CFPP-GEN-016

REPORTING OF DEFECTS AND NONCOMPLIANCES UNDER 10CFR PART 21 AND PART 50.55(e)

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Procedure Owner

Project Director

Function	Name	Signature	Date
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1.0 Purpose

This procedure establishes the methods to identify and report defects, failures to comply, and significant breakdowns in the Quality Assurance Program that could create a substantial safety hazard were it to remain uncorrected, as required by Title 10 of the Code of Federal Regulations, Part 21 (10CFR21), 10CFR Part 50.55(e), and 10CFR Part 52.

2.0 Scope

This procedure applies to CFPP Organization work activities.

3.0 Responsibilities

3.1 Project Director

The Project Director is responsible for the CFPP Organization and its activities. The Project Director is responsible for approving all CFPP Nuclear Procedures (NPs) and is the owner of this procedure. The Project Director is responsible for the process documented in this procedure and for ensuring that the process is effectively implemented. The Project Director is responsible for providing reports to the Nuclear Regulatory Commission (NRC) for 10CFR21 and 10CFR50.55(e) reportable conditions.

3.2 Quality Assurance Manager

The Quality Assurance Manager (QAM) is responsible for directing the evaluation, notifying the Project Director of potentially reportable conditions, requesting investigations, and ensuring that records are retained and 10CFR21 and 10CFR50.55(e) postings are performed.

3.3 Condition Review Group

The Condition Review Group (CRG) is responsible for evaluating the reportability of conditions adverse to quality. CFPP-GEN-020, Corrective Action Program, describes the organization of the CRG and defines the CRG's functions and responsibilities.

3.4 Preparer

The Preparer is the person assigned by the CRG to evaluate the reportability of a condition.

3.5 CFPP Organization

CFPP Organization personnel are responsible for reporting conditions adverse to quality to the CRG in accordance with CFPP-GEN-020, Corrective Action Program.

3.6 Nuclear Safety Review Committee

The Nuclear Safety Review Committee (NSRC) is an independent review body and is formed by the CRG for potential or confirmed reportable conditions that consists of knowledgeable individuals to evaluate a possible defect or noncompliance. The NSRC is also responsible for preparing the interim report as outlined in 10CFR21.21(a)(2).

4.0 Definitions

4.1 Basic Component

When applied to nuclear power plants licensed under 10CFR Part 50 or Part 52 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

- The integrity of the reactor coolant pressure boundary.
- The capability to shut down the reactor and maintain it in a safe shutdown condition.
- The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to those referred to in 10CFR50.34(a)(1), 10CFR50.67(b)(2), or 10CFR100.11 of this chapter, as applicable.

Basic components are items designed and manufactured under a quality assurance program complying with Appendix B to Part 50 of this chapter, or commercial grade items that have successfully completed the dedication process.

When applied to standard design certifications under Subpart C of Part 52 of this chapter and standard design approvals under Part 52 of this chapter, basic component means the design or procurement information approved or to be approved within the scope of the design certification or approval for a structure, system, or component, or part thereof, that affects its safety function necessary to assure:

- The integrity of the reactor coolant pressure boundary.
- The capability to shut down the reactor and maintain it in a safe shutdown condition.
- The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to those referred to in 10CFR50.34(a)(1), 10CFR50.67(b)(2), or 10CFR100.11 of this chapter, as applicable.

When applied to other facilities and other activities licensed under 10CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 of this chapter, 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 this part, and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the NRC could create a substantial safety hazard.

In all cases, basic component includes 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 Part 52 of this chapter, whether these services are performed by the component supplier or others.

4.2 Commercial Grade Item

When applied to nuclear power plants licensed pursuant to 10CFR50, commercial grade item means a structure, system, component, or part thereof that affects its safety function and that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

4.3 Critical Characteristics

When applied to nuclear power plants licensed pursuant to 10CFR50, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

4.4 Dedication

When applied to nuclear power plants licensed pursuant to 10CFR50, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10CFR50, Appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following:

- Commercial grade surveys.
- Product inspections or witness at hold points at the manufacturer's facility.
- Analysis of historical records for acceptable performance.

