REFERENCE '3'

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ANATEC INTL

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Revision Revision 2
Date September 26, 1994

TITLE: 10 CFR 21 REPORTING OF DEFECTS AND NONCOMPLIANCE

PROCEDURE INDEX

TITLE: 10 CFR 21 REPORTING OF DEFECTS AND NONCOMPLIANCE

1.0 PURPOSE

The purpose of this procedure is to establish Anatec's procedure for assuring compliance with 10 CFR 21 for evaluating and reporting defects in nuclear power plant basic components, or noncompliances to nuclear power plant regulatory requirements, that could cause a substantial safety hazard.

2.0 SCOPE

2.1 The requirements of this procedure apply to all Anatec personnel.

3.0 DEFINITIONS

3.1 Basic Component -

A. A plant structure, system, component, or part thereof necessary to assure: (a) the integrity of the reactor coolant pressure boundary, (b) the capability to shut down the reactor and to 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 10 CFR 100.11; or

B. A component, structure, system, or part thereof 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 Commission could create a substantial safety hazard. Examples of basic components are provided in Attachment 1.

3.2 Commercial Grade Item - An item that is (a) not subject to design or specification requirements that are unique to facilities or activities licensed or otherwise regulated by the NRC, (b) used in applications other than facilities or activities licensed or otherwise regulated by the NRC, and (c) to be ordered from the manufacturer or supplier on the basis of specifications set forth in the manufacturer's published product description (e.g. a catalog).

NOTE: A commercial grade item is not part of a basic component until after dedication; i.e., until it is drawn from the warehouse or stock and assigned for use or installation. The item is then designated for use as a basic component and it becomes subject to the requirements of 10 CFR 21.

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3.3 Defect -

A. A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations of 10 CFR 21 if, on the basis of an evaluation, the deviation could create a substantial safety hazard (this definition is primarily directed at the offsite supplier), or

B. The installation, use, or operation of a basic component containing a defect as defined in Para 3.3A above (this definition is primarily directed at the recipient, i.e., the user of the component or service), or

C. A deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of 10 CFR 50 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 (this definition is primarily directed at the onsite supplier), or

D. A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit as defined in the Technical Specifications (this definition is primarily directed at the licensee).

3.4 Deviation - A departure from the technical requirements included in a procurement document. Technical requirements include the requirements of applicable regulations, industry standards, and other requirements from the procurement document, e.g., vendor specifications, manufacturing information, catalog information, letters, etc. (These requirements may not be explicitly stated in the procurement document.)

3.5 Noncompliance - Failure to comply with regulatory requirements identified in Attachment 1.

3.6 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, namely:

A. Moderate exposure to, or release of, licensed material reportable under the provisions of 10 CFR 20.403 (a)(1) or 10 CFR 20.403 (b)(2), or the exposure of any individual in an unrestricted area to a whole body dose in one calendar year in excess of 0.5 rem (10 CFR 20.105).

B. Major degradation of a basic component such that a required safety function cannot be performed assuming a single failure. (Operating in a degraded mode as permitted by the Technical Specifications is not considered to be a substantial safety hazard).

C. Major deficiencies in design, construction, inspection, test, or operation of basic components that could contribute to exceeding a safety limit or result in the loss of safety function necessary to mitigate the consequences of an accident.

NOTE: By itself, a failure to comply does not necessarily result in a substantial safety hazard. If a failure to comply occurs, an evaluation must be performed to determine if a substantial safety hazard affecting a structure, system, or component was created.

4.0 REFERENCE DOCUMENTS

4.1 10 CFR 21, "Reporting of Defects and Noncompliance".

4.2 NUREG-0302, Rev.1, "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance, July 12-26, 1977."

4.3 ANATEC-06, "Document Control".

5.0 PROCEDURE

5.1 GENERAL

5.1.1 The requirements of 10 CFR 21 apply to two broad categories of nuclear power plant activities, namely: (a) defects in basic components, and services related to such, that could cause a substantial safety hazard, and (b) noncompliances with regulatory requirements that could cause a substantial safety hazard.

5.1.2 For those cases where reporting is required by other NRC regulations, duplicate evaluation and reporting under 10 CFR 21 is not required. Care shall be exercised, however, to assure that the information required by the applicable regulation is provided to the NRC within the reporting periods of each regulation.

