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☐This is a minor revision allowed by QAP 5.1 Prepared by and Issue Date:	

SUMMARY OF CHANGES

Section	Description	Type of Change
	Revision 19 changes are below	
Revision Number and Summary of Changes Table	Modified Revision Number and Summary of Changes table to accommodate Editorial changes. Added link to prior QAP revisions.	Editorial

Prior revisions of this QAP are available here: https://ecm.epri.com/otcs/cs.exe/open/1754356

1.0 Purpose and Scope

1.1 Purpose

1.1.1 To establish the method to be used to identify, evaluate, and report defects or deficiencies in Safety Related EPRI products and services that are supplied to nuclear power plants or other nuclear facilities, which fall within the scope of the Code of Federal Regulations, Title 10, Chapter 1, Part 21 (10CFR21), "Reporting of Defects and Noncompliance."

Note: *United States (US) Nuclear Regulatory Commission (NRC) Regulatory Guide 1.234, Revision 0 endorses Nuclear Energy Institute (NEI) 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," Revision 1, which was developed to incorporate previous guidance in NUREG-0302, to add additional clarity in the specific areas where issues have historically occurred, and to include experience gained from the nearly 40 years of complying with 10CFR21. NEI 14-09 will supersede NUREG-0302 and, as such, may be used for clarification, evaluating, and reporting Part 21 issues.*

1.2 Definitions

1.2.1 See QAP 5.1 for definitions.

2.0 Procedure

2.1 Definitions

2.1.1 Basic Component

1. A structure, system, or component, or part thereof that affects its safety function necessary to ensure:
   a. The integrity of the reactor coolant pressure boundary;
   b. The capability to shut down the reactor and maintain it in a safe shutdown condition; or
   c. The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §50.34(a)(1), §50.67(b)(2), or §100.11."

   Note: *Specific information is provided on the NRC website, by searching on the code section.*
2. A "Basic Component" is an item designed and manufactured under a QA program complying with Appendix B to Part 50 or commercial grade items which have successfully completed the dedication process.
3. When applied to other facilities and other activities licensed under 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 "Basic Component" means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in the applicable Code of Federal Regulation part, and in which a defect or failure to comply with any applicable regulation, order, or license issued by the NRC could create a substantial safety hazard.
4. "Basic Component" also refers to Safety Related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the

component hardware, design certification, design approval, or information in support of an early site permit application under 10CFR52, whether these services are performed by the component supplier or others.

2.1.2 Defect

1. A deviation in a Basic Component delivered to a purchaser. On the basis of an evaluation, the deviation could create a substantial safety hazard; or
2. The installation, use, or operation of a Basic Component containing a defect; or
3. A deviation in a portion of a facility which could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance; or
4. A condition or circumstances involving a Basic Component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation.

2.1.3 Deviation

1. A departure from the technical requirements included in a procurement document.

2.1.4 Discovery

1. The completion of the documentation, first identifying the existence of a deviation or failure to comply, potentially associated with a substantial safety hazard within the evaluation procedures discussed in §21.21(a).

   Note: *The submittal of an NCR or CAR into the CRS constitutes the documentation of a deviation or failure to comply and initiates the required timeline (per Attachment 1) for completing requirements under 10CFR21.*

2.1.5 Discovery Review

1. A review performed after initial screening indicates a condition exists, which could potentially be reportable pursuant to 10CFR21. The purpose of the review is to determine whether a formal Part 21 evaluation is required.

2.1.6 Evaluation

1. The process of determining whether a particular deviation could create a substantial safety hazard or determining whether a failure to comply is associated with a substantial safety hazard.

2.1.7 Substantial Safety Hazard

1. A loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety.

2.2 Reporting Safety Concerns

2.2.1 Any EPRI employee who finds a potential safety concern shall transmit that concern to the NQA Manager, who shall initiate review of the concern.

2.2.2 This reporting requirement shall apply to both Safety Related and Non-Safety Related work activities, including in-process research undertaken by EPRI employees, in which defects as defined in Section 2.1.2 are identified.

1. Safety concerns relative to the impact on any operating nuclear power plant from EPRI Safety Related or Non-Safety Related products or services shall be documented in the CRS per QAP 15.1 or QAP 16.1.
2. Safety concerns relative to the impact on any operating nuclear power plant from non-EPRI Safety Related or Non-Safety Related products or services shall be reported to the NQA Manager.