In all cases, the dedication process shall be conducted in accordance with the applicable provisions of 10CFR50, Appendix B. The process is considered complete when the item is designated for use as a basic component.

When applied to facilities and activities licensed pursuant to 10CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component.

4.5 Defect

- A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, the deviation could create a substantial safety hazard.
- The installation, use, or operation of a basic component containing a defect as defined in this section.
- A deviation in a portion of a facility subject to the early site permit, standard design certification, standard design approval, construction permit, combined license, or manufacturing licensing requirements of Part 50 or Part 52 of this chapter, provided the deviation 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.

- A condition or circumstance 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 issued under Part 50 or Part 52 of this chapter.
- An error, omission or other circumstance in a design certification, or standard design approval that, on the basis of an evaluation, could create a substantial safety hazard.

4.6 Deviation

A departure from the technical requirements included in a procurement document, or specified in early site permit information, a standard design certification, or standard design approval.

4.7 Discovery

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 10CFR21.21(a).

4.8 Evaluation

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

4.9 Noncompliance

A failure to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Nuclear Regulatory Commission relating to a substantial safety hazard.

4.10 Notification

The telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.

4.11 Substantial Safety Hazard

A loss of safety function to the extent that there is a major reduction in the degree of protection provided to the public health and safety. This includes, but is not limited to, the following:

- Moderate exposure to or release of licensed material. Moderate exposure is further clarified as a dose to an individual or to a member of the public in excess of limits defined in 10CFR Part 20.
- Major degradation of essential safety-related equipment. This phrase is considered to represent a loss of redundancy if, in conjunction with a single failure, a required safety function could not be performed.
- Major deficiencies involving design, construction, inspection, test, or use. "Major deficiency" means a condition or circumstance during which, under normal operating conditions, an anticipated transient or postulated design basis event could contribute to exceeding a safety limit or cause an accident; or, in the event of an accident due to other causes, could, considering an independent single failure, result in a loss of safety function necessary to mitigate the consequences of the accident.

4.12 Significant Breakdown in Quality Assurance

A breakdown in the quality assurance program related to the criteria in 10CFR50, Appendix B, may be a reportable deficiency, depending upon its significance. This applies to those design and construction activities affecting the safety of plant operation, including activities such as design verification, inspection, and auditing. For example, a breakdown may result from an improper identification system for nuclear safety-related materials. More specifically, the implementing procedures may be incomplete or inadequate, or the execution of adequate procedures may be incomplete, improper, or ignored. In the latter case, not following established procedures to ensure that quality assurance requirements are met may constitute a reportable breakdown in the quality assurance program.

5.0 References

5.1 CFPP-GEN-020, Corrective Action Program
5.2 CFPP-DOC-001, Document Control and Records
5.3 Title 10 of the Code of Federal Regulations Part 21 (10CFR21), Reporting of Defects and Noncompliance
5.4 NRC Regulatory Guide 1.234, Evaluating Deviations and Reporting Defects and Noncompliance Under 10CFR Part 21
5.5 NEI 14-09, Revision 1, Guidelines for Implementation of 10CFR Part 21 Reporting of Defects and Noncompliance

6.0 Procedure

The identification, evaluation and reporting of 10CFR Part 21 issues are time critical. The below table illustrates a summary of activities and the associated permissible time periods. Figure 2 also outlines a timeline that may be used as reference.

Table 1. Timeline for identification, evaluation, and reporting of 10CFR Part 21 issues,

Activity	Permissible Time
Discovery	Unspecified
Evaluation	60 days after discovery
Interim Report	60 days after discovery
Notify Project Director	5 working days after evaluation
Initial Notification to NRC	2 days after Project Director informed
Written Notification to NRC	30 days after Project Director informed
Client Notification	5 working days to notify client if not capable of performing evaluation

6.1 Posting

Subsection (a)(1) of 10CFR21.6 requires that the regulations of 10CFR21, Section 206 of the Energy Reorganization Act of 1974 and implementing procedures be posted in a conspicuous location. If it is not practical to post them in their entirety, a notice along with Section 206 may be posted to describe these regulations/procedures and include the name of the individual to whom reports may be made and the location where the regulations/procedures may be reviewed.

