



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

MEMORANDUM FOR: James M. Taylor, Executive Director for Operations

FROM: Eric S. Beckjord, Director, Office of Nuclear Regulatory Research

SUBJECT: FINAL RULEMAKING - NOTIFICATION OF INCIDENTS
10 CFR PARTS 20, 30, 40, AND 70

Enclosed for your signature is a Notice of Final Rulemaking (Enclosure 1) to be published in the Federal Register. This rulemaking would assure that prompt reporting of significant occurrences at material licensee facilities is made to the NRC so that the Commission can evaluate whether the licensee has taken the required action to protect the public health and safety and whether generic safety concerns are identified that may require prompt NRC action. The NRC has become concerned that certain provisions of § 20.403 need to be revised because licensees have not been reporting certain events that the agency felt should have been reported.

Sections (a)(3), (a)(4), (b)(3), and (b)(4) of 10 CFR 20.403 and 10 CFR 20.2202, "Notification of Incidents," regarding the loss of operations and damage to property for both immediate and 24-hour notifications would be removed and new requirements added to Parts 30, 40, and 70 as Sections 30.50, 40.60, and 70.50. No new requirements are added in 10 CFR Part 50 since Section 50.72 already contains special notification requirements for nuclear power reactors. In addition, the term "immediate notification" is defined for the added sections.

The rule is a matter of compatibility for Agreement States. The Agreement States participated in the development of this rule, and their comments were incorporated as appropriate.

The Offices of NMSS, OE, NRR, Administration, and Governmental and Public Affairs concur in the Amendment. In addition, the staff has coordinated this effort with the NRC's five regional offices. The Office of the General Counsel has no legal objections.

A handwritten signature in dark ink, reading "Eric S. Beckjord", is positioned above the typed name and title.

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosures:

1. Federal Register Notice
2. Congressional Letters
3. Draft Public Announcement
4. Weekly Report to the Commissioners

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20 55FR10590 PDR

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Author's Name:
Mate

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WASHINGTON, D.C. 20555

MAY 6 1991

MEMORANDUM FOR: Those on Attached List

FROM: Eric S. Beckjord, Director, Office of Nuclear Regulatory Research

SUBJECT: FINAL RULEMAKING - NOTIFICATION OF INCIDENTS
10 CFR PARTS 20, 30, 40, and 70

Please provide office concurrence for the enclosed final rulemaking package. This package responds to a request for rulemaking received from the Office of Enforcement in July of 1987.

The following contains a summary of this request:

1. Title: Notification of Incidents
2. RES Task Leader: Joseph J. Mate, RDB/DRA/RES (X-23795)
3. Cognizant Individuals:

John Hickey, NMSS/IMOB
Kevin Ramsey, NMSS/IMOB
Kathleen Black, AEOD NAS
John Buchanan, NRR/DRPB
Joel Lubenau, GPA/SP
Jim Myers, GPA/SP
Mike Finkelstein, OGC
Aizonia Shepard, ADM/RPB
4. Requested Action: Provide office level concurrence
5. Requested Completion Date: May 14, 1991.
6. SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to revise material licensee reporting requirements for byproduct, source, and special nuclear material regarding the incidents related to radiation safety. This action is needed to ensure that significant occurrences at material licensee facilities are promptly reported to NRC so that the Commission can evaluate whether the licensee has taken the required action to protect the public health and safety and whether generic safety concerns are identified that may require prompt NRC action.

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosure:
Memo Beckjord to Taylor
w/4 encl.

9201170054 *JSB*

AC 91-1
PDR

Addressees - Memorandum dated MAY 6 1991

Robert M. Bernero, Director, Office of Nuclear Material
Safety and Safeguards
James Lieberman, Director, Office of Enforcement
Thomas E. Murley, Director, Office of Nuclear Reactor
Regulation
Harold R. Denton, Director, Office of Governmental and
Public Affairs
William C. Parler, General Counsel
Patricia G. Norry, Director, Office of Administration

cc: Thomas T. Martin, Regional Administrator, Region I
Stewart Ebrieter, Regional Administrator, Region II
A. Bert Davis, Regional Administrator, Region III
Robert D. Martin, Regional Administrator, Region IV
John B. Martin, Regional Administrator, Region V

OGC DRAFT
COMMENTS -
REC'D 6-3-91
2:00 P.M. PICKED-UP



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Sections (a)(3), (a)(4), (b)(3), and (b)(4) of 10 CFR 20.403 and 10 CFR 20.2202, "Notification of Incidents," regarding the loss of operations and damage to property for both immediate and 24-hour notifications would be removed and new requirements added to Parts 30, 40, and 70 as Sections 30.50, 40.60, and 70.50. No new requirements are added in 10 CFR Part 50 since Section 50.72 already contains special notification requirements for nuclear power reactors. In addition, the term "immediate notification" is defined for the added sections.

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Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosures:

1. Federal Register Notice
2. Congressional Letters
3. Draft Public Announcement
4. Weekly Report to the Commissioners

Enclosure 1

Federal Register Notice

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20, 30, 40, and 70

RIN:3150 - AC 91

Notifications of Incidents

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to revise material licensee reporting requirements for byproduct, source, and special nuclear material regarding the incidents related to radiation safety. This action is needed to ensure that significant occurrences at material licensee facilities are promptly reported to NRC so that the Commission can evaluate whether the licensee has taken the required action to protect the public health and safety and whether generic safety concerns are identified that may require prompt NRC action.

EFFECTIVE DATE: [Insert a date 60 days following publication in the Federal Register.]

FOR FURTHER INFORMATION CONTACT: Joseph J. Mate, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3795.

SUPPLEMENTARY INFORMATION:

Background

Current regulations require that NRC licensees promptly report certain events involving byproduct, source, or special nuclear material that cause or threaten to cause exposure to specific levels of radiation, the release of radioactive material in specific concentrations, the loss of use of facilities for a specific duration, or damage to property in excess of a specific dollar amount. The events are to be reported either immediately or within 24 hours, depending on the nature and severity of the event as defined in § 20.403. NRC has become concerned that certain provisions of § 20.403 need to be revised because licensees have not been reporting certain significant events. Licensees who failed to report these events were cited for violation of the Commission's regulations.

On May 14, 1990, The Nuclear Regulatory Commission published a Notice of Proposed Rulemaking (55 FR 19890). The proposed amendments would delete reporting requirements based on the loss of use of facilities for a specific duration and damage in excess of a specified dollar amount. The deleted criteria would be replaced with reporting requirements that were related more closely to health and safety issues. The proposed requirements covered the following areas: inability to control licensed material, unplanned contamination events, failure of

safety equipment, personal injury events, and fires and explosions. The comment period expired July 30, 1990. Public comments were received on the proposed rule, were docketed, and may be examined at the Commission's Public Document Room located at 2120 L Street NW (Lower Level), Washington, DC.

Many of the letters received contained similar comments. These types of comments are grouped together, as appropriate, and addressed as a single issue. The NRC has identified and responded to 66 separate issues that include all of the significant points raised.

The comments received on the proposed rule have been divided into two groups. Those comments that are not applicable to a specific section of the proposed rule are grouped into a "General Comments" area. Those that are applicable to a certain portion of the rule are grouped into a section called "Specific Comments." The comments and their resolution are discussed below.

Summary and Analysis of Public Comments

General Comments

1. The rule contains reporting requirements for extremely common events. It will lead to confusion and excessive reporting. The rule needs to be altered to exclude insignificant radiation events or significant events with insignificant radiation exposure. Licensees need clear definitions that specify severity levels requiring notification like those currently in 10 CFR 20.403 (a)(1) and (a)(2) and (b)(1) and (b)(2).

Response: The NRC agrees that there is a need to make the criteria in the rule more specific. The final rule has been revised in response to this comment.

2. Modify the criteria in § 20.403 to add specific notification criteria for fires, explosions, and off site medical treatment provided that these can be clearly separated from the insignificant events. Do not modify Parts 30, 40, and 70.

Response: In developing the revised criteria for the proposed rule the NRC considered the possibility of revising Part 20 rather than establishing criteria in Parts 30, 40, and 70. To make such changes, however, would conflict with well established reporting requirements in Part 50 and would require the revision of those requirements. Placing the reporting requirements in Parts 30, 40, and 70 will provide greater assurance that persons licensed under those parts will be aware of their reporting responsibilities.

3. Justification for rule is weak; writing new rules does not mean people will comply with them. The proposed rule provides no assurance of better reporting by licensees.

Response: The NRC agrees that writing new rules in itself provides no assurance that licensees will comply with them. NRC developed the proposed criteria to reduce confusion and disagreements over what types of events should be promptly reported to the NRC. By establishing

...a written more clearly define significant events which need to be
...resources of licensees can be used more efficiently by directing
...only to those events for which reports are ^{required} warranted. A
...the rulemaking is to assure that all significant events are
...and that the NRC and industry have knowledge of and feedback
...operating experience.

4. The rule is prescriptive and eliminates the need for licensee judgment.

Response: The NRC does not feel that the revised rule is overly prescriptive. The rule provides criteria and clarification as to what events need to be reported (as discussed in item 3 above). It is recognized that the reporting of some events will involve judgment on the part of the licensee. Again, the objective is to assure that the NRC has immediate knowledge of significant events affecting public health and safety, and timely reporting of events which may involve important lessons or experience.

It contains sufficiently detailed criteria to ~~provide~~ ^{provide} requirements and ^{clarify} ~~clarify~~ what events are reportable. (minimize)

5. Establish activity thresholds for each radionuclide that would require NRC notification, such as Part 20, Appendix C. Define significant occurrences in terms of dose equivalents or concentration limits. Severity should be related to the overexposure situations.

Response: In developing the proposed rule the NRC considered the idea of providing specific activity thresholds. However, the NRC felt that such thresholds would be cumbersome and difficult to develop and use. Many licensed operations use mixtures of isotopes in different chemical forms

that pose various safety hazards. The NRC believes that the safety hazards posed by contamination incidents are best evaluated on a case-by-case basis, rather than using a generic set of contamination thresholds. However, the NRC agrees that a set of activity thresholds would be appropriate for determining what fires and explosions are reportable. The final rule has been revised to require NRC notification only for fires and explosions involving licensed material in quantities greater than the quantities specified in Appendix C of Part 20.

6. The deletion of paragraphs (a)(3), (a)(4), (b)(3), and (b)(4) of 10 CFR 20.403 is appropriate.

Response: Most of the commenters agreed, or voiced no disagreement, that these criteria did not necessarily define events affecting public health and safety and that it was appropriate to delete them.

7. Place specific reporting requirements in individual licenses. Those with emergency plans already have sufficient reporting requirements.

Response: Generic reporting requirements are best implemented by formal rulemaking procedures, including notice and comment. Placing the same reporting requirements in individual licenses is not efficient. Public notice and comment allows for comments that question the reporting requirements themselves and allows the NRC to respond to such comments. Placing the requirements in individual licenses would not allow for such a healthy dialogue.

8. The proposed amendments should be rewritten and reissued for a new comment period. They are counterproductive to strong licensee programs.

Response: The NRC believes that changes made to the proposed rule in response to the comments are of a nature that they do not necessitate the reissuance of another proposed rule and a new comment period.

9. The NRC did not consider other alternatives to rulemaking - such as issuing notices to licensees, developing/amending regulatory guides, issuing license conditions, etc.

Response: The NRC did consider alternatives such as those mentioned by the commenters, which were discussed in the draft regulatory analysis prepared for the proposed rulemaking. However, the NRC believed that certain ^{sub} sections in 10 CFR ~~20.403~~ needed to be replaced with better reporting criteria. As indicated in the regulatory analysis, rulemaking action is considered the best procedure for accomplishing this task.

10. A parallel to power reactor licensees is not proper. Most material licensees have neither the radioactive material inventory nor the stored energy to cause a release like power reactor licensees.

Response: The NRC did not intend to draw a parallel to power reactor licensees when Part 50 regulations were cited in the discussion. The NRC was merely pointing out where similar reporting requirements

already existed in Part 50 in order to illustrate why Part 50 was not included in the rulemaking. We agree that material licensees do not have the inventory or the stored energy to cause a release similar to that which could be caused by a nuclear reactor incident. Although the hazard is less from material licensees, a potential hazard nevertheless exists.

11. In the case of nuclear medicine/nuclear pharmacy, it is difficult to identify any events that would be significant enough to public health and safety to notify the NRC immediately.

Response: The NRC is very interested in incidents at medical facilities because of the proximity of the general public to areas where licensed material is used and stored. Fires, spills, or other incidents involving significant quantities of radiopharmaceuticals (e.g., therapy doses) or involving sealed sources with significant radiation levels pose potential health and safety hazards that warrant prompt notification of the NRC.

12. The revised rule should be reviewed by the NRC's Advisory Committee on Medical Uses of Isotopes.

Response: The Advisory Committee on Medical Uses of Isotopes (ACMUI) is normally requested to review rules that specifically address medical applications especially rulemakings involving Part 35. An ACMUI review has not been requested for this rule because the notification requirements are generic and go beyond medical uses of isotopes.

13. Further clarification needs to be provided regarding notification requirements for commercial nuclear power reactors. Companies holding a construction permit or operating license should be explicitly exempted for activities occurring within the protected area.

Response: The NRC does not intend for the ^{new} ~~proposed~~ criteria to apply to commercial nuclear power plants. In the discussion as well as in the ~~the~~ rule (Parts 30.50 (c)(3), 40.60 (c)(3), and 70.50 (c)(3)), the NRC specifically stated that the provisions do not apply to licensees subject to the notification requirements in 10 CFR ~~50.72~~ 50.72. If a nuclear power plant has only a Part 50 license, notification is required only under the provisions of 10 CFR ~~50.72~~ 50.72. Although the Part 50 license for a nuclear power plant contains provisions for receipt, possession, and use of byproduct, source, and special nuclear material pursuant to 10 CFR Parts 30, 40, and 70, the Part 50 provisions do not require reports under this rule. If a nuclear power plant has a separate byproduct, source, or special nuclear materials license, notification is required under the new notification requirements in Parts 30, 40, or 70; however, these requirements apply only to the activities licensed under the separate materials license and not to any other activities.

14. The NRC should provide clear guidance on its interpretation of the rule by circulating early event reports with comments on the appropriateness of the report and by providing examples of failures to report.

Response: The NRC agrees and intends to issue information notices and other guidance as appropriate to licensees as implementation issues are identified and experience is gained with the rule.

15. The NRC should more clearly define the notification requirements concerning the loss of packages of radioactive material.

Response: This rulemaking effort involves the notification requirements in 10 CFR ~~20.403~~. The loss of packages of radioactive material is covered by 10 CFR ~~20.402~~. Notification requirements for the loss and theft of licensed material are revised by the major revision to Part 20 which was published in the Federal Register in May 1991. The major revision specifies what quantities of licensed material require immediate and 30 day notifications. *when they are lost*

56 FR.
23360
(May 21, 1991)

16. The burden is estimated to be about 3 days for each notification required for large companies.

Response: The public reporting burden in the proposed rule was estimated at about four hours per response. This is an average considering both small and large licensees. We agree that a very large organization with several management levels could take a few days to complete and process such a report.

17. The subject rule and statement of considerations should make it clear that the rule would apply to uranium enrichment plants whether licensed under Part 70 or Part 76. Further, 10 CFR 50.72 and 50.73 should not apply to such facilities.

Response: The question of whether or not enrichment plants should fall under Part 70 or Part 50 is not within the scope of this rule. Currently there are no licensed enrichment plants. The question of which regulations should govern these plants is being dealt with as a separate issue. Under recent legislation (H.R. 4808), commercial uranium enrichment plants would be licensed under Parts 40 and 70, rather than Part 50.

18. Immediate and 24 hour notifications should be limited to potentially serious events where it is necessary for NRC to intervene to mitigate the effects.

final
Response: Under the rule, the immediacy of the reporting is related to the severity of the event. The licensee is responsible for the safety of the facility and for assuring proper and prompt action to protect public health and safety. The NRC monitors the licensee's actions, and makes recommendations when appropriate. The NRC also has communication channels to Federal, state and local organizations, and if necessary, can make recommendations regarding appropriate action to protect public health and safety or the environment. In all cases the NRC must be aware of significant events to ensure that appropriate and timely actions are taken.

19. We do not agree that the categorical exclusions have been met. The proposed regulation as written has a large impact and cannot be considered to be of a minor nature.

Response: The NRC does not agree that the proposed changes to the notification requirements have any significant environmental impact requiring an environmental review pursuant to Part 51. The NRC maintains that the ^{final} ~~proposed~~ rule is a clarification of existing requirements and does not change the NRC's policy that licensees should promptly report significant events. In addition, it is clear that § 51.22(c)(3) lists amendments to reporting requirements in Parts 30, 40, and 70 as categorical exclusions not requiring an environmental review.

20. The NRC is trying to cover too many different types of licensees with one set of criteria. It would be better to establish separate criteria for each type of licensee (radiography licensees 10 CFR 34, medical licensees 10 CFR 35, etc.).

Response: The NRC believes that the ~~proposed~~ notification requirements describe significant events that should be reported by all source, byproduct, and special nuclear material licensees. The NRC does not agree that developing more specialized requirements and amending more parts of the regulations would better meet the objectives of the rulemaking.

21. Frequent use of the word "any" is not consistent with the stated intent of "significant occurrences".

The NRC agrees
Response: *A* The text of each notification requirement defines the event to be reported. The NRC agrees that using the word "any" could be inconsistent with the NRC's intent to require NRC notification of significant events. The text of the rule has been modified accordingly.

agree w/ NRCSS language

22. Proposed rule should make it clear that it applies to independent spent fuel storage facilities.

Response: The NRC will consider the application of these reporting requirements to independent spent fuel storage facilities and, if appropriate, will initiate a separate rulemaking effort to amend Part 72 in order to allow public comment on that action.

23. No reports should be required for events that are concluded before any meaningful communication with and participation by the NRC is possible.

Response: The fact that the licensee has completed all necessary actions before the NRC is notified is no reason not to file a report. There may still be some action that the NRC may have to take depending on the nature of the incident. For example, the incident may have generic

safety implications not previously recognized and further NRC action, that may range from notifying other licensees to developing a rule, may be appropriate.

24. Provide further explanation and possibly examples of what "securing the material and assessing releases" means. (Used in the discussion).

Response: Although the final rule has been reworded, actions necessary to avoid overexposures and releases will usually include securing the material and assessing releases. Securing material includes actions necessary to prevent unauthorized movement of licensed material or unsafe conditions resulting from licensed material. This includes shielding exposed radiation sources, returning licensed material to storage containers, stopping a spill or the spreading of a spill, etc. Assessing releases includes efforts necessary to determine how much licensed material has escaped from the licensee's control and to determine where released material has gone. Assessment actions may include radiation surveys, contamination surveys, and analysis of air, water, and soil samples.

Specific Comments

(a) Immediate Notification.

25. Require one hour notification of the NRC and Agreement States for

incidents with substantial potential for injury to off site people.
Suggest 5 rem for one hour notification.

Response: A requirement for an additional notification is not needed. The Commission's regulations already require emergency response plans (including special notification requirements to states and other authorities) that apply to those licensees who have quantities of licensed material sufficient to result in significant doses to the public in the event of an accident (i.e. §§ 30.32i, 40.31j, and 70.22i). Those plans include criteria for taking action so that injury or harm to those off site can be minimized.

