UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
WASHINGTON, D.C. 20555

December 27, 1991

NRC INFORMATION NOTICE 91-86: NEW REPORTING REQUIREMENTS FOR CONTAMINATION EVENTS AT MEDICAL FACILITIES (10 CFR 30.50)

Addressees

All licensees authorized to use byproduct materials for human use.

Purpose

The purpose of this notice is to explain more fully the kinds of contamination events, involving byproduct material, as described in 10 CFR 30.50, that might be considered reportable to the U. S. Nuclear Regulatory Commission (NRC) by a medical facility performing procedures with byproduct material, particularly Iodine-131. It is expected that licensees will review this information, distribute this notice to responsible staff, and develop appropriate procedures for making the required notification and reports to NRC. Information contained in this notice does not constitute a new requirement, and no written response is required.

Description of Circumstances

On August 16, 1991 (56 FR 40757), NRC published a final rule (effective October 15, 1991) that amended the reporting requirements in 10 CFR 20.403 and in the new 10 CFR 20.2202, and added a new provision (10 CFR 30.50). The rule establishes new reporting requirements for "unplanned contamination" and other events. The new rule deletes the old reporting requirements based on loss of operation and cost of damage criteria, because NRC believes that these criteria do not adequately define events with significant implications for public health and safety. NRC believes that the new criteria established in 10 CFR 30.50 will more accurately define potentially significant events, affecting the public health and safety and the environment, that must be reported to NRC.

NRC is very interested in contamination incidents at medical facilities, because of the proximity of the general public to areas where byproduct materials are used and stored. Fires, spills, and other unplanned incidents involving significant quantities of radiopharmaceuticals or involving sealed sources with significant radiation levels pose potential health and safety hazards that warrant prompt notification of NRC.

Discussion

In the practice of nuclear medicine, particularly I-131 therapy procedures, contamination resulting from patient nausea, incontinence, etc., occurs with sufficient frequency as to be considered within the paramenters of normal operations. Routine decontamination procedures are established in advance of patient treatment and followed during the course of the patient treatment. Under these conditions, no report, to NRC of those contamination events that fall within pre-determined normal operations, would be required, under the reporting requirements of 30.50. However, any contamination events that fall outside normal operations may require either an immediate or 24 hour report to NRC, as enumerated in 10 CFR 30.50. All three of the conditions cited in 10 CFR 30.50(b)(1) must be met before a report is required. These could include any unanticipated event or some unanticipated deviation from a normal procedure, not covered by the preestablished decontamination procedures. In such cases, you should refer to requirements of 10 CFR 30.50, to determine if it is necessary to report the contamination event.

This information notice requires no specific action or written response. If you have any questions about the requirements of 10 CFR 30.50, please contact the technical contact listed below, or the appropriate NRC regional office.

A copy of the Federal Register Notice of the final rulemaking is attached.

John F. Greeves (for)
Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contact: Robert L. Ayres, NMSS
(301) 504-3423

Attachments:
1. 56 FRN 40757
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices

Computer Printouts: See Jacket

or claimed as a contribution. Codes can be obtained from the Division Director. The records must include:

(i) Receipts for generic promotion for each expenditure of CCC resources in excess of $25.00, all receipts for branded promotion, and all receipts for sales and trade related expenses (actual vendor invoices or restaurant checks, rather than credit card receipts);

(ii) The exchange rate used to calculate the dollar equivalent of expenses incurred in foreign currency;

(iii) The unexpended balance of each budgeted amount;

(iv) Copies of reimbursement claims to CCC against CCC resources;

(v) An itemized list of claims charged to each of the participant's CCC resources accounts; and,

(vi) Documentation supporting each transaction, including: canceled checks, receipted paid bills, contracts or purchase orders, per diem calculations and travel vouchers. Documentation in support of an EIP/MPP participant claim for reimbursement must identify each eligible direct promotional expense paid by the EIP/MPP participant or foreign third party. Documentation of each financial transaction must contain: The annual activity plan code; the activity code(s); cost code(s); country code(s); English translation of the expense; and cross references for all accounting records and supporting documentation. Codes can be obtained from the Division Director.

(4) Documentation for contributions claimed by MPP participants must include: The dates, purpose and location of the activity to which the cash or in-kind items were claimed as a contribution; who conducted the activity; the participating groups or individuals; and, the method of computing the claimed contributions. MPP participants must retain and make available for audit the following documentation related to claimed contributions:

(i) The signed agreement between the MPP participant and the individual or group making the contribution; and,

(ii) If available, copies of invoices and receipts for expenses of U.S. industry groups, individuals and foreign third parties which were not reimbursed by the MPP participant; or,

(iii) An itemized statement from the contributor on the expenses it incurred in the joint activity.

(d) *Proceeds.* Participation fees, sales or other proceeds generated by a participant activity wholly or partially reimbursed with CCC resources, must either be used to offset the expense of that activity or returned to CCC. Proceeds may not be transferred to another activity or otherwise absorbed into the participant's budget; however, this prohibition does not apply to premiums, interest or other income generated by liquidation of CCC commodity certificates or administrative fees charged to U.S. commercial entities involved in brand promotion activities when such revenue is used to offset expenses incurred by the participant in administering the brand promotion and are approved by CCC in the activity plan.

(e) *Audit procedures.* The participant must establish internal controls to attend to adverse findings and recommendations emanating from reports by internal, independent, and U.S. Government auditors and examiners. Any periodic audit reports by independent public accountants must be provided upon request to the FAS Compliance Review Staff.

§ 1485.26 Expired or terminated CCC resources.

(a) *General.* Balances of program resources provided for in the MPP or EIP/MPP agreement, but not obligated by the participant before the expiration date of the agreement, shall revert to CCC.

(b) *Procedure.* Within 6 months of a MPP or EIP/MPP agreement expiration, the participant must submit to CCC a final reimbursement claim certifying that no further claims for reimbursement will be made against such agreement. It must include the end-of-year report required in § 1485.23 and any other reports and evaluations required under this regulation.

§ 1485.27 Compliance review.

(a) *Accessibility of records.* All MPP and EIP/MPP participant records pertaining to program agreements, activity plans, reimbursement claims and contributions shall be available upon request to CCC, the FAS Compliance Review Staff, the USDA Office of the Inspector General, and the General Accounting Office, for purposes of making audits, examinations, excerpts and transcripts.

(b) *Reimbursement to CCC pursuant to compliance report findings.* (1) If CCC has reimbursed a participant or offset any advance payments with claims submitted by a participant which are later determined to be unauthorized, the participant must reimburse CCC as follows:

(i) By including in the next reimbursement claim a repayment to CCC in the form of a negative amount against the codes to which the expense was originally charged (codes can be obtained from the Division Director); or,

(ii) By issuing a check for the amount due payable to the Commodity Credit Corporation. Include a report showing reimbursements to CCC as negative amounts against the codes to which the expenses were originally charged. The report is limited to the items covered by the check. Mail the check and expense claims to: Marketing Operations Staff, Foreign Agricultural Service, United States Department of Agriculture, Washington, DC 20250-1000;

(2) In either of the preceding forms of reimbursement, include notation that the amount reimbursed is pursuant to a specific CRS report.

§ 1485.28 CCC recourse in the event of noncompliance with regulations.

(a) *General.* CCC may periodically require participants to certify compliance with the requirements of this regulation.

(b) *Procedure.* In the event of a participant's noncompliance with this Subpart, CCC may disallow a claim submitted under an agreement. This pertains to activities approved by CCC after August 16, 1991. CCC may also terminate an agreement, or use any other measure at CCC's disposal.

§ 1485.29 Applicability.

The regulations in this subpart are applicable with respect to activities, including revisions to existing activities, that are approved on or after October 1, 1991.

Signed at Washington, DC., on May 15, 1991.

Duane Acker,

Vice President, Commodity Credit Corporation and Administrator, Foreign Agricultural Services.

[FR Doc. 91-19390 Filed 8-15-91; 8:45 am]

BILLING CODE 3410-10-M

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20, 30, 31, 34, 39, 40, and 70

RIN 3150-AC91

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

necessary 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 appropriate action to protect the public health and safety and whether prompt NRC action is necessary to address generic safety concerns.

EFFECTIVE DATE: October 15, 1991.

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 (55 FR 19890), the NRC published a notice of proposed rulemaking that 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 requirements would be replaced with reporting requirements that are 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 and are available for public inspection and copying for a fee at the Commission's Public Document Room located at 2120 L Street NW (Lower Level), Washington, DC.

Comments on the proposed rule came from a variety of sources. These included universities, hospitals, other government agencies, material licensees, nuclear utilities and individual citizens. Many of the letters received contained similar comments. These comments are grouped together and addressed as a single issue. The NRC has identified and responded to 66 separate issues that include all of the significant points raised by the commenters.

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 "Specific Comments" section. The comments and their resolution are discussed below.

Summary and Analysis of Public Comments

A. General Comments

1. Comment: 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 set out in 10 CFR 20.403 (a)(1), (a)(2), (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. Comment: 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 these 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. Comment: The justification for the rule is weak; writing new rules does not mean people will comply with them. The proposed rule provides no accurance 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 criteria which more clearly define significant events that need to be reported, licensees are on notice as to those events for which reports are required. One purpose of this rulemaking is to assure that all significant events are reported, and that the NRC and industry have knowledge of and feedback from operating experience.

4. Comment: 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 comment 3 above). It is recognized that the reporting of some events will involve judgment on the part of the licensee. However, the rule must contain sufficiently defined criteria to minimize disagreements and confusion over what events are reportable.

5. Comment: The NRC should establish activity thresholds for each radionuclide that would require NRC notification, such as part 20, appendix C. Also, significant occurrences should be defined 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 these 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. Comment: The deletion of paragraphs (a)(3), (a)(4), (b)(3), and (b)(4) of 10 CFR 20.403 is appropriate.

Response: Most commenters either 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. Comment: The NRC should 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 each individual license is not efficient. Moreover, public notice and comment allows for comments that question the need for or efficiency of the reporting requirements, and allows the NRC to consider and respond to such comments. Placing the requirements in each individual license would not allow for such a healthy dialogue.

8. Comment: 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. Comment: 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. These were discussed in the draft regulatory analysis prepared for the proposed rulemaking. 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. Comment: 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. Comment: 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. Comment: 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. Comment: Further clarification needs to be provided regarding notification requirements for commercial nuclear power reactors. Companies holding 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 criteria to apply to commercial nuclear power plants. In the discussion as well as in the rule (§§ 30.50(c)(3), 40.60(c)(3), and 70.50 (c)(3)), the NRC specifically states that the provisions do not apply to licensees subject to the notification requirements in 10 CFR 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. 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. Comment: 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. Comment: 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 have been revised by the major revision to part 20 which was published in the Federal Register on May 21, 1991 (56 FR 23360). The major revision specifies what quantities of licensed material require immediate and 30 day notifications when packages are lost.

16. Comment: 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 4 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. Comment: The subject rule and statements of consideration should make it clear that the rule would apply to uranium enrichment plants whether licensed under parts 50 or 70. 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 parts 50 or 70 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. Comment: Immediate and 24 hour notifications should be limited to potentially serious events where it is necessary for NRC to intervene to mitigate the effects.

Response: Under the final rule, the timing 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. Comment: We do not agree that the categorical exclusions have been met. The proposed regulation as written has a significant environmental 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 while the final rule revises some of the existing requirements, it does not change the NRC's policy that licensees should promptly report significant events. In addition, § 51.22(c)(3) lists amendments to reporting requirements in parts 30, 40, and 70 as categorical exclusions not requiring an environmental review.

20. Comment: 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 part 34, medical licensees 10 CFR part 35, etc.).

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

21. Comment: The frequent use of the word "any" is not consistent with the stated intent of "significant occurrences."

Response: The text of each notification requirement defines the event to be reported. The word "any" has been deleted from the final rule because it is not necessary to define the event to be reported.

22. Comment: The 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. Comment: The licensee should not be required to report 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. Comment: The NRC should provide further explanation and possibly examples of what "securing the material and assessing releases" means.

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 licensed material has escaped from the licensee's control and where the released material has gone. Assessment actions may include radiation surveys, contamination surveys, and analysis of air, water, and soil samples.

