NEI 14-09, Revision 0

GUIDELINES FOR IMPLEMENTATION OF 10 CFR PART 21 REPORTING OF DEFECTS AND NONCOMPLIANCE

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Nuclear Energy Institute

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NOTICE

FOREWORD

10 CFR Part 21 requires the reporting of certain defects and noncompliances. It was first promulgated in 1977 to establish requirements for implementation of Section 206 of the Energy Reorganization Act of 1974, as amended, relating to noncompliance. At the same time, the NRC issued guidance in NUREG-0302 for implementing 10 CFR Part 21, in the form of questions and answers. Part 21 regulations have been updated several times since the original rulemaking, most recently in 2009.

Although NUREG-0302 was never revised to incorporate amendments to 10 CFR Part 21, it still provides relevant guidance for implementing 10 CFR Part 21. This document is based mostly on the guidance from NUREG-0302, and the statements of consideration for subsequent NRC rulemakings. Additional guidance is included to provide further clarity in specific areas that is consistent with NRC regulations and prior guidance. These additional areas are highlighted to direct the reader to the new content and to aid the NRC in their review.

This guidance document is intended to apply only to nuclear power plants, and their suppliers, regulated pursuant to 10 CFR Part 50 and 10 CFR Part 52. Although 10 CFR Part 21 applies to facilities, activities and basic components regulated by the NRC pursuant to other parts of Title 10 of the CFR (e.g., 10 CFR Part 30, 31, 33, 34, 35, 36, 39, 40, 60, 61, 63, 70, 71, 72, and 76), this guidance may not be applicable to these other facilities or activities.

TABLE OF CONTENTS

GUIDELINES FOR IMPLEMENTATION OF 10 CFR PART 21 REPORTING OF DEFECTS AND NONCOMPLIANCE

1 INTRODUCTION

1.1 PURPOSE

The purpose of the evaluation and reporting requirements in 10 CFR Part 21 is to enhance the Nuclear Regulatory Commission's (NRC's) "defense in depth" measures for assuring the public's health and safety. Reporting of defects and non-compliances which could create a substantial safety hazard assures that the NRC receives prompt notification of such instances. NRC first issued 10 CFR Part 21 in 1977 to assure appropriate implementation of Section 206 of the Energy Reorganization Act of 1974, as amended (ERA), which requires the reporting of certain defects and non-compliances directly to the NRC.

The purpose of this guidance is to describe an acceptable approach to comply with the requirements for evaluation and notification in 10 CFR Part 21. This guidance document also promotes consistent implementation of NRC requirements and 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 30 years of complying with 10 CFR Part 21.

The NRC issued NUREG-0302, Revision 1 in July of 1977 at the same time as the original 10 CFR Part 21 rule was published in 1977. NUREG-0302 provided guidance in the form of questions and answers on compliance with 10 CFR Part 21. The regulations have been updated several times since the original rulemaking, most recently in 2009. In 2011, the NRC identified the need for additional clarity on how to comply with 10 CFR Part 21. SECY-11-0135 identified several areas where improvements could be made.

This document is based mostly on the guidance from NUREG-0302, and the statements of consideration for subsequent NRC rulemakings. Additional guidance is included to provide further clarity in specific areas that is consistent with NRC regulations and prior guidance. These additional areas are highlighted to direct the reader to the new content and to aid the NRC in their review.

1.2 SCOPE

10 CFR Part 21 applies to entities[1] (firms, companies, institutions, corporations, organizations, partnerships, individuals, etc.) owning, operating or supplying basic components for any facility or activity licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954. 10 CFR Part 21 applies to the activities regulated under most other Parts of Title 10 of the Code of Federal Regulations.

This guidance document is intended to apply only to nuclear power plants, and their suppliers, regulated pursuant to 10 CFR Part 50 and 10 CFR Part 52. Although 10 CFR Part 21 applies to facilities, activities and basic components regulated by the NRC pursuant to other parts of Title 10 of the CFR (e.g., 10 CFR Part 30, 31, 33, 34, 35, 36, 39, 40, 60, 61, 63, 70, 71, 72, and 76), this guidance may not be applicable to these other facilities or activities.

For this reason, the approach described in this guidance has not been evaluated to determine if compliance with 10 CFR Part 21 would be assured for facilities, activities or basic components regulated under these other Parts of 10 CFR. There are notable differences in 10 CFR Part 21 as to how it applies to some of the facilities and activities regulated under these other parts, and how it applies to nuclear power plants, for example the definition of basic component. There are also some exceptions provided for some of these facilities and activities, for example 10 CFR Parts 31, 35 and 40, and Agreement States. Finally, there are also differences in how 10 CFR Part 21 is applied to these facilities and activities due to differences in the requirements of the parts under which they are regulated.

1.3 EVALUATION AND NOTIFICATION OVERVIEW

There are several elements in the process to ensure proper notification to the NRC of failures to comply and defects that could create a substantial safety hazard. The first step is to determine whether the entity's facilities or activities are subject to 10 CFR Part 21 (see Section 3). It is also important to identify the directors and responsible officers that have authority over the facilities or activities subject to 10 CFR Part 21, and to ensure they understand their responsibilities (see Section 4). In establishing a program to ensure compliance with 10 CFR Part 21, the entity needs to consider interfaces with other regulations (see Section 5), and establish procedures, maintain records, ensure proper posting related to 10 CFR Part 21, and ensure the appropriate

[1] Here the term "entity" is used as a general term for firm, company, institutions, corporation, partnership, organization, individual etc. ERA Section 206 uses "firm" and 10 CFR Part 21 uses "entity" in a broad manner so as to include organizations owned wholly or in part by Federal, State or local governments and educational institutions, as well as private businesses.

information on 10 CFR Part 21 and QA requirements is included in procurement documents (see Section 6).

When issues are identified that could be subject to 10 CFR Part 21 evaluation and reporting requirements, the entity will implement the evaluation and notification processes. The evaluation and notification processes rely upon several important terms, which have very specific definitions (see Section 2). The evaluation and notification processes begin with the discovery process, which determines whether an issue potentially subject to 10 CFR Part 21 should be evaluated (see Section 7). The point at which the discovery process documents the need to perform an evaluation marks the Point of Discovery. Deviations and failures to comply must be evaluated to determine whether the issue is reportable to the NRC (see Section 8). When a defect or failure to comply, which could create a substantial safety hazard if it were to remain uncorrected, is found to exist, then it is reportable to the NRC and all potentially affected purchasers of the Basic Component. 10 CFR Part 21 requires notification of reportable defects and failures to comply within 60 days of the Point of Discovery (see Section 9), but also permits interim notifications to the NRC and any potentially affected purchasers of the basic component if the evaluation cannot be performed within this time. However, notifications are not required if the NRC has already been adequately informed. To aid in the understanding of the evaluation and notification processes, a process flowchart is provided in Appendix A, and a screening and evaluation checklist is provided in Appendix B.

2 DEFINITIONS AND ACRONYMS

Key terms used in the requirements for the evaluation and reporting of defects and failures to comply are defined in 10 CFR 21.3. Other parts of the regulations may also contain the definitions of key terms that are important for the screening, evaluation and notification processes as they relate to those areas regulated by the NRC. This section contains the definitions for important terms used in this guidance to implement the evaluation and reporting requirements in 10 CFR Part 21.

The definitions shown in italics are quoted from NRC regulations. In many instances, additional clarifications and guidance relating to the use of the terms are also provided. These clarifications can be found in this section, and in other relevant sections of the guidance as referenced below.

2.1 ACRONYMS

CGD – Commercial Grade Dedication (or Dedication)

CGI – Commercial Grade Item

COL – Combined License

CP – Construction Permit

DC – Design Certification

ERA – Energy Reorganization Act of 1974, as amended

ESP – Early Site Permit

NRC – U.S. Nuclear Regulatory Commission

SSH – Substantial Safety Hazard

2.2 BASIC COMPONENT

Basic component. (1)(i) When applied to nuclear power plants licensed under 10 CFR 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:

(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 of this chapter, as applicable.

(ii) 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 which have successfully completed the dedication process.

(2) 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:

(i) The integrity of the reactor coolant pressure boundary;

(ii) The capability to shut down the reactor and maintain it in a safe shutdown condition; or

(iii) 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 of this chapter, as applicable.

(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 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 Commission could create a substantial safety hazard.

(4) 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.

Basic components are obtained 1) by being supplied as such under a quality assurance program pursuant to 10 CFR Part 50, Appendix B, or 2) as commercial grade items subject to the dedication process defined in 10 CFR Part 21. 10 CFR Part 21 evaluation and reporting requirements apply to basic components only after they are delivered. 10 CFR Part 21 requirements do not apply to the supply of commercial grade items because those items are not basic components until they are dedicated and delivered. 10 CFR Part 21 responsibilities for the entity that dedicated the basic component do not begin until the item is dedicated, delivered and accepted for use as a basic component.

As applied to nuclear power reactors, basic components can exist at any tier of the supply or procurement chain if they have the capability to create a substantial safety hazard.

See Section 7 for more guidance.

2.3 CONSTRUCTION

Constructing or Construction means the analysis, design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and consulting services related to the facility or activity that are safety related.

To properly comply with 10 CFR Part 21, Combined License (COL) applicants and holders licensed under 10 CFR Part 52 should incorporate the 10 CFR 21.3 definition of "constructing" or "construction."

2.4 DEDICATION

Dedication (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, 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 10 CFR Part 50, 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 holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B. The process is considered complete when the item is designated for use as a basic component.

(2) When applied to facilities and activities licensed pursuant to 10 CFR 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.

Commercial grade items (CGI) may be used in applications that affect nuclear safety if they have been dedicated. A dedicated CGI has been subjected to an acceptance process that ensures the commercial grade item is suitable to perform its safety function as a basic component. An item is considered dedicated as a basic component when the acceptance process is complete, at which point the item becomes subject to the evaluation and reporting requirements of 10 CFR Part 21.

If during the dedication process an item fails to meet the acceptance criteria, the dedication is not complete and the deficiency/deviation causing the failure does not require evaluation for reporting under 10 CFR Part 21.

Additional guidance on implementing a dedication process can be found in EPRI NP-5652 "Guideline for the Utilization of Commercial Grade Items in Nuclear Grade Safety Applications" (NCIG-07), or other equivalent EPRI guidance[2].

[2] At the time of publication, EPRI was preparing updated guidance on Commercial Grade Dedication titled "Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications," Revision 1,

Clarification of Dedication for Part 52

Although 10 CFR 21.3 does not explicitly identify the manner in which to define "dedication" for nuclear power plants licensed under 10 CFR Part 52, the definition should be interpreted and implemented as defined for nuclear power plants licensed under 10 CFR Part 50. Thus for 10 CFR Part 52 combined license (COL) applicants or COL holders, "dedication" is interpreted and implemented as the term is defined in 10 CFR 21.3. Similarly, the definitions of commercial grade item, critical characteristics, and dedicating entity should be interpreted and implemented for Part 52 nuclear power plants as they are defined in 10 CFR 21.3 for 10 CFR Part 50 reactor licensees.

2.5 DEFECT

10 CFR Part 21 has given special meaning to "defect". The same term is used in Criterion XVI, Corrective Action, of Appendix B to 10 CFR Part 50. The use of defect in this guidance is consistent with the 10 CFR Part 21 definition.

> *Defect means:*
>
> *(1) 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;*
>
> *(2) The installation, use, or operation of a basic component containing a defect as defined in this section;*
>
> *(3) 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;*
>
> *(4) 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; or*

3002002982, which is planned to supersede EPRI-NP5652 and EPRI TR-102260. The approach in EPRI-NP5652 is partially endorsed by the NRC in GL-89-02 and it is anticipated that EPRI-3002002982 will be endorsed by NRC when completed.

> *(5) 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.*

The definition of *defect* is important because it is integral to the determination of whether a Part 21 report is necessary. The definition is also complex, as it is defined by several other key terms, such as deviation, delivered, and substantial safety hazard, and it is comprised of multiple conditions.

2.6 DELIVERED

There is no definition in 10 CFR Part 21 for the term *delivered*; however, the term is used as part of the definition of *defect,* and is an important term for the evaluation and reporting of defects because it establishes a condition for determining whether a defect exists. Based on the definition of *defect*, only deviations in basic components that are delivered have the potential to be a defect. Therefore, the condition of *delivered* is logically extended to the definition of deviation even though the regulations do not explicitly make this connection. In other words, there is no value in evaluating a deviation in a basic component that has not been delivered because it could not be a defect and thus would not be reportable under Part 21. The following is the definition that should be used for *delivered* in this guidance and is further clarified below:

> "Delivered means that the purchaser has taken control of the basic component after completing an acceptance process."

A basic component is considered delivered when the purchaser has taken control of the component or service as a basic component following the completion of the acceptance process (i.e., receipt inspection and in some cases acceptance/functional testing). At that point, the control and ownership of the component transfers to the purchaser, and 10 CFR Part 21 responsibilities for reporting of defects and non-compliances come into effect. In some specific situations, such as for certified designs, *delivered* is based upon whether it has been offered for use, instead of being established by an acceptance process. See Section 7.3 for more guidance.

2.7 DEVIATION

10 CFR Part 21 has given special meaning to "deviation". The same term is used in Criterion XVI, Corrective Action, of Appendix B to 10 CFR Part 50. The use of deviation in this guidance is consistent with the 10 CFR Part 21 definition.

> *Deviation means 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.*

The definition of deviation is linked with the definition of defect because a deviation is evaluated to determine whether it is a defect that could create a substantial safety hazard, if it were to remain uncorrected. Because a defect can only exist for deviations in basic components that have been delivered, the definition of deviation inherently only applies to delivered basic components.

This definition differentiates important substantial deviations from inconsequential deviations, and ensures that evaluations are not needlessly performed on deviations that clearly cannot be defects. For example, a basic component is procured to certain requirements, and if the basic component does not meet its prescribed requirements a deviation exists. Some deviations can create a substantial safety hazard (i.e., a defect) and others cannot; therefore, a deviation of a delivered basic component must be evaluated to determine whether it could create a substantial safety hazard. See Section 7.3 for more guidance on identifying deviations.

2.8 DISCOVERY

> *Discovery means 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).*

The Point of Discovery occurs when a deviation or failure to comply is clearly identified. However, "discovery" does not occur solely when it is determined that a deviation or failure to comply exists; that is but one of three elements in the discovery. Those elements are: completion of the documentation first identifying (1), the existence of a deviation or failure to comply (2) that is potentially associated with a substantial safety hazard (3). In order for discovery to occur, some investigation and analysis is often necessary. This was acknowledged by the NRC in SECY 91-150, which stated, "Discovery is not complete until the documentation identifying the existence of a deviation or failure to comply is complete. 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 or §50.55(e)." The screening/discovery process is described in Section 7.

2.9 FAILURE TO COMPLY

The term *failure to comply* is important because failures to comply must be evaluated, and reported, if they are associated with a substantial safety hazard. Although there is no definition of *failure to comply* in 10 CFR 21.3, the use of the term in the regulation provides clarity on its definition. The following provides a definition of failure to comply, and Section 7.2 describes in more detail on how to identify a failure to comply.

> "Failure to comply means the manufacture, construction or operation of a licensed facility or activity, a basic component supplied for such facility or activity, or a design certification or design approval under 10 CFR Part 52; which is not in compliance with the Atomic Energy Act of 1954, as amended, any applicable rule, regulation of 10 CFR, order or license issued by the Commission, or a standard design approval under 10 CFR Part 52."

The requirements for evaluation and reporting in 10 CFR Part 21 treat a failure to comply similar to a deviation. The main difference is in the criteria to determine if a failure to comply exists. See Section 7.2.

2.10 Notification and Reporting

10 CFR Part 21 provides a definition for notification, but does not define reporting.

> *Notification means the telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.*

The terms *notification* and *reporting* in 10 CFR Part 21 are very similar. In most cases the terms mean the same thing, with a few minor differences. Whereas the "notification" includes both the telephonic communication and written transmittal of information to the NRC, the term "reporting" is used to mean written notification to the NRC in the form of a report.

Notification includes the initial and written notification to the NRC of a reportable defect or failure to comply. The written notification is also called a report.

Reporting includes the interim report of a deviation or failure to comply for which the evaluation continues past the 60 days from the Point of Discovery, and the report submitted to the NRC of a defect or failure to comply that could create a substantial safety hazard, if it were to remain uncorrected (written notification). The interim report and report of a defect or failure to comply must be written and submitted to the NRC.

The term "reportable defect or failure to comply" means a deviation or failure to comply that, on the basis of an evaluation, could create a substantial safety hazard if it were to remain uncorrected.

