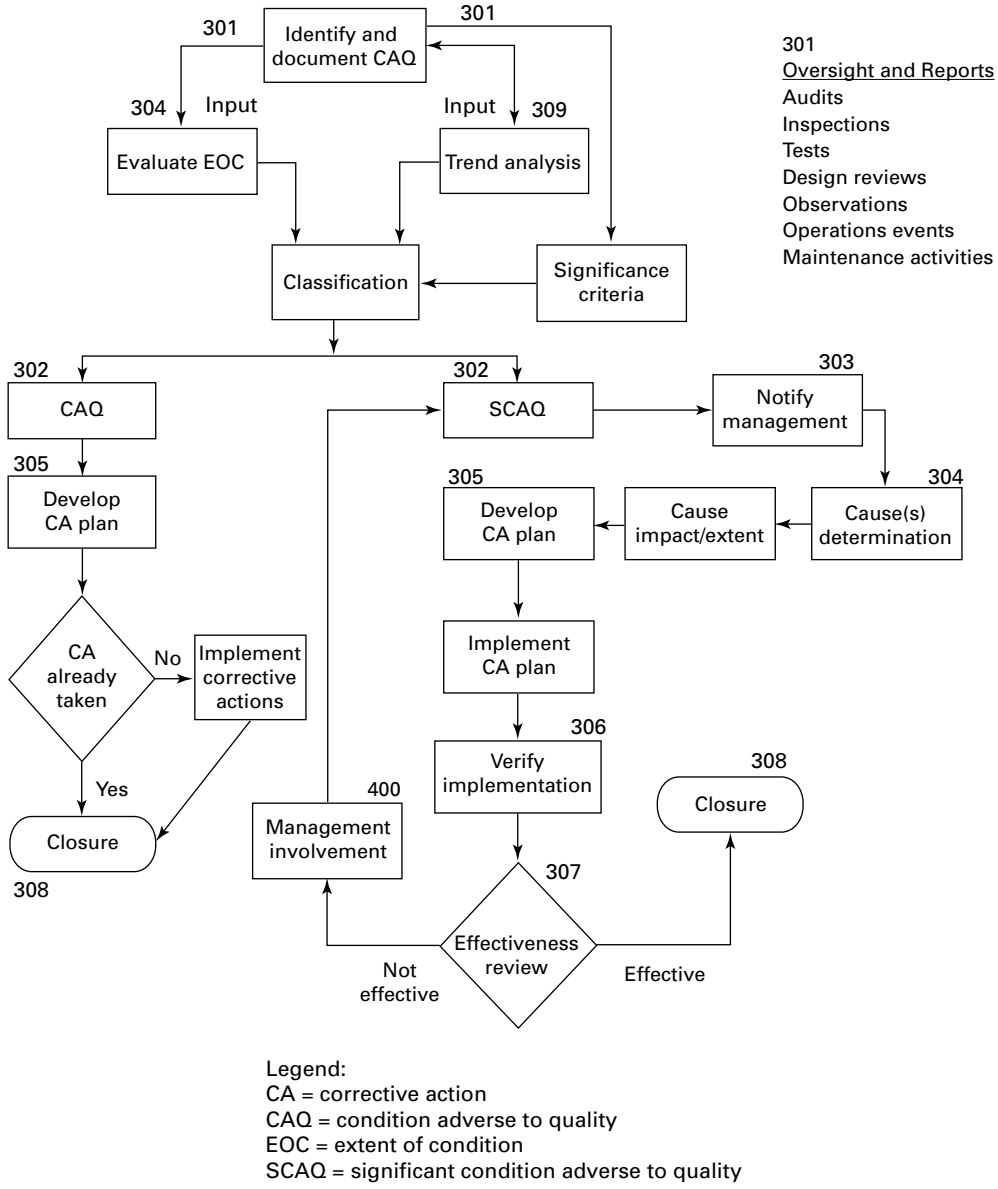
Figure 300
Corrective Action Process Chart



Legend:
CA = corrective action
CAQ = condition adverse to quality
EOC = extent of condition
SCAQ = significant condition adverse to quality

400 MANAGEMENT INVOLVEMENT

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 of this Subpart 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

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

be performed. Trend analysis may also identify potential trends requiring further investigation or continued monitoring.

(a) Analytic tools should be considered and used if appropriate. These tools include, but are not limited to, time-based reviews of data, histograms, Pareto charts, bar charts, statistical control charts, and trend charts.