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5.1.3. Attachment 1 provides examples of the equipment, services, and regulatory requirements subject to 10 CFR 21 as identified in Reference 4.2.

5.1.4. Defects or noncompliances identified through implementation of established quality control measures prior to final acceptance of services provided shall not be subject to reporting under 10 CFR 21; however, vendor caused defects or noncompliances found during these quality control measures are subject to reporting under 10 CFR 21.

5.2 PROCUREMENT DOCUMENT REQUIREMENTS

5.2.1. Quality Assurance shall assure that purchase orders for applicable equipment or services specify that 10 CFR 21 is applicable.

5.3 IDENTIFICATION, EVALUATION, AND REPORTING PROCESS

5.3.1. Anatec employees are responsible for notifying their supervisor of applicable defects or noncompliances as defined by this procedure.

5.3.2. All deviations in basic components shall be considered for reportability.

5.3.3. The form shown in Attachment 2 shall be used to document the evaluation process. This evaluation is only required for vendor-related deviations that have not been reported under 10 CFR 21.

5.3.4. The sequential number shall be obtained from the Quality Assurance Manager or his/her designee. Upon completion the form will be forwarded to the President, Anatec or his/her designee for evaluation and determination of reportability, if required.

5.3.5. In the event the organization that identifies the potential defect or noncompliance does not possess the expertise to perform the required evaluation, the information shall be provided to the appropriate organization(s) to complete and document the evaluation required by Parts II and III of Attachment 2.

5.3.6. Upon receipt and acceptance of information reasonably indicating that a defect or noncompliance is reportable under 10 CFR 21, the

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President or his/her designee shall be responsible for notifying the licensee within two (2) days of such acceptance.

5.3.7. If initial notification is by means other than written communication, a written report shall be submitted to the licensee within five (5) days of the President or his/her designee's receipt and acceptance of the information. Written notification shall be made via Attachment 2.

5.3.8. If the President has actual knowledge that the NRC has been adequately informed of a defect or failure to comply as reported above, additional notification is not required.

5.3.9. If NRC notification has not been made by the licensee, the President is required to provide initial notification to the Director of the appropriate Regional Office within two (2) days of receipt and acceptance of the information followed by a written report within five (5) days. This report shall be prepared in accordance with Attachment 3.

5.3.10. Notification of potential defects or noncompliances identified by organizations external to Anatec, that may result in 10 CFR 21 reports shall be received by the Quality Assurance Manager or his/her designee for processing, as required.

5.4 POSTING REQUIREMENTS

A copy of 10 CFR 21, Section 206 of the Energy Reorganization Act of 1974, and a copy of this procedure shall be conspicuously posted in common work areas and at Anatec corporate headquarters.

6.0 RECORDS

6.1 Records shall be maintained in accordance with Reference 4.3, Anatec's Document Control procedure.

Additional records shall be maintained documenting evaluations involving substantial safety hazards and notifications to the Nuclear Regulatory Commission (NRC).

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Prepared By: Lisa J. Gardner Date 9/26/94

Technical Review and Approval By: [signature] Date 9/26/94

Reviewed and Approved By: Lisa J. Gardner Date 9/26/94
Manager of Quality Assurance

Approved For Release: [signature] Date 9/30/94
General Manager

EXAMPLES OF EQUIPMENT AND SERVICES SUBJECT TO 10 CFR 21

The following guidance is provided on the applicability of 10 CFR 21 to nuclear power plants:

1. Applies only to safety-related equipment required to be seismic Category I.
2. Applies to services associated with applicable equipment such as design, inspection, testing, calibration, and consulting services.
3. Applies only to Federal regulatory requirements established for the radiological protection of the public (including employees) health and safety.

The following are specific examples of equipment, services and regulatory requirements that are subject to 10 CFR 21:.

Basic Components

1. Safety-related equipment.
2. Commercial grade items (e.g., bearings, relays, bar stock, and welding supplies) after dedication.
3. Security Equipment - 10 CFR 21 is only applicable to security components or systems whose failure or inoperability due to defects could permit undetected, unimpeded access of unauthorized personnel from outside the protected area to vital areas.