26. The time requirement for notification of the NRC may be severe and unrealistic in some cases.

Response: The NRC does not agree that the time requirements are severe and unrealistic. Licensees should be able to perform an initial evaluation of an event and notify the NRC within the 4 or 24 hour time limits. *See NRC comment*

27. We question the need to immediately report events regardless of quantity and type of licensed material involved.

Response: The rule has been revised so that immediate reporting is not required in all cases. Events involving very small quantities of material, such that exposures in excess of regulatory limits are not possible, would not be reportable.

28. Do toxic gas releases include gas releases (such as UF-6, NOx, hydrogen fluoride, etc.) that periodically occur but are contained and controlled by operating procedures need to be reported?

Response: Toxic gas releases would not require an immediate report provided they did not prevent the licensee from taking immediate protective actions necessary to avoid exposures and releases exceeding regulatory limits. However, even if no immediate protective actions were prevented, a report may be required if the toxic gases are also radioactive and the releases exceed the limits specified in § 20.403(a)(2) or § 20.403(b)(2).

(b) Twenty-four hour Notification

29. Licensees should not be penalized for failing to report within 24 hours, if a reasonable estimate projects that access would not be lost for more than 24 hours.

Response: If an event does not clearly meet the reporting criteria, but the licensee can not conclusively rule out the need to report the event, a conservative approach would be to notify the NRC within 24 hours. If the licensee later determines that an event was not reportable, a 30-day written report would not be required.

30. The phrase "threatens to prevent" is so vague that many everyday events may qualify for reporting.

Response: The NRC agrees with the commenter that it is difficult to provide a clear, generic definition for these words. As a result, the final rule has been revised accordingly. *see NMSS comment*

(b)(1) Contamination Events

31. Minor contamination (such as a contaminated collimator or a spill of short lived radionuclides) is common in research and medical settings. Access is restricted in the interest of ALARA and efficiency and to minimize dose. Spills of this nature should not have to be reported. The requirement appears excessive and not related to any potential hazard to the public or the environment.

Response: The NRC agrees that restricting access to allow short-lived isotopes to decay should not be a reportable event. The regulation has been revised to require no report if an area is restricted to allow isotopes with a half-life of less than 24 hours to decay.

32. How do you determine when an area is "cleaned up"? Is the definition of an "area" limited to any minimum size?

Response: This rule does not attempt to define criteria for releasing areas from radiological controls. No report would be required if an accidentally contaminated area can be decontaminated within 24 hours to levels where contamination controls for entry into the area are no more *see NMSS comment*

stringent than the controls in effect prior to the contamination accident. The definition of an "area" is not limited to any minimum size. In general, any space normally accessible to workers or the general public qualifies as an area.

33. What does a "contamination event that restricts access" mean?

Response: Contamination events that restrict access are (1) spills or other types of accidents involving radioactive material that result in elevated levels of radiation from spreadable contamination and (2) occur in areas that must be restricted by imposing additional controls to prevent individuals from spreading the contamination to themselves or to areas outside the contaminated area. Restricting access also includes additional controls to minimize radiation exposure from the *See RMSS*
comment
contamination.

34. The contamination area is unduly restrictive. It makes no distinction about the source of contamination or efforts to remove it. For hospitals either restrict the definition of a contamination event, exclude contamination from contaminated patients, or exclude temporal extensions of restricted areas beyond what would normally be necessary allowing a more deliberate pace of decontamination.

Response: The reporting requirement has been clarified to indicate that the contamination must be unplanned, however, the NRC does not agree that the term "area" is too restrictive.

35. The proposed regulation places an unnecessary burden on the licensee with restricted areas. Low action levels for contamination/whole body exposures are low because clean-up efforts can be supplemented with radioactive decay. Hence individual and collective radiation exposures may increase.

Response: The reporting requirements do not relieve licensees from their responsibility to maintain radiation exposures as low as reasonably achievable. The NRC agrees that waiting longer than 24 hours for isotopes to decay is acceptable if a significant reduction in activity will result. The final rule has been revised to not require a report if the licensee is waiting to allow isotope with half-lives less than 24 hours to decay. However, the benefit of waiting for several days or weeks for isotopes with longer half-lives to decay is questionable. In these cases, a 24-hour report is warranted.

36. The requirement to notify the NRC within 24 hours needs to be more quantitative. Specific levels of contamination should be stated.

Response: The hazards posed by radioactive contamination vary depending on the activity of the contamination, the chemical and physical form, the

normal conditions of the contaminated area, and other factors. Thus, specific contamination levels are only one measure of significance. However, the NRC agrees that if the amount of licensed material involved is not likely to result in exceeding regulatory limits, no report should be required. The final rule has been changed to require a report if the amount of licensed material involved is greater than five times the lowest annual limit on intake specified in Appendix B of §§ 20.1001 - 20.2401 of ^{10 CFR} Part 20 for the material.

37. Sentence 2 of paragraph 1 in the discussion under Contamination Events states that the "requirement is intended to cover events that cause accidental contamination in excess of the radiological conditions normally present". This standard is markedly more restrictive than the proposed standard and is inappropriate.

Response: The NRC agrees with the comment. The sentence is misleading and has been deleted from the discussion. *all NRC comment* NO

38. The rule should allow for planned activities such as maintenance or decommissioning that would result in restricting access.

Response: The NRC agrees. This criterion has been revised to clarify that it applies to unplanned contamination only.

39. It is not clear from the rule that restriction of access includes changing protocols such as adopting extra protective clothing. Need to provide more guidance.

Response: Requiring additional protective clothing or otherwise increasing radiological controls as a result of a contamination accident is significant. The final rule has been clarified to indicate that imposing additional radiological controls is considered to be a form of restricting access.

40. Allow licensees to have contaminated restricted areas in excess of 24 hours provided employees do not receive exposures in excess of the regulatory limits and no releases are being made to unrestricted areas or the environment.

Response: Licensees have been and still are allowed to have contaminated areas in excess of 24 hours if the contamination is controlled and any delay in removing the contamination is justified. This rule would only require licensees to inform the NRC of the contamination accident.

41. Change the time for loss of access from more than 24 hours to more than one working day.

Response: The NRC disagrees. A definitive time period is necessary. This time period should be the same for every day of the week regardless of the length of the work week.

(b)(2) Safety Equipment Related Events

42. Guidance is needed concerning reports to be made by licensees when a radiographer's pocket dosimeter is discharged beyond its range.

Response: A 24-hour report would not be required by this rule if a pocket dosimeter is discharged beyond its range. A pocket dosimeter does not prevent overexposure to radiation. It only indicates what dose has already been received. In fact, a discharged pocket dosimeter would tend to minimize radiation exposure because a worker normally leaves an area immediately upon discovering that his or her pocket dosimeter is offscale.

43. Wording is not clear. Use the last paragraph on page 19891 (column 3) of the Federal Register Notice.

Response: The reporting requirement has been rewritten in a format similar to the discussion in the proposed rule.

44. Events should not be reported unless they result in exceeding some existing limits. Either specify some limits or drop the requirement.

Response: The NRC agrees. The reporting requirement has been revised to indicate that, in order for a safety equipment related event to be reported, the equipment must also be necessary to prevent releases in excess of regulatory limits.

45. Delete the word "needed" at the end of the first sentence of § 30.50 (b)(2) and replace it with the phrase "required to be available and operable".

Response: The criteria has been reworded in the final rule.

46. As currently written this section could result in large numbers of reports on the malfunction of such equipment as portable survey instruments, respirators, fire extinguishers, or even flashlights.

Response: The reporting requirement has been reworded to clarify what equipment malfunctions are reportable. Equipment that is covered by the rule must be necessary for one of the safety functions specified. In other words, it must be needed to (1) prevent releases exceeding regulatory limits, (2) prevent exposures to radiation and radioactive materials exceeding regulatory limits, or (3) mitigate the consequences of accidents that could result in major property damage, widespread

contamination outside of controlled areas, and fatalities or serious injuries requiring medical treatment.

47. Determinations by licensees about whether equipment failures are reportable should be limited to realistic scenarios in order to avoid a significant number of unnecessary reports.

Response: The NRC agrees. Licensees should be realistic when they evaluate whether the function, or the availability of the function of safety equipment, was required when it failed.

48. The third example on page 19892 concerning radiography equipment conflicts with the notification requirements in § 34.30.

Response: The NRC does not agree that there is a conflict with § 34.30. The proposed rule would require a 24-hour telephone notification in addition to the 30-day written report required by § 34.30. The final rule has been clarified to indicate that a written report submitted pursuant to other regulations may be used to satisfy this rule if the report contains all of the required information and appropriate distribution is made.

49. Strict interpretation of the rule indicates that every stuck shutter requires a 24 hour report. We fail to see the need to report if the exposure limits are not exceeded.

Response: If there are problems with the design or use of a device containing a source that could cause an overexposure and the problems prevent reshielding of exposed radiation sources, the NRC may need to take prompt action to warn other device user and ensure that the manufacturer is taking appropriate corrective action. The NRC must be aware of safety equipment failures in order to ensure that preventative measures are taken before more serious incidents occur.

50. Specify what is meant by the word "needed" and what severity of potential event does the equipment protect against?

Response: The final rule states that only equipment required by regulation or licensed condition is covered by the requirement. Safety equipment is needed when a radiation hazard is present and an incident requiring the use of the safety equipment is possible. A 24-hour report is only required by the rule if the safety equipment malfunctions when a radiation hazard exists. The ^{final} rule has been reworded to clarify the types of events that safety equipment must protect against.

51. What is meant by "uncontrolled releases of radioactive material"?

Response: The NRC's intent with the use of the term "uncontrolled releases of radioactive material" was to refer to unplanned accidental releases exceeding regulatory limits. This has been clarified in the final rule.