(b) Trend charts compare the number of events over time. They could be used to measure the significance of performance (effectiveness) in a single point of time compared to the past, and to project future performance. Using a trend chart, the analyst could determine the impact of actions taken and whether corrective actions are effective. In evaluating trend charts, one must consider what variables may affect the number of events identified. If the definition of the event is changed or an activity has been added to increase the likelihood of identification and reporting, the trend results would be affected.

(c) A bar chart that displays trends by frequency or quantity, in descending order, would identify the most frequent defects. This chart-type would be used to identify whether the Pareto principle is evident in the data. A Pareto chart would be used to graphically summarize and display the relative importance of the differences between groups of data. In a Pareto chart, the analyst would graph the number of items (events, causes codes, facilities/operations/organizations) within a chosen grouping. Pareto charts could be used to visually display the major contributor to a grouping and help identify areas for further analysis.

(d) The data should then be reviewed to determine the presence of adverse or potential trends including

(1) repetitive issues, when taken collectively,

(-a) indicate a programmatic failure to properly implement the quality assurance program

(-b) may be precursors for a significant technical deficiency or problem

(-c) may reduce the margin of safety;

(-d) indicate programmatic and/or systemic issues or undesirable business risk

(2) recurrences of an event, failure, problem, or adverse condition that involves similar tasks, causes, and/or corrective actions that are significant in nature or are critical to the success of the activity as determined by management, including programmatic or systemic conditions

(3) an unacceptable or undesirable pattern (e.g., events, incidents, items, activities, processes, or causes) that is important to the degree that corrective action is deemed appropriate by management

Root cause analysis tools such as brainstorming, barrier analysis, and other cause analysis tools may be helpful in evaluating the data. The analyst should ensure that predefined trend thresholds are used in determining adverse or potential trends. Analysts or analysis teams should consider the importance of sorting data and ensuring it is reviewed at the appropriate level; not rolling up issues to such a high level that an adverse trend could not be found or so low that trends are apparent everywhere.

Trend program developers and analysts should also consider the importance of human involvement and not overly rely on cause and event codes. Human-involved cognitive analysis should be an important aspect of trending.

504 Trend Significance Analysis

Although analysts may identify adverse or potential trends as a result of their data reviews, determining the significance of the identified trends is important to help management, and those responsible for corrective action plans, to focus the appropriate resources on the identified adverse or potential trend. 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.

600 TREND REPORTING

601 Report Content

Identification of the minimum information to include in trend reports is important for the long-term continuation of the trending process. Information on the data used, the process used to determine trends, and general notes (trend determination rationale) on the results of analysis is important and should be included in trend reports so that future trend analysts have a base to understand past trend analysis. Minimum information should include the data used in the trend analysis, identification of potential trends, identification of confirmed trends, and identification of conditions adverse to quality generated as a result of trending. Identification of information that warrants further investigation or continued monitoring should also be considered.

602 Reporting Frequency

The frequency of analysis and reporting should be based on the size of the organization and the quantity of documented conditions adverse to quality or nonconformances. Some organizations may need to perform some level of trending on a monthly or quarterly basis, while other organizations may use a semiannual or annual frequency to effectively identify potential trends. Completion of the trending process and issuance of a trend report annually could be helpful as an input to the management assessment of the adequacy and effectiveness of the quality assurance program, as required by Part I, Requirement 2.

700 RECORDS

In addition to periodic trend reports, the program should define the records to be maintained that would be beneficial to personnel performing subsequent trend analysis, such as identification of potential trends, adverse trends, and discussion of methods used to evaluate trends; reference to corrective action documents; or other actions taken.

800 REFERENCES AND RECOMMENDED READING

DOE G 120.1-5, Guidelines for Performance Measurement
DOE G 231.1-2, Occurrence Reporting Causal Analysis Guide
Publisher: U.S. Department of Energy (DOE), 1000 Independence Avenue, S.W., Washington, DC 20585 (www.energy.gov)

EFCOG Guidance Document, Contractor Guide for Performance Analysis, Rev 0, April 8, 2008

EFCOG Guidance Document, Development and Use of Leading Indicators (February 1, 2011)
Publisher: Energy Facility Contractor's Group (EFCOG) (www.efcog.org)

INPO 09-011 (September 2009), Achieving Excellence in Performance Improvement
Publisher: Institute of Nuclear Power Operations (INPO), 700 Galleria Parkway, SE, Atlanta, GA 30339 (www.inpo.info)

