



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

AE-41-2

August 7, 1997

MEMORANDUM TO: Don Lanham, DCB, DISS, ADM

FROM: Stewart Schneider, DRA, ~~RRDB~~

SUBJECT: REGULATORY HISTORY FOR CRITERIA FOR THE
RELEASE OF INDIVIDUALS ADMINISTERED
RADIOACTIVE MATERIALS (10 CFR PARTS 20 AND 35)
(62FR4120, 01/29/97); FINAL RULE -- RIN 3150-AE41

Attached for your processing are regulatory documents considered to be of central relevance to the final rulemaking entitled "Criteria for the Release of Individuals Administered Radioactive Materials" (10 CFR Parts 20 and 35). Also attached is an index of these documents. The designator assigned by the Rules Review and Directives Branch is AE41-2 and is noted in the upper right hand corner of the cover page for each document.

Attachments:

1. Index
2. Documents

cc w/att 1: Betty Golden, RRDB/ADM

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Change: LM ENCL
PDR 1 - 1 w/o non-public
enclosures

RH01 1/1

L-4-1 Regulatory History

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REGULATORY HISTORY INDEX FOR

FINAL RULE

CRITERIA FOR THE RELEASE OF INDIVIDUALS ADMINISTERED RADIOACTIVE
MATERIALS

(10 CFR PARTS 20 AND 35)

RIN 3150-AE41

PDR

1. Undated Information on 100 mrem versus 500 mrem dose limit
2. ORISE Correspondence (Nursing infant info):

12/22/94	Letter from REToohey (ORISE) to Donna-Beth Howe (NRC)
03/95	Draft Report - Radiation Dosimetry and Safety (MStabin and AHach, ORISE)
04/12/95	Letter from MStabin to Donna-Beth Howe
05/31/95	Letter from SMcGuire (NRC) to REToohey
06/08/95	Tables transmitted by MStabin to SMcguire
06/27/95	Letter from REToohey to SMcGuire and final version of "Radiation Doses to a Nursing Infant From Radiopharmaceuticals Administered to the Mother"
10/13/95	Letter to MStabin from SAMcGuire
02/13/96	Correspondence from MStabin to DBHowe and ORISE comments regarding the document on the dose to nursing children
03/21/96	Letter from MStabin to SMcGuire on review of Appendix B of NUREG-1492 regarding instructing to breast-feeding women
06/25/96	Letter from MStabin to SSchneider (NRC) re dosimetry information for breast-feeding women
10/14/96	Letter from MStabin to SSchneider enclosing new materials to be included in the document regarding radiation doses to infants from the administration of nuclear medicine pharmaceuticals to women who are breast feeding
12/19/96	Tables transmitted by MStabin to SSchneider
3. Barry Siegel Correspondence (Patient Release Rulemaking)

10/26/94	Email from Barry Siegel (Mallinckrodt Institute of Radiology) to SSchneider - Patient Release Rulemaking
11/03/94	Email from Barry Siegel to SSchneider - Multiple Administrations
11/06/94	Email from Barry Siegel to SSchneider - Multiple Administrations
11/19/94	Email from Barry Siegel to SSchneider - I-131 and Breast Feeding
06/01/95	Fax to Barry Siegel from SSchneider transmitting pages 48 and 49 of FRN for review of rule language

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06/03/95	Email from Barry Siegel to SSchneider - Proposed § 35.75
06/05/95	Email from Barry Siegel to SSchneider - Proposed § 35.75
06/06/95	Email from Barry Siegel to SSchneider - § 35.75
07/17/95	Fax to Barry Siegel from SSchneider transmitting § 35.75 for comment
07/20/95	Email from Barry Siegel to SSchneider - Patient Release Criteria
07/27/95	Fax to Barry Siegel from SSchneider transmitting latest wording of rule text for § 35.75
07/27/95	Email from Barry Siegel to SSchneider - Patient Release Criteria
08/18/95	Fax to Barry Siegel from SSchneider transmitting pages 18 through 20 of FRN for review and comment
08/19/95	Email from Barry Siegel to SSchneider - Patient Release Rule
08/21/95	Fax to BSiegel from SSchneider transmitting pgs 56 and 57 for review and comment
09/08/95	Fax to BSiegel from SSchneider transmitting page 58
11/19/95	Email from BSiegel to SSchneider re Patient Release Rule
11/21/95	Fax to BSiegel from SSchneider transmitting Commission paper and § 35.75
11/25/95	Email from BSiegel to SSchneider with comments on draft Commission Paper faxed on 11/21/95
11/29/95	Email from BSiegel to SSchneider - Patient Release Rule