The QAM shall ensure that the 10CFR21 posting requirements are met.

6.2 Identification of Potential Defects and Noncompliances

As work is performed to the requirements of the CFPP Quality Assurance Program Description, CFPP Organization personnel shall identify conditions adverse to quality and report them in accordance with CFPP-GEN-020, Corrective Action Program.

Potential defects and noncompliances may be identified through the following:

- Audits of items or services offered by a supplier.
- Review of a supplier design document or a nonconformance report.
- Receipt of a supplier notification of a defect or noncompliance that invoked Part 21.

- NRC announcements of a 10CFR21 report from a utility or suppliers.
- Self-identification of a deviation or noncompliance in CFPP deliverables offered to a client for acceptance. Work "offered for acceptance" normally means, for example, drawings after all reviews have been completed and after approval for use and release for construction; specifications after being revised for contract or for construction; and procurement documents after approval and issuance to the supplier.
- Receipt of a software error report affecting a source code sold as a basic component.

An employee assigned to investigate a Condition Report (CR) in accordance with CFPP-GEN-020, Corrective Action Program, that has not been classified by the CRG as requiring evaluation for 10CFR21 reportability, who discovers a potential defect or noncompliance, shall immediately notify the CRG via a CFPP memorandum.

6.2.1 Evaluation of Conditions Adverse to Quality

The CRG shall review the CR in accordance with Appendix A to determine if the condition is potentially reportable. If the condition is determined to be potentially reportable, an evaluation shall be conducted to determine whether the condition adverse to quality could create a substantial safety hazard or whether the failure to comply is associated with a substantial safety hazard. The date of the discovery is the start of the 60-day time limit.

6.3 Evaluation

The CRG shall assign a Preparer to perform the evaluation.

If it is determined that the condition is not reportable, the Preparer shall document this in the CR. If this determination is confirmed by the CRG, then the condition is not reportable. The condition will be resolved in accordance with CFPP-GEN-020, Corrective Action Program, as appropriate.

If it is determined that the condition might be reportable, the Preparer shall note this in the CR and begin screening the concern for a potential substantial safety hazard.

6.3.1 Screening for Substantial Safety Hazard

The Preparer shall perform a screening, with assistance as needed, to determine whether a substantial safety hazard is involved. The Preparer shall perform this screening as soon as possible to ensure that the 60-day time limit is met.

If the screening determines that a substantial safety hazard does not exist, then the Preparer shall document this in the CR. If this determination is confirmed by the CRG, then the condition is not reportable. The condition will be resolved in accordance with CFPP-GEN-020, Corrective Action Program.

If the screening cannot eliminate the possibility of the condition being reportable under Part 21, the Preparer shall immediately notify the CRG. The following information shall be provided:

- A description of the possible defect or noncompliance, including identification of all affected documents.
- The client(s) and project(s) affected.
- The name (printed and signed) and title of the Preparer reporting the potential defect or noncompliance.

6.4 CRG Confirmation

Upon notification, the CRG shall confirm that the reported possible defect or noncompliance does or does not qualify as a potential defect or noncompliance associated with a substantial safety hazard under the requirements of 10CFR21.

If the reported possible defect or noncompliance is determined to not be reportable under 10CFR21, the CRG shall document that determination and the basis thereof in a memorandum addressed to the Preparer, with copies to the Project Director and the QAM. The condition will be resolved in accordance with CFPP-GEN-020, Corrective Action Program.

If the reported possible defect or noncompliance is confirmed to be reportable under 10CFR21, the CRG shall document that determination in a confirming memorandum. The CRG's memorandum shall be sent to the Project Director, QAM, the responsible Managers, and the Preparer.

Upon receipt of the memorandum indicating that the CRG has determined that a possible defect or noncompliance exists that meets the criteria outlined in 10CFR21, the Project Director shall notify the affected parties

and/or licensees by registered mail. Copies of the notification letters shall be sent to the QAM and responsible Managers.

6.5 Final Evaluation

For potential or confirmed conditions, the CRG shall form a Nuclear Safety Review Committee consisting of knowledgeable individuals to evaluate the possible defect or noncompliance. The CRG shall establish the schedule for this evaluation to ensure completion within the 60-day time limit.