B. Specific Comments

(a) Immediate Notification

1. Comment: The NRC and Agreement States should be notified within one hour for incidents with substantial potential for injury to off site people. The commenter suggests 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. §§ 30.32(i), 40.31(j), and 70.22(i)). Those plans include criteria for taking action so that injury or harm to those off site can be minimized.

2. Comment: 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. If the event does not clearly fall outside the reporting requirements, the licensee should act conservatively and report the event.

3. Comment: 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.

4. Comment: Do toxic gas releases that include gas releases (such as UF 6, NO_x, HF, 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) or in the revised § 20.2202(a)(2) or § 20.2202(b)(2).

(b) Twenty-four Hour Notification

5. Comment: 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, the licensee should act conservatively and 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.

6. Comment: 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 the phrase. As a result, the phrase has been deleted from the final rule.

(b)(1) Contamination Events

7. Comment: 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

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.

21. Comments: 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 have been reworded in the final rule.

22. Comment: As currently written, this section (Safety Equipment Related Events) 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, fatalities, or serious injuries requiring medical treatment.

23. Comment: 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.

24. Comment: The third example on page 19892 (May 14, 1990; 55 FR 19890), 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.

25. Comment: 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 users 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.

26. Comment: 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 event that safety equipment must protect against.

27. Comment: 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 releases exceeding regulatory limits. This has been clarified in the final rule.

28. Comment: 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.

29. Comment: 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.

30. Comment: Equipment failures reported under § 34.30 should be exempt from this requirement because 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

31. Comment: 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 proposed 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.

32. Comment: 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?

Response: A radioactively contaminated individual is a person who has removable surface contamination on their clothing or on accessible portions of their body that can be detected by standard methods and can be spread to other individuals. No threshold or contamination level related to regulatory limits has been provided because NRC is concerned about any contamination that is introduced into an emergency room or any other medical facility by an injured person.

33. Comment: 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.

34. Comment: The proposed rule required no report for the treatment of a

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.

8. Comment: 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 the unplanned contamination can be reduced within 24 hours to levels where contamination controls for entry into the area are no more stringent that 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.

9. Comment: 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 exposure to radiation levels elevated by the contamination.

10. Comment: 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.

11. Comment: 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 isotopes 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.

12. Comment: 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.

13. Comment: 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.

14. Comment: 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.

15. Comment: It is not clear from the rule that restriction of access includes changing protocols such as adopting extra protective clothing. The NRC needs 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.

16. Comment: Licensees should be allowed to postpone cleanup of contaminated areas for longer than 24 hours provided access is restricted, 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 postpone cleanup of contaminated areas for longer than 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.

17. Comment: 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.

18. Comment: 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 solely because a pocket dosimeter is discharged beyond its range. However, the discharge of a radiographer's pocket dosimeter may be associated with an event that requires a report pursuant to 10 CFR 20.403 (a)(1) or (b)(1) or the revised 10 CFR 20.2202 (a)(1) or (b)(1). 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.

19. Comment: The wording in the proposed rule for safety equipment related events is not clear. Use the last paragraph on page 19891 (column 3) of the Federal Register Notice (May 14, 1990; 56 FR 19890).

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

20. Comments: Events should not be reported unless they result in exceeding

superficial injury at a licensee-maintained medical facility but required a report for treatment of the same injury elsewhere. Why?

Response: Although many licensee facilities have provisions for controlling the spread of contamination, the potential for spreading contamination is sufficient to cause the NRC to reconsider its position and to decide not to exclude licensee-maintained medical facilities treating superficial wounds from this reporting requirement. 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. The rule has been appropriately revised.

35. Comment: 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 these incidents in order to ensure that appropriate radiological controls are used and to ensure that any radiological 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.

(b)(4) Fires and Explosions

36. Comment: 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 explosions of small vials and stoppered test tubes. 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 §§ 20.1001–20.2401 of 10 CFR part 20.

37. Comment: 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.

38. Comment: 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.

39. Comment: 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 of the public health and safety. Therefore, the dollar figure has been removed from the regulations.

(c) Written Reports

40. Comment: 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.

41. Comment: 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)

42. Comment: The following nuclear criticality safety events should be included in the rule as reportable events: (1) Unintended accumulation of special nuclear material in an unfavorable geometry, and (2) failure of a special nuclear material concentration monitoring instrument or a failure of a moisture detection instrument.

Response: The NRC agrees that some criticality safety events can be significant. In light of recent events at some facilities and NRC experience, the NRC believes that there may be sufficient justification to warrant incorporating into the regulations reporting requirements for certain types of events related to the criticality of fissile material. The NRC intends to study this issue further and will consider the future promulgation of additional requirements related 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

The NRC is amending the reporting requirements in § 20.403 and in the new § 20.2202 which was published in the **Federal Register** on May 21, 1991 (56 FR 23360). 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. New criteria for the reporting of significant events at material licensee facilities are added in parts 30, 40, and 70. 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). 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 parts 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 4 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 15 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.

Sections 20.403 and 20.2202 of 10 CFR part 20, 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 where such reporting is warranted, it would be better to impose specific reporting requirements for threatening events such as the bulging of a filled uranium hexafluoride container through license conditions 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 that were required before the contamination event occurred 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 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 §§ 20.1001–20.2401 of the revised part 20 issued May 21, 1991 (56 FR 23360) 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 unlikely that the area would need to be restricted for more than 1 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

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. 134, 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, 30.50, 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)).

5. 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.

* * * * *

6. 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 an 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) An 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;

(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) An 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;

(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) An 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) An 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:

(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.

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

PART 31—GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

7. 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 purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 31.5(c) (1)–(3) and (5)–(9), 31.6(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), and (8), and 31.11 (b) and (e) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 31.2 [Amended]

8. In § 31.2, paragraph (a) is amended by adding an "s" to the word "provision" and changing "30.51" to read "30.50."

§ 31.6 [Amended]

9. In § 31.6, paragraph (c) is amended by changing "30.51" to read "30.50."

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

10. 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); §§ 34.20(a)–(e), 34.21 (a) and (b), §§ 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), (d), and (f), 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), 34.28, 34.27, 34.28(b), 34.29(c), 34.30, 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]

11. In § 34.30, paragraph (a) is amended by adding "in § 30.50 and" between "specified" and "under."

PART 39—LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

12. 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, sec. 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, 39.31–39.51, 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]

13. In § 39.77, paragraph (b) is amended by removing the word "and" between "20.403," and "20.405," and adding "and 30.50" between "20.405" and "of."

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

14. 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. 223, 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. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 40.8 [Amended]

15. In § 40.8, paragraph (b) is amended by adding "40.43, 40.44, and 40.60," between "40.42," and "40.61," and paragraph (c)(1) is amended by replacing "Form NRC–2" with "NRC Form 313" and replacing "0019" with "0120."

§ 40.26 [Amended]

16. In § 40.26, paragraph (c)(1) is amended by removing "40.2" and adding "40.60" between "40.46" and "40.61."

§ 40.43 [Amended]

17. In § 40.43, paragraph (a) is amended by replacing "Form NRC–2" with "NRC Form 313."

§ 40.44 [Amended]

18. Section 40.44 is amended by replacing "Form NRC–2" with "NRC Form 313."

19. 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 an 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) An 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;

(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) An 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;

(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) An 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) An 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

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

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 100 microcuries of Y-class cobalt-60 (appendix B of §§ 20.1001–20.2401 of the revised part 20 issued May 21, 1991 (56 FR 23360)), no report would be required because five times the lowest annual limit on intake of Y-class cobalt-60 is 150 microcuries. If the licensee knows that the chemical form of cobalt-60 meets the definition of W-class material, then the higher annual limit on intake for W-class cobalt-60 may be used to determine the reporting threshold.

Safety Equipment Failure

The final rule requires licensees to report within 24 hours of discovering 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 or 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 discovering 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, because no report would be required if any spreadable contamination was removed before first aid was rendered.

Fires and Explosions

The final rule requires licensees to report within 24 hours of discovering any unplanned fire or 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 §§ 20.1001–20.2401 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.

Written Report

The requirement for a written report in the final rule is identical to the proposed rule except for a minor clarification that a report prepared pursuant to other regulations may be submitted to fulfill this requirement if

the submitted report contains all of the necessary information and the appropriate distribution is made.

Administrative Amendments Concerning Information Collection

References to obsolete NRC Form 2 in §§ 40.8(c)(1), 40.46(b), and 40.48 have been deleted in this final rule and replaced with the references to NRC Form 313.

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)(i). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 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 Desk Officer, Office of Information and Regulatory Affairs, NEOB-3019 (3150-0009, 3150-0014, 3150-0017, and 3150-0020), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The Commission prepared a regulatory analysis for this final 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 were considered necessary. Therefore, the draft regulatory analysis is adopted as the final regulatory analysis without change. The regulatory analysis is available for inspection in the NRC Public Document Room, 2120 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 effects approximately 9,100 licensees monitored by NRC under 10 CFR parts 20, 30, 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 more clearly define 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 not expected to generate a significant number of additional reports, 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 these amendments do not involve any provisions which would impose backfits on licensees as defined in § 50.109(a)(1).

List of Subjects

10 CFR Part 20

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

10 CFR Part 30

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

10 CFR Part 40

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

10 CFR Part 70

Criminal penalty, Hazardous materials-transportation, Material control and accounting, Nuclear materials, Packaging and containers, 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:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 68 Stat. 930, 933, 935, 948, 953, 954, 955, as amended (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201(b)); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 20.405 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. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 20.403 [Amended]

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.

§ 20.2202 [Amended]

3. 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

4. The authority citation for part 30 is revised to read as follows:

Authority: Secs. 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).

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

20. 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); §§ 70.8, 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. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 70.8 [Amended]

21. In § 70.8, paragraph (b) is amended by adding "70.50," between "70.39," and "70.51."

§ 70.19 [Amended]

22. In § 70.19, the introductory text paragraph (c) is amended by adding "70.50," between "§§ 70.32," and "70.51."

23. 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 an 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) An 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;

(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) An 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;

(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) An 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) An 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 prepare 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

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

(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, MD, this 5th day of August 1991.

For the Nuclear Regulatory Commission.

James M. Taylor,

Executive Director for Operations.

[FR Doc. 91-19588 Filed 8-15-91; 8:45 am]

BILLING CODE 7590-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR part 39

[Docket No. 91-NM-68-AD; Amdt. 39-8001; AD 91-17-03]

Airworthiness Directives; Fokker Model F-27 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Fokker Model F-27 series airplanes, which requires a one-time high frequency eddy current inspection to detect cracks in the actuating ram attachment lug, and replacement of the main landing gear (MLG) drag strut attachment fittings, if necessary. This amendment is prompted by recent reports of broken attachment lugs on the MLG drag strut actuating rams. This condition, if not corrected, could result in collapse of the MLG.

DATES: Effective September 20, 1991. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of September 20, 1991.

ADDRESSES: The applicable service information may be obtained from Fokker Aircraft USA, Inc., 1199 North Fairfax Street, Alexandria, Virginia 22314. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Quam, Standardization Branch, ANM-113; telephone (206) 227-2145. Mailing address: FAA, Northwest Mountain Region, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98055-4056.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations to include a new airworthiness directive, applicable to certain Fokker Model F-27 series airplanes, which requires a one-time high frequency eddy current inspection to detect cracks in the actuating ram attachment lug, and replacement of the main landing gear (MLG) drag strut attachment fittings, if necessary, was published in the Federal Register on April 23, 1991 (56 FR 18551).

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the single comment received.

The commenter requested that the FAA clarify its intent regarding the compliance time cited in paragraph A. of the Notice, specifically whether the intention was for operators to comply within 500 landings from the effective date of the AD, or within 500 landings from the airplane's first landing. The final rule has been revised to specify that compliance is required within 500 landings after the effective date of the AD.

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the change previously described. The FAA has determined that this change will neither significantly increase the economic burden on any operator, nor increase the scope of the AD.

This is considered to be interim action until final action is identified, at which time the FAA may consider further rulemaking.

It is estimated that 44 airplanes of U.S. registry will be affected by this AD, that it will take approximately 20 manhours per airplane to accomplish the required actions, and that the average labor cost will be $55 per manhour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $48,400.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and is contained in the rules docket. A copy of it may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

91-17-03. Fokker: Amendment 39-8001. Docket No. 91-NM-68-AD.

Applicability: Model F-27 series airplanes; serial numbers 10102, 10105 through 10684, 10686, 10687, and 10689 through 10692; certificated in any category.

Compliance: Required as indicated, unless previously accomplished.

To prevent collapse of the main landing gear (MLG), accomplish the following:

A. Within 180 days after the effective date of this AD, or prior to the accumulation of 500 landings after the effective date of this AD, whichever occurs first, perform a high frequency eddy current inspection of both sides of the actuating ram attachment lug in accordance with part 1 of the Accomplishment Instructions of Fokker Service Bulletin F27/54-47, dated November 30, 1990.

B. If cracks are found, prior to further flight, replace the MLG drag strut attachment fitting in accordance with part 2 of the Accomplishment Instructions of Fokker Service Bulletin F27/54-47, dated November 30, 1990.

C. An alternative method of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate.

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
91-84	Problems with Criticality Alarm Components/Systems	12/26/91	All Nuclear Regulatory Commission (NRC) fuel cycle licensees, interim spent fuel storage licensees, and critical mass licensees.
91-71	Training and Supervision of Individuals Supervised by an Authorized User	11/12/91	All NRC medical licensees.
91-66	(1) Erroneous Data in "Nuclear Safety Guide, TID-7016, Revision 2," (NUREG/CR-0095, ORNL/NUREG/CSD-6 (1978)) and (2) Thermal Scattering Data Limitation in the Cross-Section Sets Provided with the KENO and SCALE Codes	10/18/91	All fuel cycle licensees, critical mass licensees, interim spent fuel storage licensees, and all holders of operating licenses or construction permits for test, research, and nuclear power reactors.
91-65	Emergency Access to Low-Level Radioactive Waste Disposal Facilities	10/16/91	All NRC licensees.
91-60	False Alarms of Alarm Ratemeters Because of Radiofrequency Interference	09/24/91	All Nuclear Regulatory Commission (NRC) licensees authorized to use sealed sources for industrial radiography
91-49	Enforcement of Safety Requirements for Radiographers	08/15/91	All Nuclear Regulatory Commission (NRC) licensees authorized to use sealed sources for industrial radiography.
91-44	Improper Control of Chemicals in Nuclear Fuel Fabrication	07/07/91	All nuclear fuel facilities.
91-39	Compliance with 10 CFR Part 21, "Reporting of Defects and Noncompliance"	06/17/91	All Nuclear Regulatory Commission (NRC) material licensees.

LIST OF RECENTLY ISSUED
NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
91-85	Potential Failures of Thermostatic Control Valves for Diesel Generator Jacket Cooling Water	12/26/91	All holders of OLs or CPs for nuclear power reactors.
91-84	Problems with Criticality Alarm Components/Systems	12/26/91	All Nuclear Regulatory Commission (NRC) fuel cycle licensees, interim spent fuel storage licensees, and critical mass licensees.
91-83	Solenoid-Operated Valve Failures Resulted in Turbine Overspeed	12/20/91	All holders of OLs or CPs for nuclear power reactors.
91-18, Supp. 1	High-Energy Piping Failures Caused by Wall Thinning	12/18/91	All holders of OLs or CPs for nuclear power reactors.
91-82	Problems with Diaphragms in Safety-Related Tanks	12/18/91	All holders of OLs or CPs for nuclear power reactors.
91-81	Switchyard Problems that Contribute to Loss of Offsite Power	12/16/91	All holders of OLs or CPs for nuclear power reactors.
91-80	Failure of Anchor Head Threads on Post-Tensioning System During Surveillance Inspection	12/11/91	All holders of OLs or CPs for nuclear power reactors.
91-79	Deficiencies in the Procedures for Installing Thermo-Lag Fire Barrier Materials	12/06/91	All holders of OLs or CPs for nuclear power reactors.
88-92, Supp. 1	Potential for Spent Fuel Pool Draindown	11/29/91	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
CP = Construction Permit