

AMERICAN NATIONAL STANDARD

ASQ/ANSI E5:2020

Quality principles and practices for nonnuclear energy facilities

Prepared as an American National Standard by:
ASQ Energy and Environmental Division and ASQ Standards Committee



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An American National Standard approved August 6, 2020

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Contents

1. PURPOSE	14
2. SCOPE	14
3. APPLICABILITY	14
4. PRECEDENCE	15
5. DEFINITIONS	15
6. ABBREVIATIONS	17
7. ROLES AND RESPONSIBILITIES	17
8. KNOWLEDGE AND SKILLS	17
9. POLICIES	17
10. ADMINISTRATIVE AND TECHNICAL PROCESSES	17

GENERAL

11. PROCESS RISK MANAGEMENT	21
12. PROCESS DESCRIPTION DOCUMENT REVIEW	23
13. PROCESS DESCRIPTION DOCUMENT ISSUANCE	25
14. PROCESS DESCRIPTION DOCUMENT DISTRIBUTION	25

15. PROCESS DESCRIPTION DOCUMENT IMPLEMENTATION	25
16. PROCESS VERIFICATION	25
17. PROCESS VALIDATION	26
18. PROCESS PERIODIC REVIEW	28
19. PROCESS CHANGE MANAGEMENT	29
20. SOFTWARE / FIRMWARE	30
21. TRAINING	38
22. FIRE SAFETY	42
23. SECURITY	43
24. CHEMICAL CONTROL	45
25. DRUM CONTROL	47
26. WASTE MINIMIZATION AND WASTE MANAGEMENT	48
27. EMERGENCY PREPAREDNESS AND RESPONSE	53
28. MEASUREMENT	55
29. ACCEPTANCE INSPECTION, TEST, NDE, AND PSI AND ISI	58
30. QUALITY STATUS	60

31. REGULATORY REQUIREMENTS	61
32. PROCESS PERFORMANCE EVALUATION	61
33. AUDIT	61
34. ORGANIZATIONAL SELF-ASSESSMENT	65
35. PROCESS PERFORMANCE MEASUREMENT	68
36. MANAGEMENT REVIEW	69
37. EMPLOYEE CONCERNS	70
38. CONDITION REPORTING, INVESTIGATION, ANALYSIS AND CORRECTIVE ACTION	70
39. RECORDS	75
40. DATA ATTRIBUTES	77
41. CONTINUOUS IMPROVEMENT	78
42. NEW BUSINESS PROPOSALS	79
43. CUSTOMER AND CLIENT REQUIREMENTS	79

DESIGN

44. DESIGN ENGINEERING PROCESSES	79
45. DESIGN ENGINEERING PERSONNEL EDUCATION AND TRAINING	79

46. GENERAL DESIGN REQUIREMENTS	80
47. HARDWARE ITEM, EQUIPMENT AND SPECIALTY TOOLS DESIGN REQUIREMENTS	80
48. WEATHER AND CLIMATE DESIGN REQUIREMENTS	82
49. GROUND MOVEMENT DESIGN REQUIREMENTS	83
50. SUBSURFACE DATA COLLECTION DESIGN REQUIREMENTS	83
51. SOILS AND EARTHWORK DESIGN REQUIREMENTS	84
52. CONCRETE DESIGN REQUIREMENTS	84
53. PILES AND CAISSONS DESIGN REQUIREMENTS	87
54. STRUCTURES DESIGN REQUIREMENTS	88
55. GENERAL CONSTRUCTION DESIGN REQUIREMENTS	89
56. LIFTING, HOISTING AND JACKING DESIGN REQUIREMENTS	90
57. ENVIRONMENTAL, GENERAL	91
58. ENVIRONMENTAL, AIR	91
59. ENVIRONMENTAL, WATER	92
60. ENVIRONMENTAL, FUEL	92
61. ENVIRONMENTAL, LAND MANAGEMENT (INCLUDING VEGETATION AND ANIMAL MANAGEMENT)	93

62. CALCULATIONS	95
63. CALCULATION DOCUMENT APPROVAL	97
64. CALCULATION CHANGE	97
65. SUPPLIER CALCULATIONS	98
66. HARDWARE ITEM, EQUIPMENT AND SPECIALTY TOOL RISK MANAGEMENT	98
67. RELIABILITY	99
68. MAINTAINABILITY	99
69. AVAILABILITY	100
70. DESIGN REVIEW	100
71. DESIGN DOCUMENT ISSUANCE	101
72. DESIGN DOCUMENT ACCESSIBILITY	101
73. DESIGN CHANGE	101

PROCUREMENT

74. PROCUREMENT PROCESSES	107
75. PROCUREMENT REQUIREMENTS BY TYPE OF PROCUREMENT	107
76. WARRANTY	108

77. BUYER ACCEPTANCE	108
78. DESIGN DOCUMENTS	108
79. RISK MANAGEMENT DOCUMENTATION	108
80. RELIABILITY DOCUMENTATION	109
81. MAINTAINABILITY DOCUMENTATION	109
82. AVAILABILITY DOCUMENTATION	109
83. INSTALLATION INSTRUCTIONS	109
84. OPERATIONS AND MAINTENANCE MANUALS	109
85. NDE INTERPRETATION DOCUMENTS	110
86. SUPPLIER AND INDUSTRY BULLETINS	110
87. SAFETY DATA SHEETS	110
88. LEASED LIFTING AND HOISTING DEVICES	110
89. SUPPLIER PROPRIETARY DATA	110
90. SUPPLIER DOCUMENT IDENTIFYING DESIGNATOR	110
91. RIGHT OF ACCESS	110
92. SUPPLIER EVALUATION	111

93. SOURCE INSPECTION, TEST AND NDE	111
94. SOURCE AND RECEIVING INSPECTION, TEST AND NDE	111
95. PRE- AND POST-INSTALLATION INSPECTION, TEST AND NDE	114
96. STOP WORK ORDER BY ENERGY FACILITY / SITE OWNER	114
97. SUPPLIER RESPONSE TO BUYER-ORIGINATED CONDITION REPORTS	114
98. BUYER ACCEPTANCE OF DISPOSITION	114
99. SUPPLIER NOTIFICATIONS	114
100. PROCUREMENT CHANGES	115

FABRICATION, ASSEMBLY, INSTALLATION and CONSTRUCTION

101. FABRICATION, ASSEMBLY, INSTALLATION AND CONSTRUCTION PROCESSES	116
102. SITE INTERFACES	116
103. COMPATIBILITY OF SITE REQUIREMENTS	116
104. COMMUNICATION OF SITE HAZARDS	117
105. PHONETIC ALPHABET AND THREE-WAY COMMUNICATION	117
106. TIME-OUT	117
107. INSPECTION, TEST, NDE, PSI, ISI, WELDER AND SPECIAL PROCESS PERSONNEL TRAINING, QUALIFICATION AND CERTIFICATION	117

108. INTEGRATED AND STAND-ALONE PROCESS DESCRIPTION DOCUMENTS	119
109. INTEGRATED AND STAND-ALONE PROCESS DESCRIPTION DOCUMENT CONTENTS	119
110. WELD FINISH	119
111. NDE PROCESSES	120
112. HAUL PATH	126
113. DISASSEMBLY AND REASSEMBLY	127
114. IN-PROCESS INSPECTION, TEST AND NDE	127
115. PLACE-KEEPING	127
116. LABORATORY TESTING	127
117. PRE-JOB WALKDOWN AND PRE-JOB BRIEF	128
118. INSPECTION, TEST, NDE, PSI AND ISI PERFORMANCE	129
119. POST-JOB ASSESSMENT	131
120. RISK-BASED PRODUCTION	131

MAINTENANCE

121. FOREIGN MATERIAL EXCLUSION	132
122. MAINTENANCE PROCESSES	133

123. PREVENTIVE AND CORRECTIVE MAINTENANCE PROCESS DESCRIPTION DOCUMENT CHANGE	133
124. PRE- AND POST-OPERATIONAL MAINTENANCE SCHEDULES	134
125. SITE INTERFACES	134
126. COMPATIBILITY OF SITE REQUIREMENTS	134
127. COMMUNICATION OF SITE HAZARDS	135
128. PHONETIC ALPHABET AND THREE-WAY COMMUNICATION	135
129. TIME-OUT	135
130. INSPECTION, TEST, NDE PSI AND ISI PERSONNEL TRAINING, QUALIFICATION AND CERTIFICATION	135
131. INTEGRATED AND STAND-ALONE PROCESS DESCRIPTION DOCUMENTS	136
132. INTEGRATED AND STAND-ALONE PROCESS DESCRIPTION DOCUMENT CONTENTS	137
133. WELD FINISH	137
134. NDE PROCESSES	137
135. HAUL PATH	144
136. DISASSEMBLY AND REASSEMBLY	144
137. IN-PROCESS INSPECTION, TEST AND NDE	145
138. PLACE-KEEPING	145