2.11 Procurement Document

> *Procurement document means a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.*

The term *procurement document*, as defined in 10 CFR 21.3, also includes purchase orders of off-the-shelf or catalog items which are not covered by contractually-required quality assurance procedures, manufacturing codes, or specifications, provided they fall within the definition of *basic component* in 10 CFR 21.3..

Purchasing entities are responsible for ensuring appropriate requirements are provided in procurement documents. Section 6.5 provides additional guidance for including requirements in purchase documents.

2.12 SUBSTANTIAL SAFETY HAZARD

> *Substantial safety hazard means 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 any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter.*

Applicable criteria for the determination of substantial safety hazard are given in the statement of considerations of the original 10 CFR Part 21 rule (42 Fed. Reg. 28892). These criteria include: a) moderate exposure to, or release of, licensed material; b) major degradation of essential safety-related equipment; and c) major deficiencies involving design, construction, inspection, test or use. In this context the term *public* is used in a general sense and includes employees at NRC licensed facilities and members of the general public. Section 8.3 provides a detailed description of the criteria for a substantial safety hazard, and evaluating whether a substantial safety hazard exists or could be created.

3 FACILITIES, ACTIVITIES AND ENTITIES SUBJECT TO 10 CFR PART 21

Entities which operate or construct facilities, or supply basic components to these facilities are subject to 10 CFR Part 21. As defined in Part 21, the terms “constructing," "operating," and "basic component” are used to include design, inspection, testing and consulting services associated with construction, operation and basic components that are important to safety. The thrust of the regulations goes beyond those entities licensed or previously regulated by the Commission to all entities which engage in the activities described in Part 21.

The regulation explicitly addresses Part 21 obligations of entities that own, construct, operate, and supply basic components for NRC licensed reactors. The terms “constructing” and “supplying” are defined in 10 CFR 21.3. Specifically, the Commission has interpreted the term “constructing” to include the design, manufacture, fabrication, inspection, or testing of a facility or activity which is subject to 10 CFR Part 21, and consulting services related to the facility or activity that are important to safety. The term “supplying” has been defined to mean any entity which is contractually responsible for a basic component used or to be used in a facility or

activity which is subject to 10 CFR Part 21. Due to the diverse nature of this industry there are many "build to print" contracts and many "design and build," "design only," or "consult only" contracts. All entities in the supply chain that provide a basic component for a power reactor that could create a substantial safety hazard, because of a defect in the basic component, are within the scope of 10 CFR Part 21. The safety-related operations of constructing, owning, operating and supplying components each have within them safety-related activities, that is, consulting, design, inspection and test. The terms "basic component" and "operation" have been defined so as to include these safety-related activities.

An applicant becomes subject to 10 CFR Part 21 when it first engages in the activities subject to 10 CFR Part 21, as described in 10 CFR 21.2, for example, when the entity first engages in the enumerated construction activities, including safety related design work, similar to the requirements for a quality assurance program specified by 10 CFR Part 50, Appendix B, in that the requirements are effective prior to tendering an application.

A subcontractor must evaluate, and, if it discovers a defect, report or inform the purchaser if it is one of a tier of suppliers supplying components to a reactor licensed by the Commission pursuant to 10 CFR Part 50 or Part 52.

3.1 FACILITIES, ACTIVITIES AND BASIC COMPONENTS SUBJECT TO 10 CFR PART 21

The term "activity" used in 10 CFR Part 21.1(a) means any activity, except those specifically exempted, which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended. These include activities regulated by the NRC, and activities specifically included by 10 CFR 21.3 definition for basic component. The definition of basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services important to safety that are associated with component hardware, design certification, design approval, or information in support of an early site permit. Part 21 applies to any defects and noncompliance which could create a substantial safety hazard in activities that are within the regulatory authority of the NRC; therefore only those items which are safety related are within the scope of 10 CFR Part 21.

10 CFR Part 21 only applies to radiological health and safety and does not apply to non-radiological hazards. . For example, chemicals released into streams or rivers are not reportable under 10 CFR Part 21.

The following is a non-exhaustive list of activities provided as basic components to which 10 CFR Part 21 applies:

- Products or services that constitute a basic component within the meaning of 10 CFR Part 21, even where the licensee is supplying a basic component where the licensed activities

are only incidental to the products/services it supplies and the products and services themselves are not licensed.

- Off the shelf items such as material obtained from a distributor or a material supplier such as switches, pumps, respirators and filters if they are within the definition of basic component.
- Consulting service for a facility or activity that can impact safety.
- Fabrication that is not licensed, but which the finished product is used in a licensed activity.
- Security system, to the extent that failures to comply or deviations could contribute to a substantial safety hazard. Components of security systems that do not meet performance standards or which fail could present the potential for safety hazard, and should be evaluated.

3.2 ENTITIES SUBJECT TO 10 CFR PART 21

In addition to entities that hold NRC Part 50 and Part 52 licenses, 10 CFR Part 21 also applies to other entities and individuals in the nuclear industry performing activities described below, whether these are performed by the component supplier or others. For Part 50 and Part 52 reactors, any supplier of a basic component to the licensee, regardless of its position in the supply chain, is subject to the requirements in 10 CFR Part 21. The scope of 10 CFR Part 21 is not limited to the entity, but also imposes obligations on certain individuals within the entities, as discussed in Section 4.

The following is a non-exhaustive list of entities, related to nuclear power plants licensed under 10 CFR Part 50 and Part 52, for which 10 CFR Part 21 applies. .

- 10 CFR Part 50 and 10 CFR Part 52 reactor licensees, ESP holders and COL holders
- 10 CFR Part 50 and 10 CFR Part 52, applicants for licenses or permits, to the extent that they engage in the specified activities
- 10 CFR Part 52 applicants for certified designs
- Suppliers of basic components
- Entities that dedicate commercial grade items
- Entities that supply health physics services to a power plant, if the failure to provide the required service could create a substantial safety hazard
- Entities who supply waste disposal service, if the failure to provide the required service could create a substantial safety hazard
- Fuel fabricator, as suppliers to reactor licensees
- Federal, State, and local governments or agencies, if it is licensed under, or supplies to a licensee under, 10 CFR Part 50 or 10 CFR Part 52.
- Plants that manufacture products which the power industry purchases for use in both fossil and nuclear applications that are not a qualified supplier to ASME Section III

Code requirements, but do supply products meeting 10 CFR Part 50 Appendix B, if the products furnished for use in nuclear applications are basic components.

- Suppliers of consumables such as welding material and services such as calibration, where the consumable or calibration service can impact the ability of a basic component to perform a safety function, and a deviation from specified requirements of a procurement document, or failure to comply could create a substantial safety hazard.
- Suppliers of services or items performing activities within the scope of the definition for basic components.
- A consultant who conducts site investigations and prepares data on safety related site characteristics (10 CFR Part 100, Appendix A, Seismic and Geologic Siting Criteria for Nuclear Power Plants, is the governing rule.)

The following is a non-exhaustive list of entities to which 10 CFR Part 21 *does not apply*.

- Holding companies that hold stock in a subsidiary company which owns and operates a nuclear facility, and which do not themselves engage in constructing or operating the facility.
- Carriers do not fall within the definitions of licensees or suppliers as used in 10 CFR 21.2 and 21.3(1).. However, suppliers and licensees at both ends of the carrier transaction (e.g., the entity that delivers a component to a carrier and the entity that receives the component) may be subject to Part 21. This includes carriers who have approved physical security plans under 10 CFR Part 73, as these services differ from services defined in 10 CFR 21.3(a) since they are not services associated with component hardware. However, if a licensee obtains information indicating a defect in a physical security plan which is within its area of responsibility, it is required to report.
- Insurance companies which insure an NRC licensed facility and as a part of its insurance contract makes regularly scheduled inspections of these facilities and, as a result of these inspections, offers written advice to the insured concerning fire, explosion, pressure vessel and machinery breakdown protection, <u>if</u> the information is provided by the insurance company as merely a part of its own protection in supplying insurance and not as a customer contract requirement. Where the information offered by the insurance company identifies a possible defect or failure to comply, the insurance company is not <u>required</u> to report to the NRC. However, licensees receiving such information would need to address this in their procedures whether it will be necessary to conduct an evaluation. But if a licensee contracts for these services, then the insurance company would be subject to 10 CFR Part 21.
- An insurance company that performs contracted inspections associated with basic components, if the insurance company identified in the report to the purchaser all deviations from established requirements noted during its inspection. . If, after

delivery of the completed inspection report, the insurance company becomes aware of a deviation in a basic component that was not reported, the insurance company would be a) responsible for conducting an evaluation and reporting to the NRC if a defect which could create a substantial safety hazard did exist, or b) if not able to perform the evaluation – to inform the purchaser of the deviation which requires further evaluation under 10 CFR Part 21.

- An insurance or testing company that declines to approve a piece of equipment for a reason which might result in a substantial safety hazard if the equipment were used in a NRC licensed facility.

In addition to specifying those entities and individuals that are required to report defects and failures to comply, the rule also specifically states that nothing precludes individuals (including members of the general public not subject to Part 21) from reporting to the NRC a known or suspected defect or failure to comply. In the case of an employee of an entity subject to 10 CFR Part 21, it is anticipated that this individual first will bring the information to light within the organization for which they work. In the event that this channel is not available or is deemed to be ineffective to the person possessing the information, such person can contact the NRC regional office. The NRC has the ability to grant anonymity, if it is requested, within the limits allowed by law.

Contractors and suppliers who knowingly provide basic components are subject to 10 CFR Part 21 even if 10 CFR Part 21 is not referenced in their contracts or procurement documents.

3.3 NON-U.S. SUPPLIERS

Suppliers, located outside of the US, of basic components or their subcomponent parts for use in facilities in the U.S. subject to NRC regulations may, under certain circumstances be subject to 10 CFR Part 21. 10 CFR 21.2(a)(2) states that 10 CFR Part 21 applies to each individual, corporation, partnership or other entity doing business within the United States which supplies basic components for a facility or activity licensed other than for export under Parts 50 and 52. Although the phrase “Doing business within the United States” is not defined in the regulation, similar terminology has been interpreted in other contexts to include a foreign manufacturer who contracts to sell their product to a United States purchaser. The rule does not prohibit purchases from non-US suppliers of basic components.

This could mean that a foreign entity which contracts with a US purchaser to supply a basic component for a facility or activity covered by 10 CFR Part 21 would be subject to the requirements of the rule to the extent that the US has jurisdiction over the foreign entity and its officers. The penalties for noncompliance with Part 10 CFR 21 can be enforced on foreign suppliers only where the US has jurisdiction over the foreign entity and its officers.

3.4 U.S. EXPORTERS

Under international agreements the NRC receives a large amount of important nuclear safety information, on facilities similar to U.S. facilities, from foreign regulatory authorities. Most of these foreign governments do not make early announcements of all safety problems that occur in their nuclear facilities, and they do not wish to have NRC make premature announcements of those foreign problems for them. US exporters who also have the safety responsibility for similar US plants, are, of course, involved in the analysis and correction of any defects and non-compliances in the affected US plants. 10 CFR Part 21 requires only reporting information of activities in the US which fail to comply or cause a defect, it does not require reporting of information of facilities, activities or basic components outside the US, which are not regulated by the NRC. Therefore, US suppliers are not required to be the source of information of foreign plants against the will of the foreign governments involved, if such information is not necessary for domestic safety.

10 CFR Part 21 addresses the applicability of 10 CFR Part 21 to the licensed activity of exporting. Entities and individuals who are only licensed to export nuclear facilities or materials, and who do not otherwise construct or operate facilities, or perform activities or supply components to NRC licensees, are not subject to 10 CFR Part 21. Exporters that also supply basic components to NRC licensees need report only defects or failures to comply which could create a substantial safety hazard in facilities and activities within the United States. In other words, they must report on defects or failures to comply in the U. S. facilities for which they are responsible parties, but do not need to report on defects or failures to comply under 10 CFR Part 21 in overseas plants they happen to know about.

If a supplier does provide any information about the foreign experience, either voluntarily or as part of clarification to the condition existing in the US, then the information may be withheld from public disclosure if the notification falls within one of the exemptions to the Freedom of Information Act (FOIA), or if withholding is otherwise authorized by law. Examples of such information that could be exempt from public disclosure under the U. S. Freedom of Information Act:

- If the information is proprietary that is, information given in confidence whose disclosure would do substantial harm to the supplier's competitive position, the documents containing that information could be withheld under FOIA Exemption 4.

- If there is a clear statement from the involved foreign government that the information can be given to NRC only under condition that it be protected from public disclosure, that information may be withheld under either FOIA Exemption 4 or Exemption 1.

Example:

A U. S. supplier has a contract to do work in a foreign country (or possibly is an exporter to a foreign plant). In the course of this overseas work, that supplier learns of a defect in a foreign plant that reflects a similar defect in a U. S. domestic plant. In this example, the supplier is an affected entity under 10 CFR Part 21, based upon the activities performed for the nuclear plant in the US. This supplier reports to NRC the defect in the domestic reactor, but does not provide certain details about the applicable foreign experience because their overseas client or the foreign government has not given them permission to disclose the information publicly.

Discussion:

This is acceptable. The supplier does not have to supply details about the foreign plant, provided enough explanation is given to NRC in the report about the US plant to make the information usable in NRC safety work.

4 DIRECTOR AND RESPONSIBLE OFFICERS

Unlike provisions in other NRC regulations which only impose obligations on licensees, 10 CFR Part 21 imposes obligations on other entities who are involved in the nuclear industry in addition to licensees. 10 CFR Part 21 also differs from other NRC regulations in that it imposes these obligations as a direct liability on certain individuals in these entities. This special imposition of obligations makes it important for all entities involved in the nuclear industry to clearly understand their organizational responsibilities, and the responsibilities of individuals within these entities.

10 CFR Part 21 imposes a reporting responsibility upon directors or responsible officers of firms "constructing, owning, operating, or supplying the components of any facility or activity licensed or otherwise regulated pursuant to this Act." The entities subject to the regulations in Part 21 may be many procurement tiers away from the holder of a license to construct or operate a nuclear power reactor. For power reactors, all tiers who have organizational responsibility for the failure to comply or defect would be subject to enforcement action.

The individuals subject to the notification requirements of 10 CFR Part 21 have been restricted to a) directors and b) officers vested with executive authority over activities subject to 10 CFR Part 21. Any director or responsible officer subject to 10 CFR Part 21 who, after obtaining information reasonably indicating failure to comply or a defect, fails to notify the Commission is subject to enforcement action. For a more detailed discussion, please refer to the text of 10 CFR Part 21.

4.1 WHO IS A DIRECTOR OR RESPONSIBLE OFFICER

A Director is defined in 10 CFR 21.3 as *an individual, appointed or elected according to law, who is authorized to manage and direct the affairs of a corporation, partnership or other entity. In the case of an individual proprietorship, director means the individual*.

The term individual as used in 10 CFR Part 21 refers to a sole proprietorship business entity which must have procedures, keep records, etc.

Responsible officer is defined in 10 CFR 21.3 to mean *the president, vice-president or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to 10 CFR Part 21*.

President and vice president are two titles that are specified as responsible officers. The "other individuals who are vested with executive authority over activities subject to this part" would be those personnel identified in the entity's procedures who have comparable authority to that of a president or vice president. However, it is possible that individuals vested with executive authority over activities subject to 10 CFR Part 21 may not be included in the list of officers in the Articles or By-Laws. For example, if an individual with managerial authority, whether or not that person is identified as a corporate officer, is also vested with executive authority over an activity which is subject to 10 CFR Part 21, then they would qualify as a responsible officer under the regulation.

Officers with no executive authority over activities subject to 10 CFR Part 21 are not responsible officers. For example, the Vice President in Charge of Community Affairs is not a responsible officer if they have no authority over activities subject to Part 21, even though they are listed as an officer of the organization. Responsible officer is also not meant to include individuals such as project managers and QA managers. These individuals are not ordinarily vested with executive authority.

A director or officer of a co-owner entity which is a financial partner only and which has delegated all responsibility for constructing and operating the facility or activity to another owner would not have responsibility for notifying the Commission of defects or failures to comply because the facility or activity is not within their organization's responsibility. Co-owners who have retained some responsibility for constructing or operating the facility or activity would be subject to the notification requirements of 10 CFR Part 21.

An entity may not exclude any individual, who is vested with executive authority over activities subject to 10 CFR Part 21, from the requirements of 10 CFR Part 21. It is possible, however, that within the entity's organization, such as in a matrix management system, only one individual will be vested with executive authority over activities subject to 10 CFR Part 21. No mechanism

or means exists for mutual agreement to be reached before-the-fact between an entity subject to 10 CFR Part 21 and the NRC as to which individuals are to be considered responsible officers.

