

February 20, 1997

TO: The Commissioners

FROM: Hugh L. Thompson, Jr. /s/
Acting Executive Director for Operations

SUBJECT: FINAL RULE - REPORTING REQUIREMENTS FOR UNAUTHORIZED USE OF LICENSED RADIOACTIVE MATERIAL AND REVISION TO THE NRC ENFORCEMENT POLICY

PURPOSE:

To recommend that the Commission direct staff to seek additional public comment prior to finalizing a rule addressing reporting of events where intentional unauthorized use of licensed material has caused or threatens to cause exposure of individuals to radiation.

BACKGROUND:

The enclosed rulemaking was initiated in response to two incidents that occurred in the latter part of 1995, involving phosphorous-32 (P-32) internal contamination of individuals at two biomedical research facilities, the National Institutes of Health (NIH) and the Massachusetts Institute of Technology (MIT). P-32 is widely used in research institutions, as are many other radionuclides. NIH informed the NRC of an incident involving internal contamination on June 30, 1995. The MIT incident was discovered 2 months later on August 19, 1995, but was not reported to the NRC until October 16, 1995. An Incident Investigation Team (IIT) was chartered to investigate the MIT incident. The findings of the IIT were reported in NUREG-1535. Findings of the AIT were issued in Report #30-01786/95-002 on January 13, 1997. In both of these incidents, the licensees concluded that the quantities of material and levels of exposures did not exceed the regulatory thresholds in the existing requirements for reporting to the NRC.

DISCUSSION:

A proposed rule requiring licensees to notify the NRC Operations Center within 24 hours after discovering an event of this nature was published for comment in the Federal Register on January 31, 1996 (61 FR 3334). The initial comment period of 30 days ended March 1, 1996. Two comment letters received from major industry representative groups requested that the comment period be extended. An extension was granted for an additional 30 days and the extended comment period ended March 31, 1996. Eighty-six comment letters were received, 12 from power reactor licensees, 11 industry representative groups, 8 Agreement States, 44 licensees (14 Agreement State and 30 NRC), 10 private citizens, and one public interest group. In addition, the Advisory Committee on Medical Uses of Isotopes (ACMUI) discussed the proposed rule in their meeting held on February 22, 1996. In view of the short comment period, 60 days, this is an unusually high number of comment letters. Eighty-two commenters, including all eight Agreement States who commented, were opposed to the proposed rule, and only four commenters were in favor of it.

The issues expressed by the commenters concerned the need for and benefit of the rule, the burden associated with making reports on contamination events where unauthorized use could not be ruled out, Agreement State compatibility, the use of other alternatives to a rule, and the lack of an exposure threshold. A large number of commenters were concerned that licensees should be responsible for handling events such as these, that do not exceed the current NRC reporting thresholds listed in paragraph 20.2202. Further, they stated that these events should be handled by the appropriate law enforcement agency. Unless the events resulted in doses in excess of the current reporting limits, the commenters believed there would not be any health and safety issues requiring NRC involvement. The ACMUI suggested similar changes to those expressed by the commenters on the proposed rule. In general, commenters appeared to ignore, or not be swayed by, the discussions in the proposed rule which explained that the rule was needed to provide NRC with assurance that the licensee has taken the appropriate corrective actions.

To address a major concern of the commenters that the burden associated with the proposed rule is excessive, the proposed requirement to notify the NRC of events where unauthorized use could not be ruled out has been deleted from this rule. By deleting this proposed requirement, the staff believes that the potential for licensees to file an excessive number of reports is eliminated, while reports of incidents where the licensee has sufficient information that the unauthorized use was intentional will continue to be reported. Specifically, paragraph 20.2207(a) of the final rule will require licensees to notify the NRC Operations Center within 24 hours after discovering, or receiving information, or receiving an allegation, that licensed radioactive material was used intentionally for a purpose not authorized by the applicable NRC license or regulations with the potential to cause exposure.

The Federal Register notice for the proposed rule requested comments on whether the rule should be a Division 2 or 3 level of compatibility. All of the Agreement States commenting on the proposed rule preferred it to be a Division 3 level of compatibility. Subsequently, on August 1, 1996, the Conference of Radiation Control Program Directors (CRCPD) wrote to NRC Chairman Jackson, urging NRC to withdraw the rulemaking and consider alternative measures for addressing security and misuse of radioactive materials. The CRCPD also stated that, should NRC proceed with the rule, the level of compatibility should be Division 3.

Based on the August 1, 1996 letter from the CRCPD, the staff decided to forward a draft final rulemaking incorporating changes based on the comments received on the proposed rule, to the Agreement States for comment. A copy also was placed in the NRC Public Document Room (PDR). The States were allowed 35 days for comment. After reviewing the draft final rulemaking, the Organization of Agreement States (OAS) unanimously approved a motion opposing the draft final rule as written and stating that, if implemented, it should be assigned a Division 3 level of compatibility. The basis for the motion is not stated. Eleven Agreement States submitted individual comments, nine of which were opposed to the rule. In general, the comments recognized the improvement over the original proposed rule, but continued to take issue with the stated justification and benefit of the rule and requested a Division

3 level of compatibility if it is issued. One public comment opposing the draft final rule was received, and is addressed in the Supplementary Information.

Agreement State comments are addressed in the Supplementary Information as well. In addition, the draft Federal Register notice states that a compatibility level is not being assigned to the rule at this time because the Commission is presently developing implementing procedures for the new Policy Statement on Adequacy and Compatibility of Agreement State Programs, and the staff plans to apply and follow those procedures, when they are issued in final form, to determine the level of compatibility that should be assigned to the rule. The staff expects to submit a paper to the Commission in the near future requesting approval of the "Policy Statement on Adequacy and Compatibility of Agreement State programs," and associated implementing procedures.

In consideration of the number of negative comments on the proposed rule, especially from the Agreement States, the staff has developed 3 options that the Commission may want to consider: (1) withdraw the proposed rule; (2) publish the enclosed final rule; or (3) solicit additional public comment on the revised language prior to submitting the rule for approval. The staff recommends option 3 for the following reasons:

- (1) It is highly unusual for the NRC to receive so many negative comments on a proposed rule. Proceeding to publish a final rule at this time may give the appearance that the Commission has not been fully responsive to public comments.
- (2) The Commission could choose to withdraw the proposed rule on the basis of the comments received. However, the staff believes that the changes made to the rule, in response to comments, address most of the concerns raised by the commenters.
- (3) While the staff believes that we have been responsive to comments received from the public and the Agreement States, by re-publishing the revised language for a short (60-day) public comment period, the Commission would be able to make an informed decision on the appropriate disposition of the rule.

RESOURCES:

Although the current budget does not specifically identify resources to implement the new rule, the staff believes that resources budgeted for reactive inspections will be sufficient to cover inspections that may be required as a result of the rulemaking.