139. LABORATORY TESTING	145
140. PRE-JOB WALKDOWN AND PRE-JOB BRIEF	145
141. INSPECTION, TEST, NDE, PSI AND ISI PERFORMANCE	146
142. POST-JOB ASSESSMENT	148
143. RISK-BASED MAINTENANCE	149
144. FOREIGN MATERIAL EXCLUSION	149

OPERATIONS

145. OPERATIONS PROCESSES	150
146. JURISDICTIONAL CONTROL	150
147. TURNOVER FOR OPERATIONS	151
148. NORMAL AND OFF-NORMAL OPERATING PROCESSES	151
149. START-UP	151
150. RISK-BASED OPERATION	152
151. OUT-OF-SERVICE ITEMS	152
152. MODIFICATION AND MAINTENANCE DURING OPERATIONS	152
153. OPERATIONS PROCESS DESCRIPTION DOCUMENT CHANGE	153

APPENDIX A – TYPES OF RECORDS	154
APPENDIX B – REFERENCED AND RESOURCE DOCUMENTS	158

Foreword

This standard supersedes ANSI/ASQ E1-1996, *Quality Program Guidelines for Project Phase of Nonnuclear Power Generation Facilities* and ANSI/ASQ E3, *Quality Program Guidelines for Operations and Maintenance Phase of Nonnuclear Power Generation Facilities*.

The quality principles and practices in each section of this standard are intended for incorporation into the enterprise business management system to enhance the definition, attainment, verification and validation of quality for facilities in the non-nuclear energy industries, including the generation, transmission, distribution and storage of electricity, gas and steam.

The quality principles and practices in each section of this standard may be applicable to a wide range of enterprises such as owners, architect engineers and constructors, contractors, suppliers and sub-tier suppliers.

This standard, or any section therein, is intended to supplement existing management system standards, not replace them. The application of this standard, in whole or in part, is voluntary.

Given the extensive breadth of scope of the section topics and depth of specificity of the principles and practices for each topic, it is incumbent upon the enterprise to apply specific sections based on the nature and scope of work and its criticality relative to the achievement of intended quality objectives. These objectives could include the cost-effective quality of production, quality of public and employee safety and health, quality of environmental protection, quality of security, quality of emergency preparedness and response, and quality other such factors. Not all sections of this standard will be applicable at all levels in the supply chain.

The sections of this standard are organized as follows. In the Table of Contents, under “GENERAL”, the section topics are those that are potentially applicable in all phases from design through operations. Under “DESIGN” the section topics are those applicable to the design phase. Under “PROCUREMENT” the section topics are those applicable to the procurement phase. Under “FABRICATION, ASSEMBLY, INSTALLATION and CONSTRUCTION”, the section topics are those applicable to these phases in which design is converted into physical articles. “MAINTENANCE” section topics are provided before “OPERATIONS” section topics, given that some maintenance activities must be performed prior to turnover to operations.

In some instances, quality principles and practices in one section of this standard may be duplicated on one or more other sections of this standard. **The duplication is intentional to facilitate the use of the standard as a menu of stand-alone sections.**

This standard was developed in accordance with procedures established by ASQ and accredited by the American National Standards Institute.

This standard was prepared by the ANSI/ASQ E5 Writing Group of the Energy and Environmental Division of ASQ. The group members are as follows:

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1. PURPOSE

The purpose of this standard is to provide quality principles and practices that can be incorporated, in whole or in part, into the enterprise business management system, as a stand-alone standard or as a supplement to any existing standard.

2. SCOPE

This standard provides principles and practices that address the definition, attainment, verification and validation of the quality of:

- 2.1. Initial conceptual, systems and detail design of the energy source, such as an energy facility, including its hardware items, equipment and specialty tools and any modifications thereof;
- 2.2. Fabrication and assembly of the hardware items to be installed in the energy source and of equipment and specialty tools to be used at the energy source;
- 2.3. Installation of hardware items in the energy source;
- 2.4. Construction of the energy source, including backfill, concrete, and piles and caissons, and erection of the structure;
- 2.5. Operations of the energy source;
- 2.6. Maintenance of the energy source hardware items, equipment and specialty tools;
- 2.7. Safety and health of workers at the energy source and of the public;
- 2.8. Security of the energy source;
- 2.9. Environmental protection;
- 2.10. Emergency preparedness and response.

3. APPLICABILITY

3.1. Application by Project Phase

This standard is intended to be applicable throughout all phases from initiation, planning, execution, monitoring and control, and close-out.

3.2. Application Voluntarily or Contractually

This standard may be applied voluntarily or as a procurement contractual requirement, in whole or in part.

3.3. Application by Type of Energy Source

This standard may be applied for the conceptual, systems and detail design, construction, operations and maintenance of an energy generation, storage, transmission and distribution facility or to any other type of energy source.

3.4. Application by Type of Enterprise

This standard may be applied by the owner of the energy source, an AE / constructor, a contractor or sub-contractor, or a supplier or sub-supplier to any of the foregoing.

- 3.5. Application by Type of Asset and Process – The assets and processes for which the elements of this standard are to apply should be identified and documented. As a minimum, the elements of this standard should apply to assets and administrative and technical processes that impact the quality of the elements noted in Section 2, above.

4. PRECEDENCE

4.1. Within this Standard

In the event of conflict between a (a) stand-alone element in this standard and (b) an element in a referenced document in this standard, the former should take precedence.

4.2. Between this Standard and a Contract

In the event of conflict between (a) an element of this standard and a (b) procurement contractual requirement, the latter should take precedence.

5. DEFINITIONS

5.1. Dictionary and ASQ Quality Glossary Definitions

Merriam-Webster Collegiate Dictionary, 11th Edition definitions should apply for the words and terms used throughout this standard, except that a definition in the *ASQ Quality Glossary* should take precedence over a dictionary definition and except as noted in Section 5.2, below.

5.2. Special Definitions

For the purpose of this standard, the following definitions apply and take precedence over any other definitions:

5.2.1. “Administrative Process” – Any process other than a technical process.

5.2.2. “Business Management System” – A compilation of administrative and technical processes that governs the operation of the enterprise such as to achieve the mission, vision, values and goals of the enterprise.

5.2.3. “Chemical” – Any gas, liquid or solid that could be a hazard to personnel or hardware items, equipment and specialty tools if it is handled, stored, used or disposed of improperly, and that is not excluded from control by OSHA rules and regulations – including, but not limited to, abrasives, adhesives / glues / solders, cleaning agents / absorbents, crayons / markers / inks, desiccants, dye penetrants / developers / detergents, etching agents, fuels, insecticides / herbicides, leak detection fluids, lubricants / cutting fluids / hydraulic fluids, paints / coatings, sealants / solvents, tapes and wrapping materials.

5.2.4. “Condition”, as in “Condition Report” – Any problem, defect, defective, nonconformance, nonconformity, noncompliance, incident, finding, opportunity for improvement, anomaly, or other word or term indicating a less than desirable state, or a good practice.

5.2.5. “Energy Source” – A point of origin or location for energy generation, transmission, distribution or storage.

- 5.2.6. "Equipment" – Any device that is not a permanent element of the energy source, such as the facility (not permanently installed) but that is necessary for the performance of a task or multiple tasks in multiple processes, such as a rented crane, forklift truck, uninstalled measuring device, jumper, and the like.
- 5.2.7. "Facility" – Any permanent structure such as a plant, electrical substation and transmission tower and any permanent appendage to a permanent structure such as transmission and distribution wires and piping. This includes all non-nuclear power or energy facilities.
- 5.2.8. "Hardware Item" – Any physical material, part, component, subassembly, assembly, subsystem, system or structure that is integral to the energy source, such as the facility, and that is or is intended to be a permanent element of the energy source, such as the facility.
- 5.2.9. "Problem" – An actual adverse effect or an actual exacerbation of an actual adverse effect or a condition that, if not corrected, could lead to an adverse effect or the exacerbation of the effect due to:
- 5.2.9.1. An inadequacy in the design of a process;
 - 5.2.9.2. An inadequacy in the design of a hardware item, equipment or specialty tool used in a process;
 - 5.2.9.3. A nonconformance to requirement;
 - 5.2.9.4. A poor judgment or decision.
- 5.2.10. "Process" – A sub-set of a business management system, consisting of a series of tasks designed and implemented to achieve a specified objective.
- 5.2.11. "Process Description Document" – A written or a written and pictorial communication that provides prescriptive requirements and methods by which to consistently achieve the objectives of a given scope of work under given conditions or circumstances.
- 5.2.12. "Production" – The creation of a characteristic of a hardware item, equipment, specialty tool, document or process – creation either by designing the characteristic or by implementing the design for the characteristic.
- 5.2.13. "Qualified Individual" – A person who, by possession of a recognized degree in an applicable field or certificate of professional standing, or who, by extensive knowledge, training, and experience, is a subject matter expert and has successfully demonstrated the ability to do the work to which he / she is assigned.
- 5.2.14. "Specialty Tool" – Any device that is not a permanent element of the energy source, such as the facility, (not permanently installed) and that is designed specifically for the performance of a given task in a process, such as ultrasonic and borescope devices, and the like.
- 5.2.15. "Task" – A sub-set of a process constituting a single action that should be designed and implemented to achieve the objective of the process.