4.2 Notification Responsibilities of a Director or Responsible Officer

10 CFR Part 21 requires directors and responsible officers of certain entities building, operating or owning NRC-licensed facilities, or conducting NRC-licensed activities, to report any defects in components and failures to comply with NRC requirements that could result in a substantial safety hazard. Directors and responsible officers may designate an employee to notify the NRC on their behalf but they may not be relieved of the responsibility for notification of the NRC.

10 CFR 21.21(d) requires a director or responsible officer to report to NRC if they have information reasonably indicating a defect or failure to comply which could create a substantial safety hazard. The director or responsible officer would be expected to provide information on the number and location of other delivered components with similar defects to the extent that this information is known by them or their organization. 10 CFR 21.21(b)(3)(vi)states " 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 in this part." It may be difficult or impossible to trace "all" such components in use or supplied for use in the United States. The director or responsible officer would be expected to provide information on delivered components to the extent the information is known by the Director or the Director's organization.

Any responsible officer or director with executive authority over activities subject to 10 CFR Part 21 would be liable for failing to make a report concerning a defect or noncompliance concerning a basic component that is within their organization's responsibility. This includes those responsible officers who have executive authority over only a small class of activities covered by 10 CFR Part 21 (e.g., plant security, personnel, stores, etc.).

10 CFR 21.21(d)(5) permits directors and responsible officers to designate an employee to provide the notification to NRC on their behalf. The designee may accomplish the notification which includes the written report and the initial notification by means other than written communication. Even though an individual is designated to provide the notification to the NRC, the director or responsible officer retains the responsibilities.

10 CFR Part 21 does not impute knowledge to the director or responsible officer. Rather, it imposes obligations on directors and responsible officers who have knowledge of defects or failures to comply. Specifically, if a director or responsible officer authorizes a person to make notifications for them pursuant to 10 CFR 21.21(b)(4), such authorization does not relieve the director or responsible officer of their responsibility to notify the Commission. Designating an architect engineer (A/E) as the representative (to be "authorized and empowered to decide all matters...the execution and progress of the work," as stated in the licensee's Contract Documents)

does not negate the responsibility of the director or responsible officer. An “A/E” is not generally an individual. Further, within the A/E there will also be individuals subject to Part 21; for example, the "individual director or responsible officer” of the A/E.

When a director or responsible officer designates a subordinate to provide notification and the subordinate fails to comply, the director or responsible officer would be cited for the infraction if the Director has information reasonably indicating a defect or failure to comply exists and they did not have actual knowledge that the Commission has been adequately informed.

The rule recognizes, however, that in most instances some evaluation will be required to determine whether a deviation is a reportable defect, or whether a failure to comply could create a substantial safety hazard. In this regard, if a director hears or is told (e.g., telephoned by a disgruntled former employee) of a problem which is a defect or which may be a defect, but the director has no personal knowledge of the defect and its possible safety implications, it is expected that appropriate procedures would include the requirement for an evaluation where there is reason to believe that a deviation exists. Whether there is reason to believe that a deviation exists is a matter of some judgment. But if there is a basis for believing that a deviation exists, the procedures should provide for notifying those within the entity who are responsible for conducting the evaluations. It would seem that a telephone call from a former employee would be a reasonable basis for believing that a deviation exists. If the Director reported what was communicated concerning a potential failure to comply or defect to the appropriate Responsible Officer according to the corporations procedures under 10 CFR 21.2l(a) and the Responsible Officer told the Director there was no substantial safety hazard according to the evaluation, the Director may rely upon the results of the evaluation as communicated by the Responsible Officer. A Director or Responsible Officer is entitled to rely on expert guidance from others who might have more detailed knowledge of the subject.

The extent to which a Responsible Officer must go to ensure that deviations are identified is to be determined by each company subject to 10 CFR Part 21. Once a deviation is identified, the company must follow the procedures it has established to promptly evaluate deviations and to inform a Responsible Officer or Director. Once the Director or Responsible Officer obtains information reasonably indicating that a defect exists, they must inform the Commission unless they have written evidence that the Commission has already been adequately informed. This applies regardless of whether a Director is involved in the day-to-day operations of the company or if a Director obtains reportable information.

Once a Director or Responsible Officer has reported a deviation according to the appropriate internal procedure so that the “evaluation” has commenced, it is not a requirement that the Director or Responsible Officer follow through with the evaluation to see that it is conducted properly, but the Director or Responsible Officer is responsible for its execution. Procedures established under 10 CFR 21.2l(a) are required to ensure that evaluations are performed and at

least one Director or Responsible Officer is informed of any defects or reportable failures to comply.

4.3 INSTANCES WHEN THERE IS NOT A NOTIFICATION RESPONSIBILITY

If an individual or individuals subject to 10 CFR Part 21 becomes aware of a defect that is not within the responsibility of their organization they are not required by 10 CFR Part 21 to submit a notification. In such cases, the individual that gains the knowledge of a defect in an item outside their organization's area of responsibility would be encouraged to report but would not be subject to a civil penalty if they did not report it. The individual that gains the knowledge of a defect in an item outside their organization's area of responsibility would also be encouraged to notify the entity that is responsible for the defect.

An individual, such as employee, who is not subject to the 10 CFR Part 21 is not required to make a 10 CFR Part 21 notification when they gain information concerning a defect or noncompliance and therefore are not subject to civil penalties. It is anticipated that the entities within the scope of 10 CFR Part 21 will establish, if they have not already done so, a management concept such that the individual will feel free to identify their safety-related concerns in house.

10 CFR 10 CFR 21.2(d) states that "*nothing in these regulations should be deemed to preclude an individual not subject to the regulations in this part from reporting to the Commission a known or suspected defect or failure to comply and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure*". This policy is in line with the long standing Commission policy for securing safety-related information.

The statement of considerations includes the following: "Moreover, a longstanding Commission policy encourages individuals not subject to the Commission's regulations to report to the Commission a known or suspected defect or failure to comply; as authorized by law, the identity of anyone so reporting will be withheld from disclosure."

4.4 PERSONAL LIABILITY

NRC, through its enforcement of 10 CFR Part 21 requirements, may impose civil penalties, and for willful violations, attempted violations or conspiracy to violate as described in 10 CFR 21.62 may impose criminal penalties, for failure to comply with certain requirements of 10 CFR Part 21.

Failure to notify places at risk of civil penalty all Directors and Responsible Officers who had obtained information reasonably indicating a failure to comply, or a defect, and who knowingly and consciously failed to report such information. Any Director or Responsible Officer who did not have such information is not subject to a penalty for failure to report. In all of the following

cases, the Director or Responsible Officer will not be liable for a civil penalty under 10 CFR Part 21.

- If an entity clearly should have specified applicability of 10 CFR Part 21 in the procurement document but failed to do so.
- If an entity fails to properly comply with the posting requirements.
- If an evaluation of a deviation is either not conducted or is not adequately conducted.
- If the evaluation determines that a substantial safety hazard in fact does exist but the director or responsible officer is not informed.
- Failure of an employee to inform a director or responsible officer of noncompliance or a defect pursuant to procedures adopted under 10 CFR 21.21(a).

Whether or not a Director or Responsible Officer of the organization subject to Part 21 has information reasonably indicating a failure to comply or a defect that could create a substantial safety hazard were it to remain uncorrected is initially a matter of judgment. Fines are only for knowing and conscious failure to report defects. Any judgment that there does not exist a reportable condition is reviewable by the NRC. Nevertheless, if the NRC determines that there is a reasonable basis for the judgment that a reportable defect or failure to comply does not exist, the Responsible Officers and Directors would not be subject to a civil penalty for failing to notify the Commission even if the evaluation was later found to be incorrect. Thus, honest and reasonable errors in judgment or interpretation, if there exists a reasonable basis for the interpretation or judgment, could not subject the director or officer to a civil penalty. This includes a situation where new acceptance criteria are introduced after it has been determined that a defect does not exist based upon the technical evaluation.

A person charged a civil penalty under 10 CFR Part 21 is afforded an opportunity to contest the charges and may request a hearing by the Atomic Safety Licensing Board (ASLB). 10 CFR Part 21 does not address whether an individual Director or Responsible Officer who has been compelled to pay a civil penalty may be reimbursed by his/her employer. The question of reimbursement may be governed by State law.

For 10 CFR Part 21 violations other than knowing and conscious failures to report, enforcement would be subject to appropriate enforcement under 10 CFR Part 2 Subpart B. Employees would not be subject to NRC enforcement action for failing to inform a Director or Responsible Officer of noncompliance or a defect, unless the act was a deliberate violation. 10 CFR Part 21 does not include a requirement for training, and an entity cannot be cited under 10 CFR Part 21 for not conducting training on procedures.

If a Director obtains information reasonably indicating a defect or failure to comply such as, for example, through reports made by management at board meetings, and fails to make the required notification to the NRC, they would be personally liable and subject to civil or criminal

penalties. The definition of "Director" should be read to include each individual member of the board of directors and not just those directors who single-handedly possess authority to manage and direct the affairs of the corporation.

Thus, the term "Director" does apply to outside members of the Board of Directors if they are authorized to manage and direct the affairs of the corporation, partnership or other organization. If they have actual knowledge themselves, they have a duty to comply.

A Director or Responsible Officer would be liable under 10 CFR 21.61 for a failure to notify if they have information reasonably indicating a defect or failure to comply and do not have actual knowledge that the Commission has been adequately informed. Actual knowledge is more than a good faith belief. A Director or Responsible Officer would not be personally liable if they do not receive information of the existence of a defect because the evaluation is done improperly.

The issuer of the procurement document could be subject to a fine under 10 CFR Part 2, Subpart B, if they fail to specify in a procurement document for a basic component that 10 CFR Part 21 applies.

4.5 STATUTE OF LIMITATIONS AND TERMINATION OF OBLIGATIONS

Obligations to comply with 10 CFR Part 21 do not end when contractual services are completed. If after a service has been performed, an entity discovers a deviation from the contractual technical requirements, then it must evaluate it or inform the purchaser of the deviation; and if the evaluation determined that a defect exists, then a notification is required.

The imposition of a civil penalty under 10 CFR Part 21 for a knowing and conscious failure to notify the Commission of a reportable defect or failure to comply is subject to a general Federal statute of limitation for Federal fines and civil penalties. That statute (28 U.S.C. 2462) requires that Federal civil penalties be imposed within five years from the date when the claim first accrued. State statutes of limitations would not apply to 10 CFR Part 21.

5 INTERFACES WITH OTHER REGULATIONS

There are two basic ways in which 10 CFR Part 21 interfaces with other regulations:

- The reporting requirements of 10 CFR Part 21 apply to entities that are subject to the requirements of other regulations (e.g., Appendix B to 10 CFR Part 50, 10 CFR Part 52), and
- There are other regulations that define reporting requirements similar to those of 10 CFR Part 21 (e.g., 10 CFR Part 50.55(e), 10 CFR Part 50.72, 10 CFR Part 50.73, and 10 CFR 73.71).

While 10 CFR Part 21 lists other regulations that are subject to the reporting requirements, these other regulations do not usually state that 10 CFR Part 21 applies. For example, 10 CFR 50 Appendix B makes no mention of 10 CFR Part 21. This has resulted in instances where suppliers of basic components did not recognize their responsibility to comply with 10 CFR Part 21. Purchase orders to suppliers of basic components should explicitly state that 10 CFR Part 21 applies. However, a supplier that knowingly accepts a contract to supply basic components (i.e., nuclear safety related items or services) is subject to the requirements of 10 CFR Part 21 even if the contract makes no mention of 10 CFR Part 21.

Duplicate reporting under 10 CFR Part 21 is not required. The reports submitted to satisfy other regulatory reporting requirements may also be used to satisfy the reporting requirements of 10 CFR Part 21. To satisfy the requirements of 10 CFR Part 21, these reports should indicate that they are being submitted to satisfy 10 CFR Part 21 requirements and should include the information required for 10 CFR Part 21 notifications. Note that the criteria for reporting under 10 CFR Part 21 is not identical to the criteria for other regulations. The criteria for each regulation should be considered. There may be instances where the reporting criteria for another regulation have been met but a 10 CFR Part 21 notification is still required.

The following subsections provide information pertinent to specific regulations that interface with 10 CFR Part 21.

5.1 Quality Program Requirements

A quality assurance program (e.g. Appendix B of 10 CFR Part 50 for reactor licensees), when established and implemented by licensees and suppliers of basic components, is the mechanism whereby assurance is provided that deviations and non-compliances do not occur and, when they do occur, they are detected and properly addressed. For any entity responsible for 10 CFR Part 21, an approach to meet the regulations is to establish procedures to prescribe the actions necessary to select suppliers of basic components; procure, receive, accept for use, dedicate, control, and install basic components; and identify, evaluate, and report defects and failures to comply. The procedures for evaluation and reporting of defects and failures to comply will flow down from 10 CFR Part 21 the requirements for records associated with these activities.

Since not all deviations and failures to comply require evaluating or reporting under 10 CFR Part 21, an approach to meet the regulation is to ensure the quality assurance program procedures established for the control of nonconforming items and activities clearly describe the distinction between deviations and failures to comply that require an evaluation and report, and those that do not. If the differences can be clearly delineated as they pertain to the specific item or service provided, then it is easier to determine when the deviation or failure to comply must be evaluated for reportability as required by 10 CFR 21.21. 10 CFR Part 21 has given special meaning to “defect” and “deviation”. These same terms are used in Criterion XVI, Corrective Action, of Appendix B to 10 CFR Part 50. Although the special meanings of Part 21 were not developed

for the Appendix B use of the terms, the meaning of Criterion XVI of Appendix B is not changed and is consistent with the special meaning of these terms as used in 10 CFR Part 21. The terms "defect" and "deviation," as they are applied to 10 CFR Part 21 issues, are discussed more fully in Sections 2.4 and 2.6 of this document.

Any entity supplying a basic component as defined in 10 CFR 21.3(a) is subject to 10 CFR Part 21. Therefore, the provisions of 10 CFR Part 21, such as the posting requirements in 10 CFR 21.6 and the procurement document requirements of 10 CFR 21.31, would also apply. Regardless of how many controls are established by the quality assurance program or to satisfy other nationally recognized standards or agencies, there is no exemption from the provisions of 10 CFR Part 21 as they apply to the basic components they supply, whether they are items or services.

Entities which are subject to 10 CFR Part 21 may perform quality assurance program audits of potential suppliers of basic components to place or maintain them on an approved supplier list. However, these audits are not required for the specific purpose of ensuring compliance with 10 CFR Part 21.

5.2 50.72 AND 50.73

Nuclear power plant licensees under 10 CFR Part 50, or 10 CFR Part 52 after the Commission makes a finding under 10 CFR 52.103(g) are subject to the reporting requirements of 10 CFR 50.72 and 10 CFR 50.73. These regulations require the licensee to make prompt telephone notification to the NRC and to submit a written report for each operating event or adverse plant condition.

10 CFR 21.2(c) states that the evaluation of deviations and appropriate reporting of defects under 10 CFR 50.72, and 10 CFR 50.73 satisfies each person's evaluation, notification and reporting obligation to report defects under 10 CFR Part 21. The statements of consideration for the 1991 rulemaking to revise 10 CFR Part 21 (56FR36081) clarifies that the evaluation and reporting criteria in 10 CFR Part 21 and in 10 CFR 50.72/73 are similar, and duplicate evaluation and reporting is not necessary. It further clarifies that the licensee's evaluation and reporting responsibilities under 10 CFR Part 21 are satisfied by evaluating deviations of basic components, and reporting if necessary, under 10 CFR 50.72, and 10 CFR 50.73. Thus, for events evaluated under 10 CFR 50.72 and/or 50.73 a separate evaluation or report under 10 CFR Part 21 is not necessary.

Example:

A High Pressure Coolant Injection pump (a single train system) failed due to faulty seals on May 1 while in service. Previously, the seal manufacturer has issued guidance to its customers that seal material should be replaced. The utility reported the failure as a 10 CFR 50.72 as a loss of

safety function of the High Pressure Coolant Injection system. In the subsequent 10 CFR 50.73 report, the utility identified 10 CFR Part 21 as an additional reporting requirement in the Licensee Event Report.

Response:

Because the part was installed in the plant, a 10 CFR 50.72 and 10 CFR 50.73 provided the NRC with notification of the failed component. The utility also identified 10 CFR Part 21 in the cover letter of the Licensee Event Report. Accordingly, the utility complied with 10 CFR Part 21 requirements.

5.3 50.55(e)

Each holder of a 10 CFR Part 50 construction permit, a 10 CFR Part 52 manufacturing license, or a 10 CFR Part 52 combined license before the Commission makes the finding under 10 CFR 52.103(g) is subject to the requirements of 10 CFR 50.55(e). The 10 CFR 52.103(g) finding allows a 10 CFR 52 licensee to load nuclear fuel into a constructed nuclear power plant.

