RULEMAKING ISSUE
NOTATION VOTE

June 21, 2002 SECY-02-0111

FOR: The Commissioners

FROM: William D. Travers, Director
Executive Director for Operations

SUBJECT: PROPOSED RULE TO AMEND 10 CFR PART 35 TO REQUIRE LICENSEES TO NOTIFY NRC OF AN INDIVIDUAL RECEIVING A DOSE EXCEEDING 50 MILLISIEVERTS (5 REM) FROM A PATIENT RELEASED UNDER 10 CFR 35.75

PURPOSE:

To provide for Commission consideration a draft proposed rule, as requested in the Commission's October 23, 2000, Staff Requirements Memorandum, that would amend 10 CFR Part 35, "Medical Use of Byproduct Material," to require licensees to notify the U.S. Nuclear Regulatory Commission (NRC), no later than the next calendar day after the licensee becomes aware that an individual received or is estimated to have received a dose exceeding 50 millisieverts (mSv) [5 rem] from a patient released under 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material." In addition, the proposed rule would require the licensee to submit a written report within 15 days after discovery of the event and to provide a copy of the report to the identified exposed individual.

BACKGROUND:

During preparation of the final rule that would revise 10 CFR Part 35, which was affirmed by the Commission on October 23, 2000, the staff noted that licensees were not required to notify NRC when they learn that an individual received a dose in excess of the dose specified in 10 CFR 35.75 for patient release and that licensees were not required to notify the exposed individual of the exposure. The staff also noted that the Statement of Considerations for the

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final rule published on January 29, 1997 (62 FR 4120) that revised 10 CFR 35.75 did not discuss whether reporting was required if the licensee: (1) failed to comply with 10 CFR 35.75 and an individual received a dose in excess of 5 mSv (0.5 rem); or (2) complied with 10 CFR 35.75, but learned that an individual exposed to the released individual received a dose in excess of 5 mSv (0.5 rem). As a result of this information, the Commission directed that the issue of notification be addressed in a separate rulemaking.

DISCUSSION:

In Staff Requirements Memorandum (SRM) SECY-00-0118, "Final Rules - 10 CFR Part 35, 'Medical Use of Byproduct Material' and 10 CFR Part 20, 'Standards for Protection Against Radiation,'" dated October 23, 2000 (Attachment 1), the Commission disapproved the staff's recommendation to develop a rulemaking plan, with options, for revising 10 CFR Parts 20 and 35 to add a requirement for a licensee to report events in which an individual receives an exposure in excess of 5 mSv (0.5 rem) from an individual released under 10 CFR 35.75. Instead, the Commission directed the staff to develop, for Commission consideration, a proposed amendment to Part 35 that would require the licensee to notify NRC, no later than the next calendar day, after the licensee becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under 10 CFR 35.75. In addition, the rule was to include a requirement for the licensee to submit to the Commission a written report within 15 days after discovery of the event and to provide identified exposed individual(s) with a copy of the report. The reporting and notification threshold was to be consistent with the reporting and notification requirements in § 35.3047. The rulemaking was to address a patient release that was not in compliance with § 35.75, as well as a release that was in compliance, i.e., it would address instances in which the licensee either:

(1) believes the basis of the release may have been incorrect or the release instructions may have been inadequate, OR

(2) learns, through voluntary means, that the patient did not follow the physician's instructions;

AND

An individual received or is estimated to have received a dose in excess of 50 mSv (5 rem).

The Commission also instructed the staff to include language in the Statement of Consideration for the proposed rule to clearly indicate that the Commission was not modifying its previous position that:

a. the NRC does not intend to enforce a patient's compliance with the licensee's instructions; and

b. it is not the licensee's responsibility to ensure compliance by patients once they leave the licensee's facility.

During development of this proposed rule, the staff interfaced with NRC's federal Advisory Committee on the Medical Uses of Isotopes (ACMUI) and with the Agreement States as required by NRC's rulemaking policy.

ACMUI Views

The ACMUI discussed the proposed amendment to 10 CFR Part 35 at its November 2000, meeting. The ACMUI recommended that the reporting be limited to errors made in the release procedure or delivery of instructions to the patient that result in exposures to individuals other than the patient in excess of 50 mSv (5 rem). The ACMUI again discussed the rulemaking at its meeting on April 18, 2001.

Although the ACMUI acknowledged the value of reporting that a member of the public received a dose greater than 50 mSv (5 rem), the ACMUI reaffirmed its previous recommendation. In addition, members provided staff with the following specific concerns, which are listed in the Federal Register notice for the proposed rule for the purpose of soliciting public comment.

- Licensees may be reluctant to release patients under § 35.75 because of repercussions associated with the reporting requirement, such as, negative press and loss of public confidence. This will result in more expensive care for these patients.
- Licensees should be granted anonymity when reporting the event and not be held responsible for patients who disregard instructions.
- Licensees may have to report based on information that may be difficult to verify. For example, an individual could call the licensee with a concern or a question about the patient's behavior.
- Patients and licensees could be subject to intrusive investigations with possible loss of patient confidentiality.
- Dose reconstructions would be based on numerous variables with significant ranges of uncertainties.
- Low frequency of known events and problems with rule enforcement and implementation do not justify NRC resource expenditures.
- NRC and licensee effort should focus on compliance with § 35.75.

Agreement State Issues

This amendment would be a matter of compatibility between NRC and Agreement States. The compatibility classification is "C," which means an NRC program element, the essential objective of which Agreement States should adopt to avoid conflicts, duplication, or gaps in the regulation of Agreement State material on a nationwide basis, and that, if not adopted, would result in an undesirable consequence.

The draft proposed rule was forwarded to Agreement States on May 21, 2001, for comment. Comments were received from five Agreement States (Attachment 2). None of the comments supported the proposed notification requirement. Some of the comments were outside the scope of this rulemaking and are not included in the summary of comments provided below.

- The notification requirement would be both burdensome and unnecessary.
- The proposed rule would be unenforceable and would not appear to be effective in reducing risk to members of the public.
- The 500 mrem limit of 10 CFR Part 20 should be the reporting requirement.
- A reporting value of 5,000 mrem may give the NRC a false sense that the revised rule is working, when, in fact, there may be many cases of individual members of the public being exposed beyond the 500 mrem limit.
- Creating rules that are exceptions to the exposure limits of Part 20 questions the validity of the Part 20 limits.
- Licensees should not be required to report such exposures but should be required to keep a record of such exposures for review during an inspection.

RESOURCES

NRC will incur a small resource burden during development and implementation of this rule and revision of associated licensing and inspection guidance. Approximately 1.2 FTE would be needed for this rulemaking. The subsequent revision of licensing and inspection guidance would also result in some small resource burden, depending on the revisions needed. However, the revisions to inspection guidance would be addressed during the normal three-year review/revision cycle for inspection-related documents.

COORDINATION:

The Office of the General Counsel has no legal objection to the proposed rulemaking. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. The proposed rule would amend information collection requirements that must be received by the Office of Management and Budget no later than the date the proposed rule is forwarded to the Federal Register for publication.

RECOMMENDATIONS:

If the Commission decides to go forward with this proposed rule, the staff recommends the following:

1. Approve for publication, in the Federal Register, the proposed amendments to Part 35 after the revised Part 35 is published in the Federal Register.