If CFPP determines that it is unable to evaluate whether a defect or noncompliance exists or if, upon written notification, the clients and/or licensees elect to perform these evaluations and to report directly to the NRC, the Project Director shall forward the relevant information about the possible defect or noncompliance to the affected parties and/or licensees using registered mail.

If CFPP determines that it is unable to evaluate the condition, the information shall be forwarded to the affected parties and/or licensees within 5 working days of the determination. If the affected parties and/or licensees elect not to conduct the evaluation, or if CFPP disagrees with the affected parties' and/or licensees' actions or evaluations, the Project Director shall direct that the possible defect or noncompliance be evaluated by CFPP.

The Project Director shall send copies of the affected parties notification letters and subsequent disposition to the CRG, QAM and responsible PMs.

As part of its evaluation, the Nuclear Safety Review Committee shall determine whether the reported possible defect or noncompliance affects additional CFPP activities and shall recommend appropriate actions. Actions shall be added to the disposition of the associated corrective action. Actions shall be tracked to completion in accordance with CFPP-GEN-020, Corrective Action Program.

The QAM shall develop and maintain notes for meetings relating to the evaluation of the possible defect or noncompliance.

6.6 Interim Report – Internal

The CRG shall closely monitor the progress of the evaluation. If the evaluation will not be completed within the 60-day time period, the CRG shall direct the Nuclear Safety Review Committee to prepare an interim report as outlined in 10CFR21.21(a)(2). The interim report shall describe the possible defect or noncompliance that is being investigated

and shall state the date when the evaluation is expected to be completed. The CRG shall schedule preparation of the interim report to ensure that the Project Director can submit it to the NRC before the 60-day time period expires.

After completion, the CRG shall hand-deliver the interim report and a cover memorandum to the Project Director. Delivery of the interim report and cover memorandum shall be made within 5 working days of completion of the interim report.

The Project Director shall document receipt of the interim report on the cover memorandum and provide a copy of the memorandum, showing receipt date and time, to the CRG. The CRG shall provide copies of the receipted memorandum and interim report to the QAM, responsible Manager(s) and the Preparer.

6.7 Documentation of Evaluation Results and Internal Reporting

Within 2 working days of completion of an evaluation conducted by the Nuclear Safety Review Committee, the CRG shall document the evaluation results and shall send a memorandum, along with appropriate supporting documentation, to the Project Director, with copies to the QAM, responsible Manager(s) and the Preparer.

The Project Director shall return a copy of the memorandum, showing receipt date and time, to the CRG.

The CRG shall send a memorandum outlining the results of the evaluation to the Preparer. The Preparer may examine the official evaluation report file compiled and maintained by the CRG.

6.8 Notification to the NRC

6.8.1 Filing Interim Reports for Evaluations Performed In-House

If an evaluation cannot be completed within the 60-day time period, the Project Director shall transmit the interim report by registered mail to the following address along with a cover letter:

Document Control Desk
US NRC
Washington, D.C. 20555-0001

Copies of the interim report and cover letter shall be distributed to the Project Director, and QAM.

6.8.2 Filing Interim Reports for Evaluations Performed by Licensees (Affected Party)

If a possible defect or noncompliance identified by CFPP is to be evaluated by an affected party and/or licensee, the CRG shall monitor the progress of the affected parties and/or licensee's evaluations. If it appears that the NRC will not be notified by any affected party or licensee within 60 days of the date of discovery by that affected party or licensee, the CRG shall ensure that an interim report is prepared and filed with the NRC in accordance with applicable 10CFR21 procedures and Subsection 6.8.1.

6.8.3 Filing Final Reports

If an interim report has not been transmitted to the NRC and the memorandum from the CRG states that the results of the evaluation indicate that there was no defect and/or noncompliance associated with a substantial safety hazard, no further reporting action is required, except for retention of the evaluation as a quality record. The condition will be resolved in accordance with CFPP-GEN-020, Corrective Action Program, as appropriate.

If an interim report has been transmitted to the NRC, or if the memorandum from the CRG states that the results of the evaluation indicate that a defect or noncompliance associated with a substantial safety hazard exists, the Project Director shall notify the NRC as outlined above.