- 5.2.16. “Technical Process” – Any process that involves engineering principles or practices for its design, implementation, maintenance or operation.

6. ABBREVIATIONS

- 6.1. FME – Foreign material exclusion.
- 6.2. ISI – In-service inspection.
- 6.3. NDE – Nondestructive examination.
- 6.4. PSI – Pre-service inspection.
- 6.5. V&V – Verification and Validation

GENERAL

7. ROLES and RESPONSIBILITIES

The roles and responsibilities of each person, by job title, who is to take an action to comply with an element of this standard should be established and documented.

8. KNOWLEDGE and SKILLS

The knowledge, skills, type of education, level of education, qualifications and certifications required for the successful performance of each role and responsibility established per Section 7, above, should be established, documented and verifiable. Each assignment of a worker to a given role and responsibility should be subject to acceptance by a managerially and technically qualified individual who has oversight of the role and responsibility.

9. POLICIES

Each enterprise should establish policies that support the implementation of the principles and practices detailed in this standard. The policies should be established by qualified and responsible individuals. The qualifications should be documented and verifiable. The policies should be incorporated into the documented business management system, implemented and maintained.

10. ADMINISTRATIVE and TECHNICAL PROCESSES

10.1. Administrative and Technical Processes

Each action to be taken to comply with a regulatory requirement, customer, or client requirement and an element of this standard should be addressed specifically in an administrative or technical process established by qualified individuals, qualified in the subject process and quality management. These qualifications should be documented and verifiable. The administrative and technical processes should be documented in process description documents that addresses the elements of this Section 10.

10.2. Administrative and Technical Process Design

Administrative and technical processes should be designed in a fashion similar to the design of hardware items. The sequence of activities for the design of the process should be to:

- 10.2.1. Establish the top-level requirements for the design of process, including inputs and outputs, and the constraints upon the design of the process;
- 10.2.2. Establish the tasks in sequence;
- 10.2.3. Establish the detail design of each task, including the specific method for performing the task (except for methods that are “skill of the trade”), the specific equipment or specialty tool(s) to be used, and the required result of the task;
- 10.2.4. Establish the caution or warning, as may be applicable to each task;
- 10.2.5. Establish the responsibility for the performance of each task;
- 10.2.6. Incorporate the foregoing information into a process description document or written procedure in compliance with a procedure writing guideline and in accordance with Sections 10.10, 10.11 and 10.12, below.

10.3. Administrative and Technical Process Designer Qualifications

The qualifications of each person performing design of an administrative and technical process should be documented and verifiable.

10.4. Cross-reference of Law Requirement Documents to Process Description Documents

A cross-reference of the unique identifying designator, including revision designator, and the section number of each (a) applicable law requirement document and (b) process description document that specifically addresses the law requirement should be established, maintained and used to assure that each regulatory requirement is addressed in the business management system.

10.5. Discernment of Compatibility –Law Requirement Documents and Process Description Documents

A method should be established by which to readily discern the revision level of the law requirement document with which the process description document is compatible. Acceptable methods are by:

- 10.5.1. Referencing the law requirement document and its revision level in the process description document. For example, when a change is made to a process description document to be compatible with a revision of a law requirement document, the changed process description document should reference the law requirement document and its compatible revision level.
- 10.5.2. Maintaining a log for the process description document in which the law requirement document and its compatible revision level are identified.

10.6. Cross-Reference of Standard Requirements to Process Description Documents

A cross-reference of the (a) section number of each element of this standard and (b) unique identifying designator, including revision designator, of each process description document that specifically addresses the element should be established, maintained and used to assure that each element of this standard is addressed in the business management system.

10.7. Discernment of Compatibility – This Standard and Process Description Documents

A method should be established by which to readily discern the revision level of this standard with which the process description document is compatible. Acceptable methods are by:

10.7.1. Referencing this standard and its revision level in the process description document. For example, when a change is made to a process description document to be compatible with a revision to this standard, the changed process description document should reference this standard and its compatible revision level.

10.7.2. Maintaining a log for the process description document in which this standard and its compatible revision level are identified.

10.8. Cross-reference of Customer / Client Requirement Documents to Process Description Documents

A cross-reference of the unique identifying designator, including revision designator, and section number of each (a) applicable customer / client requirement and (b) process description document that specifically addresses the requirement should be established, maintained and used to assure that each customer / client requirement is addressed in the business management system.

10.9. Discernment of Compatibility – Customer / Client Requirements Documents and Process Description Document

A method should be established by which to readily discern the revision level of a customer / client requirements document with which a process description document is compatible. Acceptable methods are by:

10.9.1. Referencing the customer / client requirements document and its revision level in the process description document. For example, when a change is made to a process description document to be compatible with a revision of a customer / client requirements document, the changed process description document should reference the customer / client requirements document and its compatible revision level.

10.9.2. Maintaining a log for the process description document in which each customer / client requirements document and its compatible revision level is identified.

10.10. Process Description Document Format and Conventions

The format and conventions for each process description document should be established and documented.

10.11. Process Description Document Content

The elements of information to be addressed in each process description document should be established and documented. As a minimum, the elements of information should be as follows, as applicable:

- 10.11.1. The title, unique identifying designator, including revision designator, of the process description document;
- 10.11.2. Prerequisites for the implementation of the process, such as the acquisition of a license or permit;
- 10.11.3. Cautions and warnings relating to the process;
- 10.11.4. The unique identifying designator of each specialty designed hardware item, equipment and specialty tool needed for the implementation of the process;
- 10.11.5. The input needed for the performance of each task and the authorized source of that input to enable the required output;
- 10.11.6. The sequential listing of each task;
- 10.11.7. The job title of the person responsible for the performance of each task;
- 10.11.8. The requirement for the acceptability of each task;
- 10.11.9. The method of accomplishing each task such as to attain compliance with the requirement, including the safety and health, security, environmental protection, and emergency preparedness and response requirements, as applicable, and including, but not limited to, the following safe work practices, as applicable:
 - 10.11.9.1. Chemical protection, such as through the use of personal protective equipment;
 - 10.11.9.2. Cryogenic threats and hazards protection;
 - 10.11.9.3. Confined spaces protection;
 - 10.11.9.4. Drugs and alcohol protection and abstinence immediately preceding and during work;
 - 10.11.9.5. Electrical protection, such as the use of lock-out / tag-out;
 - 10.11.9.6. Emergency protection, such as emergency evacuation;
 - 10.11.9.7. Ergonomics injury protection, such as manual lifting injury protection;
 - 10.11.9.8. Eye protection;
 - 10.11.9.9. Fall, slip and trip protection;
 - 10.11.9.10. Fire protection;
 - 10.11.9.11. Hand injury protection;
 - 10.11.9.12. Hearing protection;

- 10.11.9.13. Hot work protection;
- 10.11.9.14. Pressurized vessel and line protection;
- 10.11.9.15. Respiratory protection;
- 10.11.9.16. Underground and overhead utilities protection;
- 10.11.9.17. Volatile liquids protection;
- 10.11.10. The quality controls, including self-check, peer check, peer inspection, or independent inspection, test, NDE, PSI or ISI to be performed for assuring compliance with each requirement;
- 10.11.11. The method of performing each quality control, the method to include such things as hold points, witness points, etc., as applicable;
- 10.11.12. Each data element for which data is to be collected and the data collection form(s);
- 10.11.13. The method of recovery from any hazard, or reference to the recovery process description document(s).
- 10.12. A process description document may include a process map, preferably prepared as a prerequisite of the process description document, itself.

