

NOV 1 5 1990 Most F/ See M For Your Action Sharb NUCLEAR REGULATORY COMMISSION

MEMORANDUM FOR: Sher Bahadur, Chief

Regulation Development Branch

Division of Regulatory Applications

FROM:

John W. N. Hickey, Chief

Operations Branch

Division of Industrial and Medical Nuclear Safety, NMSS

SUBJECT:

RESPONSES TO PUBLIC COMMENTS ON THE PROPOSED

RULE FOR NOTIFICATION OF INCIDENTS

We have reviewed the public comments and draft final rule on immediate notificatio, requirements that you transmitted to Mr. Cunningham on October 24. 1990. Our comments and recommendations are enclosed. If you have any questions about our comments, please contact Kevin Ramsey at X20534.

John W. N. Hickey, Chief

Operations Branch

Division of Industrial and Medical Nuclear Safety, NMSS

Enclosure: As stated

cc w/encl: E. Baker

T. Novak F. Congel C. Kammerer S. Treby

IMNS COMMENTS AND RECOMMENDATIONS
ON RESPONSES TO PUBLIC COMMENTS AND
THE FINAL RULE ON NOTIFICATION OF
INCIDENTS

CONTACT : KEVIN RAMSEY , x 20534

1. ADD THE FOLLOWING TO THE RESPONSE TO comment 5:
"Many licensed operations use inextures of isotopes in different chemical forms that pose various safety hazards. The staff believes that the sufety 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 fives 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."

- "The staff does not agree that the rule is counterpreductive 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 expenence serves to strengthen licensee programs, "
- 3. 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.
- 4. The following response is recommended for comment 12:

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

hazards that warrant prompt notification of the NRC. "

- "The following response is recommended for comment 13:

 "The Advisory Committee on Medical Uses of Isotopes
 (ACMIL) is normally requested to review rules that
 specifically address medical applications especially
 rulemakings involving Port 35. An ACMILI review
 has not been requested for this rule because
 the notification requirements are generic and
 go beyond medical uses of isotopes."
- 5. The following response is recommended for comment 14!

 "The phrase "threatens to cause" refers to events

 that come very close to occurring, but are
 navrously averted. The NRC requires notification

 of such "close calls" to allow preventative

 measures to be implemented before an incident
 occurs."

- 7. The following response is recommended for comment 16:
 "The staff agrees and intends to issue information notices and other guidance as appropriate to licensies as implementation issues are identified and experience is gained with the rule."
- 8. The last sentence in the response to comment 17 should be replaced with the following:

 "Notification requirements for the loss and theft of licensed material will be revised by the ingor revision to Part 20. The major revision will specify what quantities of licensed material require immediate and 30 day notifications."
- 9. The following response is recommended for comment 21:

 "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."

- 10. The following response is recommended for comment 22!

 "The steff believes that the proposed notification requirements describe significant events that should be reported by 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."
- 11. The following response is recommended for comment 23:

 "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."
- 12. The staff agrees that it would appropriate to add

 the proposed notification requirements to Part 72 and
 intends to initiate a separate relemaking effort
 to allow public comment on amending that Part. "

13. The following response is recommended for comment 26:

"Securing naterial includes actions necessary to prevent unauthorized movement of licensed material or unsage conditions resulting from licensed material. This includes shielding exposed radiation sources, returning licensed material to storage containers, stopping a sprill 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.

"The following response is recommended for comment 29:

"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 steff 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."

15. Comment 30 appears to address an equipment failure and we suggest placing it in that section of the discussion. The following response is recommended for comment 30:

by this rule of a picket dosimeter is discharged beyond its range. A pointed dosimeter does not prevent radiation exposure. It only indicates what dose has already been received. In fact, a discharged pocket dosimeter would tend to minimize radiation exposure because a worker normally leaves an area immediately upon discovering that his pocket dosimeter is offscale. "

16. The following response is recommended for comment 32:

"Immediate protective actions are those actions
necessary to maintain control of licensed material and the protect workers, the public, and the environment immediately after an incident is discovered. These actions may include stopping releases, sounding alarms, requesting help, etc.

17. We suggest deleting comment 33. These are general terms that do not require special definitions beyond what can be found in a common dictionary.

- 18, The following response is recommended for comment 35:

 "Toxic gas releases would not require NRC notification if they did not prevent immediate protective actions recessary 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)."
- 10. The following statement should be added to the response to comment 36:
 - "If the licensee later determines that an event was not reportable, a 30-day written report would not be required."
- "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 livited to any minimum size.

 In general, any space normally accessible to

workers or the general public qualifies as an area."

- 21. The following response is recommended for comment 39:

 "Contamination event: that resiriet access are spills or other accidents that result in elevated levels of loose surface contamination in areas that must be restricted by imposing additional controls to prevent individuels from spreading the cont notion to themselves or outside the area. Restricting access also includes additional controls to minimize exposure to radiation livels elevated by the contamination."
- 22. The following response is recommended for comment 40:

 "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."
- 23. The following response is recommended for comment 41:

 "The proposed notification requirements do not relieve licensees from their responsibility to m' tain radiation exposures as low as reasonably achievable. The staff agrees that uniting 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."

"The hazards possed 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."

25 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.

"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."

27. The following response is recommended for comment 46:

"Requiring additional pretective clothing on otherwise increasing contamination controls as a result of a contamination occident is significant. The final rule has been clarified to indicate that impossing additional contamination controls is considered to be a form of restricting access."

28. The following response is recommended for comment 47:

"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 renoving the isotamination is justified. This rule would only require licensees to inform the NRC of the contamination accident."

- "The notification requirement has been rewritten in a format a to the discussion in the proposed rule."
- 30. The following response is recommended for comment 50:

 "The notification requirement has been clarified to indicate that the equipment must be necessary to prevent releases in excess of regulatory limits."
- 31. The response to comment 52 should be reworded as follows:

"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 vadioactive materials, or (3) mitigate the severe consequences of an accident. Severe consequences include major property damage, widespread contamination outside of controlled areas, and fatalities or include injuries requiring medical treatment.

'In addition in "

- 32. The end of comment 54 should read "in requirements in \$34.30." The following response is recommended for comment 54:
 - "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 f. I 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 the required information and appropriate distribution is made."
- 33. The following response is recommended for comment 55:

 "If there are problems with the design or use of a device containing a source that could cause an overexposure and the problems prevent restricting 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 senous incidents occur."

- 34. The following response is recommended for comment 56:

 "Safety equipment is needed when a hazard is present and an incident requiring the use of the safety equipment is possible. Notification is only required by the propose! 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."
- 35. The following response is recommended for comment 57:

 "The staff's intent was to require notification of a malfunction involved equipment necessary to prevent unplanned, accidental releases exceeding regulatory limits."
- 36. Comment 58 should read "in prevent over exposure to radiation ..." The following response is recommended for car ment 58:

 " 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.

- 37. The following response is recommended for comment 60:

 "The staff disagrees. NRC must determine if there are generic design defects that require prompt warnings and corrective actions by the equipment manufacturer."
- 38. The response to comment 61 should read: "... may complicate treatment of the injury."
- 39. The response to comment 62 should be expanded as follows:

 "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."

- 46. The first sentence of the response to comment 63 should be remorded as follows:

 "Redicachirely contaminated individuals are those persons who have loose surface contamination on their clothing or on accessible portions of their body that can be spread to other individuals."
- 41. The response to comment 65 should be reworded as follows:
 - " The staff was attempting to minimize reports of insignificant events such as a licensee technician accidently 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 teating 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. "

- 42. We suggest deleting comment to because no specific examples were provided.
- 43. The following response is recommended for comment 67:

 "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."
- 44. The following response is recommended for comment 68:

 " 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 of an explosion or fire involves licensed material in quantities less than the quantities specified in Appendix C of Part 20."