2. Note:

   a. That the proposed amendments will be published in the Federal Register, allowing 75 days for public comment.

   b. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).

   c. That a draft Regulatory Analysis has been prepared for this rulemaking.

d. That appropriate Congressional committees will be informed of this action.

e. That a press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register.

f. An Office of Management and Budget (OMB) review is required and a clearance package will be forwarded to OMB no later than the date the proposed rule is submitted to the Office of the Federal Register for publication.

g. That resources to complete and implement this rulemaking, as well as associated licensing and inspection guidance, are included in the current FY 2002 and FY 2003 budgets.

/RA/

William D. Travers
Executive Director
for Operations

Attachments: 1. SRM SECY 00-0118
2. Agreement State Comments
3. Draft Federal Register Notice

IN RESPONSE, PLEASE
REFER TO: M001023

October 23, 2000

MEMORANDUM FOR: William D. Travers
Executive Director for Operations

FROM: Annette Vietti-Cook, Secretary ***/RA/***

SUBJECT: STAFF REQUIREMENTS - AFFIRMATION SESSION, 3:00 P.M., MONDAY, OCTOBER 23, 2000, COMMISSIONERS' CONFERENCE ROOM, ONE WHITE FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

I. SECY-00-0118 - Final Rules - 10 CFR Part 35, "Medical Use of Byproduct Material" and 10 CFR Part 20, "Standards for Protection Against Radiation"

The Commission[1] approved a final rule which revises 10 CFR Part 35 to make it more risk-informed and performance-based, and to codify requirements for certain therapeutic devices. Also, 10 CFR Part 20 is being revised in response to a Petition for Rulemaking from the University of Cincinnati to allow a licensee the discretion to permit visitors to a hospitalized radiation patient to receive up to 5 millisievert (0.5 rem) in a year from exposure to the hospitalized radiation patient.

Following incorporation of the changes in the attachment and submittal to OMB, the Federal Register notice should be reviewed by the Rules Review and Directives Branch in the Office of Administration and forwarded to the Office of the Secretary for signature and publication.
(EDO) (SECY Suspense: 2/25/01)

The Commission approved the staff decision not to submit an inspection plan with the final rulemaking, pending completion of the Medical Pilot Inspection Program that was approved by the Commission in the SRM for SECY-00-0001. However, the staff should, within 6 months of the completion of the pilot, report back to the Commission on the findings from the pilot and indicate how insights gained will be utilized.

The Commission disapproves staff's recommendation to develop a rulemaking plan, with options, for revising Parts 20 or 35 to add a requirement for a licensee to report events in which an individual receives an exposure in excess of 5 mSv (0.5 rem) from an individual released under §

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[1] Section 201 of the Energy Reorganization Act, 42 U.S.C. Section 5841, provides that action of the Commission shall be determined by a "majority vote of the members present." Commissioner Diaz was not present when this item was affirmed. Accordingly the formal vote of the Commission was 4-0 in favor of the decision. Commissioner Diaz, however, had previously indicated that he would approve this paper and had he been present he would have affirmed his prior vote.

35.75. Instead, staff should develop for Commission consideration a proposed revision to Part 35 that will require a licensee to notify NRC no later than the next calendar day after it becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under § 35.75. In addition, the rule should require the licensee to submit a written report within 15 days after discovery of the event. The proposed rule should also include a requirement for the licensee to provide identified exposed individual(s) with a copy of the report submitted to the Commission. This reporting and notification threshold would be consistent with the reporting and notification requirements in
§ 35.3047. The proposed rule should be provided to the Commission within 7 months of the date of the SRM.

This rulemaking would encompass a patient release that was not in compliance with § 35.75, as well as a release that was in compliance, i.e., it would address instances in which the licensee either:

(1) believes the basis of the release may have been incorrect or the release instructions may have been inadequate, OR

(2) learns, through voluntary means, that the patient did not follow the physician's instructions;

AND

An individual received or is estimated to have received a dose in excess of 50 mSv (5 rem).

The Statement of Consideration for the proposed rule should clearly indicate the Commission is not modifying its previous position that the NRC does not intend to enforce a patient's compliance with the licensee's instructions nor is it the licensee's responsibility to ensure compliance by patients once they leave the licensee's facility (Federal Register, Volume 62, Number 19, pages 4120-4133, January 29, 1997).

Attachment: Changes to the Attachments to SECY-00-0118

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
CIO
CFO
OCAA
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)

PDR - Advance

Attachment

Changes to the Attachments to SECY-00-0118

Changes to Attachment 6: Draft *Federal Register* Notice for Part 35

1. The alternative rule text for 10 CFR 35.3045 and 35.3047 (Attachment 8 to SECY-00-0118) should be incorporated into the final Federal Register notice for Part 35 (Attachment 6 to SECY-00-0118)

2. The statements of consideration and all supporting documents for the rule should be revised to reflect the Commission's approval of the alternative rule text for §§ 35.3045 and 35.3047 and removal of §§ 35.2045 and 35.2047.

3. In § 20.1301(c), "Dose limits for individual members of the public," for consistency with the rest of Part 20, and in line with the final NRC Metrification Policy, the SI units should consistently be in parentheses.

4. Page 1, line 12: add "more" before "risk-informed"; Perform a global search and make the same change throughout the document.

5. Page 6, line 5, regarding "Thirty-one States": verify the number of Agreement States at the time of publication - Oklahoma may have become an Agreement State

6. Page 7, line 9: add an "s" to "Use"; line 20: change "notice" to "Notice"

7. Page 8, line 5: add "; 63 FR 43580" after "(63 FR 43516"; line 6: change "proposed rule" to "document"

8. Page 8, line 6: add "at the request of stakeholders" after "November 23, 1998)"

9. Page 10, line 16: insert FR cite and date of publication of MPS

10. Page 18, line 13: add "decades of licensing and inspection experience, the States' perspectives," after "such as"; line 17: add "formal" before "risk analysis"

11. Page 23, line 10: change "subtracting" to "diverting"

12. Page 33, second paragraph: update the status of the Medical Pilot Inspection prior to publication

13. Page 35, last three lines: update prior to publication

14. Page 41, line 13: add "that we should require that" before "individuals" and delete "must."; line 14: add "we believe that we should require that" before "they" and delete

"must"

15. Page 45, lines 5 and 12: delete the first "e" in "judgement" and "judgements"; perform a global search and make the same change throughout the document

16. Page 48, line 17: change "is" to "are"

17. Page 52, line 6: add "to FDA-approved uses of byproduct material" after "... should not be limited"

18. Page 62, line 18: replace "hassles visiting another specialist" with "need to visit additional specialists"

19. Page 68, line 18: add "the" after "determine"

20. Page 72, line 5: replace "this section" with "§§ 35.490 and 35.690"

21. Page 115, delete lines 8 and 9 in their entirety; line 12: add "35.3067" to list of rule sections.

22. Page 123, line 16: change "(e)" to "(d)"

23. Page 129, replace lines 1 through 8 with the following:

    "conditions of a specific license issued by the Commission or an Agreement State. This license would require the licensee to comply with all provisions of Part 35. Section 35.49 has been modified to state that a licensee may use sealed sources or devices for medical use which are noncommercially transferred from a Part 35 licensee, i.e., if two licensees are authorized to possess sealed sources for medical use, they may transfer the sources from one to the other."