NEI 08-02, Revision 3 Corrective Action Processes for New Nuclear Power Plants During Construction
Publisher: Nuclear Energy Institute (NEI), 1201 F Street, N.W., Suite 1100, Washington, DC 20004 (www.nei.org)

NSAC 119 (June 30, 1998), Guidelines for Analyzing and Trending Incidents in Nuclear Power Plants
Publisher: Electric Power Research Institute (EPRI), 3420 Hillview Avenue, Palo Alto, CA (www.epri.com)

SUBPART 3.1-17.1
Implementing Guidance for Part I, Requirement 17: Quality Assurance Records

100 GENERAL

This Subpart provides nonmandatory guidance on records as specified in Part I, Requirement 17 for records that are generated and maintained in an electronic format as addressed in Subpart 2.17. Management controls should address how records are identified, generated, authenticated, stored, maintained, and retained per an established records program. Organizations that generate and maintain quality assurance records in an electronic format should develop controls and associated procedures that address the unique capabilities and requirements of this technology. See Part III, Subpart 3.1-17.2 for electronic record processing guidance.

101 Generation of Records

Documents produced in or transformed to electronic format should be processed in accordance with Part II, Subparts 2.7 and 2.17. Documents that are designated to become records should be legible, accurate, and completed appropriate to the work accomplished so that they can be read, understood, and traceable to the associated items or activities. Documents produced in or transformed to electronic format should be processed in accordance with a defined process with software meeting quality assurance requirements commensurate with the software use.

Electronic records systems may be used to index and store electronic records but is not limited to electronic metadata. The records system content may contain an image in a sustainable format, e.g., Tagged Image Format (TIF), Portable Document Format (PDF), or an electronic address of the location where the image is stored. Controls should be in place to ensure that the record system is maintained.

102 Authentication of Records

Statements of authenticity, handwritten signatures, electronic signatures, or any other means that ensures traceability to a specific individual or organization of authentication and associated date are acceptable methods of authentication, such that the authentication provides positive identification to the individual or organization.

If initials or codes are used for identification, then a system should be established to ensure traceability to the authenticating individual or organization. The records program should provide methods for authenticating copies of original records when the original record is contaminated or lost and a copy of the original record is available.

103 Indexing

A cataloging scheme should be developed that is an index of information about each record that will aid in retrieval of the record and associated relevant retention information. The indexing can take many forms, including directories or listings. Indices should identify summary information for the records, such as the associated item or activity, title or description, originating individual or organization, retention period (lifetime or nonpermanent), location, and the media used for retention. For nonpermanent records, the period of retention should be defined.

104 Corrected Information in Records

When records are corrected, corrections should include the date and identification of the person authorized to issue such corrections.

105 Storage

A written storage procedure should be prepared and responsibility assigned for the implementing procedure. Storage procedures are suggested that include

(a) a description of the storage facility and/or electronic records system

(b) the filing methodology to be used

(c) a method for verifying that the records received are in agreement with the transmittal process and that the records are legible

(d) a method of verifying that the records are those designated

(e) the rules governing access to and control of the files

(f) a method for maintaining control of and accountability for records removed from the storage facility or electronic records system

(g) a method for filing supplemental information and disposing of records that have met retention requirements

106 Preservation and Safekeeping

To help ensure the preservation and safekeeping of records, the following should be considered:

(a) placement of physical records for storage in steel file cabinets or in suitable containers on shelving

(b) prevention of damage from environmental conditions

(c) manufacturer's recommendations on storage

(d) measures to preclude the entry of unauthorized personnel into the records system or storage area for protection from larceny or vandalism may include access lists, locked entry, attendant security, or a combination of these measures

(e) measures for replacement restoration, or substitution of lost or damaged records

(f) inspections of records to detect deterioration and ensure sustainability

107 Facilities and Containers

Current industry practices identify the use of two methods of providing storage facilities, single or dual.

(a) Single Facilities and Containers. NFPA-232 provides a set of methods that may be used for the storage of records in vaults, file rooms, or records protection containers. Where file rooms are used, an exception to NFPA-232 should be applied to permit forced air circulation system to be used, provided it is dampered in accordance with the room rating.

(b) Dual Facilities. If storage at dual facilities for either physical or electronic records is provided, the establishment of sufficiently remote storage facilities depends on the type of hazard, such as earthquakes, fires, tornadoes, loss of power, etc., and the probability for occurrence of these hazards.

108 Retrieval

A key function of a records system is to ensure that records are retrievable through their life cycle. Records maintained at a Supplier's facility or other location should be accessible to the Owner, Purchaser, or a designated alternate.

