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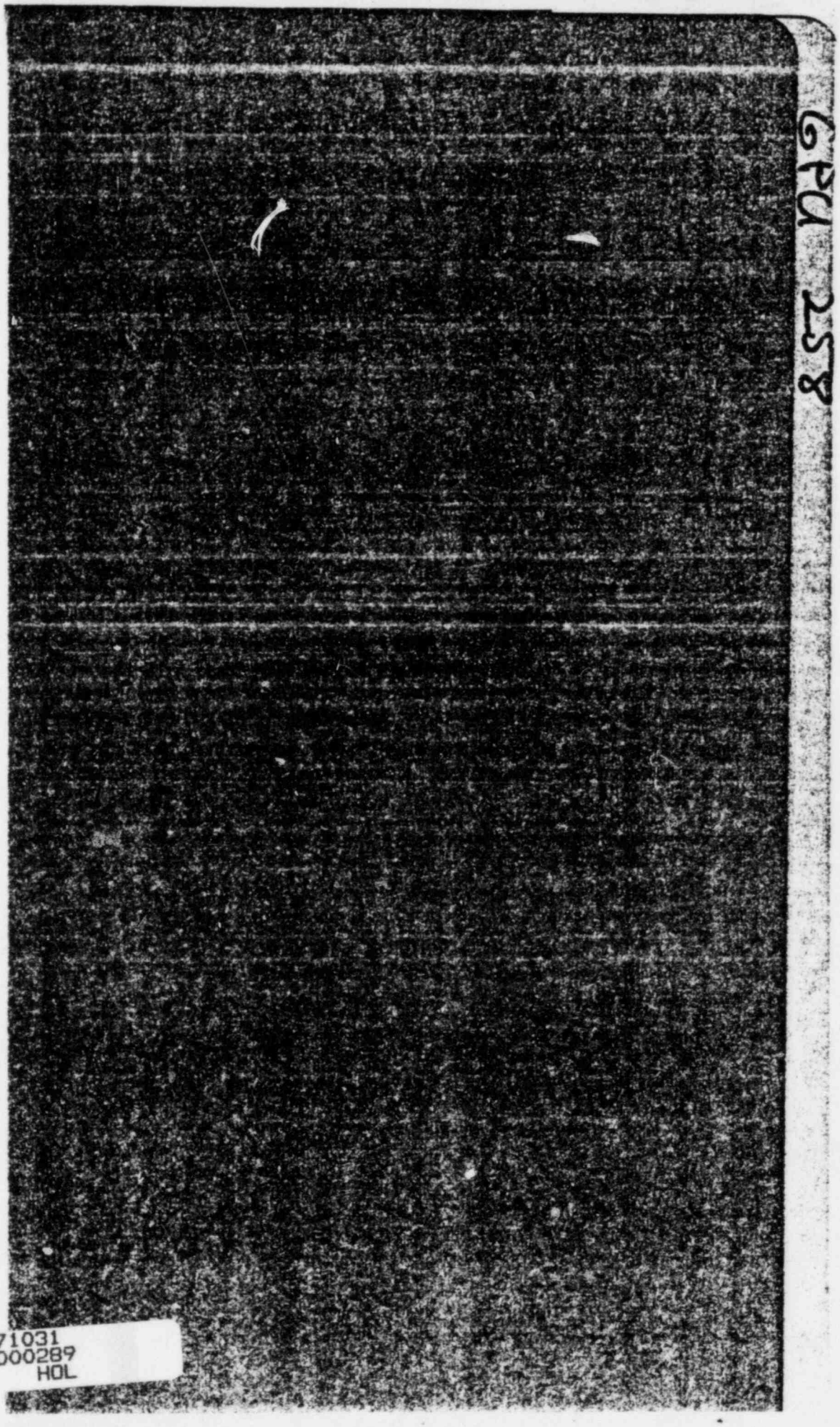

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NUREG-0302
Rev. 1

REMARKS PRESENTED (QUESTIONS/ANSWERS DISCUSSED) AT PUBLIC REGIONAL MEETINGS TO DISCUSS REGULATIONS (10 CFR PART 21) FOR REPORTING OF DEFECTS AND NONCOMPLIANCE

July 12 - 26, 1977

U. S. Nuclear Regulatory Co

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REMARKS PRESENTED (QUESTIONS/ANSWERS DISCUSSED) AT PUBLIC REGIONAL MEETINGS TO DISCUSS REGULATIONS (10 CFR PART 21) FOR REPORTING OF DEFECTS AND NONCOMPLIANCE

July 12 - 26, 1977

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Office of Inspection and Enforcement
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

FOREWORD

In enacting the Energy Reorganization Act of 1974, Congress included Section 206 which requires the reporting of defects and noncompliances directly to the Nuclear Regulatory Commission (NRC). This congressional action required that the NRC promulgate rules and regulations, as necessary, to assure appropriate implementation of Section 206. In response to this mandate, the NRC drafted a new regulation. Following a period of public comment and revision, the regulation identified as 10 CFR Part 21, Reporting Defects and Noncompliance, was published in a Federal Register Notice on June 6, 1977.

To assist NRC licensees and other firms and organizations covered by the new Part 21 regulation, public regional meetings were conducted by staff representatives to explain the rule. At these meetings the staff presented prepared remarks and answered questions on the meaning and application of the rule. Staff remarks contained in the original publication of this document were also provided to those in attendance. At each meeting the staff received a request for the questions and answers discussed by the staff to be made available for use as guidance by the nuclear industry covered by the rule. It was announced that a consolidation of the staff position question/answer guidance would be made available to each organization or firm attending these meetings and for others where a request is made in accordance with the directions printed inside the front cover of this document. The staff will be guided in its implementation and enforcement of Part 21 by the positions set forth in this document.

This revision of NUREG-0302 includes the following three parts relating to 10 CFR Part 21: 1) remarks presented by staff representatives; 2) Federal Register Notice material; and 3) a consolidation of questions and answers from the public regional meetings.

PUBLIC REGIONAL MEETINGS
(DALLAS, ATLANTA, SAN FRANCISCO, CHICAGO, PHILADELPHIA)
TO DISCUSS REGULATIONS (10 CFR PART 21)
FOR REPORTING OF DEFECTS AND NONCOMPLIANCE

July 12-26, 1977

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Welcoming Keynote Address

Good morning, ladies and gentlemen. Welcome to this meeting. I appreciate the opportunity to meet with you here today in one of the five Regional Workshop Sessions that the Nuclear Regulatory Commission is sponsoring to explain and discuss the provisions of its new regulation, 10 CFR Part 21, "Reports to the Commission Concerning Defects and Noncompliance".

I'm sure that most of you are aware of the major provision of Part 21. It has been the subject of considerable review, discussion, comment, revision and refinement since the proposed rule was first published in the Federal Register in March 1975. It is no secret that it has been one of the most controversial rules ever promulgated by the Commission and it has potentially significant implications for all members of the nuclear community, from power plant operators, nuclear steam suppliers, architect engineers and constructors to consultants and component vendors. I am certain that even the regulators will face a learning period concerning some of the legal and technical nuances of this rule as they become more involved in the enforcement of it in the months ahead. I sincerely hope that our discussions today will help us all develop a clear and common understanding of the objectives and requirements of this important new rule.

As the objective of Part 21 is to implement Section 206 of the Energy Reorganization Act, I believe stating the specific words of Section 206 will be helpful in establishing the background for the panel discussions that will follow. Section 206, as enacted, reads as follows:

"NONCOMPLIANCE

Sec. 206.(a) Any individual director, or responsible officer of a firm constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or pursuant to this Act, who obtains information reasonably indicating that such facility or activity or basic components supplied to such facility or activity--

(1) fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards, or

(2) contains a defect which could create a substantial safety hazard, as defined by regulations which the Commission shall promulgate,

shall immediately notify the Commission of such failure to comply, or of such defect, unless such person has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

(b) Any person who knowingly and consciously fails to provide the notice required by subsection (a) of this section shall be subject to a civil penalty in an amount equal to the amount provided by Section 234 of the Atomic Energy Act of 1954, as amended.

(c) The requirements of this section shall be prominently posted on the premises of any facility licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended.

(d) The Commission is authorized to conduct such reasonable inspections and other enforcement activities as needed to insure compliance with the provisions of this section."

In approving 10 CFR Part 21 as the means for implementing Section 206 of the Energy Reorganization Act of 1974, the Commission is requiring directors and responsible officers of certain firms and organizations 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.

The reporting requirement is intended to assure that the NRC receives prompt notification concerning defects or failures to comply with NRC requirements for facilities or activities licensed by the Commission which could present a substantial safety hazard. The purpose of this reporting requirement is to further enhance our "defense in depth" measures for assuring public health and safety and protection of the environment.

Now I'm sure that even from your reading of the rule and from this brief discussion you have made some important observations. For instance, you have no doubt noted that, unlike provisions of the Atomic Energy Act which impose obligations on licensees, Section 206 imposes obligations on firms and organizations who are involved in the nuclear industry as well as on firms and organizations who are NRC licensees and, further, imposes these obligations as a direct liability on certain individuals

in these firms and organizations. No doubt you are also pondering some of the other important issues and questions that were considered by the staff and commented upon profusely by many of you during the years that this rule has been in preparation. Questions, for example, like:

1. What levels of individuals in an organization are required to notify the Commission on defects and noncompliance?

2. How is a defect defined?

3. How does the Commission define a "basic component," i.e., how far down the tiers of suppliers should Part 21 be applied?

4. How should a supplier be advised of the applicability of Part 21?

5. Should reporting individuals be required to identify all facilities or activities, including exported facilities, at which a defect or failure to comply may exist?

Well, that's precisely why we are all here today - to discuss such questions. I hope that our workshop discussions today will provide answers to most, if not all, of these questions so that we can all approach the implementation of this important new rule with a common understanding of what the law requires of us.

Thank you for meeting here with us today. I hope that your visit hear will be both enjoyable and profitable.

REMARKS BY
THE OFFICE OF THE EXECUTIVE LEGAL DIRECTOR
TO PUBLIC REGIONAL MEETINGS ON 10 CFR PART 21
BY
JAMES K. ASSELSTINE
MARC R. STAENBERG

JULY 12-26, 1977

The Legislative and Legal Aspects of Part 21

The Regional Director, in his keynote address, explained the relationship of Section 206 of the Energy Reorganization Act to the new Part 21 and the basic purpose of the rule. It is interesting to note that Section 206 was not part of the Act as it was passed by the House of Representatives. This section was added by the Senate committee. The purpose of the section as explained by the Senate committee in its report was:

> to upgrade the system of detecting and anticipating the defects that increasingly have plagued the nuclear power industry and threatens its safety record on a daily basis. The application of this provision to component suppliers is intended to benefit electric utilities in particular, which usually have no way of knowing that a sealed, prefabricated part is defective until it triggers a shutdown costing tens of thousands of dollars a day in lost generating capacity.

In addition, Section 206 as enacted by the Congress was made expressly applicable to all facilities and activities which are licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

Section 206 in its final form was a substitute added by the Joint House Senate conference committee on the Energy Reorganization Act. Of interest is the fact that, as originally drafted, a failure to report could have resulted in criminal prosecution. The criminal penalties were dropped in the House Senate conference in favor of civil penalties.

Section 206 is a broadly worded statute by which Congress intended to give the NRC responsibility to flesh out the bare bones of the statutory language and to develop workable definitions of terms and a workable implementation program. Part 21 is the result of the Commission's efforts in this regard and, of necessity, goes into considerable detail in many areas where the statute did not. But even as the final rule was published on June 6, 1977, the Commission recognized that future experience and further information might warrant clarifying or other changes to the rule. It is thus not possible in these short remarks to anticipate and answer every circumstance which might arise.

With this in mind, several things about Section 206 are particularly worthwhile emphasizing. First, it imposes obligations on individuals. The language of the section refers specifically to individual directors or responsible officers, and these terms are further defined in the Commission's Part 21. Thus, under Part 21, it is individuals who may be subject to civil penalties. Our Office of Standards Development representative will be providing examples of who these individuals are.

The statute is silent on the question whether an individual director or responsible officer who has been compelled to pay a civil penalty may be reimbursed by his employer. Unlike the proposed rule, the effective Part 21 does not address the reimbursement question. The explanation which accompanied publication of the rules in the Federal Register indicates that the matter of reimbursement would be governed by State law. Second, the section clearly applies to persons not licensed or previously directly regulated by the Nuclear Regulatory Commission. Section 206 specifically mentions suppliers of components. Third, Section 206 is not unique. Other statutes impose sanctions for failure to report defects or hazards; for example, the Federal Boat Safety Act of 1971, the Consumer Product Safety Act and the National Traffic and Motor Vehicle Safety Act.

Part 21 becomes effective and binding insofar as the obligation to provide the required notification is concerned on August 10, 1977. Should any of you have the misfortune to be cited for a civil penalty under Part 21, the opportunities available to you to argue for different language in the Part in the enforcement proceeding against you will likely be very limited. Thus, if you have questions, it is better to raise them now rather than later. While the rule goes into effect shortly, you have a right under federal law to petition the Nuclear Regulatory Commission to amend the rule. The rule also provides that an exemption may be granted by the Commission upon application of an interested person when the Commission determines that such exemption is authorized by law and will not endanger life or property or the common defense and security and is otherwise in the public interest. A person may also seek an interpretation from the General Counsel of a particular section or matter covered by the rule, thereby indicating areas of concern to him. These avenues wouldn't relieve you of the obligation to comply with the Part before the petition or request was acted upon, but they would be the proper way to get your concerns before the Nuclear Regulatory Commission.

REMARKS BY
THE OFFICE OF STANDARDS DEVELOPMENT
TO PUBLIC REGIONAL MEETINGS ON 10 CFR PART 21
BY
W. E. CAMPBELL, JR
JULY 12-26, 1977

Development of the Part 21 Regulations

My objective is to provide information concerning the Part 21 rule making and related amendments to other Parts of Title 10. These amendments concern some exemptions that will be discussed by the representative of the Office of Nuclear Material Safety and Safeguards. It may be helpful if you have available your copy of the Federal Register notice concerning this effective rule making because I and other speakers will be making some references to various sections. The Federal Register notice has two parts. One is the "Statement of Considerations" or Preamble. For Federal Register notice 42FR28891 this is all the material on the first three pages down to "Part 2 - Rules of Practice". It is similar to the "legislative history" and does not have the force of law or regulation. The remaining portions of the notice will be incorporated into the Code of Federal Regulations.

As a result of the enactment of the Energy Reorganization Act of 1974, the Nuclear Regulatory Commission was required to promulgate new regulations to implement Section 206. It was decided to prepare one new Part to cover all aspects of the regulations required under Section 206 instead of preparing a separate Part for each type of license that we issue; for example, a Part 30 License or a Part 40 License or a Part 50 License. The rule making required under Section 206 of the Energy Reorganization Act could have been accomplished by making appropriate changes to the present Parts 30, 40, 50 etc., but it was felt that a better way to do it would be to have one new Part. The proposed rule was published on March 3, 1975. We received a large number of comments on the proposed rule. My first illustration indicates the source of the comments on this proposed rule.

PROPOSED PART 21
COMMENT SOURCE

	1 JAN 1976 %
UTILITY	35
NUCLEAR STEAM SUPPLIER SYSTEM	4
INDIVIDUALS	4
LAW FIRMS	4
EDUCATIONAL	3
ARCHITECT/ ENGINEER	10
CONSTRUCTOR	10
SUPPLIER	16
SOCIETY/ ASSOCIATION	5
CONSULTANTS	4
GOVERNMENTAL	4
TOTAL COMMENTS	134

Of these comments, 114 were received prior to the expiration of the extended comment period. When the comment period closed the review and resolution of these comments commenced. This review and resolution included consideration of both the comments that were on time and those that were late. To proceed to an effective rule a number of courses were available.

1) Enter into a rule making hearing.
2) Revise the rule taking into account the comments received and publish the rule again as a proposed rule for comment.
3) Revise the rule taking into account the comments received and publish as an effective rule.

Because the significant issues regarding the proposed rule were adequately discussed in the many comments received a hearing was not deemed necessary. For the same reason it was not considered appropriate to publish the rule for comment again. The staff proceeded, with Commission approval, to draft an effective regulation. As you are aware the rule has been noticed on June 6, 1977. On July 7 and 18 correction notices were published. On July 7 a notice was published which delayed the effectivity of some portions.

In attempting to achieve an effective rule that was responsive to Section 206 of the Energy Reorganization Act a number of major and minor issues were addressed. One of these issues was:

> "What level of individuals in an organization should be required to notify the Commission of defects and noncompliance?"

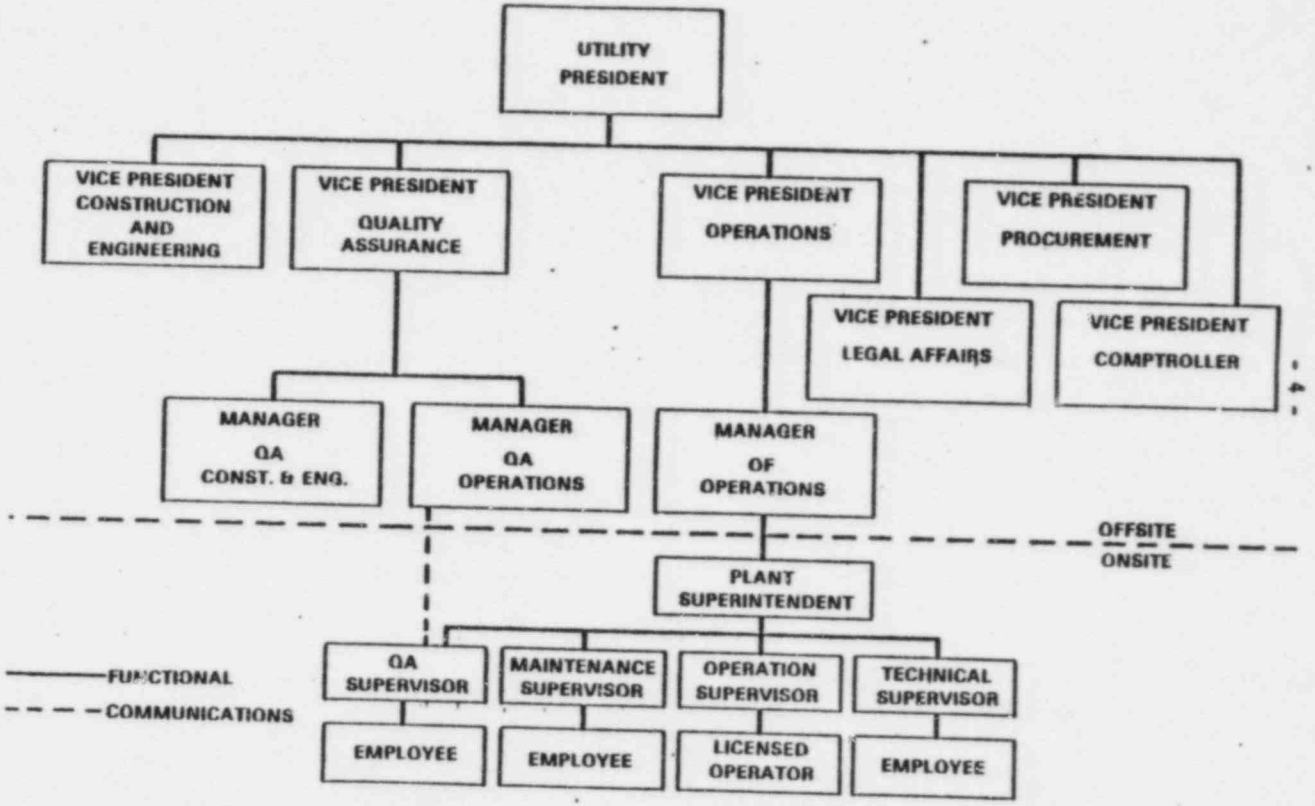
The notice of proposed rule making requested specific comments in this regard. This illustration shows a "typical utility organization (see next page). It is indicative of the organization of most licensees in that there are numerous tiers and numerous titles but in very few organizations would the titles in one organization relate to the functional descriptions in other organizations where the same title was used.

As used in Part 21, "director" was defined 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, that individual is the director. Responsible officer was defined to mean the president, vice president or other individuals in the organization of a corporation, partnership or other entity who is vested with executive authority over activities subject to Part 21. Activities such as design, construction, operation are included. An officer, for example the Vice-President in Charge of Community Affairs may not be a responsible officer in regard to Part 21. An individual subject to this part may designate another individual to provide notification to NRC for him but the individual subject to Part 21 will remain responsible for compliance with Part 21.

Another issue was:

> "How should a defect be defined?"

The Energy Reporganization Act uses the phrase "defect which could create a substantial safety hazard." It is necessary that important substantial defects be differentiated from the inconsequential defects. We have attempted to do this in the Part 21 definitions. Deviation and defect are interrelated. For example, a procurred item is required to meet certain requirements. If the item does not meet its prescribed requirements a deviation exists. Some deviations can create a substantial safety hazard and others can not. The deviations that exists at time of delivery or become known after delivery must be evaluated to determine ability to create a "substantial safety hazard". If the deviation could create a substantial safety hazard then a defect exists. These relationships will be discussed more fully as the remarks are presented.


UTILITY PRESIDENT
VICE PRESIDENT CONSTRUCTION AND ENGINEERING
VICE PRESIDENT QUALITY ASSURANCE
VICE PRESIDENT OPERATIONS
VICE PRESIDENT PROCUREMENT
VICE PRESIDENT LEGAL AFFAIRS
VICE PRESIDENT COMPTROLLER
MANAGER QA CONST. & ENG.
MANAGER QA OPERATIONS
MANAGER OF OPERATIONS
OFFSITE
ONSITE
PLANT SUPERINTENDENT
QA SUPERVISOR
MAINTENANCE SUPERVISOR
OPERATION SUPERVISOR
TECHNICAL SUPERVISOR
EMPLOYEE
EMPLOYEE
LICENSED OPERATOR
EMPLOYEE
FUNCTIONAL
COMMUNICATIONS

Part 21 has provided four definitions of defect as follows: first, a defect is a deviation in a basic component delivered to a purchaser where on the basis of an evaluation the deviation could create a substantial safety hazard (This defintion is primarily directed at the offsite supplier) or second, a defect means the installation, use or operation of a basic component containing a defect as defined above. (This definition is primarily directed at the recipient, that is user, of the component or service) or third, a defect is a deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of Part 50 provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance (This definition is primarily directed at the on-site supplier) or fourth, a defect is 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 pursuant to Part 50 (This definition is primarily directed at a specific class of licensees).

It should be noted that the definitions applicable to suppliers are pertinent only upon delivery of fabricated component. Deviations that are identified by a supplier when the product is within his control, by definition are not a defect unless they remain uncorrected upon delivery of the defective component or service.

The Procurement Document is defined in Part 21 as "A contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser."

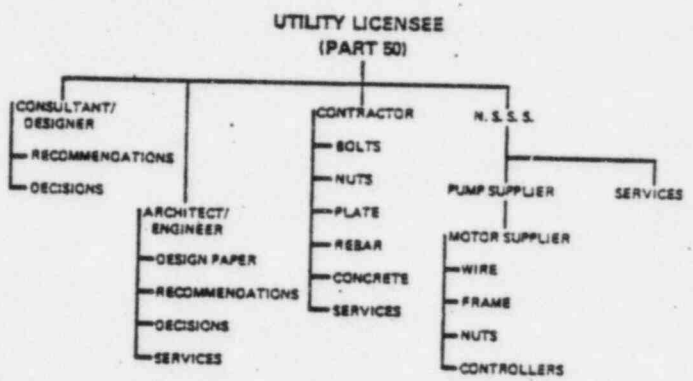
The definition includes both an inter-organizational and an intra-organizational document that defines the technical requirements. This document is the vehicle by which a supplier is informed that the procurement action comes under Part 21. To a responsible pressure vessel supplier it should be obvious his product has significant safety importance and thus is within the scope of the regulation. To a supplier of nuts and bolts, however, the safety significance is not clear; thus the applicability of Part 21 may not be known without the procurement document notification.

Section 206 of the Energy Reorganization Act used the term "basic component."

Another issue was:

> "How should the Commission define a "basic component"; for example, how far down the tiers of suppliers should Part 21 be applicable?"

Since specific guidance in relationship to safety significant items in the reactor field exists, that is, Regulatory Guide 1.29, it was decided to take advantage of it in defining basic component.



This illustration shows the numerous items, organization, activities and products that are used in the design and construction of a nuclear power reactor. It is realized that all organizations, activities and products are not such that they "could create a substantial safety hazard." "Basic component" as applied to nuclear power reactors means a plant structure, system, component of part thereof necessary to assure (1) integrity of the reactor coolant pressure boundary or (2) the capability to shut down the reactor and maintain it in a safe shut down condition or (3) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in Section 100.11 of Title 10. When applied to other regulated activities it means a component, structure, system or part thereof that is directly procured by the licensee of the facility or activity subject Part 21 and in which a defect or failure to comply could create a substantial safety hazard. The services of design, inspection, test or consultion associated with a basic component are within the scope of Part 21. These definitions will be discussed further by representatives of other offices.

Another issue was:

"How should substantial safety hazard be defined."

Substantial safety hazard means the loss of a safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety. Applicable criteria for the determination of substantial safety hazard are given in the statement of considerations. These 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. These will be discussed more by the representatives of the Office of Nuclear Reactor Regulation and Nuclear Material Safety and Safeguards.

Another issue was:

"What types of business that are not licensed or otherwise regulated are within the scope of Part 21?"

The legislation is explicit in regard to owning, constructing, operating and supplying the components. 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. The entire supply chain involved in the production of a basic component for a power reactor that could create a substantial safety hazard, because of a defect in the component, is within the scope of Part 21. The safety-related operations of constructing, owning, operating and supplying components each have within them safety-related activities, that is, consultating, design, inspection and test. The definition of "basic component" and "operation" have been defined so as to include these safety-related activities. This aspect of the proposed rule was the subject of numerous comments.

The relationship of one person subject to Part 21 to another from a different organization, who was also subject to Part 21, received many comments. Also the relationship of individuals not subject to this part was also the source of many comments.

Another issue was:

"Should an officer or director of a organization responsible for procuring or producing a component be required to make a Part 21 notification to the Commission concerning either a defect or non-compliance not within responsibility of his organization?"

If an individual or individuals subject to Part 21 becomes aware of a defect that is not within the responsibility of his organization he is not required by Part 21 to submit a notification. In such cases, the individual that gains the knowledge of a defect in an item outside his organization's area of responsibility would be encouraged to report but would not be subject to a civil penalty if he did not report it.

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

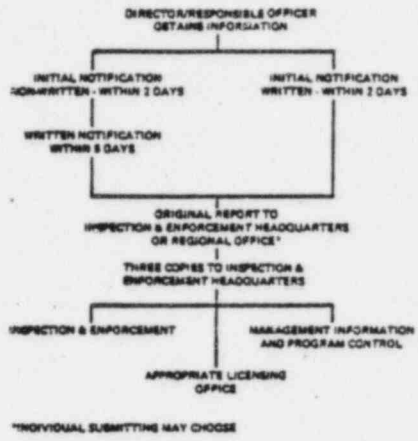
You will note that Section 21.2 states:

> "§ 21.2 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."

The time of notification is another subject of concern. The sequence of events and timing subsequent to deviation identification, evaluation and providing information to the responsible officer or director is shown on this illustration.



The rule presently is silent in regard to the time from when identification of a deviation occurs, to the time of notification to the Nuclear Regulatory Commission. At present we consider this time period to be unquantifiable for all facets of the activities regulated by NRC. The times identified are those after the responsible officer or director receives the information of the evaluation. In the event that the time between identification of the deviation and notification is provided to NRC must be quantified then it will be the subject of future regulatory action.

Part 21 is not the "last word" in the prevention of safety hazards. It will not cure the problem of an inadequate procurement document, or an inspector who doesn't inspect or faulty design. This rule is only one of a number of the reporting and notification tools presently utilized by the Nuclear Regulatory Commission to insure that we have the necessary safety-related information.

I would like at this time to call to your attention the stated Commission intentions regarding Part 21 as indicated in the statement of considerations and as discussed by the representative of the Office of the Executive Legal Director.

"The Commission intends to examine closely the implementation of Part 21 with the view to making any clarifying or other changes that may be warranted in the light of expericence. In particular, insufficient experience has been accumulated to permit the writing of a detailed regulation at this time that would provide a precise correlation of all factors pertient to the question of what is a significant safety hazard. Part 21 is intended in this regard as an initial effort to identify a number of the factors involved with the question of significant safety hazard."

REMARKS BY
THE OFFICE OF NUCLEAR REACTOR REGULATION
TO PUBLIC REGIONAL MEETINGS ON 10 CFR PART 21
BY
WILLIAM T. RUSSELL

JULY 12-26, 1977

HOW PART 21 IMPACTS REACTOR LICENSING, LICENSEES AND SUPPLIERS

My name is William Russell and I am a Project Manager in the Office of Nuclear Reactor Regulation's Division of Operating Reactors. My objective is to provide some insight as to the scope of reactor activities to which Part 21 applies, the general criteria that we will be using in our evaluation of reported Part 21 items and how we will factor this information into the reactor licensing process. I will also discuss the impact of this new rule on reactor licensees, vendors, contractors and consultants.

Background

The Energy Reorganization Act of 1974, which established the Nuclear Regulatory Commission, provided a specific review function to include "monitoring, testing and recommending upgrading of systems designed to prevent substantial health or safety hazards." In partial fulfillment of this, NRC reviews operating experience, including reports from NRC inspectors, reactor licensees and vendors. We also review information obtained from NRC research and from foreign exchange agreements. As new technical information and operating experience become available the Office of Nuclear Reactor Regulation determines whether such information could significantly alter previously determined levels of reactor safety. When we conclude that the level of safety has been or may be degraded, timely licensing action is taken. The action taken varies based upon the potential hazard to the public health and safety. These actions can range from an order to shut down a reactor to a request that affected licensees determine the effect of the new technical information or operating experience upon their facilities. Through this process of identifying and resolving technical issues and applying this information to operating reactors, a data base of experience is evolving that is having a positive impact on new plant designs.

Typical Part 21 Report Scenario

The reporting of defects and noncompliance pursuant to 10 CFR Part 21 will be incorporated into the reactor licensing process in a similar manner. A typical 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 a substantial safety hazard is involved. It is expected that 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 must be reported as a defect to the NRC. Before describing how the NRC evaluates and uses Part 21 reports, I will discuss a substantial safety hazard.

The general criteria which we will use in evaluating a substantial safety hazard are identified in the statement of consideration which was published with the new rule. These criteria include: moderate 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 equipments are necessary to ensure (1) the integrity of the reactor coolant pressure boundary, (2) the capability to shutdown the reactor and maintain it in a safe shutdown condition 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. Under the new rule these essential safety-related equipments 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 maybe a loss of safety function for the affected basic component or a major reduction in the degree of protection provided to public health and safety. Therefore, a defect in a basic component, even though a redundant component exists, could be reportable under Part 21.

The Office of Inspection and Enforcement will perform the initial evaluation of the safety significance of the reported defect or noncompliance and will evaluate the action being taken by the supplier

and licensee. I&E also determines whether an unreviewed safety issue may exist, if a licensing action is required or if inspection or enforcement action is necessary. If a licensing action or unreviewed safety issue is involved, the Office of Nuclear Reactor Regulation (NRR) would be advised and would assume lead responsibility for further NRC action. Within NRR, the Division of Operating Reactors has the responsibility to collect and evaluate experience with operating reactors to assure that appropriate and timely corrective action is taken and to feed back information to other NRR divisions conducting evaluations of proposed reactor facilities. The reported defect is also evaluated to determine if it is common to several reactor facilities. Our review may require the affected reactor licensees to submit additional information and analysis. Interim licensing action may be taken to assure the public health and safety during our review. The interim licensing action could be an order to shutdown, reduce power or other restrictions or conditions on reactor operation pending final resolution of the problem. The final licensing action could require replacement of the defective component or appropriate restrictions on reactor operation. The scenario I have just described is an example of the feedback of reports of defects and noncompliance into reactor licensing.

Impact on Reactor Licensees and Supplier Organizations

I would like to shift gears for a moment to discuss the impact of the new rule on reactor licensees and upon private industry involved in design, construction, test, inspection and consultation for nuclear reactors. For several years we have been requiring permit holders to report significant deficiencies and deviations discovered which could adversely affect the safety of future operation. This reporting is required as a condition of the facility construction permit under 10 CFR 50.55(e). Similarly, the Technical Specifications issued as a part of every power reactor operating license require the reporting of significant failures, malfunctions, degradation and deviations as Licensee Event Reports. Regulatory Guide 1.16 identifies the type of information to be reported in Licensee Event Reports. Therefore, for the power reactor licensee, the notification requirements of the new rule are different only in scope from reporting requirements which are already in place. Duplicate reporting under Part 21 is not required. For example, a Licensee Event Report, which includes all appropriate information required for a Part 21 Notification, would satisfy the requirement that the licensee's director or responsible officer has actual knowledge that the Commission has been adequately informed and a separate Part 21 Notification would not be required. Most research and test reactor licensees are subject to similar reporting requirements as conditions of their construction permits and their operating license Technical Specifications.

The notification of defects and noncompliance which could create a substantial safety hazard is necessary to insure that potential reactor safety hazards are promptly identified, evaluated and resolved. It is for this reason that the notification requirements of Part 21 include organizations supplying safety-related equipment and safety-related services. Safety-related services include design, engineering, testing inspecting and consulting services which could, if they contained defects, create a substantial safety hazard. Examples of these types of safety-related services and software are:

- Nondestructive examination of safety-related welds,
- Design of safety-related pipe hangers and supports,
- Seismic and geologic surveys for a reactor site,
- Specification of safety-related hardware characteristics,
- Computer codes for reactor analysis,
- Emergency procedures, and
- Fire protection inspections by fire consultants

Organizations providing these types of safety-related services, as well as licensees and firms that physically construct facilities or supply basic components, must establish procedures to identify deviations from technical requirements and must provide for evaluations to determine if defects exist. These procedures must also assure that directors and responsible officers are informed of the existence of defects in delivered products. For some organizations the implementation of new internal procedures for evaluation of deviations will not be required to accommodate Part 21. Company procedures for the evaluation of deviations which were previously performed as part of good engineering and management practice may be sufficient. Records in connection with design, manufacture, fabrication, placement, erection, test and inspection of basic components and facilities, sufficient to insure compliance with the new rule shall be maintained. The records required to be kept under the quality assurance programs specified under 10 CFR Part 50 Appendix B should satisfy the record keeping requirements of the new rule.

Tie-In With Safeguards Rule

Before I conclude I would like to address one additional item. When Part 21 was published in the Federal Register, the statement of considerations addressed failures to comply or defects in a security system.

The NRC recently adopted a new regulation which identified additional requirements for the physical security of nuclear power reactors. The primary safeguards concern for nuclear power reactors is for potential acts of sabotage or terrorism. Such acts are of concern because they could lead to the release of significant amounts of radioactive material which could endanger the public health and safety. Therefore, failures to comply or defects in a security system can contribute to the creation of a substantial safety hazard and are within the scope of Part 21. For example, a defect or noncompliance which allows or could allow an unauthorized individual to gain access to a vital area of a nuclear power plant without being detected by means other than visual surveillance, including remote visual-electronic surveillance, is considered to be a substantial safety hazard and is therefore reportable under Part 21.

Conclusion

In conclusion, I have outlined the basic method by which operating experience including reports of defects and noncompliance are reviewed and as appropriate fed back into the licensing process. I have also discussed the impact of the notifications and record keeping requirements of the new rule upon both reactor licensees and others in the nuclear reactor industry. The process of identifying deviations, conducting evaluations and notifying the NRC of substantial safety hazards will require additional effort and some additional costs. However, the long term benefit of being able to anticipate potential safety problems is substantial.

REMARKS BY
THE OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
TO PUBLIC REGIONAL MEETING ON 10 CFR PART 21
BY
W. A. NIXON
J. E. ROTHFLEISCH

JULY 12-26, 1977

The Impact of Part 21 on Material and Fuel Cycle Licensees and Suppliers

As a staff member of the Office of Nuclear Material Safety and Safeguards, I am going to describe, briefly, how the new regulation, Part 21, applies to material and fuel cycle licensees.

When the proposed version of Part 21 was first published, I believe many people thought it applied only to nuclear reactors. In fact, Part 21 applies, with a few exemptions I will describe later, to:

1) all byproduct material licenses issued under Parts 30 through 36
2) source material licenses issued under Part 40
3) special nuclear material licenses covered by Part 70
4) the packaging of radioactive material for transport, Part 71 and
5) fuel cycle facilities licensed under Part 50.

In earlier talks this morning, the history and legal aspects of Part 21 were discussed and the application of Part 21 to nuclear power reactors described. Rather than repeat information already presented on the general content and applicability of the rule, I will concentrate on the specific aspects of the rule that are important for determining how the rule is applied to material and fuel cycle licensees. The definition of basic component as it applies to material and fuel cycle licensees is extremely important. Basic component, for these licensees, is defined in paragraph 21.3 as "a component, structure, system or part thereof that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order or license issued by the Commission could create a substantial safety hazard." This definition limits the supplier organizations subject to Part 21 to those that directly supply the licensee. Let me repeat this, responsibility for complying with Part 21 does not, in the case of organizations supplying material and fuel cycle licensees, extend past the first tier of suppliers. The term basic component does include design, inspection, testing or consulting services important to safety that are associated with component hardware, and organizations supplying such services directly to the licensee would be subject to Part 21.

Other aspects of the new rule apply to material and fuel cycle licensees and first tier suppliers just as they do to power reactor licensees and suppliers. Of particular importance are the requirements for posting, notification, procurement documents and inspection and records. We believe that most evaluations of deviations and reports to the Commission of defects will be made by licensees, because many suppliers would not have all of the information needed to evaluate the significance of a deviation. As indicated in the Statement of Considerations, appropriate criteria for determination of the existance of a substantial safety hazard include:

- Moderate exposure to, or release of, licensed material
- Major degradation of essential safety related equipment or
- Major deficiencies involving design, construction, inspection, test, or use of licensed materials or facilities.

To the extent that failures to comply or defects in a security system could contribute to a substantial safety hazard, such failures and defects could be within the scope of Part 21. Components of security systems that do not meet performance standards or which fail could present the potential for safety hazards. When such anomalies are noted to exist they should be evaluated pursuant to Part 21.

I mentioned earlier that there were a few exemptions from Part 21. These exemptions are for some uses of radioactive materials authorized by General Licenses in 10 CFR Parts 31, 35, and 40. The exemptions in Part 31 apply to small quantity uses in safety devices, gauges, ice detection equipment and clinical or laboratory testing. The exemption in Part 35 applies to medical use of specified quantities of byproduct material. Under Part 40, users of small quantities of source material and the use of depleted uranium in certain industrial products or devices are exempt. The specific exemptions are identified in changes to the regulations associated with the adoption of Part 21.

That completes my formal presentation. We will be available this afternoon to answer any questions you may have. Thank you.

REMARKS BY
THE OFFICE OF INTERNATIONAL PROGRAMS
TO PUBLIC REGIONAL MEETINGS ON 10 CFR PART 21
AT SAN FRANCISCO, CHICAGO AND PHILADELPHIA
BY
DR. J. D. LAFLEUR, JR.
JULY 19-26, 1977

Part 21 and its Effect on Exporters

As you know, Section 206 requires reporting of defects and non-compliance in "licensed" facilities and activities.

The first version of the rule was quite worrisome to many exporters, who seemed to be placed in the role of having to report to NRC on defects in certain foreign nuclear power plants. It is not the intent of NRC to assume the responsibility for the safety of nuclear energy overseas, nor do we intend to make U. S. vendors, who happen to know about safety problems overseas, report them to us, if these problems do not affect safety in the United States.

Under international agreements we now receive a large amount of important nuclear safety information, on facilities similar to US facilities, from foreign regulatory authorities. Exporters, who also happen to 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. 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. We do not wish to lose these foreign sources of important safety information, nor do we wish to antagonize these friendly governments. Nor do we wish to make US vendors the source of information of foreign plants against the will of the foreign governments involved, if such information is not necessary for domestic safety. The new rule, and the Federal Register notice announcing it, contain clarification in regard to the applicability of Part 21 to the licensed activity of exporting. Persons who are only licensed to export nuclear facilities or materials, and who do not otherwise construct or operate facilities or activities or supply components, are not subject to the new part. Individuals subject to this part 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, not in overseas plants they happen to know about. Further, any notification submitted in accordance with Part 21 may be withheld from public disclosure if the notification falls within one of the exemptions of the Freedom of Information Act, or if withholding is otherwise authorized by law.

Let's look at a specific example:

Suppose a U. S. vendor has a contract to do work in a foreign country (or possibly is an exporter of a foreign plant). In the course of this overseas work, that vendor learns of a defect in a foreign plant that reflects a similar defect in a U. S. domestic plant. Suppose, also, that that vendor is a "responsible" party under 21, for the domestic plant. This vendor reports to NRC the defect in the domestic reactor, but does not provide certain details about the applicable foreign experience because his overseas client or the foreign government has not given him permission to disclose the information publicly.

First, does the vendor have to supply these details?

No, he does not, providing enough explanation is given to NRC to make the information usable in NRC safety work.

This leads to another question: If this vendor requests that information about the foreign experience not be publicly disclosed, will NRC honor this request? Yes, if the information is exempt from public disclosure under U. S. law, and the NRC determines that it is in the public interest to protect it.

I have two examples of such information that could be exempt from public disclosure under the U. S. Freedom of Information Act:

a) If the information is proprietary information, that is, information given in confidence, the disclosure of which would do substantial harm to the vendor's competitive position, the documents containing that information could be withheld under Exemption 4 of Freedom of Information Act.

b) 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 Exemption 4 or Exemption 1 of Freedom of Information Act.

REMARKS BY
OFFICE OF INSPECTION AND ENFORCEMENT
TO PUBLIC REGIONAL MEETINGS ON 10 CFR PART 21
BY
G. W. REINMUTH
JULY 12-26, 1977

The Inspection and Enforcement of Part 21

In the past, when a new rule or requirement was written into our regulations, we have noted that those who must apply the rule to their activities will often have difficulty in translating the requirement in the intended manner. Frequently the user will react to one extreme or the other, depending upon whether the company is the buyer or the seller.

As an example, when the 10 CFR Part 50, Appendix B quality assurance criteria were initially applied, we felt licensees frequently responded by asking more of their suppliers than was intended. On the other hand, when we inspected the licensee's own QA programs and those of his principal contractors, we noted the tendency to require less of themselves than was called for. I suppose this a normal reaction and is the consequence of writing a good portion of our rules in the form of criteria rather than in specification-type requirements.

From the words that you have heard this morning, you are by now aware that Part 21 will probably also present problems in application. It was a difficult rule to write - parts of it include words such as reasonably indicating, responsible officer, could create a substantial safety hazard, etc. Any time one has to apply these kinds of words to a specific work action, reasonable men will differ in their understandings of precisely what the words mean. The message I'm trying to convey is that Part 21 is a complex rule that must be read, studied, comprehended, judgment applied and perhaps more than a reasonable effort put forth to live with it in our everyday affairs.

With respect to the Office of Inspection and Enforcement's role in inspecting against the rule, we do not intend setting up a special new inspection program identified as the Part 21 Inspection Program. We look upon this rule as another requirement which must be covered by our current inspection programs. Those programs cover both reactor and material licensees, and the inspection of reactor contractors and vendors. Basically, Part 21 is a reporting requirement, thus our inspectors will not only be investigating and evaluating those things that are reported, but will be looking for situations or conditions which may not have been reported but should have been.

Obviously, there are other specific requirements in the rule which can and will require verification - such things as:

- Proper posting of requirements.
- Preparation and implementation of administrative procedures to assure that Part 21 type events are appropriately identified, evaluated and reported.
- Inclusion of Part 21 requirements in procurement documents.
- Maintenance of records,

and others. These, of course are the relatively easy items to address.

With respect to our enforcement of Part 21 matters, again we do not see the need for modifying our present criteria. For those of you not familiar with our practices, we define noncompliance as a failure to comply with a regulatory requirement whether that requirement is a 10 CFR regulation, a license condition or any other form of requirement. Noncompliance items are further categorized into three categories of severity: violations, infractions, and deficiencies, with a violation being the most severe category. By definition, failure to report constitutes a violation. Sanctions applied to noncompliance items are again imposed according to severity threholds. These same rules and criteria will be applied to activities falling within the scope of Part 21.

You may note that the rule permits a six month delay in implementation of the posting requirements, the preparation of internal administrative procedures and inclusion of Part 21 provisions in procurement documents. This delay was intended to allow sufficient time for planning and preparation. I must emphasize however, that after January 6, 1978, my office is obligated to enforce the rule as written, therefore our inspectors will expect to see these provisions in place after that date.

In my view, the real difficulty with Part 21 will be to decide what is or what isn't reportable under the rule. It is impossible for any of us on this panel or you in the audience to anticipate all the conditions or situations which might be reportable - or even typical ones. None of the reportable events will be black or white cases - each will required a substantial application of sound engineering judgment and evaluation - on your part and on ours. For guidance, reactor licensees may wish to review their existing procedures currently applied to the reporting of 10 CFR 50.55(e) type deficiencies, since the administrative controls that are necessary to assure satisfaction of those requirements might also be used to satisfy the Part 21 requirements. Keep in mind, however, that Part 21 covers a much broader range of activity, unlike 50.55(e) which is limited to holders of construction permits only.

For those companies not directly licensed by the NRC, but nevertheless subject to Part 21, may I suggest that you establish with your customers and suppliers a clear understanding of how you intend to administer your affairs in order to comply with the rule. Even though compliance with Part 21 may not be a requirement of current in-house contracts and may not show up in new contracts during the next several months, since this provision of the rule is not fully effective until January 6, 1978, defined suppliers of nuclear products and services should be aware that they are still subject to the Part 21 requirements. Further, the responsibility for reporting cannot automatically be delegated or assumed to be the sole responsibility of the buyer.

Since the Office of Inspection and Enforcement is the designated receiving office for Part 21 reports, I would like to point out the key details of the reporting requirements and the mechanics for doing so. This information is shown in Attachment A.

Also the names, titles, addresses and phone numbers of our Headquarters and Regional Directors are provided for your convenience in Attachment B. We hope that your need for them will be negligible.

In summary, I would like to re-emphasize that Part 21 represents a new rule - broad in its implications - but mandated by Congress. Therefore, it is in your interest to assure yourselves that you are familiar with it, difficult as it might be. We, on the other hand, are obliged to inspect for compliance and enforce its provisions.

Attachment A

Part 21 Reporting Requirements

When and how	Within two days following receipt of information. (Written or other)
	Written report within five days.
To whom	Director, Office of Inspection and Enforcement
	Regional Director, Office of Inspection and Enforcement
By whom	Individual director, responsible officer or authorized individual.
Detail required	See Part 21, Paragraph 21.21(b)(3) Other as requested by Commission Paragraph 21.21(c).

Attachment B

Office of Inspection and Enforcement

Mailing Addresses and Phone Numbers

Ernst Volgenau, Director (301) 492-7397
Office of Inspection and Enforcement
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Boyce H. Grier, Director, Region I (215) 337-1150
Office of Inspection and Enforcement
U. S. Nuclear Regulatory Commission
631 Park Avenue
King of Prussia, Pennsylvania 19406

James P. O'Reilly, Director, Region II (404) 221-4503
Office of Inspection and Enforcement
U. S. Nuclear Regulatory Commission
230 Peachtree Street, N. W., Suite 1217
Atlanta, Georgia 30303

James G. Keppler, Director, Region III (312) 858-2660
Office of Inspection and Enforcement
U. S. Nuclear Regulatory Commission
799 Roosevelt Road
Glen Ellyn, Illinois 60137

E. Morris Howard, Director, Region IV (817) 334-2841
Office of Inspection and Enforcement
U. S. Nuclear Regulatory Commission
611 Ryan Plaza Drive, Suite 1000
Arlington, Texas 76012

Robert H. Engelken, Director, Region V (415) 486-3141
Office of Inspection and Enforcement
U. S. Nuclear Regulatory Commission
1990 N. California Boulevard, Suite 202
Walnut Creek, California 94596

Part II - Federal Register Notice Material Relating to 10 CFR Part 21

With the original printing only the one available Federal Register Notice was included in NUREG-0302. This revision contains two additional Federal Register Notices which provide information on a change in the effective date for providing the Commission with notifications of a failure to comply, or a defect and editorial revisions to the 10 CFR Part 21 regulation.

ADDITIONAL MATERIAL

Title 10—Energy
CHAPTER I—NUCLEAR REGULATORY COMMISSION
Reports to the Commission Concerning Defects and Noncompliance

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to require directors and responsible officers of firms and organizations building, operating or owning NRC-licensed facilities, or conducting NRC-licensed activities, to report failures to comply with regulatory requirements and defects in components which may result in a substantial safety hazard. Also covered under the new regulations are directors and responsible officers of firms and organizations supplying safety-related components, including safety-related design, testing, inspection and consulting services.

NRC licensees and other firms and organizations covered by the new regulations must adopt internal procedures to assure that safety-related defects and noncompliance are brought to the attention of responsible officers and directors. Those individuals, in turn, will be required to notify the Commission within two days, and file a written report within five days, of learning of the defect or noncompliance. Directors and responsible officers may designate an employee to provide on their behalf the notification to NRC.

EFFECTIVE DATE: July 6, 1977. Certain obligations under the [redacted] rule are not imposed until [redacted]

FOR FURTHER INFORMATION CONTACT:

Mr. W. E. Campbell, Jr., Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Phone 301-443-5917.

SUPPLEMENTARY INFORMATION: On March 3, 1975, the Nuclear Regulatory Commission published in the FEDERAL REGISTER (40 FR 8832) for public comment proposed amendments to 10 CFR Parts 2, 21, 35, and 40 of its regulations and a proposed new Part 21 to its regulations, "Reporting of Defects and Noncompliance."

The purpose of these proposed amendments and the new proposed Part 21 is to implement section 206 of Pub. L. 93-438, the Energy Reorganization Act of 1974, as amended.

Section 206 of the Energy Reorganization Act of 1974 as amended, reads as follows:

"NONCOMPLIANCE

Sec. 206. (a) Any individual director, or responsible officer of a firm constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or pursuant to this Act, who obtains information reasonably indicating that such facility or activity or basic components supplied to such facility or activity—

(1) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards, or

(2) Contains a defect which could create a substantial safety hazard, as defined by regulations which the Commission shall promulgate, shall immediately notify the Commission of such failure to comply, or of such defect, unless such person has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

(b) Any person who knowingly and consciously fails to provide the notice required by subsection (a) of this section shall be subject to a civil penalty in an amount equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

(c) The requirements of this section shall be prominently posted on the premises of any facility licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended.

(d) The Commission is authorized to conduct such reasonable inspections and other enforcement activities as needed to insure compliance with the provisions of this section."

The new Part 21 requires that the directors and responsible officers of organizations that construct, own, operate or supply components of a facility or activity that is licensed or otherwise regulated by the Nuclear Regulatory Commission inform the Commission if they obtain information reasonably indicating that such facility, activity or basic component fails to comply with regulatory requirements relating to substantial safety hazards or that such facility, activity, or basic component contains a defect which could create a substantial safety hazard. Part 21 additional [redacted] of inform the purchaser concerning the deviation in order that the purchaser evaluate the deviation or have it evaluated. The organizations 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. If the license is other than to construct or operate a nuclear power reactor, then the organizations subject to the regulations are those organizations that directly supply the licensee of the facility or activity. The directors and responsible officers of these organizations will be subject to a fine of up to $5,000 for each deliberate failure to notify the Commission of the existence of such a defect or noncompliance. The organizations subject to Part 21 regulations must also maintain records, post copies of specific documents, inform procurement subtier suppliers of their responsibility under Part 21 and allow inspection of their premises, facilities and activities by duly authorized representatives of the Commission.

The Commission requires that a number of reports and notifications be submitted by licensees. These include licensee's report of incidents required by 10 CFR § 20.403, permit holder's notification of design or construction deficiencies required by 10 CFR § 50.55(e)(1), and licensee's report of theft or attempted theft of special nuclear material required by 10 CFR § 70.52. Other Commission regulations provide for receipt of various kinds of requests or information. For example, 10 CFR § 2.802 provides for petitions to issue, amend or rescind regulations, and 10 CFR § 19.16 provides for notifications from workers in regard to radiological hazards. These communications from licensees and the public are methods of securing information concerning the implementation effectiveness of Commission regulations. This information is an essential ingredient of sound regulation. The regulations in Part 21 add another required notification. 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.

The Commission intends to examine closely the implementation of new Part 21 with a view to making any clarifying or other changes that may be warranted in light of experience. In particular, insufficient experience has been accumulated to permit the writing of a detailed regulation at this time that would provide a precise correlation of all factors pertinent to the question of what is a significant safety hazard. Part 21 is intended in this regard as an initial effort to identify a number of the factors involved with the question of significant safety hazard. Further, additional guidance in the form of regulatory guides may be developed should experience with the application of Part 21 indicate the need for such guidance. In this regard, we expect that the implementation efforts of the staff and those subject to the rule, and the views of interested members of the public, should provide the necessary data base for such further guidance.

During the development of the Energy Reorganization Act, Congress identified a need for an effective means to "anticipate problems before the event." Section 206 was developed to fill that need.

Interested persons have been afforded an opportunity to participate in the development of Part 21 and the associated amendments. The more important changes made to Part 21 are listed below and are based largely on consideration of public comments.

(1) The individuals subject to the notification requirement of Part 21 have been restricted to (a) directors and (b) officers vested with executive authority over activities subject to this part. These individuals may identify an individual that is authorized to provide notification to the Commission.

This new part is only one of many of the reporting channels that concerns defects or noncompliance, e.g., 10 CFR 50.55(e). Individuals that are subject to the requirements of this part that become aware of a defect or noncompliance that is outside the responsibility of their organization and individuals that are not subject to the requirements of any part of Title 10 are encouraged, but not required, to report to the Commission known or suspected defects or failure to comply. As authorized by law, the identity of anyone so reporting will be withheld from disclosures.

(2) Part 21, as adopted, does not specify whether firms may reimburse directors or responsible officers for civil penalties imposed pursuant to these regulations, and instead allows this question

to be resolved in accordance with applicable state law.[1]

(3) The definition of "defect," as applied to components themselves, has been restricted to include those deviations in delivered components from technical requirements included in the procurement document that could, on the basis of an evaluation, create a substantial safety hazard. Defect also includes a deviation in a portion of the facility subject to the construction permit or manufacturing licensing requirement of Part 50 provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance. Whether such deviation could result in a substantial safety hazard is determined during the deviation evaluation. Defect also includes, for facilities licensed for operation under Part 50, any condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit as set forth in the operating license technical specifications.

(4) The definition of basic components has been divided into two parts: one part is applicable to power reactors licensed under Part 50 and the second part is applicable to activities licensed pursuant to Parts 30, 40, 70 or 71 and to other Part 50 facilities. For power reactors the definition is based on the guidance given in Regulatory Guide 1.29. For other facilities and activities, basic component has been defined as components that are directly procured by a licensee.

(5) Substantial safety hazard has been defined in terms of a major reduction in the degree of protection provided to the public health and safety. Criteria that are appropriate for determination of creation of a substantial safety hazard include:

Moderate exposure to, or release of, licensed material.

Major degradation of essential safety-related equipment.

Major deficiencies involving design, construction, inspection, test or use of licensed facilities or material.

To the extent that failures to comply or defects in a security system can contribute to a substantial safety hazard, such failures and defects are within the scope of Part 21.

(6) Clarification has been added in regard to which organizations are subject to the regulations in this part. In order that the implementation of Section 206 may be responsive to anticipation of problems before the event, a broad interpretation of "firm constructing, owning, operating or supplying the components" has been used. This interpretation includes not only licensees and organizations that physically construct facilities and physically supply components but also includes organizations that only supply safety-related services such as design, inspection, testing or consultation: e.g., site geological investigations.

This interpretation is intended to bring within the regulations in this part those various organizations that can create a substantial safety hazard considering the various methods available for consultation, procurement, design, construction, testing, inspection and operation. These methods include not only the option where design and construction are accomplished by one organization but also the option where one organization does safety-related consultation, another safety-related design and another the actual construction. Each of these organizations has the capability to generate a defect and a potential for failing to comply.

If a basic component is fabricated by one organization using a design from another organization, the possibility of creating a substantial safety hazard, based upon a faulty design, exists upon the delivery of the design that fails to comply or contains a defect. A substantial safety hazard, based upon faulty fabrication, exists upon delivery of the item that fails to comply or contains a defect. In many instances the competent fabricating organization possesses neither the capability nor the responsibility for design.

It is realized that during the activities of design and consultation there may be a stage of conceptual design or consultation in regard to feasibility. Only when such a design or consultation can result in the creation of a substantial safety hazard is it appropriate to specify the applicability of Part 21 in the procurement document.

(7) The organizations subject to this part must establish procedures to provide for correction of deviations, or evaluation of deviations or informing purchasers of the deviation so the purchaser may evaluate the deviation. These procedures must also provide for informing a responsible officer or director of the organization of any resulting defect or failure to comply.

(8) The provisions of Part 21 imposing requirements that procurement documents state, when applicable, that Part 21 applies would be applicable only to future procurements of facilities, components or services; i.e., procured on or after six months after the effective date of Part 21.

The effective date of § 21.6 dealing with posting requirements, § 21.21(a) dealing with adopting procedures, and § 21.51 dealing with maintenance of records has been deferred until January 6, 1978, to allow organizations to establish and implement procedures.

(9) The organizations subject to the regulations in Part 21 are required to prepare records in connection with their activities to assure compliance with this part. Prior to destruction of such records they shall be offered to the purchaser. It is not anticipated that these documentation requirements will necessitate any change in the documentation procedures of organizations that are presently complying with 10 CFR 50 Appendix B, "Quality Assurance Criteria."

(10) Clarification has been added in regard to the applicability of Part 21 to the licensed activity of exporting. Persons who are only licensed to export nuclear facilities or materials and who do not otherwise construct or operate facilities or activities or supply components are not subject to the new part. Individuals subject to this part need report only defects or failures to comply which could create a substantial safety hazard in facilities and activities within the United States. Further, any notification submitted in accordance with Part 21 may be exempt from public disclosure as authorized by law.

After consideration of the comments received and other factors, the Commission has adopted the amendments to Parts 2, 21, 34, 35, 40, and 70, and the new Part 21 set forth below.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following new Part 21 of Title 10, Chapter 1 of the Code of Federal Regulations, and amendments to Parts 2, 21, 34, 35, 40, and 70 are published as a document subject to codification to be effective on July 6, 1977.

PART 2—RULES OF PRACTICE

Paragraph (b) of § 2.200 is amended to read as follows:

§ 2.200 Scope of subpart.

* * * * *

(b) This subpart also prescribes the procedures in cases initiated by the staff to impose civil penalties pursuant to section 234 of the Act and section 206 of the Energy Reorganization Act of 1974.

1. A new Part 21 is added to read as follows:

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

GENERAL PROVISIONS

Sec.

[1] While agreeing with all other aspects of this Notice, Commissioner Gilinsky believes firms should be barred from reimbursing directors or responsible officers for civil penalties imposed pursuant to Part 21, on grounds that Section 206 of the Energy Reorganization Act is designed to impose personal responsibility, a goal undermined by corporate indemnification. The Commission majority believes that in accordance with the general practice of Federal regulatory bodies in analogous matters, the question of the reimbursability of such penalties should be governed by applicable state law. It notes that the adverse publicity attendant on being subjected to a civil penalty for knowingly concealing significant safety information would be a major incentive to compliance, irrespective of whether the person so penalized was later reimbursed by the company. The majority also recognizes the serious practical difficulty in attempting to differentiate between a properly awarded salary increase or bonus and an improper reimbursement. If Part 21 does not in practice appear to be accomplishing its purpose, the Commission will, of course, propose changes deemed appropriate in light of experience.

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948; sec. 234, Pub. L. 91-161, 83 Stat. 444; sec. 206, Pub. L. 93-438, 88 Stat. 1244 (42 U.S.C. 2201, 2282, 5846).

GENERAL PROVISIONS

§ 21.1 Purpose.

The regulations in this part establish procedures and requirements for implementation of section 206 of the Energy Reorganization Act of 1974. That section requires any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

§ 21.2 Scope.

The regulations in this part apply, except as specifically provided otherwise in Parts 31, 34, 35, 40, or 70 of this chapter, to each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess, use, and/or transfer within the United States source, byproduct and/or special nuclear materials, or to construct, manufacture, possess, own, operate and or transfer within the United States, any production or utilization facility and to each director (see § 21.3(f)) and responsible officer (see § 21.3(j)) of such a licensee. The regulations in this part apply also to each individual, corporation, partnership or other entity doing business within the United States, and each director and responsible officer of such organization, that constructs (see § 21.3 (c)) a production or utilization facility licensed for manufacture, construction or operation (see § 21.3(h)) pursuant to Part 50 of this chapter or supplies (see § 21.3(l)) basic components (see § 21.3 (a)) for a facility or activity licensed, other than for export, under Parts 30, 40, 50, 70, or 71. 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.[1]

§ 21.3 Definitions.

As used in this part, (a) "Basic component," when applied to nuclear power reactors means a plant structure, system, component or part thereof necessary to assure (1) the integrity of the reactor coolant pressure boundary, (2) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (3) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 100.11 of this chapter; "Basic component," when applied to other facilities and when applied to other activities licensed pursuant to Parts 30, 40, 50, 70 or 71 of this chapter, means a component, structure, system, or part thereof that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect (see § 21.3(d)) or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard (see § 21.3(k)). In all cases "basic component" includes design, inspection, testing, or consulting services important to safety that are associated with the component hardware, whether these services are performed by the component supplier or others.

(b) "Commission" means the Nuclear Regulatory Commission or its duly authorized representatives.

(c) "Constructing" or "construction" means the 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 important to safety.

(d) "Defect" means:

(1) A deviation (see §21.3(e)) 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 (see § 21.3(g)), the deviation could create a substantial safety hazard; or

(2) The installation, use, or operation of a basic component containing a defect as defined in paragraph (d)(1) of this section; or

(3) A deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of Part 50 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; or

(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 pursuant to Part 50 of this chapter.

(e) "Deviation" means a departure from the technical requirements included in a procurement document (see § 21.3 (i)).

(f) "Director" means 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.

(g) "Evaluation" means the process accomplished by or for a licensee to determine whether a particular deviation could create a substantial safety hazard.

(h) "Operating" or "operation" means the operation of a facility or the conduct of a licensed activity which is subject to the regulations in this part and consulting services related to operations that are important to safety.

(i) "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.

(j) "Responsible officer" means 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 this part.

(k) "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, other than for export, pursuant to Parts 30, 40, 50, 70 and 71.

(l) "Supplying" or "supplier" means contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in this part.

§ 21.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 21.5 Communications.

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part should be addressed to the Director.

[1] NRC Regional Offices will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear safety-related problems. The location and telephone numbers (for nights and holidays as well as regular hours) are listed below:

Region:		
I (Philadelphia)	(215)	337-1180
II (Atlanta)	(404)	221-4503
III (Chicago)	(312)	858-2660
IV (Dallas)	(817)	234-2841
V (San Francisco)	(415)	486-3141

Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, or to the Director of a Regional Office at the address specified in Appendix D of Part 20 of this chapter. Communications and reports also may be delivered in person at the Commission's offices at 1717 H Street NW., Washington, D.C.; at 7920 Norfolk Avenue, Bethesda, Md.; or at a Regional Office at the location specified in Appendix D of Part 20 of this chapter.

§ 21.6 Posting requirements.

Each individual partnership, corporation or other entity subject to the regulations in this part, shall post current copies of the following documents in a conspicuous position on any premises within the United States where the activities subject to this part are conducted (1) the regulations in this part, (2) Section 206 of the Energy Reorganization Act of 1974, and (3) procedures adopted pursuant to the regulations in this part.

If posting of the regulations in this part or the procedures adopted pursuant to the regulations in this part is not practicable, the licensee or firm subject to the regulations in this part may, in addition to posting section 206, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

The effective date of this section has been deferred until January 6, 1978.

§ 21.7 Exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

NOTIFICATION

§ 21.21 Notification of failure to comply or existence of a defect.

(a) Each individual, corporation, partnership or other entity subject to the regulations in this part shall adopt appropriate procedures to (1) provide for (i) evaluating deviations or (ii) informing the licensee or purchaser of the deviation in order that the licensee or purchaser may cause the deviation to be evaluated unless the deviation has been corrected; and (2) assure that a director or responsible officer is informed if the construction or operation of a facility, or activity, or a basic component supplied for such facility or activity:

(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order or license of the Commission relating to a substantial safety hazard, or

(ii) Contains a defect. The effective date of this paragraph has been deferred until January 6, 1978.

(b) (1) A director or responsible officer subject to the regulations of this part or a designated person shall notify the Commission when he obtains information reasonably indicating a failure to comply or a defect affecting (i) the construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under Parts 30, 40, 50, 70 or 71 and that is within his organization's responsibility or (ii) a basic component that is within his organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under Parts 30, 40, 50, 70 or 71. The above notification is not required if such individual has actual knowledge that the Commission has been adequately informed of such defect or such failure to comply.

(2) Initial notification required by this paragraph shall be made within two days following receipt of the information. Notification shall be made to the Director, Office of Inspection and Enforcement, or to the Director of a Regional Office. If initial notification is by means other than written communication, a written report shall be submitted to the appropriate Office within 5 days after the information is obtained. Three copies of each report shall be submitted to the Director, Office of Inspection and Enforcement.

(3) The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

(iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(v) The date on which the information of such defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of all such components in use at, supplied for, or being supplied for one or more facilities or activities subject to the regulations 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.

(4) The director or responsible officer may authorize an individual to provide the notification required by this paragraph, provided that, this shall not relieve the director or responsible officer of his or her responsibility under this paragraph.

(c) Individuals subject to paragraph (b) may be required by the Commission to supply additional information related to the defect or failure to comply.

PROCUREMENT DOCUMENTS

§ 21.31 Procurement documents.

Each individual, corporation, partnership or other entity subject to the regulations in this part shall assure that each [redacted] or [redacted] has, her or it on or after January 6, 1978 [redacted]

INSPECTIONS, RECORDS

§ 21.41 Inspections.

Each individual, corporation, partnership or other entity subject to the regulations in this part shall permit duly authorized representatives of the Commission, to inspect its records, premises, activities, and basic components as necessary to effectuate the purposes of this part.

§ 21.51 Maintenance of records.

(a) Each licensee of a facility or activity subject to the regulations in this part shall maintain such records in connection with the licensed facility or activity as may be required to assure compliance with the regulations in this part.

(b) Each individual, corporation, partnership, or other entity subject to the regulations in this part shall prepare records in connection with the [redacted] the regulations in this part. After delivery of the facility or component and prior to the destruction of the records relating to evaluations (see § 21.3(g)) or notifications to the Commission (see § 21.21), such [redacted] of the facility or component. If such purchaser determines any such records:

(1) Are not related to the creation of a substantial safety hazard, he may authorize such records to be destroyed, or

(2) Are related to the creation of a substantial safety hazard, he shall cause such records to be offered to the organization to which he supplies basic components or for which he constructs a facility or activity.

If such purchaser is unable to make the determination as required above then the responsibility for making the determination shall be transferred to the individual, corporation, partnership, or other entity subject to the regulations in this part that issued the procurement document to the purchaser. In the event that the determination cannot be made at that level then the responsibility shall be transferred in a similar manner to another individual, corporation, partner-

ship, or other entity subject to the regulations in this part, until, if necessary, [redacted] ma-

(c) Records that are prepared only for the purpose of assuring compliance with the regulations in this part and are not related to evaluations or notifications to the Commission may be destroyed after delivery of the facility or component.

(d) The effective date of the section has been deferred until January 6, 1978.

ENFORCEMENT

§ 21.61 Failure to notify.

Any director or responsible officer subject to the regulations in this part who knowingly and consciously fails to provide the notice required by § 21.21 shall be subject to a [redacted] in an amount not to exceed [redacted] to provide such notice and a total amount not to exceed [redacted] failures to provide such notice occurring within any period of thirty consecutive days. Each day of failure to provide the notice required by § 21.21 shall constitute a separate failure for the purpose of computing the applicable civil penalty.

NOTE.—The reporting and record keeping requirements contained in this part have been approved by the General Accounting Office under B-180225 (RO 446).

PART 31—GENERAL LICENSES FOR BYPRODUCT MATERIAL

§§ 31.2, 31.5, 31.7, 31.8, 31.10, and 31.11 [Amended]

3. In 10 CFR Part 31, § 31.2(a) is amended by changing the words "Parts 19, 20, and 36" to read "Parts 19, 20, 21, and 36."

4. In 10 CFR Part 31, §§ 31.5(c)(10), 31.7(b), 31.8(c), 31.10(b)(3), and 31.11(f) are amended by changing the words "Parts 19 and 20" to read "Parts 19, 20, and 21."

PART 34—LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

§ 34.31 [Amended]

5. In 10 CFR Part 34, § 34.31(a)(2) is amended by changing the words "Parts 19 and 20" to read "Parts 19, 20, and 21."

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

§ 35.31 [Amended]

6. In 10 CFR Part 35, § 35.31(c) is amended by changing the words "Parts 19 and 20" to read "Parts 19, 20, and 21."

PART 40—LICENSING OF SOURCE MATERIAL

§§ 40.22 and 40.25 [Amended]

7. In 10 CFR Part 40, § 40.22(b) is amended by changing the words "Parts 19 and 20" to read "Parts 19, 20, and 21."

8. In 10 CFR Part 40, § 40.25(c) is amended by changing the words "Part 20" to read "Parts 20 and 21."

PART 70—SPECIAL NUCLEAR MATERIAL

§ 70.19 [Amended]

9. In 10 CFR Part 70, § 70.19(c) is amended by changing the words "Parts 19 and 20" to read "Parts 19, 20, and 21."

Dated at Washington, D.C., this 1st day of June 1977.

For the Nuclear Regulatory Commission.

SAMUEL J. CHILK,
Secretary of the Commission.

[FR Doc.77-13967 Filed 6-3-77;8:45 am]

Title 10—Energy

CHAPTER I—NUCLEAR REGULATORY COMMISSION

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

Reports to the Commission Concerning Defects and Noncompliance

Correction

In FR Doc.77-13987 appearing in the issue for Monday, June 6, 1977 on page 28891, on page 28894 § 21.3(d)(1) should read as follows:

§ 21.3 Definitions.

* * * * *

(1) A deviation (see § 21.3(e)) 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 (see § 21.3(g)), the deviation could create a substantial safety hazard; or

* * * * *

PART 2—RULES OF PRACTICE

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

PART 31—GENERAL LICENSES FOR BYPRODUCT MATERIAL

PART 34—LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

PART 40—LICENSING OF SOURCE MATERIAL

PART 70—SPECIAL NUCLEAR MATERIAL

Reports to the Commission Concerning Defects and Noncompliance; Extension of Effective Date

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Change of effective date of final rule.

SUMMARY: The Nuclear Regulatory Commission is changing from July 6, 1977 to August 10, 1977, the effective date of its recently published regulations which require directors and responsible officers of firms and organizations building, operating or owning NRC-licensed facilities, or conducting NRC-licensed activities, or supplying safety related components to report failures to comply with regulatory requirements and defects in components which may result in a substantial safety hazard. No change is being made in those portions of the regulations now subject to the deferred effective date of January 6, 1978. This change in effective date will give persons subject to the rule additional time to establish implementing procedures.

EFFECTIVE DATE: August 10, 1977. Certain obligations under the effective rule are not imposed until January 6, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. W. E. Campbell, Jr., Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. (phone: 301-443-6917).

SUPPLEMENTARY INFORMATION: On June 6, 1977, the Nuclear Regulatory Commission published in the FEDERAL REGISTER (42 FR 28891-28896, FR Doc. 77-13937) amendments to 10 CFR Parts 2, 31, 34, 35, 40 and 70 of its regulations and a new Part 21—Reporting of Defects and Noncompliance to implement section 206 of the Energy Reorganization Act of 1974, as amended (Public Law 93-438, 88 Stat. 1246-1247). As stated in the FEDERAL REGISTER notice, the effective date of the final rule was July 6, 1977, thirty days after the date of publication, except for certain portions of the rule for which the effective date was specifically deferred until January 6, 1978. The purpose of the deferred effective date was to allow organizations to establish and implement procedures to comply with certain provisions of the rule. On June 9, 1977, the NRC staff announced that five public meetings, hosted by each of its five regional offices, would be held during the period July 12 through July 26, 1977, for the purpose of explaining the provisions of the rule and answering any questions which might be raised concerning its implementation. As the effective date of the rule approached, several organizations expressed concern that they would not be able to have adequate interim procedures in place before the rule became effective, that they needed clarification of certain provisions of the rule and that it would be particularly helpful if the effective date of the rule were deferred for a period of approximately sixty days after the date of the last scheduled regional meeting.

As noted in the recently expanded delegation of authority to the Commission's Executive Director for Operations (42 FR 33290-33291, June 30, 1977, FR Doc. 77-18968) there are at the present time only two qualified members of the Nuclear Regulatory Commission. Since the Commission lacks a quorum for the transaction of business, the requests of organizations to postpone the effect date of 10 CFR Part 21 must be addressed, if they are to be addressed at all, by the Executive Director for Operations. Upon review of the final rule in the light of the concerns expressed and after consultation with the incumbent Commissioners in accordance with the provisions of his delegated authority, the Executive Director for Operations has determined that it would be in the public interest to postpone the effective date of the final rule until August 10, 1977. This extension would give persons and organizations affected by the rule an additional fifteen days after the date of the last NRC public informational meeting in which to put interim implementing procedures in place. The Executive Director for Operations has also determined that this change in the effective date of the final rule is a minor amendment which does not substantially modify existing regulations affecting the public health and safety, the common defense and security, or substantive or procedural rights and that he has been delegated authority to issue it. Since the purpose of this change in the effective date of the final rule is to allow organizations to obtain more information about its provisions prior to implementation, the Executive Director for Operations also finds that notice and public procedure thereon are contrary to the public interest and that there is good cause to make this change in the effective date of the final rule effective immediately upon publication in the FEDERAL REGISTER without the customary thirty day notice.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following change in the effective date of Title 10, Code of Federal Regulations, Part 21 is published as a document subject to codification.

1. In FR Doc. 77-13937 appearing at page 28891 in the FEDERAL REGISTER of June 6, 1977, the Ecective Date paragraph appearing on page 28892 in column 1 is revised to read as follows:

EFFECTIVE DATE: August 10, 1977. Certain obligations under the effective rule are not imposed until January 6, 1978.

(Sec. 161, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); Sec. 201, as amended, Pub. L. 93-438, 88 Stat. 1242, Pub. L. 94-79, 89 Stat. 413 (42 U.S.C. 5841).)

Dated at Bethesda, Md., this 5th day of July 1977.

For the Nuclear Regulatory Commission.

LEE V. GOSSICK,
Executive Director for Operations.

[FR Doc.77-18689 Filed 7-6-77;10:47 am]

REPORTS TO THE COMMISSION CONCERNING DEFECTS AND NONCOMPLIANCE

Correction

In FR Doc. 77-15967 appearing on page 28891 in the issue for Monday, June 6, 1977, on page 28894, § 21.3 (a)(3) should read as follows:

(3) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 100.11 of this chapter.

Section 21.3(d)(1) should read as follows:

§ 21.3 Definitions.

* * * * *

(d) "Defect" means:

(1) A deviation (see § 21.3 (e)) in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part 21, on the basis of an evaluation (see § 21.3(g)), the deviation could create a substantial safety hazard; or

* * * * *

Part III - Consolidation of Questions/Answers from Public Regional Meetings

The answers to numerous questions contained in this part represent the NRC staff's position on questions discussed at the public regional meetings. The staff has also attempted to include representative answers for all presubmittad questions received by each Regional Office prior to the day of the public meeting.

This material is structured so that the questions and answers follow the sequence in which the Preamble and Part 21 regulations were published in the Federal Register. For the convenience of the user, further separation of the question/answer material has been accomplished by division of certain subsections.

QUESTIONS/ANSWERS RELATING TO THE
PREAMBLE TO 10 CFR PART 21

Questions/answers relating to the Preamble published in the Federal Register with 10 CFR Part 21 which have not been answered by similar questions asked on the Part 21 regulations are included below.

1. Section 206(a) was changed during the legislative drafting from "...officer of a firm..." to "...responsible officer of a firm." Which officers of a firm are not responsible?

   Response:

   "Responsible officer," as defined by the rule means 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 this part.

   Therefore, officers with no executive authority over activities subject to Part 21 are not required to provide notification. For example, an officer that is not a "responsible" officer would be the Vice President in Charge of Community Affairs. During the legislative drafting of the Energy Reorganization Act of 1974 the words director, officer, agent, employee and responsible officer were used. During the Conference Committee proceedings the word "employees" was struck and the word "responsible" added in front of "officer."

2. Section 206(a) of the Energy Reorganization Act of 1974, as amended, 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." By what authority does the Commission apply Part 21 to persons who provide only design, inspection, testing or consulting services to firms which construct, own or operate an NRC licensed facility or activity?

   Response:

   Section 206 is a broadly worded statute by which the Congress intended to give the NRC responsibility to flesh out the bare bones of the statutory language and to develop workable definitions of terms and a workable implementation program. Part 21 defines the general terms "constructing," "operating," and "basic component"

which are used in the statute to include design, inspection, testing and consulting services associated with construction, operation and basic components that are important to safety.

3. What particular actions are required by a director, responsible officer or entity subject to Part 21 during the period of July 6, 1977 and January 6, 1978 since there are different dates in various portions of Part 21.

Response:

By 42 FR 34886 the July 6, 1977 date was changed to August 10, 1977. Between this date and January 6, 1978, entities subject to Part 21 should be accomplishing actions so they will be in full compliance by January 6, 1978. In the event that a director or responsible officer after August 10, 1977 obtains information reasonably indicating a defect or failure to comply, such individual is required to notify the Commission.

4. The Preamble states that Part 21 requires that organizations establish procedures to perform evaluations or inform the purchaser in order that the purchaser evaluate the deviation or have it evaluated. Do we have an option to establish procedures "or" inform the purchaser?

Response:

It is the staff's view that the evaluation should be accomplished at the lowest level where such capability to evaluate exists.

5. The Preamble states that "The organizations 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."

   a. Does this mean that the licensee plus all tiers of suppliers would be responsible for and accountable to the Commission for any fines deemed necessary by the Commission?

   b. If the answer is yes, will the fine levied be duplicated to all involved parties or will only the "responsible" individual be held liable for the fine?

Response:

   a. Yes. For power reactors, all tiers who have organizational responsibility for the failure to comply or defect would be subject to enforcement action.

b. Any director or responsible officer subject to Part 21 who, after obtaining information reasonably indicating failure to comply or a defect, fails to notify the Commission is subject to enforcement action.

6. The Act states that the identity of anyone reporting will be withheld from disclosure, as authorized by law. Would not the Sunshine law allow these names to be released to whoever requests?

Response:

Not necessarily. The Act does not discuss nondisclosure. The regulation states in §21.2, that as authorized by law the identity of anyone not subject to the Act who provides notification will be withheld from disclosure. Exemption 7 of the Freedom of Information Act permits an agency to protect the identity of confidential sources in law enforcement investigations.

7. Do you plan to issue a Regulatory Guide on the subject of Part 21.

Response:

As indicated in the Preamble, additional guidance in the form of regulatory guides may be developed should experience with the application of Part 21 indicate the need for such guidance.

8. How many occurrences do you expect to happen each year in design, construction, and operation that would be reported under Part 21?

Response:

The NRC expects that between 50 to 60 Part 21 notifications per year will be investigated, followed-up and substantiated.

9. Has the Commission made any attempt to estimate the financial and schedular impact of Part 21 on the nuclear program?

Response:

Resource allocations for NRC implementation of Part 21 have been estimated. The compliance burden for the implementation of Part 21 (record keeping and notification) has been considered. NRC has not estimated the compliance burden of meeting the overall requirements of Part 21; e.g., establishment of procedures.

10. With regard to reimbursement for civil penalties, the regulations leave the resolution of this matter to "applicable state law." Does this pertain to the state in which the organization involved is registered, the state in which the defect occurred or the state in which the licensed facility is located?

Response:

The question of which state has jurisdiction regarding remuneration of civil penalties is itself a question of state law. Part 21 does not in any way make this determination nor does it impact upon the determination. In other words, whether an organization may reimburse one of its employees for civil penalty under Part 21 is a matter for the determination by that organization and not by the Commission.

11. The Preamble uses the words "on the basis of an evaluation." Who is responsible for the evaluation, and, if it is the licensee or supplier, could not the NRC disagree with the technical evaluation?

Response:

Whether or not he has information reasonably indicating a failure to comply or a defect is initially a matter of judgment for the directors and responsible officers in question. Of course, any judgment that there does not exist a reportable defect or failure to comply is reviewable by NRC. Nevertheless, provided that the NRC determines that there is a reasonable basis for their judgment that a reportable defect or failure does not exist, the responsible officers and directors would not be subject to a civil penalty for knowingly and consciously failing to notify the Commission even if their determination was later found to be incorrect.

12. The terms "moderate exposure," "major degradation" and "major deficiencies" provide little guidance in determining whether a "substantial safety hazard" exists. Does "moderate exposure" mean a fraction of 10 CFR Part 100 limits? Does "major degradation" mean loss of redundancy? Does "major deficiency" mean loss of function or exceeding stress allowables?

Response:

"Moderate exposure" is discussed in the Commission's Policy Statement for Abnormal Occurrence Reports and was published in the Federal Register (42 FR 10950) on February 23, 1977. This information is also included in Appendix A, "Report to Congress on Abnormal Occurrences, NUREG-0090." Exposure in excess of 25 rem whole body and exposure to an individual in an unrestricted area of 0.5 rem are guidelines for determining "moderate exposure."

"Major degradation" is considered to be a loss of redundancy if, in conjunction with a single failure, a required safety function could not be performed.

"Major deficiency" means a condition or circumstance 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.

13. The Preamble Section (5) contains a definition of substantial safety hazard which includes: "Moderate exposure to, or release of, licensed material." Is there an interpretation of the word "moderate" as used here that might be comparable to the provisions of 10 CFR Part 20?

Response:

Yes. Moderate exposure to, or release of, licensed material, reportable under the provisions of §20.403(a)(1) or §20.403(b)(2) 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 (§20.105) would constitute "substantial safety hazards."

14. What does "Moderate exposure to, or release of, licensed material," mean in milling application?

Response:

In milling applications, moderate exposure to, or release of, licensed material, means:

a. Release of licensed materials which could produce whole body exposures to individuals in unrestricted areas approaching or exceeding the permissible dose of 500 mrem in one calendar year (10 CFR 20.105(a)) or;

b. Release of radioactive materials in concentrations which, if averaged over a period of 24 hours, would exceed 500 times the limits specified for such materials in Appendix B, Table II, 10 CFR Part 20 (10 CFR 20.403(b)).

Defects in scrubbers or dust collection systems used to control releases from ore crushing and grinding operations or yellowcake drying operations might lead to releases of radioactive materials large enough to be considered substantial safety hazards.

15. Is the site security system to be deemed "safety related" in accordance with this regulation?

Response:

As stated in item (5) of the Preamble to Part 21, "To the extent that failures to comply or defects in a security system can contribute to a substantial safety hazard, such failures and defects are within the scope of 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. 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. The staff view is that 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.

16. What is the relationship between requirements for "security systems" as regards Part 21 and the implementation schedule for 10 CFR Part 73?

Response:

The Preamble published with the effective rule indicated that failures to comply or defects in security systems can contribute to a substantial safety hazard. These deficiencies and noncompliance must be evaluated pursuant to Part 21 to determine if a notification to the Commission is required. The implementation schedule for recently promulgated rules addressing physical security at nuclear power plants does not affect the requirements of Part 21. Licensees are required to comply with those portions of §73.55 which are, in effect, to comply with their approved security plans and to evaluate deficiencies in their approved security systems. The new safeguard regulation's relationship to Part 21 is no different than the relationship of any other regulation to Part 21.

17. The Preamble discusses that the organization subject to Part 21 must also maintain records. Are records maintained in accordance with our internal procedures?

Response:

The procedures for maintenance of records would be in accordance with the organization's internal procedures but must comply with §21.51.

18. How does Part 21 interact with an approved Quality Assurance Program which is the established mechanism to control defects and deviations?

Response:

A quality assurance program, for example, in accordance with Appendix B to Part 50, should be the mechanism whereby assurance is provided that deviations and noncompliances do not occur and, where they do occur, they are detected and properly dispositioned.

As stated in the Preamble to the effective Part 21, it is not anticipated that the records required by Part 21 to assure compliance with this Part will necessitate any change in the documentation procedures of organizations that are presently complying and remain in compliance with 10 CFR Part 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants. Part 21 does contain some special requirements for records relating to evaluations and notifications required by Part 21, which are in addition to the records required by Appendix B.

19. The preamble stated in the July 7, 1977 notice in the Federal Register (42 FR 34886) extending the date for implementation of certain provisions until August 10, 1977 in order that "interim implementing procedures" are required to be in place by August 10, 1977. This appears to be a new requirement not mentioned in Part 21, as promulgated. We are interested in a discussion of the NRC's basis for such interim procedures and the contemplated scope of such procedures.

Response:

Some organizations that were within the scope of Part 21 saw the need to have in place "interim procedures" between July 6, 1977 and January 6, 1978, and they requested that the July 6 date be delayed about 3 months. The Commission, by 42 FR 34886, delayed the date to August 10, 1977, in order that those organizations could "put interim implementing procedures in place." Part 21 does not require the adoption of implementing procedures until January 6, 1978.

QUESTIONS/ANSWERS RELATING TO 10 CFR PART 21

§21.1 Purpose

The regulations in this part establish procedures and requirements for implementation of section 206 of the Energy Reorganization Act of 1974. That section requires any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

1. In section 21.1(a), what is meant by "activity"?

Response:

The term "activity" used in 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. For example, these include activities regulated under 10 CFR Part 50, other licensed activities such as medical radiation therapy, industrial radiography and activities specifically included by the §21.3(a) definition for basic component.

2. Which sections of the Atomic Energy Act of 1954, as amended, and which of the Commission's rules and regulations does the Commission see as being related to a substantial safety hazard so that noncompliance with such provisions is reportable? (A list of sections and regulations would be desirable.)

Response:

While all Commission rules and regulations are publicly available through the FEDERAL REGISTER, and for the most part relate to the prevention of substantial safety hazards, it is not practical to prepare a specific list or even a precise correlation of all factors which could contribute to a substantial safety hazard.

§21.2 Scope

The regulations in this part apply, except as specifically provided otherwise in Parts 31, 34, 35, 40, or 70 of this chapter, to each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess, use, and/or transfer within the United States source, byproduct and/or special nuclear materials, or to construct, manufacture, possess, own, operate and or transfer within the United States, any production or utilization facility, and to each director (see § 21.3(f)) and responsible officer (see § 21.3(j)) of such a licensee. The regulations in this part apply also to each individual, corporation, partnership or other entity doing business within the United States, and each director and responsible officer of such organization, that constructs (see § 21.3 (g)) a production or utilization facility licensed for manufacture, construction or operation (see § 21.3(h)) pursuant to Part 50 of this chapter or supplies (see § 21.3(l)) basic components (see § 21.3 (a)) for a facility or activity licensed, other than for export, under Parts 30, 40, 50, 70, or 71. 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.

1. Since Section 206(a) refers only to "firms," why does Part 21 apply to organizations that are not firms; e.g., licensees like the National Bureau of Standards and TVA?

   Response:

   In reviewing the legislative history of Section 206 it, appears that the use of the terms "firm owning" and firm operating" were used for ease in drafting the legislation. If the term "licensee" were used, it would have to be in addition to the present terms since some licensees construct, own, and operate while others just operate. Section 206 uses "firm" 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.

2. How does Part 21 relate to activities considered under Section 274 of the Atomic Energy Act, "Cooperation with States"? For example, a teletherapy machine produced in an Agreement State and used in a licensed activity in a non-Agreement State. An opposite example should aso be discussed.

Response:

Part 21 applies (unless there exists a specific exemption) to the directors and responsible officers of organizations that construct, own, operate, or supply components of a facility or activity licensed or otherwise regulated by the Nuclear Regulatory Commission pursuant to the regulations in Title 10 of the Code of Federal Regulations. Thus the provisions of Part 21 would not apply directly to those facilities or activities which, under Section 274 of the Atomic Energy Act of 1954, as amended, and the applicable state agreement, are the regulatory responsibility of the Agreement State.

This means, in the case of the example given, that the producer of the teletherapy machine who is located in an Agreement State would not be required as a licensee to notify the Commission of a failure to comply or a defect in the construction or operation of the machine or its components which otherwise would be reportable under Part 21, although he is certainly encouraged to do so. The producer of the teletheraphy machine may nevertheless be required to report under Part 21 a defect or failure to comply in the machine in his capacity as a component supplier. If the producer directly supplies the machine to a licensee or purchaser which is subject to Part 21 such as, for example, a licensee in a non-Agreement State, the producer of the machine would be required to notify NRC if he has information of a defect or failure to comply in the machine. The user of the teletherapy machine, who is located in a non-Agreement State and who therefore is licensed or regulated by NRC, would be subject in all cases to the reporting requirements and enforcement provisions of Part 21.

Reversing the example, the producer of the machine in a non-Agreement State would be required to notify NRC of any failure to comply or any defect in the construction or operation of the machine which is reportable under Part 21, but the user of the machine who is located in an Agreement State would not be subject to these reporting requirements, although, again, he would be encouraged to report such defects or failures to comply to the Commission.

3. Are Agreeement States compelled to adopt 10 CFR Part 21 or to comply with it through licensing modifications?

Response:

No. The Commission has not forwarded Part 21 to the Agreement States for compatibility review and Agreement States are not compelled to adopt Part 21 or similar requirements.

4. What is the applicability of Part 21 to items whose fabrication is not licensed; that is, packaging (Part 71) and radiographic exposure devices (Part 34) that are utilized in a licensed activity?

Response:

If the fabrication is not licensed and the item is a "basic component" as defined in §21.3, then it is within the scope of Part 21. "Packaging," as defined in Part 71, and "radiographic exposure devices," as defined in Part 34, are in general procured by the activity licensee and would therefore be within the scope of Part 21.

5. What is the authority for the Commission's application of Part 21 to persons who are not Commission licensees?

Response:

Section 206 of the Energy Reorganization Act of 1974, as amended. Section 206(a) imposes reporting responsibility on directors and responsible officers of firms constructing, owning, operating or supplying the components of any facility or activity 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. In other words, the thrust of Section 206 goes beyond those entities licensed or previously regulated by the Commission to all entities which engage in the activities described in the statute.

The terms "constructing" and "supplying" are defined in Sections 21.3(c) and (l) of Part 21. 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 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 Part 21.

6. Are non-radiological hazards covered by Part 21? Example, chemicals released to streams or rivers.

Response:

No. Part 21 applies only to radiological health and safety.

7. Does Part 21 apply to applicants for 10 CFR Part 50 licenses as well as to NRC licensees and licensed activities?

Response:

It is the NRC staff position that Part 21 applies to applicants for 10 CFR Part 50 licenses as well as licensees. Section 21.2 is intended to specify those types of activities associated with the facilities and activities subject to licensing and regulation by the Commission which are covered by Part 21. Applicants for 10 CFR Part 50 licenses or permits, to the extent that they engage in the specified activities, are subject to Part 21. This intent is further evident in Section 21.21(b) which requires that a director or responsible officer notify the Commission when he obtains information reasonably indicating a failure to comply or a defect affecting (1) the construction or operation of a facility or activity within the United States which is subject to the licensing requirements of 10 CFR Parts 30, 40, 50, 70 or 71, or (2) a basic component for such facility or activity.

8. Please identify the threshold point at which such applicability commences in the case of a project not yet licensed (e.g., one which is in hearings regarding the issuance of a construction permit).

Response:

The NRC staff takes the view that an entity becomes subject to Part 21 at that point when it first engages in the activities subject to Part 21 which are described in Section 21.2. Thus, a utility would be subject to Part 21 when it first engages in the enumerated construction activities, including safety-related design work, for a 10 CFR Part 50 facility. This is similar to the requirements for a quality assurance program as specified by 10 CFR Part 50, Appendix B, in that the requirements are effective prior to tendering an application.

9. What are the duties and responsibilities of co-owners of a facility under Part 21 where the co-owners (a) are financial partners only, or (b) have some operational or construction responsibility for the facility?

Response:

A director or responsible officer of a co-owner organization 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 his organization's responsibility. Nevertheless, the rule, as presently drafted, requires the co-owner organization to meet certain other requirements of Part 21, including adopting internal procedures under Section 21.21(a), which are scheduled to take effect on January 6, 1978. The NRC staff recognizes that this result would be incongruous and is therefore considering possible modifications to Part 21 which would remove this incongruity.

Co-owners who have retained some responsibility for constructing or operating the facility or activity are subject to the reporting requirements of Section 21.21(b) and will be subject to other requirements of Part 21 on January 6, 1978.

10. Is a holding company subject to Part 21 where it holds stock in a subsidiary company which owns and operates a nuclear facility?

Response:

No. Holding companies which are not themselves licensed and which do not themselves engage in constructing or operating the facility would not be subject to Part 21.

11. Why was 10 CFR 20 not included along with Parts 2, 31, 34, 35, 40, and 70?

Response:

NRC does not license any facility or activity under Part 20.

12. Are general licensees (Section 31.5) exempted from Part 21?

Response:

Some general licensees, including those licensed only under §31.5, are exempt from Part 21. See item 4 on page 42 FR 28896.

13. Are firms who supply Health Physics service to a power plant subject to Part 21?

Response:

Yes - if the failure to provide the required service could create a substantial safety hazard.

14. Are medical physicists who provide consulting services such as calibration of teletherapy machines subject to Part 21? If a hospital determines that this medical physicist provided incorrect calibration charts which resulted in a substantial safety hazard, should the hospital report this under Part 21?

Response:

a. Yes - if the services of such an individual are directly procured by the licensee.

b. Yes.

15. How is Part 21 applicable to industrial radiography?

Response:

Pursuant to Section 21.1 of Part 21, the regulations apply to each entity licensed to possess, use, and/or transfer within the United States source, byproduct and/or special nuclear materials, etc. Pursuant to Section 34.31, the licensee (using sealed sources in radiography) shall not permit any person to act as a radiographer until such person "has received copies and instructions in the regulations contained in this part and the applicable sections of Parts 19, 20 and 21 of this chapter...."

In practice, each entity licensed to use radioisotopes for radiographic inspection is required, in accordance with the provisions of Part 21, to evaluate whether a deviation in a basic component delivered for use in the licensed activity is in effect a defect which could create a substantial safety hazard to operating personnel or others and, if so, to notify the Commission of such defect pursuant to §21.21. In addition, failure to comply with safety procedures or licensed conditions would also be reportable under the provisions of Part 21 if such failure could create a substantial safety hazard.

16. Are firms who supply waste dispcsal service subject to Part 21?

Response:

Yes - if the failure to provide the required service could create a substantial safety hazard.

17. Does Part 21 apply to "carriers?"

Response:

Part 21 does not apply to "carriers." Carriers do not fall within the definitions of licensees or suppliers as used in 21.2 and 21.3(1) of the regulation. However, suppliers and licensees at both ends of the carrier transaction, that is the entity that delivers a component to a carrier and the entity that receives the component, may be subject to Part 21.

18. Are carriers who have approved physical security plans under 10 CFR Part 73 subject to Part 21?

Response:

No. They are not licensed by NRC nor do they provide basic components as defined in Part 21.3(a). These services differ from services defined in §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 his area of responsibility, he is required to report.

19. Does Part 21 apply to nuclear safety programs of fuel fabricators?

Response:

Yes. Fuel fabricators are subject to Part 21 both as material licensees and in general as suppliers to reactor licensees.

20. Does Part 21 apply to Federal, State and local governments?

Response:

If an entity of the Federal government or a State or local government engages in the activities described in Section 21.2, then it is subject to Part 21.

21. Do the provisions of Part 21 apply to an educational institution which possesses a license for a research reactor or to possess byproduct or special nuclear material?

Response:

Part 21 applies not only to reactor licensees but also to source, byproduct and special nuclear material licensees. Educational institutions, as a licensee under 10 CFR Part 50 for a research

reactor or as a licensee for byproduct or special nuclear material, are within the scope of Part 21. Therefore, the provisions of Part 21 apply to the institution and to its first tier suppliers of basic components.

22. Is it planned to incorporate the requirements of 10 CFR Part 21 into the Technical Specifications of Operating Reactors?

Response:

No.

23. Is there a statute of limitations for a knowing and conscious failure to notify of a substantial safety hazard and if so, is this governed by the applicable law of the state in which the nuclear facility is located?

Response:

The imposition of a civil penalty under 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 Part 21.

24. Does an organization's obligation to comply with these rules terminate for each facility when its contractual services are completed for that facility?

Response:

No. Obligations to comply with Part 21 do not end when contractual services are completed. If after a service has been performed, an organization discovers a deviation from the contractual requirements then it must evaluate it or inform the purchaser of the deviation and if the evaluation determined that a defect exists a notification is required.

25. In 1975 the release by the NRC of information received in confidence from a foreign source caused major problems and the NRC indicated that it would take steps to correct such problems.

What actions have been taken by the NRC to protect against infringement on the practices of foreign countries related to defect reporting in the U.S.?

Response:

First, the new Part 21 requires reporting of defects in U.S. reactors, not defects in foreign reactors unless such information is necessary for the full reporting of defects and noncompliances in similar U.S. reactors. Second, in press releases and answers to questions about U.S. reactor problems, it is now our practice to avoid mention of similar foreign reactor problems. Third, NRC has advised the concerned foreign officials that NRC will take all appropriate steps to protect information which NRC receives in confidence from them.

26. Is the NRC obligated by existing agreements with foreign governmental authorities to disclose information obtained in confidence from foreign sources? If so, what is the basis for such obligations. Can the obligation be changed?

Response:

The spirit and intent of our international agreements require sharing such information. When NRC learns of defects in a U.S. reactor that reflect probable defects in similar foreign reactors, we routinely advise the foreign authorities of these possible safety problems.

NRC would normally not have to identify the foreign reactor which was the source of our original advice. If the foreign government, on hearing of the defect in a U.S. reactor, asked for more information involving the source of our advice, the staff would coordinate with the source concerning providing such information. Incidentally, our international agreements provide that the foreign government will likewise honor this commitment to non-disclosure of any information NRC does give them in confidence.

27. In the event of a Freedom of Information Act request, is the NRC confident that it can prevent disclosure of information received in confidence from foreign sources?

Response:

U.S. law provides for exemption from public disclosure of information which is "commercial confidential" or trade secrets ("proprietary"), including information which a foreign government gives us, or allows us to receive, under the condition that it be protected from disclosure (See 10 CFR 2.790(d)(2)).

28. If a request for information received in confidence from foreign sources is received in a licensing hearing, what means are available to protect the information from disclosure to intervenors?

Response:

The protection of proprietary information in a licensing hearing is the responsibility of the presiding officer. If it is found that the information sought is relevant and not otherwise available to the requesting party, then the presiding officer is empowered to order the disclosure of such information under appropriate protective condition, such as disclosure in camera, or under protective seal.

If the information sought is being protected, under international obligation at the request of a foreign government, then the protection of the national security laws may also apply.

29. Does Section 21.21(b)(3) require the identification of the source of foreign information or is the reporting requirement limited to identification of activities in the U.S. which fail to comply or caused a defect?

Response:

Part 21 requires only reporting on the U.S. plants involved - not identification of the source of foreign information.

30. How are the interests of the foreign utilities protected so that operational information from foreign utilities will continue to flow into the United States and not cease as a result of this regulation?

Response:

The protection described above applies to foreign utilities as well as to U.S. parties.

31. Will it be required to report defects which occur in foreign plants to the same depth and scope as defects which occur in U.S. facilities? If the nature of the defect report makes the identity of the foreign plant obvious, what procedures will the Commission use to assure that disclosure of the information will not be at variance or contrary to the practices of the foreign country?

Response:

No. Part 21 requires only sufficient information from foreign experience, which reflects a defect in a U.S. plant, to make the notification useable in NRC safety work. Any information given which is confidential will be protected as described above.

32. What type of security clearance, if any, will be required by U.S. suppliers in order to communicate defect information to the NRC for defect information received from foreign facilities?

Response:

To notify NRC of foreign proprietary information, no clearance is required. Those few persons who had to receive this proprietary information would have to sign agreements of confidentiality. In any discussions involving confidential foreign information, which NRC has decided to protect by classifying (or to recognize foreign classification), representatives of U.S. suppliers would need security clearances at the appropriate level.

33. Does Part 21 apply to foreign manufacturers of basic components or their subcomponent parts? Does this regulation prohibit purchases of basic components from non-U.S. suppliers?

Response:

Under certain circumstances Part 21 would apply to component suppliers located outside of the United States. Section 21.2 states that 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 30, 40, 50, 70 or 7[illegible] of the Commission's regulations. Although the phrase "doing business within the United States" is not defined specifically in the regulation, similar terminology has been interpreted, in other contexts, to include a foreign manufacturer who contracts to sell his product to a United States purchaser. This could mean that a foreign entity which contracts with a U.S. purchaser to supply a basic component for a facility or activity covered by Part 21 would be subject to the requirements of the rule to the extent that the United States has jurisdiction over the foreign entity and its officers. The rule does not prohibit purchases from non-U.S. suppliers of basic components.

34. Can the penalties for noncompliance be enforced upon foreign suppliers?

Response:

The penalties for noncompliance with Part 21 can be enforced on foreign suppliers only where the United States has jurisdiction over the foreign entity and its officers.

35. May individuals other than those required to provide notifications, including members of the general public, provide information concerning known or suspected defects or failures to comply? If yes, how?

Response:

Yes. The rule specifically states that nothing in these regulations should be deemed to preclude an individual, including members of the general public, not subject to Part 21 from reporting to the Commission a known or suspected defect or failure to comply. In the case of an employee of an organization subject to Part 21, it is anticipated first that this individual will bring the information to light within the organization for which he works. In the event that this channel is not available or is deemed to be ineffective to the person possessing the information, such person can call the regional office collect. Phone numbers are contained in the rule itself, therefore, there is a vehicle via which an individual may communicate the information to the Nuclear Regulatory Commission. If anonymity is requested, it will be granted within the limits allowed by law.

36. Who is responsible for performing evaluations of suspectsd defects which are reported to NRC by a member of the general public?

Response:

NRC will investigate, or cause to be investigated, reports of defects which are made pursuant to Part 21.

21.3 Definitions

§21.3(a) Basic Component

As used in this part, (a) "Basic component," when applied to nuclear power reactors means a plant structure, system, component or part thereof necessary to assure (1) the integrity of the reactor coolant pressure boundary, (2) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (3) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 100.11 of this chapter; "Basic component," when applied to other facilities and when applied to other activities licensed pursuant to Parts 30, 40, 50, 70 or 72 of this chapter, means a component, structure, system, or part thereof that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect (see § 21.3(d)) or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard (see § 21.3(k)). In all cases "basic component" includes design, inspection, testing, or consulting services important to safety that are associated with the component hardware, whether these services are performed by the component supplier or others.

1. How is "safe shutdown" to be interpreted?

   Response:

   The term "safe shutdown" appears in the definition of basic component in Section 21.3(a), wherein it states that basic components include plant structure, systems and components "necessary to assure. . . (2) the capability to shutdown the reactor and maintain it in a safe shutdown condition. . .". Maintenance of a safe shutdown condition refers to the ability to achieve and maintain the reactor in the cold shutdown condition for an indefinite period. Regulatory Guide 1.29 provides additional guidance which may be utilized in determining which basic components are necessary to assure "safe shutdown."

2. Does Part 21 apply to only "safety related" items?

Response:

Yes. 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 Nuclear Regulatory Commission; therefore only those items which are "safety related" are within the scope of Part 21.

3. The definition of a "basic component" is not clear, for example, does it apply to a valve supplied to a pump manufacturer for inclusion on the pump? An instrument supplied to the valve manufacturer? An electrical component (switch, relay, etc.) supplied to the above instrument supplier? How far down toward items such bolts, nuts and "raw material" does Part 21 apply in this case?

Response:

In the case of power reactors additional guidance on basic components is provided in Regulatory Guide 1.29. Additionally, each applicant for a power reactor operating license or construction permit must in his safety analysis report identify those systems, components and structures which are seismic Category I (FSAR Section 3.2.2). These equipments, components, and structures, as well as their design and safety related services, are defined as basic components in Part 21. Basic component, when applied to other regulated activities, means a component, structure system or part thereof that is directly procured by the licensee of the facility or activity subject to Part 21, in which a defect or failure to comply could create a substantial safety hazard. As applied to nuclear power reactors basic component goes down all tiers of the supply or procurement chain to all activities within the chain who have the capability to create a substantial safety hazard.

4. A plant manufactures commercial products which the power industry purchases for use in both fossil and nuclear applications:

   a. We are not a qualified supplier to ASME Code 3 requirements.

   b. We supply products meeting 10 CFR 50 Appendix B and are listed under CASE (Coordinating Agency for Supplier Evaluation).

   Do we fall under the rules of Part 21?

Response:

Yes, you do come under Part 21 if the products which you furnish for use in nuclear applications are basic components,

as defined in §21.3(a), which could create a substantial safety hazard, as defined in §21.3(k).

5. Does Part 21 also apply to suppliers of consumables such as welding material and services such as calibration.

Response:

Yes. Where the consumable or calibration service is related to a basic component and a deviation from specified requirements of a procurement document, or failure to comply, could create a substantial safety hazard.

6. Are purchased "off-the-shelf" items such as material obtained from a distributor or a material supplier or items such as switches, pumps, respirators and filters subject to 10 CFR 21?

Response:

Yes, if the off-the-shelf item is within the definition of basic component as defined in §21.3(a).

7. Is a hospital using a teletherapy machine subject to Part 21? If an interlock switch (an "off the shelf" item) fails after a period of time does the hospital have to report it under Part 21 if the switch could have resulted in a substantial safety hazard? If the answer is "yes", what parts of a teletheraphy machine are considered to be subject to Part 21?

Response:

A hospital licensed by NRC to use a teletherapy machine is subject to Part 21. A failure in any part of the machine (including off-the-shelf item) would be a reportible defect if: 1) the part that failed did not conform to the technical requirements included in the procurement document (§21.3(e)); 2) the part that failed was a basic component (§21.3(a)); and 3) the failure could, based on an evaluation, create a substantial safety hazard.

8. Which "off-the-shelf" items used by a manufacturer of teletherapy machines (examples: on-off indicators, lead, etc.) are considered to be basic components? If 100 switches are purchased by this manufacturer as "off-the-shelf" items does the procurement document have to state that these parts are subject to Part 21?

Response:

Any components procured directly by an NRC licensee in which a defect or failure could create a substantial safety hazard are basic components. If any of the 100 switches is to be used as a basic component then the procurement document must state that Part 21 applies.

9. Consider a licensee whose licensed activities are only incidental to the products/services it supplies in which case the products and/or services themselves are not licensed. Is it proper to assume that Part 21 is applicable to these products and/or services only when so stated in procurement documents?

Response:

If the product or service constitutes a basic component within the meaning of Part 21, then the licensee is subject to Part 21 as a supplier of basic components. Where the licensee is supplying a basic component, it is subject to the reporting requirements whether or not the procurement document indicates that Part 21 applies.

10. As used in Section 21.3(a) does "failure to comply" require that an evaluation be done in order to determine whether a substantial safety hazard is created?

Response:

Section 21.21(b)(1) requires that failures to comply which relate to a substantial safety hazard be reported. The rule is silent on how to determine if a failure to comply is related to a substantial safety hazard.

11. In Section 21.3(a) what is the meaning of "component hardware?" Is a consultant service which provides dosimetry services (TLD dosimeters and film badges) providing component hardware that is subject to Part 21?

Response:

As used in §21.3(a), "component hardware" would include all physical elements included by the term basic component, such as: plant, structure, system, component or part of a licensed facility.

No, dosimetry services do not constitute design, inspection, testing or consulting services important to safety that are associated with a basic component as defined in section 21.3(a).

Reporting under Part 21 would be required, however, if, in connection with the dosimetry service, there existed a failure to comply with an applicable rule, regulation, order or license of the Commission relating to a substantial safety hazard.

12. §21.3 states -- In all cases "basic component" includes design, inspection, testing, or consulting services "important to safety...". Clarify the meaning of this statement.

Response:

The broad scope of Section 206 activities of construction, operation, owning and supplying in themselves include activities such as design, consultation or inspection that are important to safety and are associated with component hardware. Thus, such activities which could in themselves result in creating or identifying a defect in associated hardware, system or structure are included in the definition of basic component. An organization may accomplish all of these activities in-house or may choose to authorize others to do some of the safety-related activities; e.g., consultation, design, inspection or tests, for it. When such contractural arrangements are made for safety-related services the organization accomplishing the service is within the scope of Part 21.

13. In paragraph 21.3(a) the last sentence seems to imply the Directors and Responsible Officers of an Authorized Nuclear Inspector organization fall under the purview of Part 21. Is this a proper assumption?

Response:

Yes, Part 21 does apply to suppliers of services or items performing activities within the scope of the definition for "basic components." This does include the contracted services of an Authorized Nuclear Inspector.

14. As background to the questions asked below, property insurance coverage for a nuclear facility can be for Fire and Extended Coverage and/or Boiler and Machinery Coverage. Such policies of insurance reportedly do not require the insurer to make inspections of an insured facility for purposes of loss prevention, but can so allow such inspections to be made if the insurer so desires. Such loss prevention inspections of an insured facility are for various purposes such as, determining the underwriting risk, calculation of premiums and loss prevention. A general question with specific examples concerning the applicability of Part 21 to such services is presented as follows:

Is an insurance company which insures an NRC licensed facility and, as a part of its insurance contract, includes and makes regularly scheduled inspections of these licensed facilities and, as a result of these inspections offers written advice to the insured concerning fire, explosion, pressure vessel and machinery breakdown protection considered to be within the category of organizations supplying safety related design, testing, inspection and consulting services? Specific examples are:

a. For Fire and Extended Coverage inspections made but not required by the insurance policy - are defects, deviation, or deficiencies which are uncovered that could result in a "substantial safety hazard" to be reported to the NRC by the insurance company as outlined in Part 21?

b. Same questions as (1), except substitute "Boiler and Machinery Coverage" for "Fire and Extended Coverage."

c. Same questions as (1) and (2), except that inspections are made because of insurance participation in MAERP or NEL-PIA.

Response:

If the information is given gratuitously by the insurance company as merely a part of its own protection in supplying insurance, in contrast with a customer contract requirement, then it does not fall within the cateogry of organizations that supply safety-related services. Where the information offered by the insurance company includes the indentification of a possible failure to comply or a defect - the insurance company is not required to report to the NRC. However, licensees receiving such information would need to address in their procedures whether it will be necessary to conduct an evaluation to determine if, indeed, a substantial safety hazard does exist. If, however, a licensee contracts for these services then the insurance company would be subject to Part 21.

15. Are insurance companies performing contracted inspections associated with basic components required to report under Part 21.

Response:

The insurance company is not required to report under §21.21b if the insurance company identified in his report to his purchaser all deviations from established requirements discovered during the inspection he was contracted to conduct.

If, after delivery of the completed inspection report, the insurance company was to become aware of a deviation in a basic component that was not reported the insurance company would a) be 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.

16. If the insurance or testing agency company 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, must the company notify NRC as outlined in Part 21?

Response:

No.

17. Does Part 21 apply to a consultant who conducts site investigations to establish geologic and seismic data for engineering analysis and design of nuclear power plant foundations and structures? If it does, give an example of a site-related defect.

Response:

The rule notes that a consulting service for a facility or activity important to safety is subject to the rule. Therefore, a consultant who conducts site investigations and prepares data on safety-related site characteristics is subject to Part 21. 10 CFR Part 100, Appendix A, Seismic and Geologic Siting Criteria for Nuclear Power Plants, is the governing rule.

The discovery and evaluation of a new site feature, such as a fault or area of unstable ground which could present a substantial safety hazard, would be reportable under Part 21 only after the originally contracted data is delivered to the purchaser and the evaluation of the new condition identifies the existence of a defect in the original data which, if used, will substantially reduce the safety function of the facility.

Definitions

§21.3(d) Defect

(d) "Defect" means:
(1) A deviation (see § 21.3 (e)) 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 (see § 21.3(g)), the deviation could create a substantial safety hazard; or
(2) The installation, use, or operation of a basic component containing a defect as defined in paragraph (d)(1) of this section; or
(3) A deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of Part 50 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; or
(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 pursuant to Part 50 of this chapter.

1. Please define or discuss the term "delivered to a purchaser for use" as used in subsection 21.3(d)(1). Does this mean that a deviation can only be classified as a defect if it was not detected by a receiving inspection? Discuss the situation where a deviation is detected by receiving inspection and a Nonconformance Report is issued. Is this a potential defect: i.e., the component was "delivered for use" by the supplier, but not "delivered for use" to the constructor or owner.

   Response:

   Section 21.3(d)(1) defines a reportable defect as a deviation in a basic component delivered to a purchaser for use in a facility or activity subject to Part 21 where it is determined that the deviation could create a substantial safety hazard. In determining whether a basic component has been delivered, the basic element, in the staff's view, 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, it is the staff's position that "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 he had delivered components with similar deviations to other facilities or activities subject to Part 21.

2. Is a nonconforming item, discovered after release by a supplier, which upon evaluation could create a substantial safety hazard but which will be reworked to full compliance with the procurement documents reportable under Part 21?

   Response:

   If a deviation -- that is, a departure from the technical requirements included in the procurement document for a basic component -- is identified in that basic component which has been delivered to a purchaser, then an evaluation must be performed. If the evaluation identifies a defect, then it must be reported even though the purchaser or supplier may subsequently rework the component to full compliance with the procurment document.

3. Does the concept of "delivered" in §21.3(d)(1) require that the basic component be turned over from one corporation or separate entity to another corporation or entity or could something be delivered within a single corporation? Suppose the fabricator of the component is also the licensee of the reactor -- at what point is there delivery so that there could be a "defect?"

   Response:

   The rule makes no distinction between inter and intra entity delivery of components as long as the transaction occurs pursuant to a procurement document. In determining whether a component has been delivered, the basic element is when the purchaser has taken control over the item.

4. Are we operating within the intent of 10 CFR Part 21 by defining, for purposes of compliance with this regulation, the term delivery to mean:

   a. that point after receipt of materials from a supplier when an inspection report, indicating acceptability of the materials for fabrication, is issued:

b. that point, after fabrication and shipment to the site where erection will be performed by a third party when an acceptance is issued by the erector;

c. that point, after fabrication and shipment to the site where the fabricator will also perform the erection, that the fabrication is offered to the client as completed.

Response:

Yes, but see response to 1 above in regard to applicability of receipt inspection.

5. If our customer purchases a nuclear plate to the requirements of the Code including ultrasonic testing to the material requirements of A578 level 1, then upgrades by test to their customer's specification which is tighter than the ASME Code and finds a rejectable indication under their customer's specification, are we responsible to report to the Commission?

Response:

No. The delivered basic component did not deviate from the procurement document specification (A578 level 1), therefore no defect exists.

6. It is the opinion of the QA Manager that Part 21 requires no change in QA Manual or procedures nor additional action. The controlled manufacturing system described in our QA Manual will prevent our offering an N-Stamped product for customer acceptance with known conditions that could:

1. Create substantial safety hazard;

2. Deviate from technical requirements included in the procurement; or

3. Contribute to exceeding a license designated safety limit.

Therefore, we believe there is no need to notify employees or vendors of Part 21 again because of our compliance with provisions of an approved QA Manual. Is this correct?

Response:

The assumption appears to be made that because a company has a controlled manufacturing system in accordance with their QA Manual,

there is no possibility that any deviation could exist in a delivered component. Therefore, the provisions of Part 21, such as the requirements of sections 21.6 and 21.31, would not apply. This assumption is incorrect. Any organization supplying a basic component as defined in Section 21.3(a) is subject to Part 21.

7. Is it the intent of Part 21 that findings currently treated under the Operational Quality Assurance Program (audit reports, nonconformance reports) may be reported to the NRC? A specific example of a nonconforming item is a power reactor is a spare part that was returned to the vendor because it did not satisfy some feature in the purchase requirements. Is this action reportable under Part 21?

Response:

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 he has delivered similar defective parts to others. A defect in a spare part which is found after it is under the control of the purchaser, that is after delivery, and receipt inspection and acceptance by the purchaser, would be reportable under Part 21.

8. If a deviation is discovered after delivery, but before installation, who do we notify? Our buyer? Owner/Operator? Do we need to notify NRC in this case?

Response:

If the supplier identifies a deviation in a delivered basic component and has evaluated the deviation and by evaluation he has determined that it could cause a substantial safety hazard, he is required to report the deviation, which is now a defect, directly to the NRC. If the supplier does not evaluate the deviation capability, then he is required to report the deviation to his buyer.

9. If in the course of fabrication, our purchaser recuts a plate and opens up a lamination that is either repairable or rejectable, whose responsibility, if any, is it to report the incident to the Commission?

Response:

It is the responsibility of the purchaser to evaluate the deviation (i.e., lamination) and if it could create a substantial safety hazard, to report the defect to the Commission.

10. When are construction activities delivered for purposes of Part 21?

Do deviations related to construction, modification or repair activities discovered as a result of planned post-installation, preoperational or startup testing at a nuclear power plant require evaluation and 10 CFR 21 reporting if the portion of the plant under test was released to the permit holder or licensee with the understanding that testing would be the proof of acceptability and that deviations would be referred back to that organization for remedy followed by subsequent tests?

Response:

Section 21.3(d)(3) identifies those deviations in a portion of a facility subject to the construction permit or manufacturing license requirements of Part 50 of the Commission's regulations which are reportable defects under Part 21. Offer for acceptance of the portion of the facility containing a deviation, within the meaning of Section 21.3(d)(3), would occur when the supplier offers control over the portion of the facilities to the owner. Thus, where a purchaser is offered responsibility for a portion of the facility for testing purposes, the purchaser would be required to evaluate any deviations in that portion of the facility and to report any defects.

11. The terminology in paragraph 21.3(d)(3) indicates that a basic component containing a deviation has been offered by the purchaser for acceptance. Many contracts for basic components of nuclear power reactors include provisions that "final acceptance" is not complete until some warranty period has expired. This warranty period may be as long as one year after commercial operation. The warranty provisions for major equipment normally require the manufacturer to be responsible for the correction of any defects that appear through the warranty period. Please discuss the interpretation of the point in time when acceptance is accomplished by the purchase.

Response:

Section 21.3(d)(3) identifies those deviations in a portion of a facility subject to the construction permit or manufacturing license requirements of Part 50 of the Commission's regulations which are reportable defects under Part 21. Offer for acceptance of the portion of the facility containing a deviation, within the meaning of Section 21.3(d)(3), would occur when the supplier offers control over the portion of the facility to the purchaser. Thus, a warranty which requires the supplier to correct deficiencas for a period of time would not postpone the applicability of

Part 21 to the purchaser. Whenever the purchaser is offered control over the portion of the facility containing the defect, he would be required to report the defect under Part 21.

12. Please discuss for design documentation, reports prepared by consultants, or similar "software" when they are considered as "delivered." Most design documents are "delivered" several times to different organizations for various purposes. A design document may be "delivered" from a design organization to the licensee for the purposes of review. This delivery is a contractually binding requirement for a design organization to provide documents for review. The design documents then may be also utilized as portions of or incorporated in procurement documents. The design documents are again "delivered" to an organization who will be providing fabrication based upon the procurement document. Do changes or modifications to design documents that have once been "delivered" to a fabricator constitute a second delivery?

Response:

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 another party which will use it in design, manufacturing or in preparing a document for the manufacturing of any basic component.

13. It is obvious that this rule requires reporting of defects related to basic components. Under what circumstances would the following design considerations be reportable under this rule:

    a. A situation wherein an analysis error is discovered.

    b. A situation wherein an analytical method is changed.

    c. A situation wherein the data base for the design or performance evaluation is changed.

    d. A situation wherein a basic criterion is changed.

Response:

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°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 SAR or in procurement documents.

14. It is understood that the correction of defects that are found within the normal course of the application of a quality assurance program complying with 10 CFR Part 50 Appendix B are not included in reporting requirements. These detections and corrections of nonconformance or defects, that occur on a day-to-day routine basis because of reviews, inspections, tests, nondestructive examinations do not appear to be within the definition of the reporting requirements of Part 21. Those items that are not detected within the normal course of the conduct of a quality assurance program and are contained in "delivered basic components" appear to be subject to evaluation and/or reporting requirements of Part 21. Please discuss the interrelationships of defect, nonconformance corrective action, repairs that are required by Appendix B of Part 50 and those definitions used for reporting requirements of "substantial safety hazards" in Part 21.

Response:

Your interpretation that detections and corrections of non-conformances or defects, that occur on a day-to-day routine basis because of reviews, inspections, tests, nondestructive examinations, "before a basic component has been delivered or offered for acceptance" would not come within the reporting requirements of Part 21 is correct. It is only after delivery of a basic component containing a deviation and the determination, by an evaluation, that the deviation is a defect that a Part 21 report need be made. Part 21 has given special meanings 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 consistant with the special meaning of these terms as used in Part 21.

15. Is receipt of a defective component reportable under Part 21, if the evaluation indicates that the component would not effect plant safety because quality assurance and quality control procedures would have prevented the component's installation?

Response:

Quality assurance inspections or tests performed by the licensee cannot be counted upon to prevent installation of defective basic components. In evaluating deviations the assumption which must be made is that the component is installed in the facility, then if it could create a substantial safety hazard it must be reported to the NRC as a defect.

16. Is it possible to classify defects or noncompliance prior to occurrence to eliminate the need for "evaluation?"

Response:

It is acceptable for an organization to specify, within their internal procedures, the general types of deviations, with appropriate evaluations, which could create substantial safety hazards and which therefore are reportable defects. However, each specific deviation must be individually evaluated. This evaluation could utilize the previously evaluated categories of deviations which are reportable as defects if the specific deviation can be categorized into one of the general types of deviations which have been previously evaluated.

17. If all technical requirements of a procurement document are verified as having been met prior to placing an item in operation, then by Part 21, would the only reportable defect involve those conditions or circumstances relating to a basic component that could contribute to the exceeding of a safety limit?

Response:

Yes. If the procurement document is not defective and all technical requirements are verified as having been met including any performance and reliability requirements, then the only defect reportable under Part 21 would relate to conditions or circumstances relating to a basic component that could contribute to exceeding a safety limit.

18. Clarification is needed regarding "conditions and circumstances." Are these referring to operating conditions?

Response:

The term "condition or circumstances" referred to appears in §21.3(d)(4), which states, "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 pursuant to Part 50 of this chapter." "Condition or circumstance" refers to those which the basic component may experience at any time. It does not refer only to reactor operating conditions. The time at which the potential exists for exceeding of a technical specification safety limit occurs after the operating license is issued and refers to reactor operating conditions in its broadest sense, in that it must include the shutdown and refueling modes.

19. Does the "safety limit" criteria have specific implications for licensees other than those related to operating reactors?

Response:

Any fuel reprocessing or enrichment facilities licensed pursuant to 10 CFR 50 would also use the "safety limit" criteria.

20. To what degree of contingency should the words "could contribute" in §21.31(d)(4) be carried?

Response:

The "condition or circumstances" should be evaluated for normal operation and anticipated transients, considering a single failure in addition to the condition or circumstance being evaluated in order to determine if a safety limit could be exceeded.

21. If the condition or circumstances in question does not, without intervening cause, reach a safety limit does it become a reportable defect?

Response:

Anticipated transients must be considered as "intervening causes." Then, if the condition or circumstance would not contribute to exceeding a safety limit, it would not be a reportable defect.

22. If the component or system is redundant or multiply redundant, when the safety limit does not reduce such degree of redundancy, would the deviation be a reportable defect?

Response:

Assuming that the question intended to address "condition or circumstance involving a basic component" it would be necessary to consider a single failure in a redundant component or system and the condition or circumstances would have to be reported if a safety limit could be exceeded.

Definitions

§21.3(f) Director

(f) "Director" means 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.

1. Please identify some situations in which a director of a corporation, in his or her capacity as director (i.e., through reports made by management at board meetings) might become personally liable under Part 21? Shouldn't the definition of "director" in §21.3(f) reflect the fact that only the board of directors, and no individual director, has authority to manage and direct the affairs of a corporation, or did NRC mean to restrict liability only to those "directors" who single-handedly possess such authority?

   Response:

   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, he would be personally liable. 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.

2. Does the term "director" include outside members of the Board of Directors?

   Response:

   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 entity. If they have actual knowledge themselves, they have a duty to comply.

Definitions

§21.3(i) Procurement Document

(i) "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.

1. Please explain what the "procurement document" is for consultant services or for a design so that it can be determined when a "deviation" has occurred. Can a "procurement document" itself be defective (i.e., contain incorrect specifications)?

   Response:

   A procurement document for consultant services is the same as a procurement document for hardware, that is a contract that defines the requirements which facilities or basic components must meet to be considered acceptable by the purchaser. A procurement document can itself be defective. For example, the specifications for the basic component could be defective.

2. Does the concept "procurement document", defined in Section 21.3(i), include purchase orders of off-the-shelf or catalogue items, which are not covered by contractually-required quality assurance procedures, manufacturing codes or specifications?

   Response:

   Yes, provided they fall within the definition of "basic component" contained in Section 21.3(a) of the rule.

Definitions

§21.3(j) Responsible Officer

(j) "Responsible officer" means 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 this part.

1. For a corporation, is the definition of responsible officer (Section 21.3(j)) limited to only those officers duly elected or appointed in accordance with state laws and corporate bylaws?

   Response:

   No. "Responsible officer" as defined in §21.3(j) includes other individuals in the organization of a corporation, partnership or other entity "who are vested with executive authority over activities subject to this part." (Emphasis added). It is possible that individuals vested with executive authority over activities subject to Part 21 may not be included in the list of officers in the Articles or By-Laws.

2. The definition of responsible officer includes "...other individual... vested with executive authority over activities subject to this part." Who is included by the words "other individuals"?

   Response:

   President and vice president are two titles that are identified in the rule. The "other individuals who are vested with executive authority over activities subject to this part" would be those personnel identified in the organization's procedures and have comparable authority to that of a president or vice president.

3. The definition of "responsible officer" published on June 6, 1977 deleted persons with "management authority" from the definition originally proposed March 3, 1975. See, 40 Fed. Reg. 8832 (1975). Should this deletion be interpreted as excluding from the definition of "responsible officer" those persons who have only managerial authority (and who may have a title, such as "vice president"), but are not corporate officers?

Response:

Not necessarily. If the individual with managerial authority, whether or not he is identified as a corporate officer, is also vested with executive authority over an activity which is subject to Part 21, then he would be a responsible officer within the meaning of Section 21.3(j).

4. In the case of a corporation is the definition of "Responsible Officer" meant to include individuals such as project managers and QA managers?

Response:

No, it is not meant to include individuals such as project managers and QA managers. These individuals are not ordinarily vested with executive authority.

5. Can an entity subject to Part 21 designate one "responsible officer," as defined in Section 21.3(j), to the exclusion of other individuals in the entity who have executive authority over activities subject to Part 21? Is it possible, as in the case of a matrix management system where all aspects of construction, design and operation of a nuclear power plant are under the control of a single individual, that only one individual will be a "responsible officer?"

Response:

An entity may not exclude any individual in its organization who is vested with executive authority over activities subject to Part 21 from the requirements of Part 21. This should be distinguished from Section 21.21(a) which is to assure that the entity informs one director or responsible officer of defects or failures to comply which are identified.

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 Part 21.

6. What mechanism or means exists for mutual agreement to be reached before-the-fact between the licensee and the NRC as to which individuals in a given organization are to be considered "responsible officers"?

Response:

None. Consistent with §21.21(a)(2), procedures shall provide for informing the director or the responsible officer designated by each organization as having the required "executive authority" over activities subject to Part 21. NRC's first observations to ascertain compliance with Part 21 will occur during inspections conducted by the Office of Inspection and Enforcement.

7. Would an officer who has executive authority over only a small class of activities covered by Part 21 (e.g., plant security, personnel, stores) be liable for failing to make a report concerning a defect or noncompliance arising outside of his area of executive authority?

Response:

Any responsible officer or director with executive authority over activities subject to Part 21 would be liable for failing to make a report concerning a defect or noncompliance concerning a basic component that is within his organization's responsibility.

Definitions

§21.3(k) Substantial Safety Hazard

(k) "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, other than for export, pursuant to Parts 30, 40, 50, 70 and 71.

1. Please elaborate on the definition of "Substantial Safety Hazard" as used in Part 21. For instance, give examples of what the NRC would consider to be a "major reduction in the degree of protection provided to public health and safety."

   Response:

   Appendix A to NUREG-0090-7, Report to Congress on Abnormal Occurrences, June 1977 lists a number of events that may help to illustrate the NRC concept of "Substantial Safety Hazard." Specific illustrations of what we would consider to be "major reduction in the degree of protection provided to public health and safety" include:

   - Exposure in excess of 25 rems, whole body (10 CFR 21.403(a)(1))
   - Exposure of an individual in an unrestricted area to more than 0.5 rem in one calendar year (10 CFR 20.105(a))
   - Release of radioactive material to an unrestricted area in excess of 500 times the limit of Appendix B, Table II, 10 CFR Part 20 (10 CFR 20.403(b))
   - Exceeding a safety limit as defined in the facility technical specifications
   - A deficiency which seriously compromised the ability of a confinement system to perform its designated function

2. Are defects in redundant components reportable under Part 21?

   Response:

   A deviation (i.e., a departure from a procurement document specification) which, based upon an evaluation, causes or could cause the

failure of a redundant basic component is a reportable defect under Part 21. 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. It is possible that the defect might also exist in the redundant basic component which could result in a loss of safety function. The existance of a defective basic component, considering a single failure of its counterpart redundant basic component, could result in a loss of safety function. Actually, the counterpart component need not fail. It could be removed from service for other reasons such as routine preventive maintenance or inspection.

3. Facility technical specifications may allow continued operation for short periods of time with a redundant component inoperable. For example, one emergency diesel generator may be inoperable for up to 72 hours, provided the other diesel generator is demonstrated to be operable in accordance with the Technical Specification action statements.

   During the period of operation with one emergency diesel generator inoperable, the "single failure" criterion of 10 CFR 50, Appendix A cannot be met. Does this represent a substantial hazard as defined in Part 21?

   Response:

   No, operation in a degraded mode; that is, operation with less than the normal minimum number components operable, but within the action statement of the limiting condition for operation of the Technical Specification, has been evaluated and found acceptable. Operation in such a mode is not considered to be a substantial safety hazard as defined in Part 21. A failure which results in operation in a degraded mode is reportable as a licensee event report.

   It is also possible that the failure could identify a deviation, i.e., a departure from the techincal requirements of the procurement document under which the component was purchased. If a deviation is identified it would have to be evaluated pursuant to Part 21.

4. Are all or some of the present Prompt Reportable Occurrences defined by operating plant technical specifications or environmental specifications considered "substantial safety hazards"?

Response:

No, not all. 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.

5. To what degree would a deficiency in a plant security system constitute a "substantial safety hazard"?

Response:

In the case of a power reactor, the rationale is that 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. The staff view is that 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. Does the "substantial safety hazard" definition include "employee safety" or does it apply to "public safety" only?

Response:

The term "public" in Section 21.3(k) includes all individuals -- that is 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.

7. In paragraph 21.3, Item (d)(4), why is not the condition or circumstance tied to a substantial safety hazard as in paragraph 21.3(d)(1) and (d)(3)?

Response:

This definition is specifically directed toward the safety limits which are a part of the Technical Specifications issued with the facilities operating license. An evaluation is implicit with this definition in order to determine if a safety limit could be exceeded and is considered a substantial safety hazard.

8. Is it permissible, in the procedures established by each organization, to define what is interpreted to be "a substantial safety hazard" for the basic components provided by that organization? It would appear to be helpful to employees of an organization to be provided with guidance in the interpretation of "substantial safety hazards" as they relate to the given basic components provided any organization. A "substantial safety hazard" within a design organization would be significantly different than a substantial safety hazard defect in a pump manufacturing organization.

Response:

Each organization subject to the rule is required to adopt procedures to "provide for evaluating deviations". It is permissible to incorporate into these procedures specific guidance, applicable to the organization, on those activities which the organization performs which could create a substantial safety hazard. This guidance could then be utilized in evaluating specific deficiencies.

9. What is the difference between a "substantial safety hazard" and "affect safe operation" in accordance with 10 CFR 50.55(e)?

Response:

"Substantial Safety Hazard" originates in Section 206 of the Energy Reorganization Act of 1974 (ERA). The ERA required that the Commission promulgate a definition of substantial safety hazard. Part 21 defines substantial safety hazard as 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 ...." The intent of "affect adversely the safety of operation" as used in §50.55e(1) refers to deficiencies which if they were to remain uncorrected could adversely affect safe operation. Specifically these deficiencies are related to (1) quality assurance programs, (2) design deficiencies which do not conform to the safety analysis, (3) construction deficiencies or damage to structure, and (4) deviation from performance specifications.

10. If defects are reported, that in the opinion of the Commission are not "substantial", will the formal resolution between the NRC and the reporter still be required?

Response:

Items which are reported pursuant to Part 21 which the Commission feels are not substantial will be so identified in the NRC's Computer File of Licensee Event Reports and Part 21 Reports. As the NRC gains experience with the implementation of Part 21, additional guidance will be provided if a significant number of "non-substantial" defects are reported.

§21.4 Interpretations

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

1. Is a written transcript of the regional meetings available?

   Response:

   No written transcript was made of the five public meetings on Part 21.

2. Do the published staff responses constitute official interpretations of the rule as provided for in Section 21.4? If not, can the published answers be relied upon for implementation guidance?

   Response:

   These responses and the responses given at the regional meetings do not constitute interpretations of the rule by the General Counsel, as provided for in Section 21.4. However, the staff will be guided in its implementation and enforcement of the rule by the position set forth in this document. Such information is provided with the intent that persons subject to Part 21 would rely upon it for guidance. Official interpretations by the General Counsel may be requested in accordance with Section 21.4.

3. How will interpretation of 10 CFR Part 21 made by the General Counsel be communicated to all organizations subject to this part?

   Response:

   Interpretations of 10 CFR Part 21 by the General Counsel will be published in the Federal Register.

4. How and when will the results of these regional meetings be reflected in 10 CFR Part 21?

   Response:

   While the Commission has no immediate plans to amend Part 21 to take into consideration comments arising at the regional meetings,

the Commission indicated in the preamble accompanying Part 21 that it "intends to examine closely the implementation of new Part 21 with a view to making any clarifications or other changes that may be warranted in light of experience". Such a reexamination by the staff is presently underway and may result in proposal of some clarifying amendments in the near future.

§21.5 Communications

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part should be addressed to the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, or to the Director of a Regional Office at the address specified in Appendix D of Part 20 of this chapter. Communications and reports also may be delivered in person at the Commission's offices at 1717 H Street NW., Washington, D.C.; at 7920 Norfolk Avenue, Bethesda, Md.; or at a Regional Office at the location specified in Appendix D of Part 20 of this chapter.

1. How will Part 21 reports be filed and distributed for NRC licensees and non-licensees and how will these reports be used?

   Response:

   We plan for copies of Part 21 reports submitted to the NRC by a licensee or nonlicensee to be placed in appropriate docket files in the public document room. Proprietary information will be protected in accordance with 10 CFR Part 2.

   NRC will utilize the Part 21 reports to evaluate the implications of reported defects, including generic implications, to assure that corrective measures are taken as appropriate for regulated activities to protect the health and safety of the public.

2. How will the Commission handle reports received that later are determined to be "non-reportable"?

   Response:

   All Part 21 reports will be transcribed into a computer retrievable file. The reports will be evaluated by IE, and if appropriate by NRR or NMSS. If a determination is made that a report should not have been submitted, we plan to indicate action in the computer file.

§21.6 Posting Requirements

Each individual partnership, corporation or other entity subject to the regulations in this part, shall post current copies of the following documents in a conspicuous position on any premises within the United States where the activities subject to this part are conducted (1) the regulations in this part, (2) Section 206 of the Energy Reorganization Act of 1974, and (3) procedures adopted pursuant to the regulations in this part.

If posting of the regulations in this part or the procedures adopted pursuant to the regulations in this part is not practicable, the licensee or firm subject to the regulations in this part may, in addition to posting section 206, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

The effective date of this section has been deferred until January 6, 1978.

1. Who is subject to the posting requirements and when do the posting requirements become effective?

   Response:

   Posting requirements become effective on January 6, 1978, and are applicable to all entities subject to the regulations in this Part, including licensees and suppliers of licensees.

2. What locations at a facility should be posted in order to comply with the posting requirements in Section 21.6?

   Response:

   Every premise where activities subject to Part 21 are conducted, must be posted in a conspicuous location. The number of posting locations that is adequate should be judged on the normal access of the individuals to the premises.

3. Will a form for Part 21 posting requirements similar to NRC-3, "Notice to Employees," be available from NRC?

Response:

Presently, NRC does not have plans to make available a Part 21 form for posting similar to the NRC-3 form.

§21.7 Exemptions

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

1. What relief is available to a utility if a sole source supplier refuses to accept a purchase order with the 10 CFR Part 21 provisions?

   Response:

   It should be pointed out that Part 21 applies to sole source suppliers of basic components for licensed nuclear facilities or activities regardless of whether the procurement document specifies Part 21 applicability or not. Should the questioned situation occur, the purchaser could request an exemption from the requirements of the rule pursuant to Section 21.7. The Commission may grant such exemptions if it determines that they are authorized by law and will not endanger life or property or the common defense and security and that they are otherwise in the public interest.

2. How does a company get an exemption to Part 21?

   Response:

   Pursuant to §21.7 company can request the Commission to grant an exemption by filing a request directly with the Commission and stating clearly the reasons why the exemption should be granted.

3. Will notifications submitted to the NRC in accordance with 10 CFR Part 21 be exempt from public disclosure?

   Response:

   If the information in the notification is identified as proprietary information--the disclosure of which will do substantial harm to an organization's competitive position--the notification could be withheld from disclosure under a Freedom of Information Act request if the Commission determines that it is in the public interest to withhold it (Exemption 4).

21.21(a) of - Notification of failure to comply or existence of a defect

(a) Each individual, corporation, partnership or other entity subject to the regulations in this part shall adopt appropriate procedures to (1) provide for (i) evaluating deviations or (ii) informing the licensee or purchaser of the deviation in order that the licensee or purchaser may cause the deviation to be evaluated unless the deviation has been corrected; and (2) assure that a director or responsible officer is informed if the construction or operation of a facility, or activity, or a basic component supplied for such facility or activity:

(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order or license of the Commission relating to a substantial safety hazard, or

(ii) Contains a defect. The effective date of this paragraph has been deferred until January 6, 1978.

1. Does the term "individual" as used in §21.21(a) (also §21.6, §21.31, §21.41, §21.51(b)) refer solely to a sole proprietorship business entity which must have procedures, keep records, etc., or does it also refer to individuals who are directors or responsible officers of corporations? The term "individual . . . subject to the regulations in this part" would seem to include directors and responsible officers of corporations. Must directors and responsible officers also have procedures, post copies of regulations, keep records, etc.?

   Response:

   The term "individual" used in the above referenced sections of the rule means individual proprietorship. Directors and responsible officers are not required to have procedures, post copies, etc.

2. What is meant by "appropriate procedures"? Does the NRC expect to issue a Regulatory Guide, or will each company be on its own?

   Response:

   "Appropriate procedures" means procedures that are sufficient to provide effective implementation of Part 21 as described in section 21.21(a). At this time, NRC does not expect to issue a Regulatory Guide on this subject. Should experience with the application of Part 21 indicate the need for additional guidance in this area, it is expected that a Regulatory Guide will be developed.

3. Is it a correct interpretation of Section 21.21(a) that appropriate procedures for evaluating deviations, informing the licensee or purchaser of deviations, and for assuring that a director or responsible officer is notified of defective conditions, need not be incorporated until January 6, 1978?

Response:

It is correct that these procedures need not be adopted until January 6, 1978.

4. What effect does the delayed effective date of the requirement to adopt "evaluation" procedures under §21.21(a) have on §21.21(b) notification requirements?

Response:

In the event that a responsible officer or director obtains information after August 10, 1977, and prior to January 6, 1978, reasonably indicating a failure to comply or a defect, such a responsible officer or director is required to notify the Commission. This reporting requirement is effective even though formal procedures for performing the evaluations are not in effect.

5. How datailed should procedure for "Evaluation of Deviations" be?

Response:

The procedure for evaluation - and the record for evaluation - should include the following:

a. review of information sufficient to describe the deviation

b. an analysis of the effect of such a deviation in a basic component if used in a facility or activity subject to Part 21

c. a conclusion based on the analysis as to whether the deviation could create a substantial safety hazard.

6. When is the earliest time that a utility needs to establish procedures required by §21.21(a).

Response:

A utility must begin to establish procedures as required by Section 21.21(a) when it first engages in any of the construction

activities, including safety-related design work, referenced in Section 21.2 and defined in Section 21.3(c) of the rule.

7. Please discuss to what extent a responsible officer should go to insure that defects are identified and reported. The specific concern here is upper level management people, such as Boards of Directors or Partnership Committees, who are not involved in day-to-day operations.

   Response:

   The extent to which a responsible officer must go to insure that deviations are identified is to be determined by each company subject to 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 a director or responsible officer obtains information reasonably indicating that a defect exists, he must inform the Commission unless he knows 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 if a director obtains reportable information.

8. Are other procedures required to be formally adopted under §21.21(a) besides those enumerated there? Specifically, must a licensee establish formal procedures to correct deviations (see 42 Fed. Reg. 28891, 28893, (7)) or to identify deviations?

   Response:

   Part 21 requires only those procedures required by §21.21(a) to be established. Other portions of NRC regulations, for example, 10 CFR Part 50, Appendix B, requires that procedures be established to identify and correct deviations, nonconformances, defects, etc.

9. In regard to procedures:

   a. Who is responsible to verify that the procedures fulfill the requirements of Part 21; and, therefore, who accepts the liability?

   b. Should Part 21 procedures be covered in the respective QA Manuals?

   c. What are acceptable procedures and criteria for auditing to ensure that all actions are in conformance with this aspect of Part 21?

Response:

a. Each organization is responsible and must assure itself that appropriate procedures are established.

b. Part 21 procedures need not be covered in QA Manuals.

c. Normal management controls are an acceptable means to verify conformance to Part 21. Quality assurance type audits are not ruquired to verify that appropriate procedures are in effect.

10. If able to do so, is the organization which issued the procurement document obligated to perform the evaluation?

Response:

Section 21.21(a) states that each organization shall establish procedures for evaluating deviations or assuring that deviations are evaluated by another organization that can perform the evaluation. It is expected that each organization discovering a deviation will perform the evaluation if it has the capability to do so. If the firm is unable to evaluate, then the information of the deviation should be passed up the tier of purchaser/supplier organizations in order that the evaluation can be performed. Procedures develcped by any organization should also cover the aspects of how they will handle receipt of information concerning deviations forwarded by their suppliers when the supplier is unable to evaluate the deviation.

11. Does 10 CFR 21 allow for a period of evaluation between the time a potential safety concern is identified and when it must be reported to NRC? If so, what period of time is considered reasonable?

Response:

The rule presently is silent in regard to the time from when the deviation is identified to the time of notification to NRC. This time is presently considered to be unquantificable for all facets of facilities and activities regulated by NRC and needs to be determined on a case-by-case basis.

12. What is the answer to the following questions:

a. Once a director or responsible officer has reported a deviation according to the appropriate internal procedure so that

"evaluation" has commenced, must the director or responsible officer follow through with the evaluation to see that it is conducted properly?

b. How could the typical corporate director or an officer with executive authority over only a small class of activities covered by Part 21 be expected to evaluate a defect that is outside of his area of expertise or authority?

Response:

a. No. It is not anticipated that a director or responsible officer will be involved in identifying "deviations."

b. He is not required to evaluate it himself. Procedures established under §21.21(a) to ensure that evaluations are performed and at least one director or responsible officer is informed of any defects or reportable failures to comply must be established by the organization.

13. The new Part 21 implies that an analysis is necessary in each instance to determine whether a significant safety hazard could have existed if a defective component had been installed in a reactor facility. Does this analysis requirement extend to components that never become the property of the reactor facility? Who should perform this analysis? How is the analysis best documented? What benefit is derived by the conduct of this analysis?

Response:

The evaluation of a deviation in a basic component that is delivered to a purchaser must be evaluated to determine whether a substantial safety hazard could be created if the component were installed in the facility even though the purchased item is rejected and never installed in a plant system.

The organization discovering the deviation should perform the evaluation or cause the evaluation to be performed by another organization. For example, for a deviation discovered by a supplier, the evaluation should be performed by the supplier, if he has the capability, or by the purchaser if the supplier does not have the capability.

In addition to the normal 10 CFR 50 Appendix B type records required for analysis of safety-related items, the Part 21 documentation of evaluations which involve a substantial safety hazard and records of notifications to the Commission, will satisfy Part 21 recordkeeping requirements.

In regard to the benefit derived in conducting evaluations of items which are never installed, the identification of a defect in a basic component that is never installed in one plant may result in identifying generic items having the same defect installed in other plants.

14. What is the utility's responsibilities when only the fuel supplier can properly evaluate the consequences of a fuel deviation to determine if a "defect" exists?

Response:

If the utility is unable to evaluate the deviation, it must consult with the supplier or use other outside consultants for the evaluation.

15. If an organization declines to adopt procedures for evaluating deviations but instead establishes procedures for informing the licensee or purchaser of such deviations, so that they may perform the evaluation, are the directors or responsible officers of the organization thereby relieved of the responsibility for notification of defects? Do these directors or responsible officers have any obligation to determine the results of the evaluation within the specified time period required for notification?

Response:

Procedures are to be adopted to evaluate deviations. For those cases where the organization does not perform the evaluation, procedures are to be adopted to inform the purchaser of the deviation so that he, or others, may perform the evaluation. The responsibility for notification resides with the organization that performs the evaluation.

16. In the situation where a licensee contracts with an agency of the United States to supply nuclear components and where the licensee can not adequately evaluate whether a substantial safety hazard exists and does not know the stresses to which the components are to be subjected, what does the licensee do when a deviation is discovered after delivery?

Response:

If the U.S. agency is a licensee then the agency would be responsible for performing the evaluation. If the agency receiving supplies is not licensed, then the supplier is not subject to Part 21 unless the unlicensed agency's facility uses the components to supply a firm within the chain of suppliers to a reactor licensee. If the unlicensed purchasing agency does do this, then the supplier becomes one of several tiers of suppliers subject to

Part 21. If the supplier is subject to Part 21 and discovers a deviation it must evaluate the deviation or inform the purchaser of the deviation so it can evaluate it.

17. Will subcontractors be required to report under similar circumstances to the above question, when supplying subcomponents or materials to be incorporated into nuclear components ultimately to be supplied to an agency of the U.S.?

Response:

A subcontractor must evaluate, and, if it discovers a defect, report or it must inform the purchaser if a.) it is one of a tier of suppliers supplying components to a reactor licensed by the Commission, or b.) it is a direct supplier of a materials licensee.

18. Are component suppliers obligated for notification requirements under Part 21 even though the procurement documents make no reference to Part 21?

Response:

Yes. Component suppliers who knowingly supply basic components are subject to Part 21 notification requirements even if Part 21 is not referenced in their contract with the purchaser.

19. 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:

    a. Might the director be liable under Part 21 if he failed to report to the NRC if, in fact, it was later determined that there was a reportable defect (i.e., is hearsay sufficient information to require reports)?

    b. Would it make any difference if the director believed it was a crank call?

    c. If the director reported what he had heard concerning a potential failure to comply or defect to the appropriate responsible officer according to the corporation's procedures under §21.21(a) and the responsible officer told the director there was no substantial safety hazard according to the "evaluation", could the director rely upon the results of the "evaluation" as told to him by the responsible officer?

Response:

a&b. Section 21.21(b) requires a director or responsible officer to report to NRC if he has information reasonably indicating a defect or failure to comply which could create a substantial safety hazard. 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. Section 21.21(a) requires that appropriate procedures be developed for conducting such evaluations. It is expected that appropriate procedures would include the requirement for an evaluation where there is reason to believe that a deviation exists.

c. 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 organization who are responsible for conducting the evaluations. For the two examples given, it seems that a telephone call from a former employee would be a reasonable basis for believing that a deviation exists.

20. Would you comment on the amount of independence of a review group from the line authority over an individual who raises an alleged defect.

Response:

The amount of independence to be given to a review group to evaluate a potential defect is to be determined by the organization establishing evaluation procedures.

21. Do you expect other outside organizations such as NSSS vendors to be involved in the evaluation of an alleged defect?

Response:

Yes. The evaluation is performed, if possible, by the organization that discovered the deviation in the delivered basic component. If that organization is a supplier who is unable to technically perform the evaluation, then the information concerning the deviation is passed to the purchaser such as the Nuclear Steam System Supplier (NSSS) who performs the evaluation. If necessary, the forwarding of a deviation for evaluation continues through the supply tiers until, if necessary, it reaches the licensee.

22. Is it proper to construe Section 21.21(a)(ii) to mean that if the responsible officer learns of an already corrected defect or deviation that would otherwise have been reportable, no report is required?

Response:

Section 21.21(a) specifies procedures to be developed to ensure that potential defects are fully evaluated. An evaluation of a potential defect is not required where the deviation has already been corrected in all basic components to which it is applicable when knowledge of the deviation is received.

In regard to reporting requirements for Part 21, they are stated in Section 21.21(b). That section, by implication, requires the reporting of defects which will be or are being corrected after the effective date of the rule. Specifically, Section 21.21(b)(3)(vii) requires that NRC be informed of the corrective action which will be or is being taken on a particular defect or failure to comply.

23. Paragraph 21.21(a)(1)(ii) implies that any deviation that has been corrected need not be reported to the purchaser for evaluation against the requirements of 10 CFR Part 21. Please clarify.

Response:

If at the time the deviation is identified, it has not been corrected, then the supplier, or where he is unable to do so, the licensee or purchaser, must evaluate the deviation and, if it is determined to be a defect, make the necessary report to NRC. This means that even if the supplier, or licensee or purchaser, believes that the deviation has been corrected after the Part 21 evaluation has begun, he must complete the evaluation and report if a defect exists.

24. On August 10, 1977 must reports be made of events or occurrences which occurred prior to the effective date of the regulation and which were previously corrected?

Response:

No.

25. Are defects which are repaired prior to delivery or final acceptance of a component or service covered by Part 21 reportable?

Response:

A deviation in a basic component cannot be a defect until that basic component has been delivered to a purchaser.

A deviation which occurs in a basic component of a portion of a facility, however, can be a potential defect subject to evaluation when the portion of the facility containing the known or undiscovered deviation is offered to the purchaser for acceptance.

26. Licensees must adopt internal procedures to assure that safety-related defects and noncompliance are brought to the attention of responsible officers and directors. Does this mean that each director and responsible officer must be notified?

Response:

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 obtains information reasonably indicating a failure to comply or a defect.

27. Persons subject to Part 21 are required also to report failures to comply with ". . . the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazard, . . ." 10 CFR Section 21.21(a)(2)(and (b).

a. Does this provision mean if a rule, regulation, order or license as a whole relates to a "substantial safety hazard," that the violation of any particular provision is covered by Section 21.21(b), even though that provision does not itself relate to any "substantial safety hazard"? To cite an extreme example: the failure to provide antitrust information as required by Part 50.

b. Does the language in Section 21.21(a)(2)(i) mean that an individual must report (a) generic or (b) non-generic items previously reported to the NRC prior to July 6, 1977, in accordance with other regulatory requirements or license provisions?

c. Must an individual also report under Section 21.21(a) o (b) incidents which he must report under other regulatory requirements or license provisions?

Response:

a. To have a failure to comply under Part 21, one must fail to comply with a particular provision covered by Section 21.21(b) and such failure must itself be related to a substantial safety hazard.

b. If they have actual knowledge that the Commission has been adequately informed prior to the effective date, then no additional notification is required.

c. If he knows that the Commission has been adequately informed of the defect or failure to comply under another regulatory requirement or licensing provision, he need not report under Part 21.

28. Please relate the phrases "failure to comply" and "substantial safety hazard" to a Part 70 licensee. Discuss 21.21(a)(2)(i) in terms of the details of rules, regulations, orders or license and the licensee's implementing procedures. Also discuss your interpretation of the phrase "relating to a substantial safety hazard" in this paragraph.

Response:

Under Section 21.21(a), a director or responsible officer must be notified of any failure to comply on the part of a Part 70 licensee with the Atomic Energy Act of 1954, as amended, or with any applicable rule, regulation, order or license of the Commission relating to a substantial safety hazard. It is not possible to identify the specific rules, regulations, or orders which could be applicable in a particular case.

The term "substantial safety hazard" is defined in Section 21.3(k) of the rule, and additional guidance is provided in the preamble to the rule and in the Commission's policy statement on abnormal occurrence reporting criteria which was published in the Federal Register on February 24, 1977 (42 F.R. 10959).

29. How broad is the definition of "applicable rule, regulation, order or license" in 21.21(a)(2)(i)? Would this include industry standards such as the ASME Code?

Response:

Industry codes that are not a part of an NRC rule, regulation order, or license are not within the scope of Part 21. Some portions of the ASME code are related to the creations of a substantial safety hazard, and are within the scope of Part 21, because it has been invoked by Section 50.55a.

30. Answer the following:

a. Does a utility have responsibility for making reports under Part 21 relative to problems or deviations in parts or systems that have not yet been delivered to it or accepted by it?

b. Is this the case even though Part 21 might require the A/E or the NSSS to make a report? (e.g., a defective component is delivered by the NSSS to the A/E and a responsible officer of the utility becomes aware of the defect.)

Response:

a. No

b. Yes

21.21(b)(1) of - Notification of failure to comply or existence of a defect

> (b)(1) A director or responsible officer subject to the regulations of this part or a designated person shall notify the Commission when he obtains information reasonably indicating a failure to comply or a defect affecting (i) the construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under Parts 30, 40, 50, 70 or 71 and that is within his organization's responsibility or (ii) a basic component that is within his organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under Parts 30, 40, 50, 70 or 71. The above notification is not required if such individual has actual knowledge that the Commission has been adequately informed of such defect or such failure to comply.

1. If a supplier or holder of a permit or license complies with applicable NRC regulations, orders, or licenses of the Commission, would the supplier or licensee not automatically comply with the safety provisions of the Atomic Energy Act of 1954, as amended? If not, what other safety requirements should the licensee look for in the Act to assure compliance?

   Response:

   The Atomic Energy Act of 1954, as amended, establishes a broad standard for providing adequate protection to the public health and safety. In applying the broad safety standard of the Atomic Energy Act to the specific situations the Commission has adopted regulations and has imposed, through the adjudicatory process, licensing requirements and conditions. Compliance with individual Commission regulations and licensing requirements would assure compliance with the broad safety requirements of the Act. There could exist a reportable defect under Part 21 which would not necessarily be a violation of a specific Commission regulation or licensing requirement.

2. Does the NRC have a recommended internal procedure for licensees to insure compliance with 10 CFR Part 21?

   Response:

   No. As stated by the preamble to the rule, if guidance is needed development of a Regulatory Guide will be considered.

3. What means will be used to eliminate conjecture, supposition and faulty reasoning in risk - benefit judgment?

Response:

This question seems to be asking what can be done to eliminate uncertainties in applying the rule. It was impossible to identify specifically each instance in which the reporting requirements would apply, and certain judgments must be made by those individuals subject to the rule and by NRC in reviewing compliance with the requirements of the rule. For example, an individual must exercise some judgment in determining whether a deviation is a defect which could create a substantial safety hazard. Nevertheless, the rule does provide guidance, as does the preamble, on the various requirements of the rule. The standard for determining whether to report a possible defect or failure to comply under Section 21.21(b) is "information reasonably indicating a failure to comply or a defect." Thus, if there is some doubt in your mind about whether a particular problem is reportable, it would probably be best to report it under Part 21.

4. Must a director or responsible officer make the judgment that information he receives "reasonably indicates" a failure to comply or a defect in the context of his own knowledge of the subject, or is he either entitled to rely on or under an affirmative duty to solicit expert guidance from others who might have more detailed knowledge of the subject?

Response:

He is entitled to rely on expert guidance from others w b might have more detailed knowledge of the subject.

5. Is it possible that a director or responsible officer not actually obtaining certain knowledge could be held liable for not reporting it, if, for example, he should have obtained information and did not, or had an agent obtain it? Specifically, if a director or responsible officer authorizes a person to make notification for him pursuant to §21.21(b)(4), does the fact that such authorization does not relieve the director or responsible officer of his responsibility to notify the Commission impute knowledge "obtained" by the designee to the director or responsible officer even though he has not actually "obtained" it?

Response:

No. 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.

6. Is it the intent of Part 21 to require, in the procedures adopted in accordance with §21.21(a), a method for responsible officers or directors to introduce questions to the organization they head to obtain an analysis with regard to safety significance?

Response:

No. That is not the intent of Part 21. However, the procedures required by §21.21(a) should provide for evaluation of deviations which are brought to the attention of the organization regardless who identifies the deviation.

7. Is the NRC the sole judge of when information received "reasonably" indicated a "substantial" defect or that the defect was "outside" the responsibility of the organization?

Response:

Whether or not he has information reasonably indicating a failure to comply or a defect within his organization's responsibility is initially a matter of judgment for the directors and responsible officers in each situation. Of course, any judgment that there does not exist a reportable defect or failure to comply is reviewable by NRC. Nevertheless, if the NRC determines that there is a reasonable basis for the judgment that a reportable defect or failure 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.

8. Suppose there is an internal disagreement, within an organization subject to Part 21 over whether a defect is reportable under 10 CFR Part 21, who makes the definitive determination? How is this determination to be documented?

Response:

The determination as to whether a deviation is a defect is made in accordance with the procedures required to be adopted per Section 21.21(a). These procedures should provide for making an evaluation in spite of internal disagreements.

9. Under §21.21(b)(1), is it correct to say that a person does not have "information reasonably indicating a failure to comply or a defect" which requires reporting until: (1) he knows of the deficiency or the noncompliance; and (2) he has evaluated, or received someone else's evaluation, that the deficiency or noncompliance relates to a substantial safety hazard? Also, as written, is it correct that no director or responsible officer has any Part 21 responsibility until after the evaluation? What duty or time limit applies to the evaluation?

Response:

The answer to the first part is yes. While there is no time limit on evaluations, within two days after the director or responsible officer obtains the information reasonably indicating a defect or failure to comply, he must report.

10. Are reports pursuant to Part 21 on subcontracted items reported to the customer, or are they reported directly to NRC with a copy submitted to the customer?

Response:

The organization which made the evaluation as defined in Part 21 is responsible for reporting the defect to NRC. It is expected that, in many cases, the subcontractor or vendor will not have sufficient information or expertise to make the evaluation to determine whether a particular deviation could create a substantial safety hazard. That is the reason that Section 21.21(a) states that the subcontractor or vendor can either evaluate the deviation or inform the licensee or purchaser of the deviation in order that the licensee or purchaser may cause the deviation to be evaluated.

11. To whom do foreign suppliers submit reports pursuant to Part 21, i.e., directly to NRC or to the U.S. purchaser?

Response:

Foreign suppliers who are subject to the requirements of Part 21 would be expected to notify NRC directly. It is also anticipated in these cases that the contractual arrangements between the purchaser and the supplier could provide for notification to the purchaser of defects identified by the foreign supplier.

12. If a firm identified a potential deviation and reports it to the responsible licensee for evaluation, is the initiating firm still responsible for reporting under Part 21?

Response:

The organization that makes the evaluation has notification responsibility. In the specific case cited, the initiating firm is not responsible for reporting under Part 21 to NRC.

13. Does a licensee have an obligation to provide a Part 21 notification if the reportable conditions are discovered by the licensee in the course of performance of licensed activities where the conditions are in the product or service of a third party?

Response:

If the licensee is procuring the product or service of the third party during licensed activities it would be within the licensee's responsibility, and therefore notification would be required.

14. Explain the difference between the reporting requirements listed below as applied to production or utilization facility licensed under Part 50: a) 50.36, b) 50.55e, c) licensee event reports, d) abnormal occurrences per section 208 of the Energy Reorganization Act, and e) Regulatory Guide 1.16.

Response:

The major difference is that the scope of Part 21 is broader, both as to whom it applies and to the nature of the activities covered. Part 50.55(e) is limited to construction permit holders and defined construction deficiencies.

Detailed dicussion of NRC reporting requirements (Part 21, 50.55(e), Licensee Event Reports, Abnormal Occurrences-Section 208) presented at each public regional meeting is repeated as follows.

Discussion at July 12-26, 1977 Public Regional Meetings on Part 21 on the Comparison of NRC Reporting Requirements - Figures 1-7

A subject which attracted many questions was the reporting requirements of Part 21 as they relate to similar requirements of other regulations. To show the similarities and differences of comparable requirements, a sequence of figures has been put together to assist in differentiating between the various reporting requirements. It is pointed out that most the information presented applies to reactors or Part 50 licensees - rather than material licensees or activities regulated under other parts of 10 CFR.

Figure 1 below lists four similar types of events which are required to be reported and the source of those requirements. The fourth event - abnormal occurrences - is not a requirement imposed directly upon the industry - rather it is one imposed by Congress upon the NRC; however, it is included since the basic source of information for reports in this case is derived from the previous three categories. Also, the criteria the NRC uses in determining what a reportable abnormal occurrence is can be used as general guidance in determining what a "substantial safety hazard" might be under Part 21.

FIGURE 1

INCIDENT OR EVENT TYPE
NRC REPORTING REQUIREMENTS

TYPE	SOURCE OF INFORMATION
DEFECTS AND NONCOMPLIANCE	ENERGY REORGANIZATION ACT OF 1974 SECTION 206 10 CFR PART 21
CONSTRUCTION DEFICIENCIES	10 CFR PART 50 PARAGRAPH 50.55(e)
REPORTABLE OCCURRENCES (LICENSEE EVENT REPORTS)	10 CFR PART 50 PARAGRAPH 50.36
ABNORMAL OCCURRENCES	ENERGY REORGANIZATION ACT OF 1974 SECTION 208

Figure 2 below shows the parties to whom the various reporting requirements apply. The significant point to note is that Part 21 is the first regulation to directly apply to not only NRC licensees but also organizations and individuals that are not licensed. Part 21 can also apply to activities performed by these parties before a CP is issued if the activity becomes associated with a licensed facility, or is otherwise regulated and could prove to be the cause of a substantial safety hazard at a later time.

FIGURE 2

APPLICABILITY OF REPORTING REQUIREMENTS

PART 21	NRC LICENSEE ORGANIZATIONS (ALL)
	NON-LICENSEE ORGANIZATIONS SUPPLYING NUCLEAR COMPONENTS AND SERVICES
	INDIVIDUALS (DIRECTOR OR RESPONSIBLE OFFICER)
CONSTRUCTION DEFICIENIES	HOLDER OF A CONSTRUCTION PERMIT
REPORTABLE OCCURRENCES	LICENSEE OF A PRODUCTION OR UTILIZATION FACILITY (PART 50)
ABNORMAL OCCURRENCES	NRC REGULATED FACILITIES AND ACTIVITIES

Figure 3 shows the relationship of reporting requirements to the classes of subject areas requiring reporting; namely, noncompliances and defects that could create substantial safety hazards in Part 21 and the four types of construction deficiencies reportable under 50.55(e). Obviously, there is some overlap between these two reporting requirements.

Overlap between Part 21 and reportable occurrences can also occur; however, the reporting threshold for reportable occurrences is considerably lower for the latter - thus, most operational type events would probably be reported to the Commission under these requirements, which appear in most operating license Technical Specifications, under Part 50, instead of under the Part 21 umbrella. In those cases where the Commission has been notified of an event via a Licensee Event Report (LER), and subsequently it is determined the event was of a type which could create a substantial safety hazard, no Part 21 report would be required where the initial reporting method has provided the information necessary in order that the Commission is adequately informed.

FIGURE 3

SUBJECT(S) REQUIRING REPORTING

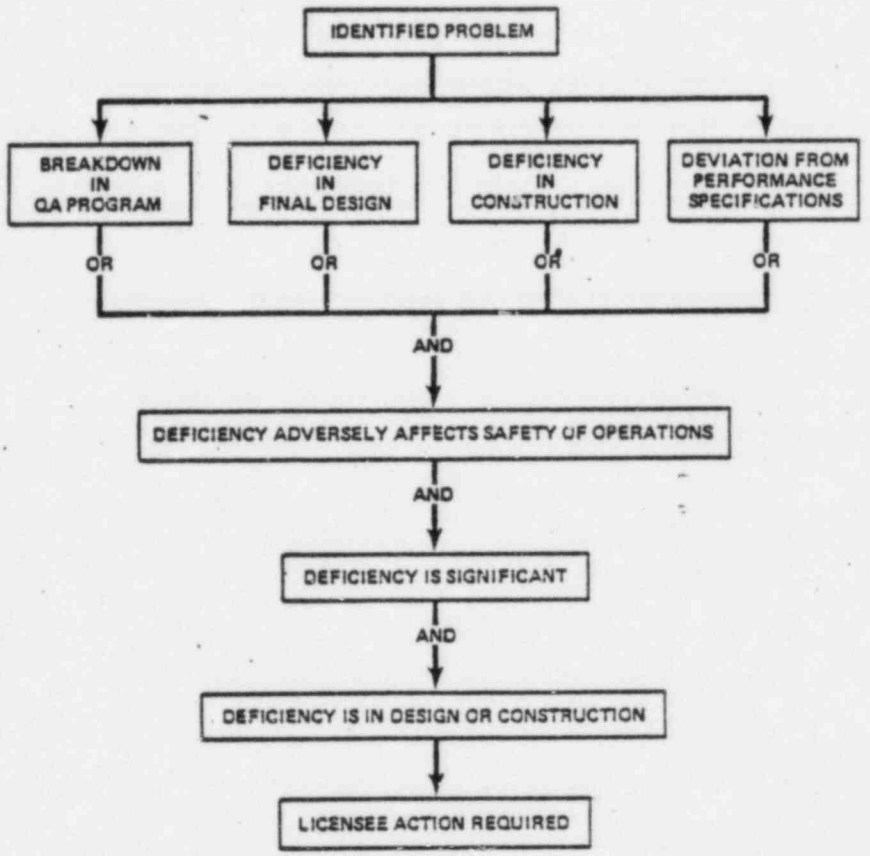
PART 21	FACILITY, ACTIVITY OR BASIC COMPONENT SUPPLIED THAT: (1) FAILS TO COMPLY WITH ATOMIC ENERGY ACT OF 1954, OR ANY APPLICABLE NRC REQUIREMENT; OR (2) CONTAINS A DEFECT WHICH COULD CREATE A SUBSTANTIAL SAFETY HAZARD
CONSTRUCTION DEFICIENCIES	(1) BREAKDOWN IN QA (2) SIGNIFICANT DESIGN DEFICIENCY (3) SIGNIFICANT CONSTRUCTION DEFICIENCY OR DAMAGE (4) SIGNIFICANT DEVIATION FROM PERFORMANCE SPECIFICATIONS
REPORTABLE OCCURRENCES (LICENSEE EVENT REPORTS)	OPERATIONAL EVENTS (9 CLASSIFICATIONS IDENTIFIED IN REGULATORY GUIDE 1.16)
ABNORMAL OCCURRENCE	AN UNSCHEDULED INCIDENT OR EVENT ASSOCIATED WITH ANY LICENSED FACILITY OR ACTIVITY THAT THE COMMISSION DETERMINES IS SIGNIFICANT FROM THE STANDPOINT OF PUBLIC HEALTH AND SAFETY.

Since many questions asked that a comparison be made between 50.55(e) type events and Part 21, Figures 4 and 5 are provided to illustrate this relationship.

Figure 4 (on a following page) shows the sequence of steps and the considerations that must be performed in determining whether a construction deficiency is reportable. There are several similarities; however, two points to emphasize are that 50.55(e) specifically says that the CP holder should assume that a deficiency is reportable on the basis that "were it not corrected" it would have adversely

Figure - 4

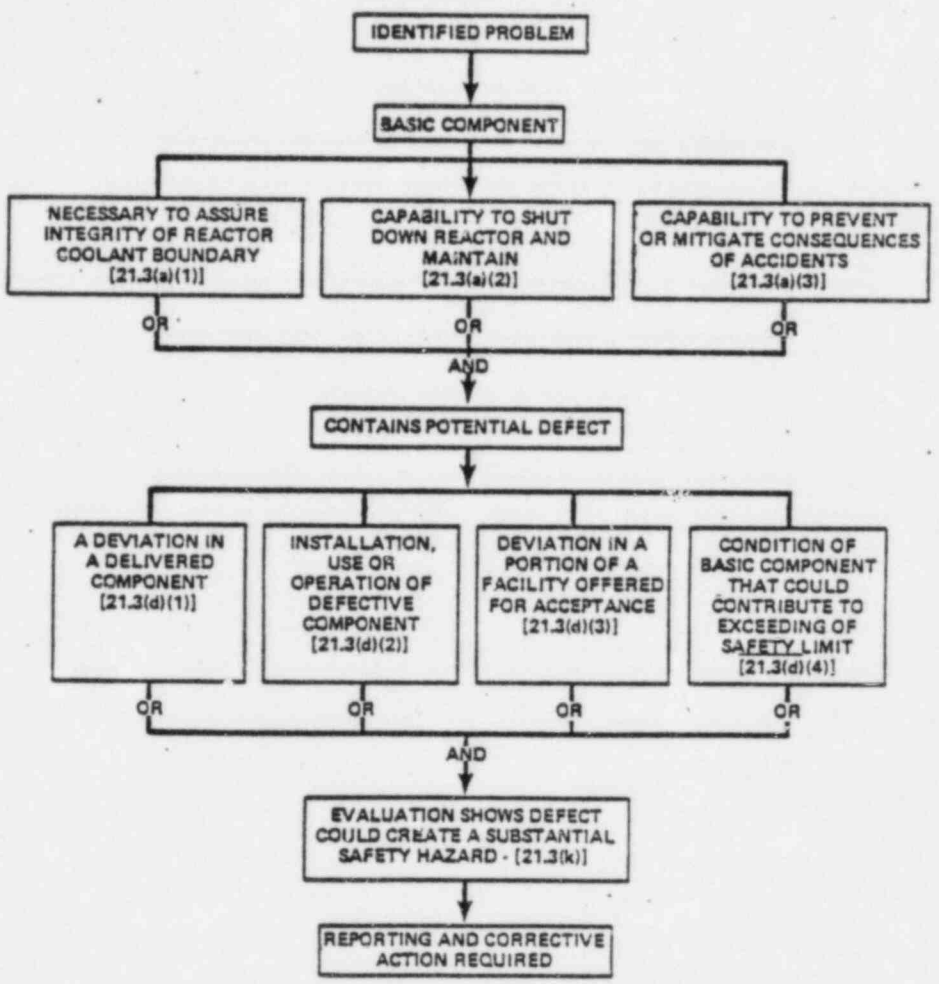
10 CFR 50.55(e)



21.21(b)(1)-9

Figure - 5 - PART 21

REPORTING REQUIREMENTS IN BASIC COMPONENTS IN POWER REACTORS



21.21(b)(1)-10

affected the safety of operation. Part 21 is not as specific as that but uses the words "could create a substantial safety hazard" which generally implies that the same assumption should be made.

The second important point under 10 CFR 50.55(e) is the use of the word "significant". What is significant? To determine that, CP holders under Part 50.55(e) are required to evaluate the event or condition to determine whether it is or is not significant. Some guidance is provided within 50.55(e) but again judgment is required.

Under Part 21 we specifically state that an evaluation of a deviation must be made to determine whether the deviation is a defect that could create a substantial safety hazard. So in this context the two rules are similar, but based on criteria established for each in determining whether the matter is "significant" or "could create a substantial safety hazard," the threshold levels of reporting vary greatly, with Part 21 the more restrictive.

Figure 5 (on the preceding page) shows a block diagram of the steps and considerations for determining reportability under Part 21. You should note the differences from the previous slide. Obviously, in putting diagrams like Figure 5 together, it is impossible to include all the detail such as the following two points which you should not overlook. The first is that Part 21 covers two phases or principal subject areas, one being defects in basic components which could create a substantial safety hazard and the second being noncompliances relating to substantial safety hazards. Figure 5 primarily addresses the defects in basic components rather than noncompliances, since the questions received in this area were greater in number, more complex and the relationships appear least understood. Next, when one talks about basic component, the first impression most of us get is that it means hardware. In the case of Part 21, specifically in paragraph 21.3(a), it states:

> "In all cases 'basic component' includes design, inspection, testing or consulting services important to safety that are associated with the component hardware, whether these services are performed by the component supplier or others."

Thus, with the very broad definition of basic component, any company providing services or activities which have a safety relationship to a defined basic component are subject to the rule. Referring to Figure 5, first, one has to have a problem which involves a basic component. Basic component is further defined by the three categories shown. Then, of course, one has to have a potential defect in the basic component which may not be a defect unless it fits one of the four categories shown following - potential defect, i.e.,

either the defect must exist in a delivered component

or

the defective component must have been installed, used, or operated

or

in the case of on-site work or software, the deviation was associated with a portion of a facility offered for acceptance

or

the conditions of the potentially defective component could have contributed to exceeding a safety limit.

Should the situation pass this far through the qualifying matrix, we arrive at the key consideration of Part 21, the evaluation as to whether the defect could, if uncorrected, create as substantial safety hazard.

Next on Figure 6, "Abnormal Occurrences," are events that NRC must report quarterly to Congress under Section 208 of the Reorganization Act of 1974.

The basic criteria used by NRC is shown in Figure 6. Note: the same words are used here as in Part 21's definition of a substantial "safety hazard," namely, "a major reduction in the degree of protection to the public health and safety. This information can be found in Appendix A of the referenced document (NUREG-0090-6, or subsequent quarterly issues of these reports to Congress) along with examples of the types of events which are considered to fall in the category of a major loss of protection to the health and safety of the public. The quarterly NUREG-0090 documents are available from the National Technical Information Service, Springfield, Virginia 22161. The present price is $3.50.

Figure 7 below lists the nine categories that are listed in operating reactor Technical Specifications and in Regulatory Guide 1.16 which is available to the licensee as guidance in reporting Licensee Event Reports (LER). Since LERs are an important source of information that will be reviewed by the NRC in determining which of these events will fit the limiting criteria for reporting of abnormal occurrences to Congress, this information may also provide useful guidance to the industry.

FIGURE 6

CRITERIA FOR EVALUATION

ABNORMAL OCCURRENCE (NRC POLICY STATEMENT - NUREG-0090-6)

EVENTS INVOLVING A MAJOR REDUCTION IN THE DEGREE OF PROTECTION TO PUBLIC.

(1) MODERATE EXPOSURE TO OR RELEASE OF, RADIOACTIVE MATERIAL LICENSED BY OR OTHERWISE REGULATED BY THE COMMISSION,

(2) MAJOR DEGRADATION OF ESSENTIAL SAFETY-RELATED EQUIPMENT, OR

(3) MAJOR DEFICIENCIES IN DESIGN, CONSTRUCTION, USE OF, OR MANAGEMENT CONTROLS FOR LICENSED FACILITIES OR MATERIALS.

FIGURE 7

CRITERIA FOR EVALUATION

LICENSEE EVENT REPORTS (REGULATORY GUIDE 1.16)

(1) FAILURE OF THE REACTOR PROTECTION SYSTEM OR OTHER SYSTEMS TO INITIATE THE REQUIRED PROTECTIVE FUNCTION IN THE APPROPRIATE TIME.

(2) OPERATION (UNIT OR SYSTEM) WHEN ANY PARAMETER IS LESS CONSERVATIVE THAN LIMITING CONDITION ESTABLISHED IN THE TECHNICAL SPECIFICATIONS.

(3) ABNORMAL DEGRADATION IN FUEL CLADDING, REACTOR COOLANT PRESSURE BOUNDARY OR PRIMARY CONTAINMENT.

(4) REACTIVITY ANOMALIES.

(5) COMPONENT FAILURE OR MALFUNCTION WHICH PREVENTS OR COULD PREVENT FUNCTIONAL PERFORMANCE IN ACCIDENT SITUATIONS ANALYZED IN SAR.

(6) PERSONNEL ERROR OR PROCEDURAL INADEQUACY WHICH PREVENTS OR COULD PREVENT FUNCTIONAL PERFORMANCE OF SYSTEMS IN ACCIDENT SITUATIONS ANALYZED IN SAR.

(7) NATURAL OR MAN-MADE CONDITIONS OR EVENTS THAT REQUIRE SHUTDOWN OR OTHER PROTECTIVE MEASURES IN ACCORDANCE WITH TECHNICAL SPECIFICATIONS.

(8) ERRORS DISCUSSED IN SAR ANALYSES OR BASES FOR TECHNICAL SPECIFICATIONS.

(9) PERFORMANCE OF STRUCTURE, SYSTEMS, OR COMPONENTS THAT REQUIRE CORRECTIVE MEASURES TO PREVENT OPERATION IN LESS CONSERVATIVE MANNER THAN THAT ASSUMED IN SAR ANALYSES OR TECHNICAL SPECIFICATIONS BASES.

In summary, it can be generally concluded that a Part 21 report is not required to report a "defect" where one of the other reporting methods has been used. However, before reaching this conclusion one should certainly consider the much broader scope and notification requirements of Part 21 carefully before concluding that a Part 21 report or related information required to adequately inform the Commission is not required. This concludes the discussion relating to Figures 1-7.

15. Must items reported as Significant Deficiencies (under 50.55(e)) or Reportable Occurrences (under 50.36) also be reported as required in 10 CFR 21?

Response:

Duplicate reporting is not required. Care should be exercised, however, to assure "that the Commission has been adequately informed" (§21.21b) and that the information specified in §21.21(b)(3) is provided should the reporting party's evaluation show that a notification is required.

16. How do we determine when to report a "problem" under the provisions of 50.55(e) vs the provisions of Part 21?

Response:

§50.55(e) requires initial reporting in 24 hours of the time licensee or his agent first identifies a significant deficiency. A followup report is required in 30 days. If evaluation requires substantial time to complete, interim report(s) are acceptable.

§21.21(b)(1) requires reporting within two days of when the director or responsible officer obtains information reasonably indicating a failure to comply or a defect" with a written report required within five days.

In all cases, the exercise of reasonable judgment is expected in reporting potentially reportable problems to avoid the severe penalties, which could be imposed should the problem turn out to be reportable.

17. 10 CFR 50.55(e), Conditions of Construction Permits, requires that the holder of a permit notify the Commission of certain designs and construction deficiencies which are also the subject of 10 CFR 21. Why has not 10 CFR 50.55(e) been deleted?

Response:

§50.55(e) requires reporting that would not be reported under Part 21. For example, 1) significant damage to a basic component following delivery to the site is reportable under 50.55(e) and not under Part 21; and 2) a significant break down in quality assurance is reportable under 50.55(e) and not under Part 21.

18. Is the determination of a "defect" based on the same criteria as provided in Part 50.55(e) and/or the requirements for technical specifications for operating plants?

Response:

No. In the case of the permit holder, however, a defect reportable under Part 21 would also be reportable under 10 CFR 50.55(e). In the case of the licensee some items could be reportable under Part 21 that are not reportable as LER.

19. Can the time period for written reports required by 10 CFR 21 be increased to be comparable to that for operation plant technical specifications (14 days)?

Response:

A petition for rulemaking is the proper vehicle to request a change to the rule.

20. The reporting requirements of 10 CFR Part 21 appear to be more comprehensive than the reporting requirements of reactor technical specifications or 10 CFR Part 20. Is it the intent of this regulation to impose reporting requirements whose scope exceeds those already in place?

Response:

It is the intent of Part 21 to require reporting of defects and noncompliance which "could" create Substantial Safety Hazards. The Congressional intent in drafting Section 206 of the Energy Reorgaization Act of 1974 was to anticipate significant safety problems before they occur. Actual "malfunctions" which are safety-related are reported in accordance with 10 CFR 50.36 and the license technical specifications. Defects, noncompliance and conditions which "could" contribute to a substantial safety hazard are reported in accordance with 10 CFR 21.21.

21. For possible problems noted under 10 CFR 50.55(e) we report to the Commission "possible significant deficiencies." Will we be allowed to report "possible defects and noncompliances" under the requirements of 10 CFR Part 21?

Response:

Yes, a report may be made during the evaluation before the conclusion is reached that the deviation is a defect. A report is not required, however, until 2 days after the responsible officer or director is informed of the conclusion reached as a result of the evaluation.

22. It appears to us that there will be more reports filed with the Commission under the requirements of 10 CFR Part 21 than under 10 CFR 50.55(e). Does the Commission have this same belief?

Response:

No. The majority of items subject to reporting under 50.55(e) would not fit the definition in Part 21 for a "defect" involving a "substantial safety hazard." For those cases where both 50.55(e) and Part 21 reporting requirements may apply, it is expected that permit holders will report only under 50.55(e) as long as they include the information required by Part 21 to adequately inform the Commission.

23. Will we be required to issue reports specifically addresssing 10 CFR 21 if the reportable item is currently covered by other regulatory requirements?

Response:

No. Information required by Part 21 notification requirements can be included in other reports submitted to satisfy other regulatory requirements.

24. Explain the relationship, including examples, between 10 CFR 21 reporting requirements and other reporting requirements such as Licensee Event Reports imposed on operating reactor licenses.

Response:

In most instances, an item which is reportable by a licensee under Part 21 is also reportable by a licensee event report. Two examples of items reportable under Part 21 that are not required to be reportable by a licensee event report follow. First is the

report required for a defect in a basic component delivered to a licensee which the licensee discovers after initial receipt inspection which has not been installed in the facility. In this instance, a licensee event report would not be required. The second is a report required for a defect or noncompliance in a security system.

25. Will you please give a couple examples of noncompliance under Part 20 and/or 34 that would require disclosure and notification under Part 21.

Response:

An example of noncompliance under Part 20 that could require notification under Part 21 is a failure to provide appropriate personnel monitoring equipment such that the occurrence creates a "substantial safety hazard."

An example of noncompliance under Part 34 that would require notification under Part 21 would be a failure to properly control access to an area where radiography is conducted so that a "substantial safety hazard" is created.

21.21(b)(2) of - Notification of failure to comply or existence of a defect

(2) Initial notification required by this paragraph shall be made within two days following receipt of the information. Notification shall be made to the Director, Office of Inspection and Enforcement, or to the Director of a Regional Office. If initial notification is by means other than written communication, a written report shall be submitted to the appropriate Office within 5 days after the information is obtained. Three copies of each report shall be submitted to the Director, Office of Inspection and Enforcement.

1. What constitutes "actual knowledge" that a defect has been reported, given the fact that individuals within a corporation must commonly rely on other individuals within the corporation to perform the requisite evaluations or to see that a letter gets mailed? If a director or responsible officer is negligent and fails to see that the proper report is made or the evaluation is done properly, wouldn't he or she be insulated from personal liability by the "knowingly and consciously" language of §21.61?

   Response:

   A director or responsible officer would be liable under §21.61 for a failure to notify if he has information reasonably indicating a defect or failure to comply and does not have actual knowledge that the Commission has been adequataly informed. Actual knowledge is more than a good faith belief. A director or responsible officer would not be personally liable if he does not receive information of the existence of a defect because the evaluation is done improperly.

2. Please discuss further what constitutes adequate verification by a responsible officer that a report has been made to the NRC. For example, does 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) constitute adequate verification?

   Response:

   Yes. Though the Commission does not require it, it would be wise for an organization to set up a procedure whereby any contacts

which would qualify as adequate Part 21 notification 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.

3. Where an extensive evaluation of a defect is required to determine whether it constitutes a substantial safety hazard, what provisions are made for notification time extensions?

Response:

As the terms are defined in Part 21, initial notification to NRC must be made to NRC within two days of when a director or responsible officer obtains information. There is no time limit in Part 21 for performing an evaluation of a deviation to determine whether it is a defect.

4. Is the 48-hour time period for "initial notification" to the Director, Office of Inspection and Enforcement, or to the Director of the Regional Office under Section 21.21(b) intended to allow for evaluation of deviations under 10 CFR Section 21.21(a)(1)(i)?

Response:

The 48-hour time period for initial notification does not begin to run until the evaluation has been completed and the director or responsible officer has been informed.

5. May we assume that reports made to the NRC Regional Director, or to his designated alternates, are acceptable in the absence of the Director himself? (Specifically the concern is for reports which must be made during vacations, holidays and weekends.)

Response:

Yes. Reports made to the Director, or to a responsible member of the Director's staff, will satisfy this requirement.

6. Do the two and five-day time limits on reporting refer to calendar days or working days?

Response:

The two and five days are calendar days, not working days.

7. Does 10 CFR 21 allow for a period of evaluation between the time a potential safety concern is identified and when it must be reported to NRC? If so, what period of time is considered reasonable?

Response:

Yes. The rule presently is silent in regard to the time from when the concern is identified and the time of report to NRC. This time is presently considered to be unquantifiable for all facets of facilities and activities regulated by NRC.

21.21(b)(3) of - Notification of failure to comply or existence of a defect

(3) The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

(iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(v) The date on which the information of such defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of all such components in use at, supplied for, or being supplied for one or more facilities or activities subject to the regulations 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.

1. §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." After we identify a defect it may be difficult or impossible to trace "all" such components in use or supplied for use in the United States. Clarify our responsibility in this regard.

Response:

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 him or his organization.

21.21(b)(4) of - Notification of failure to comply or existence of a defect

> (4) The director or responsible officer may authorize an individual to provide the notification required by this paragraph, provided that this shall not relieve the director or responsible officer of his or her responsibility under this paragraph.

1. These regulations provide that, "Directors and responsible officers may designate an employee to provide on their behalf the notification to NRC." Can this designated employee also file the written report within five (5) days? (Permission for this is not specifically addressed in the regulations, but I believe it was intended.)

   Response:

   The designee may accomplish the notification which includes the written report and the initial notification by means other than written communication.

2. When a director or responsible officer designates a subordinate to provide notification and the subordinate fails to comply, who is to be cited for the infraction?

   Response:

   The director or responsible officer would be cited for the infraction if he has information reasonably indicating a defect or failure to comply and he did not have actual knowledge that the Commission has been adequately informed.

3. How is the individual who is designated to provide the notification to function in relation to the responsible officer or director?

   Response:

   It is solely a delegation of the notification authority but the director or responsible officer retains the responsibilities.

4. The Preamble states: "The individuals subject to the notification requirements of Part 21 have been restricted to a) directors and b) officers vested with executive authority over activities subject to this Part. These individuals may identify an individual who

is authorized to provide notification to the Commission." The first sentence quoted apparently restricts the notification requirements to "...a) directors and b) officers vested with executive authority...," and the second sentence states that an individual may be authorized by the above individuals. Does this mean that by designating an 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) that the A/E will assume all liability under 10 CFR Part 21?

Response:

No. 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.

21.21(c) of - Notification of failure to comply or existence of a defect

(c) Individuals subject to paragraph (b) may be required by the Commission to supply additional information related to the defect or failure to comply.

1. Will the Commission ever require the purchaser, in the course of investigations for cause and corrective action, to divulge additional information on the supplier's activities which may lead to a determination of failure to comply with notification requirements of 10 CFR Part 21?

Response:

NRC can request the responsible individual to provide all necessary information consistent with §21.21(b)(3).

21.31 Procurement Documents

Each individual, corporation, partnership or other entity subject to the regulations in this part shall assure that each procurement document for a facility, or a basic component issued by him, her or it on or after January 6, 1978 specifies, when applicable, that the provisions of 10 CFR Part 21 apply.

1. Current contracts and purchase orders do not have to be updated to require compliance by them. We are assuming that the NRC will take responsibility for their notification. Further, if component suppliers are obligated for notification requirements under Part 21 even though the procurement documents make no reference to Part 21, what is the purpose of requiring that procurement documents include a provision that Part 21 applies?

   Response:

   The final rule has been published in the Federal Register and NRC has made substantial efforts, including scheduling of public meetings, to promote industry and public awareness and understanding of the applicability of Part 21. Beyond that, NRC does not intend to notify each supplier individually of the requirements of these regulations. As the question recognizes, component suppliers are obligated to comply with Part 21 even though the procurement documents make no reference to Part 21. The notification requirements apply where a director or responsible officer subject to the regulations obtains information reasonably indicating a failure to comply or a defect. Specification in the procurement document that Part 21 applies is designed to aid component suppliers in determining whether or not the component being supplied is a basic component within the meaning of Part 21.

2. Contracts and purchase orders issued after January 6, 1978, require clauses indicating that Part 21 is applicable. Will it

be considered sufficient by the NRC if a simple statement to the effect that "Part 21 is applicable" is included in the contract or purchase order, or will licensees or constructors be required to identify the specific application of 10 CFR 21 in contracts and purchase orders?

Response:

The simple statement that Part 21 is applicable to a specific basic component is sufficient, but the purchaser may, if he desires, be more specific.

3. In the judgment of the Commission, should purchase orders for safety-related material such as miscellaneous structural steel, anchor bolts, etc., include the requirements of 10 CFR Part 21 or should the requirements be limited to purchase orders for major safety-related equipment such as pumps and valves?

Response:

"Basic component, when applied to nuclear power reactors means a plant structure, system, component or part thereof . . ." Each procurement document for a "basic component" must specify that the provisions of Part 21 apply. Therefore, purchase orders for structural steel or anchor bolts, if they are basic components or parts of basic components, must specify that Part 21 applies.

4. What if the initial issuer of a procurement document fails to specify that Part 21 applies? Is the organization subject to fine for failure to specify that the provisions of 10 CFR Part 21 apply?

Response:

The issuer of the procurement document is not subject to a fine under Part 21, but could be subject to a fine under Part 2, Subpart B, if he fails to specify in a procurement document for a "basic component," that Part 21 applies. Applicability of a fine via Part 2, Subpart B, will be determined on a case-by-case basis.

5. Are contractors subject to Part 21 if Part 21 is not referenced in their contracts? If the answer is yes, how does an organization know when it becomes subject to Part 21?

Response:

Contractors who knowingly supply basic components are subject to Part 21 even if Part 21 is not referenced in their contracts. Part 21 has

been published in the Federal Register and states the entities to which it applies. Furthermore, the Commission has engaged in public informational meetings to further assure that the persons covered by Part 21 are aware of the rule's applicability.

6. Other than insertion of a contractual provision pursuant to 10 CFR §21.3 is the licensee responsible for assuring that contractors, suppliers, consultants, etc., comply with this regulation? Are quality assurance audits required of those organizations to audit compliance with Part 21? Does this responsibility track back to the supplier of each component and part thereof?

Response:

The licensee's responsibility for insuring compliance with the provisions of Part 21 by its contractors, suppliers, and consultants is limited to the requirement that each procurement document for a facility or basic component specifies that the provisions of 10 CFR Part 21 apply, when applicable. This same requirement applies to all other organizations which are subject to Part 21. The Energy Reorganization Act of 1974 authorizes the Commission to conduct such reasonable inspections and other enforcement activities as needed to assure compliance with the provisions of Section 206. Organizations, which are subject to Part 21, are not required to perform quality assurance-type audits on suppliers specifically for the purpose of insuring compliance with Part 21.

7. Does a purchaser have an obligation to apply 10 CFR Part 21 to long-term contracts issued prior to January 6, 1978?

Response:

A purchaser does not have an obligation to amend existing long-term contracts to specify that Part 21 applies. However, Part 21 applies to contracts which are in existence on or after August 10, 1977, if the contract is to supply a "basic component."

8. Where an NRC licensed activity has established "open orders" for spare parts with a supplier, will it be necessary to impose 10 CFR Part 21 although the order was placed prior to January 6, 1978?

Response:

Section 21.31 requires that each procurement document issued on or after January 6, 1978, specify the applicability of Part 21. Although Part 21 does not require that each procurement document already in existance on January 6 be revised to specify Part 21 applicability, the specification should be added to any subsequent amendments or orders which are issued after January 6, 1978.

9. Paragraph 21.31 requires assurance that the provisions of Part 21 shall apply to each procurement document. In item (6) of the Commission's comments on the regulations, the fourth paragraph states that during a stage of conceptual design or consultation in regard to feasibility it is appropriate to specify the applicability of Part 21 in the procurement document only when such a design or consultation can result in the creation of a substantial safety hazard. This interpretation will have an insulating effect on certain consultants. We believe it is also important to provide some protection to small equipment supply shops whose owners do not have an understanding of the law in this area and may decide to avoid the nuclear industry due to potential liability under Part 21. When adequate receipt inspection criteria can be established and subsequent inspection can be effectively conducted by the purchaser in conformance with Part 50, Appendix B, "Quality Assurance Criteria," is it necessary to specify the applicability of Part 21 in the procurement document?

Response:

If the equipment is a "basic component," then Part 21 applicability must be specified in the procurement document.

10. Is failure to comply with 21.31 subject to the reporting requirements of Part 21?

Response:

No. A failure to comply with section 21.31 is not subject to the reporting requirements of Part 21 because the failure to comply with these requirements is not related to the creation of a substantial safety hazard.

§21.41 Inspections

Each individual, corporation, partnership or other entity subject to the regulations in this part shall permit duly authorized representatives of the Commission, to inspect its records, premises, activities, and basic components as necessary to effectuate the purposes of this part.

1. What type of inspection and other enforcement action is the NRC proposing for enforcement of Part 21? Will inspections be conducted prior to notification?

   Response:

   Inspection and enforcement of Part 21 will be incorporated as an additional requirement into our current reactor, material and vendor inspection programs and will include both announced and unannounced inspections.

2. What steps are being taken to communicate a consistent position within the NRC to ensure consistent application, interpretation, and inspections?

   Response:

   Critaria for Part 21 inspections are being developed for incorporation into existing inspection procedures for use by all the Regional Offices. These criteria will be consistent with the positions set forth in this document.

3. What constitutes demonstration of compliance at a facility which has not had a defect or failure to comply requiring notification under Part 21?

   Response:

   Inspections of the posting requirements of Section 21.6, procedures required by §21.21(a), and maintenance of records under §21.51, when those provisions of Part 21 take effect, will be conducted to determine compliance with Part 21.

4. Will the NRC inspector expect to find in the supplier's QA Manual reference to and a procedure for reporting defects?

Response:

The corporate procedures should provide for the identification of deviations, (§21.3(e)) and, as appropriate, their proper disposition. This includes evaluation and notification to NRC of the defects (K21.3(d)). These procedures do not necessarily have to be included in a QA Manual.

5. What will the nature and scope of the NRC inspections be at a component manufacturer? Will they be specific investigations to assure that no components with defects as defined by Part 21, have been delivered or will they also include verification of ASME Section III Quality System implementation? If they include Section III verification, it would seem that this is a further burden and redundancy over and above inspections already being performed by the ASME, local Authorized Nuclear Inspection Agencies, Architect-Engineers, utilities and NSSS's.

Response:

The NRC's program of vendor inspection is designed to verify conformance to the 10 CFR Part 50 Appendix B criteria. These criteria, along with ASME code requirements (50.55a), are imposed upon nuclear reactor vendors and suppliers by the licensee through normal commercial procurement documents. The NRC generally depends upon licensees or their agents to verify compliance with these requirements. However, the NRC reserves the right of independant verification to assure protection of the health and safety of the public. As stated in question 1 above, Part 21 is an additional requirement which will be included within the scope of the current NRC inspections.

21.51 Maintenance of Records

(a) Each licensee of a facility or activity subject to the regulations in this part shall maintain such records in connection with the licensed facility or activity as may be required to assure compliance with the regulations in this part.

(b) Each individual, corporation, partnership, or other entity subject to the regulations in this part shall prepare records in connection with the design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of any facility, basic component supplied for any licensed facility or to be used in any licensed activity sufficient to assure compliance with the regulations in this part. After delivery of the facility or component and prior to the destruction of the records relating to evaluations (see § 21.3(g)) or notifications to the Commission (see § 21.21), such records shall be offered to the purchaser of the facility or component. If such purchaser determines any such records:

(1) Are not related to the creation of a substantial safety hazard, he may authorize such records to be destroyed, or

(2) Are related to the creation of a substantial safety hazard, he shall cause such records to be offered to the organization to which he supplies basic components or for which he constructs a facility or activity.

If such purchaser is unable to make the determination as required above then the responsibility for making the determination shall be transferred to the individual, corporation, partnership, or other entity subject to the regulations in this part that issued the procurement document to the purchaser. In the event that the determination cannot be made at that level then the responsibility shall be transferred in a similar manner to another individual, corporation, partnership, or other entity subject to the regulations in this part, until, if necessary, the licensee shall make the determination.

(c) Records that are prepared only for the purpose of assuring compliance with the regulations in this part and are not related to evaluations or notifications to the Commission may be destroyed after delivery of the facility or component.

(d) The effective date of the section has been deferred until January 6, 1978.

1. Discuss type of records required by Part 21 for Part 50 licensees and their suppliers.

Response:

As stated in the preamble to the effective Part 21, it is not anticipated that the records required by Part 21 to assure compliance with this Part will necessitate any change in the documentation procedures of organizations that are presently complying and remain in compliance with 10 CFR Part 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.

In addition, records should include the following:

a. Information sufficient to describe the deviation.

b. An analysis of the effect of such deviation in a basic component if used in a facility or activity subject to Part 21.

c. A conclusion based on this analysis as to whether the deviation could create a substantial safety hazard.

2. Is there a time limit for the transfer of records under 10 CFR Section 21.51?

Response:

No.

3. At what point can records related to evaluations and modifications be destroyed under Paragraph 21.51(a)?

Response:

Records related to evaluations and notifications that are not related to the actual creation of a substantial safety hazard can be destroyed after authorized by the purchaser, as explained in Section 21.51(b). Records relating to evaluations and notifications which are related to the actual creation of a substantial safety hazard should be retained for the life of the basic component to which the record refers.

4. Please clarify the following statement. "If such purchaser is unable to make the determination as required above then the responsibility for making the determination shall be transferred to the individual, corporation, partnership, or other entity subject to the regulations in this part that issued the procurement document to the purchaser."

Response:

The intent of this part of the rule is that, in those cases where the supplier or purchaser cannot make the determination, the responsibility for making the determination on record retention be passed up the purchaser/supplier chain to the organization which can make the determination.

5. Are supplier related requirements of Section 21.51(b) satisfied if all the documentation is turned over to the purchaser/licensee without making any determination as to whether portions of the documentation are, or are not, related to the creation of a substantial safety hazard?

Response:

Yes, supplier related requirements of 21.51b have been satisfied.

6. Paragraphs 21.6, 21.21(a), 21.31, and 21.51 are effective January 6, 1978, and the remainder are effective July 6, 1977. Paragraph 21.51 pertains to the maintenance of records and Paragraph 21.21(b) pertains to notification and written reports. Are records of notification and written reports that are required between July 6, 1977, and January 6, 1978, to be maintained in accordance with Paragraph 21.51?

Response:

It is the staff's position that an entity required to maintain records under 21.51 should maintain records of notifications and written reports made to the Commission.

21.61 Enforcement

Any director or responsible officer subject to the regulations in this part who knowingly and consciously fails to provide the notice required by § 21.21 shall be subject to a civil penalty in an amount not to exceed $5,000 for each failure to provide such notice and a total amount not to exceed $25,000 for all failures to provide such notice occurring within any period of thirty consecutive days. Each day of failure to provide the notice required by § 21.21 shall constitute a separate failure for the purpose of computing the applicable civil penalty.

1. Does failure to notify within the requirements of Section 21.21 of 10 CFR Part 21 place all directors and responsible officers at risk of civil penalty?

   Response:

   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.

2. What is the applicability of a civil penalty under Part 21 in the following instances?

   a. If an organization clearly should have specified applicability of Part 21 in the procurement document but failed to do so, will the "responsible officer or director" be liable for a civil penalty?

   b. If an organization fails to properly comply with the posting requirements, will a "responsible officer or director" be liable for a civil penalty?

   c. If an evaluation of a deviation is either not conducted or is not adequately conducted, will the "responsible officer or director" be liable for a civil penalty?

   d. If the evaluation determines that a substantial safety hazard, in fact, does exist but the "responsible officer or director" is not informed, will such "responsible officer or director" be liable for a civil penalty?

e. Can the failure of an employee to inform a director or responsible officer of noncompliance or a defect pursuant to procedures adopted under §21.21(a)(2) result in liability being incurred by the director or responsible officer?

Response:

In all of the above cases, the responsible officer or director will not be liable for a civil penalty under Part 21.

3. Since the fines are only for knowing and conscious failure to report defects, what are the sanctions for other violations of these regulations?

Response:

The enforcement of the requirements of Part 21, other than a knowing and conscious failure to report a defect or failure to comply, would be initiated, as determined appropriate on a case-by-case basis under Part 2, Subpart B, of the Commission's regulations.

4. Would an employee be subject to NRC enforcement action for failing to inform a director or responsible officer of noncompliance or a defect pursuant to procedures adopted under §21.21(a)(2)?

Response:

No.

5. Section 21.61 provides that any director or responsible officer subject to Part 21 who knowingly and consciously fails to provide the notice required by Section 21.21 shall be subject to a civil penalty. May a civil penalty for failure to notify be assessed upon a person at <u>any</u> level of the executive chain of command who, as a result of an honest and reasonable error in judgment or interpretation, fails to notify the Commission of an event which is subsequently deemed reportable?

Response:

If the director or responsible officer has been informed, based on the evaluation, that the deviation or failure does not constitute a defect or failure to comply which is reportable under Part 21, and if there is a reasonable basis for this determination, he would not be subject to a civil penalty for knowingly and

program. Unless experience indicates otherwise, no separate inspection and enforcement program for Part 21 will be implemented.

13. What are the events which would be involved in imposing a civil penalty under 10 CFR Part 21?

Response:

The Director, Office of Inspection and Enforcement, would first serve a written Notice of Violation upon the person charged. The Notice of Violation will identify the basis for the charge, the amount of the penalty which the Office Director proposes to impose, and the opportunities available to the person charged to protest the charge. The person charged may then either pay the penalty in the amount proposed or answer the Notice of Violation within the time specified in the Notice. If the person charged elects to answer, the Office Director, after considering the answer, will issue an Order dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.

The person charged may then request a hearing. If the person requests a hearing, the Commission will issue an Order for Hearing before an Atomic Safety and Licensing Board or an Administrative Law Judge. After the hearing, an Order will be issued dismissing the proceeding or imposing, mitigating, or remitting the civil penalty. Opportunity for review of the Board's or presiding officer's Order by an Atomic Safety and Licensing Appeal Board and the Commission may be available. If payment of a civil penalty is not made within the specified time period, the matter may be referred to the Attorney General for collection.