   Note: *Although the above is the preferred method of resolving safety concerns, any individual has the right to notify the NRC, directly, of a nuclear safety concern. EPRI will not in any way discriminate or retaliate against an individual for raising a safety concern directly to the NRC.*
3. EPRI is only compelled by 10CFR21 to report defects or failures to comply that could create a substantial safety hazard in facilities and activities within the United States. EPRI is not required by 10CFR21 to be the source of information of foreign plants, against the will of the foreign governments involved, if such information is not also necessary for domestic safety. If EPRI becomes aware of a defect or failure to comply, which could create a substantial safety hazard in facilities and activities within a foreign entity, EPRI may notify the foreign entity of the issue, voluntarily or as required by contract.

   Note: *If EPRI does voluntarily supply information to a foreign entity, the information may be withheld from public disclosure if the notification falls within one of the exemptions to the Freedom of Information Act (FOIA).*

2.3 Point of Discovery (Initial Screening)

2.3.1 When an NCR or CAR has been flagged as needing a Part 21 Evaluation, the NQA Manager, with technical support from the EPRI Project Manager or other technical staff, shall perform a review to determine if the identified issue is potentially associated with a substantial safety hazard and constitutes a Part 21 discovery. The confirmation of this review for Part 21 discovery shall be documented on the subject NCR or CAR. If this review determines that the issue is potentially reportable, pursuant to 10CFR21, then a discovery review process is required.

2.3.2 If it is determined that the identified deviation or failure to comply is not potentially associated with a substantial safety hazard or does not otherwise meet the criteria for a Part 21 discovery, then the item is not reportable under 10CFR21, and no further action is required.

2.4 Part 21 Discovery Review Process

2.4.1 If an NCR or CAR review, conducted per Section 2.3, concludes that a Part 21 discovery review is required, then the NQA Manager shall authorize review of the condition to assess the need for an “evaluation” as defined in 10CFR21, and shall appoint a reviewer/evaluator with the advice of the EPRI Project Manager. The EPRI Project Manager may be appointed as the reviewer/evaluator. If not performing the review, the EPRI Project Manager shall provide the reviewer/evaluator with all relevant product records and shall provide technical input to assist the evaluator in making their determination. The results of the discovery review shall be reviewed and approved by at least one level of Technical Management having oversight of the reviewer/evaluator.

2.4.2 If the discovery review determines that the deviation or failure to comply is potentially associated with a substantial safety hazard or could contribute to exceeding a Technical Specification Safety Limit, then a potential reportable condition exists, and a Part 21 evaluation is required. The NQA Manager shall review and approve the discovery review and shall document the initiation of an evaluation, per Section 2.5, if required.

2.4.3 If a Part 21 evaluation is required, then the date of approval for the NCR or CAR that first documented the deviation shall be used as the starting date for compliance with the action timelines required under 10CFR21. Attachment 1 provides a summary timeline for completing actions as required under 10CFR21.

2.5 Part 21 Evaluation

2.5.1 A Part 21 evaluation determines if the potential reportable condition actually involves a defect, as defined in Section 2.1.2, and is reportable (i.e., must be reported to the USNRC). The NQA Manager and Technical Management having oversight of the project area, with EPRI Project Manager support, shall determine if EPRI has sufficient available knowledge to correctly conclude that the potential reportable condition does or does not involve a defect.

2.5.2 If it is determined that EPRI does not have the capability to perform or complete the evaluation, then EPRI shall inform its affected customers within five working days of this determination so that these customers may evaluate the deviation or failure to comply, pursuant to 10CFR21.21(a).

2.5.3 If a potential reportable condition exists and EPRI is capable of performing the Part 21 evaluation, then a Part 21 evaluation shall be completed as soon as practical, but in no case longer than 60 calendar days from the submittal date of the NCR or CAR that initiated the evaluation. A 60 calendar day period shall include the time required to provide notifications to customers should the evaluation conclude that the safety impact cannot be determined by EPRI. The responsible EPRI Project Manager and other EPRI personnel, as appropriate, shall gather additional technical information concerning the NCR or CAR, and establish to which nuclear facilities the item(s) are required to be delivered.