11. PROCESS RISK MANAGEMENT

11.1. Process Risk Management Processes

Administrative and technical processes for process risk management should be established by qualified individuals, qualified in risk management and quality management. These qualifications should be documented and verifiable. The processes for process risk management should be documented in process description documents that address the elements in this Section 11.

11.2. Process Risk Management Scope

The enterprise should establish the criteria by which to identify the processes for which process risk management should be performed as a prerequisite to process implementation for production. As a minimum, process risk management should be performed for processes that:

- 11.2.1. Are needed for compliance with applicable law (i.e., federal, state and local government executive orders; enacted legislation, including codes; regulatory agency rules and regulations; commitments in licenses and permits; regulatory agency administrative law judge adjudications; civil law judge adjudications) and commitments to stakeholder special interest groups;
- 11.2.2. Are needed for compliance with this or other business management system standards;
- 11.2.3. Are needed for compliance with hardware item, equipment and specialty tool design standards;
- 11.2.4. Contribute significantly to technical and financial success of the enterprise;
- 11.2.5. Impact safety, security, environmental protection and emergency response;
- 11.2.6. Are difficult to perform.

11.3. Process Risk Management Personnel Qualifications

- 11.3.1. Persons who perform process risk management should have expertise in the risks associated with the quality of production, safety and health, security, environmental protection, and emergency preparedness and response, as applicable, as well as expertise in the process in question by means of their participation in the creation of the process.
- 11.3.2. The qualifications of each person performing process risk management should be documented and verifiable.

11.4. Process Risk Management Performance

Process risk management of each process description document within the scope established per Section 11.2, above, should be performed prior to the official issuance of the process description document.

11.5. Process Hazard

Each process description document should be analyzed to identify each intrinsic or extrinsic threat or hazard to production, safety and health, security, environmental protection and emergency response that may exist in the process, including each threat or hazard that may exist in a process organizational interface.

11.6. Process Risk Assessment

The initial level of risk associated with each hazard should be determined based on the level of severity of the adverse effect and the probability of the occurrence of the adverse effect. In this context, the hazard has been identified prior to the initial issuance of the process description document for production. In this case, subject matter experts should determine the level of severity of the adverse effect were it to occur and multiply that value by the probability of its initial occurrence to arrive at what is commonly referred to as the initial level of risk or Risk Priority Number (RPN).

Note: Some subject matter experts include a value for the probability of detection. It's best practice to not confound the initial level of risk by considering the existence of any detection controls. The detection controls should be considered in assessing the residual level of risk, described in Section 11.7.2, below. The ability to detect reduces risk only to the extent that the detection is timely enough to enable mitigation.

11.7. Process Risk Treatment

Each hazard for which the initial level of risk is unacceptable should be treated by changing the process description document to:

- 11.7.1. Eliminate the hazard, such as to achieve an acceptable residual level of risk;
- 11.7.2. Incorporate mitigation controls or barriers such as to achieve an acceptable residual level of risk by:

- 11.7.2.1. Reducing the likelihood of the activation of the hazard;
- 11.7.2.2. Improving the detectability of the activated hazard.
- 11.7.2.3. Mitigating the level of severity of the adverse effect;

11.8. Process Risk Management Condition Reporting

In each case for which an initial level of risk is unacceptable, a condition report should be entered into the condition reporting and corrective action process, per Section 38, below.

11.9. Process Risk Management Results Documentation

The results of the performance of each process risk management should be documented, including the:

- 11.9.1. Title and unique identifying designator, including revision designator, of the document that was risk-managed;
- 11.9.2. Date of the risk management;
- 11.9.3. Name and organizational affiliation of each participant in the performance of the risk management;
- 11.9.4. Description of each hazard that was identified;
- 11.9.5. Description of each occurrence for which the initial level of risk was unacceptable
- 11.9.6. Description of the action taken for each unacceptable initial level of risk to arrive at an acceptable residual level of risk;
- 11.9.7. Unique identifying designator of each condition report originated per Section 11.8, above;
- 11.9.8. Name of the signatory to the document, his / her title, and the date of sign-off.

12. PROCESS DESCRIPTION DOCUMENT REVIEW

12.1. Process Review Processes

Administrative and technical processes for the review of process description documents should be established by qualified individuals, qualified in the subject process and quality management. These qualifications should be documented and verifiable. The processes for process review should be documented in process description documents that address the elements of this Section 12.

12.2. Process Review Scope

The enterprise should establish the criteria by which to identify the processes for which process review should be performed as a prerequisite to process implementation for production. Review should be performed for processes involving tasks that:

- 12.2.1. Are needed for compliance with applicable law (i.e., federal, state and local government executive orders; enacted legislation, including codes; regulatory agency rules and regulations; commitments in licenses and permits; regulatory agency administrative law

judge adjudications; civil law judge adjudications) and commitments to stakeholder special interest groups;

12.2.2. Are needed for compliance with this or other business management system standards;

12.2.3. Are needed for compliance with hardware item, equipment and specialty tool design standards;

12.2.4. Involve a significant input from an external organization;

12.2.5. Contribute significantly to technical and financial success of the enterprise;

12.2.6. Impact safety, security, environmental protection and emergency response;

12.2.7. Are difficult to perform.

12.3. Process Reviewer Qualifications

12.3.1. Process description document reviewers should be qualified individuals, qualified for the subjects addressed Sections 10 and 11, above, and should be independent – i.e., they should not have contributed to the origination of the process being reviewed and not administratively report to anyone who is or was responsible for the origination of the process being reviewed.

12.3.2. The qualifications of each person performing review of process description documents should be documented and verifiable.

12.4. Process Review Performance

Process review of each process description document within the scope established per Section 11.2, above, should be performed prior to the official issuance of the process description document.

12.5. Process Review Condition Reporting

A condition report should be entered into the condition reporting and corrective action process per Section 38, below, for each condition identified in the review of the process. Each condition should be corrected prior to official issuance of the process description document.

12.6. Process Review Results Documentation

Each review of a process should be documented. The document should include the:

12.6.1. Title and unique identifying designator, including revision designator, of the document that was reviewed;

12.6.2. Date of the review;

12.6.3. Name and organizational affiliation of each participant in the review;

12.6.4. Elements of information that were reviewed;

12.6.5. Description of each condition found in the document;

12.6.6. Description of the action taken to correct the condition in the document;

12.6.7. Unique identifying designator of the condition report entered into the condition reporting and corrective action process per Section 12.5, above.

13. PROCESS DESCRIPTION DOCUMENT ISSUANCE

13.1. Process Description Document Approvals

Each person, by job title, who is required to approve each process description document as a prerequisite to its official issuance should be identified and documented. The meaning of each such approval should be defined and documented.

13.2. Process Description Document Authorization for Official Issuance

Each person, by job title, who has the final authority for the official issuance of the process description document should be identified and documented.

14. PROCESS DESCRIPTION DOCUMENT DISTRIBUTION

The methods of distributing each process description document, and each change thereto, should be established and documented. Each process description document should be distributed to each person who has a role or responsibility in implementing the process for verification, validation and production. Each administrative process description documents should be distributed also to the immediate organizational superior of the responsible person and to the management overseers.

15. PROCESS DESCRIPTION DOCUMENT IMPLEMENTATION

Process description documents should be implemented as written.

16. PROCESS VERIFICATION

16.1. Process Verification Processes

Administrative and technical processes for the verification of process description documents should be established by qualified individuals, qualified in the subject process, process verification and quality management. These qualifications should be documented and verifiable. The processes for process verification should be documented in process description documents that address the elements of this Section 16.

16.2. Process Verification Scope

The enterprise should establish the criteria by which to identify the processes for which process verification should be performed as a prerequisite to process implementation for production. Verification should be performed for processes involving tasks that:

- 16.2.1. Are needed for compliance with applicable law (i.e., federal, state and local government executive orders; enacted legislation; codes; regulatory agency rules and regulations; commitments in licenses and permits; regulatory agency administrative law judge adjudications; civil law judge adjudications) and commitments to stakeholder special interest groups;
- 16.2.2. Are needed for compliance with this or other business management system standards;

- 16.2.3. Are needed for compliance with hardware item, equipment and specialty tool design standards;
 - 16.2.4. Involve a significant input from an external organization;
 - 16.2.5. Contribute significantly to technical and financial success of the enterprise;
 - 16.2.6. Impact safety, security, environmental protection and emergency response;
 - 16.2.7. Are difficult to perform.
- 16.3. Process Verification Objective
- The process verification should be such as to assure that the process description document can be consistently implemented as written.
- 16.4. Process Verification Personnel Qualifications
- 16.4.1. Process verifiers should be qualified individuals, qualified in the subject process, process verification and quality management, and should be independent – i.e., they should not have contributed to the origination of the process being verified and not administratively report to anyone who is or was responsible for the origination of the process being verified.
 - 16.4.2. The qualifications of each person performing process verification should be documented and verifiable.
- 16.5. Process Verification Condition Reporting
- A condition report should be entered into the condition reporting and corrective action process per Section 38, below, for each condition that prevented the attainment of the verification objective, per Section 16.3, above.
- 16.6. Process Verification Results Documentation
- Each process verification should be documented. The document should include the:
- 16.6.1. Title and unique identifying designator, including revision designator, of the process description document for which the verification was made or attempted;
 - 16.6.2. Date on which the verification was made or attempted;
 - 16.6.3. Name and organizational affiliation of each participant in the verification;
 - 16.6.4. Description of the verification method;
 - 16.6.5. Description of each condition that prevented the attainment of the verification objective, per Section 16.3, above.
 - 16.6.6. Description of the action taken to correct the condition;
 - 16.6.7. Unique identifying designator of the condition report entered into the condition reporting and corrective action process per Section 16.5, above.