Initial notification shall be within 2 calendar days following receipt of the memorandum from the CRG, via facsimile to the NRC Operations Center at (301) 816-5151, followed by telephone confirmation at (301) 816-5100. In addition to the initial notification, the Project Director shall send a written notification and report by registered mail to:

Document Control Desk,
US NRC
Washington, D.C. 20555-0001

within 30 days following receipt of the memorandum from the CRG. The report shall contain all of the information specified in Section 6.9. A copy of the notification and report shall be sent to the licensees and/or affected parties, the CRG, QAM, and the responsible Manager(s).

When an evaluation is conducted and reported by an affected party and/or licensee, the responsible Manager shall obtain a copy of the affected

party's and/or licensee's final report or notification to the NRC for CFPP records. The Manager shall send a copy of the affect party's and/or licensee's report to the CRG and the Preparer, as applicable. In addition, 10CFR Part 21.5 contains information for electronic submissions.

6.9 Written Report

In accordance with 10CFR21.21(d)(4), the written report to the NRC shall include, but not be limited to, the following information, to the extent known:

- Name and address of the individual informing the NRC.
- Identification of the facility, activity, or basic component within the United States that fails to comply or contains a defect.
- Identification of firm constructing the facility or supplying the defective basic component.
- Nature of the defect or failure to comply and the substantial safety hazard that is created or could be created.
- The date on which information regarding the defect or failure to comply was obtained.
- For basic components, the quantities and locations in use at, supplied for, or being supplied for facilities or activities subject to 10CFR21.
- Corrective action taken or planned, individual or organization responsible for corrective action, and schedule.
- Advice that has been, is being, or will be given to purchasers or licensees.
- In the case of an early site permit (ESP) or combined license (COL), the entities to which the information was transferred.

6.10 Investigation Assistance

The NRC may request additional information from personnel to complete its investigation. CFPP Organization personnel shall provide assistance as requested.

6.11 Construction Deficiency Reporting – 10CFR50.55(e)

The requirements of 10CFR50.55(e) apply to the Construction Permit Holder, combined license, or manufacturing license. The Construction Permit Holder shall be responsible for reporting each deficiency in accordance with the criteria and requirements of 10CFR50.55(e). The regulation shall apply to design and construction and shall encompass all of the activities inherent in design and construction even if they are performed by agents, contractors, subcontractors, or consultants. The Construction

Permit Holder shall establish and implement a system that ensures that all reportable deficiencies are identified and reported, and the reporting requirement is imposed on its agents, contractors, and subcontractors.

Note: A process flowchart for identifying and reporting defects is shown in Figure 1.

6.12 Summary of Responsibilities

The CRG shall accomplish the following:

- Determine if the condition is potentially reportable in accordance with Appendix A.
- Ensure that an evaluation is conducted to determine whether the condition adverse to quality could create a substantial safety hazard or whether the failure to comply is associated with a substantial safety hazard.
- Notify the Project Director as soon as practical, and in all cases, within 5 working days after completion of the evaluation.
- If the evaluation is not completed within 60 days of discovery, notify the Project Director that an interim report is due to the NRC 60 days from discovery.
- If the evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery, prepare and submit an interim report. The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. The interim report shall be submitted in writing within 60 days of discovery of the deviation or failure to comply.

The Project Director shall accomplish the following:

- If the CFPP Organization cannot perform the evaluation, inform the client and/or licensees within 5 working days of the determination so that the clients and/or licensees may evaluate the deviation or failure to comply.
- Review the evaluation and determine if the condition adverse to quality is reportable under 10CFR Part 21.
- Notify the NRC Operations Center for 10CFR Part 21 reports by facsimile at (301) 816-5151 within 2 days following identification of a deviation or failure to comply. To verify that the facsimile has been received, the NRC Operations Center should be contacted at (301)

816-5100. Written notification shall be provided within 30 days of the identification of the deviation or failure to comply.

- Submit the interim report to the NRC within 60 days of discovery, if the evaluation cannot be completed within 60 days of discovery.