- 45. Replace the last two sentences of the regionse to comment 69 with the following:
 "The notification requirement has been revised to specify the guarathes in Appendix C of Part 20 as the reporting thresholds."
- "NRC agrees and the netification requirement has been revised to require no report if the fire or explosion inflicts only spechcial dimage."
- 47. We suggest deleting comment 7.5 because there is no need to address typographical errors in the proposed rule.
- 48. Fuel cycle staff have not been available to evaluate our response to comment 76. We will forward our recommendations for responding to this comment as soon as possible.

PAR: 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows: AUTHORITY: Secs. 52, 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 BY RODUCT MATERIAL

(2.) $\underline{4}$. 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, 50.55, and 30.56.

(6.) $\underline{6}$. 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 (er-threaten-te-prevent) immediate protective actions necessary to maintain and verify control 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 contamination event that (restricts) requires access by imposing coldinary contains or metabolic or met
- (2) Any event in which equipment (necessary-to-prevent-uncontrolled releases-of-radioactive-material;-or-to-prevent-overexposuresto-radiation, or to-mitigate-the consequences-of-an-accident;-is-disabled-orfails 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 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, or the availability of the

safety function - is required when the equipment is 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 (ef-a-radioactively sentaminated-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). (Netification-is-not-required-if-first-aid-at-a-licensee-maintainedmedical facility-for-a-superficial-injury-is-the-only-treatment-rendered.
- (4) Any fire or explosion damaging any licensed material or any device, in quantities greater than the limits specified in Appendix C of fact 20 container, or equipment containing licensed material. 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. To the extent that the information is available at the time of notification, the information provided in these reports must include:

to

The commercial telephone number for the NRC Operations Center is (301) (202) 951-0550.

- (1) 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 fufill this requirement if the reports contains 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) Correct ctions 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.

- of any event involving licensed material that threatens to cause an immediate disabling injury or threatens to prevent immediate protective actions necessary to maintain control of the licensed material.
- (2) (4) The provisions of § 30.50 do not apply to Licensees subject to the notification requirements in § 50.72. They do apply to resolved and test reactors possessing material licensed under Part 30.

Revise Parts 31, 34, and 39 (see attached)

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

(6.) 7. 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, 7201, 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); $\S\S40.3$, 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 $\S\S40.5$, 40.9, 40.25(c), (d)(3), and (4),

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 \$5 30.14(d), 30.34 (a) to (e), 30.41, 30.50 to 30.63 and Ports 19, 20, and 21 ...

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

\$ 31.8(c) The general license in paragraph (a) of this section is subject to the provisions of \$ 30.14(d), 30.34(a) to (e), and 30.50 to 30.63 of this chapter, and 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 reused 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 revels and concentrations of radiation, and certain other accidents as required by \$\$ 20.402, 20.403, 20.405, and 30.50 of this chapter.

40.26(c)(2), 40.35(e), 40.42, 40.60, 40.61, 40.62, 40.64, and 40.65 are issued under Sec. 1610, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

- (7.) 8. Section 40.8(b) is revised to read as follows:
- §40.8(b) The approved information collection requiremen's 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.
- (8.) 2. 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 (er-threaten-te-prevent) immediate protective actions necessary to maintain and verify control 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 contamination event that (restricts) requires access
 by imposing additional contamination controls or prohibiting entry into the area
 to the contaminated area by workers or the public to be restricted for more
 than £4 hours.
 - 13. Section 40.26 (c)(1) & revised to read as follows:

 \$ 40.26 (c)(1) The provisions of Parts 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....

- (2) Any event in which equipment (necessary-te-prevent-uncontrolled releases-of-radioactive-material;-or-to-prevent-overexposuresto-radiation, or to-mitigate-the-consequences-of-an-accident;-is-disabled-orfails-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:
 - regulatory limits, to prevent overexposures to radiation and radioactive materials, or to mitigate the severe consequences of an accident, and is required to be available and operable (ii) the safety function of the equipment, or the availability of the safety function is required when the equipment is 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 (ef-a-radioactively centaminated-individual) at a medical facility of an individual with spreadable radioactive contamination of their clothing or on accessible portions of their body. (note the examption or superficial injury has been deleted).

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- (4) Any fire or explosion damaging any licensed material or any device, in quantities greater than the horts specified in Appendix C of fact 20. container, or equipment containing licensed material. 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. 2 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.
- 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 fufill this requirement if the report contains 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 --

The commercial telephone number for the NRC Operations Center is (301) (202) 951-0550.

- (i) A description of the event, including the probable cause and the manufacturer and mode: 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;
- (7) 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 occurrence of any event involving licensed material that threatens to cause an immediate disabling injury or threatens to prevent immediate protective actions necessary to maintain control of the licensed material.
- (2) (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

9. 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).

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For the purposes of Sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); $\S\S$ 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 (d), 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)); $\S\S$ 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 $\S\S$ 70.5, 70.9, 70.20b(d) and (e), 70.38, 70.51(b) and (f) 70.50, 70.52, 70.53, 70.54, 70.55, 70.58 (g)(4), (k), and (1), 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. 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 previsions of §§ 70, 32, 70.50, 70.51,...
- 18. A new 370.50 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 the discovery of any event involving licensed material that prevents (er-threaten-te-prevent) immediate protective actions necessary to maintain and verify control of licensed material (includes fires, explosions, toxic gas releases, etc.).
- (b) Twenty-four hour notification. Fach licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material:
- (1) Any accidental contamination event that (restricts) requires access

 by imposing additional contamination controls or probability entry into the area
 to the contaminated area by workers or the public to be restricted for more
 than 24 hours.
- (2) Any event in which equipment (nesessary-to-prevent-uncontrolled releases-of-radioactive-material,-or-to-prevent-everyxposuresto-radiation, or to-mitigate-the-consequences-of-an-accident;-is-disabled-orfails 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 releases exceeding regulatory limits, to prevent overexposures to radiation and radioactive materials, or to mitigate the severe consequences of an accident, and is required to be available and speciable (ii) the safety function of the equipment, or the availability of the

safety function - is required when the equipment is 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 (ef-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-met-required-if-first-aid-at-a-licensee-maintainedmedical facility-for-a-superficial-injury-is-the-enly-treatment-rendered.
- (4) Any fire or explosion damaging any licensed material or any device, in quantities greater than the limits specified in Appendix C of Part zo container, or equipment containing licensed material. 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.³ To the extent that the information is available at the time of notification, the information provided in these reports must include:

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;

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- (iv) The isotopes, quantities, and chemical and physical form of the licensed material involved; and
 - (v) Any personnel radiation exposure data available.
- (2) Written report. Each licensee who makes a report required by paragraph (a) or (b) of this section shall prepare a written followup report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fufill this requirement if the reports contains 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;
 - (11) 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 occurrence of any event involving licensed material that threatens to cause an immediate disabling injury or threatens to prevent immediate protective actions necessary to maintain control of the licensed material.

11 4

> James M. Taylor Executive Director for Operations

MEMORANDUM FOR:

Sher Bahadur, Chief

Regulation Development Pranch

Division of Regulatory Applications

FROM:

John W. N. Hickey, Chief

Operations Branch

Division of Industrial and Medical Nuclear Safety, NMSS

SUBJECT:

RESPONSES TO PUBL COMMENTS ON THE PROPOSED

RULE FOR NOTIFICATION OF INCIDENTS

We have reviewed the public comments and draft final rule on immediate notification requirements that you transmitted to Mr. Cunningham on October 24, 1990. Our comments and recommendations are enclosed. If you have any quescions about our comments, please contact Kevin Ramsey at X20534.

Original signed by

John W. N. Hickey, Chief Operations Branch Division of Industrial and Medical Nuclear Safety, NMSS

Enclosure: As stated

cc w/encl: E. Baker

T. Novak F. Congel C. Kammerer

S. Treby

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IMNS COMMENTS AND RECOMMENDATIONS
ON RESPONSES TO PUBLIC COMMENTS AND
THE FINAL RULE ON NOTIFICATION OF
INCIDENTS

CONTACT : KEVIN RAMSEY , x 20534

1. ADD THE FOLLOWING TO THE RESPONSE TO COMMENT 5:

"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 first and explosion involving licensed material in quantities greater than the guantities specified in Appendix C of Part 20."

- "The staff does not agree that the rule is counterproductive to strong licensee programs because the staff does not agree with the view that rotification 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 expenence serves to strongthen licensee programs."
- 3. 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.
- 4. The following response is recommended for comment 12:

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

hazards that warrant prompt notification of the NRC. "

- 5. The following response is recommonded for comment 13:

 "The Advisory Committee on Medical Uses of Isotopes
 (ACMUI) is nor nally 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."
- 6. The following response is recommended for comment 14!

 "The phrase "threatens to course" 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."

- 7. The following response is recommended for comment 16:
 "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."
- 8. The last sentence in the response to comment 17 should be replaced with the following:

 "Notification requirements for the loss and theft of licensed material will be revised by the ingor revision to Part 20. The major revision will specify what quantities of licensed material require immediate and 30 day notifications."
- 9. The following response is recommended for comment 21:

 "The staff does not agree that the proposed changes to the notification requirements have any significant environmental impact requiring an environmental renew 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 cotagorical exclusions not requiring an environmental review."

- 10. The staff believes that the proposed notification requirements describe significant events that should be reported by source, byproduct, and special nuclear material licensees. The staff does not agree that decipping more special requirements and amending more Parts of the regulations would improve the rule."
- 11. The following response is recommended for comment 23:

 "The text of each notification require next 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. "
- 12. The Soldwing response is recommended for comment 24:

 "The shoff agrees that it would aggoropriate to add
 the proposed notification requirements to fart 72 and
 intends to initiate a separate rulemaking effort
 to allow public comment on amending that Part."

13. The following response is recommended for comment 26:

"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 sprill 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.

14. The following response is recommended for comment all:

" 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 stoff concerning what events are reportable. This change has not been made in \$ 20.403 because the stoff believes that events that threaten to cause overexposures or releases are significant enough to warrant prompt notification of the NRC."

- 15. Comment 30 appears to address an egupment failure and we suggest placing it in that section of the discussion. The following response is recommended for comment 30:
 - "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 discharged pocket dosimeter would tend to minimize radiation exposure because a worker normally leaves an area immediately upon discovering that his pocket dosimeter is offscale."
- 16. The following response is recommended for comment 32:

 "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 may include stopping releases, sounding alarms, requesting help, etc.
- 17. We suggest deleting comment 33. These are general terms that do not require special definitions beyond what can be found in a common dictionary.

18, The following response is recommended for comment 35:

"Toxic gas releases would not require NRC notification if they did not prevent inediate 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)."

19. The following statement should be added to the response to comment 36:

"If the licensee later determines that an event was not reportable, a 30-day written report would not be required."

"This rule does not attempt to define criteria for releasing areas from radiological controls. No NRC nothcation 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."

- 21. The following response is recommended for comment 39:

 "Contamination events that result in elevated levels or other accidents that result in elevated levels of loose surface contamination in areas that must be restricted by imposing additional controls to present individuels from spreading the contamination to themselves or outside the area. Restricting access also includes additional controls to minimize exposure to radiation levels elevated by the contamination."
- "The notification requirement has been clarified to indicate that the contamination, ist be accidental, however the stiff does not as ee that the term "area". Testriction."
- 23. The following response is recommended for commend 41:
 "The proposed netrocetion 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 re. 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, 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 warranded."

- "The following response is recommended for comment 42!

 "The hozards 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 all situations."
- 25. We suggest deteting 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.

- Whe following risponse is recommended for comment 44!

 "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! "s

 is significant and NRC notification is apprepriate."
- The following response is recommended for comment 46:

 "Requiring additional protective clothing or otherwise increasing contemination 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."
- 28. The following response is recommended for comment 47:

 "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."

- 29. The following response is recommended for comment 49:
 "The notification requirement has been rewritten
 in a format , to the discussion in the proposed
 rule."
- 30. The following response is recommended for comment 50: "The notification requirement has been clarified to indicate that the equipment must be necessary to prevent releases in excess of regulatory limits."
- 31. The response to comment 52 should be reworded as follows:

"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 need to (1) prevent unplanned releases exceeding regulatory limits, (2) prevent overexposures to radiation and vadicactive materials, or (3) mitigate the severe consequences of an accident. Severe consequences include major preparty damage, widespread contemination existed of controlled areas, and fatalities or serious injuries requiring medical treatment. In addition ..."

32. The end of comment 54 should read "... requirements in \$34.30." The following response is recommended for comment 54:

"The staff does not agree that there is a or-flict with \$ 34.30. The proposed rule would require a 24-hour telephone notification in adaption 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 of the report contains the required information and appropriate distribution is made."

33. The following response is recommended for comment 55:

"If those are problems with the design or use of a device containing a source that could cause an overexposure and the problems prevent restricting exposed radiation sources, MRC 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 setely equipment failures in order to initiate preventative measures before more serious incidents occur."

- 34. The following response is recommended for comment 56:

 "Safety equipment is needed when a 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."
- 35. The following response is recommended for comment 57:

 "The staff's intent was to require notification if a malfunction involved equipment necessary to prevent unplanned, accidental releases exceeding regulatory limits."
- 36. Comment 58 should read "... prevent over exposure to radiation..." The following response is recommended for comment 58:

 " Abhication is only required by the proposed rule for the meltunction 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 egupment necessary to minimize injuries and dumage after an accident occurs. For example, sprinkler systems are necessary to mitigate the consequences of a fire."

- 37. The following response is recommended for comment 60:

 "The staff disagrees. NRC must determine if there are generic design defects that require prompt warnings and corrective actions by the equipment manufacturer."
- 38. The response to comment 61 should read: "... may complicate treatment of the injury."
- 39. The response to comment 62 should be expanded as follows:

 "NRC believes that expressive of the general public (including medical overkers) to disposerable 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."

should be remorded as follows:

"Radioactively contaminated individuals are those persons who have loose surface contamination on their clothing or on accessible portion: of their body that can be spread to other individuals."

41. The response to comment 65 should be reworded as follows:

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

- 42. We suggest deleting comment to because no specific examples were provided.
- 43. The following response is recommended for comment 67:

 "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."
- 44. The following response is recommended for comment 68:

 " 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 of an explosion or fire mustices licensed material in quantities less than the quantities specified in Appendix C of Port 20."

PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows: AUTHORITY: Secs. 53, 63, 65, 81, 103, 104, 161, 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. 3841, 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 53.305 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 umended by revising the area code for the footnote from area code 202 to area code 301.

- 45. Replace the last two sentences of the regionse of comment 69 with the following:

 "The notification requirement has been revised to specify the quantities in Appendix C. of Part 20 as the reporting thresholds."
- the The following response is recommendeded for comment 70:

 "NRC agrees and the notification requirement has been revised to require no report of the fire or explosion inflicts only superficial damage."
- 47. We suggest deleting comment 75 because there is no need to address typographical errors in the proposed rule.
- 48. Fuel cycle staff have not been available to evaluate our response to comment 76. We will forward our recommendations for responding to this comment as soon as possible.

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

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

AUTHORITY: Sec. 81, 82 161, 182, 183, 186, 68 Ctat. 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. 938, 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.

(6.) 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 (er-threaten-te-prevent) immediate protective actions necessary to maintain and verify control 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 contamination event that (restricted) requires access by imposing additional contamination controls, or prohibiting to the contaminated area by workers or the public to be restricted for more entry into 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-overexposuresto-radiation, or to-mitigate-the-consequences-of-an-accident;-is-disabled-orfails-to-function-as-designed-when-it-is needed--Netification-is-not-required-when-an individual-component-is-disabled-or-fails-to-function-if-redundant-equipment-is operable-and-evailable-to-automatically-perform-the-required-function) is disabled or fails to function as designed when:
 - (i) the equipment is required to prevent uncontrolled releases exceeding regulatory limits, to prevent overexposures to radiation and radioactive materials, or to mitigate the severe consequences of an accident, and is required to be available and operable.

 (ii) the safety function of the equipment, or the availability of the

safety function - is required when the equipment is 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 (ef-a-radioactively eentaminated-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-maintzinedmedical factlity-for-a-superficial-injury-is-the-only-treatment-rendered.
- (4) Any fire or explosion damaging any licensed material or any device.

 In quantities greater than the limits specified in Appendix C of first 20 container, or equipment containing licensed material. 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. To the extent that the information is available at the time of notification, the information provided in these reports must include:

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The commercial telephone number for the NRC Operations Center is (301) (202) 951-0550.

- (1) 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.
- 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 fufill this requirement if the reports contains 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 --
 - (1) 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:
 - (111) 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.

- of any event involving licensed material that threatens to cause an immediate disabling injury or threatens to prevent immediate protective actions necessary to maintain control of the licensed material.
- (2) (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.

Revise Parts 31, 34, and 39 (see attached)

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

(6.) The authority citation for Part 40 is revised to read as follows:

AUTHORITY: Secs. 62, f3, 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 an anded (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), 40.45, 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),

PART 31 - GENERAL DEMESTIC 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 \$5 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 license in surgraph (a) of this section is subject to the provisions of \$ 30.14(d), 30.34(a) to (e), and 30.50 to 30.63 of this chapter, and 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 acidition 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 reused 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.

40.26(c)(2), 40.35(e), 40.42, 40.60, 40.61, 40.62, 40.64, and 40.65 are issued under Sec. 1610, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

- (7.) 8. 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.
- (8.) A new § 40.60 under Records, Inspections, Tests and Reports is added to read as follows:
- (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 (er-threaten-te-prevent) immediate protective actions necessary to maintain and verify control 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 contamination event that (restricted) requires access
 by imposing additional contamination controls or prohibiting entry into the area
 to the contaminated area by workers or the public to be restricted, for more
 than 24 hours.
 - 13. Section 40.26 (c)(1) to revised to read as follows:

 § 40.26 (c)(1) The provisions of Parts 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....

- (2) Any event in which equipment (necessary-te-prevent-uncentrelled releases-ef-radioactive-material,-er-te-prevent-everexposureste-radiation, or te-mitigate-the-consequences-ef-an-accident,-is-disabled-erfails-te function-as-designed-when-it-is neededr--Netitication-is-act-required-when-an individual-component-is-disabled-er-fails-to-function-if-redundant-equipment-is operable-and-available-te-automatically-perform-the-required-function) is disabled or fails to function as designed when:
 - (1) the equipment is required to prevent uncontrolled releases exceeding regulatory limits, to prevent overexposures to radiation and radioactive materials, or to mitigate the severe consequences of an accident, and (11) the eafety function of the equipment, or the availability of the refers function, and
 - (iii) no redundant equipment is available and operable to automatically perform the required safety function.
- (3) Any event that requires medical treatment (ef-a-radioactively essential individual with spreadable radioactive contamination on their clothing or on accessible portions of their body. (note the examption for superficial injury has been deleted).

 (Metification-is-met-required-if-fix t-aid-at-a-licensee-maintainedmedical fastlity-for-a-superficial-injury- the-enly-treatment-rendered.)
- (4) Any fire or explosion da figing any licensed material or any device, in quantities that when the hards specified in Appendix C of flut 20. container, or equipment containing licensed material. No report is required for superficial damage (i.e., surfices stains that do not affect the integrity of the licensed material or its containers.

- (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. ² To the extent that the information is available at the time of notification, the information provided in these reports must include:
 - (1) The caller's name and call back telephone number:
 - (11) 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 vailable.
- (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 fufill this requirement if the report contains 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 --

The commercial telephone number for the NRC Operations Center is (301) (202) 951-0550.

- (i) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
- (ii) The exact location of the event:
- (iii) The isotopes, quantities, and chemical and physical form of the licensed material involved;
- (iv) Date and time of the event;
- (v) Corrective actions taken or planned and the results of any evaluations or assessments; and
- (vi) The extent of exposure of individuals to radiation or to radioactive materials.
- (3) A written report shall be submitted within 30 days of occurrence of any event involving licensed material that threatens to cause an immediate disabling injury or threatens to prevent immediate protective actions necessary to maintain control of the licensed material.
- (2) (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

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, 2252, 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); \$\frac{5}{2} 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 (1), 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)); \$\frac{5}{2} 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), 70.55, 70.57(b) and (d), and 70.58 (a)-(g) (3) and (h)-(j) are issued under Sec. 1511, 68 Stat. 949, as amended (42 U.S.C. 2201(1)); and \$\frac{5}{2} 70.5, 70.9 \frac{1}{2} 0.20b(d) and (e), 70.38, 70.51(b) and (1) 70.50, 70.52, 70.53, 70.54, 70.55, \tau.58 (g)(4), (k), and (1), 70.59, and 70.60(b) and (c) are issued under Sec. \$\frac{5}{2} 10, 68 Stat. 950, as amended (42 U.S.C. 2201(c)).

16. 20. 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 [7590-01]

 is subject to the previsions of §§ 70. 32, 70.50, 70.51,...
- 18. M. A new 70.50 under Special Auclear 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 the discovery of any event involving licensed material that prevents (ex-threaten-te-prevent) immediate protective actions necessary to maintain and verify control 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 contamination event that (restricted) requires access
 by imposing additional contamination controls or prohibiting entry into the area
 to the contaminated area by workers or the public to be restricted for more
 than 24 hours.
- (2) Any event in which equipment (necessary-to-prevent-uncontrolled releases-of-radioactive-material;-or-to-prevent-syerexposuresto-radiation, or to-mitigate-the-consequences-of-an-accident;-is-disabled-orfails to function-as-designed-when-it-is neededy--Netification-is-net-required-when-an individual-component-is-disabled-or-fails-tofunction-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 wheomerofied releases exceeding regulatory limits, to prevent overexposures to radiation and radioactive materials, or to mitigate the severe consequences of an accident, and is required to be available and operable (ii) the safety function of the equipment, or the availability of the

function, and

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

- (3) Any event that requires medical treatment (ef-a-radioactively sentaminated-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). 4
 [Notification-is-not-required-if-first-aid-at-a-likensee-maintainedmedical facility-for-a-superficial-injury-is-the-enly-treatment-rendered.
- (4) Any fire comexplosion damaging any licensed material or any device.

 In quantities greater than the limits specified in Appendix C of Part 20 container, or equipment containing censed material. No report is required for superficial damage (i.e., surface stains that do not affect the integrity of the licensed material or its container.
- (3) 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. To the extent that the information is available at the time of notification, the information provided in these reports must include:

The commercial telephone number for the NRC Operations Center is (301) (202) 951-0550.

- (1) The caller's name and call back telephone number:
- (ii) A description of the event, including date and time:
- (iii) The exact location of the event;
- (iv) The isotopes, quantities, and chemical and physical form of the licensed material involved; and
- (v) Any personnel radiation exposure data available.
- (2) Written report. Each licensee who makes a report required by paragraph (a) or (b) of this section shall prepare a written followup report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fufill this requirement if the reports contains 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 --
 - (1) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
 - (11) The exact location of the event;
 - (111) 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
 - (v1) The extent of exposure of individuals to radiation or to radioactive materials.

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

James M. Taylor Executive Director for Operations