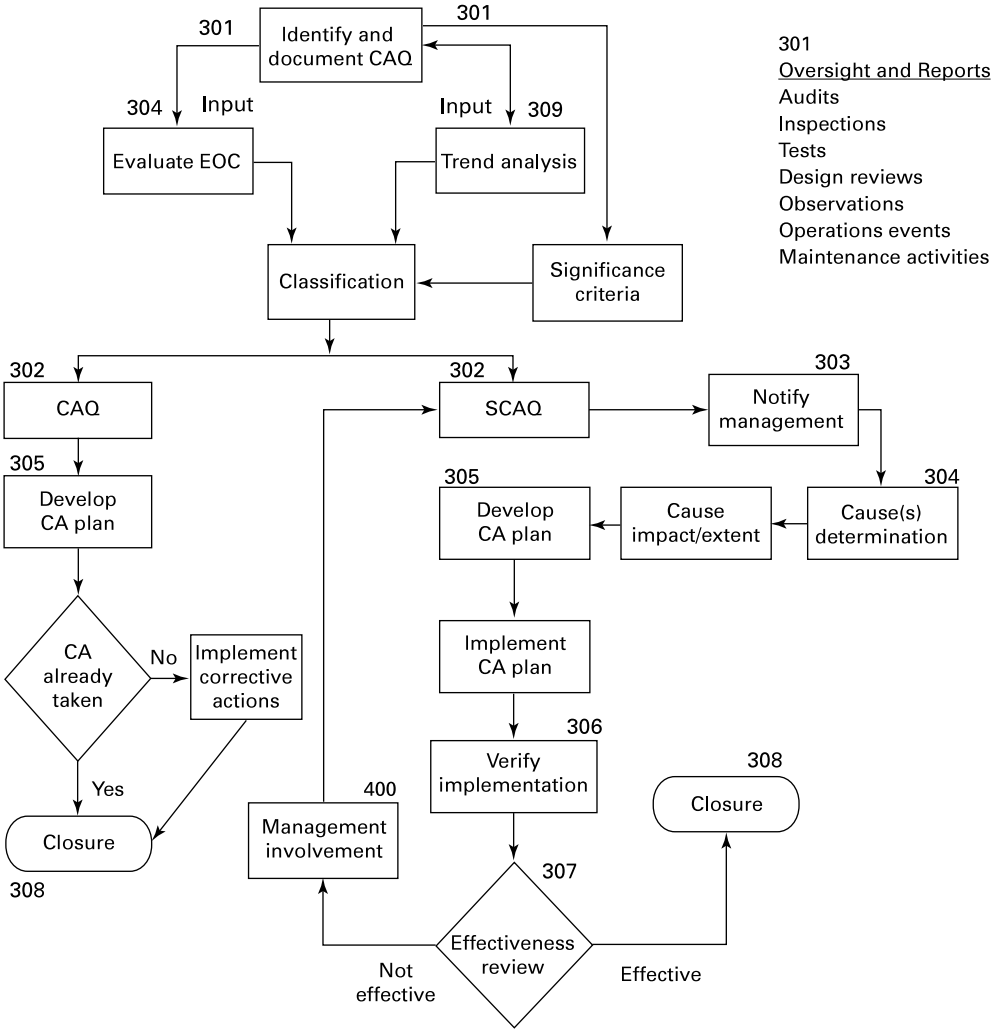
(c) a nonconservative error detected in a computer program after it has been released for use that impacts the criteria of paras. 302.1(a) through (d)

(d) the loss of essential data

(e) repeated failures to implement approved procedures, quality program documents, or technical requirements documents

(19)

Figure 300 Corrective Action Process Chart



GENERAL NOTE: CA, Corrective Action; CAQ, Condition Adverse to Quality; EOC, Extent of Condition; SCAQ, Significant Condition Adverse to Quality.

303 Report to Management

Significant conditions adverse to quality should be promptly reported to appropriate levels of management.

304 Cause Determination

The cause(s) (including apparent, contributing, and root causes based on the significance of the condition) should be identified and used to determine the action(s) necessary to correct the condition reported and preclude recurrence. Causes, corrective action(s), and follow-up action(s) should be documented.

Cause analysis should be conducted and may include apparent, contributing, and root causes based on the significance of the condition. An extent of condition should be performed, and the impact of such conditions on completed and/or related items and activities should be evaluated. The causes, corrective action(s), and follow-up action(s) should be documented.

At a minimum, methods and measures should be developed for determining the root cause(s) of significant conditions adverse to quality. Typical root cause categories may include

(a) inadequate management or supervision

(b) inadequate human performance capability or skill

(c) procedure inadequacy or error

(d) inadequate training or qualification of personnel performing work

(e) equipment or processing malfunction, inadequacy, or misuse

(f) inappropriate, self-imposed requirements or acceptance criteria

(g) unrealistic schedules that adversely impact safety or quality
(h) worker fatigue
(i) latent organizational or equipment issues
(j) safety culture impacts

305 Corrective Action Plan

The remedial action(s) should be determined, documented, and promptly implemented. The overall roles and responsibilities for implementation of corrective actions should be identified and documented. For significant conditions adverse to quality, action(s) necessary to eliminate the cause(s) should be implemented to preclude recurrence.

Where corrective or preventive measures have already been completed to address conditions adverse to quality, based on design, nonconformance, or audit program elements, further action is not required unless the conditions are judged to be significant or are determined to be ineffective. The analysis to determine the action(s) to be taken to preclude recurrence of significant conditions adverse to quality may include studies, simulations, investigations, experimentations, trending, and personnel interviews. The analysis and identified actions should be documented and may include

(a) identification of action to preclude recurrence
(b) a determination that generic implications have been considered
(c) a determination that action taken will preclude recurrence

306 Verification of Implementation

Corrective action status should be monitored. Corrective action and implementation should be verified as complete only when the actions to correct the significant condition adverse to quality, including actions to preclude recurrence, are complete and documented. When completion of corrective action cannot be promptly verified due to an extended delay from the responsible organization, modification of the original schedule and communication to the affected organization(s) should be made. Compensatory (interim) measures may be identified and implemented to allow for work activities to proceed under controlled conditions.

307 Effectiveness Review

After verification of completion of corrective action for significant conditions adverse to quality, effectiveness reviews, surveillance, or supplemental audits should be performed to determine whether actions taken have been and continue to be effective. When corrective actions have not been effective, further analysis should be performed to identify and correct the cause. In addition, the problem should receive escalated management attention.

308 Closure

After the corrective action(s) have been implemented, the corrective action(s) should be closed. For significant conditions adverse to quality, closure should not occur until after corrective action(s) have been determined to be effective in accordance with para. 307 of this Subpart.

309 Trend Analysis

Conditions adverse to quality should be reviewed periodically to determine the existence of adverse trends and repeat occurrences. Trends should be evaluated in a manner and at a frequency that ensures that significant adverse trends are identified promptly and evaluated in accordance with para. 301 of this Subpart.

400 MANAGEMENT INVOLVEMENT (19)

Appropriate levels of management should be involved in the corrective action process, and their roles and responsibilities should be documented.

500 PROCESS CHART

Figure 300 depicts the flow of activities through the basic elements described in sections 300 and 400 of this Subpart. The logic process illustrates a typical corrective action program and is provided for guidance and illustration only.

SUBPART 3.1-16.2
Implementing Guidance for Part I, Requirement 16: Trend Analysis

(19)

100 GENERAL

This Subpart provides nonmandatory guidance on trend analysis of conditions adverse to quality and other indications of quality. This guidance intends to aid in the prompt identification and correction of conditions adverse to quality that may not be readily apparent without a more thorough analysis. The guidance includes information on data collection methods, cause coding, trend thresholds, analysis frequency, reporting, and actions to address adverse trends. This guidance is not related to identifying metrics, collecting performance data, and determining trends related to process improvements in manufacturing or system performance.

Implementation of a process to evaluate assessment reports, issues, and conditions adverse to quality increases the probability of identifying conditions adverse to quality that otherwise may remain undiscovered.

200 DEFINITIONS

The following terms are used in this Subpart.

adverse trend: conditions adverse to quality that are of a repetitive nature and/or number that exceeds an established criteria or threshold, taking into consideration time frames and significance levels. General examples include

(a) recurring conditions adverse to quality that appear to be related to a common cause, or are of a like nature and are identified in multiple work activities

(b) increasing number of conditions adverse to quality that are not expected because of new or special work programs or increased quality verification activities

(c) conditions adverse to quality that are of a programmatic nature and apparently not limited to a specific organization

trend: a variable's tendency over time to increase, decrease, or remain unchanged; a pattern of events, incidents, items, activities, processes, corrective actions, or causes reflected by corrective action program data, reported nonconformances, and/or other applicable quality data. A trend could be either negative or positive.

trend analysis: a process to detect recurrence of conditions adverse to quality, as well as the relationship or similarity between different conditions in order to assure adverse trends that could result in a significant condition adverse to quality are identified and evaluated for appropriate correction (NEI 08-02).