Services (Associated with Basic Components)

1. Fire protection inspection by fire consultants.
2. Calibration services.
3. Industrial radiographic services.
4. Nondestructive examination of safety-related equipment and welds.
5. Design of safety-related equipment.

EXAMPLES OF EQUIPMENT AND SERVICES SUBJECT TO 10 CFR 21-CONT.

Services (Associated with Basic Components)-CONT.

6. Seismic and geologic surveys for a reactor site.
7. Specifications for safety-related equipment.
8. Computer codes for reactor analysis.

Regulatory Requirements

1. 10 CFR regulations pertaining to nuclear power plants.
2. Facility Operating License and appended radiologically related Technical Specifications.
3. Plans and procedures implementing Items 1 and 2 above (e.g., Nuclear Quality Assurance Program, Radiological Emergency Response Plan, Fire Protection Program, and Security Plan).

10 CFR 21 DEFECT OR NONCOMPLIANCE
IDENTIFICATION, EVALUATION, AND NOTIFICATION FORM

SEQUENTIAL NO. _____

I. IDENTIFICATION (EMPLOYEE)

Employee Name: _____ SS#_____

Date Identified: _____

Description (use attachment if necessary) _____

II. 10 CFR 21 REPORTABILITY DETERMINATION

If the answer to ANY of the following questions falls in a bracketed space, reporting under 10 CFR 21 is not required and the determination can be stopped at that point. Provide details, circumstances, and assumptions, as appropriate, to support answers on an attachment.

	YES	NO
1. Is a departure from the technical requirement in a procurement document (deviation), or a failure to comply with any applicable regulation, order, or license issued by the NRC involved?	_____	(____)
2. Has the item/activity/service been receipt inspected or otherwise accepted for use by Anatec or, in the case of a commercial grade item, has it been withdrawn from the warehouse and dedicated for use?	_____	(____)
3. Is a safety- or security-related structure, system, or component or equipment used to handle radioactive material or control personnel exposure involved (basic component)?	_____	(____)
4. Has the NRC been previously notified by the vendor or other licensee or has Anatec reported this potential defect or failure to comply under other requirements?	(____)	_____
5. Could this potential defect or failure to comply contribute to the exceeding of a safety limit, create an effect on the integrity of the reactor coolant boundary; capability to shut down the reactor and maintain it in a safe shutdown condition, or the capability to prevent or mitigate the consequences of an accident assuming a single failure?	_____	(____)
6. Could a substantial safety hazard be created? (see Definitions)	_____	(____)

If the answer to all the above questions falls in unbracketed spaces, or if answers are unknown, evaluation of 10 CFR 21 reportability is required.

Evaluation of reportability _____ is _____ is not required.

_____ / _____

Supervisor Date

(Upon completion submit to QA.)

III. EVALUATION OF REPORTABILITY

1. Not reportable under 10 CFR 21_____.
2. Consider for reporting under 10 CFR 21 _____.
3. Consider for reporting under other regulations _____.

Approved by: _____ _____
Date

Approved by: _____ _____
President, Anatec Date

IV. EXTERNAL NOTIFICATION (President)

Date recommendation received by President _____.

NRC Office notified? _____ Yes _____ No Date _____.

By _____ Phone _____ Letter _____ Other _____

Date written report submitted _____.

10 CFR 21 DEFECT OR NONCOMPLIANCE REPORT TO NRC

(SAMPLE)

DATE

COMPANY
FACILITY
RESPONSIBLE OFFICER (NAME AND TITLE)

- DATE RESPONSIBLE OFFICER RECEIVED INFORMATION
- BASIC COMPONENT OR ACTIVITY
- FIRM SUPPLYING BASIC COMPONENT OR ACTIVITY (NAME AND ADDRESS)
- DESCRIPTION OF DEFECT OR NONCOMPLIANCE AND SUBSTANTIAL SAFETY HAZARD THAT IS OR COULD BE CAUSED
- NUMBER AND LOCATION OF SUCH COMPONENTS IN USE AT, SUPPLIED FOR, OR BEING SUPPLIED FOR ONE OR MORE FACILITIES OR ACTIVITIES
- CORRECTIVE ACTION (INCLUDING RESPONSIBLE PARTY AND SCHEDULE)
- OTHER PERTINENT INFORMATION