March 22, 1996

FOR: The Commissioners

FROM: James M. Taylor,
Executive Director for Operations /s/

SUBJECT: NRC ACTIONS TO MEET THE INSPECTOR GENERAL'S RECOMMENDATIONS ON THE REPORTING REQUIREMENTS UNDER 10 CFR PART 21

PURPOSE:

To inform the Commission of the intent of the staff not to proceed with rulemaking on 10 CFR Part 21 regarding reporting requirements for materials licensees.

CATEGORY:

This paper covers a routine matter.

BACKGROUND:

In 1990, the OIG conducted a review of NRC's management and reporting requirements under 10 CFR Part 21. The report made eight recommendations, seven of which have been closed. This paper and the Attachment describe the NRC's action to complete the last OIG recommendation. However, the NRC may seek legislative changes in the future in the course of broader Congressional actions. These changes could reduce Part 21 reporting requirements for materials licensees.

DISCUSSION:

The OIG report recommended 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." As noted in the OIG followup report issued in 1994, NMSS established a system for tracking Part 21 reports related to materials licensees and issued Information Notice 91-39, "Compliance With 10 CFR Part 21, Reporting of Defects and Noncompliance," to all NRC materials licensees. The final element to resolve the OIG recommendation had two parts. The first would be a rulemaking to identify and include under Part 21 only those types of NRC materials licensees that would be capable of producing a substantial safety hazard, thereby reducing the number of licensees covered under Part 21. The second part would be to consider including similar Agreement State materials licensees under the provisions of Part 21. However, the OGC has concluded that the enabling legislation for Part 21 (i.e., Section 206 of the Energy Reorganization Act of 1974) is not applicable to Agreement States licensees. In order to expand the applicability of Part 21 to the Agreement States, the staff was considering reissuing Part 21 under the Atomic Energy Act on the basis of necessary improvements to public health and safety.

The staff planned to revise Part 21 to reduce the number of affected NRC materials licensees and to make Part 21 a matter of compatibility for Agreement State licensees, but now believes it is more appropriate to terminate the rulemaking. This is based on a review of the number and significance of the Part 21 reports submitted by materials licensees over the past 5 years. The review indicated that almost all these reports resulted from an actual problem involving an equipment failure, a misadministration, or an unintended exposure. Nothing of significance was noted that would not have come to the NRC's attention through other reporting requirements. The staff also believes that there would be insignificant safety improvements by imposing Part 21 requirements on Agreement State licensees. This is because Agreement State reporting requirements are compatible with other NRC regulations, and Agreement States receive reports similar to those submitted by NRC licensees under Part 21. In addition, the NRC and the Agreement States voluntarily share event report information through the Nuclear Materials Event Database. Finally, the present regulation does not impose a significant burden on affected licensees. Therefore, the staff has concluded that the NRC resources needed to revise Part 21, in addition to the Agreement State and licensee resources needed to implement any changes to Part 21, would outweigh the benefit of reducing the number of affected NRC materials licensees or of any potential safety benefit from imposing the regulation on the Agreement States. Accordingly, the staff proposes to retain Part 21 with regard to materials licensees as written.

The NRC has several times proposed legislation to the Congress that would amend Section 206 of the Energy Organization Act to allow civil penalties authorized by Section 206 to be imposed upon business entities that supply hazardous components to NRC-licensed facilities or NRC-regulated activities. The proposed legislation would also clarify the Commission's authority in this area. (Currently, Section 206 allows civil penalties to be imposed only upon the supplying entity's officers and directors.) Legislation that included an amendment of Section 206 passed both the Senate and the House in 1989 but never became law. Subsequent NRC efforts to obtain enactment of such legislation as part of an NRC omnibus bill also were not successful. If the Commission decides to go forward again with a legislative proposal to modify Section 206, the Commission may also wish to consider additional modifications relating to the extent of its coverage to materials licensees.

RECOMMENDATION:

That the Commission note that I have signed the attached Rulemaking Plan and that after 10 business days from the date of the paper the staff intends to terminate this rulemaking and notify the IG of this decision.

COORDINATION:

The Office of the General Counsel has no legal objection to the actions proposed in this paper.

