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DEC 05 1990

MEMORANDUM FOR: John Hickey, Chief, Operations Branch, Division of Industrial  
and Medical Nuclear Safety, NMSS

FROM: Sher Bahadur, Chief, Regulation Development Branch, Division  
of Regulatory Applications, RES

SUBJECT: PUBLIC COMMENTS ON AMENDMENTS TO 10 CFR PART 10.403

Attached per conversation of November 27, 1990 between Cheryl Trottier (NMSS) and Joe Mate (RES) is a revised set of public comments and responses as well as the revised comparative text of the final rule. These two packages include comments from NRR, AEOD, OGC, OE, (partial), NMSS and State Programs.

We intend to delete comments 9, 33, 43, 56, and 75 from the general comments material provided. Comment #76 still requires input from NMSS.

As agreed, we are awaiting your input for the statement of considerations which will be incorporated into the Federal Register notice. Please review the attached material and provide your final comments and the text for the statement of considerations. In order to meet our schedule, we need your comments by December 12th. If you have any questions, please call Joe Mate at 23795.

Sher Bahadur, Chief  
Regulations Development Branch  
Division of Regulatory Applications  
Office of Nuclear Regulatory Research

Enclosures:

1. Public Comments
2. FRN (comparative text)

cc: Mike Finkelstein, OGC  
Kevin Ramsey, IMOB/NMSS

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ENCLOSURE 1

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COMMREV/GENERAL COMMENTS

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Author's Name:  
JMATE

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October 9, 1990

General Comments

Comment

Commenter

1. 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 components. Licensees need clear cut definitions that specify severity levels requiring notification like those currently in 20.403 (a)(1) and (a)(2) and (b)(1) and (b)(2).

#1, #3,  
#12, #13,  
#14, #15,  
#20, #27,  
#33, #38  
#40

Response: We agree that there is a need to make the criteria in the proposed rule more specific. The revisions to the final rule reflect this intent to make the rule more specific relative to the criteria.

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

#4, #37  
#38

Response: In developing the revised criteria for the proposed rule the staff considered the possibility of revising Part 20 rather than establishing criteria in Parts 30, 40, and 70. To make such changes, however, would conflict with well established reporting requirements in Part 50 and would require the revision of these requirements. Therefore, the changes were made in Parts 30, 40, and 70.

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

#5, #14  
#20, #33

Response: The staff agrees that writing new rules in itself provides no assurance that licensees will comply with them. In developing the proposed criteria, there was broad staff consensus that better criteria was needed to reduce confusion and disagreements over what types of events should be promptly reported to NRC. Although a few specific cases initiated the rulemaking effort, it was the general consensus that motivated the staff to redefine what types of events warranted prompt NRC notification.

4. Rule is prescriptive and eliminates need for licensee judgment. #5

Response: The staff does not feel that the revised rule is too prescriptive. NRC must consider and review events from all



types of licensees. Material licensees do not all consistently view events in the same manner as the staff. Hence, there is a need for a rule that is somewhat prescriptive yet leaves room for judgment on the part of the licensee.

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

#5, #7  
#16, #18  
#33

Response: In developing the proposed rule the staff considered the idea of providing specific activity thresholds. However, the staff felt that such thresholds would be cumbersome and difficult to develop and use. Many licensed operations use mixtures of isotopes in different chemical forms that pose various safety hazards. The staff 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 staff 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 explosion involving licensed material in quantities greater than the quantities specified in Appendix C of Part 20.

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

#10, #13,  
#18, #23,  
#25, #31  
#33, #37  
#38

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

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

#10, #30

Response: If the NRC were to place individual reporting requirements in the individual licenses, this task would take a tremendous amount of time and effort to complete. There are more than 9,000 material licensees that fall under the purview of NRC. It would be difficult to maintain consistency with the reporting criteria specified in so many locations. The staff does not consider this to be a practical solution.

8. Proposed parts should be rewritten and reissued for a new comment period. Counterproductive to strong licensee programs.

#10, #14

Response: The staff does not agree that the rule is counter productive to strong licensee programs because the staff does not agree with the view that notification requirements are "penalties" that must be paid by licensees. By improving notification requirements, NRC is in a better position to assure proper response, to identify generic problems, and to notify other licensees of generic problems. Sharing knowledge and experience serves to strengthen licensee programs.

9. Lack of communication with inspectors or other NRC staff. General information calls no longer taken in the afternoons. Enables misunderstandings and questions to become problems.

#12

Response: Comment 9 should be deleted. Region III has determined that the commenter called once (4 years ago), got a recording, and never called back. This appears to be a one-time occurrence that does warrant a response. Comment should be deleted.

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

#21, #33

Response: NRC did consider alternatives such as those mentioned by the commenters. However, there was general agreement among the staff that certain sections in the regulation 20.403 needed to be replaced with better reporting criteria. A rulemaking action is the only appropriate process to accomplish this action.

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

#14, #20

Response: The staff did not intend to draw a parallel to power reactor licensees when Part 50 regulations were cited in the discussion. The staff was merely trying to point 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.

12. 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 NRC immediately.

#15

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 the prompt notification of the NRC.

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

#15

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.

14. What does "threatens to cause" mean in Part 20.403?

#27

Response: The phrase "threatens to cause" refers to events that come very close to occurring, but are narrowly averted. The NRC requires notification of such "close calls" to allow preventative measures to be implemented before an incident occurs.

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

#22, #36  
#15

Response: The NRC does not intend for the proposed criteria to apply to commercial nuclear power plants. In the discussion as well as in the the rule (Parts 30.50 (c)(3), 40.60 (c)(3), and 70.50 (c)(3)), the NRC specifically stated that the provisions do not apply to licensees subject to the notification requirements in Section 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, these provisions doe not constitute requirements for reporting in accordance with the new notification requirements in Parts 30, 40, or 70. 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.

16. NRC should provide clear guidance on their interpretation by circulating early event reports with comments on the appropriateness and by providing comparable early analysis of failures to report. #23, #33

Response: The staff 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.

17. NRC should more clearly define the notification requirements concerning the loss of packages of radioactive material. #25

Response: This rulemaking effort involves the notification requirements in 20.403. The loss of packages of radioactive material is covered by 20.402. The loss of radioactive material is outside the scope of this rulemaking effort. Notification requirements for the loss and theft of licensed material will be revised by the major revision to Part 20. The major revision will specify what quantities of licensed material require immediate and 30 day notifications.

18. Burden is estimated to be about 3 days for each notification required for large companies. #27

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

19. The subject rule and statement of considerations should make it clear that the rule would apply to uranium enrichment plants whether licensed under Part 70 or Part 76. Further, Part 50.72 and 50.73 should not apply to such facilities. #29, #30

Response: The question of whether or not enrichment plants should fall under Part 70 or Part 50 is not within the scope of this rule. Currently there are no licensed enrichment plants. The regulations that should govern these plants is a licensing issue that will be decided when a license is requested and issued to operate an enrichment plant.

20. Immediate and 24 hour notifications should be limited to potentially serious events where it is necessary for NRC to intervene to mitigate the effects. #33, #38

Response: It is not the policy of the NRC to intervene when the licensee is having a problem. The problem is to be solved by the licensee. NRC monitors the licensee's actions, makes

recommendations, and only intervenes if the licensee is unable or unwilling to take the necessary action to protect public health and safety or the environment. Whether or not the NRC intervenes, it must be aware of significant events to ensure that appropriate actions are taken.

21. We do not agree that the categorical exclusions have been met. The proposed regulation as written has a large impact and cannot be considered to be of a minor nature. #33

Response: The staff 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 staff maintains that the proposed rule is a clarification of existing requirements and does not change the NRC's policy that licensees should promptly report significant events. In addition, it is clear that § 51.22(c)(3) lists amendments to reporting requirements in Parts 30, 40, and 70 as categorical exclusions not requiring an environmental review.

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

Response: The staff believes that the proposed notification requirements describe significant events that should be reported for source, byproduct, and special nuclear material licensees. The staff does not agree that developing more specialized requirements and amending more Parts of the regulations would improve the rule.

23. Frequent use of the word "any" is not consistent with the stated intent of "significant occurrences". #38

Response: The text of each notification requirement defines the event to be reported. The staff does not agree that using the word "any" is inconsistent with the staff's intent to require NRC notification of significant events.

24. Proposed rule should make it clear that it applies to Independent Spent fuel storage facilities. #29

Response: The staff agrees that it would be appropriate to add the proposed notification requirements of Part 72 and intends to initiate a separate rulemaking effort in order to allow public comment on amending that part of the regulations.