7.0 Records

When completed, the following documents are quality records and shall be retained in accordance with CFPP-DOC-001, Document Control and Records:

- Evaluations of all deviations and failures to comply for a minimum of 5 years.
- Notifications sent to purchasers and affected licensees for a minimum of 5 years.
- Records of purchasers of basic components for 10 years.
- Records of purchasers for services provided for design certification or approval in accordance with 10CFR Part 52 for 15 years.

8.0 Revision History

Changes to this procedure from the preceding revision are documented in the following table.

Step	Change	Reason for Change
N/A	N/A	Initial Issue

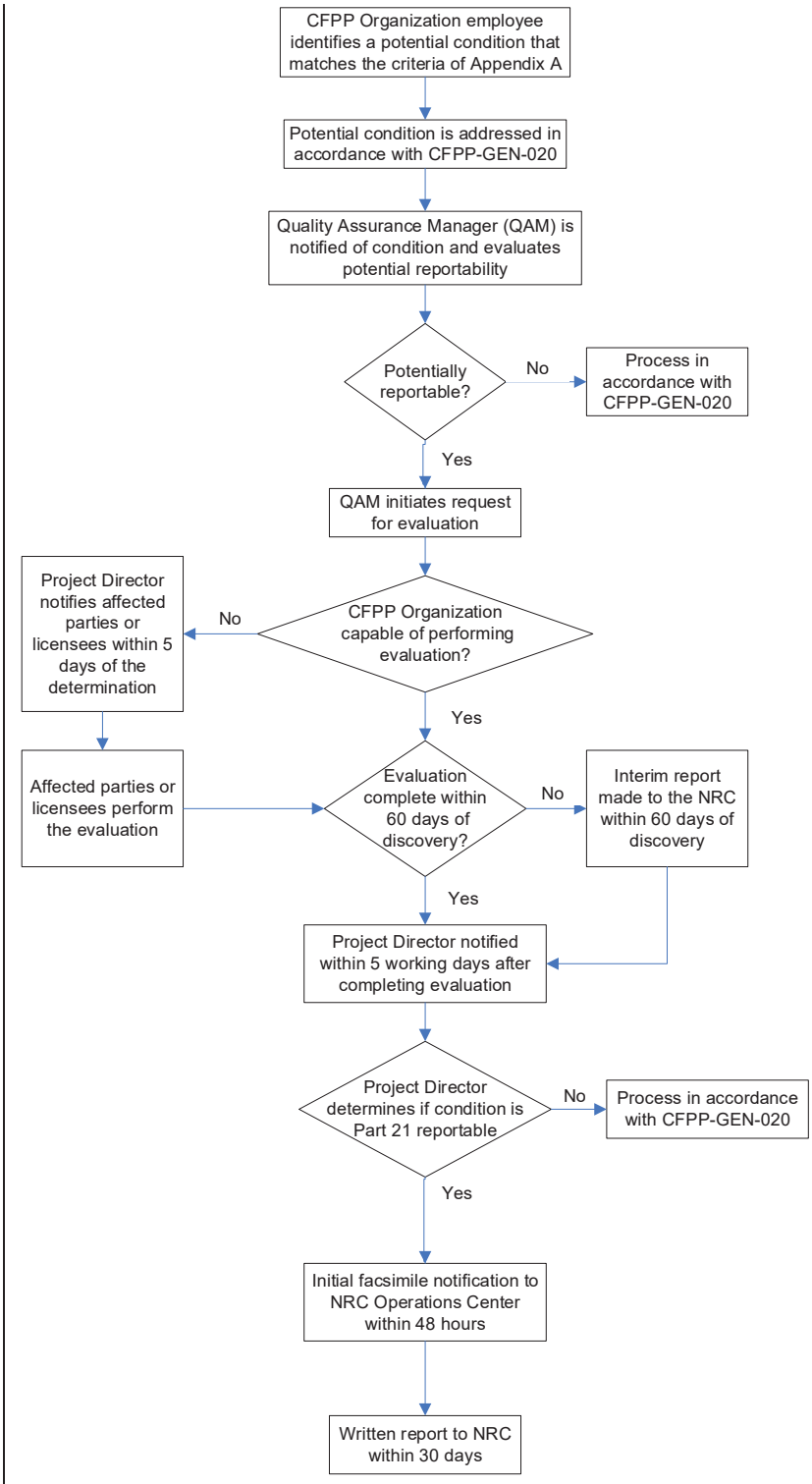

Figure 1. 10CFR Part 21 Reporting process.