4. Vugraphs

07/12/94	Agreement State Manager's Workshop - Patient Release - 10 CFR Parts 20 and 35
07/12/94	10 CFR Parts 20 and 35 - Patient Release Criteria
09/28/94	10 CFR Parts 20 and 35 - Patient Release Criteria
10/94	Patient Release - 10 CFR Parts 20 and 35
10/20/94	10 CFR Parts 20 and 35 - Patient Release Criteria
10/20/94	Additional Slides of Worth
11/09/94	10 CFR Parts 20 and 35 - Patient Release Criteria
11/18/94	10 CFR Parts 20 and 35 - ACMUI Meeting
03/12/95	10 CFR Parts 20 and 35 - ACMUI Meeting
05/12/95	10 CFR Parts 20 and 35 - ACMUI Meeting
07/05/95	10 CFR Parts 20 and 35 - Dr. Morrison Meeting
07/17/95	10 CFR Parts 20 and 35 - EDO Meeting
10/18/95	ACMUI Meeting - Update on rulemaking/guidance
11/15/95	10 CFR Parts 20 and 35 - Patient Release Criteria
11/15/96	Inspection Guidance for Final Patient Release Rule

5. 08/25/94 Comment letter from Peter Crane to John Hoyle

6. undated Notes for NMSS/RES Meeting on Patient Release Rule

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7. 09/29/94 NRC Information Notice 94-70 -- issues Associated With Use of Strontium-89 and Other Beta Emitting Radiopharmaceuticals
8. 09/29/94 NMSS/RES Meeting on Patient Release
9. 11/94 NMSS issues to be discussed at RES/NMSS meeting on 11/09/94
10. 01/24/95 Comment letter from Carol Marcus to Chairman Selin
11. 02/10/95 Letter to Carol Marcus from Eric Beckjord responding to 01/24/95 letter
12. 02/23/95 Comment letter from Peter Crane to Chairman Selin.
13. 03/30/95 Summary of Package Status - Final Rulemaking
14. 06/28/95 Agenda for 06/28/95 meeting on Patient Release on rulemaking
15. 04/12/95 Memo to DCool, STreby, RBangart from BMMorris requesting technical review of Draft Final Rule
16. 04/19/95 Memo to BMMorris from STreby responding to request for technical review dated 04/12/95
17. 05/03/95 Memo to BMMorris from RLBangart responding to request for technical review dated 04/12/95
18. 05/12/95 10 CFR 35.75 - OGC requested revisions to the FRN
19. 05/31/95 Memo to multiple - Office review and concurrence on Draft Final Rule
20. Interoffice comments on final rule:
 - 06/05/95 Memo to DMorrison from DLMeyer forwarding ADM concurrence subject to comments provided
 - 06/07/95 Email from Beth St.Mary forwarding IRM concurrence subject to changes
 - 06/08/95 Email from SShortt to SMcGuire and SSchneider forwarding OC concurrence
 - 06/08/95 Memo to MLesar from BJSelton forwarding IRMB comments
 - 06/08/95 Memo to DMorrison from STreby forwarding OGC comments concurrence deferral
 - 06/09/95 Memo to DMorrison from JLieberman forwarding OE concurrence

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| | 06/12/95 | Memo RLBangart to DLMorrison forwarding OSP concurrence/comments |
| | 06/13/95 | Memo CPaperiello to DLMorrison forwarding NMSS concurrence |
| | 06/15/95 | Memo to DLMorrison from SATreby forwarding "no legal objection" |
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| 21. | 06/08/95 | Email from LABolling to SSchneider, Subj: Recent OSP Sponsored Meetings |
| 22. | 06/14/95 | Memo to JMTaylor from DLMorrison forwarding Final Rule package |
| 23. | 06/19/95 | Email from CTrottier to SSchneider, Subj.: Patient Release |
| 24. | 09/14/95 | Memo for DACool from STreby, Subj: OGC Review of Amended Final Rulemaking Package - no legal objection |
| 25. | 11/30/95 | Revised page 17 of FRN for EDO |
| 26. | 12/12/95 | Email from BJones, OGC, to SSchneider, RES, regarding Patient Release |
| 27. | 12/21/95 | Memo to JTaylor from JCHoyle - Staff requirements - SECY-95-286 - Withdrawal of subject paper to revise reg analysis |
| 28. | 03/07/96 | Memo to JGlenn from DACool - Comments on revised FRN and Reg Analysis |
| 29. | 03/28/96 | Route slip from SSchneider/ATse, RES, to JSchlueter, EDO, forwarding Patient Release Final Rule |
| 30. | 04/09/96 | Note from JSchlueter to ATse and JGlenn - Patient Release and IG |
| 31. | 04/11/96 | Route slip from JGlenn to HThompson forwarding Final Rule package |
| 32. | 04/25/96 | Memo to DLMorrison from LJNorton, IG - Revised Final Rulemaking |
| 33. | 04/25/96 | Communications between JGlenn and JSchlueter forwarding revised package |
| 34. | 05/02/96 | Fax from JSchlueter to SSchneider attaching 4 pages with edits |
| 35. | 05/02/96 | Email from SGagner to JSchlueter forwarding revised draft press release |

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36. 05/22/96 Memo to SSchneider from MLesar - Review of SECY-95-286
37. 05/22/96 Note to Commissioner Assistants from JLBlahe, Subj: 63 comment letters received on the proposed patient release rule and associated reg guide DG-8015
38. 05/23/96 Memo to Alzonja Shepard from Brenda Jo. Shelton forwarding IRMB comments
39. 05/24/96 Memo to John L. Glenn from Brenda Jo. Shelton forwarding IRMB comments on final rule and OMB package
40. 05/24/96 IRM Comments on OMB package
41. 06/09/96 Note from Beth St. Mary to SMcGuire forwarding comments on OMB package
42. 09/03/96 NRC Form 620 - Program Official Certification for Proposed Collection of Information - signed by CATrottier
43. 09/05/96 Revised OMB package submitted to IRM
44. 09/13/96 SBRFA information sent to MLesar
45. 10/07/97 OMB package signed by GCranford
46. 10/11/96 SRM for JMTaylor and JFCordes from JCHoyle approval final rule and requesting that guidance and final rule be published at same time and also requested changes to Statement of Considerations
47. 01/21/97 Memo to DLMeyer from CATrottier - Requesting submittal of FRN to SECY for signature
48. 01/21/97 Congressional letters to Hon. Lauch Faircloth and Hon. Newt Gingrich
49. 01/23/97 FRN signed by JCHoyle
50. 01/29/97 Federal Register Notice - 62 FR 4120; Publication of final rule
51. 03/07/97 Letters to PJSeward, AMA, and BWAhluwalia, ACNM, from CATrottier regarding outcome of petitions filed by AMA and ACNM

CENTRAL FILES

1. 07/12/94 Letter to SMcGuire from CMeinhold, BNL
2. 03/03/95 Letter to AKRoecklein from ALCarsten, BNL
3. 05/24/95 Transmittal notice to SMcGuire from DKaurin, BNL
4. 06/07/95 Letter to SSchneider from DKaurin, BNL
5. 11/30/95 SECY-95-286 - Final Amendments to 10 CFR Parts 20 and 35
6. 05/08/96 SECY-96-100 - Final Amendments to 10 CFR Parts 20 and 35
7. 08/29/96 Affirmation Vote - SECY-96-100 - Commissioner Diaz

Sam Jones Information -
100 vs 500 mrem Dose Limit -

DOCUMENT

ICRP Publication 60, "1990 Recommendations of the International Commission on Radiological Protection," 1991

NCRP Report No. 116, "Limitation of Exposure to Ionizing Radiation," 1993

EPA, Draft - Federal Radiation Protection Guidance for Exposure of the General Public, 1994

ICRP Publication 68, Dose Coefficients for Intakes of Radionuclides by Workers - Replacement of ICRP Publication 61 - Includes Summary of the Current ICRP Principles for Protection of the Patient in Nuclear Medicine, 1995

RECOMMENDATION

Dose Limits in Public Exposure

The limit for public exposure should be expressed as an effective dose of 1 mSv in a year. However, in special circumstances, a higher value of effective dose could be allowed in a single year, provided that the average over 5 years does not exceed 1 mSv per year.

Nonoccupational Dose Limits: Exposure of Individual Members of the Public

5 mSv (500 millirem) annual for infrequent annual exposures

1 mSv (100 millirem) annual for continuous (or frequent) exposure

Recommendation 3

5 mSv (500 millirem) annually in certain cases (e.g. the incidental exposure of a family members, household members, or a friend or a patient being treated (or diagnosed) using radioactive materials, for certain medical procedures, primarily in the treatment of thyroid cancer using I-131)

1 mSv (100 millirem) annually

Protection of the Family and Public After Nuclear Medicine Therapy

(Limit does not apply to the care giver)
1 mGy (100 millirad) - other family and public

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DOCUMENT

ICRP Publication 68, Dose Coefficients for Intakes of Radionuclides by Workers - Replacement of ICRP Publication 61 - Includes Summary of the Current ICRP Principles for Protection of the Patient in Nuclear Medicine, 1995 (continued)

International Atomic Energy Agency (IAEA) Safety Series No. 115-1, "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources," 1994

RECOMMENDATION

Nuclear Medicine Procedures on Women

Women who are breast-feeding - The child should not be breast-fed until the radiopharmaceutical is no longer secreted in an amount estimated to give an unacceptable absorbed dose to the child.

Dose Limitation for Comforters and Visitors of Patients

5 mSv (500 milirem) - Comforter or visitor

1 mSv (100 millirem) - Children visiting patients

Maximum Activity for Patients in Therapy on Discharge from Hospital

Discharge from hospital:

- Patient shall not be discharged from hospital before the activity of radioactive substances in the body falls below 1100 MBq (30 mCi).

Note: release limit provided only for Iodide-131

- Written instructions to patients concerning contact with other persons and relevant precautions for radiation protection shall be provided as necessary.

DOCUMENT

International Atomic Energy Agency (IAEA) Safety Series No. 115-1, "International basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources," 1994 (continued)

10 CFR Part 20, 1991

ICRP Publication 52, "Protection of the Patient in Nuclear Medicine," 1987

RECOMMENDATION

Optimization of Protection for Medical Exposures

Breast-feeding

-Diagnostic exposure: interruption

Therapeutic exposure: avoidance

Part 20-Standards for the Protection Against Radiation

5 mSv (500 millirem) - Minors (occupational dose)

5 mSv (500 millirem) - Embryo/fetus (Occupational exposure of a declared pregnant woman)

50 mSv (5 rem) - Embryo/fetus (Occupational exposure of an undeclared pregnant woman)

1 mSv (100 milirem) - Members of the public

Guidelines to Good Clinical Practices

5 mCy (500 millirem) - Protection of the family

(A patient treated with gamma-emitting radionuclides should be advised not to hold children or otherwise be in intimate contact with family members for an appropriate time interval after having left the hospital. Children and pregnant women may need to avoid close proximity to the patient.)

DOCUMENT

ICRP Publication 52 "Protection of the Patient in Nuclear Medicine," 1987 (continued)

NCRP Publication 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," 1970

NCRP Commentary No. 11, "Dose Limits for Individuals who Receive Exposure from Radionuclide Therapy Patients," 1995

USPDI, Volume I - "Drug Information for the Health Care Professional," 1995

RECOMMENDATION

If the patient is a nursing mother, the child should not breast-feed until the radiopharmaceutical is no longer secreted in an amount estimated to give an acceptable absorbed dose to the child.)