10 CFR Part 21 is applicable to all entities (licensees and suppliers) that perform activities related to nuclear safety-related applications, whereas 10 CFR 50.55(e) reporting requirements do not apply to suppliers. Additionally, 10 CFR 50.55(e) was revised in 1991 to provide that the definitions of terms in 10 CFR 21.3 apply to 10 CFR 50.55(e).

10 CFR Part 21 and 50.55(e) have substantial overlap in the evaluation of a defect or failure to comply with respect to reporting requirements provided in both Parts. 10 CFR Part 21 and 50.55(e) both require evaluations of deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and in all cases within 60 days of discovery. Both Part 21 and 50.55(e) provide the same content of notification requirements as well to make reports to the NRC. 10 CFR 50.55(e) was further revised in 1991 to avoid duplicative reports to the NRC from a licensee subject to both 10 CFR Part 21 and 10 CFR 50.55(e). Specifically, 10 CFR 55.55(e)(8) states, “The requirements of 50.55(e) are satisfied when the defect or failure to comply associated with a substantial safety hazard has been previously reported under part 21.”

However, there is a unique reporting requirement in 10 CFR 50.55(e) that is not found in 10 CFR 21. The reporting criterion in 10 CFR 50.55(e)(3)(iii)(C) pertains to the construction or manufacture of a facility or activity, or a basic component supplied for such facility or activity which, “Undergoes any significant breakdown in any portion of the quality assurance program conducted under the requirements of Appendix B to 10 CFR Part 50 which could have produced a defect in a basic component. These breakdowns in the quality assurance program are reportable whether or not the breakdown actually resulted in a defect in a design approved and released for construction, installation, or manufacture.”

Based on the requirements of 10 CFR Part 21 and 10 CFR 50.55(e), evaluations of deviations and failures to comply associated with a construction permit or license activity need to include evaluation of the basic component "substantial safety hazard" criteria found in both 10 CFR Part 21 and 10 CFR 50.55(e) as well as the evaluation for possible significant breakdown in any portion of the Quality Assurance program found in 10 CFR 50.55(e)(3)(iii)(C).

Therefore, evaluations and notification under 10 CFR 50.55(e) satisfy the requirements of 10 CFR Part 21. Evaluations of deviations or failures to comply performed by a 10 CFR Part 52 licensee of a nuclear plant under construction, 10 CFR Part 50 construction permit holder, or a 10 CFR Part 52 manufacturing license holder can be conducted and reported to the NRC, if needed, as a combined 10 CFR 21/50.55(e) report. Implementation of 10 CFR Part 21/10 CFR 50.55(e) is recommended to be performed to include both aspects of the required evaluation process.

5.4 73.71

Physical security and safeguards requirements for nuclear power plants and materials are established in 10 CFR Part 73. These include requirements for reporting safeguards events in 10 CFR 73.71. Sabotage or terrorism are a concern because they could lead to the release of a significant amount of radioactive material thereby endangering public health and safety. Therefore, it is possible that failures to comply or defects in a security system could contribute to the creation of a substantial safety hazard and would be within the scope of 10 CFR Part 21.

To the extent that a failure to comply or defect in a security system can contribute to a substantial safety hazard, such failures and defects are within the scope of 10 CFR Part 21. In the case of a power reactor, the rationale is that an act of sabotage or terrorism could result in potential offsite exposure comparable to that which could occur as a result of an accident.

The relationship of 10 CFR Part 73 with 10 CFR Part 21 is no different than the relationship of any other regulation and Part 21. Licensees are required to evaluate deficiencies in their approved security plans. Reporting of defects or failures to comply made under 10 CFR 73.71 do not require a separate 10 CFR Part 21 notification, provided the report under 73.71 satisfied the notification requirements of 10 CFR 21.21.

An example of a defect or noncompliance in a security system is one which could allow access of an unauthorized individual to a vital area without being detected by the security system. Detection of the unauthorized individual by random visual surveillance or by remote visual electronic surveillance does not provide a continuous capability for initial detection and therefore is not considered to be a detection by the security system. This represents a major reduction in the degree of protection to public health and safety and is therefore a substantial safety hazard, and would require notification to the NRC.

6 AN ENTITY'S 10 CFR PART 21 PROGRAM

In order to comply with 10 CFR Part 21, entities will need to establish procedures, maintain records, place postings, and include requirements related to 10 CFR Part 21 in the procurement documents for basic components. Although not required by 10 CFR Part 21, entities should also ensure adequate training on the roles and responsibilities of individuals in the organization for complying with 10 CFR Part 21 requirements.

6.1 PROCEDURES

10 CFR 21.2(a) requires each entity subject to 10 CFR Part 21 to establish appropriate procedures to provide for informing the Director or the Responsible Officer designated by each organization as having the required "executive authority" over activities subject to 10 CFR Part 21. "Appropriate procedures" means procedures that are sufficient to provide effective implementation of 10 CFR Part 21 evaluation and notification requirements.

The primary objective of the evaluation and notification requirements of 10 CFR Part 21 is to ensure that issues associated with delivered basic components that are potentially associated with a substantial safety hazard, are identified, evaluated, documented, and reported to the NRC and all potentially affected purchasers, if necessary. To achieve this objective, the procedures should:

- Describe how deviations and failures to comply are identified and documented,
- Identify who has the responsibility for performing the evaluation,
- Describe the purpose of the evaluation,
- Provide instructions to perform 10 CFR Part 21 evaluations,
- Provide guidance for performing and documenting the evaluation,
- Include requirements to inform a Director or Responsible Officer of 10 CFR Part 21 reportable conditions, and
- Provide instructions to perform 10 CFR Part 21 notifications of reportable conditions

A licensee, and suppliers of basic components to the licensee, must begin to establish procedures as required by 10 CFR 21.21(a) before it first engages in any of the construction activities, including safety related design and analysis work, identified in 10 CFR 21.3.

Each entity subject to 10 CFR Part 21 is responsible and must assure itself that appropriate procedures are established. Normal management controls are an acceptable means to verify conformance to 10 CFR Part 21. Quality assurance type audits are not required to verify that appropriate procedures are in effect, and 10 CFR Part 21 procedures do not need to be covered in QA Manuals, for either Purchasers or Suppliers.

An entity's procedures should provide guidance to assist in identifying and evaluating the types of deviations and failures to comply associated with their scope of supply. The procedures should also caution that there could be other types of deviations and failures to comply that were not considered by the procedural guidance.

Procedures should define the responsibilities for review and approval of the evaluation. The procedures required by 10 CFR 21.21(a) should provide for evaluation of deviations which are brought to the attention of the entity regardless of who identifies the deviation. The procedure for evaluation should ensure the evaluation performs and the corresponding records produce the following information:

- Review of information sufficient to describe the deviation or failure to comply
- Information sufficient to describe the evaluation,
- An analysis of the effect of the deviation or failure to comply in a basic component if used in a facility or activity subject to 10 CFR Part 21.
- A conclusion based on this analysis as to whether the deviation or failure to comply could create a substantial safety hazard.

10 CFR Part 21 does not require that procedures provide a method for Responsible Officers or Directors to introduce questions to the organization they head to obtain an analysis with regard to safety significance. However, procedures must provide for notification of a "Director or Responsible Officer". This procedural designation, however, does not absolve other Directors or Responsible Officers from reporting if he/she obtains information reasonably indicating a failure to comply or a defect.

Though 10 CFR Part 21 does not require it, it would be wise for an entity to set up a procedure whereby any contacts which would qualify as adequate 10 CFR Part 21 notification to the NRC would be documented. Where the notification was oral, a record of the conversation should be forwarded to a Director or Responsible Officer who should also receive copies of the written report. For example, receipt of a record of a telephone conversation with an NRC regional office making the initial notification (made by the person designated as responsible for making such initial notifications) constitutes adequate verification.

6.2 RECORDS

The maintenance of records related to 10 CFR Part 21 evaluations of deviations and failures to comply, and notifications sent to purchasers and affected licensees shall be maintained in accordance with 10 CFR 21.51. The time limits for the maintenance of records are established in 10 CFR 21.51(a).

Related records as described in 10 CFR 21.51 can be maintained in accordance with an entity's internal procedures provided the procedures comply with the retention requirements specified in 10 CFR 21.51.

6.3 POSTING

Content of Postings

All entities subject to 10 CFR Part 21 are required to post current copies of Section 206 of the Energy Reorganization Act of 1974 and of the regulation and implementing procedure, or a notice which describes the regulation and procedure, including the name of the individual to whom reports may be made, and states where a copy of the current revision resides for viewing by all employees if it is not posted.

Section 206 of the Energy Reorganization Act was issued in 1974 and has not changed. 10 CFR 21.6(a)(1)(iii) indicates that procedures implementing the requirements of Section 206 of the Energy Reorganization Act of 1974 and 10 CFR Part 21 are adopted/established by the entities subject to Part 21. Those implementing procedures, either directly or by reference, should be included in the posting, as required by 10 CFR 21.6.

Examples:

- Posting locations may include a copy of the implementing procedures; or
- For companies who have more than a limited number of locations where postings are to be placed, that company may, for their convenience, reference a location on the posting where the company's 10 CFR Part 21 compliant procedures reside, rather than posting those procedures at every location where postings are placed. In addition to the description of the hard copy location, an electronic link reference may be included.
- A company who establishes that the only "official" location of a procedure is in a records retention system may reference the location of that procedure for employees to review or consult.

Types and Locations of Postings

A notice which describes the regulations/procedures, including a contact and location, should be placed in conspicuous locations on every premise where activities subject to 10 CFR Part 21 are conducted such that all employees who are performing activities subject to 10 CFR Part 21 will have access to observe them at some point during their daily activities.

Postings may be as hard copies, digital copies, or a combination of both. In addition, links to electronic postings may be identified. These should be placed in/on electronic "sites" commonly

frequented by workers during the performance of work subject to 10 CFR Part 21. Contractors providing basic components under the company's 10 CFR Part 50, Appendix B program must also have access to postings.

Although the 10 CFR Part 21 posting requirements are limited to premises within the US, it is expected that locations outside the US, where activities subject to 10 CFR Part 21 are conducted, also comply with the posting requirements.

Examples:

- Hard Copies – Actual printed media copy of 10 CFR Part 21 or a notice identifying the hard copy location and, if also desired, an electronic link to 10 CFR Part 21.
- Electronic Copies – An electronic file may be identified with an electronic link to 10 CFR Part 21.
- Posters should be placed where employees frequent during the performance of their 10 CFR Part 21 related work, such as:

Hard Copies	**Electronic Copies (links on)**
• Lunch Rooms • Break Rooms • Copy Rooms • Plant Portals and entry ways • Entry ways into buildings • Entry ways into auditoriums	• Company Home Pages • Company Engineering Home Pages • Company Quality Home Pages • Company Procurement Home Pages • Company Services Home Pages • Company Regulatory Affairs Home Pages

Alternatives

10 CFR Part 21.6(b) indicates that there may be reasons that posting of specific portions of the regulation or the implementing procedure may be impractical and alternate solutions are acceptable as long as the location where access to the regulation and implementing procedure is identified in the notice that is posted. In all cases the individual to be contacted should be identified on the posted notice.

Examples:

- A company who has more than a limited number of locations where postings are to be placed may reference a location where the company's 10 CFR Part 21 compliant procedure resides, rather than posting it at every location where postings are placed. In addition or in lieu of a description of the location for retrieval of the hard copy, an electronic link may be referenced.

- A company who establishes a single "official" posting location where all employees pass through may reference the location of that procedure for employees to review or consult in the posted notice(s).

- A company who has remote workers, workers who are working at customers' facilities or in short duration assignments may be given electronic access to the posted requirements of 10 CFR Part21 on company based electronic locations.

6.4 TRAINING

10 CFR Part 21 does not establish requirements for training of personnel involved in 10 CFR Part 21 activities. However, as a good practice, appropriate familiarization and training in the requirements of 10 CFR Part 21 should be provided initially, and, as appropriate, on an ongoing basis, as necessary. Training may be in the form of classroom, computer based, read and sign, review of pertinent operating experience, or ongoing work experience. The important aspect is that individuals involved in activities associated with 10 CFR Part 21 compliance remain cognizant of the entity's responsibilities under this regulation, and their individual role in satisfying Part 21 requirements. This only includes individuals that perform 10 CFR Part 21 activities; it does not include general employees that do not perform activities subject to 10 CFR Part 21.

Example #1:

Procurement Specialists and Quality Assurance inspectors receive introductory training in the form of computer based familiarization with the requirements of 10 CFR Part 21. The utility has no ongoing training program, but the Quality Assurance organization routinely inspects supplier compliance with the regulation. Additionally, the Procurement Specialists include 10 CFR Part 21 requirements in procurement documents and must be familiar with aspects of the rule. Also, the Procurement Specialists review 10 CFR Part 21 notifications and determine if the part has been purchased by the utility. Do these training programs provide sufficient training on 10 CFR Part 21?

Response:

Yes. Initial familiarization training and ongoing work experience are appropriate training methods in familiarization of the 10 CFR Part 21 requirements.

Example #2:

The Engineering staff is not given formal 10 CFR Part 21 training, but may be required to perform a 10 CFR Part 21 evaluation in accordance with the detailed corporate procedure for 10 CFR Part 21 evaluations. Is a formal training program necessary for the Engineering staff?

Response:

No. In the performance of the evaluation, it is expected that the corporate procedure will guide the Engineering staff in the process for determining compliance with 10 CFR Part 21. Accordingly, the familiarization gained through the on the job activities provides a sufficient background in the aspects of 10 CFR Part 21. On the job activities associated with 10 CFR Part 21 serve as a valuable training tool in familiarizing personnel with the requirements of 10 CFR Part 21.

Example #3:

Quality Assurance inspectors receive introductory and continuing training in the form of read-and-sign familiarization with the requirements of 10 CFR Part 21 as set forth in implementing procedures and changes thereto. The licensee has no ongoing training program, but the Quality Assurance organization routinely inspects suppliers of basic component as well as performs receiving inspection. Additionally, Engineering and Procurement personnel include 10 CFR Part 21 requirements in procedures and procurement documents and must be familiar with aspects of the rule applicable to their areas of responsibility. Is a formal training program necessary for the Engineering, Procurement, and Quality Assurance staff?

Response:

No. In the development of procurement documents, performance of supplier evaluations, and performance of receipt inspections, it is expected that the corporate procedures will guide the Engineering, Procurement, and Quality Assurance staff in the process of complying with 10 CFR Part 21. Accordingly, the familiarization gained through the on the job activities provides a sufficient background in the aspects of 10 CFR Part 21. On the job activities associated with 10 CFR Part 21 serve as a valuable training tool in familiarizing personnel with their responsibilities in order to satisfy the requirements of 10 CFR Part 21.

6.5 PROCUREMENT DOCUMENTS

Quality Requirements in Procurement Documents

Procurement documents are addressed in 10 CFR Part 21.31, which requires that they state the applicability of 10 CFR Part 21 to the supplier of basic components. Basic components can only be supplied if they are procured through an NRC compliant quality assurance program. Thus

applicable quality assurance requirements and 10 CFR Part 21 requirements both apply together for the procurement of basic components.

Basic components are obtained either 1) by being supplied as such under a quality assurance program pursuant to NRC's quality assurance requirements in the applicable part of Title 10 Code of Federal Regulations, or 2) as commercial grade items subjected to the dedication process defined in 10 CFR Part 21. Part 21 requirements do not apply to the supply of commercial grade items prior to their dedication and delivery as basic components. 10 CFR Part 21 evaluation and reporting requirements only apply to dedicated basic components after they are delivered. 10 CFR Part 21 responsibilities for the entity that dedicated the basic component do not begin until the item is dedicated, delivered and accepted for use as a basic component.

For nuclear power plants, the applicable quality assurance requirements for procuring basic components are specified in 10 CFR Part 50, Appendix B. Specifically, Criterion IV, "Procurement Document Control" of Appendix B requires that purchasers contractually impose Appendix B quality assurance requirements on suppliers supplying safety-related materials, parts and services. Thus, for procurements of basic components, which impose 10 CFR Part 21 requirements on suppliers, the procurement documents should also impose the applicable Appendix B quality assurance requirements on the supplier.

For procurements of basic components, where 10 CFR Part 21 and applicable NRC quality assurance requirements apply to the procurement, the procurement documents should clearly communicate the applicability of these requirements to the supplier. Procurement documents should ensure that accurate 10 CFR Part 21 contact information is provided including mailing addresses, e-mail addresses, and telephone numbers, as applicable. It is also important that the procurement documents clearly indicate that the materials/components/services are being supplied as safety-related.