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

Response: The fact that the licensee has completed all necessary actions before NRC is notified is no reason not to file a report. There may still be some action that NRC may have to take depending on the nature of the incident. (i.e. warning other licensees of generic problems).

26. Provide further explanation and possibly examples of what securing the material and assessing releases means. (Used in the discussion). #38

Response: Securing material includes actions necessary to prevent unauthorized movement of licensed material or unsafe conditions resulting from licensed material. This includes shielding exposed radiation sources, returning licensed material to storage containers, stopping a spill or the spreading of a spill, etc. Assessing releases includes efforts necessary to determine how much licensed material has escaped from the licensee's control and to determine where released material has gone.

#### Comments on the Actual Rule

30.50 Notification Requirements.

30.50a Immediate Notification.

27. Require one hour notification of NRC and Agreement States for incidents with substantial potential for injury to off site people. Suggest 5 min for one hour notification. #2

Response: There are already regulations that require emergency response plans (including special notification requirements) for those licensees that have enough licensed material to cause significant offsite. (i.e. § 30.32i, 40.31j, and 70.22i).

28. Use the language in the supplementary information (p. 19891-column 1) in order to avoid numerous additional reporting events. Wording would be: Immediate notification is required only if #13, #19

events or conditions involving licensed material threaten an immediate disabling injury or threaten to prevent immediate protective actions necessary to protect the public health or the environment.

Response: The staff concurs with the suggestion and it has been incorporated into the final rule. See 30.50 (c)(3), 40.60 (c)(3), and 70.50 (c)(3).

29. "Threatens to prevent" is so vague that everyday events may qualify for reporting. #14, #40

Response: The requirement to notify the NRC of events that threaten to prevent actions necessary to maintain control of licensed material has been changed to a 30-day reporting requirement. This will allow licensees to consult the staff concerning what events are reportable. This change has not been made in § 20.403 because the staff believes that events that threaten to cause overexposures or releases are significant enough to warrant prompt notification of the NRC.

30. Guidance is needed concerning reports to be made by licensees when radiographers' pocket dosimeter is discharged beyond its range. #16

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

31. The time requirement may be severe and unrealistic in some cases. #24

Response: The staff 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 an event does not clearly fall outside of the notification requirements, the licensee must be conservative and report the event.

32. What is meant by "immediate protective actions"? #33

Response: Immediate protective actions are those actions necessary to maintain control of licensed material and to protect workers, the public, and the environment immediately after an incident is discovered. These actions will vary depending on the incident. These actions could include stopping releases, sounding alarms, requesting help, etc.

33. What is meant by "an event" and "necessary"? Definitions for these and other terms should be provided.

Response: These are general terms that do not require special definitions beyond what can be found in a common dictionary.

34. Question the need to immediately report events regardless of quantity and type of licensed material involved. #34

Response: The quantity and type of material will determine if immediate protective actions are necessary to protect the health and safety of the workers or the public. Events involving small quantities of material (less than the limits specified in Part 20) requiring no immediate protective actions would not be reportable. The quantity and type of licensed material is a factor to be included in the licensee's evaluation of an event.

35. Do toxic gas releases include gas releases (such as UF-6, NOx, hydrogen fluoride, etc.) that periodically occur but are contained and controlled by operating procedures need to be reported? #38

Response: Toxic gas releases would not require NRC notification as long as they did not prevent the licensee from taking immediate protective actions necessary to maintain control of licensed material. However, a notification 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).

#### 30.50b Twenty-four hour Notification

36. 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. #23

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



30.50(b)(1) Contamination

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

#1, #5,  
#8, #10,  
#18, #21,  
#22, #25,  
#33, #34,  
#37, #38,  
#39, #40

Response: The staff agrees that restricting access to allow short-lived isotopes to decay should not be a reportable event. The regulation has been revised to exempt reports of areas restricted to allow isotopes with a half-life of less than 24 hours to decay.

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

#5

Response: This rule does not attempt to define criteria for releasing areas from radiological controls. No NRC notification would be required if an accidentally contaminated area can be decontaminated within 24 hours to levels where contamination controls for entry into the area are no more stringent than the controls in effect prior to the contamination accident. The definition of an "area" is not limited to any minimum size. In general, any space normally accessible to workers or the general public qualifies as an area.

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

#8

Response: Contamination events that restrict access are spills or other types of accidents that result in elevated levels of loose surface contamination 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.

40. Area is unduly restrictive. Makes no distinction about the source of contamination or efforts to remove it. For hospitals either restrict the definition of 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.

#1, #26  
#31

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

41. Proposed regulation places 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. #12, #13

Response: The proposed notification requirements do not relieve licensees from their responsibility to maintain radiation exposures as low as reasonably achievable. The staff 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 require no notification 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 notification is warranted.

42. Requirement to notify NRC within 24 hours needs to be more quantitative. Specific levels of contamination should be stated. #20, #25 #33

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. The need to impose additional contamination controls is a better indicator of a significant event than a specific contamination level which may not be significant in all situations.

43. In the second sentence of the supplementary information under contamination events on page 19891 (column 2) delete the words, "normally present" and insert words "specified in 10 CFR 20.405". #29

Response: We suggest deleting comment 43 because the discussion for the proposed rule will not be reissued and there is no need to address the wording of that discussion. There will be a statement of consideration section in the new rule, therefore, the comment is applicable.

44. 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 radiological conditions normally present". This standard is markedly lower than the proposed standard and is inappropriate. #30

Response: The staff does not agree. Accidental contamination of work areas sufficiently above normal conditions to warrant additional contamination controls and entry requirements for more than 24 hours is significant and NRC notification is appropriate.

45. Rule should allow for planned activities such as maintenance or decommissioning that would result in restricting access. #19, #34

Response: Agree. This criteria has been revised to clarify that it applies to accidental contamination only.

46. It is not clear from the rule that restriction of access includes changing protocols such as adopting extra protective clothing. Need to provide more guidance. #33

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

47. Allow licensees to have contaminated restricted areas in excess of 24 hours provided employees are not exposed to exposures in excess of the regulatory limits and no releases are being made to unrestricted areas or the environment. #34

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

48. Change the time for loss of access from more than 24 hours to more than one working day. #40

Response: Disagree. 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.

### 30.50(b)(2) Equipment

49. Wording is not clear. Use the last paragraph on page 19891 (column 3) of the Federal Register Notice. #4

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

50. Events should not be reported unless they result in exceeding some existing limits (spillage of a few grams of natural uranium from crack in a pipe valve or drum). Either specify some limits or drop the requirement. #13, #14, #22, #2, #39

Response: The notification requirement has been clarified to indicate that the equipment must be necessary to prevent releases in excess of regulatory limits.

51. 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". #17

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

52. As currently written this section could result in large numbers of reports on the malfunction of such equipment as portable survey instruments, respirators, fire extinguishers, or even flashlights. #19

Response: The notification 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 unplanned releases exceeding regulatory limits, (2) prevent overexposures to radiation and radioactive materials, or (3) mitigate the severe consequences of an accident. Severe consequences include major property damage, widespread contamination outside of controlled area, and fatalities or serious injuries requiring medical treatment.

53. 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. #23

Response: Agree. Licensees should be realistic when they evaluate whether the function or the availability of the function of safety equipment was needed when it failed.

54. The third example on page 19892 concerning radiography equipment conflicts with the notification requirements in § 30.34. #25

Response: The staff 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 now 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.

55. 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. #28

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

56. Specify what is meant by the word "needed" and what severity or potential event does the equipment protect against? #33, #38

Response: Safety equipment is needed when a radiation hazard is present and an incident requiring the use of the safety equipment is possible. Notification is only required by the proposed rule if the safety equipment malfunctions when a radiation hazard exists. The rule has been reworded to clarify the types of events that safety equipment protect against.

57. What is meant by "uncontrolled releases of radioactive material"? #38

Response: The staff's intent was to require notification of a malfunction involving equipment necessary to prevent unplanned accidental releases exceeding regulatory limits.

58. What is meant by the words "prevent exposure to radiation and mitigate the consequences of an accident"? #38

Response: Notification is only required by the proposed rule for the malfunction of equipment necessary to prevent exposures exceeding regulatory limits for workers and the public. Equipment used to minimize exposures and not to prevent overexposures are not covered by the proposed rule. Mitigating the consequences of an accident refers to equipment necessary to minimize injuries and damage after an accident occurs. For example, sprinkler systems are necessary to mitigate the consequences of a fire.

59. 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". #38

Response: Disagree. Operative equipment only replaces inoperative equipment if it is used. If the operative redundant equipment does not go into service automatically, the safety function will be lost for some undetermined period of time.



60. Equipment failures reported under 34.30 should be exempt from this requirement since most incidents regarding radiography equipment failure are detected and resolved by the licensee usually within 24 hours. #40

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

### 30.50(b)(3) Medical Treatment

61. 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 NRC. A laceration to a lab workers hand may require sutures where the radiation component may be insignificant. Current rule would require the reporting of an event even if the medical treatment was not related to the contamination issue. #1, #15  
#27, #37

Response: 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 the injury.

62. Notification should only be required if contamination of the individual or treating medical facility exceeds NRC regulatory limit, license limit, or NRC unrestricted release limit. #13

Response: NRC believes that exposure of the general public (including medical workers) to dispersible contamination should be as low as reasonably achievable. Therefore, any detectable amount of dispersible contamination introduced into a medical facility by a contaminated person is reportable.

63. What is a radioactively contaminated individual? Need a threshold dose or contamination level criteria. #14, #27, #33

Response: A radioactively contaminated individual is a person who has loose surface contamination on their clothing or on accessible portions of their body that can be spread to other individuals.

64. Change the word "rendered" in the last sentence to the word "required." #20

Response: 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. This statement has been deleted from the final rule (see comment #65 below).

65. No notification is required for the treatment of a superficial injury at a licensee-maintained medical facility but is required for treatment of the same injury elsewhere. Why? #23, #33

Response: The staff was attempting to minimize reports of insignificant events such as a licensee technician accidentally puncturing his hand with a syringe containing a radiopharmaceutical. Although many licensee facilities have provisions for controlling the spread of contamination, the staff has reconsidered its position and decided not to exclude licensee-maintained medical facilities treating superficial wounds from this notification requirement. An individual with a superficial wound can still spread significant amounts of contamination around the medical facility. In addition, it would be unusual to have dispersible surface contamination introduced into emergency rooms or other receiving areas even in licensee-maintained facilities.

66. In addition to first aid for a superficial injury, there are other incidents of medical treatment that should not be reported (Note contact with the commenter failed to provide examples of what this other type of treatment might be). #24

Response: We suggest deleting comment 66 because no specific examples were provided.

67. 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? #38

Response: NRC has decided to require notification of any injured person introducing dispersible surface contamination into medical facilities regardless of who maintains the facility. NRC must be aware of such incidents in order to ensure that appropriate contamination controls are used and to ensure that any medical consequences caused by the contamination are properly addressed.

#### 30.50(b)(4) Fire or Explosion

68. The most common type of explosion in medical, biomedical research, and radiopharmaceutical operations is screwcap vials or stoppered test tubes containing tissue samples with only traces of radionuclides. Do these types of explosions have to be reported? #1

Response: When the proposed rule was drafted, NRC did not intend to include small vials and stoppered test tubes as explosions. NRC agrees that fire and explosions involving trace quantities of licensed material should not be reportable. The notification requirement has been revised to require no report if an explosion or fire involves licensed material in quantities less than the quantities specified in Appendix C of Part 20.

69. In the case of fires, the hazard of the fire may greatly outweigh the hazards of release. Need quantitative threshold limits for licensees.

#1, #15,  
#20, #33,  
#37

Response: We agree that the fire usually poses the greatest hazard. However, if radioactive material is involved, NRC needs to insure that appropriate controls are used during firefighting and cleanup operations. The notification requirement has been revised to specify the quantities in Appendix C of Part 20 as the reporting thresholds.

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

#23

Response: NRC agrees and the notification requirement has been revised to require no report if the fire or explosion inflicts only superficial damage. Superficial damage is defined as damage that does not affect the integrity of the licensed material or its container.

71. Paragraphs 2, 3, and 4 on page 19891, column 2, regarding fires are not clear. There is normally some delay in responding to an emergency. NRC should define the length of the delay that is reportable.

#33

Response: A normal delay in responding to an event would not be reportable such as the time to drive to the site or the time to call the fire dept. However, once the responders are available and able to do the job, any additional delay would be reportable.

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

#38

Response: A dollar figure regardless of amount is not necessarily indicative of the hazard to the public health and safety. That is only the dollar figure has been removed from the regulation.

30.50(c) Reports

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

#13



Response: There is a need for licensees to document the results of their investigation when a problem occurs. Not all incidents are investigated by NRC. Additionally when NRC does investigate an incident, its review of the details may lead to a different conclusion than that of the licensee. Licensee reports would be useful in determining what corrective actions may be needed, if any, to preclude the incident from reoccurring. #13

74. Personnel radiation exposure data may at times be difficult to obtain. #24

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

#### 40.60(b)(3) Medical Treatment.

75. Change the word "significant" in the 6th line of the Federal Register Notice (P19894) column 3 (40.60(b)(3) to "superficial." #40

Response: We suggest deleting comment 75 because there is no need to address typographical errors in the proposed rule.

76. The following nuclear criticality safety events should be included in the rule as reportable events: #27

- a. Unintended accumulation of SNM in an unfavorable geometry system.
- b. Failure of an SNM concentration monitoring instrument or a failure of a moisture detection instrument.

Response: TO BE DETERMINED

ENCLOSURE 2

Document Name:  
PART 20 FRN/COMP

Requestor's ID:  
BONSBY

Author's Name:  
MATE

Document Comments:  
CB 12/03/90 COMPARATIVE TEXT FOR PART 20 FRN

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, 936, 937, 948, as amended (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201); Secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 20.408 also issued under Secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

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

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

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

(8.) 4. The authority citation for Part 30 is revised to read as follows:

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

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

For the purposes of Sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 30.3, 30.34(b)(c) and (f), and 30.41(a) and (c), and 30.53 are issued under Sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 30.6, 30.9, 30.36, 30.50, 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)).

(4) 5. Section 30.8(b) is revised to read as follows:

§ 30.8(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.

(5.) 6. A new § 30.50 under Records, Inspections, Tests, and Reports is added to read as follows:

§ 30.50 Notification requirements.

(a) Immediate notification. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after the discovery of any event involving licensed material that prevents ~~(or threaten to prevent)~~ immediate protective actions necessary to ~~(maintain and verify control)~~ avoid an over-exposure or release of licensed material (includes fires, explosions, toxic gas releases, etc.).

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

(1) Any ~~(accidental)~~ unplanned contamination event that ~~(restricts)~~ requires access to the contaminated area by workers or the public to be restricted by imposing additional contamination controls, or prohibiting entry into the area for more than 24 hours. No report is required if access to the area is restricted to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) Any event in which equipment ~~(necessary to prevent uncontrolled releases of radioactive material; or to prevent overexposure to radiation, or to mitigate the consequences of an accident; is disabled or fails to function as designed when it is needed;--Notification is not required when an individual component is disabled or fails to function if redundant equipment is operable and available to automatically perform the required function)~~ is disabled or fails to function as designed when:

(i) the equipment is required to prevent (uncontrolled) unplanned releases exceeding regulatory limits, to prevent overexposures to radiation and radioactive materials, or to mitigate the severe consequences of an accident, and

(ii) ~~(the safety function of)~~ the equipment is required to be



available and operable - (~~or the availability of the safety function is required~~) when the normal equipment (~~is~~) was disabled or fails to function, and

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

(3) Any event that requires medical treatment (~~of a radioactively contaminated individual~~) at a medical facility of an individual with spreadable radioactive contamination on their clothing or on accessible portions of their body. (~~note the exemption for superficial injury has been deleted~~).

~~(Notification is not required if first aid at a licensee maintained medical facility for a superficial injury is the only treatment rendered).~~

(4) Any accidental fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material in quantities greater than the limits specified in Appendix C of Part 20. No report is required for superficial damage (i.e., surface stains that do not affect the integrity of the licensed material or its container).

(c) Preparation and submission of reports. Reports filed with the NRC pursuant to this section must have the names of persons who have received exposure to radiation stated in a separate part of the report. 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.<sup>1</sup> To the extent that the information is available at the time of notification, the information provided in these reports must include:

<sup>1</sup> The commercial telephone number for the NRC Operations Center is (301) ~~(202)~~ 951-0550.

- (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.



(3) A written report shall be submitted within 30 days of the occurrence of any event involving licensed material that (~~threatens-to~~) could have caused an immediate disabling injury or (~~threatens-to~~) could have prevented immediate protective actions necessary to maintain control of the licensed material.

(3) (4) The provisions of § 30.50 do not apply to Licensees subject to the notification requirements in § 50.72. They do apply to research and test reactors possessing material licensed under Part 30.

#### PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

7. Section 31.2 (a) is revised to read as follows:

§31.2 (a) The general licenses provided in this part are subject to the provision of §§ 30.14(d), 30.34(a) to (e), 30.41, 30.50 to 30.63 and Parts 19, 20, and 21...

8. Section 31.8(c) is revised to read as follows:

§31.8 (c) The general licenses in paragraph (a) of this section is subject to the provisions of §§ 30.14(d), 30.34(a) to (e), 30.50 to 30.63 of this chapter, and to the provisions of Parts 19, 20, and 21...

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

9. Section 34.30 is revised to read as follows:

§ 34.30 In addition to the notification and reporting specified in § 30.50 and other sections of this chapter...

PART 39 - LICENSES AND RADIATION SAFETY REQUIREMENTS FOR  
WELL LOGGING

10. Section 39.77(b)(2) is revised to read as follows:

§ 39.77(b)(2) The licensee shall notify the Commission of the theft or loss of radioactive materials, radiation overexposures, excessive levels and concentrations of radiation, and certain other accidents as required by §§ 20.402, 20.403, 20.405, and 30.50 of this chapter.

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

(6.) 11. 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(h) 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. 2271(o)).

(7.) 12. Section 40.8(b) is revised to read as follows:

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

13. Section 40.26(c)(1) is revised to read as follows:

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

(8.) 14. A new § 40.60 under Records, Inspections, Tests and Reports is added to read as follows:

§ 40.60 Notification requirements.

(a) Immediate notification. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after discovery of any event involving licensed material that prevents ~~(or threaten to prevent)~~ immediate protective actions necessary to ~~(maintain and verify control)~~ avoid an overexposure or release of licensed material (includes fires, explosions, toxic gas releases, etc.).

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

(1) Any ~~(accidental)~~ unplanned contamination event that ~~(restricts)~~ requires access to the contaminated area by workers or the public to be restricted by imposing additional contamination controls or by prohibiting entry into the area for more than 24 hours.

(2) Any event in which equipment ~~(necessary to prevent uncontrolled releases of radioactive material; or to prevent overexposure to radiation, or to mitigate the consequences of an accident; is disabled or fails to function as designed when it is needed;--Notification is not required when an individual component is disabled or fails to function if redundant equipment is operable and available to automatically perform the required function)~~ is disabled or fails to function as designed when:

(i) the equipment is required to prevent (uncontrolled) unplanned releases exceeding regulatory limits, to prevent overexposures to radiation and radioactive materials, or to mitigate the severe consequences of an accident, and

(ii) ~~(the safety function of)~~ the equipment is required to be available and operable ~~(--or the availability of the safety function--is required)~~ when the normal equipment (is) was disabled or fails to function, and

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

(3) Any event that requires medical treatment ~~(of a radioactively contaminated individual)~~ at a medical facility of an individual with spreadable radioactive contamination on their clothing or on accessible portions of their body. ~~(note the exemption for superficial injury has been deleted).~~  
~~(Notification is not required if first aid at a licensee maintained medical facility for a superficial injury is the only treatment rendered.~~

(4) Any accidental fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material in quantities greater than the limits specified in Appendix C of Part 20. No report is required for superficial damage (i.e., surface stains that do not affect the integrity of the licensed material or its container).

(c) Preparation and submission of reports. Reports filed with the NRC pursuant to this section must have the names of persons who have received exposure to radiation stated in a separate part of the report. 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.<sup>2</sup> 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;

<sup>2</sup> The commercial telephone number for the NRC Operations Center is (301) (202) 951-0550.

- (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.

(3) A written report shall be submitted within 30 days of the occurrence of any event involving licensed material that (threatens-to) could have caused



an immediate disabling injury or (threatens-to) could have prevented immediate protective actions necessary to maintain control of the licensed material.

(3) (4) The provisions of § 40.60 do not apply to licensees subject to the notification requirements in § 50.72. They do apply to research and test reactors possessing material under Part 40.

#### PART 70 - DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

15. The authority citation for Part 70 is revised to read as follows:  
AUTHORITY: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, Sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282); Secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246, (42 U.S.C. 5841, 5842, 5845, 5846).

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

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

(c), (d), (e), and (g), 70.36, 70.51(c)-(g), 70.56, 70.57(b) and (d), and 70.58 (a)-(g) (3) and (h)-(j) are issued under Sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 70.5, 70.9, 70.20b(d) and (e), 70.38, 70.51(b) and (i) 70.50, 70.52, 70.53, 70.54, 70.55, 70.58 (g)(4), (k), and (l), 70.59, and 70.60(b) and (c) are issued under Sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

16. Section 70.8(b) is revised to read as follows:

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

17. Section 70.19(c) is revised to read as follows:

§ 70.19(c) The general license in paragraph (a) of this section is subject to the provisions of §§ 70.32, 70.50, 70.51, 70.52, 70.55, 70.56, 70.61, 70.62, and 70.71, and to the provisions of Parts 19, 20 and 21 of this chapter. In addition, persons who receive title to, own, acquire, deliver, receive, possess, use or transfer one or more calibration or reference sources pursuant to this general license:

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

§ 70.50 Notification requirements.

(a) Immediate notification. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after discovery of any event involving licensed material that prevents ~~(or-threaten-to-prevent)~~ immediate protective actions necessary to ~~(maintain-and-verify-control)~~ avoid an over exposure or release of licensed material (includes fires, explosions, toxic gas releases, etc.).



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

(1) Any ~~(accidental)~~ unplanned contamination event that ~~(restricts)~~ requires access to the contaminated area by workers or the public to be restricted by imposing additional contamination controls, or prohibiting entry into the area for more than 24 hours.

(2) Any event in which equipment ~~(necessary-to-prevent-uncontrolled releases-of-radioactive-material;-or-to-prevent-overexposure-to-radiation, or to-mitigate-the-consequences-of-an-accident;-is-disabled-or-fails to function-as-designed-when-it-is needed;--Notification-is-not-required-when-an individual-component-is-disabled-or-fails-to-function-if-redundant-equipment-is operable-and-available-to-automatically-perform-the-required-function)~~ is disabled or fails to function as designed when:

(i) the equipment is required to prevent (uncontrolled) unplanned releases exceeding regulatory limits, to prevent overexposures to radiation and radioactive materials, or to mitigate the severe consequences of an accident, and

(ii) (the-safety-function-of) the equipment is required to be available and operable - (or-the-availability-of-the-safety-function-is-required) when the normal equipment (is) was disabled or fails to function, and

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

(3) Any event that requires medical treatment ~~(of-a-radioactively contaminated-individual)~~ at a medical facility of an individual with spreadable radioactive contamination on their clothing or on accessible portions of their body. ~~(note-the-exemption-for-superficial-injury-has-been-deleted).~~

~~(Notification is not required if first aid at a licensee maintained medical facility for a superficial injury is the only treatment rendered.~~

(4) Any accidental fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material in quantities greater than the limits specified in Appendix C of Part 20. No report is required for superficial damage (i.e., surface stains that do not affect the integrity of the licensed material or its container).

(c) Preparation and submission of reports. Reports filed with the NRC pursuant to this section must have the names of persons who have received exposure to radiation stated in a separate part of the report. 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.<sup>3</sup> 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 a written followup report within 30 days of the initial report. Written reports prepared pursuant to

<sup>3</sup> The commercial telephone number for the NRC Operations Center is (301) (202) 951-0550.

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.

(3) A written report shall be submitted within 30 days of the occurrence of any event involving licensed material that (~~threatens-to~~) could have caused an immediate disabling injury or (~~threatens-to~~) could have prevented immediate protective actions necessary to maintain control of the licensed material.

(3)(4) The provisions of § 70.50 do not apply to licensees subject to the notification requirements in § 50.72. They do apply to research and test reactors possessing material licensed under Part 70.

Dated at Rockville, Maryland this \_\_\_\_\_ day of \_\_\_\_\_ 1990.

For the Nuclear Regulatory Commission.

---

James M. Taylor, Executive Director  
for Operations.

# ROUTING AND TRANSMITTAL SLIP

Date

12-12-90

TO: (Name, office symbol, room number,  
building, Agency/Post)

Initials

Date

1. JOE MATE

2.

3.

4.

5.

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

DO NOT use this form as a RECORD of approvals, concurrences, disposals,  
clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)

Room No.—Bldg.

MIKE FINKELSTEIN

Phone No.

5041-102

U.S.GPO:1985-0-491-247/20041

OPTIONAL FORM 41 (Rev. 7-75)

Prescribed by GSA  
FPMR (41 CFR) 101-11.206





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

16 F 17  
AC 91-1  
PDR

DEC 05 1990

MEMORANDUM FOR: John Hickey, Chief, Operations Branch, Division of Industrial  
and Medical Nuclear Safety, NMSS

FROM: Sher Bahadur, Chief, Regulation Development Branch, Division  
of Regulatory Applications, RES

SUBJECT: PUBLIC COMMENTS ON AMENDMENTS TO 10 CFR PART 20.403

Attached per conversation of November 27, 1990 between Cheryl Trottier (NMSS) and Joe Mate (RES) is a revised set of public comments and responses as well as the revised comparative text of the final rule. These two packages include comments from NRR, AEOD, OGC, OE, (partial), NMSS and State Programs.

We intend to delete comments 9, 33, 43, 66, and 75 from the general comments material provided. Comment #76 still requires input from NMSS.

As agreed, we are awaiting your input for the statement of considerations which will be incorporated into the Federal Register notice. Please review the attached material and provide your final comments and the text for the statement of considerations. In order to meet our schedule, we need your comments by December 12th. If you have any questions, please call Joe Mate at 23795.

Sher Bahadur, Chief  
Regulations Development Branch  
Division of Regulatory Applications  
Office of Nuclear Regulatory Research

Enclosures:

1. Public Comments
2. FRN (comparative text)

cc: Mike Finkelstein, USC ✓  
Kevin Ramsey, IMOE, NMSS

OGC COMMENTS

12-13-90

P.M.

9501170016

ENCLOSURE 1

October 9, 1990

General Comments

Comment

Commenter

1. 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 components. Licensees need clear cut definitions that specify severity levels requiring notification like those currently in 20.403 (a)(1) and (a)(2) and (b)(1) and (b)(2).

#1, #3,  
#12, #13,  
#14, #15,  
#20, #27,  
#33, #38  
#40

Response: We agree that there is a need to make the criteria in the proposed rule more specific. The revisions to the final rule reflect this intent to make the rule more specific relative to the criteria.

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

#4, #37  
#38

Response: In developing the revised criteria for the proposed rule the staff considered the possibility of revising Part 20 rather than establishing criteria in Parts 30, 40, and 70. To make such changes, however, would conflict with well established reporting requirements in Part 50 and would require the revision of these requirements. Therefore, the changes were made in Parts 30, 40, and 70.

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

#5, #14  
#20, #33

Response: The staff agrees that writing new rules in itself provides no assurance that licensees will comply with them. In developing the proposed criteria, there was broad staff consensus that better criteria was needed to reduce confusion and disagreements over what types of events should be promptly reported to NRC. Although a few specific cases initiated the rulemaking effort, it was the general consensus that motivated the staff to redefine what types of events warranted prompt NRC notification.

4. Rule is prescriptive and eliminates need for licensee judgment. #5

Response: The staff does not feel that the revised rule is too prescriptive. NRC must consider and review events from all

types of licensees. Material licensees do not all consistently view events in the same manner as the staff. Hence, there is a need for a rule that is somewhat prescriptive yet leaves room for judgment on the part of the licensee.

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

#5, #7  
#16, #18  
#33

Response: In developing the proposed rule the staff considered the idea of providing specific activity thresholds. However, the staff felt that such thresholds would be cumbersome and difficult to develop and use. Many licensed operations use mixtures of isotopes in different chemical forms that pose various safety hazards. The staff 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 staff 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 explosion involving licensed material in quantities greater than the quantities specified in Appendix C of Part 20.

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

#10, #13,  
#18, #23,  
#25, #31  
#33, #37  
#38

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

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

#10, #30

Response: If the NRC were to place individual reporting requirements in the individual licenses, this task would take a tremendous amount of time and effort to complete. There are more than 9,000 material licensees that fall under the purview of NRC. It would be difficult to maintain consistency with the reporting criteria specified in so many locations. The staff does not consider this to be a practical solution.

8. Proposed parts should be rewritten and reissued for a new comment period. Counterproductive to strong licensee programs.

#10, #14

REVISED  
WORDS

Question #7 Response.

Generic reporting requirements are best implemented by formal rulemaking procedures, including notice and comment. Placing the same reporting requirements in individual licenses lacks efficiency, reliability, and openness. Public notice and comment allows for comments that question the reporting requirements themselves and allows the staff to respond to such comments. Placing the requirements in individual licenses does not allow for such a healthy dialogue.



#8 Response

The staff believes that changes made to the proposed rule to incorporate the listed comments are of a nature that does not necessitate the resumption of another proposed rule and a new comment period.

Response: NRC did consider alternatives such as those mentioned by the commenters. However, there was general agreement among the staff that certain sections in the regulation 20.403 needed to be replaced with better reporting criteria. A rulemaking action is the only appropriate process to accomplish this action.

*is the best procedure for accomplishing this goal.*

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

#14, #20

Response: The staff did not intend to draw a parallel to power reactor licensees when Part 50 regulations were cited in the discussion. The staff was merely trying to point 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.

12. 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 NRC immediately.

#15

Response: The staff does not agree that the rule is counter productive to strong licensee programs because the staff does not agree with the view that notification requirements are "penalties" that must be paid by licensees. By improving notification requirements, NRC is in a better position to assure proper response, to identify generic problems, and to notify other licensees of generic problems. Sharing knowledge and experience serves to strengthen licensee programs.

9. Lack of communication with inspectors or other NRC staff. General information calls no longer taken in the afternoons. Enables misunderstandings and questions to become problems.

Response: Comment 9 should be deleted. Region III has determined that the commenter called once (4 years ago), got a recording, and never called back. This appears to be a one-time occurrence that does warrant a response. Comment should be deleted.

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

#21, #33

Response: NRC did consider alternatives such as those mentioned by the commenters. However, there was general agreement among the staff that certain sections in the regulation 20.403 needed to be replaced with better reporting criteria. A rulemaking action is the only appropriate process to accomplish this action.

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
#15

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 the prompt notification of the NRC.

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

#15

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.



14. What does "threatens to cause" mean in Part 20.403?

#27

Response: The phrase "threatens to cause" refers to events that come very close to occurring, but are narrowly averted. The NRC requires notification of such "close calls" to allow preventative measures to be implemented before an incident occurs.

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

#22, #36  
#39

Response: The NRC does not intend for the proposed criteria to apply to commercial nuclear power plants. In the discussion as well as in the the rule (Parts 30.50 (c)(3), 40.60 (c)(3), and 70.50 (c)(3)), the NRC specifically stated that the provisions do not apply to licensees subject to the notification requirements in Section 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, these provisions doe not constitute requirements for reporting in accordance with the new notification requirements in Parts 30, 40, or 70. 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.

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16. NRC should provide clear guidance on their interpretation by circulating early event reports with comments on the appropriateness and by providing comparable early analysis of failures to report. #23, #33

Response: The staff 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.

17. NRC should more clearly define the notification requirements concerning the loss of packages of radioactive material. #25

Response: This rulemaking effort involves the notification requirements in 20.403. The loss of packages of radioactive material is covered by 20.402. The loss of radioactive material is outside the scope of this rulemaking effort. Notification requirements for the loss and theft of licensed material will be revised by the major revision to Part 20. The major revision will specify what quantities of licensed material require immediate and 30 day notifications.

18. Burden is estimated to be about 3 days for each notification required for large companies. #27

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

19. The subject rule and statement of considerations should make it clear that the rule would apply to uranium enrichment plants whether licensed under Part 70 or Part 76. Further, Part 50.72 and 50.73 should not apply to such facilities. #29, #30

Response: The question of whether or not enrichment plants should fall under Part 70 or Part 50 is not within the scope of this rule. Currently there are no licensed enrichment plants. The regulations that should govern these plants is a licensing issue that will be decided when a license is requested and issued to operate an enrichment plant.

20. Immediate and 24 hour notifications should be limited to potentially serious events where it is necessary for NRC to intervene to mitigate the effects. #33, #38

Response: It is not the policy of the NRC to intervene when the licensee is having a problem. The problem is to be solved by the licensee. NRC monitors the licensee's actions, makes



recommendations, and only intervenes if the licensee is unable or unwilling to take the necessary action to protect public health and safety or the environment. Whether or not the NRC intervenes, it must be aware of significant events to ensure that appropriate actions are taken.

21. We do not agree that the categorical exclusions have been met. The proposed regulation as written has a large impact and cannot be considered to be of a minor nature. #33

Response: The staff 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 staff maintains that the proposed rule is a clarification of existing requirements and does not change the NRC's policy that licensees should promptly report significant events. In addition, it is clear that § 51.22(c)(3) lists amendments to reporting requirements in Parts 30, 40, and 70 as categorical exclusions not requiring an environmental review.

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

Response: The staff believes that the proposed notification requirements describe significant events that should be reported for source, byproduct, and special nuclear material licensees. The staff does not agree that developing more specialized requirements and amending more Parts of the regulations would improve the rule.

23. Frequent use of the word "any" is not consistent with the stated intent of "significant occurrences". #38

Response: The text of each notification requirement defines the event to be reported. The staff does not agree that using the word "any" is inconsistent with the staff's intent to require NRC notification of significant events.

24. Proposed rule should make it clear that it applies to Independent Spent fuel storage facilities. #29

Response: The staff agrees that it would be appropriate to add the proposed notification requirements of Part 72 and intends to initiate a separate rulemaking effort in order to allow public comment on amending that part of the regulations. ✓

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

Response: The fact that the licensee has completed all necessary actions before NRC is notified is no reason not to file a report. There may still be some action that NRC may have to take depending on the nature of the incident. (i.e. warning other licensees of generic problems).

26. Provide further explanation and possibly examples of what securing the material and assessing releases means. (Used in the discussion). #38

Response: Securing material includes actions necessary to prevent unauthorized movement of licensed material or unsafe conditions resulting from licensed material. This includes shielding exposed radiation sources, returning licensed material to storage containers, stopping a spill or the spreading of a spill, etc. Assessing releases includes efforts necessary to determine how much licensed material has escaped from the licensee's control and to determine where released material has gone.

#### Comments on the Actual Rule

#### 30.50 Notification Requirements.

##### 30.50a Immediate Notification.

27. Require one hour notification of NRC and Agreement States for incidents with substantial potential for injury to off site people. Suggest 5 rem for one hour notification. #2

Response: There are already regulations that require emergency response plans (including special notification requirements) for those licensees that have enough licensed material to cause significant doses offsite. (i.e. § 30.32i, 40.31j, and 70.22i).

28. Use the language in the supplementary information (p. 19891-column 1) in order to avoid numerous additional reporting events. Wording would be: Immediate notification is required only if #13, #19

events or conditions involving licensed material threaten an immediate disabling injury or threaten to prevent immediate protective actions necessary to protect the public health or the environment.

Response: The staff concurs with the suggestion and it has been incorporated into the final rule. See 30.50 (c)(3), 40.60 (c)(3), and 70.50 (c)(3).

29. "Threatens to prevent" is so vague that everyday events may qualify for reporting.

#14, #40

Response: The requirement to notify the NRC of events that threaten to prevent actions necessary to maintain control of licensed material has been changed to a 30-day reporting requirement. This will allow licensees to consult the staff concerning what events are reportable. This change has not been made in § 20.403 because the staff believes that events that threaten to cause overexposures or releases are significant enough to warrant prompt notification of the NRC.

*threatens to prevent still too vague to enforce.*

30. Guidance is needed concerning reports to be made by licensees when radiographers' pocket dosimeter is discharged beyond its range.

#16

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

31. The time requirement may be severe and unrealistic in some cases.

#24

Response: The staff 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 an event does not clearly fall outside of the notification requirements, the licensee must be conservative and report the event.

32. What is meant by "immediate protective actions"?

#33

*define in the rule*

Response: Immediate protective actions are those actions necessary to maintain control of licensed material and to protect workers, the public, and the environment immediately after an incident is discovered. These actions will vary depending on the incident. These actions could include stopping releases, sounding alarms, requesting help, etc.

33. What is meant by "an event" and "necessary"? Definitions for these and other terms should be provided.

Response: These are general terms that do not require special definitions beyond what can be found in a common dictionary.

34. Question the need to immediately report events regardless of quantity and type of licensed material involved. #34

Response: The quantity and type of material will determine if immediate protective actions are necessary to protect the health and safety of the workers or the public. Events involving small quantities of material (less than the limits specified in Part 20) requiring no immediate protective actions would not be reportable. The quantity and type of licensed material is a factor to be included in the licensee's evaluation of an event.

35. Do toxic gas releases include gas releases (such as UF-6, NOx, hydrogen fluoride, etc.) that periodically occur but are contained and controlled by operating procedures need to be reported? #38

Response: Toxic gas releases would not require NRC notification as long as they did not prevent the licensee from taking immediate protective actions necessary to maintain control of licensed material. However, a notification 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).

#### 30.50b Twenty-four hour Notification

36. 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. #23

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

30.50(b)(1) Contamination

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

#1, #5,  
#8, #10,  
#18, #21,  
#22, #25,  
#33, #34,  
#7, #38,  
#39, #40

Response: The staff agrees that restricting access to allow short-lived isotopes to decay should not be a reportable event. The regulation has been revised to exempt reports of areas restricted to allow isotopes with a half-life of less than 24 hours to decay.

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

#5

Response: This rule does not attempt to define criteria for releasing areas from radiological controls. No NRC notification would be required if an accidentally contaminated area can be decontaminated within 24 hours to levels where contamination controls for entry into the area are no more stringent than the controls in effect prior to the contamination accident. The definition of an "area" is not limited to any minimum size. In general, any space normally accessible to workers or the general public qualifies as an area.

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

#8

Response: Contamination events that restrict access are spills or other types of accidents that result in elevated levels of loose surface contamination 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.

40. Area is unduly restrictive. Makes no distinction about the source of contamination or efforts to remove it. For hospitals either restrict the definition of 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.

#11, #26  
#31



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

41. Proposed regulation places 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. #12, #13

Response: The proposed notification requirements do not relieve licensees from their responsibility to maintain radiation exposures as low as reasonably achievable. The staff 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 require no notification 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 notification is warranted.

42. Requirement to notify NRC within 24 hours needs to be more quantitative. Specific levels of contamination should be stated. #20, #25 #33

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. The need to impose additional contamination controls is a better indicator of a significant event than a specific contamination level which may not be significant in all situations.

~~43. In the second sentence of the supplementary information under contamination events on page 19891 (column 2) delete the words, "normally present" and insert words "specified in 10 CFR 20.405".~~ #29

Response: We suggest deleting comment 43 because the discussion for the proposed rule will not be reissued and there is no need to address the wording of that discussion. There will be a statement of consideration section in the new rule, therefore, the comment is applicable.

44. 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 radiological conditions normally present". This standard is markedly lower than the proposed standard and is inappropriate. #30

Response: The staff does not agree. Accidental contamination of work areas sufficiently above normal conditions to warrant additional contamination controls and entry requirements for more than 24 hours is significant and NRC notification is appropriate.

45. Rule should allow for planned activities such as maintenance or decommissioning that would result in restricting access. #19, #34

Response: Agree. This criteria has been revised to clarify that it applies to accidental contamination only.

46. It is not clear from the rule that restriction of access includes changing protocols such as adopting extra protective clothing. Need to provide more guidance. #33

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

47. Allow licensees to have contaminated restricted areas in excess of 24 hours provided employees are not exposed to exposures in excess of the regulatory limits and no releases are being made to unrestricted areas or the environment. #34

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

48. Change the time for loss of access from more than 24 hours to more than one working day. #40

Response: Disagree. 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.

### 30.50(b)(2) Equipment

49. Wording is not clear. Use the last paragraph on page 19891 (column 3) of the Federal Register Notice. #4

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



50. Events should not be reported unless they result in exceeding some existing limits (spillage of a few grams of natural uranium from crack in a pipe valve or drum). Either specify some limits or drop the requirement. #13, #14, #22, #32, #39

Response: The notification requirement has been clarified to indicate that the equipment must be necessary to prevent releases in excess of regulatory limits.

51. 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". #17

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

52. As currently written this section could result in large numbers of reports on the malfunction of such equipment as portable survey instruments, respirators, fire extinguishers, or even flashlights. #19

Response: The notification 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 unplanned releases exceeding regulatory limits, (2) prevent overexposures to radiation and radioactive materials, or (3) mitigate the severe consequences of an accident. Severe consequences include major property damage, widespread contamination outside of controlled area, and fatalities or serious injuries requiring medical treatment.

53. 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. #23

Response: Agree. Licensees should be realistic when they evaluate whether the function or the availability of the function of safety equipment was needed when it failed.

54. The third example on page 19892 concerning radiography equipment conflicts with the notification requirements in § 30.34. #25

Response: The staff 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 now 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.

55. 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. #28

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

56. Specify what is meant by the word "needed" and what severity or potential event does the equipment protect against? #33, #38

Response: Safety equipment is needed when a radiation hazard is present and an incident requiring the use of the safety equipment is possible. Notification is only required by the proposed rule if the safety equipment malfunctions when a radiation hazard exists. The rule has been reworded to clarify the types of events that safety equipment protect against.

57. What is meant by "uncontrolled releases of radioactive material"? #38

Response: The staff's intent was to require notification of a malfunction involving equipment necessary to prevent unplanned accidental releases exceeding regulatory limits.

58. What is meant by the words "prevent exposure to radiation and mitigate the consequences of an accident"? #38

Response: Notification is only required by the proposed rule for the malfunction of equipment necessary to prevent exposures exceeding regulatory limits for workers and the public. Equipment used to minimize exposures and not to prevent overexposures are not covered by the proposed rule. Mitigating the consequences of an accident refers to equipment necessary to minimize injuries and damage after an accident occurs. For example, sprinkler systems are necessary to mitigate the consequences of a fire.

59. 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". #38

Response: Disagree. Operative equipment only replaces inoperative equipment if it is used. If the operative redundant equipment does not go into service automatically, the safety function will be lost for some undetermined period of time.

60. Equipment failures reported under 34.30 should be exempt from this requirement since most incidents regarding radiography equipment failure are detected and resolved by the licensee usually within 24 hours. #40

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

### 30.50(b)(3) Medical Treatment

61. 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 NRC. A laceration to a lab workers hand may require sutures where the radiation component may be insignificant. Current rule would require the reporting of an event even if the medical treatment was not related to the contamination issue. #1, #15  
#27, #37

Response: 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 the injury.

62. Notification should only be required if contamination of the individual or treating medical facility exceeds NRC regulatory limit, license limit, or NRC unrestricted release limit. #13

Response: NRC believes that exposure of the general public (including medical workers) to dispersible contamination should be as low as reasonably achievable. Therefore, any detectable amount of dispersible contamination introduced into a medical facility by an injured person is reportable.

63. What is a radioactively contaminated individual? Need a threshold dose or contamination level criteria. #14, #27, #33

Response: A radioactively contaminated individual is a person who has loose surface contamination on their clothing or on accessible portions of their body that can be spread to other individuals.

64. Change the word "rendered" in the last sentence to the word "required." #20

Response: 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. This statement has been deleted from the final rule (see comment #65 below).

65. No notification is required for the treatment of a superficial injury at a licensee-maintained medical facility but is required for treatment of the same injury elsewhere. Why?

#23, #33

Response: The staff was attempting to minimize reports of insignificant events such as a licensee technician accidentally puncturing his hand with a syringe containing a radiopharmaceutical. Although many licensee facilities have provisions for controlling the spread of contamination, the staff has reconsidered its position and decided not to exclude licensee-maintained medical facilities treating superficial wounds from this notification requirement. An individual with a superficial wound can still spread significant amounts of contamination around the medical facility. In addition, it would be unusual to have dispersible surface contamination introduced into emergency rooms or other receiving areas even in licensee-maintained facilities.

66. In addition to first aid for a superficial injury, there are other incidents of medical treatment that should not be reported (Note contact with the commenter failed to provide examples of what other type of treatment might be).

#24

Response: We suggest deleting comment 66 because no specific examples were provided.

67. 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?

#38

Response: NRC has decided to require notification of any injured person introducing dispersible surface contamination into medical facilities regardless of who maintains the facility. NRC must be aware of such incidents in order to ensure that appropriate contamination controls are used and to ensure that any medical consequences caused by the contamination are properly addressed.

#### 30.50(b)(4) Fire or Explosion

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

#1

Response: When the proposed rule was drafted, NRC did not intend to include small vials and stoppered test tubes as explosions. NRC agrees that fire and explosions involving trace quantities of licensed material should not be reportable. The notification requirement has been revised to require no report if an explosion or fire involves licensed material in quantities less than the quantities specified in Appendix C of Part 20.

69. In the case of fires, the hazard of the fire may greatly outweigh the hazards of release. Need quantitative threshold limits for licensees.

#1, #15,  
#20, #33,  
#37

Response: We agree that the fire usually poses the greatest hazard. However, if radioactive material is involved, NRC needs to insure that appropriate controls are used during firefighting and cleanup operations. The notification requirement has been revised to specify the quantities in Appendix C of Part 20 as the reporting thresholds.

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

#23

Response: NRC agrees and the notification requirement has been revised to require no report if the fire or explosion inflicts only superficial damage. Superficial damage is defined as damage that does not affect the integrity of the licensed material or its container.

71. Paragraphs 2, 3, and 4 on page 19891, column 2, regarding fires are not clear. There is normally some delay in responding to an emergency. NRC should define the length of the delay that is reportable.

#33

Response: A normal delay in responding to an event would not be reportable such as the time to drive to the site or the time to call the fire dept. However, once the responders are available and able to do the job, any additional delay would be reportable.

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

#38

Response: A dollar figure regardless of amount is not necessarily indicative of the hazard to the public health and safety. ~~That is~~  
~~only~~ The dollar figure has been removed from the regulation.



#### 30.50(c) Reports

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

#13

Response: There is a need for licensees to document the results of their investigation when a problem occurs. Not all incidents are investigated by NRC. Additionally when NRC does investigate an incident, its review of the details may lead to a different conclusion than that of the licensee. Licensee reports would be useful in determining what corrective actions may be needed, if any, to preclude the incident from reoccurring. #13

74. Personnel radiation exposure data may at times be difficult to obtain. #24

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

*to the licensee*

40.60(b)(3) Medical Treatment.

~~75. Change the word "significant" in the 6th line of the Federal Register Notice (P19894) column 3 (40.60(b)(3)) to "superficial." #40~~

Response: We suggest deleting comment 75 because there is no need to address typographical errors in the proposed rule.

76. The following nuclear criticality safety events should be included in the rule as reportable events: #27

- a. Unintended accumulation of SNM in an unfavorable geometry system.
- b. Failure of an SNM concentration monitoring instrument or a failure of a moisture detection instrument.

Response: TO BE DETERMINED

*not to be included under the category medical*

ENCLOSURE 2

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, 936, 937, 948, as amended (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201); Secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 20.408 also issued under Secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

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

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



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

(8.) 4. The authority citation for Part 30 is revised to read as follows:

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

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

For the purposes of Sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 30.3, 30.34(b)(c) and (f), and 30.41(a) and (c), and 30.53 are issued under Sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 30.6, 30.9, 30.36, 30.50, 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)).

(4) 5. Section 30.8(b) is revised to read as follows:

§ 30.8(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.

(5.) 6. A new § 30.50 under Records, Inspections, Tests, and Reports is added to read as follows:

necessary to maintain control of licensed material and to protect workers, the public, and the environment immediately after an incident is discovered.

§ 30.50 Notification requirements.

(a) Immediate notification. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after the discovery of any event involving licensed material that prevents (or-threaten-to-prevent) immediate protective actions necessary to (maintain-and-verify-control) avoid an over-exposure or release of licensed material (includes fires, explosions, toxic gas releases, etc.). *Immediate protective action are those actions*

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

(1) Any (accidental) unplanned contamination event that (restricts) requires access to the contaminated area by workers or the public to be restricted by improving additional contamination controls, or prohibiting entry into the area for more than 24 hours. No report is required if access to the area is restricted to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) Any event in which equipment (necessary-to-prevent-uncontrolled releases-of-radioactive-material;-or-to-prevent-overexposure-to-radiation, or to-mitigate-the-consequences-of-an-accident;-is-disabled-or-fails to function-as-designed-when-it-is needed;-Notification-is-not-required-when-an individual-component-is-disabled-or-fails-to-function-if-redundant-equipment-is operable-and-available-to-automatically-perform-the-required-function) is disabled or fails to function as designed when:

(i) the equipment is required to prevent (uncontrolled) unplanned releases exceeding regulatory limits, to prevent overexposures to radiation and radioactive materials, or to mitigate the severe consequences of an accident, and

(ii) (the-safety-function-of) the equipment is required to be

available and operable - (if the availability of the safety function is required) when the ~~normal~~ equipment (if) was disabled or fails to function, and

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

(3) Any event that requires medical treatment ~~(of a radioactively contaminated individual)~~ at a medical facility of an individual with spreadable radioactive contamination on their clothing or on accessible portions of their body. (note the exemption for superficial injury has been deleted).  
~~(Notification is not required if first aid at a licensee maintained medical facility for a superficial injury is the only treatment rendered).~~

(4) Any accidental fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material in quantities greater than the limits specified in Appendix C of Part 20. No report is required for superficial damage (i.e., surface stains that do not affect the integrity of the licensed material or its container).

(c) Preparation and submission of reports. Reports filed with the NRC pursuant to this section must have the names of persons who have received exposure to radiation stated in a separate part of the report. 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.<sup>1</sup> To the extent that the information is available at the time of notification, the information provided in these reports must include:

<sup>1</sup> The commercial telephone number for the NRC Operations Center is (301) (202) 951-0550.

- (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.

(3) A written report shall be submitted within 30 days of the occurrence of any event involving licensed material that (threatens-to) could have caused an immediate disabling injury or (threatens-to) could have prevented immediate protective actions necessary to maintain control of the licensed material.

(3) (4) The provisions of § 30.50 do not apply to Licensees subject to the notification requirements in § 50.72. They do apply to research and test reactors possessing material licensed under Part 30.

#### PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL.

7. Section 31.2 (a) is revised to read as follows:

§31.2 (a) The general licenses provided in this part are subject to the provision of §§ 30.14(d), 30.34(a) to (e), 30.41, 30.50 to 30.63 and Parts 19, 20, and 21...

8. Section 31.8(c) is revised to read as follows:

§31.8 (c) The general licenses in paragraph (a) of this section is subject to the provisions of §§ 30.14(d), 30.34(a) to (e), 30.50 to 30.63 of this chapter, and to the provisions of Parts 19, 20, and 21...

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

9. Section 34.30 is revised to read as follows:



§ 34.30 In addition to the notification and reporting specified in § 30.50 and other sections of this chapter...

PART 39 - LICENSES AND RADIATION SAFETY REQUIREMENTS FOR  
WELL LOGGING

10. Section 39.77(b)(2) is revised to read as follows:

§ 39.77(b)(2) The licensee shall notify the Commission of the theft or loss of radioactive materials, radiation overexposures, excessive levels and concentrations of radiation, and certain other accidents as required by §§ 20.402, 20.403, 20.405, and 30.50 of this chapter.

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

(6.) 11. 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. 161c, 68 Stat. 950, as amended (42 U.S.C. 2201(c)).

(7.) 12. Section 40.8(b) is revised to read as follows:

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

13. Section 40.26(c)(1) is revised to read as follows:

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

(8.) 14. A new § 40.60 under Records, Inspections, Tests and Reports is added to read as follows:

§ 40.60 Notification requirements.

(a) Immediate notification. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after discovery of any event involving licensed material that prevents (or-threaten-to-prevent) immediate protective actions necessary to (maintain-and-verify-control) avoid an overexposure or release of licensed material (includes fires, explosions, toxic gas releases, etc.).

Immediate protective actions are those actions necessary to maintain control of licensed material and to protect workers, the public, and the environment immediately after an incident is discovered. The discovery of any of the following events involving licensed material:

(1) Any (accidental) unplanned contamination event that (restricts) requires access to the contaminated area by workers or the public to be restricted by imposing additional contamination controls or by prohibiting entry into the area for more than 24 hours.

(2) Any event in which equipment (necessary-to-prevent-uncontrolled releases-of-radioactive-material;-or-to-prevent-overexposure-to-radiation, or to-mitigate-the-consequences-of-an-accident;-is-disabled-or-fails-to function-as-designed-when-it-is needed;--Notification-is-not-required-when-an individual-component-is-disabled-or-fails-to-function-if-redundant-equipment-is operable-and-available-to-automatically-perform-the-required-function) is disabled or fails to function as designed when:

(i) the equipment is required to prevent (uncontrolled) unplanned releases exceeding regulatory limits, to prevent overexposures to radiation and radioactive materials, or to mitigate the severe consequences of an accident, and

(ii) (the-safety-function-of) the equipment is required to be available and operable (--or-the-availability-of-the-safety-function--is-required) when the normal equipment (is) was disabled or fails to function, and

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

(3) Any event that requires medical treatment ~~(of a radioactively contaminated individual)~~ at a medical facility of an individual with spreadable radioactive contamination on their clothing or on accessible portions of their body. ~~(note-the-exemption-for-superficial-injury-has-been-deleted).~~  
~~(Notification-is-not-required-if-first-aid-at-a-licensee-maintained medical facility-for-a-superficial-injury-is-the-only-treatment-rendered.~~

(4) Any accidental fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material in quantities greater than the limits specified in Appendix C of Part 20. No report is required for superficial damage (i.e., surface stains that do not affect the integrity of the licensed material or its container).

(c) Preparation and submission of reports. Reports filed with the NRC pursuant to this section must have the names of persons who have received exposure to radiation stated in a separate part of the report. 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.<sup>2</sup> 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;

<sup>2</sup> The commercial telephone number for the NRC Operations Center is (301) (202) 951-0550.

- (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.

(3) A written report shall be submitted within 30 days of the occurrence of any event involving licensed material that (threatens-to) could have caused

V NGE



an immediate disabling injury or (threatens-to) could have prevented immediate VAGUE  
protective actions necessary to maintain control of the licensed material.

(3) (4) The provisions of § 40.60 do not apply to licensees subject to the notification requirements in § 50.72. They do apply to research and test reactors possessing material under Part 40.

#### PART 70 - DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

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

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

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

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

(c), (d), (e), and (g), 70.36, 70.51(c)-(g), 70.56, 70.57(b) and (d), and 70.58 (a)-(g) (3) and (h)-(j) are issued under Sec. 1611, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 70.5, 70.9, 70.20b(d) and (e), 70.38, 70.51(b) and (i) 70.50, 70.52, 70.53, 70.54, 70.55, 70.58 (g)(4), (k), and (l), 70.59, and 70.60(b) and (c) are issued under Sec. 1610, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

16. Section 70.8(b) is revised to read as follows:

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

17. Section 70.19(c) is revised to read as follows:

§ 70.19(c) The general license in paragraph (a) of this section is subject to the provisions of §§ 70.32, 70.50, 70.51, 70.52, 70.55, 70.56, 70.61, 70.62, and 70.71, and to the provisions of Parts 19, 20 and 21 of this chapter. In addition, persons who receive title to, own, acquire, deliver, receive, possess, use or transfer one or more calibration or reference sources pursuant to this general license:

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

§ 70.50 Notification requirements.

(a) Immediate notification. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after discovery of any event involving licensed material that prevents (~~or threaten to prevent~~) immediate protective actions necessary to (~~maintain and verify control~~) avoid an over exposure or release of licensed material (includes fires, explosions, toxic gas releases, etc.).

← Immediate protective actions are those actions necessary to maintain control of licensed material and to protect workers, the public, and the environment immediately after an incident is discovered.

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

(1) Any ~~(accidental)~~ unplanned contamination event that ~~(restricts)~~ requires access to the contaminated area by workers or the public to be restricted by imposing additional contamination controls, or prohibiting entry into the area for more than 24 hours.

(2) Any event in which equipment ~~(necessary-to-prevent-uncontrolled releases-of-radioactive-material;-or-to-prevent-overexposure-to-radiation, or to-mitigate-the-consequences-of-an-accident;-is-disabled-or-fails to function-as-designed-when-it-is needed;--Notification-is-not-required-when-an individual-component-is-disabled-or-fails-to-function-if-redundant-equipment-is operable-and-available-to-automatically-perform-the-required-function)~~ is disabled or fails to function as designed when:

(i) the equipment is required to prevent (uncontrolled) unplanned releases exceeding regulatory limits, to prevent overexposures to radiation and radioactive materials, or to mitigate the severe consequences of an accident, and

(ii) ~~(the-safety-function-of)~~ the equipment is required to be available and operable - (or-the-availability-of-the-safety-function-is-required) when the ~~normal~~ equipment (is) was disabled or fails to function, and

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

(3) Any event that requires medical treatment ~~(of-a-radioactively contaminated-individual)~~ at a medical facility of an individual with spreadable radioactive contamination on their clothing or on accessible portions of their body. ~~(note-the-exemption-for-superficial-injury-has-been-deleted).~~

~~(Notification is not required if first aid at a licensee maintained medical facility for a superficial injury is the only treatment rendered.~~

(4) Any accidental fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material in quantities greater than the limits specified in Appendix C of Part 20. No report is required for superficial damage (i.e., surface stains that do not affect the integrity of the licensed material or its container).

(c) Preparation and submission of reports. Reports filed with the NRC pursuant to this section must have the names of persons who have received exposure to radiation stated in a separate part of the report. 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.<sup>3</sup> 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 a written followup report within 30 days of the initial report. Written reports prepared pursuant to

<sup>3</sup> The commercial telephone number for the NRC Operations Center is (301) ~~(202)~~ 951-0550.

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.

(3) A written report shall be submitted within 30 days of the occurrence of any event involving licensed material that ~~(threatens-to)~~ could have caused an immediate disabling injury or ~~(threatens-to)~~ could have prevented immediate protective actions necessary to maintain control of the licensed material.

(3)(4) The provisions of § 70.50 do not apply to licensees subject to the notification requirements in § 50.72. They do apply to research and test reactors possessing material licensed under Part 70.



Dated at Rockville, Maryland this \_\_\_\_\_ day of \_\_\_\_\_ 1990.

For the Nuclear Regulatory Commission.

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James M. Taylor, Executive Director  
for Operations.