James M. Taylor
Executive Director for Operations

Attachment: Rulemaking Plan

ATTACHMENT

Rulemaking Plan

Reporting of Defects and Noncompliance -- Materials Licensees

Regulatory Problem and Issues to be Resolved

The NRC's Office of the Inspector General (OIG), in a November 1990 report entitled "Review of NRC Management of Reporting Requirements Under 10 CFR Part 21," concluded that the NRC's understanding of its role under Section 206 of the Energy Reorganization Act of 1974 (ERA) was not well defined. The Office of Nuclear Material Safety and Safeguards (NMSS) materials licensees and vendors were included in the context of the rule but implementation of the rule's provisions regarding these licensees and vendors was not clear. Inspections by the NRC revealed that many nonreactor licensees were confused about the applicability of Part 21 to their programs. The OIG recommended that the Commission either develop a program to clarify Part 21 for nonreactor licensees or, if Section 206 of the ERA was not applicable to them, revise Part 21 to exclude nonreactor licensees from its scope. Subsequent to the OIG recommendation, the NRC's Office of the General Counsel (OGC) determined that Section 206 of the ERA is applicable to NRC nonreactor licensees but not to Agreement State licensees. Although Part 21 is not applicable to Agreement States, some Agreement State licensees voluntarily submit Part 21 reports.

NRC reminded all NRC materials licensees of the applicability of Part 21 reporting requirements on June 17, 1991, in NRC Information Notice No. 91-39: Compliance with 10 CFR Part 21, "Reporting of Defects and Noncompliance." The guidance identifies as a "substantial safety hazard" the exposure of 0.5 rem (whole body or its equivalent to other body parts) to an individual in an unrestricted area in a period of a year or less.

This rulemaking plan has been developed to address the following questions related to Part 21 as it applies to materials licensees:

(1) Are there any categories of materials licensees whose operations do not warrant application of Part 21 requirements to them?

Because the ERA encompasses all activities "licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended," the activities of all NRC materials licensees and their vendors are within the scope of Section 206 of the ERA as implemented by Part 21. However, the ERA allows the NRC to determine the applicability of Part 21, restricting it to only those entities (licensees and vendors) whose operations could pose a "substantial safety hazard" as defined by NRC. By implementing a rule change that redefines the threshold for reporting (e.g., defining a substantial safety hazard as 25 rem total effective dose equivalent), the operations of certain of these licensees and vendors would not have the potential to result in a significant safety hazard because of defective components or noncompliance. Following this rationale, the NRC needs to determine whether some of the materials licensees can or should be exempted from the provisions of Part 21.

(2) With regard to materials licensees, should Part 21 be made a matter of compatibility between the NRC and the Agreement States?

Because Section 206 of the ERA is not applicable to the Agreement States, Part 21 regulations would have to be promulgated under the broad authority of the Atomic Energy Act (based on the NRC's mandate to protect public health and safety) to require Agreement State licensees to meet these requirements. The NRC needs to determine whether Part 21 reporting requirements should be repromulgated under the Atomic Energy Act and then made a matter of compatibility for the Agreement States.

Current Rule Requirements

10 CFR Part 21, "Reporting of Defects and Noncompliance," was issued on June 6, 1977, and applies to all NRC reactor and materials licensees and certain unlicensed suppliers but is not applicable to Agreement State licensees. Part 21 establishes procedures and requirements for implementing Section 206 of the Energy Reorganization Act of 1974 (42 U. S.C. 5846).

Part 21 requires that licensees notify the Commission of (i) equipment defects that could create a substantial safety hazard or (ii) failures to comply with regulatory requirements relating to substantial safety hazards. (Defect, in the context of Part 21, is a departure from the technical requirements (deviation) that could create a substantial safety hazard.) Reporting enables the NRC to determine if a defect or noncompliance is generic in nature and to verify

that appropriate measures are being taken to protect the public health and safety.

The purpose of Section 206 is to improve the system for detecting and anticipating defects in the nuclear industry, especially in components that could pose a "substantial safety hazard." Section 206 was made expressly applicable to all facilities and activities that are licensed or otherwise regulated pursuant to the Atomic Energy Act and to the Energy Reorganization Act of 1974. While the legislative history indicates that the main focus of Section 206 was on nuclear power plants, it also applies to nonreactor licensees. Section 206 provides that the Commission will define by regulation a "substantial safety hazard."

The principal requirements of Part 21 are the following:

(1) Each individual, corporation, partnership, or other entity subject to Part 21 must post required documents, in a conspicuous location, on any premises within the United States where the activities subject to Part 21 are conducted. These include a copy of the Part 21 regulation, Section 206 of the ERA, and procedures developed pursuant to Part 21 (10 CFR 21.6).

(2) Each individual, corporation, partnership, or other entity subject to Part 21 must adopt procedures to evaluate deviations and failures to comply and determine whether they pose a substantial safety hazard [10 CFR 21.21(a)].

(3) Each supplier of a basic component, or a service associated with a basic component, who is not capable of determining whether a defect exists, must inform the purchasers or affected licensees so that they can evaluate the deviation or failure to comply [10 CFR 21.21(b)].

(4) A director or responsible official who is subject to Part 21 must report defects to the NRC [10 CFR 21.21(c)].

(5) Procurement documents issued for a facility or a basic component must state that Part 21 applies to the procurement (10 CFR 21.31).

(6) Recordkeeping must be maintained in connection with the licensed facility or activity to assure compliance with the regulation (10 CFR 21.51).

Regulatory Problem To Be Resolved

The objective of this Rulemaking Plan is to consider (1) the need to revise Part 21 reporting so that these requirements are imposed on appropriate NRC materials licensees and (2) the need for consistency in reporting between NRC and Agreement State materials licensees.

The staff must consider whether continuing to subject all NRC materials licensees to Part 21 notification requirements is cost effective or necessary for adequate protection of the public health and safety. For most materials licensees, the reporting and evaluation requirements of Part 21 do not correspond with the degree of hazard posed by the activities of these licensees. This Rulemaking Plan is intended to consider restricting the applicability of the Part 21 requirements to those entities[(1)] whose operations could create a "substantial safety hazard" as defined by the NRC. Additionally, the NRC will consider the need for consistency between the NRC and the Agreement States. As mentioned earlier in this paper, Section 206 of the ERA, as implemented by Part 21, is not applicable to the Agreement States.

There are approximately 22,000 NRC and Agreement State materials licensees. Most of these licensees are small and conduct operations that do not require sophisticated quality assurance programs. Many of these licensees are also not always capable of performing detailed evaluations of devices or equipment. There is also a reasonable expectation that problems that user licensees have with pieces of equipment would be reported to the supplier. In most cases, the supplier would be in a better position to determine whether a problem warranted a report under Part 21. For this reason, consideration could be given to putting more burden of reporting such defects on the supplier or vendor of the equipment. However, if a report was not made in parallel by the user to the NRC, there could be a temptation, due to financial reasons, for the vendor not to treat the issue as a generic problem. However, as revealed by a review of Part 21 reports, many, if not most, of the reports from users were not considered to constitute an actual substantial safety hazard, indicating that reports made by users were not a significant burden.

Existing reporting requirements, other than those in Part 21, cover many of the types of events which could result in a safety hazard as defined in Part 21. However, these reporting requirements focus on actual events or occurrences rather than on the potential for such events, as is the case for Part 21. The following list includes the most important of these reporting requirements for materials licensees:

§ 20.1906 -- Contamination/radiation levels on shipping packages.
§ 20.2201 -- Lost/stolen material.
§ 20.2202 -- Overexposures and releases (actual and threatened).
§ 30.50(b)(2) -- Safety equipment failure (Parts 40 and 70 also).
§ 34.25(d) -- Leaking radiography source.
§ 34.30(a) -- Radiography component failure.
§ 35.33(a) -- Medical misadministration.
§ 35.39(e)(2) -- Leaking medical source.
§ 36.83(a) -- Irradiator events (including facility and equipment).
§ 39.35 -- Leaking well logging source.

Part 21 states that the notification to NRC is not required if the licensee or responsible officer has actual knowledge that the Commission has been notified in writing of the defect or the failure to comply. Therefore, events that require a written report under another part of Chapter I of the Code of Federal Regulations, and would also require a report under Part 21, would only require one report.

Preliminary Regulatory Analysis

There were four options considered during the development of this preliminary Regulatory Analysis.

Option 1

No regulatory change alternative. Do not change Part 21.

Option 2

Similar to option 1, in that Part 21 for NRC materials licensees is not changed, but repromulgate Part 21 under the Atomic Energy Act so that all Agreement State materials licensees would have the same reporting requirements as

NRC materials licensees.

Option 3

Revise the "substantial safety hazard" definition in Part 21 so that reporting requirements would apply only to those entities whose operations have a reasonable potential of posing such a hazard. A threshold, 25 rem total effective dose equivalent (TEDE) over 2 hours, would be established by rule as the occupational or public dose that would be considered a substantial safety hazard. The definition of substantial safety hazard would also include medical misadministrations resulting in a dose at least 50 percent higher than prescribed in the written directive. Based on the revised substantial safety hazard definition, materials licensees would determine whether they had the capability of producing a substantial safety hazard. If not, they would be excluded from Part 21 reporting requirements. The rule would be promulgated under the Atomic Energy Act to allow inclusion of similar Agreement State licensees.

Option 4

This option would be similar to option 3. However, rather than specifying a threshold dose, it would specify a threshold quantity of radioactive material. This threshold quantity would be the basis for identifying those licensees for whom a potential for a substantial safety hazard could occur because of defects or noncompliance. The definition for medical licensees would be the same as option 3 -- a dose at least 50 percent higher than prescribed in the written directive. This option would eliminate a large number of materials licensees from Part 21 requirements and be applicable to only major licensed facilities and suppliers of radioactive material and storage devices capable of producing a substantial safety hazard. The threshold quantity for sealed sources would be based on an external dose of 25 rem TEDE over a period of 2 hours at a distance of 1 meter.(2) The threshold quantity for unsealed material would be based on an inhalation dose of 25 rem TEDE or 300 rem TEDE to the thyroid, whichever is more restrictive. A quantity threshold of radioactive materials commensurate with this exposure level would be developed by NRC and established in the regulation. This would exempt licensees who do not have radioactive material above the threshold levels and suppliers of equipment that is intended for use with radioactive material below the threshold levels. These threshold levels would not apply to medical licensees because of the significant difference under which medical radioactive material is used. The rule would be promulgated under the Atomic Energy Act to allow inclusion of similar Agreement State licensees.

Evaluation of Options

In the development of this Rulemaking Plan, the staff conducted a preliminary Regulatory Analysis to define reasonable alternatives. The results of the preliminary Regulatory Analysis, however, have enabled the staff to make a recommendation as to the most appropriate option. The staff believes that, at this time, a rulemaking to change Part 21 is not needed. The basis for this decision is discussed below.

Option 1

This option, although intended to provide a baseline for comparison, has become the preferred option. In the development of this Rulemaking Plan, the staff reviewed all Part 21 reports in the Office for Analysis and Evaluation of Operational Data's (AEOD) Nuclear Materials Event Database (NMED) system. There also may be other events that could fall within Part 21 reporting requirements that might not show up in this data base. For example, a Part 21 report is not required if a report is made through other requirements. In such cases the NRC is still able to evaluate the problem and take appropriate actions. The AEOD database of Part 21 reports for materials licensees provides the following information:

- From 1990 to August 1995 there have been 42 events reported.
- The events were split almost evenly between medical licensees and all other materials licensees.
- Although Part 21 is not a matter of compatibility for Agreement States, about 25 percent of these reports were made by Agreement State licensees.
- All the reports were as a result of an actual problem involving an equipment failure, a misadministration, or an unintended exposure, except for a design problem involving heat treatment for packing nuts on a uranium hexafluoride cylinder (it was later determined that this was not a substantial safety hazard).
- Over one-third of these events, although in the data base, did not involve a generic problem or were not judged, under the existing conservative criteria, to be a substantial safety hazard.
- Information was generally not provided in the database as to whether the event was reported under requirements other than Part 21. However, most of the 42 events should have been reported under requirements other than Part 21.

The seven events judged to be the most significant based on NRC's actions are summarized below. The NRC's actions included issuance of 1 Information Notice, 3 Confirmatory Action Letters, and 5 Violations or Orders.

- An irradiator's source rack position indicator malfunctioned. This incident was reported to the NRC's Operations Center, and with Region II's permission, fixes were made that same day. The manufacturer issued a service bulletin and shipped replacement switches to all customers. The existing requirements did not prevent the incident and NRC would have become aware of the incident with or without a Part 21 report. The NRC issued an Information Notice regarding this incident.
- The most serious violation, which resulted in a patient's death, was a medical misadministration that was also investigated by the FDA. The existing requirements did not prevent the incident and NRC would have become aware of the incident without a Part 21 report.
- As a result of misadministrations during brachytherapy treatment, six patients received overdoses on the order of 25 percent. A violation and a Confirmatory Action Letter were issued.
- A source assembly used in industrial radiography failed as a result of improper design, but was not detected until a failure occurred. An NRC order to stop use and a Confirmatory Action Letter were issued.
- A poorly designed clamping adapter for a brachytherapy machine was discovered after an estimated 26-rem dose to the extremity occurred to the licensee's radiation safety officer (also reported under Part 20). A Confirmatory Action Letter was issued as a result.
- Two violations were issued were for not providing a Part 21 report. One of these was in 1991 and the other involved a difference in interpretation of NRC regulations. The abstract indicates that a substantial safety hazard did not exist.

Conclusions from the AEOD data base are:

- Reporting under Part 21 for materials licensees has not provided a significant benefit to public health and safety.

- In the example of the death of the patient, it is unlikely that the degree of engineering sophistication would be present among most materials licensees to predict this equipment failure before the fact. The NRC Incident Investigation Team report (NUREG-1480) did not attribute any weakness in Part 21 as a cause of the event.
- The significant events that have required a Part 21 report also meet other NRC reporting requirements. Due to the similarity of Agreement States reporting requirements with NRC requirements, it is very likely that any significant issues occurring in Agreement States would be brought to the attention of the appropriate regulatory agency.
- Based on the small number of total Part 21 reports and the fact that many of these reports were below the threshold of a potential substantial safety hazard, the current regulation does not appear to be a significant burden to NRC licensees.(3)

Option 2

This option would remove the inconsistency between NRC and Agreement State licensees, but it would impose a burden on the approximately 15,000 Agreement State materials licensees to initiate and implement Part 21 procedures. Costs would be from developing evaluation procedures, citing Part 21 in procurement documents, recordkeeping, notification, and defect evaluation. Although the cost for each licensee is relatively minor, the total regulatory burden in the aggregate would be significant. As concluded from the AEOD data base, imposing Part 21 requirements on Agreement State licensees is unlikely to provide a significant benefit to public health and safety. Option 2, therefore, does not appear to be cost beneficial with regard to balancing costs and benefits.

Option 3

Over 90 percent of nonmedical NRC and Agreement State materials licensees and about two-thirds of medical licensees would likely be exempted from the Part 21 reporting requirements based on the proposed definition of substantial safety hazard (i.e., a 25 rem dose threshold level and medical misadministration resulting in a dose at least 50 percent higher than prescribed in the written directive). All fuel cycle licensees would be covered under Part 21. The basis for a the proposed definition of substantial safety hazard is contained in Attachment 1.

This option would require all materials licensees to make an initial evaluation to determine whether Part 21 applies to them. This could result in some inconsistencies among materials licensees. For a typical licensee we estimate this evaluation would cost $2,000, and therefore result in an estimated burden of $44 million for the 22,000 licensees.

The NRC considered exempting all medical licensees based on the desire to minimize overlapping regulations of the FDA consistent with the President's Executive Order 12866. FDA regulations and guidance documents, which include reporting requirements, are extensive. The Memorandum of Understanding between NRC and FDA acknowledged overlap between the agencies. Reducing this overlap would help to reduce reporting burdens. However, after evaluating FDA regulations, the staff does not believe that they provide a margin of safety equivalent to that contained in Part 21. FDA regulations are defined in terms of doses that could cause death or serious injury -- a TEDE of several hundred rem would be required. The occupational and public dose of 25 rem TEDE considered in this option would not be reportable under FDA regulations. Therefore, the staff does not recommend using existing FDA regulations as a basis for exempting medical licensees from Part 21. Attachment 2 provides a more complete evaluation of FDA's reporting requirements.

Option 3 does not appear to be cost beneficial with regard to balancing costs and benefits. Because the current costs of implementing Part 21 are minimal (i.e., approximately 10 reports a year with minimal annual maintenance costs), it would take many years just to recover the costs of rulemaking and the adoption of new procedures.

Option 4

The number of licensees exempted would be similar to option 3. However, this option would be less costly to licensees than option 3, while focusing on those facilities and suppliers with the greatest potential for public health and safety impact. Having the NRC specify a threshold curie content would significantly clarify and simplify licensee determination as to applicability of the rule. A quantity threshold of radioactive material for these devices would be established in the regulation, thereby exempting all other licensees and suppliers. Each licensee would be responsible to make this determination as to their applicability to Part 21. However, we estimate this determination would be a nominal cost for each licensee. Fuel cycle and medical licensees would be treated the same as option 3.

Option 4 also does not appear to be cost beneficial with regard to balancing costs and benefits. Because the current costs of implementing Part 21 are minimal (i.e., approximately 10 reports a year with minimal annual maintenance costs), it would take a number of years just to recover the costs of rulemaking and the adoption of new procedures.

OGC Legal Analysis

The Office of the General Counsel has no legal objection to the staff's preferred option to terminate further consideration of rulemaking to amend Part 21 with regard to materials licensees. Adoption of this option would leave the current requirements of Part 21 in force, requiring all NRC materials licensees and their vendors to (1) post required documents related to Part 21 in a conspicuous location, (2) adopt procedures to evaluate deviations and failures to comply and determine whether they pose a substantial safety hazard, (3) report defects to the NRC within certain timeframes, and (4) include in procurement documents for basic components that Part 21 applies to the procurement. The responsibilities of materials licensees for reporting defects and noncompliance were reiterated in NRC Information Notice No. 91-39: Compliance with 10 CFR Part 21, "Reporting of Defects and Noncompliance," issued on June 17, 1991.

In a previous memorandum in response to a request by the OIG, OGC provided its analysis regarding the applicability of Part 21 to materials licensees. In an additional memorandum dated June 21, 1995, from F. Cameron, OGC, to F. Combs, NMSS, OGC provided the rationale for its legal opinion that the enabling legislation for Part 21 (i.e., Section 206 of the ERA) was not applicable to Agreement State licensees. At that time, OGC indicated that to make these requirements applicable to the Agreement States, Part 21 requirements would have to be promulgated under the broad authority of the Atomic Energy Act to provide for the health and safety of the public. In a June 9, 1995, memorandum from F. Cameron, OGC, to C. Prichard, RES, OGC provided an analysis of the potential legal issues to be addressed if the other options were pursued.

Agreement State Implementation Problems

Two jurisdictional issues are involved in Agreement State implementation.

Issue 1

Since Part 21 reporting requirements are not now a matter of compatibility with Agreement States, Agreement States do not need to have the same or similar reporting requirements. Therefore, Agreement States do not have to require Part 21 reports from licensees. Options 2, 3, and 4 would require consistent treatment of NRC and Agreement State licensees performing the same activities. Therefore, promulgation of revised reporting requirements under these options would be under Atomic Energy Act authority and would be made a matter of compatibility.

Issue 2

Agreement States have told NRC that they do not have authority over either nonlicensed (by the State) suppliers or out-of-State suppliers. Therefore, under options 2, 3, and 4, the Agreement States may have to enact legislation to address this situation.

Supporting Documents

Options 2, 3, and 4 would require a Regulatory Impact Analysis that will identify impacts and benefits to various types of licensees based upon various scenarios. No backfit analysis would be needed since the rule would not impact reactor licensees. An OMB Paperwork Reduction Act statement would be required. Depending upon the number of licensees potentially affected, this could require significant justification. Also, if small licensees are affected, a justification to satisfy the Regulatory Flexibility Act would be required. No Environmental Impact Statement or Environmental Assessment would be needed as these regulatory options would fall under categorical exemption 10 CFR 51.22(c)(3)(iii) which exempts reporting requirements. For options 3 and 4, guidance for licensees, NRC license reviewers, and NRC inspectors would need to be revised and expanded.

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1. This could include licensees and nonlicensed suppliers of equipment that is engineered in such a manner as to reduce the effects of radiation. An example from the latter category is a supplier of a shielding device that is intended to be used with a source capable of producing a significant safety hazard.

2. The basis for the time and distance assumptions are as follows. The 1 meter distance is consistent with other dose limits in Part 20. The 2 hour time period is consistent with how Part 21 is applied to reactor licensees. For reactor licensees, the term "basic component" is defined, in part, as a component with the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in 10 CFR 100.11. Section 100.11 discusses a whole body dose of 25 rem and a thyroid dose of 300 rem over a 2 hour period.

3. Based on discussion with Regional staff, materials licensees do not appear to be spending significant resources to maintain their Part 21 reporting programs.