17. PROCESS VALIDATION

17.1. Process Validation Processes

Administrative and technical process for the validation of process description documents should be established by qualified individuals, qualified in the subject process, process validation and quality management. These qualifications should be documented and verifiable. The processes for process validation should be documented in process description documents that address the elements of this Section 17.

17.2. Process Validation Scope

The enterprise should establish the criteria by which to identify the processes for which process validation should be performed as a prerequisite to process implementation for production.

Validation should be performed for processes involving tasks that:

- 17.2.1. Are needed for compliance with applicable law (i.e., federal, state and local government executive orders; enacted legislation, including codes; regulatory agency rules and regulations; commitments in licenses and permits; regulatory agency administrative law judge adjudications; civil law judge adjudications) and commitments to stakeholder special interest groups;
- 17.2.2. Are needed for compliance with this or other business management system standards;
- 17.2.3. Are needed for compliance with hardware item, equipment and specialty tool design standards;
- 17.2.4. Involve a significant input from an external organization;
- 17.2.5. Contribute significantly to technical and financial success of the enterprise;
- 17.2.6. Impact safety, security, environmental protection and emergency response;
- 17.2.7. Are difficult to perform.

17.3. Process Validation Objective

The process validation should be such as to assure that the objectives of the process are fit for purpose in the context of system or energy facility operation and that the objectives can be consistently achieved with the implementation of the process description document as written.

17.4. Process Validation Personnel Qualifications

- 17.4.1. Process validation personnel should be qualified individuals, qualified in the subject process, process validation and quality management, and should be independent – i.e., they should not have contributed to the origination of the process being validated and not administratively report to anyone who is or was responsible for the origination of the process being validated.
- 17.4.2. The qualifications of each person performing process validation should be documented and verifiable.

17.5. Process Validation Condition Reporting

A condition report should be entered into the condition reporting and corrective action process

per Section 38, below, for each condition that prevented the attainment of the validation objective, per Section 17.3, above.

17.6. Process Validation Results Documentation

Each process validation should be documented. The document should include the:

- 17.6.1. Title and unique identifying designator, including revision designator, of the process description document for which the validation was made or attempted;
- 17.6.2. Date on which the validation was made or attempted;
- 17.6.3. Name and organizational affiliation of each participant in the validation activity;
- 17.6.4. Description of the validation method;
- 17.6.5. Description of each condition that prevented the attainment of the validation objective, per Section 17.3, above.
- 17.6.6. Description of the action taken to correct the condition;
- 17.6.7. Unique identifying designator of the condition report entered into the condition reporting and corrective action process per Section 17.5, above.

18. PROCESS PERIODIC REVIEW

18.1. Process Periodic Review Processes

Administrative and technical processes for the periodic review of process description documents should be established by qualified individuals, qualified in management review and quality management. These qualifications should be documented and verifiable. The processes for the periodic review of processes should be documented in process description documents that address the elements of this Section 18.

18.2. Process Periodic Review Scope

Each process description document for which initial review is required per Section 12, above, should be periodically reviewed.

18.3. Process Periodic Review Frequency

The frequency for the periodic review of each process description document should be based at least on the residual levels of risk for the hazards that remain in the process.

18.4. Audit or Self-Assessment Alternative

An audit or self-assessment of the process description document may be substituted for the periodic review if the audit / self-assessment is performed within the specified review period for process description document.

18.5. Process Periodic Review Personnel Qualifications

- 18.5.1. Process periodic reviewers should be qualified individuals, qualified in the subject process and quality management, and should be independent – i.e., they should not have contributed to the origination of the process being reviewed and not

administratively report to anyone who is or was responsible for the origination of the process being reviewed.

18.5.2. The qualifications of each person performing periodic review of a process should be documented and verifiable.

18.6. Process Periodic Review Condition Reporting

A condition report should be entered into the condition reporting and corrective action process per Section 38, below, for each condition identified in the periodic review of the process.

18.7. Process Periodic Review Results Documentation

Process description document periodic review results should be documented.

18.8. Process Periodic Review Results Document Contents

Each process periodic review results document should include the:

18.8.1. Title and unique identifying designator, including revision designator, of the process description document that was reviewed;

18.8.2. Date of the review;

18.8.3. Name and organizational affiliation of each person who participated in the review;

18.8.4. Description of each condition identified in the review;

18.8.5. Description of each action taken to correct the condition;

18.8.6. Unique identifying designator of each condition report entered into the condition reporting and corrective action process per Section 18.6, above.

19. PROCESS CHANGE MANAGEMENT

19.1. Process Change Management Processes

Administrative and technical processes for process description document change management should be established by qualified individuals, qualified in process change management and quality management. These qualifications should be documented and verifiable. The processes for process change management should be documented in process description documents that address the elements of this Section 19.

19.2. Process Change Management Personnel Qualifications

19.2.1. Process change management personnel should be qualified individuals, qualified in the process change management and quality management.

19.2.2. The qualifications of each person performing process change management should be documented and verifiable.

19.3. Process Description Document Change

Subsequent to any change to a design document for a hardware item, equipment or specialty tool used in an administrative or technical process description document, the affected process description document should be correspondingly changed, as necessary. The process description

document change should be officially issued prior to the further implementation of the affected administrative or technical process.

19.4. Cross-Reference of Design Documents to Process Description Documents

A cross-reference of the unique identifying designator, including revision designator, of each (a) each hardware item, equipment and specialty tool design document and (b) process description document in which the hardware item, equipment or tool is applied should be established, maintained and used to identify the possible need to change a process description document to be consistent and compatible with a change to a design document.

19.5. Discernment of Compatibility – Design and Process Description Documents

A method should be established by which to readily discern the revision level of the hardware item, equipment or specialty tool design document with which the process description document is compatible. Acceptable methods are by:

19.5.1. Referencing the design document and its revision level in the process description document. For example, when a change is made to a process description document to be compatible with a revision of a design document, the changed process description document should reference the design document and its compatible revision level.

19.5.2. Maintaining a log for the process description document in which the design document and its compatible revision level are identified.

19.6. Process Reverification and Revalidation

Subsequent to any significant change to a process description document, the process should be re-verified and re-validated in accordance with Sections 16 and 17, above.

20. SOFTWARE / FIRMWARE

20.1. Software / Firmware Processes

Administrative and technical processes should be established by qualified individuals, qualified in information technology and quality management. These qualifications should be documented and verifiable. The processes for software / firmware should be documented in process description documents that address the elements of this Section 20.

20.2. Software / Firmware Task Identification

In each process description document, in each task, any software / firmware that is necessary for or involved in the performance of the task should be identified. The elements of identification should include:

20.2.1. Whether the software / firmware controls the process task or is supportive of human control of the task;

20.2.2. Whether the software / firmware is the same as, or different from, software used in other process tasks;

20.2.3. Whether the software / firmware installation is cloud-based (i.e., installed on a remotely accessible fileserver) or local (i.e., installed on a specific hardware item, equipment or specialty tool).