24. Page 135, line 8: replace "This section was proposed" with "Paragraph (d) was added"; line 10: replace "This section" with "Paragraph (d)(1)"

25. Page 145, line 11: delete "and"

26. Page 156, lines 12/13: Revise to state "... proposed wording was not clear *when applied to minor (ministerial) changes to the licensee's radiation protection program*, we revised the rule ...."

27. Page 165, line 8: change "23360" to "34104"; line 9: change "May 21, 1991" to "July 25, 1991"

28. Page 170, line 3: add "prescribed" before "dose"

29. Page 171, line 7: add "potential" after "based on the"

30. Page 180, Comment paragraph, revise line 4 as follows: "... is used, cesium-137 (Cs-137) ...brachytherapy"

31. Page 181, line 3: change “Cesium-137" to “Cs-137"

32. Page 192, line 9: change “(G)” to “(F)”

33. Page 196: delete the last line

34. Page 197, line 8: change “Aus” to “AUs”

35. Page 209, line 4: add a space after “1.11"; line 7: add a space after “1.11"; line 19: add “kilobecquerel” before “kBq” and put “kBq” in parentheses; line 20: change “0.555" to “0.56" in two places. The staff should perform a global search and make the change to line 20 in other places, as needed.

36. Page 209, line 19: add “(final rule paragraph (c))” after “paragraph (b)”; line 20: add “(final rule paragraph (d))” after “paragraph (c)”

37. Page 211, line 7: add a space after “3.7"

38. Page 221: *Mobile Medical Service* -- The Response to Issue 2 on page 221 of the FRN regarding mobile medical service needs to be revised. Specifically, the last sentence is unclear and could be interpreted to mean that byproduct material could be delivered to the client’s address, if the material is secured against unauthorized removal, regardless of whether the client is an NRC or Agreement State licensee. Such an interpretation is not consistent with the preceding 3 sentences in the Response, the discussion on page 449 of the FRN or the proposed final 35.80(b). The staff should review the statements of consideration and the rule text to ensure that they consistently reflect the staff’s position on whether, and under what conditions, byproduct material could be delivered directly to a client that is not a licensee.

39. Page 231, line 5: add “cobalt-57" before “Co-57" and put “Co-57" in parentheses

40. Page 233: insert the Section 35.190 material (from pages 236-7) here -- it was out of order; label issues “1" and “2"

41. Page 234, line 11: add “(Mo-99)” after “molybdenum-99"; line 16: change “molybdenum-99" to “Mo-99"

42. Page 235, lines 3/4: change “molybdenum-99" to “Mo-99"; line 5: change “kilobecquerel” to “kBq” and change “molybdenum-99" to “Mo-99" and change “megabecquerel” to “MBq” and change “technetium-99m” to “Tc-99m”; line 6: change “molybdenum-99" to “Mo-99" and change “technetium-99m” to “Tc-99m”; line 7: add an “s” to “page”

43. Pages 247 and 248, Issue 3, Response: Revise the first sentence of the response to state “ ... individual is likely to exceed 5 mSv (0.5 rem).” Delete the remainder of the paragraph. Revise the first sentence in the second paragraph of the response to state “... for other reasons because compliance with § 35.75 ensures that the maximally exposed ....”

44. Page 249, line 8: delete “iodine” and the parentheses around “I-131"

45. Page 251, lines 1 and 11: delete “other”

46. Page 252, line 9: Insert an introductory sentence explaining that the comment pertained to all sources used under § 35.400.

47. Page 252, line 10: revise this sentence to match the regulations: “using a system or source traceable to NIST and published protocols accepted by nationally recognized bodies or by a calibration laboratory accredited by AAPM.

48. Page 261, line 5, after “... in a year.”: Revise to add reference to the new provision for visitors (§ 20.1301).

49. Page 264, lines 4/5: delete “and” and add “and NIST” after “ACMP”

50. Page 267, line 14: change the parentheses to brackets, add “palladium-103" before “Pd-103" and put “Pd-103" in parentheses

51. Page 272, line 4: add “(Sr-90)” after “strontium-90"; line 5: change “strontium-90" to “Sr-90"

52. Page 272, line 4: change “improperly decaying the” to “improperly calculating the decay of sealed”

53. Page 273, lines 11, 15, 16, and 19: change ”strontium-90" to “Sr-90"

54. Page 273, line 18: change “had decayed the” to “had calculated the decay of the”

55. Page 274, lines 2 and 9: change ”strontium-90" to “Sr-90"

56. Page 278, lines 11/12: revise this sentence to match the regulations: “using a system or source traceable to NIST and published protocols accepted by nationally recognized bodies or by a calibration laboratory accredited by AAPM.

57. Page 293, line 15: add “gamma stereotactic radiosurgery” after “all patient”

58. Page 297, line 7: add the titles (or a footnote with the titles) for the three example documents

59. Page 301, line 6: add “(Ir-192)” after “iridium-192"; lines 12 and 13: change “iridium-192" to “Ir-192"

60. Page 304, line 3: add “in the final rule” after “However,”; line 6: delete “in the final rule”

61. Page 306, line 15: add the title for NUREG/CR-6276

62. Page 318, line 11: add “<www.nrc.gov>” after “Internet site”

63. Page 326, lines 1/2/3: delete the first sentence of the response; line 5: add additional

sentence “In order for new or revised requirements to be codified in Part 35, a public rulemaking process under the Administrative Procedure Act must be followed including the development of a cost-benefit analysis made available for public comment.”

64. Page 331, line 17: Insert the following at the beginning of this comment: “A comment received stated that the patient’s privacy and confidentiality are “ignored” with NRC recordkeeping....”

65. Page 339, line 9: add a space after “30"

66. Page 351, line 13: add “(3.3 feet)” after “1 meter”

67. Page 355, line 4: change “radiation surveys of patients and human research subjects” to “surveys after source implant and removal”

68. Page 360, last line: change “35.2636" to “35.2635"

69. Page 362, Section 35.2643: Delete the second and third sentences under Issue 1, Response.

70. Page 363, Section 35.2647: Delete the second and third sentences under Issue 1, Response.

71. Page 387: Delete the second, third, and fifth sentences in the first paragraph. Revise the fourth sentence to state “The occurrence of such *an unintended dose* does not ....”

72. Page 397 (see also pages 405 and 407), line 15: revise to place “D (H&S)” in quotes.

73. Page 416, line 14: change “diplomats” to “diplomates”; perform a global search and make the same change throughout the document

74. Page 422, line 13: add “as described in § 35.1000, i.e., applications” after “... byproduct material”; line 16: add “(1)” after “(d)” and add “additional” before “information”; line 18: add the following additional sentences at the end of the paragraph “This additional submittal will provide NRC with information on the radiation safety aspects of the specific medical use of the material. Applicants for uses under § 35.1000 must also submit the information required by paragraphs (b) and (c) of this section.

