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INTEC	Management Control Procedure	For Additional Info: http://EDMS
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USE TYPE 3

Change Number: 323345

1. PURPOSE

Evaluate *deviations* (see def.) and *violations* (see def.) to determine whether a *substantial safety hazard* (see def.) exists; maintain records associated with such evaluations; and report *defects* (see def.) and *failures to comply* (see def.) to the Nuclear Regulatory Commission (NRC).

2. SCOPE AND APPLICABILITY

This procedure applies to:

- A. The NRC-licensed possession or transport of source material, byproduct material, special nuclear material, spent fuel, or high level radioactive waste
- B. The *construction* (see def.) or operation of an Independent Spent Fuel Storage Installation (ISFSI) pursuant to 10 CFR Part 72
- C. Supplying *basic components* (see def.) or *services for basic components* (see def.) for a facility or activity licensed (or license application pending) by NRC.

3. PREREQUISITES

None

4. INSTRUCTIONS

4.1 Identifying Deviations and Violations

- 4.1.1 Any employee: Identify deviations associated with basic components with a nonconformance report (NCR) per MCP-538, "Control of Nonconforming Items."
- 4.1.2 Identify violations associated with basic components on ICARE per MCP-598, "Corrective Action System."

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NOTE 1: *The responsible manager for the Fort St. Vrain (FSV) Independent Spent Fuel Storage Installation (ISFSI) is the FSV ISFSI manager (identified on the Document Availability notice).*

NOTE 2: *The responsible manager for the Three Mile Island Unit 2 (TMI-2) ISFSI is the TMI-2 ISFSI manager (identified on the Document Availability notice).*

NOTE 3: *The responsible manager for the NRC-licensed transportation packages used for the transport of TMI-2 core debris or FSV spent nuclear fuel is the Packaging and Transportation Department manager.*

NOTE 4: *The responsible manager for the Idaho Spent Fuel Facility (ISFF) is the ISFF Manager (identified on the Document Availability notice).*

4.1.3 Notify the responsible manager.

4.1.4 Responsible Manager: Identify deviations or violations requiring Part 21 evaluations as any condition meeting all of the following:

- A. Is associated with an activity described in Step 2 of this procedure
- B. Is associated with a basic component or a service for a basic component
- C. Is not the subject of a Part 21 report already furnished to NRC and which identifies DOE or the contractor for the Idaho Cleanup Project (ICP) as a recipient of this report
- D. Has completed *discovery* (see def.).

4.2 Evaluating Deviations and Violations

4.2.1 Responsible Manager: Inform the INTEC Clean-Up Project Area Project Manager of the status of the evaluation.

4.2.2 If the deviation or violation is associated with the FSV ISFSI, TMI-2 ISFSI, or ISFF then also inform the ISFSI Safety Review Committee Chair and the appropriate DOE-ID Facility Director of the status of the evaluation.

4.2.3 Responsible Manager: Perform one of the following steps:

- 4.2.3.1 Evaluate deviations and violations within 60 days of discovery to determine whether such deviation or violation could create a substantial safety hazard, were it to remain uncorrected.

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OR

4.2.3.2 If an evaluation cannot be completed within 60 days of discovery, prepare an interim report for DOE submittal, within 60 days of discovery, to NRC.

4.2.4 Determine if the construction or operation of a facility or activity, or a basic component or services for basic components supplied for such facility or activity:

A. Fails to comply with any applicable NRC regulations, order (from NRC pursuant to 10 CFR Part 2), license, or certificate relating to a substantial safety hazard

OR

B. Contains a defect.

4.2.5 Obtain additional information and resources as needed to complete the evaluation in a timely manner.

4.2.6 Upon completion of the evaluation, transmit the evaluation and all relevant documents used to perform the evaluation to records (see Section 5).

4.2.7 Immediately notify (in no case later than 5 days after completion of the evaluation) and forward a copy of the completed evaluation to the INTEC Clean-Up Project Area Project Manager .

4.2.8 For issues related to the FSV ISFSI, TMI-2 ISFSI, or ISFF forward a copy of the completed evaluation report to the ISFSI Safety Review Committee Chair and to the appropriate DOE-ID Facility Director.

4.2.9 If the deviation or violation is related to a basic component or services for basic components supplied by contractor or DOE-ID, and if contractor doesn't have the capability to perform the evaluation described above, then provide the notification described in Step 4.3.3 within five working days of the discovery of deviation or violation.

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4.3 Notification of Defects and Failures to Comply

NOTE: *Communications with NRC are made by DOE personnel. The 2 day verbal notification and the 30 day written report are to be performed by the responsible DOE officer (see def.).*

- 4.3.1 INTEC Clean-Up Project Area Project Manager: Upon notification of defects or failures to comply, ensure the appropriate responsible officer (see def.) within DOE is notified immediately upon completion of the evaluation to permit the notification by DOE to NRC within 2 working days.
- 4.3.2 Ensure the preparation of a written report for submittal to NRC by DOE within 30 days of the completion of the evaluation. Ensure the written report includes:
- A. Name and address of the individual(s) informing the NRC
 - B. Identification of the facility, activity, or the basic component supplied for such facility or activity which fails to comply or contains a defect
 - C. Identification of the firm or organization constructing the facility or supplying the basic component which fails to comply or contains a defect
 - D. Nature of the defect or failure to comply and the safety hazard which is created or could be created
 - E. The date on which such defect or failure to comply was discovered
 - F. The number and location of all affected basic components in use at, supplied for, or being supplied for one or more facilities or activities subject to the regulations of 10 CFR Part 21
 - G. Corrective actions planned or completed, the names of individuals or organizations responsible for such actions, and the expected completion dates
 - H. Advice related to the defect or failure to comply given or planned to be given to purchasers or licensees.
- 4.3.3 If the deviation or violation is related to a basic component or services for basic components supplied by the contractor or DOE-ID, then prepare notifications to all purchasers, known recipients, and affected licensees.

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5. RECORDS

Evaluations of deviations and violations; and relevant supporting documents

Notifications sent to purchasers, recipients, and affected licensees

Reports of defects and failures to comply sent to NRC

NOTE: *The Records Schedule Matrix, located on the intranet at http://edms.inel.gov/docs/matrix/mtx_menu.html, and the applicable facility, organization, program, or project records management plan and record types list provide current information on uniform file codes, disposition authorities, and retention periods for these records.*

6. DEFINITIONS

Basic Components. A structure, system, or component (SSC), or part thereof that affects the safety function of the SSC, procured by the licensee of a facility or activity subject to this procedure (or procured by the contractor for DOE when DOE is the licensee); and in which a defect or failure to comply could create a substantial safety hazard.

Commercial Grade Item. An item that is: (1) not subject to design or specification requirements that are unique to a nuclear facility, (2) used in applications other than a nuclear facility, and (3) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

Construction. Constructing or construction includes the analysis, design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity within the scope of this procedure; also included are consulting services of such facility or activity.

Dedication. An acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component is deemed equivalent to an item designed and manufactured under an approved quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses; supplemented as necessary by one or more of the following: commercial grade surveys, product inspections or holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. Dedication occurs after receipt and after that item is designated for use as a basic component.

Defect. A deviation in a basic component delivered to a purchaser for use in a facility or an activity if, on the basis of an evaluation, the deviation could create a substantial safety hazard.

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Deviation. A departure from the technical requirements included in (or incorporated by reference in) a procurement document. A procurement document, for the purposes of this definition, is a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

Discovery. The completion of the documentation first identifying the existence of a deviation or violation potentially associated with a substantial safety hazard. Time for investigation is permitted before declaring discovery if the first documentation may be reasonably characterized as identifying a potential deviation or violation. In those cases where there is a period of investigation before discovery is declared, it is expected that such investigation will be aggressively scheduled.

Many reports of suspected deviations, such as Suppliers Process Deficiency Reports, are provided to the vendor as comments to resolve. In such a case, discovery is not reached until the vendor accepts the deviations or until attempts to resolve the comments and the vendor's proposed resolutions are rejected by the licensee (DOE-ID) or its contractor.

Failure to Comply. A violation or possible violation which creates, or could create if left uncorrected, a substantial safety hazard.

Responsible Officer. An individual in the organization who is vested with executive authority over activities covered by the scope of this procedure.

Services for Basic Components. The safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services associated with the component hardware whether these services are performed by the component supplier or others.

Substantial Safety Hazard. 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 for an facility or activity licensed, other than for export, pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of 10 CFR. The evaluation of deviations and failures to comply (to determine whether a substantial safety hazard exists or could exist) should include the safety analysis report for the associated facility or activity. An affirmative answer to any of the following questions is sufficient for a substantial safety hazard determination:

- A. Could the condition create a substantial safety hazard resulting in exposure to or release of licensed material resulting in a condition reportable pursuant to 10 CFR 20.2202(b)?
- B. Could the condition create a substantial safety hazard resulting from a degradation of safety function of the basic component to the extent there is a major reduction in the degree of protection required by NRC to ensure public health and safety?

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- C. Could the condition create a substantial safety hazard resulting from a deficiency of a safety-related service for a basic component to the extent that there is a major reduction in the degree of protection required by NRC to ensure public health and safety?

Violation. A violation, as used in this procedure, is limited to consideration of violations of applicable NRC requirements. Such applicable NRC requirements are: any applicable NRC regulation, order, certificate of compliance, or license. Such violation is covered by this procedure even if it is only a concern that a violation might have occurred (in other words, if the possible violation has not resulted in an NRC-cited violation).