109 Records Transfer to Owner or Purchaser

Records accumulated at various locations, prior to transfer, should be made accessible to the Owner or Purchaser directly or through the procuring organization. For records transferred to the Owner or Purchaser, it is recommended that the Owner or Purchaser inventory the submittals, and acknowledge receipt.

Prior to transfer of the Supplier's records, the Supplier should consider the following:

(a) ASME Boiler and Pressure Vessel Code requirements are met

(b) regulatory requirements are satisfied

(c) operational requirements are satisfied

(d) warranty consideration is satisfied

(e) Owner's or Purchaser's requirements are satisfied

110 Record Destruction

Records may be destroyed once all retention requirements are met and in accordance with the records program, which should contain a record retention schedule, procedural guidance for obtaining final disposition approvals, and final record disposition mechanisms commensurate with the actual records index and computer program used.

The records program should have a means to suspend the destruction of specified information in the case of foreseeable, pending, or actual litigation or government investigation, commonly referred to as a legal or litigation hold.

A process should be established to destroy records to document required approvals, such as department owner, legal reviews, business needs, and the destruction.

200 LIST OF TYPICAL LIFETIME RECORDS

The following is a list of typical lifetime records categories and example record types or titles containing information meeting Part I, Requirement 17. Other records are also listed in Part I sections. The nomenclature of these may vary.

201 Design and Safety Basis Records

(a) applicable codes and standards used in design

(b) computer programs or corresponding mathematical model

(c) design drawings

(d) design calculations and record of checks

(e) approved design change requests

(f) design deviations

(g) design reports

(h) design verification data

(i) design criteria or design input data

(j) design specifications and amendments

(k) safety, hazards, and accident analysis reports

(l) stress reports for code items

(m) systems descriptions

(n) systems process and instrumentation diagrams

(o) technical analysis, evaluations, and reports

(p) software evaluation reports and acceptance test plans and reports

(q) computer program verification and validation data

202 Procurement Records

(a) procurement specifications

(b) purchase order and contracts (unpriced) including amendments
(c) evaluated supplier listing

203 Manufacturing Records

(a) applicable code data reports
(b) as-built drawings and records
(c) Certificate of Compliance
(d) inspection and test data
(e) heat treatment records
(f) location of weld filler material
(g) major defect repair records
(h) nonconformance reports
(i) performance test procedure and results records
(j) pipe and fitting location report
(k) pressure test results (hydrostatic or pneumatic)
(l) NDE final results or review/evaluation results
(m) welding procedures
(n) welder qualification reports
(o) certified material test report

204 Installation Construction Records

204.1 Civil

(a) check-off sheets for tendon installation
(b) concrete design mix reports, cylinder test reports, and charts
(c) concrete placement records
(d) inspection reports for channel pressure tests
(e) material property reports
(f) pile drive log and load test reports
(g) procedure for containment vessel pressure proof test and leak rate tests and results
(h) reports for periodic tendon inspection and testing
(i) subsurface investigation results
(j) embed as-builts

204.2 Welding

(a) test results
(b) heat treatment records
(c) NDE procedures
(d) material property records
(e) NDE final results or review/evaluation results
(f) weld location diagrams
(g) weld procedures
(h) welding qualification

204.3 Mechanical

(a) cleaning procedures and results
(b) code data reports
(c) installed lifting and handling equipment procedures, inspection, and test data
(d) lubrication procedures
(e) material properties records
(f) pipe and fitting location reports
(g) pipe hanger and restraint data
(h) pressure test results (hydrostatic or pneumatic)
(i) safety valve response test procedures
(j) NDE final results or review/evaluation results

204.4 Electrical and I & C

(a) cable installation procedures and results; pulling tension data, separation data, splicing procedures, and terminating procedures
(b) certified cable test reports
(c) relay test procedures
(d) voltage breakdown test results on liquid insulation

204.5 General

(a) as-built drawings and records
(b) final inspection reports and releases
(c) nonconformance reports, causal analysis, and trending
(d) specifications and drawings
(e) construction records

205 Preoperational and Start-Up Test Records

(a) power source procedures and results
(b) final system adjustment data
(c) pressure test results (hydrostatic or pneumatic)
(d) initial start-up heat procedures and results
(e) initial reactor/facility loading data, test procedures, and results
(f) instrument AC system and inverter test procedures and reports
(g) on-site emergency power source energizing procedures and test reports
(h) facility load ramp change data
(i) facility load step change data
(j) power transmission substation test procedures and results
(k) preoperational test procedures and results
(l) primary and secondary auxiliary power test procedures and results
(m) reactor/facility protection system tests and results
(n) start-up logs
(o) start-up test procedures and results
(p) station battery and DC power distribution test procedures and reports
(q) water chemistry report

206 Operation Records

(a) records and drawing changes identifying facility design modifications made to systems and equipment described in the Final Safety Analysis Report
(b) new and irradiated fuel/nuclear material inventory, fuel/nuclear material transfers, and assembly fuel/nuclear material-depletion history records
(c) off-site environmental monitoring survey records
(d) spent fuel/nuclear material shipment records
(e) facility radiation and contamination survey results

(f) radiation exposure records for individuals entering radiation control areas

(g) records of gaseous and liquid radioactive material released to the environs

(h) records of transient or operational cycles for those facility components designed for a limited number of transients or cycles

(i) training and qualification records for current members of the facility-operating staff

(j) in-service inspection records

(k) records of reviews performed for changes made to procedures or equipment, or reviews of tests and experiments

(l) surveillance activities, inspections, and calibrations required by the technical specifications records

(m) records of reactor/facility tests and experiments

(n) changes made to operating procedures

(o) low-level radioactive waste shipments records

(p) sealed source leak test results

(q) records of annual physical inventory of all sealed source material

(r) logs of facility operation covering time interval at each power level

(s) records and logs of maintenance activities, inspections, repair, and replacement of principal items of structures, systems, and components

(t) water chemistry reports

(u) operational, shift supervisor, and control room logs

(v) event reports

(w) fire protection records

(x) nonconformance/corrective action reports

(y) facility equipment operations instructions

(z) emergency plan and procedures

(aa) quality assurance and quality control manuals

(bb) applicable records noted in other sections of this Subpart for any modifications or new construction applicable to structures, systems, or components

(cc) evaluation of results of reportable safety concerns as required by regulations

(dd) annual environmental operating report

(ee) annual facility operating plan

(ff) records to support licensing conditions such as safeguards and special nuclear material accountability

(gg) results for in-use testing

207 Decommissioning and Destruction

(a) radiological survey results prior and during destruction

(b) waste container inspection and test reports

(c) waste packing inspection results

(d) nondestructive assay results for processed waste

(e) nonconformance reports

(f) waste form documentation and compliance certification

(g) waste labeling and tracking

(h) waste management record

SUBPART 3.1-17.2
Implementing Guidance for Part I, Requirement 17: Quality Assurance Records, Electronic Records

100 GENERAL

This Subpart provides nonmandatory guidance on records, as specified in Part I, Requirement 17 that are generated and maintained in an electronic format, as addressed in Part II, Subpart 2.17.

Organizations that generate and maintain quality assurance records in an electronic format should develop controls and associated procedures that address the unique capabilities and requirements of this technology. Electronic record controls should address how electronic records are identified, generated, authenticated, stored, and maintained per the required retention schedule. Part III, Subpart 3.1-17.1 also includes standard record processes that apply to all records regardless of format or medium and should be used in conjunction with this Subpart.[1],[2]

101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in this Subpart.

electronic signature: an electronic sound, symbol, or process, attached to or logically associated with a contract or other records and executed or adopted by a person with the intent to sign the record.

sustainable format: computer program file format that meets as many of the following criteria as possible:

(a) publicly and openly documented
(b) nonproprietary
(c) widespread use
(d) self-documenting
(e) can be opened, read, and accessed with readily available tools
(f) longevity of use and support is favorable

Examples of sustainable format are Tagged Image Format (TIF) or Portable Document Format (PDF).

200 AUTHENTICATION OF RECORDS

Provisions for the authentication of electronic records should provide for the use of automated systems for the identification and signature recognition of the personnel performing the record authentication.

201 Electronic Signatures

If electronic codes or user account information (e.g., username and password) is used for identification, controls should be established to ensure traceability to the authenticating individual or organization. Consideration should be given to periodically requiring the establishment of new user passwords. Methods for authenticating electronic records should meet applicable regulations and laws, such as the U.S. eSIGN law,[3] with electronic methods documented in applicable processes.

Electronic signatures based on biometrics should have a documented process to associate the initial biometric capture to the individual.

Electronic signatures that are not based on biometrics should employ at least two distinct verification components, such as user identification and password. Electronic signatures based upon biometrics should be controlled to ensure that they cannot be used by anyone other than the legitimate owners.