52. What is meant by the words "prevent overexposures to radiation, and to mitigate the consequences of an accident"?

Response: To prevent overexposures means to prevent exposures exceeding regulatory limits for workers and the public. The rule has been revised to clarify this point. To mitigate the consequences of an accident means to minimize serious injuries and severe damage after an accident occurs. For example, a sprinkler system would mitigate the severe damage that could be caused by a fire.

53. The use of the word "automatically" is confusing and should be deleted. Change the last sentence to read "if redundant equipment which performs the required function is operative".

Response: The NRC agrees that the word "automatically" is confusing. The term "redundant" is used to describe independent trains of equipment which perform the same function with the same level of effectiveness and

reliability. A manually operated backup to an automatically initiated safety system would not be considered redundant.

54. Equipment failures reported under § 34.30 should be exempt from this requirement since most incidents regarding radiography equipment failure are detected and resolved by the licensee usually within 24 hours.

Response: The NRC disagrees. The NRC must determine if there are generic design defects that require prompt warnings and corrective actions by the equipment manufacturer.

(b)(3) Personal Injury Events

55. The degree of personal injury has no bearing on the potential of the radiation hazard and may result in reporting many incidents of no significance to the NRC. A laceration to a lab worker's hand may require sutures where the radiation component may be insignificant. The current rule would require the reporting of an event even if the medical treatment was not related to the contamination issue.

Response: The NRC is concerned about the spread of contamination at the medical facility and the possible exposure of the general public to radiation and radioactive contamination. In addition, there is always the possibility that radiation may complicate the treatment of an injury.

56. Notification should only be required if contamination of the individual or treating medical facility exceeds NRC regulatory limits, license limits, or NRC unrestricted release limits. What is a radioactively contaminated individual?

See NRC's language
Response: A radioactively contaminated individual is a person who has loose surface contamination, that can be detected by standard methods, on their clothing or on accessible portions of their body that can be spread to other individuals. No threshold or contamination level related to regulatory limits has been provided because NRC is concerned about all contamination and not just contamination above a certain level.

57. Change the word "rendered" in the last sentence to the word "required."

Response: Although the statement has been deleted from the rule, NRC is concerned about what was actually done to the contaminated individual. The fact that the treatment may not have been required does not eliminate the radiation hazard.

58. The proposed rule required no report for the treatment of a superficial injury at a licensee-maintained medical facility but required a report for treatment of the same injury elsewhere. Why?

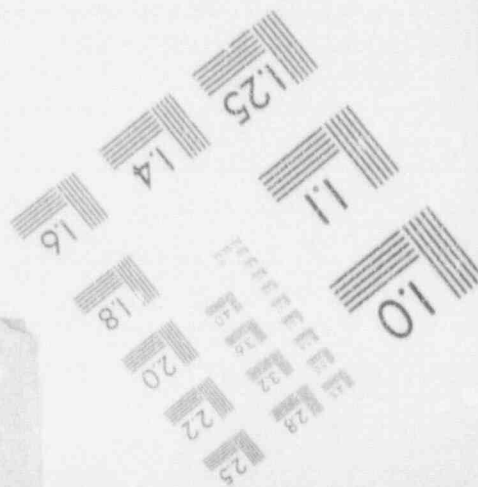
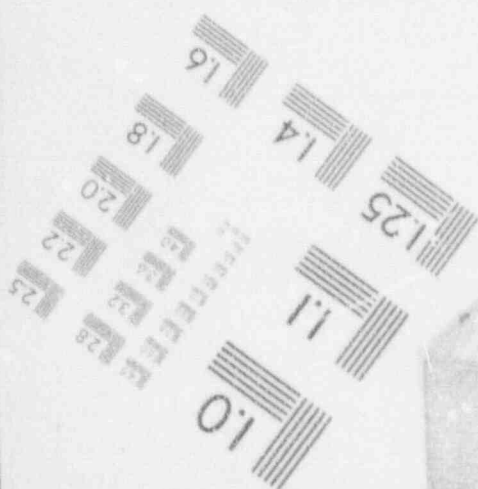
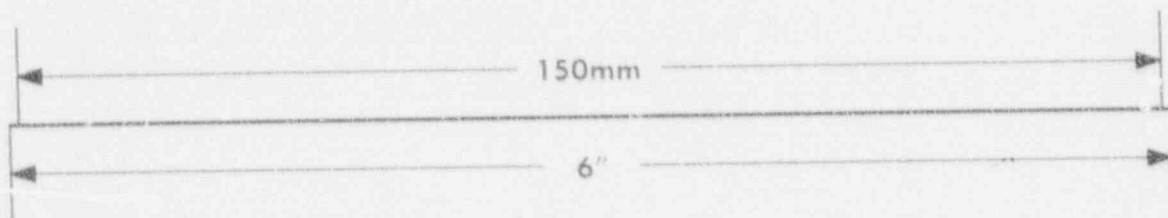
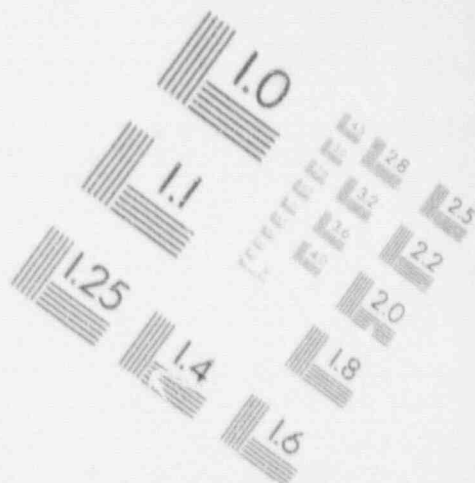
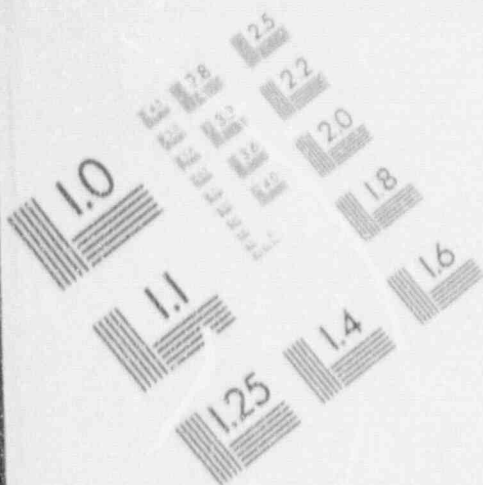
Response: The NRC was attempting to minimize reports of insignificant events such as a licensee technician accidentally puncturing his hand with a syringe containing a radiopharmaceutical. Although many licensee facilities have provisions for controlling the spread of contamination, the NRC has reconsidered its position and decided not to exclude licensee-maintained medical facilities treating superficial wounds from this reporting requirement. The rule has been appropriately revised. An individual with a superficial injury could still spread significant amounts of contamination around the medical facility. In addition, very few reports are expected even if superficial injuries are included.

59. We have incorporated and maintained appropriate emergency plans, personnel training, and decontamination facilities at a local hospital to specifically cope with medical treatment. Would this be considered a licensee maintained facility?

Response: The NRC has decided to require reports of any injured person introducing spreadable contamination into a medical facility regardless of who maintains the facility. The NRC must be aware of such incidents in order to ensure that appropriate radiological controls are used and to ensure that any medical consequences caused by the contamination are properly addressed. Since the exception for a licensee maintained facility has been removed from the rule, the above question, regarding interpretation of the rule, is moot.

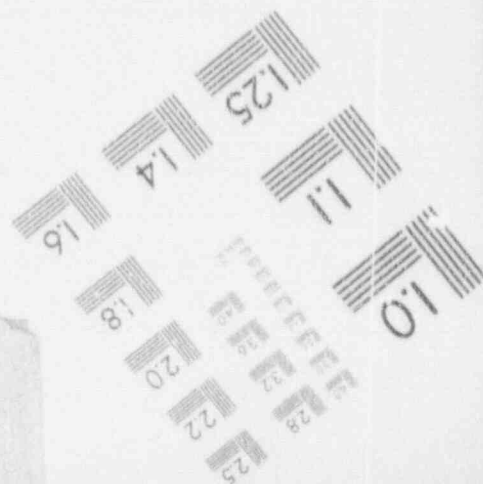
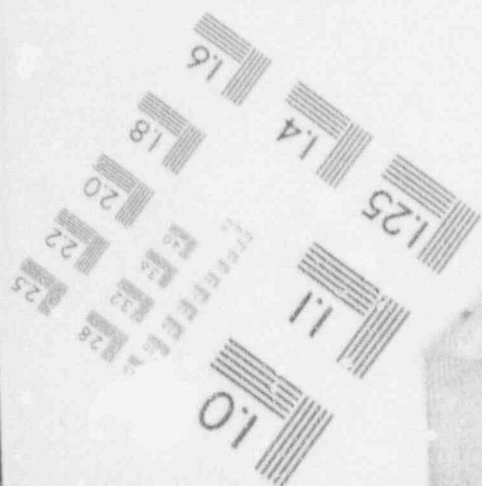
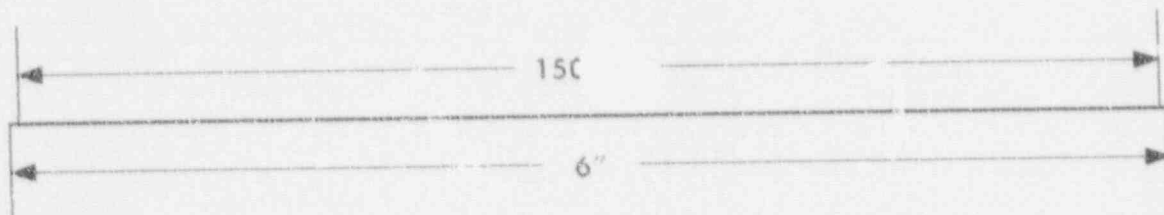
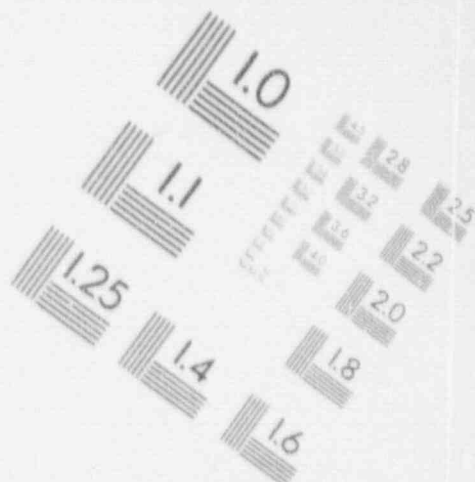
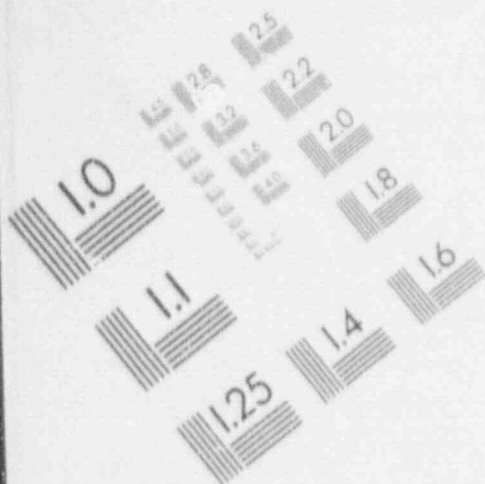
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IMAGE EVALUATION
TEST TARGET (MT-3)



1

IMAGE EVALUATION
TEST TARGET (MT-3)



(b)(4) Fires and Explosions

60. The most common type of explosions in medical, biomedical research, and radiopharmaceutical operations involve screwcap vials or stoppered test tubes containing tissue samples with only traces of radionuclides. Do these types of explosions have to be reported?

Response: When the proposed rule was drafted, NRC did not intend to include small vials and stoppered test tubes as explosions. NRC agrees that fires and explosions involving trace quantities of licensed material should not be reportable. The notification requirement has been revised to only require a report if an explosion or fire involves licensed material in quantities greater than five times the lowest annual limit on intake specified in Appendix B of Part 20.

10 CFR
to §§ 20.1001 - 20.2411

61. In the case of fires, the hazard of the fire may greatly outweigh the hazards of the release. There should be quantitative threshold limits for licensees.

Response: The NRC agrees that the fire usually poses the greatest hazard. However, if a significant amount of licensed material is involved, the NRC needs to ensure that appropriate controls are used during firefighting and cleanup operations. The notification requirement has been revised to establish a reporting threshold of five times the lowest annual limit on intake because the NRC believes it is unlikely

that an individual would inhale or ingest more than 20 percent of the material dispersed.

62. A report should not be required if there is only superficial damage to licensed materials.

Response: The NRC agrees and the reporting requirement has been revised to require no report if the damage to the licensed material or its container does not affect the integrity of the licensed material or its container.

63. Retain a significant dollar figure in the range of \$10,000 for property damage.

Response: The NRC disagrees. A dollar figure for property damage, regardless of amount, is not necessarily indicative of the hazard to the public health and safety. Therefore, the dollar figure has been removed from the regulations.

(c) Written Reports

64. Licensee duplication of written reports prepared by NRC inspectors does not appear to be justified.

Response: The NRC believes that separate reports serve a useful function. The licensee is directly responsible for the safety operations of the facility and is most knowledgeable about the event, its causes, consequences and appropriate corrective actions. The licensee reports contain useful information on the event and its implications. NRC inspections focus on selected events, and on the status and completeness of corrective action. Thus, NRC reports generally have a different objective than licensee event reports.

65. Personnel radiation exposure data may at times be difficult to obtain.

Response: The NRC recognizes that there may be times when it is difficult to obtain radiation exposure data. Only data that is available to the licensee is required to be reported.

(d) Criticality Safety in § 70.50(a)(2)

66. The following nuclear criticality safety events should be included in the rule as reportable events: Failure of a special nuclear material concentration monitoring instrument or a failure of a moisture detection instrument.

see
NRC
January

Response: The NRC agrees. An additional reporting requirement has been added to Part 70 to immediately report any event that places special nuclear material in a geometry unfavorable to criticality safety. No additional requirements were added for monitoring equipment because the rule already requires reports of equipment failures under § 70.50(b)(2).

Discussion

56 FR. 23560
(May 21, 1991)

The NRC is amending the reporting requirements in § 20.403 and in the new § 20.2202 which was published in the Federal Register in May 1991. The amendments will ensure that events having significant implications for public health and safety are reported. The rule is a matter of compatibility for Agreement States. The Agreement States participated in the development of this rule and their comments were incorporated as appropriate.

Paragraphs (a)(3), (a)(4), (b)(3), and (b)(4) of § 20.403 and § 20.2202 dealing with loss of operation and cost of damage are being deleted because the NRC believes these criteria do not adequately define events with significant implications for public health and safety. For example, the periodic loss of operation of a facility may not be related to any potential hazard to the public or the environment. The same is true for the cost of repairing damage, which may be high for reasons unrelated to any potential hazard from licensed material. *The deleted* sections are being replaced with *for the reporting of significant events at* new criteria in Parts 30, 40, and 70. *material* *incidents facilities* *are added* The NRC believes the new criteria will more accurately define potentially significant events affecting the health and safety of the public and the environment that must be reported to the NRC. The final rule also contains administrative changes to requirements for general licenses (10 CFR ~~31.2~~ ^{31.2}). These changes specify that general licensees who were previously required to report incidents pursuant to the deleted requirements, must continue to report incidents pursuant to the new reporting requirements.

Revisions to Part 50 are not needed because similar reporting requirements are already addressed in § 50.72. Part 50 licensees subject

to the requirements in §50.72 are specifically exempted from this rule to avoid conflicting regulations. However, certain Part 50 licensees (e.g., research and test reactors) are not subject to the reporting requirements in § 50.72 and if they possess material licensed under Part 30, 40, or 70, they will be subject to the new reporting requirements.

The intent of these amendments is to require prompt reports (either immediately or within 24 hours) to the NRC of safety related events that may require prompt action to protect the health and safety of the public and the environment. The NRC will evaluate the hazard and the corrective actions taken by the licensee and may dispatch NRC staff to the site of the event, activate the NRC incident response center, or issue warnings of generic hazards to other licensees. The final amendments for Parts 30, 40, and 70 are almost identical. Therefore, the discussion that follows is organized by the type of requirement rather than by the sections in the regulations where the requirement is found.

Immediate Notification

A period of 4 hours will be the maximum time allowed for "immediate notification" by material licensees. It is intended that licensees will notify the NRC of incidents as soon as possible, but in no case later than 4 hours after discovery of a reportable incident. Four hours was used because many smaller material licensees do not have the capability to quickly assess and respond to events that reactor licensees possess and because the degree of hazard posed by nonreactor events is typically much smaller than the hazard posed by reactor events.

Control of Licensed Material

> The final rule requires licensees to notify the NRC as soon as possible but not later than four hours after the discovery of any event involving licensed material that prevents immediate protective actions necessary to avoid either exposures to or releases of radioactive materials that could exceed regulatory limits. The requirement in the proposed rule was changed to define immediate actions in terms of exposures and releases rather than actions necessary to maintain and verify control of licensed material. This was done to clarify what types of actions warrant an immediate report to the NRC.

The NRC expects licensees to report as soon as possible any event where personnel normally able to take an immediate protective action are somehow prevented from taking the action. An immediate protective action is an initial action taken after a hazardous situation is identified to minimize exposures to radiation or radioactive materials, or to minimize releases of radioactive materials. Immediate actions would normally be taken within fifteen minutes of identifying the hazard. The NRC does not expect immediate reports of normal delays associated with sounding alarms and responding to the site of the emergency. However, if alarms cannot be sounded or personnel cannot respond, an immediate report (within 4 hours) would be required. A normal delay in responding to an event such as the time to drive to the site or the time to call the fire department would not be reportable. However, once the responders are available and able to do the job, any additional delay would be reportable.

Examples of cases where an immediate report would be required include: a toxic gas leak near a radiography operation that prevents the radiographer from immediately reshielding the source to reduce a high radiation field around the leak; a fire that prevents workers from immediately securing a ventilation system to stop a release of airborne radioactive material exceeding regulatory limits; and a collapsed ceiling from an explosion that prevents workers from immediately closing a valve to stop a release of radioactive material exceeding regulatory limits.

Not needed already addressed Sections 20.403 and 20.2202
Sections 20.403 and § 20.2202 still require reports of exposures and releases exceeding specified limits. This new requirement addresses emergency situations where immediate actions normally possible to control radiation or radioactive material are prevented even if the limits in Part 20 are not exceeded. This information is needed to assure the Commission that adequate substitute actions are taken.

Because it is difficult to establish a clear, generic definition of a "threat," the final rule has been revised to delete the requirement to report events that threaten to prevent immediate protective actions. The NRC agreed with several commenters that it would be better to impose reporting requirements for threatening events such as the bulging of a filled uranium hexafluoride container by license condition or other methods where clear definitions of specific threats can be provided.

Contamination Events

The final rule requires licensees to notify the NRC within 24 hours of discovering any unplanned contamination event that requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or prohibiting entry into the area. If a licensee discovers that an area has unexpectedly been contaminated with licensed material, the Commission expects the licensee to impose appropriate controls to keep exposures and releases as low as reasonably achievable (ALARA) until the area can be decontaminated. If controls beyond those required before the contamination event are necessary for more than 24 hours, the Commission expects the licensee to report the event.

In response to numerous comments that a 24-hour report is not necessary for small quantities of material or material with a short half-life, the final rule has been revised/modified to exempt certain contamination events from the new reporting requirement. A report is ^{only} ~~now~~ required if the access to the contaminated area is restricted for more than 24 hours, and the quantity of material involved is greater than five times the lowest annual limit on intake in Appendix B of ^{§ 20.101 - 20.240 of 10 CFR} the ~~revised~~ Part 20 (issued ^{SL FR 23360, 23409} May 21, 1991) for the material, and the reason for the restriction is other than to allow isotopes with a half-life less than 24 hours to decay. The activity threshold of five times the annual limit on intake was chosen because the NRC believes it is unlikely that any individual exposed to contamination would inhale or ingest more the 20 percent of the material dispersed. The half-life threshold of 24 hours was chosen because a significant amount of decay would occur each day and it is 3 days

unlikely that the area would need to be restricted for more than one week.

Reports of unplanned contamination events that exceed the activity, half-life and access restriction thresholds are necessary to assure the Commission that contaminated areas are being decontaminated in a safe and timely manner. In addition, prompt action may be necessary to correct conditions that may lead to additional contamination problems. Examples of reportable events include: a spill of licensed material in the form of a fine powder that requires workers to use additional respiratory protection for more than 24 hours; a leaking shipping container that requires a normally unrestricted shipping facility to be locked up for more than 24 hours; and contamination from a leaking sealed source that requires workers in the area to wear additional protective clothing for more than 24 hours. However, if a spill involved a short-lived isotope such as technetium-99m (6 hour half-life) and entry into the area was prohibited for two days to allow the material to decay, no report would be required. In addition, if the leaking source discussed above contained only 500 microcuries of cobalt-60, no report would be required because five times the annual limit on intake of cobalt-60 is 1,000 microcuries. *See NRC language*

Safety Equipment Failure

The final rule requires licensees to report within 24 hours of discovery any event in which equipment is disabled or fails to function as designed if: (1) the equipment is required by regulation or license condition to prevent releases and exposures exceeding regulatory limits, or to mitigate the consequences of an accident, and (2) the equipment is required to be available and operable when it is disabled or fails, and (3) no redundant equipment is available and operable to perform the required safety function when the failure occurs. This reporting requirement includes equipment failure, equipment damage, and procedural errors which cause equipment to fail or be disabled.

The final requirement has been rewritten and clarified in several ways. Only equipment that is required by regulation or license condition is covered by the rule. Furthermore, the equipment must be required to prevent releases or exposures exceeding regulatory limits. The accident consequences to be mitigated by the equipment include major property damage, widespread contamination of uncontrolled areas, or fatalities or serious injuries requiring medical treatment. The following are examples of reportable events:

1. Failure of an interlock system required by regulation or license condition that allows a door to an area to be opened when high radiation levels exist in the area.
2. Damage to a filtered ventilation system required by regulation or license condition that permits effluent air to bypass filters during

operations. This bypass could result in either releases exceeding regulatory limits or exposing personnel to levels of airborne radioactive material exceeding regulatory limits.

3. Failure of equipment or shielding materials required by regulation or license condition to shield radiation sources.
4. Failure of monitoring equipment required by regulation or license condition to verify that safe criticality conditions exist while special nuclear material is being handled.
5. Loss of water pressure which disables a sprinkler system during a period when the availability of the system is required by regulation or license condition.

This information is necessary to assure the Commission that when the function of required safety equipment has been lost, the licensee has taken appropriate action to compensate for the lost safety function or to eliminate the hazard requiring the safety function. This information is also necessary to identify significant safety equipment failures that may require prompt action to prevent similar problems at other licensed facilities.

Personal Injury Events

The final rule requires licensees to report, within 24 hours of discovery, any event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body. This information is necessary to assure the Commission that appropriate actions have been taken both to control the spread of contamination and to perform any necessary decontamination. Prompt action may also be required to investigate the cause of the injury and to prevent additional contamination problems.

This requirement has been rewritten to clarify that only spreadable contamination is covered by the rule and that planned medical treatments known to cause spreadable contamination are not covered by the rule. The exemption for first aid at a licensee maintained medical facility for a superficial injury was deleted because the NRC agreed with commenters that a significant contamination event could still occur even if the injury was only superficial and the medical facility was licensed to handle radioactive material. The NRC does not expect that deleting this exemption will result in numerous reports of insignificant events, such as a medical technician accidentally puncturing his hand with a syringe containing a radiopharmaceutical because no report would be required if spreadable contamination was ~~removed~~ before first aid was rendered.

would not occur

NO
WRONG
WORDS TO
USE

Fires and Explosions

The final rule requires licensees to report, within 24 hours of discovery, any unplanned fire or any explosion damaging licensed material, or any device, container, or equipment containing licensed material in quantities greater than five times the lowest annual limit on intake specified in Appendix B of Part 20 for the material. This information is necessary to assure the Commission that appropriate actions have been taken to detect and control any releases that may have occurred. Prompt action may be required to verify survey results and establish radiological controls for recovery efforts. This requirement was revised to specify unplanned fires and explosions so as to clarify that planned applications of licensed material in fires and explosions by the military or other licensees are not covered by this rule. In response to several requests by commenters, an activity threshold of five times the lowest annual intake limit was added to define what quantities of licensed material are considered significant. This threshold is identical to the threshold for reporting contamination events and is chosen for the same reason. The requirement was also modified because the NRC agreed with one commenter that a 24-hour report should not be required if there is no damage that affects the integrity of the licensed material or its container.

In the event of a fire or explosion, an immediate report would be required if licensee personnel or firefighters were prevented by radiation hazards or other conditions from performing immediate protective actions that they would normally be able to perform (see discussion above on Control of Licensed Material). However, if no

immediate protective actions were prevented, but the licensed material or its container sustained damage that affected the integrity of the licensed material or its container, a 24-hour report would be required. If within 24 hours of discovering the fire or explosion, the licensee has not verified whether any reportable damage occurred, the licensee must act conservatively and report the event.

Criticality Safety Events

In response to a suggestion by one commenter, an additional reporting requirement has been added to the final rule that requires Part 70 licensees to report as soon as possible after discovery any event that places special nuclear material in a geometry unfavorable to criticality safety. The NRC believes that this additional requirement clearly is appropriate and that requesting additional public comment is not necessary. This information is needed to assure the Commission that appropriate action is taken to place the material in a safe geometry. Prompt action may be required to correct unsafe conditions that could result in a criticality accident.

Written Report

The requirement for a written report in the final rule is identical to proposed rule except for a minor clarification that a report prepared pursuant to other regulations may be submitted to fulfill this requirement if the substituted report contains all of the necessary information and the appropriate distribution is made.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(3). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this regulation.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget approval numbers 3150-0009, 3150-0014, 3150-0017, and 3150-0020.

Public reporting burden for this collection of information is estimated to average 4 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 regarding this burden estimate or any

other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (MNBB-7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Paperwork Reduction Project (3150-0014, 3150-0017, 3150-0020, and 3150-0009), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The Commission requested public comments on the draft regulatory analysis, but no comments were received. No changes to the draft regulatory analysis are considered necessary, so a new regulatory analysis has not been prepared for the final rule. The draft analysis is available for inspection in the NRC Public Document Room, 1220 L Street, NW (lower level), Washington, DC.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. The final rule affects > approximately 9,100 licensees monitored by NRC under 10 CFR Parts ²⁰30, 40, and 70. The licenses are issued to academic institutions, medical institutions, and industrial entities. The final rule is being issued in order to reduce misunderstandings by material licensees and to clarify

the types of events that must be reported to the NRC. No report would be required of licensees unless there is an incident involving licensed material that meets the requirements specified in the amendments. Since the revised reporting requirements are essentially the same as the current reporting requirements, the impact on licensees should be minimal.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this final rule and therefore a backfit analysis is not required because the amendments do not contain any provisions which would impose backfits on licensees as defined in § 50.109 (a)(1).

List of Subjects in 10 CFR Parts 20, 30, 40, and 70

10 CFR PART 20

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

10 CFR PART 30

Byproduct material, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR PART 40

Government contracts, Hazardous materials-transportation, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR PART 70

Hazardous materials-transportation, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

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. 553, the NRC is adopting the following amendments to 10 CFR Parts 20, 30, ^{31, 34, 39}40, and 70.
^ ^

PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

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

Check with Mike Lessor - what about new part 20 - § 20.2202

Authority: Secs. 53, 63, 67, 81, 103, 104, 161, 68 Stat. 930, 933, 935, 936, 937, 948, as amended (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201); Secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846). Section 20.408 also issued under Secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

For the purposes of Sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 20.101, 20.102, 20.103(a), (b), and (f), 20.104(a) and (b), 20.105(b), 20.106(a), 20.201, 20.202(a), 20.205, 20.207, 20.301, 20.303, 20.304, and 20.305 are issued under Sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 20.102, 20.103(e), 20.401-20.407, 20.408(b), and 20.409 are issued under Sec. 161c, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 20.403 [Amended]

See NRC change - HHS rules + records OK'd this format

2. In § 20.403, the semicolon and the word "or" following paragraph (a)(2) are removed and a period is inserted, and the semicolon and the word "or" following paragraph (b)(2) are removed and a period is inserted, and paragraphs (a)(3), (a)(4), (b)(3), and (b)(4) are removed.

3. In § 20.403, paragraph (d)(2) is amended by revising the area code for the footnote from area code 202 to area code 301.

§ 20.2202 [Amended]

4. In § 20.2202, the semicolon and the word "or" following paragraph (a)(2) are removed and a period is inserted, and the semicolon and the word "or" following paragraph (b)(2) are removed and a period is inserted, and paragraphs (a)(3), (a)(4), (b)(3), and (b)(4) are removed.

PART 30 - RULE OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF
BYPRODUCT MATERIAL

5. The authority citation for Part 30 is revised to read as follows:

Authority: Sec. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, Sec. 234, 83, Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); Secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 30.7 also issued under Pub. L. 95-601, Sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 30.34(b) also issued under Sec. 184, 68, Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under Sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

For the purposes of Sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 30.3, 30.34(b)(c) and (f), and 30.41(a) and (c), and 30.53 are issued under Sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 30.6, 30.9, 30.36, 30.51, 30.52, 30.55, and 30.56(b) and (c) are issued under Sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 30.8 [Amended]

6. In § 30.8, paragraph (b) is revised to read as follows:

§ 30.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in § 30.15, 30.19, 30.20, 30.32, 30.34, 30.36, 30.37, 30.38, 30.50, 30.51, 30.55, and 30.56.

* * * * *

7. A new § 30.50 under "Records, Inspections, Tests, and Reports" is added to read as follows:

§ 30.50 Reporting requirements.

(a) Immediate report. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after the discovery of any event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(b) Twenty-four hour report. Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material:

- (1) Any unplanned contamination event that:
 - (i) requires access to the contaminated area, by workers or the

public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area, and

(ii) involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of §§ 20.1001-20.2401 of 10 CFR Part 20 for the material, and

(iii) has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) Any event in which equipment is disabled or fails to function as designed when:

(i) the equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident, and

(ii) the equipment is required to be available and operable when it is disabled or fails to function, and

(iii) no redundant equipment is available and operable to perform the required safety function.

(3) Any event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) Any unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(i) the quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of §§ 20.1001-20.2401 of 10 CFR Part 20 for the material, and

(ii) the damage affects the integrity of the licensed material or its container.

(c) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees shall make reports required by paragraphs (a) and (b) of this section by telephone to the NRC Operations Center.¹ To the extent that the information is available at the time of notification, the information provided in these reports must include:

- (i) The caller's name and call back telephone number;
- (ii) A description of the event, including date and time;
- (iii) The exact location of the event;
- (iv) The isotopes, quantities, and chemical and physical form of the licensed material involved; and
- (v) Any personnel radiation exposure data available.

(2) Written report. Each licensee who makes a report required by paragraph (a) or (b) of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, with a copy to the appropriate NRC Regional office listed in Appendix D of 10 CFR Part 20. The reports must include the following --

¹The commercial telephone number for the NRC Operations Center is (301) 951-0550.

(i) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(ii) The exact location of the event;

(iii) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(iv) Date and time of the event;

(v) Corrective actions taken or planned and the results of any evaluations or assessments; and

(vi) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(3) The provisions of § 30.50 do not apply to licensees subject to the notification requirements in § 50.72. They do apply to those Part 50 licensees possessing material licensed under Part 30, who are not subject to the notification requirements in § 50.72.

PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

8. The authority citation for Part 31 continues to read as follows:

Authority: Secs. 81, 161, 183, 68 Stat. 935, 948, 954, as amended (42 U.S.C. 2111, 2201, 2233); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842).

Section 31.6 is also issued under sec. 274, 73 Stat. 688 (42 U.S.C. 2021).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 31.5 (c)(1)-(3) and (c)(4), 31.8(c), 31.10(b), and 31.11(b), (c), and (d) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C.

2201(b); and §§ 31.5 (c)(4), (5), (8), and 31.11(b) and (e) are issued under sec. 1610, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 31.2 [Amended]

9. In § 31.2, paragraph (a) is revised to read as follows:

§ 31.2 Terms and conditions.

(a) The general licenses provided in this part are subject to the provisions of §§ 30.14(d), 30.34(a) to (e), 30.41, 30.50 to 30.63 and Parts 19, ...

§ 31.8 [Amended]

10. In § 31.8, paragraph (c) is revised to read as follows:

§ 31.8 Americium-241 in the form of calibration or reference sources.

* * * * *

(c) The general license in paragraph (a) of this section is subject to the provisions of §§ 30.14(d), 30.34(a) to (e), and 30.50 to 30.63 of this chapter, and ...

* * * * *

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

11. The authority citation for Part 34 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended, (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Section 34.32 also issued under sec. 206, 88 Stat. 1246, (42 U.S.C. 5846).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§34.22, 34.23, 34.24, 34.25 (a), (b), and (d), 34.28, 34.29, 34.31, (a) and (b), 34.32, 34.33, (a), (c), and (d) 34.41, 34.42, 34.43(a), (b), and (c), and 34.44 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§34.11(d), 34.25 (c) and (d), 34.26, 34.27, 34.28(b), 34.29(c), 34.31(c), 34.33 (b) and (e), and 34.43(d) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 34.30 [Amended]

12. In § 34.30, paragraph (a) is revised to read as follows:

§ 34.30 Reporting requirements.

(a) In addition to the reporting requirements specified in § 30.50 and under other sections of this chapter, ...

* * * * *

PART 39 - LICENSES AND RADIATION SAFETY REQUIREMENTS
FOR WELL LOGGING

13. The authority citation for Part 39 continues to read as follows:

Authority: Secs. 53, 57, 62, 63, 65, 69, 81, 82, 161, 182, 183, 186, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, s.c. 234, 83 Stat. 444, as amended (42 U.S.C. 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2112, 2201, 2232, 2233, 2236, 2282); Secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

For the purposes of Sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 39.15, 39.17, 39.31-39.51, 39.61-39.77 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 39.15, 39.33 - 39.43, 39.61 - 39.67, 39.73 - 39.77 are issued under sec. 161o, 68 Stat. 950 as amended (42 U.S.C. 2201 (o)).

§ 39.77 [Amended]

14. In § 39.77, paragraph (b) is revised to read as follows:

§ 39.77 Notification of incidents and lost sources, abandonment procedures for irretrievable sources.

* * * * *

(b) The licensee shall notify the Commission of the theft or loss of radioactive materials, radiation overexposures, excessive levels and

concentrations of radiation, and certain other accidents as required by §§ 20.402, 20.403, 20.405, and 30.50 of this chapter.

* * * * *

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

15. The authority citation for Part 40 is revised to read as follows:

Authority: Secs. 62, 63, 64, 65, 81, 161, 182, 183, 186, 68 Stat. 932, 933, 935, 948, 953, 954, 955, as amended, Secs. 11e(2), 83, 84, Pub. L. 95-604, 92 Stat. 3033, as amended, 3039, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2014 (e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2232, 2233, 2236, 2282); Sec. 274, Pub. L. 86-373, 73 Stat. 688 (42 U.S.C. 2021); Secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Sec. 375, 92 Stat. 3021, as amended by Pub. L. 97-415, 96 Stat. 2067 (42 U.S.C. 2022).

Section 40.7 also issued under Pub. L. 95-601, Sec. 10, 92 Stat. 2951 (42 U.S.C. 5841) Section 40.31(g) also issued under Sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under Sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 40.71 also issued under Sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

For the purposes of Sec. 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 40.3, 40.25(d)(1)-(3), 40.35(a)-(d), and (f) 40.41(b) and (c), 40.46, 40.51(a) and (c), and 40.63 are issued under Sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 40.5, 40.9, 40.25(c), (d)(3), and (4), 40.26(c)(2), 40.35(e), 40.42, 40.60, 40.61, 40.62, 40.64, and 40.65 are issued under Sec. 161n, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 40.8 [Amended]

16. In § 40.8, paragraph (b) is revised to read as follows:

§ 40.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 40.25, 40.26, 40.31, 40.35, 40.42, 40.60, 40.61, 40.64, 40.65, and Appendix A.

* * * * *

§ 40.26

[Amended]

17. In § 40.26, paragraph (c)(1) is revised to read as follows:

§ 40.26 General license for possession and storage of byproduct material as defined in this part.

* * * * *

(1) The provisions of Part 19, 20, 21, and §§ 40.1, 40.2a, 40.3, 40.4, 40.5, 40.6, 40.41, 40.46, 40.60, 40.61, 40.62, 40.63, 40.65, 40.71, and 40.81 of Part 40 of this chapter; and

* * * * *

18. A new § 40.60 under "Records, Reports, and Inspections" is added to read as follows:

§ 40.60 Reporting requirements.

(a) Immediate report. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after the discovery of any event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(b) Twenty-four hour report. Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material:

(1) Any unplanned contamination event that:

(i) requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area, and

(ii) involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of §§ 20.1001-20.2401 of 10 CFR Part 20 for the material, and

(iii) has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) Any event in which equipment is disabled or fails to function as designed when:

(i) the equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident, and

(ii) the equipment is required to be available and operable when it is disabled or fails to function, and

(iii) no redundant equipment is available and operable to perform the required safety function.

(3) Any event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) Any unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(i) the quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of §§ 20.1001-20.2401 of 10 CFR Part 20 for the material, and

(ii) the damage affects the integrity of the licensed material or its container

(c) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees shall make reports required by paragraphs (a) and (b) of this section by telephone to the NRC Operations Center.¹ To the extent that the information is available at the time of notification, the information provided in these reports must include:

(i) The caller's name and call back telephone number;

(ii) A description of the event, including date and time;

(iii) The exact location of the event;

¹The commercial telephone number for the NRC Operations Center is (301) 951-0550.

(iv) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(v) Any personnel radiation exposure data available.

(2) Written report. Each licensee who makes a report required by paragraph (a) or (b) of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, with a copy to the appropriate NRC regional office listed in Appendix D of 10 CFR Part 20. The reports must include the following --

(i) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(ii) The exact location of the event;

(iii) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(iv) Date and time of the event;

(v) Corrective actions taken or planned and the results of any evaluations or assessments; and

(vi) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(3) The provisions of § 40.60 do not apply to licensees subject to the notification requirements in § 50.72. They do apply to those Part 50 licensees possessing material licensed under Part 40 who are not subject to the notification requirements in § 50.72.

PART 70 - DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

19. The authority citation for Part 70 is revised to read as follows:

Authority: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, Sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282); Secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246, (42 U.S.C. 5841, 5842, 5845, 5846).

Sections 70.1(c) and 70.20a(b) also issued under Secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 70.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 70.21(g) also issued under Sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under Sec. 57d, Pub. L. 93-377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under Sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.61 also issued under Secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.62 also issued under Sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

For the purposes of Sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 70.3, 70.19(c), 70.21(c), 70.22(a), (b), (d)-(k), 70.24(a) and (b), 70.32(a)(3), (5), (6), (d), and (i), 70.36, 70.39(b) and (c), 70.41(a), 70.42(a) and (c), 70.56, 70.57(b), (c), and (d), 70.58(a)-(g)(3), and (h)-(j) are issued under Sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201 (b)); §§ 70.7, 70.20a(a) and (d), 70.20b(c) and (e), 70.21(c), 70.24(b), 70.32(a)(6), (c), (d), (e), and (g), 70.36, 70.51(c)-(g), 70.56, 70.57(b) and (d), and 70.58 (a)-(g) (3) and (h)-(j) are issued under Sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 70.5, 70.9, 70.20b(d) and (e), 70.38,

70.51(b) and (i) 70.50, 70.52, 70.53, 70.54, 70.55, 70.58 (g)(4), (k), and (l), 70.59, and 70.60(b) and (c) are issued under Sec. 1610, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 70.8 [Amended]

20. In § 70.8, paragraph (b) is revised to read as follows:

§70.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 70.19, 70.20a, 70.20b, 70.21, 70.22, 70.24, 70.32, 70.33, 70.34, 70.38, 70.39, 70.50, 70.51, 70.52, 70.53, 70.57, 70.58, 70.59, and 70.60.

* * * * *

§ 70.19 [Amended]

21. In § 70.19, paragraph (c) is revised to read as follows:

§70.19 General license for calibration or reference sources.

* * * * *

(c) The general license in paragraph (a) of this section is subject to the provisions of §§ 70.32, 70.50, 70.51, 70.52, 70.55, 70.56, 70.61, 70.62, and 70.71, and to the provisions of Parts 19, 20, and 21 of this

chapter. In addition, persons who receive title to, own, acquire, deliver, receive, possess use or transfer one or more calibration or reference sources pursuant to this general license:

* * * * *

22. A new § 70.50 under "Special Nuclear Material Control, Records, Reports and Inspections" is added to read as follows:

§ 70.50 Reporting requirements.

(a) Immediate report. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after the discovery of any event that:

(1) prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.), or

(2) places special nuclear material in a geometry unfavorable to criticality safety.

(b) Twenty-four hour Report. Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material:

(1) Any unplanned contamination event that:

(i) requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area, and

(ii) involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of §§ 20.1001-20.2401 of 10 CFR Part 20 for the material, and

(iii) has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) Any event in which equipment is disabled or fails to function as designed when:

(i) the equipment is required by regulation or licensee condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident, and

(ii) the equipment is required to be available and operable when it is disabled or fails to function, and

(iii) no redundant equipment is available and operable to perform the required safety function.

(3) Any event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) Any unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when

(i) the quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of §§ 20.1001-20.2401 of 10 CFR Part 20 for the material, and

(ii) the damage affects the integrity of the licensed material or its container.

(c) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees shall make reports required by paragraphs (a) and (b) of this section by telephone to the NRC Operations Center.¹ To the extent

- (i) The caller's name and call back telephone number;
- (ii) A description of the event, including date and time;
- (iii) The exact location of the event;
- (iv) The isotopes, quantities, and chemical and physical form of the licensed material involved; and
- (v) Any personnel radiation exposure data available.

(2) Written report. Each licensee who makes a report required by paragraph (a) or (b) of this section shall prepare a written followup report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, with a copy to the appropriate NRC regional office listed in Appendix D of 10 that the information is available at the time of notification, the information provided in these reports must include: CFR Part 20. The reports must include the following --

- (i) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

¹The commercial telephone number for the NRC Operations Center is (301) 951-0450.

- (ii) The exact location of the event;
- (iii) The isotopes, quantities and chemical and physical form of the licensed material involved;
- (iv) Date and time of the event;
- (v) Corrective actions taken or planned and the results of any evaluations or assessments; and
- (vi) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(3) The provisions of § 70.50 do not apply to licensees subject to the notification requirements in § 50.72. They do apply to those Part 50 licensees possessing material licensed under Part 70 who are not subject to the notification requirements in § 50.72

Dated at Rockville, Maryland, this _____ day of _____, 1991.

For the Nuclear Regulatory Commission.

James M. Taylor
Executive Director for Operations

Enclosure 2

Congressional Letters



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

The Honorable Peter H. Kostmayer, Chairman
Subcommittee on Energy and the Environment
Committee on Interior and Insular Affairs
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee on Energy and the Environment and the Committee on Insular Affairs is a copy of the Federal Register notice of a final rule that will amend the reporting requirements for material licensees to ensure that events having significant implication for public health and safety are properly reported. Certain sections of 10 CFR 20.403 are being deleted because these criteria do not adequately define events with significant implications for public health and safety. The deleted sections are being replaced with new criteria in Parts 30, 40, and 70 that will more accurately define potentially significant events affecting health and safety of the public and the environment.

The proposed rule on this subject was published in the Federal Register on May 14, 1990, (55 FR 19890). The NRC received 40 letters of comment on this subject. The NRC staff has identified 66 separate topics, which are responded to in the Federal Register notice. Revisions, mainly clarifying and editorial, have been made in the final rule as a result of the comments received.

Sincerely,

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosure:
Federal Register notice

cc: The Honorable John J. Rhodes



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

The Honorable Bob Graham, Chairman
Subcommittee on Nuclear Regulation
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee on Energy and the Environment and the Committee on Insular Affairs is a copy of the Federal Register notice of a final rule that will amend the reporting requirements for material licensees to ensure that events having significant implication for public health and safety are properly reported. Certain sections of 10 CFR 20.403 are being deleted because these criteria do not adequately define events with significant implications for public health and safety. The deleted sections are being replaced with new criteria in Parts 30, 40, and 70 that will more accurately define potentially significant events affecting health and safety of the public and the environment.

The proposed rule on this subject was published in the Federal Register on May 14, 1990, (55 FR 19890). The NRC received 40 letters of comment on this subject. The NRC staff has identified 66 separate topics, which are responded to in the Federal Register notice. Revisions, mainly clarifying and editorial, have been made in the final rule as a result of the comments received.

Sincerely,

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosure:
Federal Register notice

cc: The Honorable Alan K. Simpson



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

The Honorable Philip R. Sharp, Chairman
Subcommittee on Energy and Power
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee on Energy and the Environment and the Committee on Insular Affairs is a copy of the Federal Register notice of a final rule that will amend the reporting requirements for material licensees to ensure that events having significant implication for public health and safety are properly reported. Certain sections of 10 CFR 20.403 are being deleted because these criteria do not adequately define events with significant implications for public health and safety. The deleted sections are being replaced with new criteria in Parts 30, 40, and 70 that will more accurately define potentially significant events affecting health and safety of the public and the environment.

The proposed rule on this subject was published in the Federal Register on May 14, 1990, (55 FR 19890). The NRC received 40 letters of comment on this subject. The NRC staff has identified 66 separate topics, which are responded to in the Federal Register notice. Revisions, mainly clarifying and editorial, have been made in the final rule as a result of the comments received.

Sincerely,

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosure:
Federal Register notice

cc: The Honorable Carlos J. Moorhead

Enclosure 3

Draft Public Announcement

DRAFT PUBLIC ANNOUNCEMENT

The Nuclear Regulatory Commission is amending the reporting requirements in 10 CFR 20.403 (new §20.1202) to ensure that events having significant implications for public health and safety are properly reported.

Paragraphs (a)(3), (a)(4), (b)(3), and (b)(4) of §20.403 dealing with loss of operation and cost of damage are being deleted because the staff believes these criteria do not adequately define events with significant implications for public health and safety. The deleted sections are being replaced with new criteria in Parts 30, 40, and 70. The staff believes the new criteria will more accurately define potentially significant events affecting the health and safety of the public and the environment. The final rule contains administrative changes to requirements for general licenses. These changes specify that general licensees who were previously required to report incidents pursuant to the deleted requirements, must continue to report incidents pursuant to the new reporting requirements.

Revisions to Part 50 are not needed because similar reporting requirements are already addressed in §50.72. Part 50 licensees subject to the requirements in §50.72 are specifically exempted from this rule to avoid conflicting regulations. However, certain Part 50 licenses (e.g., research and test reactors) are not currently subject to the reporting requirements in §50.72. If they possess material licensed under Parts 30, 40, or 70, they will be subject to the new reporting requirements.

The intent of these amendments is to require prompt reports to the NRC of safety related events that may require prompt or immediate action to insure the health and safety of the public and the environment. The NRC will evaluate the hazard and the corrective actions taken by the licensee and may dispatch NRC staff to the site of the event, activate the NRC incident response center, or issue warnings of generic hazards to other licensees.

Enclosure 4

Weekly Report to the Commissioners

DAILY STAFF NOTES

OFFICE OF NUCLEAR REGULATORY RESEARCH

Final Rule Signed by EDO

On _____, 1991, The Executive Director for Operations approved a final rule that amends 10 CFR Parts 20, 30, 40, and 70. This rulemaking will amend the reporting requirements for material licensees to ensure that events having a significant implication for public health and safety are properly reported. Certain sections of 10 CFR 20.403 are being deleted because these criteria do not adequately define events with significant implications for public health and safety. The deleted sections are being replaced with new criteria in Parts 30, 40, and 70 that will more accurately define significant events affecting the health and safety of the public and the environment.

This notice informs the Commission that, in accordance with the rulemaking authority delegated to the EDO, the EDO has signed this final rule and proposes to forward it on _____ to the Office of the Federal Register for publication, unless otherwise directed by the Commission.