20.3. Software / Firmware Database

A software / firmware database should be established, documented and maintained to identify each item of software / firmware. For each item of software / firmware, the database should identify the:

- 20.3.1. Title or nomenclature of the software / firmware;
- 20.3.2. Unique identifying designator, including the revision identifier of the software / firmware;
- 20.3.3. Source of the software / firmware, in-house or procured;
- 20.3.4. Name and contact information of the supplier of the software / firmware, if applicable;
- 20.3.5. Unique identifying information for the license for the software / firmware, if applicable;
- 20.3.6. License basis (e.g. user, computer, location, enterprise, etc.) for the software, if applicable;
- 20.3.7. Terms of the license (e.g., perpetual, limited, open / freeware), if applicable;
- 20.3.8. Name of the custodian of the software / firmware and his / her contact information;
- 20.3.9. Third parties used in the production or operation of the software / firmware, if any;
- 20.3.10. Certifications associated with use of software / firmware;
- 20.3.11. Stand-alone, hosted (client/server), or cloud-based application of the software / firmware;
- 20.3.12. Internal or external server(s) to which the software / firmware connects;
- 20.3.13. Physical location of the software / firmware servers / data centers;
- 20.3.14. Data back-up / recovery system(s) for the software / firmware;
- 20.3.15. Open source for the software / firmware, if applicable;
- 20.3.16. Encryption process for the software / firmware, if applicable;
- 20.3.17. Ability of the software / firmware to change settings on other operating hardware items, equipment or specialty tools, if applicable;
- 20.3.18. Design, design review, verification and validation (V&V) requirements for the procurement for the software / firmware and its user's manual, if applicable; (This can be done by reference to a separate document[s].)
- 20.3.19. Design, design review and V&V for the in-house production of the software / firmware and its user's manual; (This can be done by reference to a separate document[s].)
- 20.3.20. Design review results;
- 20.3.21. V&V results;
- 20.3.22. Application of the software / firmware, including the
 - 20.3.22.1. Installation documentation, with the dates of installation and any modification or customization involved in the installation;

20.3.22.2. Maintenance log, with a description and resolution of each incident that required re-boot, patch, upgrade or an amendment to the installation.

20.3.22.3. Name of each individual who performed the software installation or maintenance work, and his / her organizational affiliation and contact information.

20.3.22.4. Identification of audits of the software / firmware.

20.4. Software / Firmware Design Requirements

20.4.1. The scope, basic design criteria and functionality of the software / firmware should be established and documented.

20.4.2. The specific requirements for the design of the software / firmware and user's manual should be established and documented.

20.4.3. The specific requirements for the design of the software / firmware should address the data attributes of Section 40, below, as applicable.

20.4.4. The specific requirements for the use of the firmware should address the ability of firmware to function satisfactorily in its electromagnetic environment without introducing intolerable disturbances to that environment or to other hardware items, equipment or specialty tools. Design practices such as the following should be considered for use to minimize the potential for electromagnetic interference:

20.4.4.1. Computer cables routed in separate raceways from other cables;

20.4.4.2. Cables in raceways stacked in order of voltage levels in order to maintain maximum distance between high voltage cables and low-level signal cables;

20.4.4.3. Cables shielded;

20.4.4.4. Use of twisted shielded pair cable with one end grounded;

20.4.4.5. Wireless transmission of data.

20.5. Software / Firmware and User's Manual Design Review Requirements

Software / firmware and user's manual design review requirements should be established and documented. This should include the points in the development cycle at which each design review is to be accomplished, the objectives of each design review, and the name(s) of the individual(s), by job title, who are authorized to designate the successful completion of each review.

20.6. Software / Firmware and User's Manual Design Review Personnel Qualifications

20.6.1. Persons who perform design review of software / firmware and user's manuals should be qualified in the applicable elements of information technology and software quality / firmware quality management and should be independent – i.e., they should not have contributed to the origination of the documents being reviewed or administratively report

to anyone who is or was responsible for the origination of the documents being reviewed.

20.6.2. The qualifications of each person who performs software / firmware and user's manual design review should be documented and verifiable.

20.7. Software / Firmware and User's Manual Design Review Performance

20.7.1. Software / firmware and user's manual design reviews should be performed in accordance with the requirements established per Section 20.5, above

20.7.2. The software / firmware and user's manual design review results should be documented. The document should provide the:

20.7.2.1. Title or nomenclature of the software / firmware / user's manual reviewed;

20.7.2.2. Unique identifying designator, with its revision designator, of the software / firmware / user's manual reviewed;

20.7.2.3. Name of each participant in the design review and his / her organizational affiliation;

20.7.2.4. Date of the review;

20.7.2.5. Stage in the development cycle at which the review was performed;

20.7.2.6. Identification of each characteristics of the software / firmware and user's manual that was reviewed;

20.7.2.7. Results of the review;

20.7.2.8. Conditions identified as a result of the review, if any;

20.7.2.9. Action taken for each identified condition;

20.7.2.10. Unique identifying designator of each condition report originated per Section 20.14, below;

20.7.2.11. The name and organizational affiliation of the person(s) who has approval authority for the successful completion of the design review.

20.8. Software / Firmware V&V Requirements

20.8.1. Software / firmware V&V requirements should be established and documented by qualified individuals, qualified in the applicable elements of information technology and software / firmware quality management, and who are independent – i.e., they should not have contributed to the origination of the software / firmware being assessed by V&V or administratively report to anyone who contributed to the origination of the software / firmware being assessed by V&V.

20.8.2. The qualifications of persons who establish software / firmware V&V requirements and who perform software / firmware V&V should be documented and verifiable.

20.8.3. The V&V requirements document should:

- 20.8.3.1. Bear the title or nomenclature and unique identifying designator, including revision designator, of the document;
- 20.8.3.2. Include verification that the correct software / firmware and supporting deliverables were acquired in accordance with the purchase order;
- 20.8.3.3. Identify the title or nomenclature of the software / firmware to be V&V tested;
- 20.8.3.4. Identify the unique identifying designator, including revision designator, of the software / firmware to be V&V tested;
- 20.8.3.5. Identify each point in the software / firmware development cycle at which each V&V test is to be performed;
- 20.8.3.6. Identify the objective(s) of each V&V test;
- 20.8.3.7. Describe the method for V&V testing each software / firmware performance requirement, including the specific identification of each hardware item, equipment and specialty tool used in the test method.
- 20.8.3.8. Include the following validation elements:
 - 20.8.3.8.1. Compliance with regulatory requirements;
 - 20.8.3.8.2. Compliance with suitability, accuracy, operability, interoperability, security and functional standards;
 - 20.8.3.8.3. Compliance with fault-tolerance, recoverability and compliance with reliability standards;
 - 20.8.3.8.4. Compliance with understandability, learnability, attractiveness and usability standards;
 - 20.8.3.8.5. Compatibility with the foregoing criteria through re-usability, if customized programming is required;
 - 20.8.3.8.6. Compliance with time behavior, resource utilization and efficiency standards;
 - 20.8.3.8.7. Compliance with analyzability, changeability, stability, testability and maintainability standards;
 - 20.8.3.8.8. Compliance with adaptability, installability, co-existence ability, replaceability and portability standards.
- 20.8.4. Each validation test should be such as to demonstrate that:
 - 20.8.4.1. The requirements are met with the proper inputs;
 - 20.8.4.2. Improper inputs are identified, the process is safely stopped, and the recovery with proper inputs results in requirements being met;
 - 20.8.4.3. Any failure will not damage or disable the hardware item, equipment or specialty tool that uses or is affected by the software / firmware;
 - 20.8.4.4. The requirements for such things as integration, interface and compatibility are met.

20.8.5. Validation should include a comparison with the results of methods that can be accomplished independently of the subject software, such as

- 20.8.5.1. Hand calculations;
- 20.8.5.2. Other proven software;
- 20.8.5.3. Measurements;
- 20.8.5.4. Simulated data.

20.9. V&V Performance Results Documentation

20.9.1. V&V should be performed in accordance with the requirements established per Section 20.8, above.

20.9.2. The results V&V should be documented. The documentation should include the:

- 20.9.2.1. Title or nomenclature and unique identifying designator, including revision designator, of the software / firmware that was assessed by V&V;
- 20.9.2.2. Name, organization affiliation and role of each person who participated in the V&V;
- 20.9.2.3. Title or nomenclature and the unique identifying designator of each test that was performed per Section 20.8.3, above;
- 20.9.2.4. Results of each test;
- 20.9.2.5. Nature of each comparison that was performed per Section 20.8.5, above;
- 20.9.2.6. Results of each comparison;
- 20.9.2.7. Description of each condition that was identified during the V&V, if any;
- 20.9.2.8. Action taken for each identified condition;
- 20.9.2.9. Identification of each condition report originated per Section 20.14, below.

20.10. Software / Firmware Procurement

In addition to the requirements above, for software / firmware developed by a supplier, the following also should be procured:

- 20.10.1. The software / firmware user's license;
- 20.10.2. A software / firmware user's manual;
- 20.10.3. Software / firmware user training;
- 20.10.4. Software / firmware maintenance.