For nuclear power plants (licensed under Part 50 or Part 52), the purchaser should also require the supplier to pass down 10 CFR Part 21 and quality assurance requirements in procurement documents for basic components being supplied by sub-suppliers. This includes requiring their sub-supplier to pass down the requirements to their supplier, and so on down the supply chain for all procurements of items and services being supplied as basic components for which a defect could result in a substantial safety hazard. 10 CFR Part 21 requirements do not need to be passed down to suppliers of commercial grade items.

Each procurement document for a basic component must specify that the provisions of 10 CFR Part 21 apply. Therefore, purchase orders for structural steel or anchor bolts, if they are procured directly as basic components, must specify that 10 CFR Part 21 applies. If these materials are procured as commercial grade items to be dedicated by the licensee or by a service supplier contracted to be the dedicating entity, then the procurement documents do not need to specify

that the provisions of 10 CFR Part 21 apply to the material suppliers. 10 CFR Part 21 will apply to the dedicating entity.

Example #1:

What specific information should be included in procurement documents as part of the information that is applicable to 10 CFR Part 21?

Response:

The entity procuring the items or services must include in the procurement documentation:

- Notification that the items or services being supplied are safety-related and must be supplied as basic components
- Notification that the requirements of 10 CFR Part 21 are applicable to the order
- Notification that the relevant requirements (e.g. 10 CFR Part 50, Appendix B) of a compliant QA program approved by the purchaser are applicable to the order

Additional information that may be included, but is not required by 10 CFR Part 21, includes:

- Documentation requirements such as:
  - Required certifications of compliance and conformance
  - Required submittals such as drawings, bills of material, technical manuals, documents that describe the materials provided, installation and maintenance instructions, and special procedure processes
  - Hold and verification points
  - Rights of Access
- Technical requirements:
  - Critical information that impose conditions or restrictions

Example #2:

A 10 CFR Part 50 NRC licensed facility is procuring safety-related valves from a supplier whose 10 CFR Part 50, Appendix B compliant QA program the facility has approved, and includes the following requirements stated in their contract and purchase order:

- *The Supplier shall comply with applicable 10 CFR Part 50, Appendix B quality assurance requirements.*
- *The Supplier shall comply with the requirements of 10 CFR Part 21.*
- *The Supplier shall ensure that the applicable quality and Part 21 requirements are passed-down through the sub-tier supplier chain to all sub-suppliers in procurement documents for orders that supply basic components.*

Discussion:

The objective of requirements imposed on the supplier and sub-tier supplier is to ensure that 10 CFR Part 21 and QA requirements are applied to all suppliers of basic components. This meets the requirements of Part 21 and 10 CFR Part 50, Appendix B.

7 DISCOVERY OF AN ISSUE SUBJECT TO 10 CFR PART 21

10 CFR 21.2(a)(1) requires the evaluation of deviations and failures to comply in order to identify whether they could result in a substantial safety hazard, if they were to remain uncorrected. Prior to an evaluation, it first must be determined that a deviation or failure to comply exists; which is called discovery. Discovery is a process that concludes by determining whether an evaluation is required. If it is determined that there is a deviation or failure to comply, then the point at which this is documented marks the Point of Discovery, and an evaluation must be performed, as described in Section 8.

7.1 Discovery Process and Point of Discovery

Discovery is not solely when it is determined that a deviation or failure to comply exists, that is but one of three elements in the discovery. Those elements are: 1) completion of the documentation first identifying, 2) the existence of a deviation or failure to comply, and 3) it is potentially associated with a substantial safety hazard. In order for discovery to occur, some investigation and analysis is often necessary. This was acknowledged by the NRC in SECY 91-150, which stated, *"Discovery is not complete until the documentation identifying the existence of a deviation or failure to comply is complete. 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 or §50.55(e)."*

In many cases, issues are first identified and documented within a licensee's corrective action process. At this point there may not be enough information to recognize it as a Part 21 issue, and only when the issue is clearly identified as a potential Part 21 issue is the Point of Discovery established. Thus, discovery is a process that takes time and may not occur immediately when an issue is first documented in the corrective action process. It is expected that the investigation/screening of the issue to determine potential Part 21 applicability should be timely. A delayed investigation should not be used as a means to delay evaluation and could be considered a violation of 10 CFR Part 21.

Issues that are identified and documented within the nonconformance and corrective action processes may need to be considered for evaluation and notification in accordance with 10 CFR Part 21. Depending on the size of the entity and nature of the business, these processes can generate a significant number of reports (e.g., condition reports, corrective action reports,

and nonconformance reports). Only a subset of these reports identify issues that require additional actions to address 10 CFR Part 21 concerns, but the total number of reports can present a significant challenge in considering the applicability of 10 CFR Part 21 for each one. Prior to entering an issue into the Part 21 discovery process, the entity will need to identify whether an issue entered into a problem identification and resolution program (e.g., corrective action program) needs to be considered for Part 21 applicability. The main consideration is whether the issue is a nonconforming condition or condition adverse to quality relating to a facility, activity or basic component. If an issue is determined to meet these conditions, then it needs to be considered for Part 21 applicability and is entered into the Part 21 program, starting with the discovery process.

A screening is one approach to formalize the process of discovery that determines whether the issue is associated with a deviation or a failure to comply with a regulation. The screening process is a review performed to determine whether a given nonconforming condition or condition adverse to quality[3] represents a deviation or failure to comply that is potentially associated with a substantial safety hazard, and if so, to document this determination. The screening that culminates in the point of discovery should be timely, and without undue delay in determining whether a Part 21 evaluation is warranted. In many cases, the determination of whether a Part 21 evaluation is necessary depends upon the unique conditions of the issue and upon what is known about the issue. Therefore, the amount of time that is reasonable to complete a screening (i.e. the discovery process) is not fixed, but rather depends on the complexity of the issue being investigated.

The screening process culminates in the point of discovery for deviations and failures to comply that require evaluation, or the determination that the issue does not require a Part 21 evaluation. The evaluation starts at the point of discovery and determines whether there is a defect or failure to comply that could create a substantial safety hazard and must be reported to the NRC in accordance with 10 CFR Part 21. In most cases, a deviation or failure to comply can only be identified through additional investigation performed as part of the discovery process. However, in some cases there may be enough information in the original problem identification/corrective action report to determine whether the issue is a deviation or failure to comply. In these situations, the point of discovery should be established as the first report containing sufficient information to make this determination.

[3] Issues identified in the corrective action program that are not associated with a nonconforming condition or condition adverse to quality, and thus would clearly not require a Part 21 evaluation or notification, (e.g., a condition report indicating that there is a trip hazard in an office hallway) need not be screened.

If there is sufficient information from the screening process to determine whether or not the issue must be reported, then the properly documented results of the screening process may be credited as the 10 CFR Part 21 evaluation.

The screening process is implemented by personnel that have knowledge of the pertinent regulatory and technical requirements. The screening process may be conducted by a single person or by a designated group, such as a regulatory compliance team or material review board. The results of the screening process conducted by a single person should be reviewed separately by another individual with knowledge of the regulatory/technical requirements to ensure that the conclusions are sound and sufficiently substantiated by the objective evidence.

The screening process could be led by personnel in a variety of departments, e.g. Quality Assurance, Engineering, Operations. Personnel from other departments may also be included in the screening process, or receive actions resulting from the screening process. The personnel implementing the screening process should be guided by a procedure or checklist to ensure the appropriate factors are considered and the results of the screening process are properly documented.

The supplier's screening process should consider whether they have the capability to perform an evaluation, if one is determined to be necessary. If it is obvious that the supplier does not have the capability to perform an evaluation, then the screening process should result in an action to inform purchasers and affected licensees accordingly.

The screening process considers several factors in determining whether an issue requires a Part 21 evaluation. The specific factors to be considered by an entity may vary somewhat depending on the nature of the business, but are focused on the determination of whether a deviation or failure to comply exists, as described in Sections 7.2 and 7.3.

7.2 FAILURE TO COMPLY

Failure to comply means that the facility or activity regulated by the NRC, or basic component of such facility or activity, does not comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order or license of the commission and is potentially associated with a substantial safety hazard. The requirements for evaluation and notification in 10 CFR Part 21 treat a failure to comply similar to a deviation. The main difference is in the criteria to determine if a failure to comply exists.

In the context of 10 CFR Part 21, a failure to comply exists if:

- The manufacture, construction, or operation of a licensed facility or activity,
- A basic component supplied for such facility or activity, or
- A design certification or design approval under 10 CFR Part 52,

is not in compliance with:

- The Atomic Energy Act of 1954, as amended, or
- Any applicable rule, regulation of 10 CFR, order, or license issued by the Commission, or
- A standard design approval under 10 CFR Part 52,

and it is potentially associated with a substantial safety hazard.

A non-compliance with an industry code (e.g., the ASME code) could also constitute a *failure to comply* in the context of 10 CFR Part 21, if the code is invoked by an applicable rule, regulation, order, or license.

Only failures to comply that are potentially associated with a substantial safety hazard are required to be evaluated. In the context of the discovery process, potentially associated with a substantial safety hazard means a failure to comply which is related to the performance of a safety function. This criteria in the discovery process assures that unnecessary evaluations are not performed on failures to comply that clearly could not result in a substantial safety hazard and do not need to be reported to the NRC.

7.3 Deviation in a Delivered Basic Component

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 must be evaluated. A typical issue that may be encountered is a deviation in the technical requirements of a procurement document or specified in early site permit information, a standard design certification or standard design approval. Not all deviations require an evaluation, only those that are related to a basic component that has been delivered. In order to determine whether an evaluation is needed two questions must be answered. The issue is a deviation if both questions are answered "yes".

1. Does the issue constitute a deviation associated with a basic component?

The evaluation requirements of 10 CFR Part 21 only apply to a deviation associated with a basic component. Deviation, as defined in 10 CFR Part 21.3 (see Section 2.6) is 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. The definition of basic component in 10 CFR Part 21.3, as clarified in Section 2.1, should be used to determine if the issue impacts a basic component. Commercial grade items (including those that have not yet completed a commercial grade dedication acceptance process) are not basic components and are not subject to 10 CFR Part 21 evaluation and reporting requirements.

It should be noted that procurement documents created by a basic component service supplier can be defective and therefore reportable to the regulator. For example, the supplied specifications for a basic component could be defective if the critical design characteristics for an

item were not properly determined and/or documented due to an inadequate design/procedural process, resulting in procurement of an item that would not prevent or mitigate a substantial safety hazard.

Additionally, an analysis error, modeling error, or data input error could be reportable under Part 21 where such an error is detected after delivery of the analysis data to the purchaser.

If the issue is a deviation associated with a basic component, then Question #2 should be answered; otherwise the issue is not subject to 10 CFR Part 21 and no further investigation is necessary.

2. Has the basic component with a deviation been delivered?

The evaluation requirements of 10 CFR Part 21 only apply to a deviation of a basic component if that basic component has been delivered.

In determining whether a basic component has been delivered, the fundamental element is when the purchaser has taken control over the item. Normally, this would occur when the purchaser or its agent (e.g., a shipper) receives the component. However, the purchaser may be entitled, either through contractual provision or ordinary commercial practice, to conduct a receiving inspection before taking final acceptance of the component. In that case, "delivery" would not occur and therefore no notification to NRC by the purchaser would be required where the purchaser conducts the authorized receipt inspection and rejects and returns the component to the supplier within a reasonable period of time after receipt of the component. In this same situation, the supplier who receives the rejected component would be required to evaluate the deviation and report an identified defect if they had delivered components with similar deviations to other facilities or activities subject to Part 21.

A basic component is considered delivered when the purchaser has taken control of the component or service as a basic component following the completion of the acceptance process (i.e., receipt inspection and in some cases acceptance/functional testing). At that point, the control and ownership of the component transfers to the purchaser, including 10 CFR Part 21 responsibilities for reporting. At any time prior to the owner accepting and taking control of the basic component, any departure from a technical requirement included in a procurement document is not required to be evaluated under Part 21 by the purchaser or the supplier because no substantial safety hazard can be created. However, the supplier retains full 10 CFR Part 21 responsibilities if the basic component was delivered to another purchaser. It is expected that the purchaser enter the issue and the basis for rejection into the corrective action process with documentation of the contact information with the supplier/manufacturer also included in the corrective action process. The purchaser should promptly communicate the rejection to the supplier, so that the supplier can determine the extent of condition and determine whether the basic component was delivered to another purchaser with the deviation. If the supplier identifies

a deviation in basic components delivered to other facilities or activities subject to Part 21, then the supplier should notify the other purchasers, and evaluate and report the defect pursuant to 10 CFR Part 21.

With respect to design, Part 21 is only applicable when such design (or consultation) can result in the creation of a substantial safety hazard. During the activities of design and consultation, there may be stages of conceptual design in regard to feasibility. Conceptual designs are not subject to Part 21. However, a "defect" in a design which is used in a procurement document is reportable under Part 21. Therefore, a design document, consultation or other software should be considered "delivered" for purposes of reporting defects under Part 21 when it has been communicated to a purchaser which will use it in design, manufacturing or in preparing a document for the manufacturing of any basic document.

The concept of "delivered" is not addressed specifically when the basic component is turned over from one corporation or separate entity to another corporation or entity or delivered within a single corporation. The rule makes no distinction between inter and intra organization delivery of components as long as the transaction occurs pursuant to a procurement document. In determining whether a basic component has been delivered, the fundamental element is when the purchaser has taken control over the item. For example, if the fabricator of the component is also the licensee of the reactor, the point of delivery is when the organization authorized to use it as a basic component has taken control over the item.

For purchasers, the rejection of a basic component prior to completing the acceptance process, for example during a receipt inspection, would result in the basic component not being delivered. Thus, the purchaser does not need to perform a Part 21 evaluation.

For suppliers, the response to this question, in the case of a basic component being rejected before completing the acceptance process may depend upon some investigation of the extent of condition. For example, if the supplier determines that the basic component with a deviation has not been delivered to the purchaser for the issue in question, then they should also investigate whether the basic component has been delivered to other purchasers with a deviation. Once the supplier identifies that the basic component with a deviation has been delivered to at least one purchaser, then the investigation of the extent of condition is not necessary to determine if an evaluation is necessary; however, further investigation of the extent of condition may be necessary in order to notify affected purchasers.

As an example, a spare part received at a power reactor facility which is returned as a result of the initial receipt inspection would not be reportable under Part 21 by the purchaser. The supplier would be required to report the item if they have delivered similar defective parts to others, if the evaluation were to determine that a substantial safety hazard had been or could have been created. A defect in a spare part which is found after it is under the control of the purchaser

(i.e., after delivery, receipt inspection, and acceptance by the purchaser) would be reportable under Part 21.

When associated with construction activities, either new plant construction or new system construction takes place, the point of delivery may vary depending on the issue that is identified.

If a deviation from technical requirements is associated with a non-performance based issue (e.g., material composition, physical dimensions), the point of delivery is when the basic component has been accepted for installation. If the deviation is associated with a performance based issue (e.g., current output, flow, pressure, temperature) and is established by contract that acceptable completion of component/system turnover to the plant establishes the transfer of ownership, then the point of delivery is when all successful installation/system testing has been completed.

If the basic component with a deviation has been delivered, then an evaluation is necessary and should be performed as described in Section 8.

Clarification of Deviation and Delivery for 10 CFR Part 52 Design Certifications

In the context of a design certification, 10 CFR 21.3 defines a *deviation* as a departure from a "technical requirement" included in a standard design certification. It is important to note that not all of the information contained within a design certification document (DCD) represents "technical requirements" in the context of this definition. For example, non-safety information within the DCD should be excluded. In the DCD the safety classification requirements established in DCD Section 3.2 require that any Systems, Structures, or Components (SSCs) that perform safety functions (as defined by 10 CFR 50.2) are classified as safety-related. The definition of safety-related in 10 CFR 50.2 is consistent with the definition of a "basic component" under 10 CFR 21.3. Therefore, non-safety SSCs would not be a "basic component" and not subject to consideration as a "technical requirement."

Likewise, system and operational description information contained within the DCD does not necessarily constitute a "technical requirement." This information conveys how a design solution was created to satisfy certain technical requirements, but may not represent a requirement on the design itself. For example, a normal flow rate would not be a technical requirement. However, a prescribed maximum or minimum required flow rate to satisfy a safety design basis would constitute a technical requirement. Likewise, descriptions of system alignments (e.g., "the pump is normally started with the discharge valve closed") is not a requirement for the component or something that can be procured and therefore, is not a "technical requirement" under the context of this definition in Part 21.

In the context of a design certification, a "technical requirement" as used in the definition of Part 21 for a deviation would be represented by:

- A prescribed safety design basis requirement established in the Final Safety Analysis Report (FSAR). Examples:
    - Equipment is designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, and external missiles without loss of capability to perform the intended safety function
- A prescribed performance acceptance criteria established in the FSAR. Examples of prescriptive design basis requirements would be as follows:
    - Minimum or maximum containment isolation valve closure times
    - Minimum net positive suction head (NPSH) for safety-related pumps
    - Seismic or equipment qualification requirements supporting a safety function
    - Minimum or maximum system design temperatures/pressures necessary to perform a safety function
- Information that typically would be provided in a design or procurement specification. This is consistent with information in the NRC memorandum dated 10/5/2009, "Revision 1 To NRC Responses to 10 CFR Part 21 and Fuel Cycle Facility Questions Received During the Vendor Workshop on New Reactor Construction In December, 2008," that basically refers to deviations in information in the DCD that would be offered to a licensee. This is also reinforced in RIS 2010-05 where the NRC clarified that Part 21 applies to information that is within the scope of supply of the Design Certification and refers to deviations in the information in the DCD that would be offered to a licensee. Such information would typically include that information specified in the DCD that would need to be verified to demonstrate that the component would be able to perform its designed function (e.g., IST requirements, EQ requirements, design information needed to demonstrate conformance with Tech Specs, ITAAC, etc.)
- FSAR prescribed materials to be used for construction/fabrication. Examples:
    - Material Specifications for the RCPB Components
    - Control Rod Drive Mechanism Materials
    - Pressure-Retaining Material Specifications for Engineered Safety Features
    - Material Properties – Reactor Containment Building

It should also be noted that, per RIS-2010-05, a revision to a DCD does not alleviate the obligation to review the revision and its basis for Part 21 applicability and subsequent reportability. For example, if a revision was made to a DCD to correct an error related to a technical requirement associated with a basic component, the error still needs to be evaluated under Part 21. The delivery of safety-related engineered construction documents, purchase orders, or shop drawings to a licensee that conflict with the DCD could also be determined to be a deviation if they differ from the technical requirements in the DCD.

As explained in the statement of considerations for the 2007 changes to Part 52 (72 FR 49352, August 28, 2007) the NRC regards the standard design certification applicant as supplying a component of an activity which is otherwise regulated by the NRC. The activity that is regulated by the NRC is the design certification rulemaking, and/or the Part 52 regulatory regime in which a design certification rule may be referenced in a subsequent licensing application. The DCD becomes subject to Part 21 when it is first docketed. It is noted that the applicant may have Part 21 responsibilities in the pre-application activities. If the design organization discovers a deviation in the design, which has been offered for use, the design organization is obligated to comply with the provisions of Part 21. Safety-related design, analysis and consulting services should be procured and controlled in a manner sufficient to allow compliance with the requirements of 10 CFR Part 21.

As noted in RIS-2010-05, the design certification applicant has a current obligation under 10 CFR Part 21 to report to the NRC any identified deviations or failure to comply within its scope of supply that could create a substantial safety hazard. This obligation exists even if the COL applicant did not actually contract with the DC applicant to provide further design and engineering for the standard design certification. As stated in the second key principle of reporting under Section 206 of the ERA, the reporting obligation of a design certification applicant under 10 CFR Part 21 continues until the termination or expiration of the standard design certification; or until the termination or expiration of the last license referencing the design certification applicant's design certification.

Examples of Deviations to a Technical Requirement in the Design Certification:

*A safety-related component is identified in DCD Section 3.11 a*s being qualified for a mild environment. Due to an error in a calculation, it is later determined that the location of the component is actually a harsh environment. Therefore, the component would not be qualified for the environment it needs to survive during a design basis accident and perform its safety function.

It is discovered that the load combination table in the Main Steam Relief Isolation Valve Design Specification did not agree with the load combination for ASME Class 2 and 3 components in DCD Section 3.9.3. The DCD specifies that thermal effects are to be applied to the Emergency Loading condition. This was not specified in the loading combination table in the design

specification. This would represent a deviation from a technical requirement specified in the design certification.

It is discovered that the material grade for the CRDM latch unit in the design specification does not agree with that specified in DCD Section 4.5. This would represent a deviation from a technical requirement specified in the design certification.

Example #1:

An Issue Report has been written by a combined operating license applicant (COLA) for a nuclear power plant design certification document (DCD). The DCD has been approved and certified by NRC and a COLA has been submitted to NRC for their review. The COLA has discovered that the normal flow rate of the feedwater system in the standard design certification is in error; however, all minimum and maximum specified values are correct. The COLA holder enters this into their corrective action program. As part of the 10 CFR 21 screening, the COLA holder determines that the normal flow rate is not a technical requirement in the DCD, and therefore does not constitute a deviation as defined in Part 21.

Discussion:

The COLA holder appropriately complied with Part 21. Because the normal flow rate does not affect any safety functions, it is not a technical requirement. Only departures in technical requirements are considered deviations.

7.4 Examples of the Discovery Process

Example #1:

Relay Model XY-01, a basic component, supplied for the Low Pressure Coolant Injection System was accepted by the licensee but not installed. During startup testing on May 1st, it was identified that the relay contacts were deficient and not closing properly. This issue was immediately entered into the corrective action program. There was no information that indicated the issue was due to a deviation or failure to comply. As part of the investigation, the relay was removed and sent to a laboratory to identify the cause of the failure. The review by the laboratory was concluded and documented on June 1st, which determined that a faulty manufacturing process was utilized to manufacture this relay. The review of the laboratory report and procurement documents concluded that the relay has a deviation. The licensee also concluded that the deviation potentially associated with a substantial safety hazard because the failure of the relay to close properly could prevent the relay from performing its safety function. The licensee concluded that this provided sufficient information that a deviation exists that is potentially associated with a substantial safety hazard; i.e., it was determined that a Part 21 evaluation is needed. This information was documented in the corrective action process on June

2nd. The licensee declared June 2nd to be the date of the Point of Discovery for the 10 CFR Part 21 evaluation (i.e., start of the 60 day evaluation clock).

Discussion:

Because the licensee had accepted the basic component, and the part was on the shelf, but not yet installed, the licensee maintained 10 CFR Part 21 responsibility for the part. Although the issue (failure of relay contacts during startup testing) was immediately documented in the corrective action program, the licensee did not have information to reasonably determine whether the failure was due to a deviation from technical requirements in procurement documents, nor whether the deviation was potentially associated with a substantial safety hazard. The laboratory analysis was conducted promptly, followed by a prompt review of the laboratory report, procurement documents, and the effect on the ability to perform the intended safety function. Accordingly, the licensee's determination of point of discovery was in compliance with the requirements of 10 CFR Part 21.

Example #2:

On October 1st, leakage from a safety-related check valve was observed during startup testing of the plant. This issue was immediately entered into the corrective action program. Upon further investigation which concluded on October 2nd, it was determined that the leakage was caused by the valve body material, which was not in conformance with the owner specifications referenced in the procurement documents (i.e. a deviation). Furthermore, on October 15th the licensee concluded that the deviation in the material could prevent the valve from performing its safety function. This issue was entered in the corrective action process on October 15th and the licensee declared this to be the point of discovery. The licensee began a 10 CFR Part 21 evaluation on October 15th commencing the 60 day evaluation period.

Discussion:

This is an example of how not to determine the point of discovery. The licensee was not in compliance with 10 CFR Part 21. The licensee had clear indication on October 2nd that the supplier had provided a valve body with a deviation from the licensee's design specifications, and that this deviation is potentially associated with a substantial safety hazard. Delaying the commencement of the evaluation until October 15th, and declaring this the point of discovery, was not appropriate with the available evidence.

Example #3:

On April 1st, the licensee identifies during receipt inspection that a switch, provided as a basic component, does not meet the material specifications in the procurement documents originally supplied to the supplier (i.e. a deviation). The receipt inspector documents the rejection in the

corrective action process, and sends an e-mail to the supplier documenting the basis for rejection that same day. The licensee does not perform a Part 21 evaluation. The supplier acknowledges receipt of the e-mail on April 2nd, and enters the issue into their corrective action process. The supplier performed an assessment to determine whether the basic component was delivered to another purchaser. On April 3rd the supplier determines that the basic component was delivered to one other purchaser with the same deviation, and determines that the point of discovery begins as of April 3rd, when they first identified the deviation of a delivered basic component and the supplier begins the 60-day evaluation process associated with 10 CFR Part 21.

Discussion:

The licensee never had a responsibility under 10 CFR Part 21. Because the item was rejected during the receipt inspection, the licensee never accepted the item and its control and ownership was never transferred to the licensee. The supplier was compliant with Part 21 by beginning the evaluation process once they determined there was a deviation in a delivered basic component to another purchaser.

8 EVALUATION PROCESS

The purpose of the evaluation is to perform a review of deviations and failures to comply to determine whether they are reportable to the NRC pursuant to 10 CFR 21.21. Deviations and failures to comply that are potentially associated with a substantial safety hazard must be evaluated to determine whether they could create a substantial safety hazard if they were to remain uncorrected. The Point of Discovery (see Section 7) marks the initiation of the evaluation process. The evaluation process is subject to the 60 day time period, and will determine whether a notification is required, as discussed in Section 9. If the evaluation concludes that the issue could create a substantial safety hazard, the issue must be reported to the NRC.

8.1 EVALUATION RESPONSIBILITIES

Suppliers that discover a deviation or failure to comply are responsible for performing the evaluation, or if the supplier does not have the capability to perform the evaluation responsibility, the supplier is responsible for informing the purchaser(s) that the evaluation is being transferred to the purchaser. Purchasers that discover a deviation or failure to comply, or are informed by a supplier that the evaluation responsibility has been transferred to the purchaser are responsible for performing the evaluation. If a purchaser is also a supplier and does not have the capability to perform the evaluation, then the purchaser, as a supplier, is responsible for informing their purchaser that the evaluation responsibility is being transferred. This may continue until the responsibility is transferred to the final end user (i.e., licensee) for evaluation.

The entity responsible for performing the Part 21 evaluation should communicate with other parties (e.g., suppliers and purchasers) as necessary to obtain the information needed to complete the evaluation. These communications could help improve the efficiency of the evaluation, as demonstrated in the following examples. Suppliers may not fully understand the use by purchasers of the basic component supplied, and therefore may need additional information from the purchaser in order to determine the safety significance of the deviation or failure to comply in order to determine whether it could create a substantial safety hazard. Purchasers may not fully understand the detailed designs and analyses performed by the supplier, and these details could have a significant effect on the determination of whether the basic component would still be able to perform its safety function and whether the deviation or failure to comply could create a substantial safety hazard.

Within the entity responsible for performing the evaluation, the evaluation is typically performed by one or more persons to ensure that the evaluation is performed with a complete understanding of the pertinent regulatory requirements and technical basis of the associated structures, systems and components related to the deviation or failure to comply. Personnel from the Engineering Department, or other departments, that are familiar with the relevant safety analyses are typically involved in the evaluation. The evaluation process typically includes or is monitored by personnel from the Quality Assurance Department or from another department with responsibilities for regulatory compliance.

Some entities may be able to identify a set of general deviations associated with the items and/or services they supply or procure. In these instances, an entity may rely upon a previously performed general evaluation that can be used in the evaluation of an actual deviation or failure to comply that occurs later. In order to evaluate actual deviations and failures to comply by using a general evaluation performed in advance, the entity should do the following:

- Perform a detailed evaluation for each of the general deviations or failures to comply. Document the impact on the item or service and whether a substantial safety hazard could be created by the deviation.
- Evaluate a specific deviation or failure to comply for a specific item by simply determining whether the deviation is consistent with one of the general deviations that were already evaluated in detail. Perform a more detailed evaluation for those deviations that are not addressed by the evaluations already performed.

The results of the evaluation must be documented and should be reviewed separately by another individual with sufficient knowledge to ensure that the conclusions are sound and sufficiently substantiated by the objective evidence. However, the level of effort needed to conduct and document a given evaluation may vary significantly based on the complexity of the issue and the difficulties encountered in obtaining the information needed to complete the evaluation. In some instances, for example when there is obvious need to report the defect or failure to comply, the

results of a screening process, as described in Section 7, can satisfy the requirement for an evaluation.

8.2 Communication Between Suppliers and Purchasers During the Evaluation and Notification Process

10 CFR Part 21 does not contain requirements for the communication of deviations and failures to comply between the purchaser and supplier. However, communications between the supplier and purchaser is a good practice and maintaining these open communications is encouraged.

Once a deviation or failure to comply of a basic component is identified, the entity that identified this condition is encouraged to communicate the finding to others in their supply chain for the affected basic component. If the discovering entity is the supplier, then an affected entity would be the purchasers to whom the basic components have been delivered; or if the discovering entity is the purchaser, then the affected entity would be the supplier. The benefit of notification of affected entities is to establish communications and information sharing that may be helpful to perform the evaluation and determination of whether a report to the NRC is necessary.

If the purchasers or affected licensees discover a deviation or failure to comply of a basic component that has been delivered for use from a supplier, the purchasers or affected licensees are encouraged to notify the supplier of the discovery of the deviation or failure to comply. Notification to the supplier in writing is preferred. The notification to the supplier would allow them to perform an assessment to determine if the supplier delivered basic components with the same deviation to other customers. The supplier is also encouraged to assist the purchasers or affected licensees in their evaluation of the identified deviation or failure to comply.

The entity that discovered the deviation or failure to comply has the responsibility to complete the evaluation within 60 days from discovery or submit an interim report if the evaluation cannot be completed within 60 days. The discovering entity also has the responsibility to make a Part 21 notification to the NRC. However, any other entity may also make the Part 21 notification, even if they do not have the responsibility under Part21.

Example #1:

A sub-supplier delivered a basic component to the first tier Supplier to a Part 50 nuclear power plant licensee (Purchaser). After the Supplier delivered the basic component to the licensee, the Supplier identified that the sub-supplier deviated from the technical requirements in the Supplier's procurement documents. The point of discovery was appropriately established and the evaluation was promptly initiated by the Supplier.

The Supplier notified the Purchaser that the basic component supplied to them contains a deviation, but did not provide details on the nature of the deviation. Although there has been some communication between the purchaser and supplier, including the purchaser providing

some details about the use of the basic component in question, the Supplier has not requested the Purchaser to perform an evaluation per Part 21.21(b).

Due to the complexity of the issue, the evaluation could not be completed within 60 days, and the Supplier appropriately issued a 60 day Interim Report to the NRC, the Purchaser, and any other Purchasers potentially affected by the deviation under evaluation. The Purchaser has concluded that even though the Supplier has issued a 60 day interim report, the purchaser does not have any responsibility to perform an evaluation or make a notification to the NRC.

Discussion:

The Purchaser is correct in determining it does not have a responsibility to independently evaluate the deviation or failure to comply or make a notification to the NRC. The responsibility to evaluate and notify rests entirely with the entity that discovers the deviation or failure to comply. Part 21.21(b) describes the process for a Supplier that discovered the deviation to transfer responsibility to evaluate and notify to the Purchaser. However, the supplier has not transferred responsibility up the supply chain to the purchaser, and thus the Supplier still owns the responsibility to evaluate and notify.

The Supplier's notification to the Purchaser that they have been supplied a basic component with a deviation, and the collection of information on how the Purchaser uses the basic component followed good practices for communications in order to help facilitate the Supplier's evaluation. It would have also been a good practice for the Supplier to share the details of the deviation with the Purchaser.

8.2.1 Transfer of Parts by Purchasers – Original Seller and New Seller's Responsibilities

There may be instances when a purchaser of a basic component may in turn sell that basic component to another utility or transfer it between plants that it owns. When a licensee sells a "Basic Component" to another utility (whether for $0.00 or for an established value) the utility acts as a 10 CFR 50, Appendix B supplier and as such carries the responsibility of "Reporting Defects and Noncompliances" per the requirements of 10 CFR Part 21, whether or not the purchase documents indicate those requirements. The sale of that "Basic Component" to another utility does not relieve the original Seller of the "Basic Component" of its responsibilities to "Report Defects or Noncompliances" for the original delivery of the "Basic Component".

For example, a nuclear power plant may purchase or transfer a basic component from a sister plant (a plant of the same design by the same supplier). In these cases, purchasers may only purchase "Basic Components" from qualified 10 CFR 50 Appendix B suppliers, utilizing purchase documents, referencing the requirements of 10CFR Part 21. Once a Purchaser obtains a "Basic Component" it must maintain traceability of that "Basic Component". In order to

provide a "Basic Component" to a sister plant within a utility, the utility would retain documentation indicating the disposition (e.g., sale, transfer) of that "Basic Component" within the utility so that any notification by the original Seller who identifies a Part 21 concern can be forwarded to the "Purchaser" for appropriate action (Reportability – 10 CFR 21.21(d), Transfer of Information -10CFR21.21(b) or 60-Day Interim Notification – 10CFR21.21(a)(2)).

A utility may sell a "Basic Component" to another utility as a "Non-Basic Component" or as "Commercial Grade". That will relieve the initial purchaser from all 10 CFR Part 21 responsibilities, other than to address any "Reporting of Defects and Noncompliances" from the original seller. If the subsequent purchaser chooses to use the item as a "Basic Component" it would then be required to dedicate that component and assume the 10 CFR Part 21 responsibilities.

Examples:

If a utility has three licensed operating nuclear plants (plants A, B and C) and a Supplier provides a "Basic Component" to that utility for plant A, the Supplier is responsible to notify the utility at plant A if it identifies an issue subject to 10CFR Part 21. The utility at plant A is required to evaluate the communication sent by the Supplier and take appropriate actions.

If a utility has three licensed operating nuclear plants (plants A, B and C) and a Supplier provides a "Basic Component" to that utility for plant A, but the utility transfers the "Basic Component" to plant B, the Supplier is responsible to notify the utility at plant A if it identifies an issue subject to 10CFR Part 21. The utility at plant A is required to communicate the Supplier's communication to plant B so that plant B can evaluate the communication sent by the Supplier and take appropriate actions.

If a utility has three licensed operating nuclear plants (plants A, B and C) and a Supplier provides a "Basic Component" to that utility for plant A, but the utility sells the "Basic Component" to another utility as a "Basic Component" pursuant to 10 CFR 50, Appendix B, the Supplier is responsible to notify the utility at plant A if it identifies an issue subject to 10CFR Part 21. The utility at plant A is required to communicate the Supplier's communication to the utility/plant that procured the "Basic Component", so that the purchaser of that "Basic Component" can evaluate the communication sent by the Supplier and take appropriate actions.

If a utility has three licensed operating nuclear plants (plants A, B and C) and a Supplier provides a "Basic Component" to that utility for plant A, but the utility sells the "Basic Component" to another utility as a "Commercial Grade" component, the Supplier is responsible to notify the utility at plant A if it identifies an issue subject to 10CFR Part 21. The utility at plant A is not required to communicate the Suppliers communication to the

utility/plant that procured the former "Basic Component" because it was sold as a "Commercial Grade" component.

8.2.2 Notification Responsibility when Purchaser's Regulatory Status has Changed

At some time in the future, a licensee to construct and/or operate a nuclear power plant under 10 CFR Part 50 or Part 52 may decide to decommission the nuclear power plant. This change in regulatory status does not negate the Supplier's responsibility to evaluate deviations and failures to comply of basic components provided to the Purchaser, or to notify the Purchaser if they determine the deviation or failure to comply could create a substantial safety hazard.

8.3 TRANSFER OF EVALUATION AND REPORTING RESPONSIBILITIES

Each entity with 10 CFR Part 21 responsibilities that discovers a deviation or failure to comply that is potentially associated with a substantial safety hazard must evaluate the deviation or failure to comply to determine if it could create a substantial safety hazard, were it to remain uncorrected.

For a supplier, the evaluation can result in one of the following possible four (4) outcomes:

- The Supplier does not have sufficient knowledge to be able to determine if a Reportable Condition exists or not. In this case, the Supplier must inform the purchasers or affected licensees within five working days of that determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply per 10 CFR Part 21.21(b).

- The supplier has the knowledge to complete the evaluation within 60 days and concludes that the departure or failure to comply could NOT potentially result in a substantial safety hazard. In this case no reportable condition exists and no Part 21 related communications are required.

- The supplier has the knowledge to complete the evaluation, and within 60 days concludes that the departure or failure to comply could result in a substantial safety hazard if it remained uncorrected. In this case, notification to the NRC and all affected purchasers is required under Part 21.21(d).

- The supplier has the knowledge to complete the evaluation, but the issue is too complicated or requires actions that would not result in a resolution of the evaluation within 60 days from the "Date of Discovery". In this case, the submission of an interim report to the NRC and all potentially affected purchasers is required under Part 21.21(a)(2).

10 CFR 21.21(b) allows the transfer of responsibility for evaluation and reporting to the purchaser. This may continue up the supply chain all the way to the licensee. This transfer of

evaluation up the supply chain should only be exercised when the supplier does not have the capability or sufficient knowledge to determine if the defect or failure to comply could result in a substantial safety hazard were it to remain uncorrected. These conditions may exist for a supplier of basic Components for a number of reasons. If the supplier determines that it does not have the capability to perform an evaluation and determines whether there is a reportable defect or failure to comply per 10 CFR 21.21(a) then the supplier must notify, within five (5) working days of that determination, all potentially affected purchasers of this determination, that the responsibility for performing the evaluation and reporting is being transferred to them, pursuant to 10 CFR 21.21.

The notification should be provided in writing within five working days of the determination that the supplier cannot perform the evaluation. The notification should be addressed to the contact specified in the purchasing documents or as provided by the purchaser. This transference document should clearly state that the intention of the notification is to meet the requirements of 10 CFR 21.21(b) and that it is provided so that the recipient is notified that they are responsible for the completion of the evaluation to determine reportability pursuant to 10 CFR Part 21.

The supplier of the basic component that contains a deviation or failure to comply, but does not have the capability to perform the evaluation, should make this determination promptly and in no instance should take more than the full 60 days from the Date of Discovery. The supplier is expected to provide continued technical support (to the extent possible) to assist the purchaser in performing the evaluation through reaching a reportability determination with regard to whether the defect or failure to comply could result in a substantial safety hazard.

Additionally, supplier information necessary to perform the evaluation and any available information that would support a written report required by 10 CFR 21.21(d)(4)(i)–(ix) should be included in the text of the 10 CFR 21.21(b) notice to transfer the evaluation responsibility to the purchaser.

Examples of reasons where the supplier may not have the ability to perform a Part 21 evaluation include:

- The Supplier may be filling a purchaser's "min-max" inventory request where the purchaser has not designated the end use of the basic component and therefore, the supplier, in kind cannot make a determination of reportability.

- The Supplier may be filling a purchasers request for a basic component for a system that is new and the supplier has no information as to the effect that the deviation from technical requirements will make to the safe operation of that new system.

- The Supplier may be filling a purchase request for a basic component where the purchaser does not provide the application for which the purchaser plans to utilize the basic component.

8.4 EVALUATION METHODOLOGY

Evaluations are performed to determine whether a deviation or failure to comply could create a substantial safety hazard, if it were to remain uncorrected. Not all deviations or failures to comply need a detailed evaluation to determine whether they could create a substantial safety hazard. In order to avoid performing unnecessary detailed evaluations of deviations and failures to comply, when it can be quickly determined that they clearly cannot create a substantial safety hazard, the evaluation process begins with an initial filtering of issues.

In the initial filtering of the evaluation process, it is determined whether the deviation or failure to comply affects the ability of the facility, activity or basic component from performing a safety function. This initial filtering is at a low level of significance, as compared to substantial safety hazard, and can quickly identify those deviations and failures to comply that clearly could not result in a substantial safety hazard. If a deviation or failure to comply does not meet the initial filtering criteria, then it is not reportable under 10 CFR Part 21 and a more detailed evaluation is not necessary. If the deviation or failure to comply does meet the criteria, then a more detailed evaluation is necessary.

The evaluation is primarily focused on whether the condition "could create a substantial safety hazard, if it were to remain uncorrected". The evaluation needs to consider all potential sequences, events, and configurations relevant to the deviation or failure to comply, and determine whether a substantial safety hazard could result, if the deviation or failure to comply goes uncorrected.

The evaluation should consider normal conditions and associated transients. In evaluating deviations and failures to comply the assumption which must be made is that the component is installed in the facility, and that delivered items are used for their intended application. The evaluation should not credit QA/QC measures as a means of mitigating a substantial safety hazard (e.g., conclude that a substantial safety hazard could not be created, because the licensee's test performed during installation would have identified the issue). A key component of the evaluation is "if it were to remain uncorrected", therefore, quality assurance inspections or tests performed by the licensee cannot be counted upon to prevent installation of defective basic components.

The evaluation must consider the possibility that the issue associated with a given item could impact or be present on other items in process or previously supplied (i.e., consider the extent of the condition). To address this concern, the evaluation should:

- Identify the other items that have the condition, so the specific applications involved are known and considered in the evaluation, or
- Conservatively evaluate the impact of the issue on the worst-case application with which it could be associated.

If a basic component with a deviation or failure to comply has a redundant component, the evaluation must still consider the failure of the redundant component. The existence of a defective basic component, considering a single failure of its counterpart redundant basic component, could result in a substantial safety hazard. It is possible that the defect might also exist in the redundant basic component which could result in a loss of safety function. Actually, the counterpart component need not fail, and the evaluation must consider other conditions where the redundant component would be unavailable to perform the safety function. For example, it could be removed from service for other reasons such as routine preventive maintenance or inspection.

Facility technical specifications may allow continued operation for short periods of time with a redundant component inoperable. Operation in such a mode is not considered to be a substantial safety hazard as defined in 10 CFR Part 21. However; it is possible that the failure could identify a deviation, i.e., a departure from the technical requirements of the procurement document under which the component was purchased. If the deviation is for a basic component that has been delivered, then it would need to be evaluated pursuant to 10 CF Part 21.

There could be instances where a basic component has been delivered and contains a deviation that could have affected the safety function of the basic component, yet there is still not a potential for a substantial safety hazard. An example is the discovery of a deviation in a reactor core analysis after the reactor core has completed its cycle, the fuel has been discharged from the reactor and a new reactor core has begun operation. As core design analyses are unique to the individual reactor and specific cycle, the deviation would not exist for other cycles or other purchasers. In this case, the safety function was fulfilled and it is not possible for the reactor core with the deviation to ever be put back into service. Thus the deviation could never create a substantial safety hazard and an in-depth evaluation to of the deviation is not necessary. In cases where it can be documented that there is no potential for a substantial safety hazard, reporting is not required.

8.5 Substantial Safety Hazard

Depending on the complexity of the issue, analyses and calculations may need to be performed to evaluate the safety significance. In some cases, judgment may also be needed to determine whether an issue constitutes a *substantial safety hazard*. Generally speaking, a substantial safety hazard is a major reduction in the degree of protection provided to public health and safety. The three categories of substantial safety hazards are Moderate Exposure, Major Degradation, and Major Deficiency.

Moderate exposure – "Moderate exposure" is considered exposure in excess of 25 rem whole body and exposure to an individual in an unrestricted area of 0.5 rem. Moderate exposure to, or release of, licensed (i.e., radioactive) material, reportable under the provisions of 10 CFR 20.2202(a) or the exposure of any 'individual in an unrestricted area to a dose to the whole body in any period of one calendar year in excess of 0.5 rem (10 CFR 20.1301(c)) would constitute "substantial safety hazards."

Major degradation – "Major degradation" is considered to be a loss of redundancy in essential safety related equipment if, in conjunction with a single failure, a required safety function could not be performed. Therefore, a deviation or failure to comply that causes or could cause a redundant basic component to fail, such that it could not perform its safety function, is a substantial safety hazard. The loss of safety function of a basic component is considered a major reduction in the degree of protection provided to the public health and safety. Exceeding a safety limit as defined in the facility technical specification is considered a major degradation.

Major deficiency – "Major deficiency" means a condition or circumstance involving the design, construction, inspection, test or use of licensed material or safety related equipment, which under normal operating conditions or anticipated transient 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. A deviation or failure to comply which seriously compromised the ability of a confinement system to perform its designated function is considered a major deficiency.

An analysis error, modeling error, or data input error could be reportable under Part 21 where such an error is detected after delivery of the analysis data to the purchaser. In these instances, an evaluation would have to be performed to determine the significance of the error --- that is, the reduction in degree of protection provided to public health and safety. For example, an ECCS related error which results in a calculated change of peak clad temperature of less than specified value that is 20 degrees F is not considered to be a substantial safety hazard. Regarding a change in a basic criterion, if a criterion used for the design of a basic component is changed such as to potentially result in a major reduction in the degree of protection provided for the public health and safety, then such a change would be reportable if the design data has been delivered for use in final design, the FSAR, or in procurement documents.

Clarification for Nuclear Power Plants under Part 50 and Part 52

Not all of the present Prompt Reportable Occurrences defined by operating plant technical specifications or environmental specifications are considered "substantial safety hazards." For example, some prompt reportable occurrences result from a failure-to meet action statements which are required by Technical Specification limiting conditions for operation and would not be reportable under Part 21.

In the case of a power reactor, an act of sabotage or terrorism could result in potential offsite exposures comparable to those which could occur as a result of an accident. An example of a defect or noncompliance in a security system is one which could allow access of an unauthorized individual to a vital area without being detected by the security system. Detection of the unauthorized individual by random visual surveillance or by remote visual electronic surveillance is not considered to be a detection by the security system. This represents a major reduction in the degree of protection to public health and safety and is, therefore, a substantial safety hazard and would require notification to the NRC.

The term *public* in the definition of substantial safety hazard includes all individuals, both employees at a facility or activity licensed or otherwise regulated by the Commission and members of the general public. Of course, the degree of protection afforded and the criteria for determining whether a substantial safety hazard could be created will vary for different types of individuals (e.g., radiation workers as opposed to members of the general public) depending on whether the event is a low probability major accident or a more probable occurrence, and whether the potential release is to a restricted or an unrestricted area.

8.6 Example of the Evaluation Process

One scenario for a safety-related defect reported by a basic component supplier for a power reactor facility may start with the discovery that a basic component already furnished by that supplier deviates from the procurement document specifications. The supplier would evaluate the deviation or would report the deviation to the purchaser to allow the purchaser to determine if it is potentially associated with a substantial safety hazard. In most instances the supplier's evaluation would require discussion with the purchaser. If, based upon this evaluation, it is concluded that the deviation could create a substantial safety hazard then the deviation would be reported as a defect to the NRC.

The general criteria used by the supplier in evaluating ta substantial safety hazard include: moderator exposure to, or release of, licensed material; major degradation of essential safety related equipment; and major deficiencies in design, construction, inspection, test or operation. For a power reactor, Regulatory Guide 1.29, identifies the essential safety related equipment which must remain functional during the Safe Shutdown Earthquake. These safety related equipment are necessary to ensure 1) the integrity of the reactor coolant pressure boundary, 2) the capability to shut down the reactor and maintain it in a safe shutdown conditions and 3) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposure comparable to the guideline exposure of 10 CFR Part 100. These essential safety related equipment are defined as basic components. Major degradation of such basic components or a condition or circumstance involving a basic component that could contribute to exceeding a safety limit is considered a substantial safety hazard. In the case of a redundant basic component, a condition, circumstance or deviation which could cause a failure of that component must be evaluated to determine if there may be a loss of safety function for the

affected basic component or a major reduction in the degree of protection provided to the public health and safety. Therefore, a defect in a basic component, even though a redundant component exists could be reportable under Part 21.

9 NOTIFYING THE NRC

A director or responsible officer, or a designee, is required to notify the NRC of failures to comply and defects that could create a substantial safety hazard, if it were to remain uncorrected. A determination of whether this exists is made by an evaluation, as described in Section 8, and the evaluation is subject to a 60 day time period from the Point of Discovery (see Section 7).

Typically, the director and responsible officers are not the persons performing the evaluation of the deviation or failure to comply. It is expected that the personnel notify the director or responsible officer when a deviation or failure to comply is discovered and keep them informed of the progress of the evaluation.

Notifications to the NRC, if required, should be completed as soon as practicable and in all cases within 60 calendar days from the Point of Discovery. If the evaluation cannot be completed within 60 days, an interim report must be submitted to the NRC within 60 days from the Point of Discovery. If the evaluation determines that the deviation or failure to comply could not create a substantial safety hazard within 60 days, then no notification is necessary.

When personnel in the organization reporting to a director or responsible officer perform an evaluation and determine that the failure to comply or defect could create a substantial safety hazard, the personnel must notify the director or responsible officer as soon as practicable, and in all cases within five (5) working days of the date of the completion of the evaluation. If personnel cannot complete the evaluation within 60 days, they should notify the director or responsible officer sufficiently in advance so that the director or responsible officer can submit an interim report to the NRC.

Notification to the NRC is not required if the director or responsible officer has actual knowledge that that the NRC has been notified in writing of the defect or failure to comply.

9.1 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 must be submitted in writing within 60 days from the Point of Discovery or the deviation or failure to comply.

9.2 NOTIFICATION

The director or responsible officer must provide an initial notification to the NRC within two (2) calendar days of being informed of the failure to comply or defect that could create a substantial

safety hazard. The director or responsible officer must also provide a written notification to the NRC within 30 calendar days of being informed of the failure to comply or defect that could create a substantial safety hazard. The initial and written notifications should be made as follows:

Initial Notification – The initial notification to the NRC Operations Center can be by facsimile at (301) 816-5151 or by telephone (301) 816-5100. The preferred method is by facsimile, and the director or responsible officer should call the NRC Operations Center to verify receipt of the facsimile. The initial notification should state that a 10 CFR Part 21 reportable item or condition was discovered.