COORDINATION:

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

RECOMMENDATION:

That the Commission:

1. Direct staff to solicit additional public comment on the revised rule language before submitting the rule to the Commission for approval.
2. Note that, if the Commission approves the Notice of Final Rulemaking and revision to the NRC Enforcement Policy for publication ([Enclosures 1 and 2](#)):
 - a. The Commission must certify that the rule, if promulgated, will not have a negative economic impact on a substantial number of small entities in order to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b);
 - b. The Regulatory Analysis has been included in the Federal Register notice;
 - c. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the reasons for it as required by the Regulatory Flexibility Act;
 - d. The staff has determined that this is not a "major" rule as defined in the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 804(2). OGC has confirmed this determination with OMB. The appropriate Congressional and GAO contacts will be informed ([Enclosure 3](#));
 - e. The final rule contains information collection requirements that are subject to review by OMB. Upon approval, request for review and clearance will be sent to OMB;
 - f. The staff has not prepared an environmental assessment because of the categorical exclusion given in 10 CFR 51.22(c)(3)(iii) for amendments to NRC regulations regarding reporting requirements;
 - g. The Agreement States will be sent a copy of the final rule upon approval for publication;
 - h. A public announcement will be issued ([Enclosure 4](#));
 - i. The appropriate Congressional committees will be informed ([Enclosure 5](#));
 - j. Copies of the Federal Register notice of final rulemaking will be distributed to all licensees. The notice will be sent to other interested parties upon request.

Hugh L. Thompson, Jr.

Enclosures: As Stated (5)

ENCLOSURE 1

[7590-01-P]

NUCLEAR REGULATORY COMMISSION
10 CFR Part 20
RIN: 3150-AF44
Reporting Requirements for Unauthorized Use
of Licensed Radioactive Material AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations on the unauthorized use of licensed radioactive material by individuals. The final rule requires licensees to notify the NRC Operations Center, by telephone, within 24 hours of discovering, or receiving information, such as an allegation, that licensed radioactive material was used intentionally for a purpose not authorized by the applicable NRC license or regulations and such use had the potential to cause exposure regardless of the exposure level. By a separate action published today in the Federal Register, the Commission has issued a modification to the Enforcement Policy that reflects these amendments to 10 CFR Part 20.

EFFECTIVE DATE: (60 days after publication)

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Background

During 1995, the NRC responded to two incidents involving phosphorous-32 (P-32) internal contamination of individuals at biomedical research facilities. These events occurred at the National Institutes of Health (NIH) and Massachusetts Institute of Technology (MIT). P-32 is widely used in research institutions, as are many other radionuclides.

These two incidents raised the following issues. First, the current regulations do not require reporting of events such as these if the events do not involve quantities of material or potential exposures that exceed the current regulatory reporting thresholds. Second, when there is information available regarding an intentional unauthorized use with the potential to cause exposure regardless of the level, the NRC needs to have the assurance that the appropriate corrective actions are being taken by the licensee and to determine whether there is a need for NRC action. A proposed rule requiring licensees to notify the NRC Operations Center after discovering an event involving unauthorized use of radioactive material was published for comment in the Federal Register on January 31, 1996 (61 FR 3334).

Discussion of comments received and summary of requirements in the final rule.

This section includes a discussion of the significant issues raised by public comment and how they were resolved. Eighty-six comment letters were received on the proposed rule, 12 from power reactor licensees, 11 industry representative groups, 8 Agreement States, 14 Agreement State licensees, 30 NRC material licensees, 10 private citizens, and 1 public interest group. In addition, the transcript of the Advisory Committee on Medical Uses of Isotopes (ACMUI) meeting held on February 22, 1996, was reviewed in preparing the final rule. Eighty-two of the commenters opposed the proposed rule; four were in favor of the proposed rule.

After revising the proposed rule in response to comments received, a draft of the final rule was sent out to the Agreement States for an additional round of comment. The draft was also placed in the NRC Public Document Room (PDR).

Eleven Agreement States submitted individual comments, nine of which were opposed to the rule, and the Organization of Agreement States (OAS) submitted a motion opposing the draft final rule.

The ACMUI proposed similar comments to those received during the public comment period.

In addition, one comment was received opposing the draft final rule from a member of the public. The commenter cited a concern that procedural departures in medical use "could be punished under this new rule." However, this rulemaking does not impose new requirements concerning what constitutes intentional misuse. Rather, it requires certain reports that involve intentional misuse of licensed material under current definitions, within the

context of *existing regulatory requirements*. In response to this comment, the text of the Supplementary Information has been changed to clarify this point.

Public Comments on the Proposed Rule

1. Withdraw the proposed rule.

Comment. Thirty-six commenters suggested that the proposed rule be withdrawn. They stated that basing a rulemaking on only two incidents was not justified. Of this group, 26 commenters stated that regulations already exist to cover such incidents, such as 10 CFR 30.10, Deliberate misconduct, 10 CFR 20.2201, Reports of theft or loss of licensed material, 10 CFR 20.2202, Notification of incidents, and 10 CFR 30.50(a), Reporting requirements. Of the eight Agreement States that provided comments, all stated that the proposed rule should be withdrawn. One Agreement State commented that this rule may violate the intent of that State's Regulatory Reform Act of 1995, that requires the State's regulatory system not impose excessive, unreasonable, or unnecessary obligations. This State commented that this rule is unnecessary.

Response. A review of the regulations was conducted during development of the proposed rule and again when preparing the final rule. The NRC determined that none of the existing regulations cover the circumstances reflected in these types of incidents. Section 20.2201 only applies to theft or loss of material above a specified quantity and 20.2202 only applies to incidents in which the exposure is above the occupational limits in Part 20. The Deliberate Misconduct Rule (56 FR 40664), such as in 30.10, addresses an intentional act or omission that an individual knows (1) would cause a licensee to be in violation of a rule, regulation, order, or license; or (2) to be in violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee or a contractor to the licensee. While such activities are prohibited under this section, there is no provision for reporting such incidents to the NRC. The reporting requirements in 30.50(a) only address situations where exposure to radiation or radioactive materials could exceed regulatory limits or releases of licensed materials could exceed regulatory limits from events such as fires, explosions, or toxic gas releases. Thus, the NRC continues to believe that the existing regulations do not cover all instances of intentional use of licensed radioactive material for a purpose that is not authorized by the Commission and that the Commission has a compelling need to be advised of all such occurrences to assure that the licensee is in control of the situation and that it is not escalating.

2. If the proposed rule is finalized, revise it.

Comment. Twenty-nine commenters addressed the "allegedly intentional" clause. Some of these commenters provided revised language and some suggested that the "allegedly intentional" clause be deleted. Several other commenters argued that "allegedly intentional" was too broad a phrase and would result in licensees spending more time and money than the 20 hours stated in the proposed regulatory analysis for the proposed rule to evaluate an incident and would detract from their ability to perform their other duties. They stated that this would place an undue burden on small licensees whose resources are already limited and that the burden associated with this rule was not consistent with the as low as is reasonably achievable (ALARA) principle.

Comment. Thirty commenters suggested that a threshold be established so that every contamination event would not be reported. These commenters stated that if the rule were finalized, as proposed, licensees would be forced to report any contamination found during a routine survey. Some of the commenters asserted that this would result in more than 20 events per year being reported, and at a much higher cost than presented in the regulatory analysis for the proposed rule. One commenter suggested that a threshold be set at 10 percent of the occupational exposure limits in Part 20 and that activity levels, such as the microcurie quantities of Appendix C to 10 CFR Part 20 be used. This commenter stated that activity levels would be easier to calculate in a short time compared to dose assessment results.

Comment. Forty-nine commenters suggested that the NRC be more specific with respect to the type of events to be reported.

Comment. Eight commenters suggested that "intentional" be defined for the purpose of this rule.

Comment. Thirty-two commenters suggested that the requirement to report events where unauthorized use could not be ruled out within 48 hours be deleted. They stated that it was too vague, burdensome, and restrictive, and they would be forced to report every contamination to avoid a Severity Level III violation.

Comment. One commenter suggested that we broaden the rule to include non-intentional or accidental loss or misplacement of licensed materials.

Response. The NRC agrees with some of these suggestions and has revised the final rule to reduce the burden

and to clarify the types of events to be reported. The NRC never intended that licensees should report routine contamination events. The NRC believes it has reduced the likelihood that licensees will report any contamination event simply because they cannot rule out unauthorized use within 48 hours by deleting that proposed requirement. Other revisions to the final rule are intended to clarify when the NRC must be notified. Specifically, a report is required when information involving intentional unauthorized use with the potential to cause exposure regardless of the level is identified, or if information is received by the licensee, such as when a licensee receives an allegation. By "identified" the Commission means that if during a licensee's normal review of a contamination event the licensee concludes that the event was a result of an intentional unauthorized use with the potential to cause exposure regardless of the level, the licensee is expected to report. An "allegation" received from an individual that he or she believes the act is intentional needs to be reported. An allegation must be reported regardless of whether or not the licensee discounts it. The intent of this rule is not to require licensees to report allegations that turn out to be unfounded. Should a licensee's employee allege that another employee has contaminated their workspace with radioactive material and survey results indicate no contamination then this allegation is not reportable. The term "intentional" is used to clarify that accidental contamination need not be reported unless the dose exceeds the limits of 20.2202. In addition, the rule has been revised to make clear that *unintentional* unauthorized use need not be reported, unless of course, dose limits are exceeded.

The NRC is not adopting the suggestion to broaden the rule to include non-intentional or accidental loss or misplacement of licensed materials. Loss of licensed radioactive material is already covered under 10 CFR 20.2201. The reporting requirement does not have an exposure threshold because any intentional unauthorized exposure of workers or members of the public needs prompt corrective actions to ensure that the individual who caused the event does not continue to expose others to radiation, including exposure to potentially greater quantities of radiation. Examples of the types of events that should be reported under this rule are provided in the summary of requirements section of this notice.

3. Regulatory analysis is incomplete and did not consider many other possible alternatives.

Comment. Twenty-four commenters stated that the regulatory analysis was incomplete. They stated that the estimated time to conduct an investigation was not long enough, nor was the cost adequate. They also stated that this situation could be taken care of by an information notice or a generic letter, instead of a rule.

Response. The NRC considered the most common alternatives to rulemaking in the regulatory analysis. Use of an information notice or a generic letter is only appropriate for providing information on safety issues to licensees where there is not an intention to establish a new requirement. Requirements must be communicated through regulations, license amendments, or orders. Amending each of the NRC 6,660 materials licenses and the 110 reactor licenses to include license conditions to cover these incidents would be more costly than issuing a regulation. This is addressed in the regulatory analysis section of this notice. Based on the comments received on the proposed rule, the time estimated to investigate an incident has been increased to 40 hours in the final regulatory analysis. Because the final rule only requires the reporting of events where the licensee discovers, or receives information or an allegation of intentional unauthorized use with the potential to cause exposure, the estimated number of reports has been decreased from 20 to 10 per year.

4. Stay within own jurisdiction, do not interfere in criminal investigations.

Comment. Twelve commenters recommended that the NRC not interfere in criminal investigations and that the NRC should stay within its own jurisdiction.

Response. Intentional unauthorized use of licensed radioactive material that causes, or has the potential to cause, an exposure to an individual does fall within the NRC's jurisdiction as covered by Section 223 of the Atomic Energy Act. The NRC needs to be made aware of incidents where licensed radioactive material was used intentionally for a purpose not authorized by the license in order to fulfill its responsibility to protect public health and safety.

5. Severity Level III violations for failure to report an event is too harsh.

Comment. Fifteen commenters stated that the severity level was too harsh and was not warranted by the incidents. They feared that even if they reported what turns out later to be a non-event, it would still be cited by "over-zealous" inspectors.

Response. Consideration of Severity Level III violations for failure to report an event under this new regulation was chosen because it is necessary for the NRC to obtain this information in order to carry out its regulatory responsibility of investigating deliberate violations. Additionally, failure to report an event is of significant regulatory concern because of the potential of occurrence of more widespread acts. This clearly meets the definition of Severity Level III in the Commission's Enforcement Policy. The NRC believes that it needs to receive prompt reports so that it may investigate the acts, and have assurance that the licensee is in control of the situation and that the situation is not escalating.

6. Violation of ALARA principle.

Comment. Forty commenters stated that the concept presented in this rule was not consistent with the ALARA principle. They also stated that it

would mean every event of contamination and exposure regardless of the level would have to be reported. One commenter provided an example of the researcher that injects a rat with radioactive material to study some organ function, an authorized use. When the cells in the organ thought to absorb the material do not, the researcher withdraws some of these cells, cultures them, and injects them with the radioactive material to determine why the cells did not absorb the material. This commenter stated that this would be viewed as an unauthorized use by the rule as it is proposed because injecting cells was not listed on the license as an authorized use. Another commenter provided examples of walking out of a laboratory with a slightly contaminated lab coat on or forgetting to put a check source back in its proper location after use.

Response. Because the Commission has decided to require reports only in cases where the licensee identifies, or receives information, such as an allegation of intentional unauthorized use with the potential to cause exposure, the NRC believes that the reporting burden associated with this final rule will be minimal. This projected annual burden is estimated to be 400 hours and assumes there will be 10 events for all licensees. Reporting will be required only if the licensee identifies, or receives information, such as an allegation, that licensed radioactive material was used intentionally for a purpose not authorized by the applicable license or regulations and this use had the potential to cause exposure regardless of the level. Evaluations of radiation exposure would continue in accordance with NRC regulations, licenses, and licensees' ALARA programs.

In the case described involving the researcher's withdrawing organ cells and exposing them to radioactive material, this experiment is integral to the researcher's study of the organ function, which is an authorized use; therefore, it is not a violation and is not reportable. Licensees should assure that, during the licensing process, they request sufficient authority to cover their intended uses. However, even if the facts are changed to indicate that the experiment was not authorized *and* caused or threatened to cause an exposure to an individual, a report would not be required under this rule unless there was information, or an allegation, that the unauthorized use was intentional (*i.e.*, that it was not accidental, inadvertent, or due to a misinterpretation of the requirements) and caused or threatened to cause an exposure to an individual.