20.11. Software / Firmware Security

- 20.11.1. Access to the software / firmware should be limited to only authorized users such as to protect the software / firmware from unauthorized change or use.
- 20.11.2. Access to facility security data should be limited to those who have a need to know.
- 20.11.3. The cyber security requirements of Sections 23.5 – 23.8, below, should be applied to software / firmware, as applicable.

20.12. Software / Firmware Adverse Contingency Planning

- 20.12.1. A copy of each version of the software should be retained for a specified time period or for a time period during which specified conditions exist.
- 20.12.2. The design parameters for each version of firmware should be documented and maintained.
- 20.12.3. A process(es) by which to recover from a catastrophic loss of the software / firmware should be established, documented and maintained.

20.13. Software / Firmware Storage

Requirements for software / firmware storage should be established and documented taking into consideration the software's / firmware's susceptibility to damage from chemicals, dirt, dust, humidity, light, magnetic fields, radiation, temperature, vibration and similar considerations, and, if the software / firmware was procured, the supplier's recommendations.

20.14. Software / Firmware Condition Reporting

A condition report should be entered into the condition reporting and corrective action process per Section 38, below, for each condition identified during software / firmware and user's manual design review and V&V per Sections 20.7 and 20.9, above, and for each condition identified following the official issuance of the software.

20.15. Software / Firmware and User's Manual Official Issuance

20.15.1. Software / Firmware and User's Manual Approvals

The identification of each person, by job title, who is required to approve each version of the software / firmware document and user's manual as a prerequisite to its official issuance should be established and documented. The meaning of each such approval should be defined and documented.

20.15.2. Software / Firmware Authorization for Official Issuance

The identification of each person, by job title, who has the final authority for the official issuance of the software / firmware document and its user's manual should be established and documented.

20.16. Software / Firmware Maintenance

For each item of software / firmware:

- 20.16.1. Maintenance should be performed as recommended by the software / firmware publisher, including the application of patches or upgrades as required to retain security, correct functionality and warranty.
- 20.16.2. Maintenance should be performed as required by the operator organization to maintain compatibility with design changes to hardware items, equipment and specialty tools, policy changes and regulatory changes.

- 20.16.3. A maintenance log should be prepared and maintained and for each item of software / firmware. The log should:
 - 20.16.3.1. Identify the title / nomenclature of the software / firmware;
 - 20.16.3.2. Identify the unique identifying designator of the software / firmware, including its revision designator;
 - 20.16.3.3. Describe each maintenance action and for each such action, the:
 - 20.16.3.3.1. Date of the action;
 - 20.16.3.3.2. Specific part(s) of the software / firmware that was acted upon;
 - 20.16.3.3.3. Nature of the action – e.g. what was done;
 - 20.16.3.3.4. Results of the action;
 - 20.16.3.3.5. Remediation, if any, in response to the results of the action, including the remediation of any hardware item, equipment, specialty tool or process to which the deficient software / firmware was applied;
 - 20.16.3.3.6. The name of each person who participated in the action and his / her organizational affiliation and contact information.

20.17. Software / Firmware Training

- 20.17.1. Users of the software / firmware should be trained in accordance with the user's manual and Section 21, below.
- 20.17.2. Users of the software / firmware should be qualified based on their demonstrated ability to understand and correctly apply the software / firmware. These qualifications should be documented and verifiable.

20.18. Software / Firmware Change Management

- 20.18.1. The configuration of each version of the software / firmware should be documented.
- 20.18.2. A new, unique identifying designator or a new revision number should be used for each version to the software / firmware.
- 20.18.3. A cross-reference of the unique identifying designators of each (a) software / firmware document, (b) software / firmware user's manual, (c) software / firmware V&V requirements document, (d) administrative and technical process description document in which the software / firmware is used or referenced and (e) hardware item, equipment and specialty tool to which the software / firmware is applied should be established, documented and maintained. This cross-reference should be used to identify the possible need to change a user's manual, V&V requirements document, process description document, hardware item, equipment or specialty tool to be

consistent and compatible with a change to the software / firmware document and vice-versa.

20.18.4. Discernment of Compatibility – Software / Firmware Document and Related Documents

A method should be established by which to readily discern the revision level of the software / firmware document with which the related documents identified in Section 20.18.3, above, are compatible. Acceptable methods are by:

20.18.4.1. Referencing the software / firmware document and its revision level in each related document. For example, when a change is made to a user's manual to be compatible with a revision to a software / firmware document, the changed user's manual should reference the software / firmware document and its compatible revision level.

20.18.4.2. Maintaining a log for each related document in which the software / firmware document and its compatible revision level are identified.

21. TRAINING

21.1. Training Processes

The administrative and technical processes for training should be established by qualified individuals, qualified in training and quality management. These qualifications should be documented and verifiable. The processes for training should be documented in process description documents that address the elements of this Section 21.

21.2. Training Scope

The enterprise should establish the criteria by which to identify the processes for which workers should be trained. As a minimum, workers should be trained for processes that:

21.2.1. Are needed for compliance with applicable law (i.e., federal, state and local government executive orders; enacted legislation; codes; regulatory agency rules and regulations; commitments in licenses and permits; regulatory agency administrative law judge adjudications; civil law judge adjudications) and commitments to stakeholder special interest groups;

21.2.2. Are needed for compliance with this or other business management standards;

21.2.3. Are needed for compliance with hardware item, equipment and specialty tool design standards;

21.2.4. Contribute significantly to technical and financial success of the enterprise;

21.2.5. Are inherently risky from the perspective of safety and health, security, environmental protection and emergency response;

21.2.6. Are difficult to perform.

21.2.7. Involve unique or unusual tasks;

21.2.8. Are performed infrequently.

21.3. Training Process Description Document Contents

The training process description documents per Section 21.1, above, should address:

21.3.1. The scope of the types of processes for which training should be required;

21.3.2. Identification of persons to be trained for each process;

21.3.3. Analysis of the tasks for each process;

21.3.4. Determination of training requirements for each process;

21.3.5. Determination of trainer qualifications and certifications;

21.3.6. Development of training materials;

21.3.7. Determination of the training schedules and venues;

21.3.8. Implementation of the training;

21.3.9. Assessment of the training;

21.3.10. Management of change.

21.4. Trainee Identification

Persons who are to be assigned to implement a given process should be identified as trainees for that process;

21.5. Analysis of Process Tasks

21.5.1. Each task in each officially issued administrative or technical process description document prepared per Section 21.1, above, and within the training scope per Section 21.2, above, should be analyzed to identify the personal attributes, such as knowledge, skills, qualifications, certifications and any other attributes, such as aptitude and behavior needed in order to successfully perform the task – including the safety and health, security, environmental protection and emergency preparedness and response elements of the task. The task analyses should be documented.

21.5.2. The analysis of process tasks should be performed by qualified individuals, including those who participated in the origination of the administrative or technical process description document and representatives of those who will implement the process.

21.5.3. The analysis of process tasks should be performed prior to the production implementation of any process.

21.6. Training Requirements

21.6.1. Training requirements should be established and documented for each process, based on the results of the analysis of process tasks performed per Section 21.5, above.

21.6.2. The training requirements document should identify the things that are to be imparted to trainees, including as a minimum, as applicable, each element of information, skill and method for practicing the skill.

21.7. Trainer Qualifications and Certifications

The qualifications and certifications needed to become the presenter of training for each administrative and technical process description document should be established, documented and verifiable. The qualifications and certifications should be based on the training requirements documented per Section 21.6, above.

21.8. Training Materials

The training materials to be used for the implementation of the training should be developed based on the training requirements documented per Section 21.6, above – materials such as PowerPoint presentations, models, simulators, etc. The training material, itself or the design for a training device should be documented.

21.9. Training Schedules and Delivery Modes – The schedules and venues for the implementation of training should be established and documented. Each training course should include a definition of the acceptable delivery method, such as instructor-led or self-guided, and the prescribed style of interaction, such as remotely accessed online, recorded on-line or in-person, hands-on / practical.

21.10. Training Implementation

21.10.1. Trainees should be trained in accordance with the training requirements document, per Section 21.6, above, prior to the implementation of the process for verification, validation and production.

21.10.2. Any trainee who demonstrates a lack of the required knowledge, skill or other necessary attributes subsequent to the completion of the training should be retrained, remediated, reassigned or otherwise precluded from assignment for the given process.

21.10.3. The date of each training session, the name of the trainer for the session, and the names of the trainees who attended the session should be documented in a training roster.

21.10.4. Important elements of training should be reinforced during routine worker supervision and pre-job briefings.

21.10.5. A method should be established and documented by which to train a single worker who is newly assigned to an ongoing process for which all other workers have been previously trained. The date of each such training, the name of the trainer and the name of the trainee should be documented.