Written Notification – A written notification must be addressed to the NRC's Document Control Desk and mailed to the: U.S. Nuclear Regulatory Commission, Washington, DC 20555-001, or hand delivered at 11555 Rockville Pike, Rockville, MD. Electronic submissions are also permissible provided it is in a manner that enables the NRC to receive, read, authenticate, distribute, and archive, and process and retrieve it a single page at a time. The written notification must provide the following information:

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 these components in use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in 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.
ix. In the case of an early site permit, the entities to whom an early site permit was transferred.

If the information in the initial notification to the NRC is provided in writing and contains all of the information required for a written notification, then that notification satisfies the requirement for both the initial notification and the written notification.

9.3 Actual Knowledge that the NRC Has Been Adequately Informed

In 10 CFR 21.1, Purpose, the NRC requires the reporting of defects and failures to comply that could result in a substantial safety hazard (i.e. a Reportable Condition). However, this 10 CFR 21.1 further clarifies that if "…he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply," then there is no need to continuously report the same issue from various sources and for various reasons.

The regulation goes on to state, in 10 CFR 21.21(d)(2), Notifications, that the "Director or Responsible Officer" need not provide a notification to the NRC "if the director or responsible officer has actual knowledge that the Commission has been notified in writing of the defect or the failure to comply." This addition of "notification in writing" provides an additional level of detail with regard to what must be in place to allow a licensee to not report a condition determined to be reportable. This is clear if the report previously supplied is a 10 CFR Part 21 Reportable Condition.

Licensees may also submit reports of issues under other Parts of the regulations in 10 CFR (Examples: 10 CFR Parts 30, 40, 52, 60, 61, 63, 70, 71, 72), although typically for reasons different than reporting defects or failures to comply. However, a separate notification under Part 21 is not necessary if equivalent reporting through other mechanisms has already been performed. Reports to the NRC for other purposes are considered to meet the reporting requirements of 10 CFR Part 21, if those reports clearly identify that the issue is being reported under 10 CFR Part 21, and the report includes the information required in the nine (9) areas in 10 CFR 21.21(d)(4), and are submitted in writing. See Section 5.2 for reporting under 10 CFR 50.72, 50.73, Section 5.3 for reporting under 50.55(e), and Section 5.3 for reporting under 73.71.

10 REFERENCES

1. 10 CFR Part 21, Reporting of Defects and Noncompliance
2. 40 Fed. Reg. 8832, 1975, Proposed 10 CFR Part 21 Rule
3. 42 Fed. Reg. 28893, 1977, Final 10 CFR Part 21 Rule
4. 43 Fed. Reg. 48622, 1978, Final 10 CFR Part 21 revision
5. 53 Fed. Reg.44594, 1988, Proposed 10 CFR Part 21 revision
6. 56 Fed. Reg.36081, 1991, Final 10 CFR Part 21 revision

7. EPRI NP-5652 “Guideline for the Utilization of Commercial Grade Items in Nuclear Grade Safety Applications” (NCIG-07), 1988

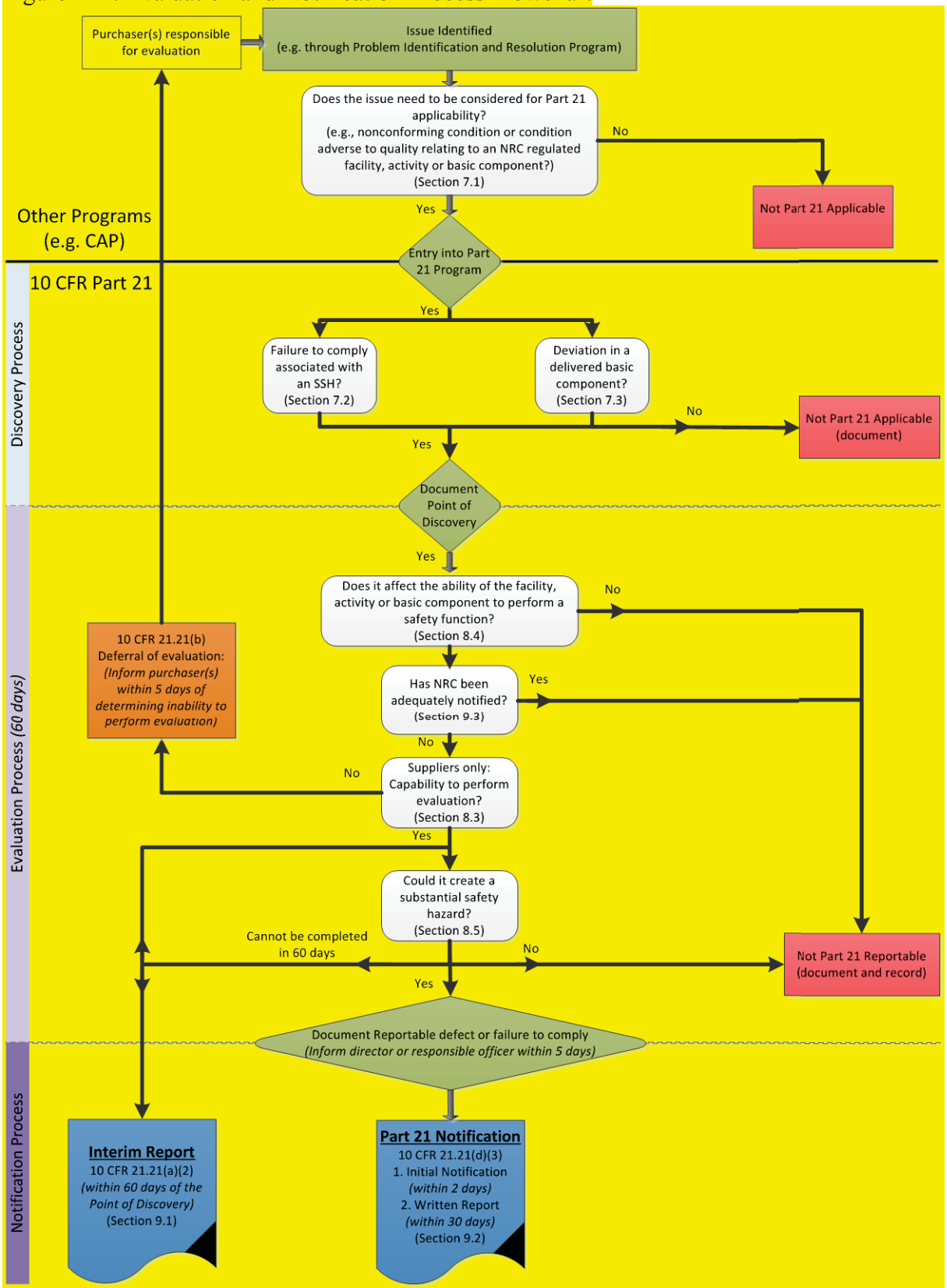
8. NUREG-0302, Revision 1 “Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Non-Compliance”, July 12-26 1977

9. RIS 2010-05, “Applicability of 10 CFR Part 21 Requirements to Applicants for Standard Design Certifications Applicability of 10 CFR Part 21 Requirements to Applicants for Standard Design Certifications,” May 24, 2010

APPENDIX A – EVALUATION AND NOTIFICATION FLOWCHART

The discovery, evaluation and notification process is described in Sections 7, 8 and 9. This flowchart is provided as graphical representation of the process. It contains the important steps and decision points of the discovery process, the evaluation process, and the notification process. It does not contain all of the details needed to consider an issue. It does, however, provide references to relevant sections of this guidance and sections of 10 CFR Part 21 where the details can be found. The flowchart is designed to be used by either a supplier or purchaser; however, the use of the flowchart and resulting decisions and steps may vary between suppliers and purchasers depending on the conditions surrounding the issue.

Figure A-1: Evaluation and Notification Process Flowchart



APPENDIX B – EVALUATION AND NOTIFICATION CHECKLIST TEMPLATE

The form below represents an example checklist that is formatted to assist a purchaser or supplier in implementing the evaluation and notification process. A supplier or purchaser may modify the questions in this form as necessary to make it more appropriate for their use.

10 CFR Part 21 Discovery and Evaluation Checklist	Page __ of __
10 CFR Part 21 Checklist No.: Part21-	MCR, CDN, CN No.:

Part 21 Discovery Section

(The performance of discovery process should be timely and completed without undue delay.)

If the issue involves an only item, proceed to Question A.

If issue involves a service, proceed to Question B.

A. For issues involving only an item, did the item fail in-service in conditions <u>other than</u> the following: • The in-service failure is identified as a normal end of life issue. • The in-service failure is identified as a calibration or instrument tolerance issue. • The in-service failure is due to normal expected usage of a component such as installation, rework, repair, post-maintenance testing, etc. • The in-service failure is environmentally induced where abnormal operational parameters exceed technical requirements (for example, dirt in the system, exceeding temperature, pressure, hydraulic stresses, structural stresses, voltage, amperage, electrical load, etc.). The in-service failure is identified by normal operational checks, tests, inspections, or due to trouble alarms, provided the failure is **not** a departure from an item's technical requirements identified in a procurement document (as determined by question C).	☐ Yes ☐ No

If the answer to Question A is **"No,"** the condition is **NOT REPORTABLE** by the Company under 10 CFR 21. Check the "No" box in Question A and document the basis for the determination in Section I.

If the answer to Question A is **"Yes,"** the issue is <u>potentially subject</u> to 10 CFR 21. Check the "Yes" box in

10 CFR Part 21 Discovery and Evaluation Checklist	Page __ of __
10 CFR Part 21 Checklist No.: Part21-	MCR, CDN, CN No.:

Question A and proceed to Question B.

B. Does the issue involve a failure to comply that is potentially associated with a substantial safety hazard? Failure to comply means the manufacture, construction or operation of a licensed facility or activity, a basic component supplied for such facility or activity, or a design certification or design approval under 10 CFR Part 52; which is not in compliance with the Atomic Energy Act of 1954, as amended, any applicable rule, regulation of 10 CFR, order or license issued by the Commission, or a standard design approval under 10 CFR under 10 CFR Part 52. A failure to comply is considered to be potentially associated with a substantial safety hazard if the failure to comply affects the performance of a safety function.	☐ Yes ☐ No

If the answer to Question B is **"No,"** proceed to Question C.

If the answer to Question B is **"Yes"**, the issue is a failure to comply that may be reportable under 10 CFR Part 21, and requires an evaluation, check the "Yes" box in Question C and document the basis for all "Yes" answers in Questions A and B in Section E.

C. Does the issue involve a deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in 10 CFR Part 21?	☐ Yes ☐ No

If the answer to Question C is **"No,"** 10 CFR Part 21 does not apply. No further screening is necessary and an evaluation is not required. Check the "No" box in Question G and document the basis for all "NO" answers in Questions B and C in Section D.

If the answer to Question C is **"Yes,"** the issue is a deviation that may be reportable under 10 CFR Part 21, and requires an evaluation, check the "Yes" box in Question C and document the basis for all "Yes" answers in Questions A and C in Section E.

Section D: Evaluation is NOT REQUIRED: Document basis for determining the issue is not a deviation or failure to comply potentially associated with a substantial safety hazard. Attach this form and any supporting documentation to the CDN, MCR, or CN *(No further action is required once the basis has been documented.)*

10 CFR Part 21 Discovery and Evaluation Checklist Page __ of __	
10 CFR Part 21 Checklist No.: Part21-	MCR, CDN, CN No.:

Section E: Evaluation is REQUIRED: Document basis for determining the issue is a deviation or failure to comply potentially associated with a substantial safety hazard, and record the date this documentation was completed. Attach this form and any supporting documentation to the CDN, MCR, or CN *(This is the point of discovery, and an evaluation is required. Proceed to Question F.)*

Date of Point of Discovery: _MM/DD/YYYY__

Part 21 Evaluation Section

(If during the course of performing the evaluation, it is determined it cannot be completed within 60 days of the Point of Discovery, as documented in Section J, proceed to Section S and complete an interim report.)

F. Is the deviation or failure to comply credibly potentially related to a substantial safety hazard? I.e., could it affect a safety function(s)?	☐ Yes ☐ No

If the answer to Question F is **"No,"** 10 CFR Part 21 does not apply. No further evaluation is necessary. Check the "No" box in Question F and document the basis in Section K.

If the answer to Question F is **"Yes,"** the deviation or failure to comply requires a more detailed evaluation to determine if it is reportable under 10 CFR Part 21. Proceed to Question G.

G. Does the director or responsible officer have actual knowledge that the NRC has been adequately informed of the defect or failure to comply.	☐ Yes ☐ No

If the answer to Question G is **"Yes,"** evaluation and notification are not required. Check the "Yes" box in Question G and document the basis in Section K.

If the answer to Question G is **"No,"** the deviation or failure to comply must be evaluated under 10 CFR 21. For suppliers, proceed to Question H. For purchasers, proceed to Question I.

10 CFR Part 21 Discovery and Evaluation Checklist Page __ of __	
10 CFR Part 21 Checklist No.: Part21-	MCR, CDN, CN No.:

H. (For suppliers only) Does the entity have the capability to perform an evaluation of the deviation or failure to comply potentially associated with a substantial safety hazard?	☐ Yes ☐ No

If the answer to Question H is **"No,"** the evaluation of the deviation or failure to comply potentially associated with a substantial safety hazard must be transferred to the purchaser(s). Check the "No" box in Question H, notify the purchaser(s) within five (5) days that the evaluation is being transferred and they now are responsible for performing the evaluation in accordance with 10 CFR 21.21(b), and document this in Section J.

If the answer to Question H is **"Yes,"** the evaluation of the deviation or failure to comply potentially associated with a substantial safety hazard must be performed by the Company under 10 CFR 21. Proceed to Question I.

I. Could the deviation or failure to comply create a substantial safety hazard, if it were to remain uncorrected?	☐ Yes ☐ No

If the answer to Question I is **"No,"** the deviation or failure to reply cannot create a substantial safety hazard, if it were to remain uncorrected, and is NOT Reportable to the NRC. Check the "No" box in Question I and document the basis for the "No" response in Section K.

If the answer to Question I is **"Yes,"** the defect or failure to comply could create a substantial safety hazard, if it were to remain uncorrected, and **IS REPORTABLE** by the Company under 10 CFR 21. Check the "Yes" box in Question I and proceed to Section L.

Section J: (For suppliers only) Transfer of evaluation. Document the basis for transferring the evaluation and the notification of purchasers, including date. *(No further action is required once the basis has been documented.)*

Date Purchaser(s) notified: _MM/DD/YYYY__

Section K: Notification is NOT REQUIRED: Document basis for determining the issue is not reportable. I.e., the deviation or failure to comply could not create a substantial safety hazard, if it were to remain uncorrected, or the defect or failure to comply has been previously reported to the NRC. Attach this form and any supporting documentation to the CDN, MCR, or CN *(No further action is required once the basis has been documented.)*

10 CFR Part 21 Discovery and Evaluation Checklist	Page __ of __
10 CFR Part 21 Checklist No.: Part21-	MCR, CDN, CN No.:

Section L: Notification is REQUIRED: Document basis for determining the issue is a reportable defect or failure to comply (i.e., it could create a substantial safety hazard, if it were to remain uncorrected), and record the date this documentation was completed. Notify the director or responsible office of this determination within five (5) days of the completion of the evaluation and document the date they were notified. Attach this form and any supporting documentation to the CDN, MCR, or CN *(Proceed to Section M to document the notification and reporting to the NRC.)*

Date Evaluation was Completed: _MM/DD/YYYY__

Date the Director or Responsible Offices was Notified: _MM/DD/YYYY__

Section M: Documentation of notification and reporting to the NRC.

Interim Report

If during the course of performing the evaluation, it is determined it cannot be completed within 60 days of the Point of Discovery, as documented in Section J, an interim report must be submitted to the NRC within 60 days of the Point of Discovery.

Date Interim Report was submitted to the NRC: _MM/DD/YYYY__

Interim Report included all required information: ☐ Yes ☐ No

Document confirmation the NRC receive the Interim Report:

Initial Notification

If Notification is required (Section R), then the director or responsible officer, or their designee, must provide the NRC initial notification within two (2) days of the director or responsible officer being notified.

Date Initial Notification was provided to the NRC: _MM/DD/YYYY__

10 CFR Part 21 Discovery and Evaluation Checklist	Page __ of __
10 CFR Part 21 Checklist No.: Part21-	MCR, CDN, CN No.:

Document method to provide Initial Notification and confirmation the NRC receive it:

Written Report

If Notification is required (Section R), then the director or responsible officer, or their designee, must submit a written report to the NRC within 30 days of the director or responsible officer being notified.

Date Written Report was submitted to the NRC: _MM/DD/YYYY__

Written Report included all required information: ☐ Yes ☐ No

Document confirmation the NRC receive the Written Report: