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 § 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

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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.

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”