7. Agreement State Comments

Comment on Proposed Rule. The eight Agreement States providing comments were all of the view that the rule if promulgated should be designated a Division 3 rather than Division 2 item of compatibility. Specifically, the State of Illinois commented that although the Federal Register notice for the proposed rule stated that this rule would make the Agreement State regulations "consistent" with the NRC regulations, they believe that it only addresses the NRC's ability to communicate with its licensees and should be designated a Division 3 item of compatibility. New York State commented that: "Any additional reporting requirements should be based on a clear need for the regulatory agency to take immediate action to protect health, safety, or property; not for the agency to perform functions that every licensee should be prepared and qualified to undertake, whether a licensee is dealing with an 'intentional' or unintentional incident." Georgia and Colorado commented that this rule has not been justified from a health and safety perspective. Colorado stated that States, like Federal agencies, are also being required to demonstrate that the benefit of any rule justifies the regulatory burden. Washington referred to its Regulatory Reform Act of 1995 and stated that this rule would fail the tests required by the act, specifically that Washington's [S]ystem not impose excessive, unreasonable or unnecessary obligation; to do so only serves to discredit government, makes enforcement of essential regulations more difficult, and detrimentally affects the economy of the State and the well being of our citizens. Rules must be based on common sense, use the least burdensome alternative, have a meaningful public role in development, and emphasize education and assistance before the imposition of penalties. NRC's proposed rule would fail these tests if the rule were attempted to be promulgated in this State.

Therefore, the State of Washington concluded that the rule should be designated as a Division 3 item of compatibility. Iowa, Tennessee, and New Hampshire agreed with the position taken by Illinois, New York, Colorado, Washington and Georgia in response to the proposed rule.

Comment on Draft Final Rule. The Organization of Agreement States (OAS) unanimously approved a motion opposing the draft final rule as written and stating that, if implemented, it should be designated a Division 3 item of compatibility. The basis for the motion is not stated. Eleven Agreement States submitted individual comments, nine of whom opposed the rule. In general, the commenters recognized the improvement over the original proposed rule, but continued to take issue with the stated justification and benefit of the rule, and requested that it be designated a Division 3 item of compatibility if issued. Colorado suggested that an alternative regulation be considered that would require licensees to investigate and document any misuse of materials. Regarding the regulatory analysis, which addresses the costs to the Agreement States to adopt a comparable rule, Colorado commented that 72 hours would be a better estimate of the time required to conduct a reactive inspection. Georgia commented that 0.25 FTE would be a better estimate of the cost to complete a compatible rule. Georgia also commented on examples of events that occurred in the past where notification would be required under this rule, stating that they were of concern to radiation workers, but not "of public health and safety consequence." Iowa commented about resources to investigate reports involving machine-produced and naturally occurring sources of radiation, which are regulated by Agreement States but not by the NRC.

Response. The Commission is presently developing implementing procedures for the new Policy Statement on Adequacy and Compatibility of Agreement State Programs which will likely

provide increased flexibility to States when adopting regulations. Given the development of implementing procedures for the new Policy Statement, the Commission does not plan to assign a compatibility component at this time. Rather, a compatibility component will be assigned to this rule based on the new implementing procedures, when they are issued in final form.

The primary benefit of reporting events such as these is to prevent further events from occurring regardless of the exposure or contamination level. The reporting requirement allows the NRC or State regulatory agency to investigate while the facts and evidence are fresh, alert other law enforcement agencies that may wish to do the same, and assure that the licensee is in control of the situation and that it is not escalating. In a given situation involving deliberate contamination, additional contamination events may be occurring concurrently but initially may remain undetected by the licensee. Even though a deliberate contamination event may involve only minor exposure, it is unlikely that the perpetrator precisely measured the amount of licensed material used in the act, and there is no guarantee that the next exposure will be minor if additional acts are undertaken. Where a potential perpetrator might otherwise view such an act as mere "horseplay," there is a deterrent effect that stems from the fact that these acts are taken seriously by the NRC or State regulatory agency, as well as by the licensee; that they must be reported; and that they may be subject to criminal and civil sanctions. Without this rule, the NRC would not be able to assess promptly the licensee's actions to prevent further exposures and possible harm to other individuals, as well as to determine whether the NRC needs to be involved in the matter.

In response to Colorado's and Georgia's comments, the NRC believes that this rule is justified from a health and safety perspective. In particular, the NRC includes the health and safety of radiation workers as an integral component of its overall mission of protecting public health and safety. In the course of investigating the NIH and MIT events and developing the regulatory analysis for this rule, a search was performed on the NRC's Nuclear Materials Events Database to determine if events of this nature had occurred in the past and had been reported. The results of this search indicated that eight events had occurred and been reported in the past and that these events occurred at both NRC and Agreement State licensed facilities. Since the proposed rule was published, the NRC has become aware of an additional event involving intentional contamination of the lock on an employee's locker at a nuclear pharmacy facility. While none of these cases indicated that serious harm was done to an individual, these other events indicate that the recent events are not isolated occurrences.

Colorado has suggested an alternative rule that would require licensees to investigate and document misuse of materials; however, preparing and retaining the required documentation would pose a greater burden on licensees as compared to the reporting requirement in the final rule. Additionally, the NRC or State regulatory agency likely would not find out about the misuse until it reviewed the documentation during a routine inspection, which could be some time after the event. At that point, if further investigation were warranted, it would be severely hindered by the time lapse, as it was in the case involving contamination of the employee's locker noted above.

The regulatory analysis was changed to incorporate Georgia's estimate of 0.25 FTE to promulgate a comparable rule. While Colorado estimated 72 hours to conduct a reactive inspection, the 125 hour estimate given in the regulatory analysis is based on NRC's experience conducting reactive inspections. If Agreement States include machine-produced and naturally occurring sources of radiation in any rulemaking, their costs may increase. However, these sources are not under NRC jurisdiction and therefore they are not addressed in the cost considerations for NRC rulemakings.

In response to Illinois' comment regarding the use of the word "consistency," the NRC agrees that this is not the correct word to use with respect to NRC and Agreement State regulations. The correct word is "uniformity" according to Section 2, Rule Categorization of the State Agreements Program, Division I, B. Policy, B.7 - Criteria for Compatibility Determinations, "Under this procedure, pertinent NRC rules are categorized according to the degree of uniformity necessary between NRC and Agreement State requirements."

In response to New York's comment that the agency should not perform the licensee's functions, the NRC does not intend to substitute its actions for the corrective actions that the licensee should be taking to protect public health and safety. Rather, the role of the regulatory agency is to confirm and ensure that the licensee is taking these actions. The regulatory agency also needs the information in order to determine whether it should take enforcement action, including action directly against the individual responsible for the event, such as prohibiting the individual from engaging in licensed activities.

In response to Washington's comment regarding the need for regulations to have a meaningful public role, this rule is intended to improve the protection of public health and safety from intentional unauthorized use of licensed radioactive material.

8. Backfit Analysis

Comment. One commenter (NEI) argued that it was both an incorrect interpretation of 50.109, the Backfit Rule, and an unwise policy choice to conclude that the proposed rule is not a backfit on the grounds that recordkeeping and reporting requirements are not backfits. The commenter argued that the statements of consideration (SOC) for the 1985 Backfit Rule (50 FR 38097, September 20, 1985) reflected the Commission's view that backfitting addresses new regulatory burdens imposed on licensees "regardless of their source." further, the commenter noted that the SOC discussed the burden that can be imposed as a result of "extensive information requests," and argued that the Backfit Rule "recognizes that new information requests issued under 50.54(f) could sometimes represent a backfit." In addition, the commenter argued that from a policy standpoint, it would be unwise to exclude the proposed rule from the "disciplined review process" of the Backfit Rule. The commenter noted that the proposed rule would require use of extensive resources to investigate suspect events, develop a reporting procedure, and train licensee personnel. In view of these resource expenditures, the commenter concluded that the NRC should follow the Backfit Rule in order to ensure that the resource burden of the rule is "carefully considered and justified."

Response. The Commission acknowledges that the final rule, even as modified from the proposed rule, will impose some burden on affected licensees. Furthermore, the Commission agrees that the imposition of information collection and reporting should be subject to a

"disciplined process" and criteria which assure that such burdens are justified, and are tailored to minimize the burdens on licensees consistent with the informational needs of the Commission. However, both as a matter of law and as a matter of policy the Commission does not believe that this consideration must or, as a matter of policy, should be accomplished under 50.109.

The commenter argues that the statement in the 1985 SOC that the Backfit Rule addresses new regulatory burdens "regardless of the source," is evidence that the Commission intended information collection and reporting requirements to be within the scope of the Backfit Rule. That statement was intended to address the question of whether the Backfit Rule should be limited to regulatory burdens imposed by rulemaking or be extended to other regulatory actions; it does not address the question of whether information collection and reporting requirements, regardless of the source of the imposition (e.g., by rule, order or new staff interpretations), should be deemed "backfits." See SOC Question 1, 50 FR at 38097; 50 FR at 38101, columns 1 and 2). The commenter also refers to a statement in the 1985 SOC with respect to "extensive information requests," implicitly suggesting that the Commission intended that all information requests not within the purview of 50.54(f) be treated as backfits. The commenter also argues that it would be inconsistent to treat some information requests as backfits, yet have no backfit controls for new recordkeeping and reporting requirements. The passage cited by the commenter does not support the view that the Commission intended all information requests outside of the scope of 50.54(f) to be treated as backfits. Read in context, the passage simply reflects the Commission's view that information requests be carefully evaluated for their impact on licensees:

The amendment of 50.54(f) should be read as indicating a strong concern on the part of the Commission that extensive information requests *be carefully scrutinized by staff management prior to initiating such requests*. The Commission recognizes that there may be instances where it is not clear whether a backfit will follow an information request. Those cases should be resolved in favor of analysis. In short, *staff management should develop an internal review process to ensure that there is a rational basis for all information requests*, even where it is not clear that a backfit will result. (emphasis added)

With respect to the commenter's view that it would be inconsistent to treat new recordkeeping and reporting requirements as not subject to backfit controls, the Commission believes that the appropriate "backfitting controls" for information collection and reporting requirements are found in the regulatory analysis and 50.54(f)-like criteria, as discussed below.

In the Commission's view, the applicability of the Backfit Rule to information collection and reporting requirements turns on whether it is reasonable to consider such requirements as "procedures or organization required to...operate a facility" under 50.109(a)(1). An interpretation that information collection and reporting requirements constitute such operating procedures would lead to either: (a) an evaluation of new or changed information collection and reporting requirements against the criteria in 50.109(a)(3), viz., that there is a "substantial increase" in the overall protection of the public health and safety, and that the "direct and indirect costs of implementation...are justified in view of this increased protection," or (b) a determination that one or more of the three "exceptions" in 50.109(a)(4) apply. After considering many rulemakings which proposed new or changed information collection and reporting requirements, the Commission regards it as problematic in demonstrating that a collection and/or reporting of information, by *itself* results in a "substantial increase" in protection to the public health and safety. The usefulness of information rests upon its contribution to determining whether or not a safety problem exists, in assessing the extent and potential impacts of such a problem, and in formulating appropriate responses to address the problem. While information is a necessary antecedent to proper regulatory action (including a determination that further action is not necessary), it is not appropriate (because of "double-counting") to attribute actual safety benefits to information where the actual benefits rely upon further regulatory (or voluntary licensee) action. Nor does a traditional cost-benefit consideration address the benefits of information where the agency concludes that further regulatory action is unnecessary (for such reasons as the safety problem does not exist, or is of a low risk, or cannot be reasonably addressed in a cost-beneficial manner). For analogous reasons, it is often difficult to characterize an information collection and reporting requirement as "necessary" for adequate protection or for compliance with existing Commission requirements or licensee commitments⁽¹⁾. In view of these issues, the Commission concludes that information collection and reporting requirements should not be considered to be "procedures...required to operate a facility" under 50.109(a)(1).

While application of the Backfit Rule to information collection and reporting requirements is not required or appropriate, the Commission recognizes that information collection and reporting requirements do have resource impacts on licensees. Therefore, the Commission agrees with the commenter that there should be a disciplined process with criteria for assessing whether an information collection and reporting requirement is (1) justified, and (2) has been carefully tailored to obtain the proper information in a manner which minimizes the resource impact on licensees. The process which provides that discipline is the regulatory analysis. Under the Commission's current guidelines for performing regulatory analyses, NUREG/BR-0058, all proposed requirements, including information collection and reporting requirements, must be evaluated to determine the significance of the matter to be addressed, the costs of imposing the requirement, and whether there are any alternatives for addressing the matter. The Commission believes that the standard for assessing the reasonableness of information requests should be analogous to the standard identified by the commenter, the 50.54(f) requirement that "the burden to be imposed upon respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information." The NRC Staff has adopted this standard in analyzing information collection and reporting requirements.

In summary, the Commission concludes that the nature of information collection and reporting requirements precludes application of the backfit criteria in 50.109(a)(3), and that preparation of a regulatory analysis and a statement addressing the criteria of 50.54(f) provide the necessary regulatory discipline for evaluating the burdens imposed by information and collection requests. Additionally, all information collection and reporting requirements are subject to review by the Office of Management and Budget (OMB) which provides yet another regulatory discipline for evaluating the burdens imposed. Therefore, the Commission declines to adopt the commenter's proposal.

Summary of Requirements of the Final Rule

Although the proposed rule would have been codified at 20.2205, this section has subsequently been used; therefore, the final rule will be codified at

20.2207. The final rule requires each licensee to notify the NRC within 24 hours after identifying, or receiving information, such as an allegation, that licensed radioactive material was used intentionally for a purpose not authorized by the applicable NRC license or regulations and that such unauthorized use may have caused, or threatens to cause an exposure to an individual, regardless of whether or not it exceeds the regulatory exposure limit as identified in 20.2202. The NRC is primarily interested in receiving reports of events involving the intentional contamination of an individual or an individual's food, drink, or personal belongings with radioactive material regardless of the amount of material used or the resulting exposure level therefrom. This would include an event such as one where radioactive material was intentionally placed in a water cooler. By use of the term "identified," the Commission means that if, during a review of a contamination event, the licensee concludes that the event resulted from an intentional unauthorized use, the licensee is expected to report. Any allegation received from an individual that he or she believes the act is intentional must be reported regardless of whether or not the licensee discounts it. The term "intentional" is used to clarify that accidental contamination need not be reported when the dose received does not exceed the limits of 20.2202. Discovering contamination during a routine survey of an area in which radioactive material is used on a regular basis for a purpose authorized by the license or regulations, such as a nuclear pharmacy or a research laboratory, would not be considered reportable, but may indicate that the licensee needs to focus attention on the techniques and procedures followed by workers using radioactive material.

This reporting requirement is being adopted to ensure that the NRC is made aware of any intentional use of licensed radioactive material for a purpose not authorized by the applicable license or regulations and where there is the potential for exposure, in order to take the necessary follow-up actions or to conduct investigations in a timely manner. The NRC needs to have prompt assurance that the licensee is taking the appropriate actions to assess the consequences of the situation and to take the necessary steps to reduce any likelihood that further exposures would occur. These licensee actions could consist of identifying the causes of the event, securing the affected area and accounting for all licensed radioactive material, surveying the area and the personnel working in that area, processing the dosimetry worn by personnel working in that area, performing bioassays of the personnel in the affected area, taking the appropriate actions to prevent a recurrence of the event, and notifying law enforcement agencies.

The reporting requirement does not have an exposure threshold because intentional unauthorized exposure of workers or members of the public in and of itself needs prompt corrective actions to ensure that the individual who caused the event does not continue to expose others to radiation.

Intentional unauthorized use of licensed material with the potential to cause exposure is a violation of NRC requirements. It may be subject to civil and criminal sanctions. Further, it raises integrity questions as to whether the perpetrator should be employed in the nuclear industry. NRC needs to receive reports of intentional misuse in order to decide whether to investigate these acts. Such acts also may indicate that other NRC requirements were violated, and those violations also may warrant enforcement action.

As a point of clarification, a misadministration, as defined in 35.2, would not be reported under 20.2207. Medical use of byproduct material, which requires the supervision of an authorized user, is subject to the regulations in 10 CFR Part 35 and is specifically excluded from the scope of 10 CFR Part 20 regulations. The terms "medical use" and "authorized user" are defined in 10 CFR 35.2. However, the intentional administration of licensed radioactive material to an individual that does not fall within the definition of "medical use" in 10 CFR Part 35 is for a purpose not authorized by the regulations and would, therefore, be reportable under 20.2207. An example of such a situation would be the intentional administration of material by one technician to another technician outside of the scope of an authorized user's supervision, regardless of the reason for the unauthorized administration.

The NRC has considered the impact on licensees from these new requirements and has weighed them against the benefits. In those instances where the licensee believes the exposures of individuals resulted from intentional unauthorized use, licensees will have to notify the NRC Operations Center. Such events are expected to be rare. By the licensees' reporting of this information early, the NRC will be able to assess promptly the licensees' actions to prevent further exposures and possible harm to other individuals, as well as to determine whether the NRC needs to be involved in the matter. Licensees have an obligation to expend the effort and resources necessary to identify the causes of events involving the intentional unauthorized use of licensed radioactive material regardless of this new reporting requirement. Specifically, the existing regulatory framework includes the requirements of 20.1101, Radiation protection programs, that require licensees to "develop, document, and implement a radiation protection program ... sufficient to ensure compliance with the provisions of this part." Section 20.1501 requires licensees to "make surveys necessary to comply with the regulations of this part." Intentional unauthorized use with the potential to cause exposure is a serious violation and, as such, licensees must take appropriate action to assure that it does not recur.

The following examples are provided of events to clarify when reports would and would not be needed.

1. Examples where a notification would be required include events involving, or similar to, the intentional contamination of an individual or an individual's food, drink, or personal belongings, as well as the following actual events:
 - a. A sealed radiation source (used to check the response of radiation survey instruments) was placed in a worker's pocket. The worker was unaware that the source was in his pocket. The worker stated that someone must have removed this strontium-90 source from its storage place and intentionally hidden it in a pocket of his clothing in the change room while he was working inside a contaminated area. The worker's statement constitutes an allegation for the purposes of this rule; therefore, this event would be reportable.
 - b. In an effort to entrap a suspected thief who had been stealing workers' valuables from a dressing/change room at a licensed facility, health physics technicians, who were aware of NRC regulations and license conditions, affixed low-levels of radioactive contamination onto some dollar bills and left this contaminated money in a wallet. While this activity successfully led to the apprehension of the thief by setting off the alarm on the sensitive portal exit contamination monitor, it constitutes intentional use of licensed radioactive material for a purpose that is not authorized by the license or regulations; therefore, this event would be reportable.
 - c. A laboratory assistant, who had reported the vandalism of a hematology laboratory, was found to have iodine-

125 contamination on her lab coat. Analysis also showed iodine-125 in her urine. Subsequently, the laboratory assistant confessed that she vandalized the lab and intentionally ingested the iodine-125. This constituted an intentional use of licensed radioactive material for a purpose not authorized by the license or regulations; therefore, this event would be reportable.

- d. Laboratory personnel were scanning samples for disposal when they discovered that a post-doctorate researcher was contaminated with a radioactive substance. Later analysis determined that the researcher was internally contaminated with P-32. Surveys of the laboratory and surroundings revealed only one instance of contamination, which was isolated to a food item partially consumed by the researcher. The licensee investigated further and ruled out accidental contamination of the food. Although the perpetrator had not been identified, the licensee had information that licensed material had been used intentionally for a purpose not authorized by the license or regulations; therefore, this event would be reportable.
2. Examples of events that have occurred and that would not be covered by this requirement include the following incidents:
- a. In an effort to add realism to radiation worker training on how to perform surveys the instructor used sealed radioactive instrument check sources to provide the trainees with realistic instrument responses. The license authorized the use of sealed radioactive instrument check sources to determine instrument response. This use of licensed radioactive material was for a purpose authorized by the license; therefore, it would not be reportable.
 - b. A routine surface contamination (smearable or swipe) survey at a licensed facility revealed detectable loose surface contamination on the passageway floor of an area not controlled as a contaminated area. The location, level, and type of contamination led the radiation protection staff to conclude that it was likely that workers exiting the immediate worksite inadvertently tracked contamination outside the posted loose-surface contaminated area into the unposted, "clean" passageway. Since the contamination was not intentional, the event would not be reportable.
 - c. A radiographer intentionally failed to perform a survey and subsequently received an overexposure while performing radiographic operations. The event would not be reportable under this rule because radiography was a purpose authorized by the license and regulations; however, the event would be reportable under 20.2202 on the basis of the overexposure.

The intent of this rule is not to require licensees to report allegations that turn out to be unfounded. Should a licensee's employee allege that another employee has contaminated their workspace with radioactive material and survey results indicate no contamination, then this allegation is not reportable.

Enforcement Policy

In light of the purpose of this final rule the NRC is amending the NRC Enforcement Policy, NUREG-1600, (60 FR 34381; June 30, 1995), to state that a failure to meet 20.2207 may be considered a violation of significant regulatory concern. Such a violation could be characterized as a Severity Level III violation and be subject to an assessment of civil penalties.

Agreement State Compatibility

A compatibility level is not being assigned to this rule at this time. The Commission is presently developing implementing procedures for the new Policy Statement on Adequacy and Compatibility of Agreement State Programs.

Staff plans to apply and follow those procedures, when issued in final form, to determine the level of compatibility which should be assigned to this rule.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a "major rule" and has verified this determination with the Office of Information and Regulatory Affairs of the Office of Management and Budget.

Environmental Impact: Categorical Exclusion

The NRC has determined that final rule regulation is the type of action described as a categorical exclusion in 51.22(c)(3)(iii), reporting requirements. Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150-0014.

The public reporting burden for this collection of information is estimated to average 40 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments on any aspect of this collection of information, including suggestions for reducing the burden, to the Information and Records Management Branch (T-6F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0014), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Regulatory Analysis

The NRC has considered the impact on licensees from these new requirements and has weighed them against the benefits. Under the final rule, the licensee would be required to report promptly to NRC within 24 hours after identifying, or receiving information, such as an allegation, that licensed radioactive material was used intentionally for a purpose not authorized by the applicable NRC license or regulations, and which may have caused, or threatens to cause an exposure to an individual, regardless of whether or not it exceeds the regulatory exposure limit as identified in 20.2202. These types of events are expected to be rare. By reporting this information promptly, the NRC would be able to assess quickly the licensee's actions to prevent further exposures and possible harm to other individuals.

The NRC has considered five alternatives: (1) take no action, (2) amend each license, (3) issue an information notice, (4) issue a generic letter or (5) amend the regulations.

The first alternative is not acceptable because the NRC would not be made aware promptly of some intentional unauthorized use which caused or threatened to cause the exposure of an individual. Thus, the NRC would not always be able to take the necessary follow-up actions or to conduct investigations in a timely manner.

Under the second alternative, the only benefit of amending licenses would be in the resources saved in promulgating a new regulation. However, the costs to amend licenses for the more than 6,700 NRC licensees would be much higher than the costs for amending the regulation.

The third and fourth alternatives are not acceptable as they are not enforceable.

The fifth alternative is acceptable because it provides assurance that licensees will promptly report events of intentional unauthorized use of licensed radioactive material. The NRC needs to have assurance that the licensee is taking the appropriate actions to assess the consequences of the situation and to reduce any likelihood that further exposures would occur. The NRC believes that this benefit outweighs the costs to the licensees.

The cost to the NRC to perform reactive inspections of events reported under new 10 CFR 20.2207 is estimated to be 0.6 FTE. This cost is calculated using the number of events, 10, multiplied by the number of FTE necessary to investigate one of these events, or 125 hours per event based on NRC experience. The cost is based on a professional staff year, \$125,000 per staff per year, which includes the pro-rated values for secretarial and managerial support, and any benefits that are hourly rated. This cost of \$75,000 is spread over all 6,700 NRC licensees.

The cost to the Agreement States to perform reactive inspections is estimated to be 1.2 FTE. This cost is calculated using the criteria stated above for the NRC. It projects 20 events reported per year, since there is roughly a two to one ratio of Agreement States to NRC States. The cost to the Agreement States to revise regulations is estimated to be 11.6 FTE, considering 29 Agreement States that would have to revise their regulations at 0.25 FTE per Agreement State. The total cost of \$1,600,000 for revising the regulations and conducting reactive inspections is spread over the 29 Agreement States.

The costs to all licensees of the final rule are estimated as follows: Based on the past experience, the occurrence of events that would be covered by this rule is expected to be rare. The number of such events is estimated at thirty per year. The NRC further estimates that 40 hours would be required to determine the cause of each event, prepare the report, complete management review, and make a telephone report. The total estimated burden to all licensees would be 1,200 hours per year. Assuming administration costs of \$45 per hour for 20 hours, and labor costs of \$120 per hour for 20 hours, the total cost would be about \$99,000 per year. However, the NRC recognizes that to some extent licensees are already expending effort to identify the causes of many events involving the intentional unauthorized use of licensed radioactive material independently of this new reporting requirement.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the NRC certifies that this rule, if adopted, will not have a significant economic impact upon a substantial number of small entities. The final rule affects all licensees. The cost of the final requirement is indicated in the Regulatory Analysis. This cost would be incurred only by a licensee who is required to report an event. The estimated cost of reporting a single event is \$3,300.

Backfit Analysis

The NRC has determined that the nature of the information collection and reporting requirements of the final rule preclude reasonable application of the backfit criteria in 50.109(a)(3). However, the information collection and reporting requirements contained in this addition to the Commission's regulation have been subjected to the analysis required under 50.54(f), which reflects the Commission's view that information requests be carefully evaluated for their impact on licensees. The burden imposed on the licensee as estimated in the regulatory analysis is justified in view of the potential safety significance of the information requested. Further, the regulatory analysis provides the necessary regulatory discipline and rational basis for evaluating the burdens imposed by information and collection requests.

List of Subjects in 10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendment to 10 CFR Part 20.

PART 20--STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows:

AUTHORITY: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953, (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

2. Section 20.1009, paragraph (b) is revised to read as follows:

20.1009 Reporting, recordkeeping, and application requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in 20.1101, 20.1202, 20.1204, 20.1206, 20.1301, 20.1302, 20.1501, 20.1601, 20.1703, 20.1901, 20.1902, 20.1904, 20.1905, 20.1906, 20.2002, 20.2004, 20.2006, 20.2102, 20.2103, 20.2104, 20.2105, 20.2106, 20.2107, 20.2108, 20.2109, 20.2110, 20.2201, 20.2202, 20.2203, 20.2204, 20.2205, 20.2206, 20.2207, and appendices F and G to 10 CFR Part 20.

* * * * *

3. Section 20.2207 is added to read as follows:

20.2207 Reports of unauthorized use of licensed radioactive material.

(a) The licensee shall notify the NRC Operations Center by telephone as soon as practical but not later than 24 hours after receiving information or identifying an intentional act involving unauthorized use of licensed radioactive material that may have caused, or threatens to cause an exposure to an individual, whether or not it exceeds the regulatory exposure limits as identified in 20.2202.

(b) Reports made by licensees in response to the requirement of this section must be made as follows:

- (1) Licensees having an installed Emergency Notification System shall make reports to the NRC Operations Center, and
- (2) All other licensees shall make reports by telephone to the NRC Operations Center (301-816-5100)
- (3) Reporting events under 20.2201 and 20.2202 continue to apply. A report is not required by paragraph (a) of this section if a notification has already been made under 20.2201 or 20.2202.

Dated at Rockville, Maryland, this _____ day of _____ 1996.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission.

ENCLOSURE 2

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NUREG - 1600]

Policy and Procedure for Enforcement Actions; Intentional Misuse of Licensed Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement: Amendment

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its "General Statement of Policy and Procedure for NRC Enforcement Actions" to add an example for categorizing the significance of a failure to notify the NRC of intentional misuse of licensed material as required by the regulations governing standards for protection against radiation. By a separate action published in this issue of the Federal Register, the Commission has issued a final rule amending Part 20 to add 20.2207. This modification to the Enforcement Policy reflects that amendment.

EFFECTIVE DATE: This action is effective on [30 days after publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: James Lieberman, Director,
Office of Enforcement,
U.S. Nuclear Regulatory Commission,
Washington, DC 20555,
(301) 415-2741.

SUPPLEMENTARY INFORMATION:

Background

The Commission's "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy or Policy) was first issued on September 4, 1980. Since that time, the Enforcement Policy has been revised on a number of occasions. On June 30, 1995 (60 FR 34381), the Enforcement Policy was revised in its entirety and was also published as NUREG-1600. The Policy recognizes that violations have differing degrees of safety significance. As reflected in the severity levels, safety significance includes actual safety consequence, potential safety consequence, and regulatory significance.

The proposed rulemaking to add 20.2207 to 10 CFR Part 20, Standards for Protection Against Radiation, (changed from 20.2205 in the proposed rulemaking) stated that the NRC intends to consider amending the Enforcement Policy to state that a failure to comply with 10 CFR 20.2207 may be considered a violation of significant regulatory concern and may be characterized as a Severity Level III violation. This failure is a significant regulatory concern because the NRC needs to receive reports of deliberate misuse of licensed material to carry out its regulatory responsibility. Specifically, the NRC needs these reports to determine whether it should investigate the intentional misuse; take enforcement action, including action directly against the individual responsible for the deliberate act; and develop additional regulatory requirements to protect public health and safety. Consistent with the proposed rulemaking, a revision to the Enforcement Policy is warranted to provide guidance on categorizing potential violations of 20.2207.

Therefore, "Supplement IV--Health Physics (10 CFR Part 20)" of the Policy is being modified by adding Example C.14. to provide an example of a violation categorized at Severity Level III involving failure to make a report of deliberate misuse of licensed material to the NRC as required by 10 CFR 20.2207.

Paperwork Reduction Act Statement

This policy statement does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval number 3150-0011. The approved information collection requirements contained in this policy statement appear in Section VII.C.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

Accordingly, the NRC Enforcement Policy is amended as follows:

GENERAL STATEMENT OF POLICY AND PROCEDURE FOR NRC ENFORCEMENT ACTIONS

In Supplement IV, paragraph C(13) is revised and paragraph C(14) is added to read as follows:

Supplement IV--Health Physics (10 CFR PART 20)

C. Severity Level III--Violations involving for example:

13. A breakdown in the radiation safety program involving a number of violations that are related (or, if isolated, that are recurring) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities; or
14. A failure to notify NRC of an intentional misuse of licensed material as required by 10 CFR 20.2207.

* * * * *

Dated at Rockville, Maryland, this ____ day of _____ 1996.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission.

ENCLOSURE 3

Mr. Robert P. Murphy
General Counsel
General Accounting Office
Room 7175
441 G. St., NW
Washington, DC 20548

Dear Mr. Murphy:

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801, the Nuclear Regulatory Commission (NRC) is submitting a final rule that will require licensees to notify the NRC Operations Center after receiving information that licensed radioactive material was used intentionally for a purpose not authorized by the license or NRC regulations. The final rule is intended to alert the NRC promptly of intentional events that may lead to exposures of individuals, but are not covered under existing regulations.

We have determined that this rule is not a "major rule" as defined in 5 U.S.C. 804(2). We have confirmed this determination with the Office of Management and Budget.

Enclosed is a copy of the final rule that is being transmitted to the Office of the Federal Register for publication. The Regulatory Flexibility Certification and Regulatory Analysis are included in the final rule. This final rule is scheduled to become effective 30 days after publication in the Federal Register.

Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: Final Rule

The Honorable Al Gore
President of the United
States Senate
Washington, DC 20510
Dear Mr. President:

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801, the Nuclear Regulatory Commission (NRC) is submitting a final rule that will require licensees to notify the NRC Operations Center after receiving information that licensed radioactive material was used intentionally for a purpose not authorized by the license or NRC regulations. The final rule is intended to alert the NRC promptly of intentional events that may lead to exposures of individuals, but are not covered under existing regulations.

We have determined that this rule is not a "major rule" as defined in 5 U.S.C. 804(2). We have confirmed this determination with the Office of Management and Budget.

Enclosed is a copy of the final rule that is being transmitted to the Office of the Federal Register for publication. The Regulatory Flexibility Certification and Regulatory Analysis are included in the final rule. This final rule is scheduled to become effective 30 days after publication in the Federal Register.

Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: Final Rule

The Honorable Newt Gingrich
Speaker of the United States
House of Representatives
Washington, DC 20515
Dear Mr. Speaker:

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801, the Nuclear Regulatory Commission (NRC) is submitting a final rule that will require licensees to notify the NRC Operations Center after receiving information that licensed radioactive material was used intentionally for a purpose not authorized by the license or NRC regulations. The final rule is intended to alert the NRC promptly of intentional events that may lead to exposures of individuals, but are not covered under existing regulations.

We have determined that this rule is not a "major rule" as defined in 5 U.S.C. 804(2). We have confirmed this determination with the Office of Management and Budget.

Enclosed is a copy of the final rule that is being transmitted to the Office of the Federal Register for publication. The Regulatory Flexibility Certification and Regulatory Analysis are included in the final rule. This final rule is scheduled to become effective 30 days after publication in the Federal Register.

Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: Final Rule

ENCLOSURE 4

NRC REVISES REGULATIONS TO REQUIRE REPORTING OF UNAUTHORIZED USE OF RADIOACTIVE MATERIALS

The Nuclear Regulatory Commission is amending its regulations to require that licensees notify the NRC operations center no later than 24 hours after learning of any intentional unauthorized use of licensed radioactive material.

NRC is taking this action as a result of two recent incidents--one at the National Institutes of Health, Bethesda, Maryland, and the other at the Massachusetts Institute of Technology, Cambridge, Massachusetts--involving internal contamination of individuals with phosphorus-32.

A proposed rule on the reporting requirement was published in the Federal Register on January 31, 1996 (61 FR 3334). As a result of comments received, the NRC has deleted a proposed requirement for licensees to report events if unauthorized use cannot be ruled out within 48 hours. Other changes are described in a notice published in the _____(date) edition of the Federal Register.

The amendments will be effective on _____ (30 days after publication of the Federal Register notice).

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ENCLOSURE 5

The Honorable Lauch Faircloth, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The NRC has sent to the Office of the Federal Register for publication the enclosed revisions to the Commission's rules in 10 CFR Part 20. The final rule will require licensees to notify the NRC Operations Center after receiving information that licensed radioactive material was used intentionally for a purpose not authorized by the license or NRC regulations. The final rule is intended to alert the NRC promptly of intentional events that may lead to exposures of individuals, but are not covered under existing regulations.

Sincerely,
Dennis K. Rathbun, Director

Enclosures: 1. Public Announcement
 2. Federal Register Notice

cc: Senator Bob Graham

The Honorable Dan Shaefer, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington, DC 20515
Dear Mr. Chairman:

The NRC has sent to the Office of the Federal Register for publication the enclosed revisions to the Commission's rules in 10 CFR Part 20. The final rule will require licensees to notify the NRC Operations Center after receiving information that licensed radioactive material was used intentionally for a purpose not authorized by the license or NRC regulations. The final rule is intended to alert the NRC promptly of intentional events that may lead to exposures of individuals, but are not covered under existing regulations.

Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures: 1. Public Announcement
 2. Federal Register Notice

cc: Representative Frank Pallone

1. The Commission notes that if an information collection and reporting requirement were found to be necessary for adequate protection or compliance with the Commission's requirements or written license commitments, the Section 50.109(a)(3) analysis of costs and benefits need not be prepared. The discipline that the commenter is alluding to is the cost-benefit analysis that must be completed for all rulemakings.