Digital signatures with public/private key technology are acceptable. Appropriate digital signature certificate authority use, unique user identification, information technology infrastructure, and file security controls to invalidate signature on change of file content are required.

The integrity of the records in the new system or media should be verified. It is recommended that a not easily alterable format be used to ensure that the content, context, and structure are maintained consistently with the original record copy. A sustainable format should be used commensurate with the retention period of the record.

When a record is converted to electronic media, the authentication of that record does not need to be reperformed.

[1] Adams Accession No. ML15099A561, Safety Evaluation of Duke Energy Carolinas, LLC — Amendment 40 to the Quality Assurance Topical Report.

[2] Adams Accession No. ML16194A323, Palo Verde Nuclear Generating Station, Units 1, 2, and 3 — Request to Change the Quality Assurance Program Description.

[3] Electronic Signatures in Global and National Commerce Act, Public Law 106-229.

300 GENERATION OF RECORDS

Electronic records may be generated using several different methods. These methods may include direct digital conversion from a source format to a sustainable record format, electronic data compilation, electronic mail, and records resulting from the conversion from one media type to another.

Electronic data designated to be records should be traceable or related to the associated items or activities. This can be accomplished by developing a naming scheme for both the electronic data itself and the media (e.g., file folders and CDs) that are used to store the electronic data.

301 Electronic Records Systems

The electronic records system consists of an electronic database and digital repository with the functionality to create and maintain human-readable, formatted electronic records and metadata.

Controls should be in place to ensure that the electronic records system establishes and maintains the electronic record content, context, and structure.

(a) The content is the digital file (image, text, graphics) in a sustainable format.

(b) The context is the metadata held within the file, such as the actual file properties, data fields, or tagged fields. The record file context may also be represented in the database table properties as data fields when the file lacks the rich metadata structure (e.g., image scans) or the records system does not have robust content searching capabilities.

(c) The structure is the file functionality needed to properly convey the content and context into a human-readable form and format.

Electronic mail may be used as a quality record if the controls provided in this Subpart are utilized. Electronic mail should be traceable to the subject of the record, originator, recipient(s), and date of origination. The information content and metadata contained in the electronic mail are acceptable as a record, provided that the electronic mail system prevents unauthorized alterations or changes. Corrections to e-mail should be processed in the same manner as the original and should amend/supplement the original record.

302 Conversion of Media

Conversion of a record from one media type to another should include verification to ensure that content, context, and structure are maintained. The conversion process includes conversion from/to various media forms, including hardcopy, photographic, optical, magnetic, or other media forms. The conversion process may involve scanning the original hardcopy record to create digital content in a sustainable record format. The conversion may include methods for converting scanned text to searchable formats (e.g., optical character recognition).

Verification should include reviews of the page, paragraph, and individual record configuration to ensure such information adequately represents the original document. This also applies to the situation where an electronic record is the original. When the conversion involves an electronic migration, a statistically valid sample set should be selected for verification purposes. Any recognized sampling standard that provides requirements for inspection and acceptance sample size may be used as a basis for the development of a sample set verification plan. To prevent data corruption or loss during the conversion process, the records program owner should approve any changes to the database context or structure.

303 Indexing Records

Electronic records should be indexed to provide for the timely retrieval of the record. Organizations should develop and document external and/or internal indexing methods using standard nomenclature for the index system(s).

External indexing includes the labeling of records stored on external off-line media. External labeling should be developed and attached to the media used. For example, magnetic tapes should include the recording density, number of tracks, block size, types of internal labels, and if the tape is part of a multi-reel set. Internal indexing of electronic records should enable the user to identify and access a specific record by using a table of contents, directory, metadata (e.g., record identifier, key word, etc.), or other index strategy. In some cases, the index may be automatically created by the system, while in other cases, the originator may generate it.

400 RECEIPT CONTROL OF RECORDS

Part I requirements for receipt controls remain applicable for electronic records; however, additional transfer processes utilizing automated methods may also be utilized.

The records submittal and receipt process may be entirely electronic using, but not limited to, the following methods:

(a) record-by-record processing using human interaction to place records into records system where some indexing functions are automated

(b) record-by-record processing using computer program transfer based on completion of source documents in source system, e.g., specified data field capture in an XML file that will pair index data with the record content file that is ingested into the records system

(c) workflow process output to records system, e.g., document approval workflow using electronic or digital signatures and e-mail capture and ingestion into the records system using rule-based processes