21.11. Training Effectiveness Assessment

21.11.1. The initial presentation of each training for a given administrative or technical process description document or for a change to the document should be assessed for effectiveness and the assessment should be documented.

- 21.11.2. The assessment should be performed by anyone who participated in the preparation of the given process description document or its change.

21.12. Training Condition Reporting

A condition report should be entered into the condition reporting and corrective action process per Section 38, below, for each condition identified in training assessment. Each condition should be corrected prior to any subsequent presentation of the training.

21.13. Training Document Change

21.13.1. Training Requirements, Materials and Schedule Document Change

Training requirements documents, training materials documents and training schedules should be changed in accordance with the identified need for change per Sections 21.13.2 and 21.13.4, below. The impact of these changes on trainer qualifications and certifications should be considered. The changes to these documents should be officially issued prior to worker re-training per Section 21.13.6, below.

21.13.2. Cross-Reference of Process Description Documents to Training Requirements Documents

A cross-reference of the unique identifying designator, including revision designator, of each (a) process description document for which training is required and (b) corresponding training requirements document should be established, maintained and used to identify the possible need to change a training requirements document to be consistent and compatible with a change to the process description document.

21.13.3. Discernment of Compatibility – Process Description and Training Requirements Documents

A method should be established by which to readily discern the revision level of the process description document with which the training requirements document is compatible. Acceptable methods are by:

- 21.13.3.1. Referencing the process description document and its revision level in the training requirements document. For example, when a change is made to a training requirements document to be compatible with a revision of a process requirements document, the changed training requirements document should reference the process description document and its compatible revision level.

- 21.13.3.2. Maintaining a log for the training requirements document in which the process description document and its compatible revision level are identified.

21.13.4. Cross-Reference of Training Requirements Documents to Training Materials and Schedules Documents

A cross-reference of the unique identifying designator, including revision designator, of each (a) training requirements document and (b) corresponding training materials and training schedule document should be established, maintained and used to identify the possible need to change a training materials or training schedule document to be consistent and compatible with a change to the training requirements document.

21.13.5. Discernment of Compatibility – Training Requirements and Training Materials / Schedule Documents

A method should be established by which to readily discern the revision level of the training requirements document with which the training materials / schedule document is compatible. Acceptable methods are by:

21.13.5.1. Referencing the training requirements document and its revision level in the training materials / schedule document. For example, when a change is made to a training materials / schedule document to be compatible with a revision of a training requirements document, the changed training materials / schedule document should reference the training requirements document and its compatible revision level.

21.13.5.2. Maintaining a log for the training materials / schedule document in which the training requirements document and its compatible revision level are identified.

21.13.6. Worker Re-training

Workers should be re-trained in accordance with any change to the training requirements documents. Such re-training should be performed prior to the further implementation of the process for reverification, revalidation or production.

21.14. Training Reinforcement

Important elements of training should be reinforced throughout all phases of activity – design, production, maintenance and operations.

22. FIRE SAFETY

22.1. Fire Prevention and Protection Processes

The process for fire prevention and protection should be established by qualified individuals, qualified in fire prevention and protection and quality management. These qualifications should be documented and verifiable. The processes for fire safety should be documented in process description documents that address the elements of this Section 22.

22.2. Control of Welding, Cutting, Grinding and Open Flame Work

Prior to the start of welding, cutting, grinding and open flame work:

- 22.2.1. The supervisor of the job should be trained in basic industrial fire prevention and firefighting.
- 22.2.2. Equipment being used for the welding, cutting, grinding and open flame work should be checked to assure that it is in a safe working condition. Oxyacetylene equipment should be checked for leaks.
- 22.2.3. Moveable combustible material within a 35-foot radius of the work area should be removed from the work area.
- 22.2.4. Non-removable combustible material within a 35-foot radius of the work area should be protected from flame or sparks, such as with a flame-proof cover.
- 22.2.5. Fire extinguishers, fire hoses and other appropriate fire-fighting equipment should be within a reasonable distance of the work area.
- 22.2.6. At least one worker in the work area should be designated to watch for smoldering sparks and potential fires. This worker should be trained in basic industrial fire prevention and firefighting and should be responsible for activating or assuring the activation of a fire alarm, as necessary.
- 22.2.7. Following the completion of the work, the worker designated for the fire watch should perform a check to assure that the work area is free of any potential source for fire.
- 22.2.8. If the work is to be started subsequent to the completion of construction and turnover for operations, as a prerequisite to the work, a work permit should be issued by Operations.

22.3. Control of Fire Loads

- 22.3.1. To the extent practicable, combustible materials should be stored away from vital areas of the energy facility.
- 22.3.2. An extensive amount of combustibles should not be accumulated in any one area.
- 22.3.3. Waste, debris, scrap, rags, spills and any other combustibles resulting from work activity should be removed upon completion of the activity or upon completion of a shift following which there is no work activity – whichever comes first.
- 22.3.4. Timbers and wood products in vital areas of the energy facility should be treated with flame retardant.

23. SECURITY

23.1. Security Processes

The administrative and technical processes for security should be established by qualified individuals, qualified in security and quality management. These qualifications should be

documented and verifiable. The processes for security should be documented in process description documents that address the elements of this Section 23.

23.2. Security Process Scope

Security process description documents should address:

23.2.1. Monitoring of the energy facility;

23.2.1. Access controls established per Section 23.4, below;

23.2.2. Drug and alcohol controls established per Section 23.4, below;

23.2.3. Cyber security, per Section 23.5, below;

23.2.4. Physical access controls.

23.3. Security Personnel Training, Qualifications and Certifications

Security personnel, including cyber security personnel, should be trained, qualified and certified per Section 21, above, and their training, qualifications and certifications should be documented and verifiable.

23.4. Access Control

23.4.1. Personnel access to the energy facility as a whole and to selected high-risk or sensitive areas of the energy facility should be appropriately limited on the basis of need.

23.4.2. Persons should have to log in and out of each high risk and sensitive area of the energy facility and the access and egress log should be maintained.

23.4.3. Piggybacking or tailgating should be prohibited at secured access points.

23.4.4. Compliance with regulatory requirements for drug and alcohol control should be assured.

23.5. Cyber Security

Cyber security incidents, including malicious logic, phishing / spear phishing, network exploitation, denial of service, physical incursions and social engineering, should be prevented by:

23.5.1. Establishing data access controls;

23.5.2. Training employees;

23.5.3. Certifying employees and the organization as a whole;

23.5.4. Testing employees and the networks;

23.5.5. Practicing with drills and exercises.

23.5.6. Cyber security training, testing and practicing network and network activities in which an accurate representation of the network and network activities should be used, with assurance that the training / testing / practicing network is completely separate from the production / operational network.

23.6. Security Drills and Exercises

Drills and exercises for security processes should be planned, scheduled and documented. The drills and exercise schedule should be based on the level of risk and complexity of the process.

23.7. Security Process Testing

Each security process should be tested in accordance with a documented plan. The frequency of testing should be based on the level of risk and complexity of the process.

23.8. Security Condition Reporting

A condition report should be entered into the condition reporting and corrective action process per Section 38, below, for each condition identified during security training, security drills / exercises, security tests and security process implementations in response to real events. Each condition should be corrected prior to any subsequent performance of the affected type of drill / exercise or test.

23.9. Security Process Real Event, Security Test and Security Drill and Exercise Results Assessment and Documentation

Security process real event and security drill / exercise performance results should be assessed and the assessments should be documented. Each such document should include the:

23.9.1. Title of the security real event / test / drill / exercise;

23.9.2. Unique identifying designator of the security real event / test / drill / exercise;

23.9.3. Date of the security real event / test / drill / exercise;

23.9.4. Name and organizational affiliation of the person directing the security real event response / test / drill / exercise;

23.9.5. Roster of the participants in the security real event / test / drill / exercise;

23.9.6. Security real event / test / drill / exercise scenario;

23.9.7. Description of each condition identified in the security real event / test / drill / exercise;

23.9.8. Description of each action taken to correct the condition;

23.9.9. Unique identifying designator of the condition report entered into the condition reporting and corrective action process per Section 23.8, above.

24. CHEMICAL CONTROL

24.1. Chemical Control Processes

The administrative and technical processes for chemical control should be established by qualified individuals, qualified in chemical control and quality management. These qualifications should be documented and verifiable. The processes for chemical control should be documented in process description documents that address the elements of this Section 24.

24.2. Chemical Control Process Description Document Contents

The chemical control process description document(s) should require the: