



OFFICE OF THE INSPECTOR GENERAL

U.S. NUCLEAR REGULATORY COMMISSION

Review of NRC Management of Reporting Requirements Under 10 CFR Part 21

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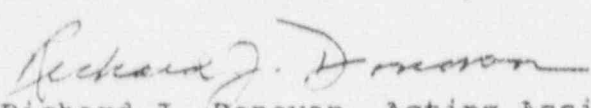


UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

November 30, 1990

OFFICE OF THE
INSPECTOR GENERAL

MEMORANDUM FOR: James M. Taylor
Executive Director for Operations

FROM: 
Richard J. Donovan, Acting Assistant
Inspector General for Audits

SUBJECT: OFFICE OF THE INSPECTOR GENERAL REPORT ON
THE REVIEW OF NRC MANAGEMENT OF REPORTING
REQUIREMENTS UNDER 10 CFR PART 21

Attached is the Office of the Inspector General's (OIG) report on our review of NRC Management of Reporting Requirements Under 10 CFR Part 21. The report makes eight recommendations. On October 19, 1990, the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research provided his comments on a draft of our report. The Deputy Executive Director agreed with seven of the eight recommendations. He disagreed with recommendation 1.

We have reviewed his comments and asked the Office of the General Counsel to review our concern regarding recommendation 1.

The Office of the General Counsel provided their comments on November 9, 1990. Based on our findings regarding recommendation 1 and the Office of the General Counsel's opinion, we believe that recommendation 1 should be implemented. Therefore, we are submitting, under separate cover, a request to the Executive Director for Operations to provide a resolution to recommendation 1.

Attachment:
As stated

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REVIEW OF NRC MANAGEMENT OF REPORTING
REQUIREMENTS UNDER 10 CFR PART 21

EXECUTIVE SUMMARY

INTRODUCTION

The Office of the Inspector General (OIG) has reviewed the Nuclear Regulatory Commission's (NRC) implementation of procedures and management of reports received in accordance with the Code of Federal Regulations, Title 10, Part 21 (10 CFR Part 21), "Reporting of Defects and Noncompliances." Part 21 of Title 10 establishes procedures and requirements for licensees and vendors to report defects and noncompliances associated with equipment, components and material to NRC.

NRC issued 10 CFR Part 21 to meet the requirements of Section 206 of the Energy Reorganization Act of 1974, as amended. Section 206 requires notification to NRC of: 1) any failure to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of NRC relating to substantial safety hazards, and 2) any defect which could create a substantial safety hazard.

OBJECTIVES AND SCOPE

The objectives of our review were to determine:

1. if 10 CFR Part 21 and proposed revisions are adequate for assuring compliance with Section 206 of the Energy Reorganization Act of 1974, as amended; and
2. if NRC's management of 10 CFR Part 21 is adequate to assure proper resolution of defects reported.

OIG conducted its review from August 1989 through April 1990. During the review, OIG held discussions with over 125 different individuals employed by NRC and NRC licensees. OIG visited the five NRC Regional Offices and 14 different commercial nuclear reactor sites. OIG reviewed and gathered documents from various NRC organizations.

OIG analyzed the 1974 enactment of Section 206 of the Energy Reorganization Act by Congress, the 1977 issuance of 10 CFR Part 21 by NRC, and proposed revisions to Section 206 and 10 CFR Part 21 (from 1985 to the present).

FINDINGS

As the result of this review, OIG has identified concerns in three areas: 1) NRC actions associated with commitments made after the nuclear accident at Three Mile Island, 2) management of 10 CFR Part 21 reports within NRR, and 3) management of 10 CFR Part 21 reports within NMSS.

CONCLUSIONS

NRC has not completed its commitments in implementing TMI Action Plan II.J.4. August 1980 was the original date for proposing revisions to 10 CFR Part 21. As of October 31, 1990, the Commission had not approved a final revision to 10 CFR Part 21.

Based on our review of NRR's Management of 10 CFR Part 21 reports, OIG believes improvements can be made to make the system more accurate, reliable, and effective.

Section 206 of the Energy Reorganization Act of 1974 and its legislative history does not clearly show that Congress was concerned with NMSS type licensees. Although NRC decided to include NMSS in the scope of the rule, NMSS has not developed a policy or program for its implementation.

RECOMMENDATIONS

As a result of the findings identified during this review, OIG has provided eight recommendations for resolution of the findings in this report.

AGENCY COMMENTS

The Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research provided comments on a draft copy of this report on October 19, 1990 (See Appendix VI). The Deputy Executive Director agreed with all recommendations except recommendation 1. In recommendation 1, OIG recommended the Executive Director for Operations submit to the Commissioners a revision to 10 CFR Part 21 that includes a specific time frame in the rule itself for the evaluation of deviations. The Deputy EDO responded that the staff had previously recommended such revisions to the Commission, but the Commission did not approve them. The Commission instructed the EDO to revise 10 CFR Part 21 to provide for the evaluation of deviations "as soon as practicable" and that a specific timeframe be discussed in the Supplemental Information.

OIG is concerned that the inclusion of a specific time frame in the Supplemental Information would have little or no regulatory effect if the agency sought to take enforcement action. Therefore, OIG requested the Office of the General Counsel (OGC)

to review this concern and to determine what effect the Supplemental Information would have as a regulatory tool. OGC determined that NRC's current proposed revision to 10 CFR Part 21 would not be enforceable unless the licensee or vendor included a specific time frame in their procedures. Specifically, OGC opined that:

Section 21.21 as finally proposed establishes no fixed deadline for completion of the required evaluation which can be enforced. The discussion explaining the section serves to encourage the affected persons to establish reasonable target dates in their procedures for evaluation of deviations. It also suggests that 60 days would be a reasonable period for completion of such evaluation. However, as the regulation is written (requiring nominal time limits in connection with evaluation procedures) and as the explanation is presented the 60 day period would have no binding effect as a deadline. (See Appendix VII for the full text of OGC's opinion.)

OIG believes that without the inclusion of a specific timeframe in the text of the rule, NRC's regulatory effectiveness under 10 CFR Part 21 will be lessened. In addition, we believe that a specific timeframe in the rule meets the intent of Section 206 of the Energy Reorganization Act of 1974, as amended. Therefore, OIG is requesting, under separate cover, that the EDO provide resolution for recommendation 1.

TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
Background	1
Objectives	3
Scope	3
Methodology	4
FINDINGS	5
Actions associated with commitments made after TMI	5
Management of 10 CFR Part 21 reports within NRR	5
Lack of policy and program within NMSS	6
DETAILS OF THE REPORT	6
REVISION TO 10 CFR Part 21 - TMI	6
Conclusion	8
NRR MANAGEMENT OF 10 CFR PART 21 REPORTS	8
Tracking and Accountability of 10 CFR Part 21 Reports	9
A Significant Number of 10 CFR Part 21 Reports Remain Open	9
The Number of 10 CFR Part 21 Reports is Overstated	9
NRR is Performing Duties of Licensees and Vendors	10
OGCB Performs Little Follow-up with NRC Action Offices	11
Verification of Actions Taken Needs Strengthening	12
10 CFR Part 21 Reports Need Common Identifier Numbers	13
Procedures and Instructions for Handling 10 CFR Part 21 Reports	14
10 CFR Part 21 Training	14

Observation Regarding Distribution of 10 CFR Part 21 Report Information	14
Conclusion	15
NMSS MANAGEMENT OF 10 CFR 21 PART REPORTS	15
Conclusion	16
RECOMMENDATIONS	17
AGENCY COMMENTS	18
OIG ANALYSIS OF STAFF COMMENTS	19
OIG FINDING	19
Staff Comment	19
OIG FINDING	20
Staff Comment	20
OIG Analysis	20

APPENDICES

I	Section 206 of the Energy Reorganization Act of 1974 and Definitions Associated With 10 CFR Part 21
II	Memorandum from V. Stello, OIE to R. Minogue, CSD, October 22, 1980
III	Summary of Proposed Revisions to 10 CFR Part 21 Contained in SECY Papers Submitted to the Commissioners Between December 1985 and August 1989
IV	Closeout Action Codes Used in the 10 CFR 21 Log Maintained by the Generic Communications Branch
V	Procedures and Instructions Associated with NRR Management of 10 CFR 21 Reports Reviewed and Analyzed by OIG
VI	Memorandums from J. Sniezek, EDO, to W. Glenn, OIG, October 19, 1990
VII	Memorandum from J. Cho, OGC to R. Donovan, OIG, November 9, 1990
VIII	Major Contributors to this Report

REVIEW OF NRC MANAGEMENT OF REPORTING
REQUIREMENTS UNDER 10 CFR PART 21

INTRODUCTION

The Office of the Inspector General (OIG) reviewed the U.S. Nuclear Regulatory Commission's (NRC) implementation of procedures and management of reports received in accordance with the Code of Federal Regulations, Title 10, Part 21 (10 CFR Part 21), "Reporting of Defects and Noncompliance." Part 21 of Title 10 establishes the procedures and requirements for licensees and vendors to report defects and noncompliances associated with equipment, components and material to NRC.

NRC issued 10 CFR Part 21 to meet the requirements of Section 206 of the Energy Reorganization Act of 1974, as amended. Section 206 requires notification to NRC of: 1) any failure to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of NRC relating to substantial safety hazards and 2) any defect which could create a substantial safety hazard. (See Appendix I for the complete text of Section 206 and definitions associated with 10 CFR Part 21.)

Background

A Congressional committee made Section 206 part of the Energy Reorganization Act of 1974. The identified intent of Section 206 was to: 1) upgrade the system of detecting and anticipating the defects that increasingly had plagued the nuclear power industry and threatened its safety record and 2) assure NRC had prompt information concerning defects in major components of facilities subject to licensing which could create a substantial safety hazard.

The legislative history revealed Congress believed electric utilities usually had no way of knowing that a sealed, prefabricated part was defective until it triggered a shutdown costing tens of thousands of dollars a day in lost generating capacity. Component failures were cited as accounting for more than half of the abnormal occurrences in nuclear power plants reported to the Atomic Energy Commission in 1973. Additionally, the Congressional committee dealing with enactment of Section 206 believed that NRC's need for information on nuclear defects was equal to the Consumer Product Safety Commission's need for product safety information.

Section 206 of the Energy Reorganization Act of 1974 also required NRC to publish rules and regulations, as necessary, to assure appropriate implementation of that section. NRC issued 10 CFR Part 21 in June 1977 and it became effective in August 1977.

Part 21 of Title 10 requires that directors and responsible officers of firms and organizations building, operating, or owning NRC licensed facilities, or conducting NRC licensed activities to report defects and noncompliances in basic components that could create a substantial safety hazard. Also covered by this regulation are directors and responsible officers of firms and organizations supplying basic components and safety related design, testing, inspection, and consulting services.

Organizations covered by 10 CFR Part 21 must adopt procedures to assure that deviations are evaluated to determine if a defect exists that could create a substantial safety hazard. Such evaluated defects must be brought to the attention of responsible officers. The procedures must also describe the method for notifying officers. Responsible officers must notify the NRC either orally or in writing within two days of learning that a defect exists. If oral notification takes place initially, a written report must be filed within five days of learning of the defect. Responsible officers who deliberately fail to report defects to the Commission are subject to a civil penalty.

The 1979 nuclear reactor accident at the Three Mile Island Nuclear Power Station (TMI) affected the reporting requirements identified in 10 CFR Part 21. As a result, NRC published NUREG-0660, "NRC Action Plan Developed as a Result of the TMI-2 Accident." NRC developed the Action Plan to provide a comprehensive and integrated plan to NRC to correct and improve the regulation and operation of nuclear facilities.

As part of this plan, Action Item II.J.4, "Revise Deficiency Reporting Requirements," stated as its objective, "To clarify deficiency reporting requirements to obtain uniform reporting and earlier identification and correction of problems." The description of this action said NRC would improve 10 CFR Part 21 or Section 206, as necessary, to assure the prompt reporting of all reportable items and the submittal of complete information. August 1980 was the completion date for the actions to resolve this item.

Within NRC, two offices have the primary regulatory authority over licensees and vendors responsible for reporting under 10 CFR Part 21. The Office of Nuclear Reactor Regulation (NRR) has responsibility for the licensing and regulatory oversight of nuclear reactors in the private sector. These include both the nuclear power reactors operated by electric utilities and non-power research reactors, such as those operated by various universities. NRR manages the 10 CFR Part 21 process with licensees and vendors associated with the construction and operation of these reactors.

The Office of Nuclear Material Safety and Safeguards (NMSS) administers the regulation of nuclear materials, as distinct from nuclear reactor facilities. NMSS regulates nuclear materials by conducting three broad programs in the areas of fuel fabrication, material safety, and waste management activities. According to the Director, NMSS, his office manages the 10 CFR Part 21 process with material licensees having national significance.

NRC's five Regional Offices also regulate both reactor and nuclear material activities. The Regional Offices manage the 10 CFR Part 21 process with material licensees located in their regions which do not have generic implications of national significance.

Objectives

OIG developed two objectives for this review:

1. to determine if 10 CFR Part 21 and proposed revisions are adequate for assuring compliance with Section 206 of the Energy Reorganization Act of 1974, as amended; and
2. to determine if NRC's management of 10 CFR Part 21 reports is adequate to assure resolution of defects reported.

Scope

OIG conducted this review from August 1989 through April 1990. OIG initially limited its review of 10 CFR Part 21 reports (and associated documentation) to those received by NRC from January 1986 to December 1989. OIG was originally told that no computerized tracking system existed for those reports submitted before 1986; however, the tracking system and files for earlier 10 CFR Part 21 reports were found when the audit field work was nearly completed. OIG determined that the dates originally selected were adequate for completing the objectives of the review. Therefore, OIG did not perform a review of the pre-1986 10 CFR Part 21 report files. OIG believed reports submitted before 1986 would not reflect the current NRC program for managing 10 CFR Part 21.

OIG analyzed the 1974 enactment of Section 206 of the Energy Reorganization Act by Congress, the 1977 issuance of Part 21 by NRC, and proposed revisions to Section 206 and 10 CFR Part 21 (from 1985 to present).

OIG learned during this review that other NRC rules for reporting to the agency are closely associated with 10 CFR Part 21. One such rule is that dealing with reporting of construction deficiencies (10 CFR 50.55e). Another is the immediate

notification requirements for operating nuclear power reactors (10 CFR 50.72). One other rule is the licensee event report system (10 CFR 50.73). OIG reviewed the other rules only with respect to their impact on NRC's management of 10 CFR Part 21.

During the review, OIG held discussions with 30 NRC personnel in Headquarters, 24 NRC Regional personnel, 35 NRC Resident Inspectors, and 37 licensee representatives employed by 12 utilities. OIG interviewed Headquarter's representatives within the Offices of: 1) Nuclear Reactor Regulation (NRR), 2) Nuclear Material Safety and Safeguards (NMSS), 3) Investigation (OI), 4) Enforcement (OE), 5) the General Counsel (OGC), 6) Nuclear Regulatory Research (RES), 7) Analysis and Evaluation of Operational Data (AEOD), 8) the Secretary of the Commission (SECY), and 9) the Commissioners (OCM). OIG traveled to the 5 Regional Offices and 14 different commercial nuclear power sites.

Methodology

OIG established specific audit methodology to determine if: 1) 10 CFR Part 21 meets the requirements of Section 206; 2) NRC's internal procedures and instructions provide adequate guidelines for assuring compliance with 10 CFR Part 21; 3) NRC's implementation of procedures and instructions is adequate for assuring resolution of 10 CFR Part 21 reports submitted; and 4) NRC's tracking system for 10 CFR Part 21 reports submitted is adequate for its intended use, accurate in the information provided, and assures that issues identified are resolved prior to closure.

OIG reviewed and gathered documents from the various Headquarters Offices, Regional Offices, Resident Inspector Offices, and licensees contacted during the review. OIG compared the legislative history associated with the enactment of Section 206 of the Energy Reorganization Act of 1974, as amended, to the original 10 CFR Part 21 issued in 1977 and various proposed revisions initiated between 1985 and the present.

OIG evaluated a stratified statistical sample of 10 CFR Part 21 reports submitted to NRC between January 1986 and December 1989 as identified in the 10 CFR Part 21 Log maintained by the Generic Communications Branch, NRR. OIG chose the sample population from all 10 CFR Part 21 reports identified as "Closed."

OIG conducted this review in accordance with generally accepted Government auditing standards.

FINDINGS

As the result of this review, OIG has identified concerns in three areas: 1) NRC actions associated with commitments made after the TMI accident, 2) management of 10 CFR Part 21 reports within NRR, and 3) management of 10 CFR Part 21 reports within NMSS. Specifically, these concerns are:

Actions associated with commitments made after TMI

1. Commitments to the President's Commission on the Accident at Three Mile Island dealing with revisions to 10 CFR Part 21 and/or Section 206 scheduled for 1980 are not complete.

Management of 10 CFR Part 21 reports within NRR

2. The tracking and accountability of 10 CFR Part 21 reports submitted is inadequate.
 - Many 10 CFR Part 21 reports have remained unresolved since 1986.
 - The number of 10 CFR Part 21 reports recorded is overstated because many entries in the tracking log are not 10 CFR Part 21 reportable issues.
 - NRR performs some of the 10 CFR Part 21 duties required of licensees and vendors.
 - Follow-up on 10 CFR Part 21 reports assigned to action offices is not routinely performed.
 - ** Follow-up by Regional Offices is not always consistent or clearly understood.
 - ** One action office did not receive 59 reports assigned to it from 1986 and 1987.
 - ** The licensee for Comanche Peak was not aware of and had not evaluated 67 reports potentially applicable to the Comanche Peak Nuclear Power Station.
 - Verification of completion for licensee and vendor actions does not always occur.

- 10 CFR Part 21 reports are not uniquely identified.
- 3. Documentation supporting resolution of 10 CFR Part 21 reports is insufficient and not centrally located.
- 4. Internal procedures and instructions are outdated.
- 5. 10 CFR Part 21 training is inadequate.

Lack of policy and program within NMSS

- 6. Due to uncertainty associated with the enactment of Section 206, it is unclear whether 10 CFR Part 21 should include NMSS.
- 7. NMSS has not established a policy concerning management of 10 CFR Part 21 reports.
- 8. NMSS has not defined how to resolve submittal of 10 CFR Part 21 reports.

During this review, OIG told appropriate NRC officials of those 10 CFR Part 21 reports which had not been addressed and appeared to require immediate attention.

DETAILS OF THE REPORT

The following sections detail the information obtained during the review which provide the basis for the identified findings. The details address revision to 10 CFR Part 21 as the result of the TMI accident, NRR management of 10 CFR Part 21 reports, and NMSS management of 10 CFR Part 21 reports.

REVISION To 10 CFR PART 21 - TMI

As a result of the Three Mile Island nuclear reactor accident in 1979, NRC published NUREG-0660, "NRC Action Plan Developed as a Result of the TMI-2 Accident." NRC developed the Action Plan to provide a comprehensive and integrated plan for the actions judged necessary by NRC to correct and improve the regulation and operation of nuclear facilities. The experience from the accident and the official studies and investigations of the accident were the basis for the plan.

As part of this plan, Action Item II.J.4, "Revise Deficiency Reporting Requirements," states as its objective, "To clarify deficiency reporting requirements to obtain uniform reporting and earlier identification and correction of problems." The description of this action says NRC would improve 10 CFR Part 21,

as necessary, to assure the prompt reporting of all reasonable items and the submittal of complete information. August 1980 was the completion date for proposing actions to resolve this item.

In an October 1980 memorandum to the Director, Office of Standards Development, the Director, Office of Inspection and Enforcement (IE), proposed 12 revisions to 10 CFR Part 21 (See Appendix II). The memorandum pointed out that 10 CFR Part 21 required revision in response to the TMI Action Plan based on the former Office of Inspection and Enforcement's experience. The Director, IE, noted that IE had identified multiple problems during their inspections of the application of 10 CFR Part 21.

The memorandum addressed two major concerns. One was in implementing the reporting requirements with non-licensees. The other dealt with the need to drop duplicate reporting requirements for licensees identified in different 10 CFR Code sections.

Documentation indicates the next attempt to revise 10 CFR Part 21 did not occur until the issuance of SECY-85-399 in December 1985. SECY 85-399 was intended to: 1) drop duplicate evaluation and reporting; 2) set up a uniform threshold for reportable defects; 3) set up time limits for evaluation and reporting; and 4) set up a uniform content for reporting. The Commissioners did not approve these revisions.

In an October 1986 memorandum to the Executive Director for Operations, the Secretary of the Commission said, "The Commission...believes that the rulemaking package should be revised to...eliminate changes to the current Part 21 with the exception of the provision that reporting under 50.55(e) or 50.73 satisfies Part 21."

NRC staff made additional attempts to revise 10 CFR Part 21. They submitted three additional SECY papers dealing with revisions to 10 CFR Part 21 to the Commission between March 1988 and August 1989. The Commissioners did not adopt any of the proposed revisions for final notification of rulemaking. Comments provided by the Commissioners informed the staff of actions necessary to provide an acceptable revision to 10 CFR Part 21. (See Appendix III for summary of proposed revisions.)

OIG believes the most significant revision in the December 1985 and March 1988 SECYs was including a time frame for the evaluation of deviations. The last SECY, issued in August 1989, states the staff believes that 60 days is adequate for evaluating most deviations. This provision is included in the supplemental information to the proposed rule and is not a requirement.

OIG asked both NRC and utility officials their opinions about the need for a specified timeframe for evaluation of deviations. Of

those who responded, 69.2 percent said they believed that a time frame was necessary. Another 9.6 percent said to leave the rule as it was. The remaining 21.2 percent did not offer a specific response to the question posed. Of those not offering a specific response, many said problems with vendors extending the evaluation process and not reporting promptly will continue if a specific time frame is not included. They said this occurred because the rule does not include a time frame for evaluating deviations.

Conclusion

NRC has not completed its commitments in implementing TMI Action Plan Item II.J.4. August 1980 was the original date for proposing revisions to 10 CFR Part 21. However, the first formal submittal of a proposed revision for 10 CFR Part 21 to the Commissioners did not take place until 1985. Additionally, at the time OIG completed its field work for this review, the Commission had not approved a final revision to 10 CFR Part 21.

Section 206, as enacted by Congress, requires the immediate notification of defects which could create a substantial safety hazard to the Commission. OIG believes having a time frame for the evaluation of deviations better meets the intent of Congress' desire to assure NRC has prompt information concerning defects with substantial safety hazards.

NRR MANAGEMENT OF 10 CFR PART 21 REPORTS

The Office of Nuclear Reactor Regulation (NRR) directs all license and inspection activities associated with the design, construction, and operation of nuclear power plants and nonpower reactors. In 1990, there are 112 power reactors licensed to operate, 3 scheduled for completion by 1995, and 7 partially completed but with construction deferred. In addition, there are 48 nonpower reactors licensed in 27 states, with one under construction and one having a construction permit pending. There are thousands of vendors who supply parts and services for these reactors.

Within NRR, the Generic Communications Branch (OGCB), Division of Operational Events Assessment, has the primary responsibility for coordination of 10 CFR Part 21 reports received by NRC. Additionally, OGCB:

Develops guidance and guidelines for immediate corrective actions...resulting from screening of operational events. Analyzes vendor and construction deficiency reports, significant event related generic safety issues and potential generic safety questions identified by Regional offices; and identifies appropriate Agency actions to minimize the recurrence

of similar events. Prepares and coordinates all NRC information notices and bulletins related to power reactors; coordinates preparation and issuance of generic letters, including all NRR activities and interactions with CRGR; and tracks bulletins and generic letters through closeout.

NRC management gave the responsibility for coordination of 10 CFR Part 21 reports to OGCB at the time NRC reorganized in 1987.

Tracking and Accountability of 10 CFR Part 21 Reports

OGCB manages the receipt and disposition of 10 CFR Part 21 reports and related documents. This is aided by a computer based tracking system identified as the 10 CFR Part 21 Log (the Log). The Log contains a summary of each 10 CFR Part 21 report submitted by use of both descriptive and coded entries. The Log provides the following information regarding each report: 1) an OGCB assigned five digit number for tracking; 2) a licensee and vendor code identifying the submitter and those affected; 3) the date of the report; 4) the ten digit Document Control System accession number assigned when received by NRC; 5) an acronym of the NRC action office and identity of the individual assigned to resolve the report; 6) a code identifying the basis for closure; and 7) a brief description of the reported information, including cross reference to any other known related reports.

A Significant Number of 10 CFR Part 21 Reports Remain Open

In analyzing the information contained in the Log, OIG was interested in the number of 10 CFR Part 21 reports received and processed. At the time of this review, the Log registered the receipt of 966 documents from January 1986 to December 1989. The Log revealed that 199 (20.6 percent) of the 966 total entries remained open. Seventy two (39.6 percent) submitted in 1989 remained open. Another 34 (19.8 percent) submitted in 1988 remained open. More significantly, 32 (14.5 percent) submitted in 1987 and 61 (15.6 percent) submitted in 1986 were still open.

The Number of 10 CFR Part 21 Reports Is Overstated

According to OGCB, the NRC Document Control Desk (DCD) initially receives and reviews all documents submitted to NRC to determine their routing. If a document is applicable to 10 CFR Part 21, DCD will route it to OGCB. Other organizations within NRC may also receive and route applicable 10 CFR Part 21 documents to OGCB.

OIG's review and analysis of information contained in the Log showed that the number of 10 CFR Part 21 reports OGCB receives and processes is inaccurate and overstated. This is because

OGCB records all documents received from DCD and all documents identifying 10 CFR Part 21 related information as 10 CFR Part 21 reports in the Log. OIG discovered many documents either have nothing to do with 10 CFR Part 21 or do not contain information which meets the reporting requirements of 10 CFR Part 21.

OIG found that "NO21" is coded for many entries. This means these items are not 10 CFR Part 21 issues and should not have been sent by DCD as 10 CFR Part 21 reports. OIG found that "NO21" is coded for 60 (13.8 percent) of the entries in the Log from January 1987 to December 1989.

Additionally, OIG found 93 (51.1 percent) of the 182 10 CFR Part 21 report entries for 1989 do not meet the requirements for reporting under the rule. These 93 reports provide either 1) follow-up information to previously submitted 10 CFR Part 21 reports, 2) statements of actions taken on previously reported issues, 3) reports of "potential" rather than "actual" 10 CFR Part 21 defects, or 4) other various types of information that are not 10 CFR Part 21 issues. Many of these items are cross referenced to other entries in the Log. OIG found the same condition exists for 1986 to 1988 as well.

NRR Is Performing Duties of Licensees and Vendors

In review of the Log, OIG found many entries for "potential" rather than "actual" defects reported. Part 21 of Title 10 requires the reporting of defects which could create substantial safety hazards. It does not require the reporting of potential defects. Defects are identified when evaluations are performed for deficiencies which may create substantial safety hazards.

If vendors do not perform their own evaluation of a deviation, they must inform licensees or purchasers of products or services with the deviation so they may cause the deviation to be evaluated. Those regulated by 10 CFR Part 21 are required to maintain records to assure compliance with the regulations set forth by the rule.

OIG discovered NRR has assumed some responsibilities for evaluating defects identified in 10 CFR Part 21. Since taking on this responsibility, NRR has not documented its evaluations. OIG found no documentation to support that "potential" defects had ever been evaluated. OIG was told in these cases NRR usually determines the items are not safety significant and no further action is warranted. Additionally, NRR provides no written justification for making such a determination.

NRR is not required to accept reports of "potential" defects. However, if NRR accepts the report of a "potential" defect it should assure that an evaluation takes place to resolve the questionable item. When NRR determines "potential" defects

require no further evaluation by licensees or vendors, NRC has become the evaluator and should document its decision. If NRR determines further action is warranted, NRR should assure that either the vendor or affected licensees make an evaluation. This would assure compliance with the requirements of 10 CFR Part 21.

OGCB Performs Little Follow-up with NRC Action Offices

OGCB initially reviews each 10 CFR Part 21 report and decides what actions are necessary. OGCB then determines if it will take responsibility for coordination of required actions to resolve the reported issue. If not, OGCB will assign this responsibility to another action office. OGCB then uses the Log to document responsibility for resolution and closure.

OIG found that OGCB does not routinely follow up to assure the assigned office took action to resolve the 10 CFR Part 21 reports.

OIG reviewed the Log for the period January 1987 through December 1989 which showed 574 documents recorded as 10 CFR Part 21 entries. Of these, OGCB retained responsibility for resolving 290 (50.5 percent) reports. OGCB assigned the Vendor Inspection Branch (RVIB) in NRR 193 (33.6 percent) reports. OGCB assigned the remaining 91 (15.9 percent) reports to various other action offices. OIG has determined that, once assigned by OGCB, the management process for the resolution and close out of reports is not always effective.

OIG reviewed 4 of the 91 10 CFR Part 21 reports received between 1987 and 1989 that were transferred to technical branches within NRR. The OIG review showed: one report received no action; actions taken for another report were indeterminate; one report was resolved; and the last report was still open. However, according to the Log, this report was closed in March 1988. OGCB said they perform little follow-up to reports sent to other cognizant technical branches to assure resolution and closure.

OGCB assigns some 10 CFR Part 21 reports to the Regions for action. OGCB uses the code "NGTR" (considered non-generic - assign to Region) in the Log to show that a Regional office is responsible for resolution. OIG found that one Region was not aware "NGTR" meant the Region should take follow-up action for such coded reports. This Region had not taken any action on 10 CFR Part 21 reports coded this way before the OIG review. However, the Region did start action as a result of OIG's finding.

OIG discovered the Vendor Inspection Branch (RVIB) did not receive 59 assigned reports from 1986 and 1987. Of these, 38 had

originally been assigned to the former Vendor Protection Branch in 1986. Based on this OIG finding, RVIB is currently taking actions to resolve these reports.

OIG prompted a discovery that Comanche Peak licensee personnel were not aware of 67 separate 10 CFR Part 21 reported issues contained in the OGCB Log and Region IV 10 CFR Part 21 Log. This occurred because NRC's Comanche Peak Special Project personnel at Headquarters did not supply the information to the site. As a result, Comanche Peak licensee representatives began a review of these reports to determine their impact.

Verification of Actions Taken Needs Strengthening

OIG is concerned with the OGCB method of assigning closure codes and verifying actions taken. Appendix IV to this report identifies the closure codes used in the OGCB Log to identify the various methods used to close 10 CFR Part 21 reports. OIG was unable to find any procedure or instruction defining the application for these codes. Additionally, no criteria exists which defines required actions before applying the codes.

OIG is particularly concerned with the staff's frequent use of the codes VASU (Vendor Actions Sufficient) and LISU (Licensee Actions Sufficient) for closing 10 CFR Part 21 reports. OIG analyzed the report closure codes for 1988 and 1989. OIG found "VASU" and/or "LISU" applied to 50 percent (69/138) of the reports closed in 1988 and to 62.7 percent (69/110) closed in 1989. In addition, OIG was told many of these closed reports have no additional information to support the staff's determination other than that initially reported.

Representatives of OGCB and RVIB told OIG these codes show they have determined that 1) the issues have been adequately identified, 2) the appropriate licensees or vendors have been informed, and 3) appropriate corrective actions have been proposed to resolve the identified defects. They did not believe further actions were warranted.

NRC personnel in the Regions do not routinely perform inspections to assure action on 10 CFR Part 21 reports unless directed by an Information Notice (IN), a Bulletin or the "NGTR" closure code. However, OIG discovered that different Regional Offices follow up on 10 CFR Part 21 reports in different ways. Two Regions did not have any follow-up format in place, even though their Regional instructions show the requirement for follow-up. The other three Regions perform follow-up actions on reports affecting nuclear power stations in their regions. These three Regions have an open item list which identifies 10 CFR Part 21 reports affecting the various sites in their region. The Regional Office personnel, Special Projects personnel, and Resident Inspectors (RI) interviewed said follow-up is performed in accordance with

the requirements identified in the inspection procedures listed in the mandatory inspection program for their sites.

OGCB and RVIB representatives said they believe Regional inspectors and RIs perform follow-up action for INs at the nuclear power stations. Some RIs said they did not follow up on INs unless directed by the Region or a Temporary Instruction. Some Regional personnel said RIs can determine on which reports they will follow up. OIG was told limited resources within NRC prevented follow-up on all INs written as the result of 10 CFR Part 21 activities. However, OIG found there were only 42 INs identified in the closure codes for resolving 10 CFR Part 21 reports from 1986 to 1989. OIG believes this number of INs is not a significant number of INs requiring follow-up over a four year period.

NRR officials informed OIG that, if the 10 CFR Part 21 process fails, NRC has other methods to assure that nuclear reactor facilities are safe for operation, such as: 1) Resident Inspector and Region based inspections; 2) the licensee event reporting system under 10 CFR Part 50.73; 3) the immediate notification requirements for operating nuclear power reactors under 10 CFR 50.72; and 4) the Systematic Assessment of Licensee Performance inspections conducted on a regularly scheduled basis. Representatives from NRR said these programs provide the agency with confidence that substantial safety hazards will not go undetected, even if a 10 CFR Part 21 issue has not been adequately resolved.

10 CFR Part 21 Reports Need Common Identifier Numbers

OIG found there is no consistency within NRC for maintaining a specific reference number for 10 CFR Part 21 reports. NRC does not maintain a specific number for 10 CFR Part 21 reports like other NRC generated documents (for example, Information Notices, Bulletins, Generic Letters).

The NRC Document Control Desk assigns a ten digit accession number to 10 CFR Part 21 reports it receives. OGCB then assigns a five digit identification number. NRC does not communicate this five digit number to the reporting licensee or vendor. OGCB said all NRC personnel involved with any particular 10 CFR Part 21 report should always use the assigned five digit number for any reference. OIG discovered some Regional Offices have also assigned their own 10 CFR Part 21 report numbers to those reports affecting nuclear power stations in their regions. Individuals cannot refer to one specific 10 CFR Part 21 report number for discussion purposes when performing follow-up activities. This also occurs when additional communication on the reported issues is necessary with others outside NRC.

Procedures and Instructions for Handling 10 CFR Part 21 Reports

OIG reviewed 21 different procedures and instructions for NRC's management of 10 CFR Part 21. These procedures and instructions provide guidance to both Headquarters and Regional personnel in managing and regulating the 10 CFR Part 21 process. This guidance is provided in the form of Manual Chapters, Inspection Procedures and NRR Office Letters. In many instances the guidance is general in nature and, in others, the guidance appears to be outdated because of changes in NRC's regulations and organization. In at least one instance, the Inspection Procedure for "Followup on Corrective Actions for Violations and Deviations" has not yet been issued.

While we recognize that many of these guidance documents pertain to more than just 10 CFR Part 21 reports, we believe that 21 separate documents to address the management of 10 CFR Part 21 reports may result in untimely and inappropriate action by the cognizant NRC office. Because 10 CFR Part 21 issues are, by definition, safety significant, we believe NRC's management of these issues should be consolidated into a separate set of instructions. (See Appendix V for the procedures and instructions reviewed and analyzed by OIG.)

10 CFR Part 21 Training

OIG discovered that little, if any, training has taken place within NRR or the Regions regarding the management of 10 CFR Part 21 reports. Resident Inspectors at the various sites told OIG they had received no formal 10 CFR Part 21 training. Similarly, individuals responsible for coordinating 10 CFR Part 21 reports within OGCB also said they had received no formal training. However, they have received on-the-job training from other personnel they were replacing. Without formal training, NRC cannot assure that those directly involved in the 10 CFR Part 21 process know or understand their responsibilities.

Observation Regarding Distribution of 10 CFR Part 21 Report Information

OIG became aware that OGCB distributes the Log on a monthly basis to appropriate Headquarters and Regional offices. The July 1989 Log was distributed to the five Regional Offices, ten NRR managers and the Director, Office for Analysis and Evaluation of Operational Data. The purpose of the distribution is to identify to the recipients all 10 CFR Part 21 reports received and closed during a specific period. The memorandum sent with the Log asks recipients to supply information about additional known 10 CFR Part 21 reports not shown in the Log. Distribution usually includes a complete listing of all reports received in a given year, regardless of the date of distribution. This results in a

duplicate distribution of information several times over the period of a year, resulting in a waste of resources to review redundant information.

Some licensees said receipt of information contained in the Log would be helpful to them in review of issues potentially affecting their nuclear power stations. These licensees said a document similar to a NUREG published for Licensee Event Reports would be of use to them.

OIG presents these observations to NRR management for consideration with no specific recommendations.

Conclusion

Based on its review of NRR's management of 10 CFR Part 21 reports, OIG believes improvements can be made to make the system more accurate, reliable and effective.

OIG found the system for tracking and accounting for 10 CFR Part 21 reports is not accurate and contains information that overstates the number of reports received. In addition, the system does not provide accurate and reliable information on the status of 10 CFR Part 21 reports. The number of open 10 CFR Part 21 reports is growing and a large number are still unresolved after four years.

OIG found that NRR performs little follow-up on licensees' and vendors' actions to assure that such actions have in fact taken place. OIG recognizes NRC has other programs to identify problems at reactor and vendor sites, but these programs tend to be reactive in nature. The intent of Section 206 and NRC's implementing regulations in 10 CFR Part 21 is to identify defects before they can become a risk to the health and safety of the public at the reactor sites.

In addition, the files, records and other documentation which provide evidence of actions taken on 10 CFR Part 21 reports are not centralized, sometimes non-existent, or inadequate to assure that corrective actions have been effective.

Little or no formal training has been provided to those personnel having direct responsibility for overseeing the resolution of 10 CFR Part 21 reports.

NMSS MANAGEMENT OF 10 CFR PART 21 REPORTS

NMSS directs all license and inspection activities associated with fuel fabrication and related facilities. NMSS also directs licensing and inspection activities with users of nuclear material and transport of nuclear material. NMSS license and inspection activities also include organizations involved with

safe management and disposal of low level and high level nuclear waste, as well as decontamination and decommissioning of facilities and sites. In 1990, there are 12 fuel fabrication and related facilities licensed to operate. Additionally, NRC has issued about 8,000 licenses for medical, academic, and industrial uses of nuclear materials. There are over 7 million clinical procedures using radioactive material performed annually for diagnosis and 200 thousand for treatment of patients.

Universities, colleges, and other academic institutions use nuclear material in course work and research. Industrial applications such as radiography, gauging devices, gas chromatography, well logging, and smoke detectors also use nuclear material.

The Director, NMSS, said that NMSS has not implemented a policy or procedures related to 10 CFR Part 21. He said NMSS has not regulated material licensees for 10 CFR Part 21 because there never was a firm belief that Section 206 applied.

OIG discussed the enactment of Section 206 and issuance of 10 CFR Part 21 with the Director and Deputy Director, NMSS, and one of the originators of 10 CFR Part 21. These individuals were in the former Office of Standards Development (OSD) when NRC initiated the rule.

They informed OIG that NRC management directed OSD to develop NRC's regulation for implementing the requirements of Section 206. They said they believed Congress, in enacting Section 206, had been concerned with vendors who supplied components to nuclear reactor facilities. Also, Congress wanted to make vendors responsible for their defects and the concern with defective components was the implication to all nuclear power reactors.

These former OSD employees said OSD held discussions with legislative representatives and everything discussed pointed to a concern with operating reactors. They discussed the scope of the legislation with the Commission and all context was in terms of nuclear power reactors. Furthermore, the emphasis of Section 206 was on safety and the assumption of reducing basic major accidents from occurring. They said, because Section 206 did not omit NMSS types of licensees and vendors, NRC management determined the scope of the rule was to include NMSS.

Conclusion

OIG learned that NRC's understanding of the original enactment of Section 206 of the Energy Reorganization Act of 1974 was unclear. The available legislative history does not clearly show that Congress was concerned with NMSS type licensees.

Although NRC decided to include NMSS in the scope of the rule, NMSS has not developed a policy or program for its implementation. Unless NRC revises the rule to drop the inclusion of NMSS licensees, OIG believes NMSS should establish a policy and develop a program for managing 10 CFR Part 21 reports.

RECOMMENDATIONS

As a result of this review, OIG is making eight recommendations to improve the management and resolution of 10 CFR Part 21 reports.

To assure the resolution of Action Item II.J.4 of the TMI Action Plan and provide a rule more suited for regulation and enforcement, OIG recommends:

1. the EDO submit to the Commissioners a revision to 10 CFR Part 21, including in the text of the rule a specific time frame for evaluation of deviations in identifying defects which could create substantial safety hazards.

To improve the effectiveness of NRR's management and resolution of 10 CFR Part 21 reports, OIG recommends:

2. the Director, NRR, develop procedures which prescribe the OGCB management process for 10 CFR Part 21 reports and specifically address the OIG findings noted in this report; and,
3. the Director, NRR, provide for adequate training to all individuals involved in the managing and closeout of 10 CFR Part 21 reports.

To clarify the intent of Section 206 and its application to NMSS type licensees, OIG recommends:

4. the Office of the General Counsel (OGC) determine whether Section 206 of the Energy Reorganization Act of 1974, as amended, is applicable to NMSS licensees and vendors and advise the EDO of those actions necessary to comply with the Act.

If OGC determines that the scope of Section 206 does not include NMSS licensees, OIG recommends:

- 5a. the EDO to direct the NRC staff to revise 10 CFR Part 21 by dropping NMSS licensees from its scope.

If OGC determines Section 206 is applicable to NMSS or the EDO decides to leave NMSS licensees in the scope of 10 CFR Part 21, OIG recommends:

- 5b. the Director, NMSS, establish a policy for NMSS management of 10 CFR Part 21 with its licensees and vendors, including the development of instructions and a tracking system for managing that policy.

To improve the effectiveness of NRR's management and resolution of 10 CFR Part 21 reports, OIG recommends:

6. the Director, NRR, review and revise the Manual Chapters and Inspection Procedures used to describe NRR's management and regulation of 10 CFR Part 21 reports;
7. the Regional Administrators review their procedures to assure consistency with procedures revised by Headquarters; and,
8. the Director, NRR, consider consolidating all procedures and instructions pertaining to 10 CFR Part 21 issues into a single source document.

AGENCY COMMENTS

The Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research provided comments on a draft copy of this report on October 19, 1990. The Deputy Executive Director agreed with all recommendations except recommendation 1.

In Recommendation 1, OIG believed the revision to 10 CFR Part 21 should include in the text of the rule a specific timeframe for the evaluation of deviations to identify defects which could create substantial safety hazards. In his response, the Deputy EDO stated that staff has previously recommended to the Commission such revisions, but the Commission did not approve the proposed revisions.

The Commission directed the EDO to revise 10 CFR Part 21 to provide for the evaluation of deviations to identify defects "as soon as practicable" and that the staff should discuss a specific timeframe for evaluation of deviations in the Supplemental Information.

After reviewing the Deputy EDO's comment and the revised proposed revisions, OIG requested OGC to review the issue to determine whether the inclusion of a specific timeframe in the Supplemental Information would be enforceable from a regulatory standpoint.

OGC provided their comments by memorandum dated November 9, 1990 (See Appendix VII). OGC informed OIG that, "Valid regulations have the force of law. Explanatory material accompanying a regulation has no force in and of itself. It carries weight only to the extent it helps to clarify a regulation that is open to interpretation."

The OGC analysis further points out that as the regulation is written (requiring nominal time limits in connection with evaluation procedures) and as the explanation is presented, the 60 day period referred to in the Supplemental Information would have no binding effect as a deadline. According to OGC, the only way the 60 day time limit or some other specific time limit would be enforceable is if it were included in the procedures of licensees and vendors.

OIG believes the inclusion of a specific timeframe in the regulation would be more effective as a regulatory tool and would meet the intent of Section 206 of the Energy Reorganization Act of 1974 as amended. The purpose of Section 206 was to ensure that the Commission has prompt information concerning safety defects. Therefore, OIG is requesting the EDO, by separate memorandum, to review recommendation 1 and to reconsider the need to include a specific timeframe in the regulations.

OIG ANALYSIS OF STAFF COMMENTS

Enclosure 1 to the Deputy EDO's response to the draft report contains the staff's comments regarding certain findings presented in OIG's draft report. Following is OIG's analysis of the staff's comments where OIG believes the staff may not have fully understood our concern.

OIG FINDING

The number of 10 CFR Part 21 reports recorded is overstated because many entries in the tracking log are not 10 CFR Part 21 reportable issues.

Staff Comment

The staff agrees that some notifications contained in the tracking log are not 10 CFR Part 21 notifications. OGCB, due to variance of interpretations of the rule's reporting requirements throughout industry, frequently receives notifications from licensees and vendors which report "potential" defects or are not specifically identified as 10 CFR Part 21 notifications. This typically occurs because the licensee or vendor is unsure whether the identified deviation meets the reporting requirements of 10 CFR Part 21. All of these notifications are treated by OGCB as

if they were reportable 10 CFR Part 21 issues and appropriate actions (such as initial screening, entry into the 10 CFR Part 21 tracking system, and, if warranted, detailed follow-up review or issuance of a generic communication) are taken. NRR does not perform its evaluation to determine if the reported deficiency represents a substantial safety hazard that should have been reported under 10 CFR Part 21. NRR performs these actions to carry out its safety responsibility to identify and address potentially significant safety issues. NRR actions are not dependent upon whether the notification meets the legal requirements for reportability contained in 10 CFR Part 21. NRR actions are considered a conservative approach to carrying out its safety responsibility.

OIG FINDING

NRR performs some of the 10 CFR Part 21 duties required of licensees and vendors.

Staff Comment

The staff does not agree with the OIG finding. As noted above, NRR does not review information submitted by licensees and vendors to determine if the deficiency creates a substantial safety hazard and was properly reported in accordance with 10 CFR Part 21. NRR reviews information to determine if it represents a significant safety issue and if all potentially affected licensees have been properly informed. NRR activities do not assume the duties and responsibilities of licensees and vendors of evaluating defects identified, nor do they relieve licensees and vendors of their responsibilities to perform their own evaluations or cause the evaluation to be conducted by licensees or purchasers or products or services. The staff, through its audit and inspection activities, examines the effectiveness of licensees' and vendors' programs to fulfill their 10 CFR Part 21 obligations. The NRC staff does prudently consider all information which it receives which bears on reactor safety.

OIG Analysis

OIG is addressing these two findings and the staff's comments as one because they are interrelated.

One of the objectives of OIG audit was to review NRC's management of 10 CFR Part 21 reports. In order to accomplish this objective OIG needed to know how many Part 21 reports were reported to NRC and how the staff handled the reports through resolution. Resolution to OIG meant that the reported issue was addressed by the affected licensee, verified by the cognizant regional office, and reported back to OIGCB for closure.

The staff agrees with OIG's finding that the number 10 CFR Part 21 reports recorded is overstated, but disagrees that NRR performs some of the duties that licensees and vendors are required to perform under 10 CFR Part 21.

The staff agrees that NRC frequently receives notifications from licensees and vendors which report "potential" defects or are not specifically identified as 10 CFR Part 21 notification. The staff's comment points out that "NRR does not perform its evaluation to determine if the reported deficiency represents a substantial safety hazard that should have been reported under 10 CFR Part 21." However, the staff's statement preceding this statement states:

All of these notifications ['potential' defects or notices not specifically identified as 10 CFR Part 21 notifications] are treated by OGCB as if they were reportable 10 CFR Part 21 issues and appropriate actions (such as screening, entry into the 10 CFR Part 21 tracking system, and, if warranted, detailed follow-up review or issuance of a generic communication) are taken. Further, the staff points out that NRR reviews the information to determine if it represents a "significant safety issue" and if all potentially affected licensees have been properly informed.

OIG agrees that the staff should be concerned with issues that bear on reactor safety, but if the staff reacts to all issues reported "as if they were reportable 10 CFR Part 21 issues" and performs an evaluation to determine whether it represents a "significant safety issue", then such actions do appear to be duties at least similar to those required of licensees and vendors under 10 CFR Part 21.

According to OIG's audit, once NRR makes these reviews, the issue is closed by NRR and no follow-up is made to determine whether in fact the "potential" defects represent substantial safety hazards.

SECTION 206 OF THE ENERGY REORGANIZATION ACT OF 1974
AND DEFINITIONS ASSOCIATED WITH 10 CFR PART 21

Section 206 of the Energy Reorganization Act of 1974 states:

(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 following definitions are contained in 10CFR21:

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.

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 the rule.

Deviation means a departure from the technical requirements included in a procurement document.

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

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

Defect means: (1) a deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the rule if, on the basis of an evaluation, 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 (1); or (3) a deviation in a portion of a facility

subject to the construction permit or manufacturing licensing requirements of Part 50 of 10 CFR, Chapter 1 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 10 CFR, Chapter 1.

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 off-site exposures.

When applied to other facilities and to other activities licensed pursuant to Parts 30, 40, 50, 60, 61, 70, 71 or 72 of 10 CFR, Chapter 1, basic component 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 rule and in which failure to comply with any applicable regulation in the rule, order, or license issued by NRC could create a substantial

safety hazard.

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. A commercial grade item is not a part of a basic component until after dedication.

Commercial grade item means an item that is: (1) not subject to design specification requirements unique to facilities or activities licensed by NRC; (2) used in applications other than facilities and activities licensed by NRC; and, (3) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example a catalog).

A commercial grade item becomes a basic component after receipt when that item is designated, or dedicated, for use as a basic component.

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 by NRC.

OCT 22 1980

MEMORANDUM FOR: Robert B. Minogue, Director
Office of Standards Development

FROM: Victor Stello, Jr., Director
Office of Inspection and Enforcement

SUBJECT: RECOMMENDED REVISION TO 10 CFR 21 BASED ON IE EXPERIENCE -
TMI ACTION PLAN ITEM 2.J.4

The purpose of this memorandum is to request preparation of a revision to 10 CFR 21 which, in my view, is necessary to permit proper inspection and enforcement actions. We have identified multiple problems during IE inspections of the application of 10 CFR 21 and from meetings concerning 10 CFR 21 which I have had with several Nuclear Steam System Suppliers. The TMI Action Plan does require IE to propose changes to 10 CFR 21 based on its inspection and enforcement experience.

IE experience indicates that most of the problems in implementing the reporting requirements of 10 CFR 21 are with non-licensees. For example, we have noted inordinate delays by one non-licensee in evaluation of potential substantial safety hazards, which under current rules could remain in the evaluation process for an indefinite time. I am especially concerned that a safety-related event could occur at an operating licensed facility while the recognized causative defect remains unreported and in the process of evaluation by a non-licensee.

IE experience with 10 CFR 21 reports from licensees indicates a need to eliminate duplication of reporting requirements between the various applicable sections of the regulations. The IE staff is evaluating the pros and cons of revising reporting requirements for each type of license to eliminate duplication and to include the provisions of Section 206 of the Reorganization Act. This would result in making 10 CFR 21 applicable specifically to non-licensed organizations. We will advise you separately of the results of that evaluation.

The following summarizes problems relative to 10 CFR 21 and proposed solutions:

1. Problem: Licensees have generally duplicative reporting requirements under 10 CFR 21 and other sections of 10 CFR such as 50.72, 50.36, and 50.55(e). This has caused some confusion, duplicate reporting, and unnecessary effort by licensees, especially those covered by both 10 CFR 50 and 10 CFR 21.

CONTACT: J. M. Taylor, IE
49-27068

Robert B. Minogue

- 2 -

Proposed Solution: Revise 10 CFR 21 to specify those other reporting sections of 10 CFR under which 10 CFR 21 problems may acceptably be reported to the NRC.

2. Problem: Organizations subject to 10 CFR 21 are not consistently and properly defining a "substantial safety hazard." Also in some cases they are not utilizing the guidance on this subject contained in NUREG 0302, Rev. 1, or they are treating this guidance listing as both inclusive and exhaustive.

Proposed Solution: Expand the 10 CFR 21 definition of substantial safety hazard, utilizing NUREG 0302, to include but not be limited to any problem which could cause:

- . Exceeding a safety limit as defined in the facility technical specifications;
- . a basic component not being able to perform its intended safety function when actually called upon to work; this includes systems or components which provide redundant capability in this area;
- . an accidental criticality;
- . exposure in excess of 25 REMs, whole body;
- . exposure of an individual in an unrestricted area to more than 0.5 REM in one calendar year;
- . release of radioactivity to an unrestricted area in excess of 10 times the Technical Specification limit (this does not apply to instantaneous release limit).

3. Problem: For licensed activities other than those for reactors under 10 CFR 50, both the licensees and our inspectors are uncertain as to what types of problems constitute a "substantial safety hazard" under 10 CFR 21.

Proposed Solution: In addition to the definitions of substantial safety hazards in 2 above, provide additional descriptions of substantial safety hazards unique to each licensed activity under 10 CFR where appropriate.

4. Problem: With regard to potentially reportable problems under 10 CFR 21, adequate distinction is not being made between evaluating and reporting those problems which affect an operating reactor and those which affect a reactor under design/construction. Based on impact on reactor safety, special attention must be applied to those problems affecting operating reactors.

Proposed Solution: Revise 10 CFR 21 to define a problem of "immediate safety significance" as one which is or could be a substantial safety hazard involving an operational reactor (a reactor that has been or will shortly be critical).

5. Problem: The current requirements permit directors and responsible officers to remain aloof and uninformed concerning potentially reportable problems under 10 CFR 21 during the period from identification through evaluation and until subordinates make a positive determination that the problem is required to be reported to the NRC. Thereby the person with maximum judgment capability and experience, as well as maximum responsibility under the law, remains detached during the problem identification/evaluation process which in some cases is taking more than one year to complete. This situation could be especially detrimental to safety when potential problems are of "immediate safety significance" as defined above.

Proposed Solution: Revise 10 CFR 21 to require that the designated director or responsible officer be informed of all potentially reportable problems affecting an operational reactor under 10 CFR 21 coincident with the problem being referred to the appropriate within-company group responsible for evaluating the problem. 10 CFR 21 should further require that such director or officer determine whether the problem is or is not of "immediate safety significance". If he determines that it is, he should be required to report that item to the NRC within 48 hours while having evaluation of the problem continued.

6. Problem: After a problem is first identified as potentially reportable under 10 CFR 21 by an individual within a licensee's or non-licensee's organization, inordinate delays (as long as 12 months) are occurring before the problem is even referred to the appropriate, within-company group responsible for evaluating the problem. Such delays are currently additive to evaluation times before an item is referred to a responsible officer or director for possible reporting to the NRC.

Proposed Solution: Revise 10 CFR 21 to specifically limit the time between first identification of a potentially reportable problem under 10 CFR 21 and the time it is referred for evaluation to a maximum of fourteen (14) days.

7. Problem: There is no control of the time extent being utilized to evaluate potentially reportable problems under 10 CFR 21 after they are referred to the responsible within-company evaluation group. IE experience indicates that in some cases evaluation is taking more than one year to complete.

Proposed Solution: 10 CFR 21 should be revised to require the designated director or responsible officer to approve the time span permitted for evaluation after he has been informed of a potentially reportable problem and after he has determined whether such problem is or is not of "immediate safety significance". The NRC should be notified of permitted time spans for problems of "immediate safety significance" and periodically notified for any other problem for which the time span exceeds six (6) months.

8. Problem: In those cases where a supplier-purchaser relationship is not involved, 10 CFR 21 currently allows destruction of records of evaluation of potentially reportable problems after a within-company determination has indicated that a substantial safety hazard is not involved. Destruction of

such records has hindered IE inspections to insure that potentially reportable problems are thoroughly evaluated at organizations such as Nuclear Steam System Suppliers and Architect/Engineers.

Proposed Solution: Revise 10 CFR 21 to require retention of records of evaluation of potentially reportable problems; the duration of retention should be the same as specified for quality assurance records maintained under 10 CFR 50 Appendix B.

9. Problem: 10 CFR 21 currently waives notification of NRC of a reportable problem if the responsible individual has actual knowledge that the Commission has been adequately informed. This has led to a number of instances where telephone calls or other nondocumented means of communication are regarded as adequate notification increasing the possibility of inadequate followup concerning a substantial safety hazard.

Proposed Solution: Revise 10 CFR 21 to require that the only acceptable and recognized means of informing the Commission is through a written report submitted in accordance with any of the NRC reporting requirements with the report to include the information currently required by 10 CFR 21.21(b)(3).

10. Problem: 10 CFR 21 currently limits NRC contact for additional information concerning a reported problem to the party who initiated the report. This has restricted NRC's ability to obtain important information. For example, when a defective vendor supplied component is reported by an architect/engineer, NRC should have the option to require the responsible vendor to supply information concerning other purchasers and users of the same defective component.

Proposed Solution: Revise 10 CFR 21 to state that any party associated with a reported problem may be required to supply additional information related to the defect or failure to comply.

11. Problem: Inspections have indicated that some organizations subject to 10 CFR 21 have not established management controls and procedures to assure that all provisions of that regulation are met. This problem was the subject of IE Information Notice No. 79-30 dated December 6, 1979.

Proposed Solution: Revise 10 CFR 21 to require affected organizations to establish management controls and procedures to ensure compliance with the regulation. 10 CFR 50, Appendix B should be referenced as including acceptable criteria for this action.

12. Problem: For certain reactor plants, one organization is the designer and constructor and, in some cases, is also the operator. Thus, under 10 CFR 21 definitions, basic components are never "delivered" under a "procurement document" as with most plants where a supplier-purchaser relationship exists. In the case where one organization fulfills multiple roles, the practice has grown of identifying and correcting 10 CFR 21 problems without reporting such problems to the NRC.

SUMMARY OF PROPOSED REVISIONS TO 10 CFR PART 21
CONTAINED IN SECY PAPERS SUBMITTED TO THE COMMISSIONERS
BETWEEN DECEMBER 1985 AND AUGUST 1989

SECY-85-399 was published in December 1985. This SECY was created to propose changes to 10CFR21 and 50.55(e). The revisions proposed appear to address the majority of concerns identified by the then Director, IE in a memorandum of October 1980. In particular, the SECY proposed to define time limits for evaluation of deficiencies which may be defects with substantial safety hazards.

A memorandum of October 1986 from the Secretary to the Executive Director for Operations (EDO) indicated the Commission had disapproved the proposed amendments. The Commission believed the rulemaking package should be revised to eliminate changes to the current Part 21 with the exception of the provision that reporting under Parts 50.55(e) or 50.73 satisfied 10CFR21. Other directives not relevant to 10CFR21 were also given. The staff noted the Commission's comments and submitted another SECY.

SECY-88-72 was issued in March 1988. This SECY provided two alternative revisions to 10CFR21 and 50.55(e). The first

alternative was fully responsive to the Commission's October 1986 direction regarding amendments to 10CFR21 and 50.55(e). It would have eliminated duplicative evaluation and reporting, established a uniform threshold for defects that needed to be reported, established a uniform content for safety defect reporting, and made other minor changes.

The second alternative, in addition to the items listed for the first alternative, would also have established time limits for evaluation and reporting of defects, extended the time limit for submittal of written 10CFR21 reports following the initial notification, required construction permit holders to notify vendors of vendor-related defects, and made other minor changes.

The staff recommended that the Commission approve publication of the proposed amendments in the second alternative. It should be noted that NMSS, RES, NRR, and Regions I, II, III and IV all specifically endorsed the second alternative proposed. Most of these cited as the reason for their endorsement the additional requirement of defining a specific time frame for performance of evaluations. Other Office endorsements of the proposed revisions did not cite a preference of one alternative over the other, but

no comments were made to disagree with the identified time frame for evaluations.

In a June 1988 memorandum, the Secretary indicated the Commission had approved the second proposed revision with modification, one being the removal of the time frame for evaluation. The Commission's proposed wording would have those covered by the rule, "Evaluate deviations to identify defects as soon as practicable." The Commission directed the staff to discuss in the Supplemental Information to the rule the Commission's belief that, in most cases, 30 days is a reasonable time to complete the evaluation of deviations. The staff responded with a new SECY.

SECY-88-258 was issued in September 1988 responding to the direction provided in the Secretary's memorandum of June 1988. The proposed 30 day time frame for evaluation of potential defects was removed from the text of the rule. Instead, timeliness of evaluation is discussed in the Supplemental Information in the proposed Federal Register Notice. In summary, this discussion indicates that 30 days is a reasonable time to perform an evaluation.

This SECY was approved by the Commission in October 1988, including the proposed Federal Register Notice to be published requesting comments on the rule change. The Federal Register published these proposed revisions in November 1988.

Published in August 1989, SECY 89-246 was initiated to obtain approval to publish final amendments that clarify the criteria and procedures for the reporting of safety defects by licensees and non-licensees and reduce duplicate reporting. The SECY identified that 35 separate entities commented on the proposed amendments published in the Federal Register in November 1988. According to this SECY, over half of the persons responding to the proposed amendments commented that 30 days was not adequate for evaluation of more complex issues. Based on these comments, the supplemental information in this new SECY indicated the staff believed that most deviations should be evaluated within 60 days. Additionally, the proposed revised rule required that procedures for evaluating potential defects and failures to comply specify nominal time limits for the completion of each phase of the evaluation process. It was recognized that, in taking regulatory actions, the times which are specified in the procedures are nominal targets only.

In a memorandum of May 1990, the Secretary notified the EDO that the Commission had "...agreed in principle" with the final rulemaking. This final proposed rulemaking left in tact the intent of the requirement that procedures are to be developed by licensees and vendors designating nominal time frames for evaluation. Also, the supplemental information retained the discussion that 60 days was sufficient time to evaluate most deviations. Other modifications identified in the memorandum were to be made by the staff. Resubmittal of a revised paper for affirmation at a future meeting was directed.

CLOSEOUT ACTION CODES USED IN THE
10 CFR 21 LOG MAINTAINED
BY THE GENERIC COMMUNICATIONS BRANCH

<u>ABBREVIATIONS</u>	<u>CLOSEOUT ACTION CODE MEANING</u>
VASU	VENDOR ACTIONS SUFFICIENT
BUIS	BULLETIN ISSUED
INIS	INFORMATION NOTICE ISSUED
CTBI	COGNIZANT TECHNICAL BRANCH INFORMED
FRNW	FAILURE CONSIDERED RANDOM OR NORMAL WEAR
NGTR	CONSIDERED NON-GENERIC, ASSIGN TO REGION
LPSP	CONSIDERED LOW PRIORITY SAFETY PROBLEM
NO21	ITEM IS NOT A TRUE 10CFR21 ISSUE
LISU	LICENSEE ACTIONS SUFFICIENT
RISC	RECOMMEND TECHNICAL SPECIFICATION CHANGES
RGSC	RECOMMEND NRC REGULATORY GUIDES OR STANDARDS CHANGES
PADC	REQUIRE PROCEDURAL OR ADMINISTRATIVE CHANGES
DEVE	REQUIRE DESIGN VERIFICATION
HACH	REQUIRE HARDWARE CHANGES

NOTE: There is no procedure or instruction describing what is meant by these closeout action codes or what criteria must be satisfied to apply these codes in the 10 CFR Part 21 Log.

PROCEDURES AND INSTRUCTIONS ASSOCIATED
WITH NRR MANAGEMENT OF 10 CFR PART 21
REPORTS REVIEWED AND ANALYZED BY OIG

NRC INSPECTION MANUAL CHAPTER 0970

"Potentially Generic Items Identified by Regional Offices" -
(12/6/88)

This manual chapter provides NRR guidance for processing potentially generic safety questions and potentially generic construction deficiency reports after they have been identified by the regional offices. The chapter delineates the activities performed by the Division of Operational Events Assessment (DOEA), NRR, regarding operational safety data, including 10 CFR Part 21 reports. It also states that the Generic Communication Branch (OGCB), DOEA, NRR, is responsible for coordinating and ensuring the review and closeout of 10 CFR Part 21 reports.

This chapter discusses, in relation to DOEA and OGCB responsibilities, the responsibility of the regional offices regarding potentially generic safety questions (PGSQs). The chapter states that regional offices "should be alert to two general categories of information that should be brought to the attention of OGCB". One category is licensee and vendor reports that when first received do not appear to be of generic applicability, but more information as it becomes available results in a change of opinion. The other category involves the occurrence of a series of similar or related events. When reviewed independently the events may not appear significant, but when reviewed together they may become a potentially generic safety question.

The chapter states that OGCB screens, reviews, and tracks 10 CFR Part 21 reports. Therefore, the regional offices do not have to submit these notifications as PGSQs. The chapter points out that OGCB should be contacted if a 10 CFR Part 21 report is submitted solely to a regional office. This chapter does not provide any specific information other than this general guidance on 10 CFR Part 21 reports in relation to PGSQs.

NRC INSPECTION MANUAL CHAPTER 2515

"Light-water Reactor Inspection Program - Operations Phase" -
(8/30/88)

Appendix A to this manual chapter lists the fundamental inspection program procedures that are required to be implemented for each operating nuclear power station. Appendix B to the chapter lists the regional initiative and reactive inspection program procedures that are not mandatory. Of these procedures, eight pertain to 10 CFR Part 21 reports. Four are in Appendix A and four are in Appendix B.

Appendix A to NRC Inspection Manual Chapter 2515

Inspection Procedure 90712

"In-Office Review of Written Reports of Nonroutine Events at Power Reactor Facilities" - (8/13/84)

This procedure identifies actions to be taken by either resident or region-based inspectors when the regional office receives written reports of nonroutine events from licensees. For purposes of the procedure, the generic term "event report" refers to different types of reports, among them 10 CFR Part 21 reports. The procedure states that "IE may also request, at times, that certain types of event reports be inspected at the site," including written reports required by 10 CFR Part 21 that were submitted by the facility or that were determined by others to be applicable to the facility.

Inspection Procedure 92700

"Onsite Followup of Written Reports of Nonroutine Events at Power Reactor Facilities" - (8/13/84)

The inspection objective of this procedure is "to determine whether NRC licensees have taken corrective action(s) as stated in written reports of the events and whether responses to the events were adequate and met regulatory requirements, license conditions, and commitments." Again this procedure appears to be directed toward actions initiated by the licensee. The procedure states, "IE may request that a specific nonroutine event written report or a category of such reports be inspected; however, it is expected that for the majority of nonroutine events the cognizant first line supervisor and inspector will determine whether or not a site inspection will be performed."

The procedure identifies the types of reports that may be inspected at the site, including written reports required by 10 CFR Part 21 that were submitted by the facility or that were determined by others to be applicable to the facility.

Inspection Procedure 92702

"Followup on Corrective Actions for Violations and Deviations"

Although this procedure has not yet been issued, it is cited in Chapter 2515 as a mandatory inspection procedure.

Inspection Procedure 93702

"Onsite Followup of Events at Operating Power Reactors" -
(8/13/84)

The inspection objective of this procedure is "to provide onsite inspection of events at operating power reactors." The only reference to 10 CFR Part 21 is contained in Inspection Requirement 02.01c, and no specific action is given.

Appendix B to NRC Inspection Manual Chapter 2515

Inspection Procedure 36100

"10 CFR 21 Inspection" - (4/1/83)

The inspection objective of this procedure is "to determine whether organizations and individuals subject to 10 CFR Part 21 regulations have established and are implementing procedures and controls to ensure the reporting of defec's and noncompliances." The inspection measures established include verification "that the following procedures or controls have been established and are adequate to assure implementation of 10 CFR Part 21 requirements."

The procedures and controls listed are the following: controls or procedures for posting; procedures for evaluating deviations or informing the licensee or purchaser of deviations; procedures for informing a director or responsible officer of deviations that were evaluated to be a defect or of failures to comply that related to a substantial safety hazard; controls or procedures that will assure that a director or responsible officer will inform the Commission as required when receiving information of a defect or reportable failure to comply; controls or procedures to assure that each procurement document for a facility or a basic component, when applicable, specifies that the provisions of 10 CFR Part 21 apply; controls or procedures to assure licensee maintenance of records; and controls or procedures to assure the preparation and appropriate disposition of records.

Other than requiring verification that procedures and controls are in place, this procedure does not require any verification of specific actions taken by a licensee in resolving a 10 CFR Part 21 report initiated by that licensee. Additionally, the procedure does not indicate that verification is required for specific actions that a licensee should have taken regarding a 10 CFR Part 21 report that was generated by another entity and that affected the licensee's facility.

Inspection Procedure 90713

"In-Office Review of Periodic and Special Reports" - (10/3/85)

The inspection objective of this procedure is "to ascertain whether the information reported by the licensee is technically adequate and satisfies applicable reporting requirements established in the Technical Specifications (TS), the license, and 10 CFR." The procedure states, "This procedure is designed primarily to provide a vehicle for tracking time expended in regional review of licensee reports. The licensee reports to be reviewed under this procedure are those repetitive and special status reports, identified in the license, the TS and 10 CFR, including appendices, which are addressed to the regional office or IE for action." There is no direct indication that 10 CFR Part 21 reports are included in the scope of the procedure; however, OIG believes that the reference to "10 CFR" implies that 10 CFR Part 21 is included. This two-page procedure provides little direction regarding its implementation.

Inspection Procedure 90714

"Nonroutine Reporting Program" - (10/1/80)

The inspection requirement of this procedure is to verify that administrative controls have been established for the following: the prompt review and evaluation of off-normal events, the prompt review of planned and unplanned maintenance and surveillance testing activities, the reporting of safety-related events internally and to NRC, and the completion of corrective actions relating to safety-related operating events. The procedure also requires verification that these administrative controls "contain provisions for recognition and reporting of events that are covered by 10 CFR Part 21."

Under "Inspection Guidance", the procedure states that 10 CFR Part 21 establishes specific requirements for the reporting of nonroutine events. It also states, "It should be verified that the licensees [sic] practices and procedures are consistent with these requirements, to assure proper reporting of events." The procedure only requires verification that administrative controls

are in effect and that they meet the requirements for assuring the proper reporting of events.

Inspection Procedure 92720

"Corrective Action" - (3/14/86)

The inspection objective of this procedure is "to determine whether the licensee has developed a comprehensive corrective action program to identify, follow, and correct safety-related problems." The inspection requirements are the following: (1) review the licensee's policy statements and administrative procedures for identifying problems and determine whether management controls have been established for the tracking and resolution of problems identified; (2) determine if the procedures, policies, and/or instructions provide actions to resolve the issues, including reporting to the NRC, if required; and (3) select at least four items from the problems identified in each of the categories identified in the procedure and review the licensee's response to the issues. The review called for in the last requirement should include an evaluation of the adequacy of the technical disposition of the issue, including hardware checks if appropriate. The specific guidance provided in the procedure is, "Inspectors should review the procedure used by licensed operators for determining the reportability of operational events. Reporting requirements to the NRC are set forth in 10 CFR Part 21, 10 CFR 50.72 and 10 CFR 50.73."

MANUAL CHAPTER 1100, MC 1105

"Reports of Nonroutine Events" - 10/1/76

As stated in the manual chapter, "The purpose of this instruction is to provide a uniform method for screening and evaluating reports of nonroutine events for which the Office of Inspection and Enforcement is the primary recipient." The chapter provides little guidance on nonroutine events. It cites two inspection procedures (90712B, "In-Office Review of Event Reports," and 92700B, "Licensee Event Followup") to be followed for screening, reviewing, following up and closing out nonroutine events. On the basis of the date of the chapter and the titles of more current inspection procedures addressing the same areas, this chapter appears to be outdated.

MANUAL CHAPTER 2700

"Vendor Inspection Program (VIP)" - (3/24/87)

The purpose of this chapter is to establish general requirements and provide guidance for the inspection by the Vendor Programs Branch (VPB) of nuclear steam system suppliers, architect engineering firms, suppliers of products and/or services, independent testing laboratories performing equipment qualification tests, and holders of NRC licenses in vendor-related areas.

(NOTE: The Vendor Programs Branch is now the Vendor Inspection Branch (VIP). See the note in the discussion of I&E Manual Chapter 2710, which follows, for clarification.)

The objective of this chapter is "to obtain sufficient information through inspection activities at vendor and licensee facilities to ensure that root causes of reported problems are being determined and suitable corrective action developed, vendors are complying with applicable NRC and industry requirements, licensees are adequately overseeing vendors, adequate interfaces exist between licensees and vendors, and licensees are implementing the equipment environmental qualification rule (10 CFR 50.49)."

Under "General Policies", the chapter states, "The selection of vendors for inspection is based on the significance to safety of the equipment or services provided, the frequency and significance to safety of problems identified with vendor supplied equipment or services, the number of licensees affected by the problem identified, the performance history of a vendor, and allegations received regarding a vendor. Vendors also are selected for inspection based on recommendations made by the regional offices. These recommendations should be made to the Chief, Vendor Program Branch."

The emphasis of the program has shifted "from programmatic inspections to followup on reported problems, design activities, and to examine licensee acquisition and use of vendor information. The focus of inspections is to ensure the vendor or licensee has determined the root cause of problems and that suitable corrective action is being or has been developed, design packages are technically accurate, and licensees are receiving vendor information and using it appropriately. However, inspections of programmatic aspects of vendor and licensee programs are necessary to ensure procedures are in place that effectively identify, evaluate, and act on potential or identified problems and take action to prevent recurrence, and adequately control other activities such as design."

Included as part of the inspections is verification that component/material suppliers conform to "Commission regulations requiring significant safety hazards to be identified, evaluated and reported by the manufacturer of the safety-related equipment." In doing this, "at least one potentially reportable event receiving evaluation under 10 CFR Part 21 procedures should be examined at each company."

MANUAL CHAPTER 2710

"Reactor Systems Inspection Program" - (10/1/82)

This chapter addresses the inspection of architect-engineers (AEs), nuclear steam supply system vendors (NSSSs), and engineering service organizations (ESOs). One of the inspection objectives is "to ascertain that applicable licensing commitments and criteria are passed on to manufacturers and suppliers of safety-related equipment and services, and procurement controls are effective in assuring compliance with these commitments and criteria." 10 CFR Part 21 requirements would fall within the scope of this objective.

(NOTE: This chapter states that the Chief, Vendor Programs Branch, Region IV, has "lead responsibility for the inspection of system designs and design control in those areas where the AE/NSSS has contractual responsibility. This includes both programmatic and technical inspections." It should be noted that the Vendor Programs Branch is now the Vendor Inspection Branch, which is located in headquarters as part of the Office of Nuclear Reactor Regulations (NRR). This change occurred during the reorganization in 1987. Therefore, this chapter is out of date.)

The chapter states that the program for ESOs (subcontractors to an AE, NSSS, or licensee) will be implemented "on an ad hoc basis depending on need and the safety significance of the work that has been or is being performed." Under "Inspection Bases" it states that the entire program "covers the inspection of activities conducted pursuant to 10 CFR 50 and 10 CFR Part 21 regulations." However, the chapter points out,

10 CFR 21 requirements are directly applicable to AEs, NSSSs, and ESOs and form the basis for inspections designed to investigate or ensure the reporting of defects to the NRC. 10 CFR 50 requirements are applicable to the applicant/licensee who is held responsible for ensuring that the requirements and related commitments in the SAR are, as applicable, passed on to each of its agents. In either case,

enforcement action, where deficiencies are identified, will be based on requirements of 10 CFR 21 or 10 CFR 50 and licensee SAR commitments as appropriate.

In regard to the periodic assessment inspections for this activity, the chapter states, "These inspections relate principally to AEs and NSSSs, but will include ESOs as necessary." Preparation for these inspections includes an in-office review of 10 CFR Part 21 reports as they relate to the organization being inspected. The chapter states, "These periodic assessment inspections of AE, NSSS, or certain ESO activities at a specific plant site will generally be performed once a year but they must be performed every two years."

OFFICE LETTER NO. 1300

Procedures for Handling 10 CFR Part 21 and 10 CFR 50.55(e) Notifications of Defects, Noncompliances, and Construction Deficiencies" - (7/22/87)

Thomas E. Murley, Director, NRR, sent this office letter to all NRR employees. The opening paragraph of the letter states, "This procedure contains guidance that describes actions to be taken upon receipt of notifications of defects, noncompliances with U.S. Nuclear Regulatory Commission (NRC) regulations, and design and construction deficiencies. The division of responsibility within the Office of Nuclear Reactor Regulation (NRR), and the NRR interaction with other offices are described."

After providing an overview of general definitions associated with 10 CFR Part 21 and 10 CFR 50.55(e), the letter points out that "initial notification of any defects or noncompliances should be made to the NRC Operations Center." Information copies of the notification are then distributed through NRC's Regulatory Information Distribution System (RIDS) to all NRR divisions, the Office for Analysis and Evaluation of Operational Data, the NRR or Office of Nuclear Material Safety and Safeguards Project Manager of any identified facility, and the regional offices.

The letter points out that OGC is responsible for the initial review of all 10 CFR Part 21 reports. It states, "Until specifically identified as being the responsibility of another NRR branch, any notification received through the RIDS distribution should be considered to be 'for information only.'" It states, "Review action includes evaluation of the described safety issue, determination of the generic implications, requesting the involvement of other NRC offices when appropriate, and making recommendations regarding 10 CFR Part 21... notifications that may require licensing board notification.... Review responsibility of notifications involving complicated

issues which cannot be properly evaluated by OGCB will be transferred to the appropriate NRR branch for follow up and resolution." It further states, "OGCB, in conjunction with other NRC organizations, will determine, where appropriate, the need to issue an information notice or bulletin regarding a reported defect, noncompliance, or construction deficiency."

Whenever the review responsibility is transferred from OGCB to another NRR branch, the assigned reviewer is responsible for "determining whether the information in the notification is generic or plant specific." If the reviewer determines that other plants are affected, the reviewer is responsible for notifying OGCB and the corresponding project manager. The reviewer is also responsible "for providing OGCB with a basis for a licensing action (if any), or a basis for determining whether the indicated defect or noncompliance is generic or unique to a facility."

Approximately every month, OGCB issues a list of the 10 CFR Part 21 notifications that have been received within the last 6 months and their current status. The list includes a brief description of the notification, the branch responsible for the review, and the current review status.

OIG believes this office letter provides only the general guidance identified previously. It does not prescribe what specific actions are required to accomplish the general activities identified in the letter. OIG was told this was the only procedure available that described the 10 CFR part 21 management process within OGCB.

NRR OFFICE LETTER NO. 1301

"Analysis and Feedback of Operational Safety Data" - (2/8/88)

This office letter, also sent by the Director, NRR, to all NRR employees, presents NRR's "procedures for handling the operational safety data reported, developed, or compiled by NRC and for providing feedback into the licensing, inspection, and safety information programs." The operational safety data includes 10 CFR Part 21 reports. The objective of the letter is "to ensure that significant operational safety data is identified, reviewed, and incorporated into NRR licensing, inspection, and safety programs and activities."

The letter states that the Division of Operational Events Assessment (DOEA) has "the lead responsibility within NRR for reviewing operational safety data and coordinating efforts with other NRC offices that share responsibility for operational safety data reviews." DOEA also has the lead responsibility "for

developing and implementing a coordinated NRC-wide program to manage and track the identification, collection, prioritization, evaluation, and closeout of generic safety issues related to inadequate conformance with NRC requirements." Included are those defects, noncompliances, and construction deficiencies described in NRR Office Letter No. 1300.

The responsibilities of the Reactor Projects Divisions, the Division of Engineering and Systems Technology, the Division of Reactor Inspection and Safeguards, the Division of Radiation Protection and Emergency Preparedness, and the Inspection, Licensing and Research Integration Branch are generally described.

Again, OIG believes this letter provides only the general guidance identified previously. It does not prescribe specific actions required to accomplish the general activities identified in the letter.

Temporary Instruction 1105/2 (Rev. 1)

"Reporting of Defects and Noncompliances - Part 21 Reports" - (7/1/78)

This was a temporary instruction.

REGIONAL INSTRUCTIONS

The following regional instructions were reviewed:

- Region I Instruction 1540.2/0 - "Processing of 10 CFR 21 Reports" - (2/15/87)
- Region II Instruction 1340, Rev. 3 - "Handling of Non-Routine Event Reports Within Region II (50 Docket Facilities, Non-Security Related Events" - (3/5/87)
- Region III Memorandum DRP24 - "Handling of 10 CFR Part 21 Reports for Power and Non-Power Reactors" - (2/29/88)
- Region IV Regional Office Policy Guide PG 4056.1 - "Handling of 10 CFR 21 Reports" - (7/18/88)
- Region V Region V Instruction No. 0402, Rev. 6 - "Handling of Licensee Event Reports (LER's), 10 CFR 21 Reports, and 10 CFR 50.55(e) Items" - (3/8/89)

The Region I instruction references 10 CFR Part 21; NUREG-0302; and IE Manual, Inspection Procedures Nos. 36100, 90712, and 92700. It states that all technical staff members should be familiar with these documents. The instruction provides the procedures for processing 10 CFR Part 21 reports submitted by telephone, as well as those submitted in writing. Resident inspectors are required to assign each 10 CFR Part 21 report an outstanding items number and enter it in the Outstanding Items List (OIL) for the facility to which they are assigned. They are to verify that the licensee has received notification of the defect or noncompliance and to provide appropriate followup. Furthermore, the resident inspector normally has the responsibility for closing out the 10 CFR Part 21 item. The outstanding item may be closed out if (1) the resident inspector has verified that the licensee has received a copy of the report from the reporting company, (2) it has been entered into a licensee tracking system, and (3) responsibility for licensee action has been assigned.

The Division of Reactor Safety and the Division of Radiation Safety and Safeguards are to perform normal handling, followup, and closeout in the same manner as that for following up IE bulletins and information notices.

The Region II instruction provides no specific information regarding the followup and closeout of 10 CFR Part 21 reports affecting nuclear plants in that region. The instruction only discusses how 10 CFR Part 21 reports are entered into the Technical Support Staff Open Item List.

The Region III instruction also does not provide specific information regarding the followup and closeout of 10 CFR Part 21 reports. It discusses the log published by NRR for the tracking of all 10 CFR Part 21 reports submitted by licensees and vendors. It states that the Technical Support Section is assigned the responsibility for reviewing the NRR log quarterly and for determining which issues the region should follow up pursuant to Inspection Procedure 92700. Other than this information, no specific information on the followup of 10 CFR Part 21 reports is provided in Region III.

The Region IV instruction provides a flow path for processing 10 CFR Part 21 Reports within the region that affect plants in that region. However, there is little specific information on (1) how the followup is performed, (2) when followup is required, or (3) the requirements for ensuring the closeout of 10 CFR Part 21 reports.

The Region V instruction references IE Manual Chapter 1110, Temporary Instruction 1105/2, and Inspection Procedures 90712 and 92700. The instruction describes how 10 CFR Part 21 reports

will be processed. 10 CFR Part 21 reports are entered on the Outstanding Items List for the Region V plants that may be affected. The Region V project inspector is responsible for reviewing the 10 CFR Part 21 reports in accordance with Inspection Procedure 90712 and may document the review in an inspection report.

Resident inspectors will conduct onsite followup in accordance with Inspection Procedure 92700 to verify that the licensee has received and reviewed the 10 CFR Part 21 report and has taken appropriate actions. The results are to be documented in an inspection report, as appropriate.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

APPENDIX VI
Page 1 of 10

OCT 19 1990

MEMORANDUM FOR: William L. Glenn
Acting Assistant Inspector General for Audits
Office of the Inspector General

FROM: James H. Sniezek
Deputy Executive Director for Nuclear Reactor
Regulation, Regional Operations and Research
Office of the Executive Director for Operations

SUBJECT: DRAFT OIG AUDIT REPORT ON NRC MANAGEMENT OF REPORTING
REQUIREMENTS UNDER 10 CFR PART 21

We have reviewed the draft OIG audit report regarding NRC's management of reporting requirements under 10 CFR Part 21.

The Generic Communications Branch (OGCB) of NRR has the overall responsibility for determining and implementing policies and direction for the NRC staff's 10 CFR Part 21 activities associated with nuclear power reactors. To put our comments in perspective, it is important to emphasize that the NRC staff's goal in implementing the 10 CFR Part 21 notification management process is to ensure that licensees and vendors have effective 10 CFR Part 21 programs in place to identify, assess and report deficiencies, that licensees have been adequately informed of potentially safety significant notifications that may be applicable to their facilities, and that licensees have effective programs in place to evaluate reported deficiencies to identify applicable safety significant notifications and take appropriate corrective actions. It is not the NRC staff's intent to verify, other than on a sample basis, that licensees take appropriate corrective actions to correct identified deficiencies. However, NRC does ensure that licensees have appropriate mechanisms in place to address operational experience information (such as 10 CFR Part 21 reports received from vendors, NRC information notices and bulletins, and INPO SEE-IN reports) and take appropriate corrective action through a post-TMI action requirement (NUREG-0737, Item I.C.5). Inspection guidance to verify the effectiveness of licensees' programs (on a sample basis) is contained in various NRC Inspection Manual Chapters. These inspection functions are utilized to assure that each licensee has an effective operational experience feedback program in place and are relied upon by the staff to provide

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William L. Glenn

-2-

assurance that licensees effectively respond to applicable 10 CFR Part 21 reported deficiencies. Similarly, for example, when the NRC requests, through issuance of a bulletin or generic letter, that licensees take specific actions to address an identified deficiency, the staff does not always verify by inspection that each licensee has complied with the requested actions, but may rely upon the licensees' confirmation that requested actions have been completed. When inspection verification is warranted generically, specific inspection guidance is provided through issuance of a temporary instruction.

The following comments related to the draft audit report's recommendations are forwarded for your consideration. Comments related to specific audit findings are provided in Enclosure 1. In addition, a general overview of the NRC staff's intended 10 CFR Part 21 management process for nuclear power reactors is provided in Enclosure 2. We will reflect this 10 CFR Part 21 management process in revised Manual Chapters and Inspection Procedures, as well as in additional training of key personnel.

Recommendation 1

The EDO submit to the Commissioners a revision to 10 CFR Part 21 that includes in the text of the rule a specific timeframe for the evaluation of deviations to identify defects which could create substantial safety hazards.

Response

The staff has previously recommended to the Commission that such revisions be incorporated into 10 CFR Part 21; however, the Commission did not approve the proposed revisions. The Commission directed, in NRC memorandum from Samuel J. Chilk to Victor Stello, Jr., dated June 10, 1988, that the staff revise 10 CFR Part 21 to provide for the evaluation of deviations to identify defects "as soon as practicable" and that the staff should discuss a specific timeframe for the evaluation of deviations in the Supplemental Information. The Commission believes that, in most cases, 30 days is a reasonable time to complete the evaluation of deviations. Whereas, the time to complete the evaluation was the subject of considerable comment in response to publication of the proposed rule, consideration is being given to extending the nominal time limit to 60 days in the Supplemental Information to the final rule.

Recommendation 2

The Director, NRR, develop procedures which prescribe the OGCB management process for 10 CFR Part 21 notifications and specifically address the OIG findings noted in the draft audit report.

Response

We agree that updated procedural guidance is appropriate and will develop such guidance. The completion date for this activity will be determined upon publication of the final OIG audit report.

William L. Glenn

-3-

Recommendation 3

The Director, NRR provide adequate training to all individuals involved in the managing and closeout of 10 CFR Part 21 notifications.

Response

We agree that additional training of key personnel involved in NRC's 10 CFR Part 21 notification management process is desirable and will proceed with this training. The completion date for this activity will be determined upon publication of the final OIG audit report.

Recommendation 4

The Office of the General Counsel determine whether Section 206 of the Energy Reorganization Act of 1974, as amended, is applicable to NMSS licensees and vendors and advise the EDO of those actions necessary to comply with the Act.

Recommendation 5a

If OGC determines that the scope of Section 206 does not include NMSS licensees, OIG recommends that the EDO direct the NRC staff to revise 10 CFR Part 21 by dropping NMSS licensees from its scope.

Recommendation 5b

If OGC determines Section 206 is applicable to NMSS or the EDO decides to leave NMSS licensees in the scope of 10 CFR Part 21, OIG recommends that the Director, NMSS, establish a policy for NMSS management of 10 CFR Part 21 with its licensees and vendors, including the development of instructions and a tracking system for managing that policy.

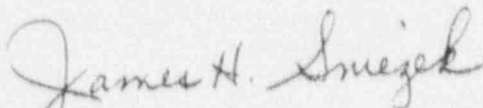
Response

OGC has advised the staff that the statute encompasses all activities "licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended ..." and therefore the activities of material licensees and their vendors are within the scope of Section 206 of the Act. This view of the scope of Section 206 of the Act is embodied in 10 CFR Part 21. Thus, it is not necessary for OGC to revisit the issue of the scope of the Act. However, the staff agrees that NMSS and OGC should address the options available regarding the actions necessary to comply with the Act with regard to material licensees and vendors. Accordingly, we agree that the Director, NMSS working with OGC should reexamine 10 CFR Part 21 and the implementing procedures to determine the best means for materials licensees' and vendors' compliance with Section 206. The completion date for this activity will be determined upon publication of the final OIG audit report.

William L. Glenn

-4-

Should you have any questions regarding these comments, please contact my office.



James H. Sniezek
Deputy Executive Director for Nuclear Reactor
Regulation, Regional Operations and Research
Office of the Executive Director for Operations

Enclosures:

- 1) Comments Related to Specific OIG Audit Findings
- 2) Interded 10 CFR Part 21 Management Process for
Nuclear Power Reactors

Enclosure 1

COMMENTS RELATED TO SPECIFIC OIG AUDIT FINDINGS

OIG FINDING

Many 10CFR21 reports have remained unresolved since 1986.

STAFF COMMENT

The staff agrees with the OIG finding. However, the Generic Communications Branch (OGCB), during the period in which the OIG audit was being conducted, has increased its efforts to address the backlog of outstanding 10 CFR Part 21 notification reviews. As of September 7, 1990, approximately 95% of 1987, 90% of 1988, and 84% of 1989 10 CFR Part 21 notification reviews have now been completed. It is important to note that OGCB routinely performs an initial screening of each 10 CFR Part 21 notification upon receipt to determine whether prompt regulatory action (such as issuance of an information notice or bulletin) is warranted. Frequently, even though OGCB concludes, based on the information provided with the notification, that there is no immediate safety concern requiring prompt regulatory action, OGCB will forward the notification to another branch to confirm, with respect to the handling of the technical issue and the potential for broader generic applicability, this initial assessment or to allow the branch to take the information into account in its ongoing activities (e.g. scheduling of vendor inspections). OGCB also has increased its efforts to address the backlog of outstanding pre-1987 10 CFR Part 21 notification reviews in other branches.

OIG FINDING

The number of 10CFR21 reports recorded is overstated because many entries in the tracking log are not 10CFR21 reportable issues.

STAFF COMMENT

The staff agrees that some notifications contained in the tracking log are not 10 CFR Part 21 notifications. OGCB, due to the variance of interpretations of the rule's reporting requirements throughout industry, frequently receives notifications from licensees and vendors which report "potential" defects or are not specifically identified as 10 CFR Part 21 notifications. This typically occurs because the licensee or vendor is unsure whether the identified deviation meets the reporting requirements of 10 CFR Part 21. All of these notifications are treated by OGCB as if they were reportable 10 CFR Part 21 issues and appropriate actions (such as initial screening, entry into the 10 CFR Part 21 tracking system, and, if warranted, detailed follow-up review or issuance of a generic communication) are taken. NRR does not perform its evaluation to determine if the reported deficiency represents a substantial safety hazard that should have been reported under 10 CFR Part 21. NRR performs these actions to carry out its safety responsibility to identify and address potentially significant safety issues. NRR actions are not dependent upon whether the notification meets the legal requirements for reportability contained in 10 CFR Part 21. NRR actions are considered a conservative approach to carrying out its safety responsibility.

-2-

OIG FINDING

NRR performs some of the 10CFR21 duties required of licensees and vendors.

STAFF COMMENT

The staff does not agree with the OIG finding. As noted above, NRR does not review information submitted by licensees and vendors to determine if the deficiency creates a substantial safety hazard and was properly reported in accordance with 10 CFR Part 21. NRR reviews information to determine if it represents a significant safety issue and if all potentially affected licensees have been properly informed. NRR activities do not assume the duties and responsibilities of licensees and vendors of evaluating defects identified, nor do they relieve licensees and vendors of their responsibilities to perform their own evaluations or cause the evaluation to be conducted by licensees or purchasers of products or services. The staff, through its audit and inspection activities, examines the effectiveness of licensees' and vendors' programs to fulfill their 10 CFR Part 21 obligations. The NRC staff does prudently consider all information which it receives which bears on reactor safety.

OIG FINDING

Followup on 10CFR21 reports assigned to action offices is not routinely performed.

STAFF COMMENT

The staff agrees with the OIG finding that followup on 10 CFR Part 21 notifications assigned to action offices, as performed by OGCB, could be improved. OGCB has routinely highlighted to action offices, through such mechanisms as the monthly 10 CFR Part 21 memo, open 10 CFR Part 21 notifications. OGCB has improved its process for ensuring that the secondary review of 10 CFR Part 21 notifications is accomplished in a timely manner. Improvements made include reducing the number of notifications assigned to action offices by utilizing available expertise within OGCB and modifying the monthly 10 CFR Part 21 memo to include, on a quarterly basis, a branch by branch listing of open 10 CFR Part 21 notifications.

OIG FINDING

Verification of completion for licensee and vendor actions does not always occur.

STAFF COMMENT

The staff agrees with the OIG finding. However, it is important to emphasize that the OGCB's goal in implementing the 10 CFR Part 21 notification management process is to ensure that licensees have been adequately informed of potentially safety significant notifications that may be applicable to their facilities. It is not the intent to verify, other than on a sample basis, that licensees take appropriate corrective actions to correct identified deficiencies. Inspection guidance to verify the effectiveness of

-3-

licensees' operational experience feedback programs (on a sample basis) is contained in various NRC Inspection Manual Chapters. These inspection functions are utilized to assure that licensees effectively respond to applicable 10 CFR Part 21 reported deficiencies. The staff, through vendor inspections, also examines the effectiveness of vendors' 10 CFR Part 21 programs.

OIG FINDING

Internal procedures and instructions are outdated.

STAFF COMMENT

The staff agrees that internal procedures and instructions need updating.

OIG FINDING

10CFR21 reports are not uniquely identified.

STAFF COMMENT

The use of unique identifiers will be addressed as necessary when updating internal procedures and instructions.

OIG FINDING

Documentation supporting resolution of 10CFR21 reports is insufficient and not centrally located.

STAFF COMMENT

The staff agrees that, in some cases, documentation supporting resolution of 10 CFR Part 21 notifications is not complete nor centrally located. The staff intends to address this finding when updating internal procedures and instructions.

OIG FINDING

10CFR21 training is inadequate.

STAFF COMMENT

The staff agrees that additional training of key personnel involved in NRC's 10 CFR Part 21 notification management process is warranted.

INTENDED 10 CFR PART 21 MANAGEMENT PROCESS FOR
NUCLEAR POWER REACTORS

The Generic Communications Branch (OGCB) of NRR has the overall responsibility for the NRC staff's 10 CFR Part 21 activities related to nuclear power reactors. The primary focus of the 10 CFR Part 21 management process is to ensure that licensees are adequately informed of potentially safety significant notifications that may be applicable to their facilities. A basic premise is that licensees and vendors have effective programs in place to identify, assess, and report deficiencies to the NRC and that licensees furthermore have effective programs in place to evaluate safety significant deficiencies and take appropriate corrective actions. Vendors who report defects to the NRC are required to also inform the NRC of the location of affected components at nuclear facilities (to the extent known) and any advice related to the defect that has been, is being, or will be given to purchasers or licensees. The existence and adequacy of licensee and vendor programs is verified on an audit basis by NRC inspections.

All 10 CFR Part 21 notifications received are entered into a tracking system by OGCB and initially screened to determine, based upon their safety significance and generic applicability, the need for prompt regulatory action. As appropriate, prompt regulatory action may consist of issuance of an information notice or bulletin. Even when OGCB concludes that there is no immediate safety concern requiring prompt regulatory action, OGCB forwards the more significant notifications to other technical branches to obtain confirmation of its initial assessment or to provide the technical branches with information for their use in other ongoing branch activities. For example, selected notifications are sent to the Vendor Inspection Branch for their use in scheduling and performing vendor inspections. Each notification is reviewed technically and to determine if all potential users of a defective product have been appropriately notified. OGCB is responsible for tracking and ensuring the closeout of all reviews of 10 CFR Part 21 notifications. A listing of recently received 10 CFR Part 21 notifications is distributed to selected NRC organizations each month. Branch by branch listings of open 10 CFR Part 21 notifications are distributed quarterly.

Inspections (on an audit basis) to assure that licensees have appropriate mechanisms in place to address operational experience information (such as 10 CFR Part 21 notifications received from vendors, NRC information notices and bulletins, and INPO SEE-IN reports) and take appropriate corrective actions are performed by NRC resident and regional inspectors with the support of headquarters based personnel. The NRC staff does not intend to verify, other than on a sample basis, that a licensee or vendor has taken appropriate actions to address each deficiency. Regional personnel are not required to review any 10 CFR Part 21 notification unless requested to do so by NRR. If additional inspection activities by the regions are necessary for a number of plants a temporary instruction is issued.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

APPENDIX VI
Page 9 of 10

OCT 19 1990

MEMORANDUM FOR: William L. Glenn
Acting Assistant Inspector General for Audits
Office of the Inspector General

FROM: James H. Sniezek
Deputy Executive Director for Nuclear Reactor
Regulation, Regional Operations and Research
Office of the Executive Director for Operations

SUBJECT: DRAFT OIG AUDIT REPORT ON NRC MANAGEMENT OF REPORTING
REQUIREMENTS UNDER 10 CFR PART 21

We have reviewed the additional recommendations contained in your memorandum of September 26, 1990 concerning instructions and procedures describing the NRC process for managing 10 CFR Part 21. The following comments are forwarded for your consideration.

Recommendation 1

The Director, NRR review and revise the Manual Chapters and Inspection Procedures used to describe NRR's management and regulation of 10 CFR Part 21 reports.

Recommendation 3

The Director, NRR consider consolidating all procedures and instructions pertaining to 10 CFR Part 21 issues into a single source document.

Response

We agree that revised Manual Chapters and Inspection Procedures are warranted and will make necessary revisions. We also agree that consolidation of the numerous 10 CFR Part 21 related procedures and instructions may be warranted and consideration will be given to revising the Manual Chapters and Inspection Procedures appropriately. The completion date for these activities will be determined upon publication of the final OIG audit report.

CONTACT: Jack Ramsey, NRR
492-0828

William L. Glenn

-2-

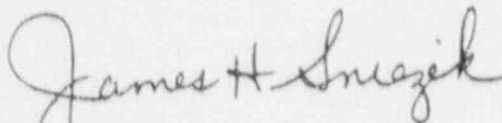
Recommendation 2

The Regional Administrators review their procedures to assure consistency with procedures revised by Headquarters.

Response

We intend to develop procedural guidance and to perform additional training of key personnel involved in the NRC's 10 CFR Part 21 management process as part of our efforts to address the OIG findings noted in your draft audit report. After applicable Manual Chapters and Inspection Procedures are revised the regional offices will then be requested to update their procedures to assure consistency. The completion date for this activity will be determined upon publication of the final OIG audit report.

Should you have any questions regarding these comments, please contact my office.



James H. Sniezek
Deputy Executive Director for Nuclear Reactor
Regulation, Regional Operations and Research
Office of the Executive Director for Operations



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WASHINGTON, D. C. 20555

APPENDIX VII
Page 1 of 2

November 9, 1990

MEMORANDUM FOR: Richard Donovan, OIG
FROM: ^{SC} John Cho, OGC
SUBJECT: LEGAL EFFECT OF EXPLANATORY STATEMENT
IN RULEMAKING

You asked for our opinion on the legal effect of a statement contained in the explanatory section of a rulemaking but not in the rule itself.

The question is raised in the context of the requirement in 10 C.F.R. 21.21 concerning the evaluation of safety defects by persons subject to the regulation. The regulation itself is silent as to when such evaluation must be completed. However, earlier, in connection with a proposed revision of Part 21, the staff recommended that section 21.21 include a provision requiring completion of such evaluation within a specified time frame. The Commission's response was a directive that the regulation specify completion of such evaluation "as soon as practicable," accompanied by an explanation indicating that 30 days is a reasonable time within which to complete the evaluation.

The staff since has proposed final regulations. They provide that affected persons must adopt appropriate procedures that, inter alia, "contain nominal time limits for completion of each separate phase of the evaluation process." Proposed final § 21.21(b). The accompanying discussion explains that:

"[n]o amendment is being implemented to set a specific time limit for evaluation of deviations. . . . In general, the Commission believes that most deviations should be evaluated within 60 days."

It explains further:

Although no time limit for evaluation is contained in the final amendments, to assure that some reasonable time limit is followed, § 21.21(b) and § 50.55(e)(2) are being added. These sections require that entity's procedures for evaluating potential defects and failures to comply associated with a substantial safety hazard include specific nominal time limits for the completion of each phase of the evaluation process. As an example, if the procedures contain requirements for several organizational levels to review the deviation,

- 2 -

then a time limit for each of these levels to perform the review shall be included in the procedures. The Commission is aware that several entities have target time frames in procedures (formal or informal) for the completion of each phase or level of review. This practice has the potential to be an excellent method of keeping the evaluations timely. In developing these time limits for the required procedures, where they do not already exist, vendors, licensees, and construction permit holders are expected to make a good faith effort to arrive at reasonable times. It will be recognized in future regulatory action that these times which are specified in the procedures are nominal targets. Actual times for more complex evaluations may be adjusted based on the complexity of the issue.

Valid regulations have the force of law. Explanatory material accompanying a regulation has no force in and of itself. It carries weight only to the extent it helps to clarify a regulation that is open to interpretation.

Turning to the question you raised, section 21.21 as finally proposed establishes no fixed deadline for completion of the required evaluation which can be enforced. The discussion explaining the section serves to encourage the affected persons to establish reasonable target dates in their procedures for evaluation of deviations. It also suggests that 60 days would be a reasonable period for completion of such evaluation. However, as the regulation is written (requiring nominal time limits in connection with evaluation procedures) and as the explanation is presented, the 60 day period would have no binding effect as a deadline.¹

cc: J. Fitzgerald

¹The procedures adopted pursuant to proposed final section 21.21(b), however, would be enforceable. If such procedures contained definite time limits, the failure to meet the prescribed time limits would be a violation of the required procedure. If the procedures contained only nominal time limits (as called for by the section), failure to meet them would normally not be a violation of the procedure.

MAJOR CONTRIBUTORS TO THIS REPORT

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