7. REFERENCES

None

8. APPENDIXES

Appendix A, Procedure Basis

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Appendix A

Procedure Basis

Step	Basis	Source	Citation
Entire procedure	Written procedures shall be established, implemented, and maintained for the following: administrative controls.	FSV ISFSI TS TMI-2 ISFSI TS ISFF TS	5.4.1.a
Entire procedure	Written procedures shall be established, implemented, and maintained for the following: reporting.	FSV ISFSI TS TMI-2 ISFSI TS ISFF TS	5.4.1.n 5.4.1.o
4.2.2, 4.2.8	<p>The regulations in this part apply ... to each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess, use, or transfer ... source material, byproduct material, special nuclear material, and/or spent fuel and high level radioactive waste, or to construct, manufacture, possess, own, operate, or transfer ... any ... independent spent fuel storage facility (ISFSI); and to each director and responsible officer of such a licensee.</p> <p>The regulations in this part also apply to each individual, corporation, partnership, or other entity ..., and each director and responsible officer of such organization, that constructs ... an ISFSI ... or supplies basic components for a facility or activity licensed under parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter.</p>	FSV ISFSI TS TMI-2 ISFSI TS ISFF TS	
4.2.1, NOTE	<p>(1) Evaluate deviations and failures to comply to identify defects and failures to comply ... as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected, and</p> <p>(2) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery ... , an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person...</p>	10 CFR 21.21(a)(1) and (2)	

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Step	Basis	Source	Citation
4.2.2 and 4.2.7	The Safety Review Committee shall provide oversight of TMI-2 ISFSI operation by performing reviews of: <ul style="list-style-type: none"> a. Performance indicators (audit findings, reportable events and conditions, Technical Specification violations); 	TMI-2 and FSV ISFSI TS	5.2.4
4.2.7	Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in Section 21.21(a)(1) or Section 21.21(a)(2) if the construction or operation of a facility or activity, or a basic component supplied for such facility or activity— <ul style="list-style-type: none"> (i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to a substantial safety hazard, or (ii) Contains a defect. 	10 CFR 21.21(a)(3)	
4.2.8 and 4.3.3	If the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to Section 21.21(a).	10 CFR 21.21(b)	
4.3.1	Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at 301-816-5151 or by telephone at 301-816-5100 within two days following receipt of information by the director or responsible corporate officer under paragraph (a)(1) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in Section 21.21(a)(2).	10 CFR 21.21(d)(3)(i)	
4.3.1, 4.3.2	All reports required by 10 CFR Part 72 for the TMI-2 and FSV ISFSIs and all reports required by the TMI-2 and FSV ISFSI licenses and TS, shall be submitted by the Manager of DOE-ID or the DOE-ID Facility Director.	FSV ISFSI TS TMI-2 ISFSI TS ISFF TS	5.6.1

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Step	Basis	Source	Citation
4.3.2	Written notification to the NRC at the address specified in Section 21.5 within 30 days following receipt of information by the director or responsible corporate officer under paragraph (a)(3) of this section, on the identification of a defect or a failure to comply.	10 CFR 21.21(d)(3)(ii)	
4.3.2	<p>The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:</p> <ul style="list-style-type: none"> (i) Name and address of the individual or individuals informing the Commission. (ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect. (iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect. (iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply. (v) The date on which the information of such defect or failure to comply was obtained. (vi) In the case of a basic component which contains a defect or fails to comply, the number and location of all such components in use at, supplied for, or being supplied for one or more facilities or activities subject to the regulations of this part. (vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action. (viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees. 	10 CFR 21.21(d)(4)	

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Step	Basis	Source	Citation
5	Retain evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation Suppliers of basic components must retain any notifications sent to purchasers and affected licensees for a minimum of five years after the date of notification	10 CFR 21.51(a)(1) 10 CFR 21.51(a)(2)	
6 Discovery	The definition of “discovery” is being added to the regulations. The time limit for evaluation of deviations and failures to comply begins on the date a deviation or failure to comply is discovered. Thus, in order to complete the documentation, some evaluation must take place to identify a deviation or failure to comply. Further, the discovery process is intended to be included in the procedures necessary to comply with part 21...	56 FR 56083, statements of consideration provided with 10 CFR Part 21 rulemaking.	
6 Substantial Safety Hazard	The criteria for determining the existence of a substantial safety hazard and, consequently, whether a defect is reportable under Part 21 are given ... as: - Moderate exposure to or release of licensed material. Moderate exposure is further clarified as exposure to in excess of 25 rem to the whole body and exposure to an individual in an unrestricted area of 0.5 rem; - 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; or - Major deficiencies in design, construction, inspection, test, or use. “Major deficiency” means a condition or circumstance which, under normal operating conditions, a... design basis accident could ... 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.	56 FR 56083, statements of consideration provided with 10 CFR Part 21 rulemaking. “Moderate” exposure or release corresponds to the exposure or release limits requiring 24-hour notifications; the 24-hour notification limits are now found at 10 CFR 20.2202(b).	