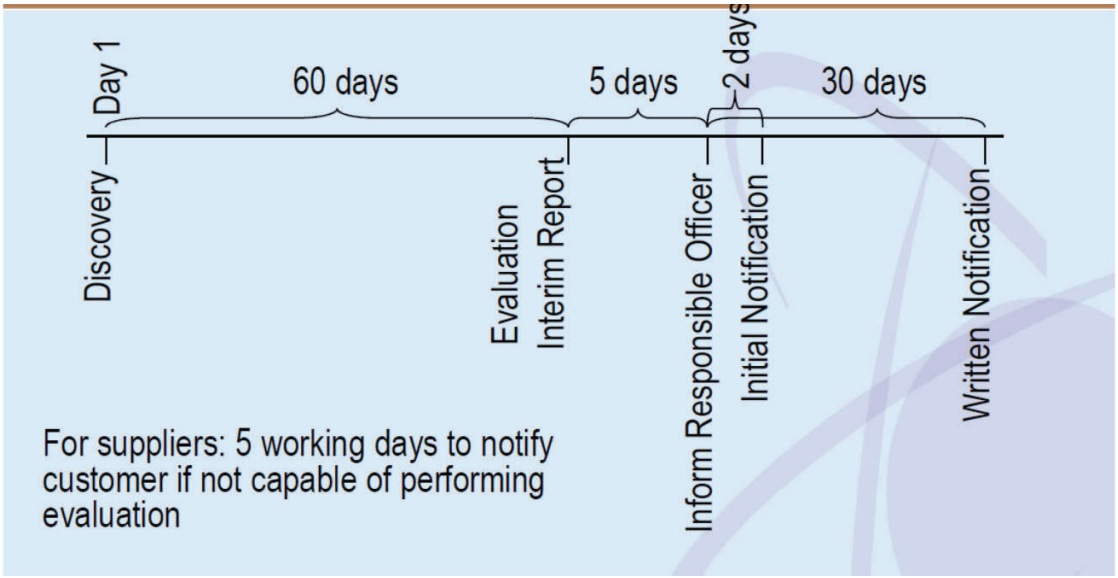

Figure 2. 10CFR Part 21 reporting timeline.

Appendix A – 10CFR Part 21 and Part 50.55(e) Reportability Guidelines

These questions provide the criteria for evaluating 10CFR Part 21 and Part 50.55(e) reportability using the definitions provided in Section 4.0 of the parent procedure:

I. Does the condition adverse to quality involve a basic component within CFPP's scope?
   a) If NO, the condition is NOT reportable under 10CFR Part 21 or Part 50.55(e).
   b) If YES, the condition may be reportable under 10CFR Part 21 or Part 50.55(e).

II. Does the condition adverse to quality in the basic component that has been offered for acceptance contain or involve a defect or failure to comply?
   a) If NO, the condition is NOT reportable under 10CFR Part 21 or Part 50.55(e).
   b) If YES, the condition may be reportable under 10CFR Part 21 or Part 50.55(e).

III. Could the defect in the basic component create a substantial safety hazard?
   a) If NO, the condition is NOT reportable under 10CFR Part 21 or Part 50.55(e).
   b) If YES, the condition is reportable under 10CFR Part 21 or Part 50.55(e) unless previously documented as described below.

IV. Does CFPP have actual knowledge that the NRC has been adequately informed of the defect or failure to comply?
   a) If YES, the condition is not reportable under 10CFR Part 21 or Part 50.55(e).
   b) If NO, the condition is reportable under 10CFR Part 21 or Part 50.55(e).

V. Did the Quality Assurance Program undergo a significant breakdown that could have produced a defect in a basic component?
   a) If YES, the condition is reportable under 10CFR Part 50.55(e).
   b) If NO, the condition is NOT reportable under 10CFR Part 50.55(e).