75. Page 423: Combine the last two paragraphs on page 423.

76. Page 427, line 10: add “the current” after “... we do not believe that”

77. Page 430, line 11: change “tied” to “limited”

78. Page 431, line 21: change “not clearly understood” to “subject to misinterpretation”

79. Page 433, line 19: add “for certain procedures” after “rule”

80. Page 440, line 8: add “or by” before “a decay correction”; line 10: delete the semicolon

81. Page 442, line 5: add “or by” before “a decay correction”; line 7: delete the semicolon; line 15: add “by” before “combination”

82. Page 443, lines 16 and 19: add a space after “1.11"

83. Page 446, line 19: delete “a” and add an “s” to “directive” and change “was” to “were”; line 20: change “in an area(s)” to “areas”

84. Page 450, second paragraph, last two sentences: combine as follows and move up to be the third sentence in the new paragraph: “This change provides licensees with greater flexibility in handling radioactive waste and codifies current licensing practice.”

85. Page 451, line 14: add “associated with administrations of unsealed byproduct material” after “... levels of risks”

86. Page 452, line 19: add “for use in research” after “(e.g., radiochemicals)”; line 20: add “accepted by FDA” after “IND protocol” and delete “for use in research”

87. Page 453, line 13: add a comma and “Program-Specific Guidance About Medical Use Licenses” after “NUREG-1556, Vol. 9"

88. Page 455, line 8/9: add a space between these lines; line 10: add “for use in research” after “(e.g., radiochemicals)”; line 11: add “accepted by FDA” after “IND protocol” and delete “for use in research”

89. For publication purposes, ADM should ensure that the use of abbreviations and symbols are used consistently through Section V and are consistent with the rules of the *Office of the Federal Register.*

90. Page 461, line 2: change “instruction and training” to “safety instruction”; line 11: add “that” before “patients” and add “would” before “receive”

91. Page 461, lines 4/5: change “in accordance with” to “under”

92. Page 466, line 1: change “in accordance with” to “under”

93. Page 467, last line: add a space after “and”

94. Staff should do a global review of the citations to the AAPM documents (including title, if referencing a new AAPM document) to make sure that they are complete and consistently presented in the FRN and acronyms are used whenever possible.

95. Page 476, line 2: add “at least” before “annual instruction”; line 3: replace “device” with “unit” and add “at least” before “annual practice.”

96. Page 480, line 1: delete second “the current”

97. Page 480, line 14: replace “monthly” with “once in each calendar month”

98. Page 518, last line and top of page 519: update to provide status of publication of the revised MPS; page 519, line 1: change “addresses” to “addressed”

99. Page 537, lines 10 and 11: Revise to state “. . . visitors to an individual who cannot be released under § 35.75, to . . .” This change should be reflected in other appropriate sections in the statements of consideration and in the supporting documentation for the rule.

100. Page 548, line 22: change “several medical disciplines are practiced” to “more than one medical discipline is practiced”. This change should be reflected in other appropriate sections in the statements of consideration and in the supporting documentation for the rule.

101. Page 585, lines 18 and 19: Change “cannot be released in accordance with” to “cannot be released under”.

102. Page 586, lines 14/15: change “that cannot be released in accordance with” to “who cannot be released under”

103. Page 594, line 17: revise to read “ ... human research subjects who are receiving brachytherapy and cannot be released under § 35.75.” The change from using the term “implant therapy” to “brachytherapy” should be reflected in other appropriate sections in the statements of consideration and in the supporting documentation for the rule.

104. Page 595, line 12: Revise to state “... human research subject who is receiving brachytherapy and cannot be released under § 35.75 ...."

Changes to Attachment 9: Assessment of Federal Regulations and Policies on Family

1. Page 1, line 22: change “mSV” to “mSv”; line 27: replace “eight” with “$8.7" and delete “dollars”

2. Page 1, line 26: add “and Agreement States” after “NRC”

Changes to Attachment 10: Draft Final *Federal Register* Notice for Enforcement Policy

1. Page 1, line 14: change “or” to “of”

2. Page 2, line 10: add “, email rwb1@nrc.gov” after “(301) 415-2741"

3. Page 2, line 15: hyphenate “risk informed” and “performance based”; line 17: change “will” to “would”

4. Page 3, lines 1/2: delete the first full sentence; line 4: replace “It was” with “The terms “written directive” and “misadministration” were”

5. Page 4, line 2: delete the comma after “medical events” and replace “such as” with “(e.g.,”; line 4: add “)” after “follow procedures”

Changes to Attachment 11: Letter to University of Cincinnati

1. Page 1, line 10: change “milliSievert” to “millisievert”

2. Page 2: combine third, fourth and fifth full paragraphs into a single paragraph

3. Page 2, line 16: delete “the” before ”request” and add “(2)” after “request” and delete “(2)” after petition; line 31: change “of” to “in” and delete “(“; line 33: delete “)”; line 34: add a period after “radiation patients” and capitalize “however”; line 36: add “in the petition to require licensees to instruct visitors about radiation safety” after “(4)”

Changes to Attachment 12: Draft Final Regulatory Analysis

1. Use numbers rather than words for radiological units to be consistent with the rest of the documents. (i.e., use “5 mSv”, not “five mSv”, see page 1-3 for some specific examples)

2. Page 5-39, lines 16 and 22: change “0.555" to “0.56"; line 31: add a space between “to” and “151"

3. Page 6-5, second to last line: add “revising” before “10 CFR Part 35"

Changes to Attachment 13: Draft Final Environmental Assessment

1. Page 2, line 35: add a space before “mSv” (2 places)

2. Page 3, line 30: add a space before “mSv”

3. Page 4, line 12: add a space before “mSv”

4. Page 5, line 21: add a space before “mSv”; line 24: add “and Measurements” after “National Council on Radiation Protection”

From: "Collins, Steve" <Collins@idns.state.il.us>
To: "Walter, David" <dwalter@adph.state.al.us>, <bat@nrc.gov>
Date: 6/14/01 12:26PM
Subject: RE: STP-01-044

I like the idea of revisiting Part 20. Let us consider changing the dose limit for members of the public to 200 or 300 or 500 mrem per year (plus ALARA) and a lot of the non-health physics concerns will go away. A lot of the policy disagreement could also go away if EPA would change the federal guidance to match. We all know that 500 mrem plus ALARA resulted in almost the same level of protection of the public as 100 mrem has, but it cost a lot less.

-----Original Message-----
From: dwalter@adph.state.al.us [mailto:dwalter@adph.state.al.us]
Sent: Thursday, June 14, 2001 10:11 AM
To: bat@nrc.gov
Cc: phl@nrc.gov; lab@nrc.gov; rjd@nrc.gov; dsf1@nrc.gov; cxh@nrc.gov; mhoward@gw.odh.state.oh.us; pan@nrc.gov; mur@nrc.gov; TFY@nrc.gov
Subject: STP-01-044

Ms. Torres:

I would like to offer some comments regarding the proposed rule change to 35.75. I personally am against this proposed rule, as well as the new 5,000 mrem notification limit for the embryo/fetus or nursing child (35.3047).

Some questions immediately come to mind. Why is such a rule needed in the first place? Is there a problem with released patients exposing so many members of the public to greater than 500 mrem that the medical community needs such an exception? How many reports of exposures exceeding 500 mrem has the NRC received? If the number is few, then what is the need for such a rule? Let the 500 mrem limit of Part 20 be the reporting requirement. If there have been many reports of exposures exceeding 500 mrem, perhaps the answer lies not in changing the reporting limits, but in finding the root cause of these overexposures.

In my opinion, this change seems to muddy the waters even further. It makes no sense to have so many different exposure limits for the public, much less confusing the issue further by saying that if you exceed the specified limits, you don't need to report it to the NRC. It appears to trivialize your own limits, and says they are of no consequence. I can assure you that the licensee is going to worry more about the reporting level than the actual exposure limit. This is further compounded by making an apparent distinction between medical and non-medical exposures. It appears the NRC equates 5,000 mrem of gamma radiation exposure from a released patient to 100 mrem of gamma radiation

exposure from an industrial gauge. We all know that this is not true, but these medical exceptions are now the norm, and give that appearance.

Creating so many rules that are exceptions to the most basic exposure limits of Part 20 essentially questions the validity of these limits. Instead of the confusion of constant special exceptions, maybe the NRC should revisit Part 20

Thank you for this opportunity to comment on the proposed rule. Please feel free to contact me if you have any questions. If you wish to talk to me, I may be reached by phone at 334-206-5391.

David Walter

CC: "Lohaus, Paul" <phl@nrc.gov>, "Bolling, Lloyd" <lab@nrc.gov>, <rjd@nrc.gov>, <dsf1@nrc.gov>, <cxh@nrc.gov>, <mhoward@gw.odh.state.oh.us>, <pan@nrc.gov>, <mur@nrc.gov>, <TFY@nrc.gov>

Division of Environmental Safety, Health & Analytical Programs
Bureau of Environmental Radiation
Radioactive Materials Section
PO Box 415
Trenton, NJ 08625-0415
Phone (609)-984-5462
Fax (609) –633-2210

June 19, 2001

Dear Sir,

The following are the New Jersey State Department of Environmental Protection's comments on NRC=s proposed rule 10 CFR 35.3075 for reporting excessive exposures to individuals as a result of patients released as per 10 CFR 35.75.

1 What was the rationale for selecting 5,000 mrem as the value for reporting exposure to individuals? This value is 50 times the "Dose Limits for Individual Members of the Public" listed in 10 CFR 20.1301, and 10 times the limiting value listed for "Release of Individuals Containing Radiopharmaceuticals or Permanent Implants" listed in 10 CFR 35.75.

2 If NRC is attempting to use the reported information as feed back on their revised patient release limits and NRC only anticipates one reported event per year, then there will be very little information available. Perhaps NRC should have chosen a lower reporting value such as 1,000-2,000 mrem, which would not put the individual into the realm of the occupational radiation worker and would provide more feed back on the revised patient release limits. This would provide more useful feed back on the revised patient release limits. By having a reporting value of 5,000 mrem NRC may get a false sense that the revised rule is working, when in fact there may be many cases of individual members of the public being exposed beyond the 500-mrem limit.

3 After reviewing the Advisory Committee on Medical Uses of Isotopes concerns, one would have to realistically question whether licensees would take the time and make an effort to report such incidents? Additionally, how would the licensee ever become aware of circumstances that would lead to excessive exposures?

4 NRC's concerns for their rules to be less intrusive into the practice of nuclear medicine may result in them being more intrusive on the general public as a result of increased

patient excreta contaminating trash which sets off radiation monitors at landfills and incinerators. Perhaps NRC should have reporting or records requirements for incidents involving patient excreta contaminated trash which sets off radiation monitors as a means of providing feedback on the impact of their patient release rule.

5 Lastly, if licensees end up not being required to report such exposures, they should be required to keep a record of such exposures for review during an inspection.

Should you have any questions regarding the above comments, please call John Feeney (609) 984-5555.

Sincerely,

John Feeney, License Administrator
Radioactive Materials Section

Ms. Betty Ann Torres
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Ms. Torres:

Staff members of the Texas Department of Health, Bureau of Radiation Control have reviewed the predecisional draft proposed rule concerning a notification requirement associated with the patient release rule in 10 CFR 35.75. We offer the following comments for consideration.

The rule as written is not workable and is unenforceable. The only reporting that should be required in this situation, if any, would be in the instance where the exposure to a member of the public came from a mistake in calculation by the physician or physicist or wrong patient directions from the physician. It is highly unlikely that a patient will admit that he or she did not follow the direction of the physician, for example, that he or she decided to fly to Hawaii with a child on his or her lap. In this situation, the fault is not with the facility, but with the patient. Therefore, if a member of the public does receive a dose in excess of the limit, reporting of it should be limited to errors on the part of the licensee. Another issue that makes the rule difficult to enforce is the lack of actual data to support the overexposure without dose reconstruction (time/distance factors). The licensee would have to depend on the input of the released patient and/or the person exposed for verification of an estimated dose.

This requirement does not appear to be effective in reducing risk to members of the public, especially when compared to the added cost to the licensee. Therefore, it can be considered both burdensome and unnecessary.

We appreciate the opportunity to comment on the predecisional draft proposed rule. If you have any questions or need further information, please contact me at 512-834-6688 or E-mail address: richard.ratliff@tdh.state.tx.us

Sincerely,

Richard Ratliff, P.E., Chief
Bureau of Radiation Control

From: "Frazee, Terry" <Terry.Frazee@DOH.WA.GOV>
To: "'bat@nrc.gov'" <bat@nrc.gov>
Date: 7/11/01 9:04PM
Subject: STP-01-044 (RE: 10 CFR 35.75)

I read with interest the comments from David Walter (sent via e-mail on June 14). I agree with Mr. Walter that the proposed rule is of questionable value and should not be promulgated. While I agree with NRC that there may be potential for members of the public to be "overexposed" due to patients released under 35.75, the root of the problem is not the rule but the Regulatory Guide.

NUREG 8.39 allows the licensee to "adjust" the assumptions made for determining the "activity" that may be contained in a patient at release (and presumably not cause an exposed individual to exceed the 5 rem dose limit). While the "baseline" used in setting up NUREG 8.39 is essentially the same as used for many years (the Iodine 131 release value in the table is 33 mCi instead of the previous 30 mCi release rule), the concern is that "occupancy" and other factors can be altered to allow patients to be released with hundreds of millicuries of residual activity! With this much activity, any deviation from the "expected behavior" can result in greater exposure to the public.

I believe the proper solution to the concern that NRC has expressed should be to re-evaluate NUREG 8.39 and set release values (in activity) for various radionuclides (and "chemical" forms) based on conservative assumptions, without allowing for "tweaking" by the licensee. Standardized patient instructions should be reviewed and set for the various treatment methods in current use. NRC should promptly update the NUREG when appropriate. This will simplify life for all parties involved.

As far as the proposed rule is concerned there are several problems: the first being the assumption this will be "minimal cost" to the licensee. Another problem is certain to be enforcement. The rule requires that the licensee "report any dose ... that an individual receives ... " Even though the notification requirement states that this is "after the licensee becomes aware ... " it is clear that every licensee will need to be diligent in talking with patients after treatment to assess how well they complied with instructions given by the licensee. If they do not make an attempt to assess this, they cannot report any dose "that an individual receives". This adds to the licensee's task for EVERY patient. "Time is money." The regulatory analysis on the cost of the rule is therefore totally inadequate and misleading. Finally, if the regulators don't ask about this area of regulation, and enforce licensee efforts to comply, then the rule should not exist. Only write rules we intend to enforce.

Thank you for the opportunity to comment.

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"The Department of Health works to protect and improve the health of people

in Washington State."
****

This message from Terry C. Frazee
e-mail terry.frazee@doh.wa.gov

Quick ways to reach me:
Voice = 360-236-3221
FAX = 360-236-2255

Also, visit our Home Page at
http://www.doh.wa.gov/ehp/rp

CC: "Demaris, Curt" <Curt.Demaris@DOH.WA.GOV>, "Erickson, John (DOH)" <John.Erickson@DOH.WA.GOV>, "NRC-Lloyd (E-mail)" <lab@nrc.gov>, "SR-6-AL-DavidWalter (E-mail)" <dwalter@adph.state.al.us>

STATE OF ILLINOIS
DEPARTMENT OF NUCLEAR SAFETY

1035 OUTER PARK DRIVE • SPRINGFIELD, ILLINOIS 62704
217-785-9900 • 217-782-6133 (TDD)

George H. Ryan
Governor

Thomas W. Ortciger
Director

July 24, 2001

Betty Ann Torres
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Re: Request for Comment on Predecisional Draft Amendment to 10 CFR 35.75 (STP-01-044)

Dear Ms. Torres:

The Illinois Department of Nuclear Safety (Department) hereby submits its comments on the predecisional draft amendment to 10 CFR 35.75. The letter requests comment on the development of a proposed "Patient Release Rule" which would require, among other things, notification of the NRC after a licensee becomes aware that an individual received or is estimated to have received a dose exceeding 5 rem from a patient who was released in accordance with 10 CFR 35.75. The Department's specific comments follow:

1. Since NRC now intends to make doses to the public from therapy patients reportable again, the reference for dose limits for individual members of the public in 10 CFR 20.1301(a)(1) that excludes "exposure from individuals administered radioactive material and released again in accordance with 10 CFR 35.75" should be moved to 10 CFR 20.1301(c). This would prevent the need for medical licensees to apply for a higher dose limit, and all the current reporting requirements already published in the regulations (10 CFR 20.2202 and 20.2203) would be enforceable again. This would obviate the need for another cumbersome reporting system strictly for medical treatments. In addition, the current reporting requirements of 10 CFR 20 have been effective for many years and are more appropriate for protecting public health and safety.

2. The content of the report to be filed does not need to be detailed by regulation to a greater degree than that already addressed in 10 CFR 20. The predecisional amendment requires a certification that the exposed individuals be notified. If it is not possible to specifically identify them or notify them, the licensee should be given the opportunity to explain such and not be held accountable for other portions of the reporting requirement.

3. The Department agrees with the ACMUI in that the licensee should not be held responsible for ensuring compliance by patients that have ignored those instructions specifically addressed by the licensee/physician. However, the licensee/physician should be held accountable for proper implementation of 10 CFR 35.75 in evaluating whether or not the patient is a viable candidate for release and for providing "reasonable" instruction and safety procedures. Towards that end, it may be beneficial to have the physician sign a patient evaluation form to certify that they are professionally satisfied that the patient is most likely to comply with the provided instructions and is suitable for release. Several tools are available and discussed in peer reviewed journals that include the use of Karnofsky scores to evaluate patient conditions and modeling of potential exposures to members of the public.

4. The Department agrees with the ACMUI that dose reconstruction and verification of estimated exposure can be difficult and can include a significant margin of error. However, this is nothing new. Every dose limit in 10 CFR 20 can be affected by contributing/mitigating factors based on individual circumstances, and these elements should be evaluated in conjunction with the regulatory agency to determine the extent of their significance. Similarly, if the licensee is in disagreement with how the information is handled or processed, there are avenues available to them for expressing their concerns and seeking immediate correction. Such is the case with any regulatory relationship regardless of the nature of the action taken by the agency's representatives.

5. The Department disagrees with the ACMUI that anonymity should be ensured for licensees under these circumstances. Any radiation safety program at a medical facility should currently have mechanisms in place to address public responses to these incidents. The medical community needs to review the risk vs. benefit of these treatments and take responsibility for decisions made under 10 CFR 20.110 and 35.75.

6. The Department would question the basis, including supporting data, for NRC's statements regarding the low frequency of known events associated with patient release. Simply because NRC does not keep records on such events, does not mean that such events are not occurring. Such events have occurred in Agreement States and means of addressing them have been problematic because hospitals will accept no responsibility in the matter (as noted in this predecisional amendment). Our state has experienced this with an NRC licensee that disregarded certain requirements of 10 CFR 35.75, released the patient for additional medical care in our state and subsequently rebuffed our inquiries for further information about doses to the public. The NRC Regional office was ultimately notified to address the licensee's release criteria.

The State of Illinois has not adopted the patient release language contained in 10 CFR 35 for the very reasons addressed by this predecisional draft along with other unresolved issues. Illinois is currently granting patient release under specific license conditions contained in a license amendment. The notifications mentioned are certainly part of our concern. Subsequent steps of addressing the concerns of the exposed members of the public and incidents beyond the control of the licensee have not been fully addressed by this proposal. In addition, as pointed out in the supporting information, the NRC is the responsible regulatory agency for only 1,655 medical licensees whereas there are 4,138 such licensees under the jurisdiction of Agreement States. Follow up actions by licensees and the states should be revisited for impact on resources if these changes become final. The impacts could be substantial for the Agreement States since we have responsibility for the majority of these licensees.

Thank you for the opportunity to comment. Please contact me at (217) 785-9947 if you have any questions.

Sincerely,

Joseph G. Klinger, Chief
Division of Radioactive Materials

JGK:CGV:DMP

cc: James Lynch, NRC Region III

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN: # 3150-AG81

Notification Requirement

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend certain provisions of its regulations that govern the medical use of byproduct material. The proposed rule would require a licensee to notify the NRC and an identified exposed individual shortly after the licensee becomes aware that the individual received or is estimated to have received a dose exceeding 50 millisievert (mSv) [5 rem] from a released patient who had been administered radioactive material. In addition, the proposed rule would require a licensee to submit a written report to the NRC within 15 days after discovery of the event and to provide a copy of the report to the identified exposed individual. NRC is specifically soliciting comments on issues raised by the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

DATES: The comment period expires **[insert 75 days after publication in the Federal Register].** Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit comments to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff.

Deliver comments to 11555 Rockville Pike, Rockville, MD, between 7:30 am and 4:15 pm on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking website (http://ruleforum.llnl.gov) . This site provides the capability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415-5905, or e-mail CAG@nrc.gov.

Certain documents related to this rulemaking, including comments received, may be examined at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. These same documents may also be viewed and downloaded electronically via the rulemaking website.

Documents created or received at the NRC after November 1, 1999, are also available electronically at the NRC's Public Electronic Reading Room on the Internet at http://www.nrc.gov/NRC/ADAMS/index.html. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by email to PDR@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Betty Ann Torres, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 [telephone, (301) 415-0191, email: BAT@nrc.gov .]

SUPPLEMENTARY INFORMATION:

Background

The NRC regulates the use of byproduct material in medicine for diagnosis and treatment of disease and research programs. Each year in the United States, radioactive pharmaceuticals or radioactive implants are administered to several million patients. These patients can expose other individuals to radiation until the radioactive material has decayed or has been excreted. The doses received from different radionuclides can vary greatly even though the quantities of the radionuclides may be equal. For this reason, on June 15, 1994 (59 FR 30724), the NRC proposed a revision of the regulations at 10 CFR 35.75, “Release of individuals containing unsealed byproduct material or implants containing byproduct material,” to make the criteria for patient release dose-based, rather than activity-based. A dose-based criteria provides a uniform measure of protection to exposed individuals. The final rule was published January 29, 1997 (62 FR 4120), and allows individuals who have received byproduct material to be released “if the total effective dose equivalent to any individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).”

Patient release is governed by 10 CFR 35.75, because the current regulations, 10 CFR 20.1002, 20.1003, and 20.1301(a)(1), provide that the dose limits in Part 20 do not apply to: (1) doses from background radiation; (2) exposure of patients to radiation for the purpose of medical diagnosis or therapy; (3) exposure from individuals administered radioactive material and released in accordance with § 35.75; or (4) exposure from voluntary participation in medical research programs.

Discussion

In 1997, the NRC initiated a rulemaking process that would result in a complete revision of 10 CFR Part 35, “Medical Uses of Byproduct Material.” The Commission supported continuation of the medical use program with decreased oversight of low-risk activities and continued emphasis on high-risk activities. The primary purpose of the revision of 10 CFR Part 35 was to restructure the regulation into a more risk-informed and more performance-based regulation.

A final rule that revised 10 CFR Part 35 was published on April 24, 2002, and becomes effective October 24, 2002. During consideration of this rule, the Commission noted that licensees were not required to notify the NRC if they learned that an individual received a dose in excess of the dose specified in 10 CFR 35.75 from a patient released under that provision. The Commission also noted licensees were not required to notify the exposed individual of the exposure. The Statement of Considerations for the January 29, 1997, final rule (62 FR 4120) revising 10 CFR 35.75 did not discuss whether reporting was required if the licensee failed to comply with 10 CFR 35.75 and an individual received a dose in excess of 5 mSv (0.5 rem), or complied with 10 CFR 35.75, but learned that an individual exposed to the released individual, nevertheless, received a dose in excess of 5 mSv (0.5 rem). As a result, the NRC subsequently decided to address the issue of notification and reporting in these situations in a separate rulemaking.

This proposed rule would require a licensee to notify the NRC and an identified exposed individual no later than the next calendar day or 24 hours, respectively, after the licensee becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a released individual who contains unsealed byproduct material or implants containing byproduct material. The proposed rule also would require a licensee to submit a written report to the NRC within 15 days after discovery of the event, and to provide a copy of the report to the identified exposed individual. This rulemaking would encompass a patient release

where a licensee fails to comply with § 35.75, as well as a release that was in compliance. The Commission believes that the most likely basis for reporting will be instances in which the licensee either:

(1) believes the basis of the release may have been incorrect or the release instructions may have been inadequate; or

(2) learns, through voluntary means, that the patient did not follow the physician's instructions.

If the patient did not follow the physician's instructions, please note that the Commission is not modifying its previous position of January 29, 1997 (62 FR 4120), that:

(1) The NRC does not intend to enforce a patient's compliance with the licensee's instructions; and

(2) The licensee is not responsible for ensuring compliance by patients once they are released from the licensee's facility.

Although this rule would result in a minimal increase in regulatory burden, the Commission believes that the information obtained in accordance with the proposed notification and reporting requirement is needed. There would be no change to the safety standards and dose limits currently in place. However, reporting exposures greater than 50 mSv (5rem) would provide information that can be used to determine if the assumptions used for patient release remain valid. In addition, such reports can illuminate whether any regulatory modifications are needed in this area in order to maintain public health and safety. With this information available to allow feedback on the outcomes achieved under the current regulations, the Commission believes that NRC's regulatory program would be strengthened.

Coordination with the Advisory Committee on the Medical Uses of Isotopes

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) is an advisory body established to advise the NRC staff on matters that involve the administration of byproduct material and radiation from byproduct material. The NRC discussed this rulemaking with the ACMUI at public meetings held on November 8-9, 2000 and April 18, 2001. In November 2000, the ACMUI recommended that NRC limit the reporting requirement to only those instances where the licensee made an error in the release of the patient, or errors made in delivery of instructions to the patient. In April 2001, the ACMUI reaffirmed its previous position. Members of the ACMUI also expressed concern about implementation, inspection, and enforcement of the rule. The transcripts of both meetings are available for review on the NRC website at http://www.nrc.gov/NRC/ADAMS/index.html. The ADAMS document accession numbers are ML003772075 for the November 2000, ACMUI meeting transcript and ML011380698 for the April 2001, ACMUI meeting transcript. During the April discussion of this issue, ACMUI indicated the following concerns. NRC is soliciting public comments on these issues as they relate to the proposed rule.

- Licensees may be reluctant to release patients under § 35.75 because of repercussions associated with the reporting requirement, such as, negative press and loss of public confidence. This will result in more expensive care for these patients.
- Licensees should be granted anonymity when reporting the event and not be held responsible for patients who disregard instructions.
- Licensees may have to report based on information that may be difficult to verify. For example, an individual could call the licensee with a concern or a question about the patient's behavior.

- Patients and licensees could be subject to intrusive investigations with possible loss of patient confidentiality.
- Dose reconstructions would be based on numerous variables with significant ranges of uncertainties.
- Low frequency of known events and problems with rule enforcement and implementation do not justify NRC resource expenditure.
- NRC and licensee effort should focus on compliance with § 35.75.

Consistency with the 2000 Medical Policy Statement

The proposed rule is consistent with the NRC's revised Medical Policy Statement (MPS) which became effective August 3, 2000 (65 FR 47654). The overall goals of the regulatory program concerning the medical use of byproduct material are to focus NRC regulation of medical use on those medical procedures that pose the highest risk and to structure its regulations to be more risk-informed and more performance-based.

The first statement of the MPS is "NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public." The proposed rule is consistent with this statement because the purpose of the rule is to further the protection of the health and safety of individuals exposed to patients who have been administered radioactive material by providing a feedback mechanism for significant deviations from the expected outcome of releasing a patient.

The proposed rule is also consistent with the second statement, "NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of

workers and the general public," because the regulatory purpose of the reporting requirement is focused on a significant deviation from a dose threshold as opposed to medical judgment.

The third statement, "NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's direction," is not relevant to this proposed rule because the rule would further the radiation safety of individuals exposed to the patients, rather than the radiation safety of the patients themselves.

The fourth statement of the MPS is "NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety." This statement is not relevant to the proposed rule because there are no industry and professional standards to be considered in developing this notification and reporting requirement.

Discussion of Proposed Amendments by Section

Table of Contents

The Table of Contents is revised to reflect that a new section is being added to the rule.

§ 35.8, "Information collection requirements: OMB approval."

This section is revised to add § 37.3075 to the list of approved sections with information collection requirements.

§ 35.75, “Release of individuals containing unsealed byproduct material or implants containing byproduct material.”

This section is revised to add a statement that refers to the notifications required by § 35.3075.

§ 35.3075, “Report and notification of a dose greater than 50 mSv (5 rem) to an individual from a patient released under § 35.75.”

This new section would be added to 10 CFR Part 35 to require that a licensee notify the NRC and the affected individual no later than the next calendar day or 24 hours, respectively, after the licensee becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under 10 CFR 35.75. This rulemaking includes instances where the licensee: (1) believes the basis of the release may have been incorrect or the release instructions may have been inadequate; or (2) learns, through voluntary means, that the patient did not follow the physician’s instructions. In addition, the revised rule would require the licensee to submit a written report to the NRC within 15 days after discovery of the event and to provide the exposed individual with a copy of that report.

Agreement State Compatibility

Under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs” approved by the Commission on June 30, 1997, and published in the Federal Register on September 3, 1997 (62 FR 46517), this proposed rule would be a matter of compatibility between the NRC and Agreement States, thereby providing consistency among the Agreement State and NRC requirements. A Compatibility “C” designation means that the essential objectives of an NRC program element should be adopted by Agreement States to avoid conflicts, duplication, or gaps in the regulation of agreement material on a nationwide basis. The manner in which the essential objectives are addressed need not be the same as NRC, provided the essential objectives are met. A Compatibility Category “D” designation means an NRC program element which does not need to be adopted by Agreement States for purposes of compatibility.

The proposed revision to 10 CFR 35.8 would be classified as Compatibility Category “D.” The proposed revision to 10 CFR 35.75 would be classified as Compatibility Category “C”. The proposed revision of 10 CFR Part 35 in Subpart M, “Reports,” adding a notification and reporting requirement under a new 10 CFR 35.3075 also would be classified as Compatibility Category “C.”

Plain Language

The Presidential memorandum dated June 1, 1998, entitled “Plain Language in Government Writing” directed that the Government’s writing be in plain language. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the heading “ADDRESSES” above.

Voluntary Consensus Standards

The National Technology Transfer Act of 1995 (Pub. L. 104-113), requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with the applicable law or otherwise impractical. In this proposed rule, the NRC would revise 10 CFR Part 35 to add 10 CFR 35.3075 to require notification and reporting when a licensee becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under 10 CFR 35.75. This action does not constitute the establishment of a standard that establishes generally-applicable requirements.

Environmental Impact: Categorical Exclusion

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

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

The burden to the public for this information collection is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The

U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collection contained in the proposed rule and on the following issues:

- Is the proposed information collection necessary for the proper performance of the functions of NRC, including whether the information will have practical utility?
- Is the estimate of burden accurate?
- Is there a way to enhance the quality, utility, and clarity of the information to be collected?
- How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for reducing this burden, to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or by internet electronic mail at BJS1@nrc.gov ; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0010), Office of Management and Budget (OMB), Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by **[insert 30 days after publication in the Federal Register]**. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis

NRC's Medical Use Program includes the regulation of the use of byproduct material in medical diagnosis, therapy, and research. There are approximately 1,655 NRC licenses authorizing the medical use of byproduct material under 10 CFR Part 35. There are approximately 4,138 State licenses in Agreement States authorizing the medical use of byproduct material. The Commission is proposing a revision to 10 CFR Part 35 that would require a licensee to notify and report to the NRC if an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under 10 CFR 35.75. In addition, the licensee must also notify and provide a written report to the identified exposed individual.

The options are either:

(1) Do not require the licensee to notify and report to the NRC and an identified exposed individual when an individual receives an exposure greater than 50 mSv (5 rem) from a patient released under 10 CFR 35.75; or

(2) Require the licensee to notify and report to the NRC and an identified exposed individual in such an event.

With no rulemaking action, costs to licensees are not affected. With a rulemaking action, minimal cost increases are anticipated from the notification and reporting requirements proposed by this rulemaking. Because dose received by an individual from a patient released under 10 CFR 35.75 is not currently reportable, no database exists for determining the frequency of this type of event. The Nuclear Materials Events Database (NMED) (1995 to present) identified 15 incidents that resulted in overexposures to the public, but there were no reports of overexposures to members of the public as a result of being exposed to patients released under 10 CFR 35.75. However, for the purpose of this regulatory analysis, the assumption is that NRC will receive one

notification and report per year from the entire medical community, not per licensee. Listed below is an estimate of the increased cost anticipated from the notification and submission of a written report to the NRC and identified exposed individual when the licensee becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under § 35.75.

Assumptions:		
Total annual reports from all licensees:		1
Total phone reporting time (hours)		0.5
Technical staff hourly rate:		$ 143
Total Annual Cost Increase for Licensees:		$ 72

Assumptions:		
Total annual license events requiring reporting under § 35.75:		1
Total report preparation time (hours)	5	
Technical staff hourly rate:		$ 143
Total Annual Cost Increase for Licensees:		$ 715

From this analysis, the estimated total annual increased cost to the medical community is anticipated to be $787 for a licensee who notifies and submits a written report to the NRC and identified exposed individual when the licensee becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under § 35.75.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the NRC certifies that this proposed rule, if promulgated, will not have a significant economic impact on a substantial

number of small entities. This proposed rule adds a reporting requirement for an incident which is estimated to occur infrequently. Therefore, the economic impact on small entities is negligible.

Backfit Analysis

The NRC has determined that the backfit rules (10 CFR 50.109, 72.62, or 76.76) do not apply to this proposed rule because these amendments do not involve any provision that would impose backfits as defined in the backfit rule. Therefore, a backfit analysis is not required.

List of Subjects

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

For reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Part 35.

PART 35 — MEDICAL USE OF BYPRODUCT MATERIAL

1. The authority citation for Part 35 continues to read as follows:

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

2. In the Table of Contents under Subpart M, Reports, the following heading is added:

* * * * *

35.3075 Report and notification of dose to an individual from a released patient.

* * * * *

3. In § 35.8, paragraph (b) is revised to read as follows:

§ 35.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26. 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047, 36.3067, and 35.3075.

* * * * *

4. In § 35.75, paragraph (e) is added to read as follows:

§ 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

* * * * *

(e) The licensee shall notify the NRC and file a report, if required, in accordance with § 35.3075.

5. Section 35.3075 is added under Subpart M to read as follows:

§ 35.3075 Report and notification of dose to an individual from a released patient.

(a) A licensee shall report any dose greater than 50 mSv (5 rem) total effective dose equivalent that an individual receives from a patient released under § 35.75.

(b) The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after the licensee becomes aware of an event that requires a report in paragraph (a) in this section.

(c) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after the licensee becomes aware of a dose to an individual that requires a report in paragraph (a) in this section. The individual(s) receiving a dose described in paragraph (a) is referred to as identified exposed individual(s).

(1) The written report must include —

(i) The licensee's name;

(ii) The estimated dose(s) to the identified exposed individual(s);

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) What actions, if any, have been taken or are planned to prevent recurrence;

(vi) Certification that the licensee notified the identified exposed individual(s).

(2) The report shall not contain the names of the identified exposed individual(s), the individual released under § 35.75, or any other information that could lead to the identification of the exposed individual(s) or the individual released under § 35.75.

(d) The licensee shall provide notification of the event to the identified exposed individual(s) no later than 24 hours after the licensee becomes aware of an event that would require reporting under paragraph (a) of this section.

(e) The licensee shall provide the identified exposed individual(s) with a copy of the report submitted to the Commission.

Dated at Rockville, Maryland, this _____ day of _____, 2002.

For the Nuclear Regulatory Commission.

_____
Annette L. Vietti-Cook,
Secretary of the Commission.