5 mSv (500 millirem) - Other persons

Limits for Release of Radionuclide Therapy Patients

50 mSv (5rem) annually - Adults Family Members

5 mSv (500 millirem) annually - Adults Family Members (training and individual monitoring)

1 mSv (100 millirem) annually - Children and Pregnant Women of Patient's Family

1 mSv (100 millirem) annually - Co-workers

5 mSv (500 millirem) annually - Co-workers (controlled conditions - limited number)

1 mSv (100 millirem) annually - General Public

Dose is specific to radiopharmaceutical -

((e.g. ¹³¹I resume when the likelihood of the infant's ingested effective dose equivalent (EDE) is below 1 mSv (100 millirem))

DOCUMENT

USPD1, Volume I - "Drug Information for the Health Care Professional," 1995 (continued)

American College of Radiology, "Radiation Bioeffects and Management Test and Syllabus," 1991

RECOMMENDATION

(e.g. Tc 99m Albumin Aggregated - without discontinuation of breast-feeding, the radiation dose to breast-fed infant will be less than 20 millirems after the mother receives a 4 mCi dosage, therefore, because of potential risk to the infant from radiation exposure, discontinuation of nursing is recommended for 6 to 12 hours.)

(e.g. Sodium phosphate P 32 may be distributed into breast-milk. Because of the potential risk to the infant from radiation exposure, breast-feeding should be discontinued.)

Chapter 23: Medical Radionuclides

1 mSv (100 millirem) annually - Nursing child is a member of the general public

ICRP 68, 1995

1 mGy (100 millirads) - Family and Public

(Limit does not apply to those who attend the patient at home.)

NCRP Commentary No. 11, 1995

1 mSv (100 millirem) annually - Children and Pregnant Women of Patient's Family

50 mSv (5rem) annually - Adults Family Members

5 mSv (500 millirem) annually - Adults Family Members (training and individual monitoring)

1 mSv (100 millirem) annually - Co-workers

5 mSv (500 millirem) annually - Co-workers (controlled conditions - limited number)

1 mSv (100 millirem) annually - General Public

USPDI, 1995

Dose is specific to radiopharmaceutical -

((e.g. ¹³¹I resume when the likelihood of the infant's ingested effective dose equivalent (EDE) is below 1 mSv (100 millirem))

(e.g. Tc ^{99m} Albumin Aggregated - without discontinuation of breast-feeding, the radiation dose to breast-fed infant will be less than 20 millirems after the mother receives a 4 mCi dosage, therefore, because of potential risk to the infant from radiation exposure, discontinuation of nursing is recommended for 6 to 12 hours.)

USPDI, 1955 (Continued)

(e.g. Sodium phosphate P 32 may be distributed into breast-milk. Because of the potential risk to the infant from radiation exposure, breast-feeding should be discontinued.)

10 CFR Part 20, 1995

5 mSv (500 millirem) - §20.1207 Occupational dose limits for minors. The annual occupational dose limit for minors are 10 percent of the annual dose limits ((5 rems) or (0.05 Sv)) specified for adult workers in §20.1201

5 mSv (500 millirem) - §20.1208 Dose to an embryo/fetus. (due to occupational exposure of a declared pregnant woman)

1 mSv (100 millirem) - §20.1301 Dose limits for individual members of the public.

EPA, Draft - Federal Radiation Protection Guidance for Exposure of the General Public, 1994

5 mSv (500 millirem) annually in certain cases.

(e.g. the incidental exposure of a family members, household members, or a friend to a patient being treated (or diagnosed) using radioactive materials, for certain medical procedures, primarily in the treatment of thyroid cancer using I-131)

NCRP Commentary No. 9, 1994

If the dose to the embryo, fetus, or nursing child from an unintended exposure is less than or equal to an effective dose of 50 mSv (5 rem), there is no harm from deterministic effects and the risk of stochastic effects is less than one percent.

NCRP Report No. 116

1 mSv (100 millirem) annual for continuous (or frequent) exposure

5 mSv (500 millirem) annual for infrequent annual exposures

American College of Radiology, 1991

1 mSv (100 millirem) annually - Nursing child (Member of Public)

ICRP Publication 52, 1987

5 mGy (500 millirem) - Protection of the family

NCRP Publication 37, 1970

5 mSv (500 millirem) - Other persons