300 TRENDING PROGRAM

A trending program should be developed and implemented to identify adverse trends or issues significant to quality (such as repetitive failures or process weaknesses). This review should be conducted to identify generic issues and vulnerabilities before significant problems result. Management personnel responsible for the work activities should be responsible for identification of thresholds for trending to determine the presence of adverse trends, repetitive failures, process weaknesses, or other indicators of extent of cause or condition beyond the immediate problem identified. To identify patterns that warrant broad corrective actions, trending could also be accomplished using detailed codes and data analysis techniques for certain work processes.

Adverse trends should be reported to management responsible for the work process and documented in accordance with the organization's corrective action program. Management should provide oversight of the trending process to assure the process is properly implemented. Each organization that implements a trending program should develop process that addresses the following basic elements:

(a) Determine what quality data to collect and how to collect it.

(b) Using an organization-specific definition of trend, create thresholds or minimum/maximum values that require more detailed analysis to determine if a trend exists.

(c) Identify trend analysis expectations and reporting time frames.

(d) Define the trend analysis techniques; consider using root-cause analysis techniques and qualified analysts.

(e) Document procedural steps for the data collection and analysis process, and include the minimal information to include in trend analysis reports.

(f) Define steps to take upon identification of a potential or adverse quality trend, including allowing for more analysis before declaring that a potential trend is an adverse trend.

400 DATA COLLECTION

401 Program and Preparation for Effective Trending

The organizations responsible for trend analysis should take the following steps to develop a trending program:

(a) Determine the data to be trended. First determine what data are available by taking into consideration benchmarking, or consulting with other similar organizations/entities to identify potential data to collect.

(b) Identify data sources. Typical sources used in trend analysis processes are conditions adverse to quality, such as audit findings, corrective action reports, nonconformance reports, occurrences, and supplier issues. Other sources that may not specifically identify adverse quality items but could provide early indication of potential issues or future issues include independent and management assessment reports, work travelers, software trouble logs, and/or periodic reports to management (e.g., progress reports where information is provided to management on impediments to completing tasks).

(1) Although corrective action reports and nonconformance reports typically provide specific data on item or condition and may provide cause information, additional background information might need to be researched. Additional information such as location, organization, event or issue codes, and/or cause codes, can be helpful in sorting and evaluating information for trends. If this information is not available in a deficiency database (or similar), then a more detailed review of the deficiency reports is needed to collect this data for use in trending.

(2) Although the primary driver for trend analysis is for the discovery of adverse trends, review of data and the identification of potential positive trends may aid in determining corrective action effectiveness.

(3) Traditionally, trend data is based on audit findings, corrective action reports, and nonconformance reports. The review of assessment reports and similar reports may identify data that could be potential issues, such as observations and recommendations that do not, at the time, meet the definition of a finding/noncompliance but could provide insight into the implementation of a program and aid in determining adverse trends.

402 Data Collection Sources and Methods

Nonconformance reports, corrective action reports, audit findings, and similar issue systems are the typical resources of trend input data; however, information from other systems should also be considered (e.g., occurrence reports, health and safety issue reporting, test or inspection defect reports, assessment reports, and/or nontraditional issue information). A system of trend codes should be developed and disseminated to provide consistent and clearly defined sets of codes. Trend codes should include both cause codes and event codes. Since these codes are normally entered by a human, reassessment of the codes may be needed during trend analysis to ensure that the codes used are supported by the issue data.

Although raw information from these sources can be used in the trending process, providing additional information to aid in sorting the issues could result in a more effective and efficient trend analysis process. The following additional sorting categories should be considered:

(a) organization
(b) process/procedure
(c) locations
(d) dates/times

500 TREND ANALYSIS PROCESS

501 Graded Approach to Trending

One type or technique of trending may not be practical for all conditions or organizations. Therefore, a thoughtful approach to trending, which takes into consideration requirements and/or industry best practices, should be implemented by each organization performing trend analysis. Organizations developing a trend analysis program should consider a graded approach that considers risk as related to the formality of trend analysis performance, the identification of trends, and actions to be taken when potential and adverse trends are found.

502 Trend Analysis Staff and Teams

Analysts performing trending should have appropriate training and skills. In addition to understanding the trending process and procedures, personnel performing trending should have an understanding of the data being trended, corrective action processes, and cause-analysis techniques. Skills or training in statistics and Six Sigma processes may be useful.

503 Data Sorting and Categorization

Trend analysis should be performed on a regular basis, using consistent staff whenever possible, and supplemented as needed by subject matter experts. Consideration should be given to using analysis teams that include representatives from a standard set of disciplines or management representatives.

The end result of the quantitative and qualitative analysis of the data should be the confirmation that an adverse trend does or does not exist. When an adverse trend is identified, an analysis of its significance should