2.5.4 As a part of the evaluation, the EPRI Project Manager shall attempt to make the following determinations.

1. Does the item fail to comply with the Atomic Energy Act of 1954 (as amended), as reflected in Parts 30, 40, 50, 60, 61,70, 71, or 72 of the Code of Federal Regulations, Chapter 10?
2. Does the item contain a defect, as defined in Section 2.1.2?

2.5.5 Technical Management, having oversight of the project area, shall review and approve results of the evaluation.

2.5.6 If neither condition listed in Section 2.5.4 is determined to apply, it shall be documented by the NQA Manager and EPRI Project Manager in the NCR or CAR that initiated the Part 21 actions and shall be stored in approved QA locations per QAP 17.1.

2.5.7 If the review listed in Section 2.5.4 cannot be completed, because EPRI does not have the capability to determine if a defect exists, the NQA Manager and responsible Technical Management shall transmit the necessary information to the customers, within five working days of this determination, to allow those organizations to perform additional evaluations of the deviation to determine its effect(s) on each of their individual nuclear facilities to which the item was supplied.

2.6 Notification

2.6.1 If final determination cannot be made within 60 calendar days, an interim report shall be submitted to the NRC, prior to the 60th day, describing the deviation or failure to comply that is being evaluated and indicating when the evaluation will be completed.

2.6.2 If either condition listed in Section 2.5.4 is found to apply, then the following actions shall be performed:

1. The EPRI Project Manager or NQA Manager shall inform the CNO of the finding, as soon as practicable and, in all cases, within five working days of the completion of the evaluation.
2. Within two days of the notification in 2.6.2.1, above, the CNO shall notify the NRC, of the defect or failure to comply, either by telephone or fax.
3. Within 30 days of receiving the notification described in 2.6.2.1, the CNO shall supply the NRC with a written notification (report) of the defect or failure to comply. This report shall provide the information delineated in 10CFR21.21(d)(4).

2.6.3 Copies of the Section 2.6.2 notification may also be supplied to the affected customers.

2.6.4 EPRI shall supply additional information to the NRC, as requested.

2.6.5 EPRI will, per the requirements of 10CFR21, permit the NRC to inspect records, premises, activities, and Basic Components or Safety Related documentation as well as software associated with any report filed with the Commission.

2.7 Postings

2.7.1 Per 10CFR21.6 (2) (b), a copy of Section 206 of the Energy Reorganization Act of 1974 and a notice, which identifies internet access to the current regulation (10CFR21), internet access to the current revision of this procedure, and contact data for reporting safety concerns, shall be posted in a conspicuous position (high employee traffic areas such as main building entrances, break rooms, or cafeterias) in the EPRI facilities in which work under the scope of 10CFR21 are being performed.

2.7.2 Posting of notices shall be coordinated by the QA Staff and implemented by the NQA Department.

1. Electronic postings (including Section 206 of the Energy Reorganization Act of 1974) shall be accessible via the EPRI intranet, or equivalent, for use by individuals working away from EPRI facilities. Nuclear Sector staff shall be notified whenever the electronic posting location is changed.

3.0 References

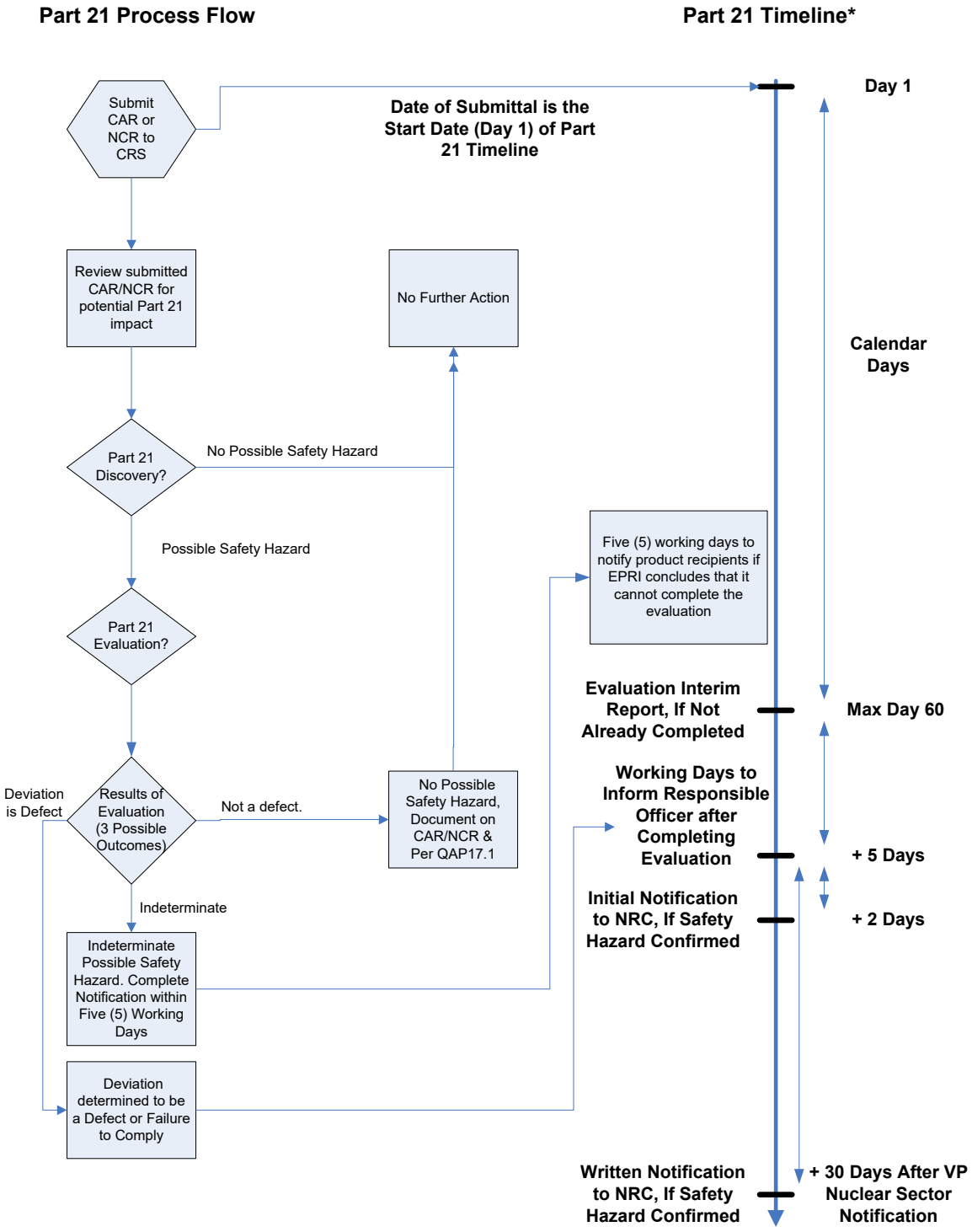
3.1 QAP 5.1 Preparation Review and Approval of Quality Affecting Documents
3.2 QAP 15.1 Nonconforming Materials, Parts, or Components
3.3 QAP 16.1 Corrective and Preventive Action
3.4 QAP 17.1 Quality Records
3.5 QAP 17.4 Quality Records - NQA Department
3.6 10 CFR Part 21
3.7 US NRC Regulatory Guide 1.234, Revision 0
3.8 NEI 14-09, Revision 1
3.9 NUREG-0302, Revision 1

4.0 Records

The Quality Records that shall be maintained related to this QAP are identified in QAP 17.4.

5.0 Attachments

5.1 Attachment 1 Part 21 Summary Timeline



* Per NRC Workshop on Vendor Oversight for New Reactor Construction, "10 CFR Part 21: Requirements and Guidance", December 10, 2008.

5.2 Attachment 2 EPRI Part 21 Posting Locations

Note: *Room number, links and locations may change without need to update this section.*

Palo Alto

Building A
Right side of A1 elevator
Left side of A2 elevator

Building B
Left side of Room #B2039

Charlotte

Building 1
Breakroom #505

Building 2 (1st floor)
Breakroom #108

Building 3
Breakroom #803

Knoxville

Building 1
Break Room #132
Kitchen #177

Building 2A
Break Room #297

Building 2B
Kitchen #209

Dallas

Mailroom

Electronic Postings:

Part 21 Posting Information for internal EPRI employees is available via the Nuclear Quality Programs SharePoint site: https://electricpowerresearch.sharepoint.com/teams/NuclearQA
See:

Part 21 Posting Information for Vendors Working Under the EPRI NQA program is located on the public EPRI website: https://www.epri.com/research/sectors/nuclear/links
See: