HOLY REDEEMER HEALTH SYSTEM
MINISTRY OF THE SISTERS OF THE HOLY REDEEMER

HOLY REDEEMER HOSPITAL AND MEDICAL CENTER

NMSS1

RECEIVED
REGION 1
2007 JUL 25 AM 10 08

July 23, 2007

U.S. Nuclear Regulatory Commission
Region I
Attn: Medical Licensing Assistance Section
474 Allendale Road
King of Prussia, PA 19406-11415

03003044

Amendment to NRC License No. 37-05089-01

Dear Sir/Madam:

We are writing to inform you that we have new authorized users and a new Radiation Safety Officer.

June 30, 2007 was the last day that Drs. Kessler, Wurtele, Jacobstein, Krakovitz and DePersia provided support to our Nuclear Medicine services. Dr. Howard Kessler was also the Radiation Safety Officer. Please delete these individuals from our license.

The new physicians, categories of use, and licenses they are currently on, or have been on very recently, are as follows:

Eli F. Dweck, M.D. 35.100, 35.200, and 35.300
NRC License No. 37-18263-01 & 37-17643-01
PA. License No. PA-0378 & PA-0317

Debra S. Fineman, M.D. 35.100, 35.200, and 35.300
NRC License No. 37-18263-01 & 37-17643-01
PA. License No. PA-0378 & PA-0317

Martin A. Graber, M. D. 35.100, 35.200 and 35.300
NRC License No. 34-16710-01

140861

NMSS/RGN1 MATERIALS-002

1648 HUNTINGDON PIKE • MEADOWBROOK, PA 19046
215-947-3000 • www.holyredeemer.com

Drueding Center/
Project Rainbow
•
Holy Redeemer
Hospital and
Medical Center
•
Holy Redeemer
Physician and
Ambulatory Services
•
Holy Redeemer
Managed Care
Organization
•
Holy Redeemer
Visiting Nurse
Agency-NJ
•
Holy Redeemer
Home Health and
Hospice Services
•
The
Lafayette-Redeemer
•
St. Joseph's Manor
•
Redeemer Village

HOLY REDEEMER HEALTH SYSTEM
MINISTRY OF THE SISTERS OF THE HOLY REDEEMER

HOLY REDEEMER HOSPITAL AND MEDICAL CENTER

Michael B. Kates, M.D. 35.100, 35.200, and 35.300 (except thyroid carcinoma)
NRC License No. 37-18263-01 & 37-17643-01
PA. License No. PA-0378 & PA-0317

Robert L. Lantieri, M.D., already an authorized user on our license in categories 35.100, 35.200 and 35.300, has reviewed with Dr. Kates the additional requirements, i.e. detailed patient instructions, 35.75 release criteria, for the use of I-131 in the treatment of thyroid carcinoma. Drs. Lantieri, Dweck and Fineman will be the authorized user for these treatments.

In addition, Mr. Kenith L. Hogue, M.S., the medical physicist in Radiation Oncology, has provided an inservice to Dr. Kates in which he has explained all the requirements and hospital procedures of the I-125 brachytherapy seed program. Documentation of this training is attached. Dr. Michael B. Kates, M.D. is our new Radiation Safety Officer.

If you have any questions please do not hesitate to contact me at 215.938.2006. Thank you for your assistance.

Sincerely,

Catherine A. Egan

Catherine Egan
Vice President

Enclosures

Drueding Center/
Project Rainbow
•
Holy Redeemer
Hospital and
Medical Center
•
Holy Redeemer
Physician and
Ambulatory Services
•
Holy Redeemer
Managed Care
Organization
•
Holy Redeemer
Visiting Nurse
Agency-NJ
•
Holy Redeemer
Home Health and
Hospice Services
•
The
Lafayette-Redeemer
•
St. Joseph's Manor
•
Redeemer Village

1648 HUNTINGDON PIKE • MEADOWBROOK, PA 19046
215-947-3000 • www.holyredeemer.com

HOLY REDEEMER HOSPITAL

DEPARTMENT OF RADIATION ONCOLOGY

BRACHYTHERAPY INSERVICE SIGN-IN SHEET

Date performed: July 18, 2007 **By:** Kenith L. Hogue, MS

TOPICS COVERED:

Overview of the Brachytherapy Procedure for Prostate Implants

Safety Precautions with respect to the OR and PACU Staff, patient and general public

Contact Numbers

REVIEW OF 10 CFR PART 35

Part 35--medical use of byproduct material

- Subpart A--General Information
- Subpart B--General Administrative Requirements
- Subpart C--General Technical Requirements
- Subpart F--Manual Brachytherapy
- Subpart L--Records
- Subpart M--Reports
- Subpart N—Enforcement

Questions and Concerns

PRINTED NAME	SIGNATURE
Michael Kates MD	MD

1 Radiation Therapy In-Service

Presented by

Kenith L. Hogue, MS
Clinical Medical Physicist
University of Pennsylvania at
Holy Redeemer Hospital
Charles and Betty Bott Cancer Center

July 18, 2007

2 Internal Radiation Therapy (Brachytherapy)

- Internal Radiation Therapy (Brachytherapy) Internal radiation therapy, also called Brachytherapy, refers to methods of radiation delivery in which radioactive material is implanted directly into or near a tumor

3 Advantages of Brachytherapy

- Allows the doctor to give a higher total dose of radiation
- Concentrates the radiation in the tumor
- Lessens damage to normal tissue near the cancer
- Can be the best way to treat certain types of cancer
- Can also be an alternative to surgery

4 BRACHYTHERAPY

- Sometimes brachytherapy is done in conjunction with external radiation therapy
- Brachytherapy delivers a "boost" (higher dose) to help destroy the main mass of tumor cells
- The radioactive material is sealed in a metal seed and placed directly into or near the cancer site

5 BRACHYTHERAPY

- Interstitial brachytherapy involves placing radiation seeds directly placed into the tumor or tissue at risk using a needle applicator
- Intracavitary brachytherapy involves the use of special applicators or small tubes (catheters) that are placed within body cavities that are near the tumor

6 BRACHYTHERAPY

- Devices are then 'loaded' with radioactive sources

7 Types of Brachytherapy

- High Dose Rate (HDR) Brachytherapy
- Low Dose Rate (LDR) Brachytherapy

8 High Dose Rate (HDR) Brachytherapy

- Most commonly an outpatient procedure where very effective high-dose radioactive sources are removed after only a few minutes
- Radiation oncologist places a catheter in or near the tumor, and then directs the procedure remotely from outside the treatment room
- A computer sends a radioactive source through the catheter to the treatment site

9 Low Dose Rate (LDR) brachytherapy

- Can be either temporary or permanent
- An outpatient procedure where the radioactive sources are left in place permanently (i.e. Prostate Cancers)
- An inpatient procedure where the radioactive sources are left in place temporarily (i.e. Gynecological Cancers)

10 Radiation Safety Precautions

- Because the sources are emitting radioactivity, safety precautions are necessary to reduce exposure to family members and the general public
- The permanent sources (seeds) become less and less radioactive each day until the radiation diminishes to an undetectable level

11 I-125 Radioactive Seeds

12 SAFETY DURING IMPLANT (I-125)

- ROLES
  - R.N.
  - Scrub
  - RSO
  - Ultrasound/X-Ray Technologist

Patient Positioning-prep-drape
Table Attachment Assembly

13 SAFETY DURING IMPLANT(I-125)

- Sterile vs Clean
- Room Diagram

- Attire
- Paperwork
- Map Readings, Dosimetry

14 Post Operative

- Radiation Safety
- Patient Transfer-PACU
- Paperwork
- Clean Up/ Turnover Operating Room

15 Patient in PACU

- Surveys should be performed to measure the magnitude and extent of radiation levels of the patient
- Distinguish from the radiation background around the patient implanted with brachytherapy sources
- These surveys may include radiation surveys of a facility room (e.G., Operating room suite) after the patient with implanted sources has been removed from the room
- Radiation surveys in and around the patient's room after the implant
- Visual surveys of the patient's bed after the implant

16 Sharing Of A Brachytherapy Patient Room

In the current Part 35, we permit the sharing of a brachytherapy patient room with another individual undergoing radiation therapy. In the final rule, we have, however, clarified that the other "individual undergoing radiation therapy" refers to other brachytherapy patients

- The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 1mSv (100 mrem) in a year, exclusive of the dose contributions, in part, from exposure to individuals administered radioactive material and released in accordance with § 35.75. Section

17 PATIENT EMERGENCY

- Sections 35.11 and 35.27 permit an individual to use byproduct material under the supervision of an AU. Nevertheless, an AU, and not a designee, is responsible for the medical use and supervision of the byproduct material
- In the event of a medical emergency with a patient or human research subject implanted with brachytherapy source(s), we believe that because of the doses administered under § 35.400, an AU must be notified
- This notification cannot be delegated to a designee

18 RELEASE OF PATIENTS

- 35.75 allows release of patients administered byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (500 mrem)
- If the licensee confines a patient receiving brachytherapy and has not authorized the release of the patient under § 35.75, the licensee must limit the total effective dose equivalent to individual members of the public to less than 1mSv (100 mrem) in a year
- Alternatively, if the licensee authorizes the release of the patient receiving brachytherapy under § 35.75, the licensee must make the determination that the total effective dose equivalent to any other individual is not likely to exceed 5 mSv (500 mrem)
- Provide the released individual, or the individual's parent or guardian, with instructions on actions recommended to

maintain doses to other individuals as low as is reasonably achievable
- In all cases, the licensee is required, under § 20.1101, to conduct operations to achieve doses that are as low as is reasonably achievable

19

Safety Instruction

- Personnel caring for patients or human research subjects, who have received a brachytherapy implant and cannot be released in accordance with § 35.75, receive instruction
- Include information on how to minimize radiation exposures to the public and workers and the radiation safety actions to be taken in the case of a death or a medical emergency
- We also believe this requirement is consistent with ALARA principles
- Radiation safety training is not required of all hospital staff
- Refresher training is warranted because of the potential for unnecessary exposure to workers and the public if needed safety precautions are not observed

20

"Radioactive Materials" signs be posted

- Visibly post the patient's or human research subject's room with a "radioactivematerials" sign
- There is flexibility in determining where to place the posting so that it is visible
- This requirement would not preclude placing a sign on the chart provided the sign would be visible to someone entering the treatment room
- Notations as to where and how long visitors may stay may be placed in the patient's chart or posted on the door

21

Issue 4: Why is there a difference in the time periods to notify the AU and the RSO, or his or her designee, if the patient or human research subject dies or has a medical emergency?

- We have maintained the difference in the notification time periods. These
- differences recognize that, in the event of a medical emergency, the notification should be as
- soon as possible, rather than immediately, because the licensee's primary responsibility during
- a patient's medical emergency is the care of the patient.

22

Issue 5: Following a patient emergency, when should an AU versus an RSO be notified and can a physician designee be notified if the AU is not available?

- Sections 35.11 and 35.27 permit an individual to use byproduct material under the supervision of an AU
- Nevertheless, an AU, and not a designee, is responsible for the medical use and supervision of the byproduct material
- Therefore, under § 35.415(c) an AU and **not** a designee must be notified in the event that a patient or human research subject has a medical emergency or dies
- The RSO is responsible, in accordance with § 35.24, for implementing the radiation protection program. Therefore, we believe that notification of the RSO, or his or her designee, provides additional assurance that appropriate corrective actions to respond to the radiation safety hazard associated with the

emergency or death are taken

23 Issue 6. Were there any other changes made in this section between the proposed and final rule?

- Response. Yes. Paragraph (a) was reworded to make it clear that the requirements in § 35.75 apply to the release of individuals, not to the confinement of individuals
- In addition, paragraph (c) was restructured to clarify our intent that, for the purpose of this section, **only the RSO may have a designee**

24 Issue 9: Do the manufacturer's measurements need to be performed consistent with those required by the licensee?

- Comment. A commenter suggested that for the manufacturer's accepted measurements, the phrase "that are made in accordance with the requirements of this section" be deleted
- Response. This phrase has been retained. To ensure the same level of calibration, we believe that unverified calibrations performed by the manufacturer must meet the same standard of calibration as the calibrations required of the licensee

25 Issue 11: Should the accuracy of source activity or output determination be stated in the rule?

- Comment. A commenter suggested that the accuracy for I-125 be changed to 10 percent because a 5 percent accuracy is not possible
- Response. We deleted the reference to +/- 5 percent from § 35.432(c)(1) of the proposed rule. We do not believe that the accuracy of the source activity or output measurement needs to be stated in the rule because the published protocol addresses the accuracy requirement

26 **Section 35.2067, Records of possession of sealed sources and brachytherapy sources**

- Issue 1: Why should licensees maintain records of negative leak tests?
- Comment. A commenter agreed with retention of positive leak test records but not with the requirement to maintain records of negative tests
- Response. The rule requires records of all leak tests required by § 35.67(b) to show that leak tests were performed
- The final rule requires records of the test results, but a licensee has flexibility in how it records the test

results

- For negative leak tests, a licensee may simply document that the measured activity is "negative."

27 Issue 2: Should this section make a reference to § 35.2406, Records of brachytherapy source inventory?

- Comment. A commenter asked that we add a reference which states that additional brachytherapy records may be required by § 35.2406
- **Response.** We do not believe this reference is needed
- Redundancy and cross referencing in the rule has been eliminated unless it is needed to make the rule more understandable

28 **Section 35.2092, Records of decay-in-storage**

- Issue 1: Are the requirements in this section already covered by § 20.2103, Records of surveys?
- Comment. Commenters did not believe this section was needed because radiation surveys are addressed in § 20.2103
- Response. 10 CFR Part 20 contains general provisions on records. It does not provide specific recordkeeping requirements for disposal of waste through decay-in-storage
- Section 35.2092 is needed to specify what Part 35 licensees must document in the records required by § 35.92

29 Issue 2: Were there any other changes made in this section between the proposed and final rules?

- Response. Yes. We revised the first sentence to replace the term "made in accordance with" with the phrase "as required by."
- We believe this makes the sentence more readable
- We also deleted the requirement to document the name of the radionuclide that was disposed
- We do not believe it is necessary for the licensee to document what material was disposed of because § 35.92 no longer requires that the material be held for 10 half lives
- However, this does not preclude the licensee from including this information in the record.

30 **Section 35.2310, Records of safety instruction**

- Issue 1: Is it necessary to maintain records of safety instruction given to non-film badged workers?
- Comment. According to commenters, it is excessive to require the licensees to maintain records of training given to non-film badged allied health care workers, who received instruction in accordance with §§ 35.310, 35.410 or 35.610
- Response. Records of all individuals receiving safety instruction in accordance with
- §§ 35.310, 35.410 or 35.610 are needed to document that the instruction was provided by the licensee
- We believe that it is important that personnel, caring for patients or human research subjects who have received radiopharmaceutical therapy (and cannot be released in accordance with § 35.75), receive instruction in limiting radiation exposure to the public or occupational workers and what actions should be taken in the case of a medical emergency or death

31 **Section 35.2630, Records of dosimetry equipment**

- Issue 1: Can the record retention period be changed from "for the duration of the license" to 3 years?
- Comment. A commenter suggested that the record retention period could be changed to "three years after the last calibration."
- Response. We have not changed the record retention period in this section

- The dosimetry equipment calibrations, intercomparisons, and comparisons performed to show compliance with § 35.630 are necessary to document that the correct radiation dose is delivered to the patient or human research subject
- If there is a future question about whether the correct radiation dose was delivered to a patient or human research subject, we believe that these records should be available to document that calibration of the therapy unit was madewith properly calibrated instruments

32 Issue 2: Were there any other changes made in this section between the proposed and final rules?

- Response. Yes. Paragraph (b)(2) was revised to require licensees to include the manufacturer's name for the instruments that are calibrated, intercompared, or compared in accordance with § 35.630
- This change is consistent with requirements in other sections to include the manufacturer's name of other types of equipment

33 **Section 35.3045, Report and notification of a medical event**

- Issue 1: Do stakeholders think that the term "medical event" is an improvement over the use of the term "misadministration" in the current Part 35?
- Comment. Commenters supported the use of the term "medical event." One commenter agreed with the change, but could see no reason for "candy coating" the term "misadministration."
- Response. We have used the term "medical event" in the final rule because some believe the term "misadministration" has a negative connotation that implies negligence on the part of the physician or other hospital workers
- The term "medical event" more correctly and simply conveys that the byproduct material or radiation from byproduct material was not administered as directed by the AU

34 Issue 2: Are the reporting requirements for medical events necessary?

- Events that result from poor radiation protection practices are covered in the primary regulations for the use of radioactive material, e.g., inadequate survey of a patient following an HDR treatment
- If such problem areas in licensees' programs are brought to their attention, licensees can correct the problems before they result in medical events
- Other commenters expressed concern that the overall wording in this section is subject to a great deal of interpretation and debate over whether specific actions are appropriate for a particular patient and whether an event is a reportable medical event
- Therefore, the NRC should develop more specific language describing a medical event in order to avoid intrusion into medical judgments. It should be made clear that medical events are major deviations from a planned treatment that have or could have significant effects on the patient
- These effects include either a reduction in the possibility of tumor control or an increase in the possibility of complications
- In addition, licensees should be able to appeal to medical experts if NRC staff determines that an incident is a reportable medical event

35 REPORTING AND NOTIFICATION REQUIREMENTS

- Reporting and notification requirements in this section are necessary so that the NRC is aware of events that trigger the thresholds for medical events to determine what actions, if any, need to be taken to prevent recurrence; so that other licensees can be made aware of generic problems that result in medical events; and so that patients can make timely decisions regarding remedial and prospective health care
- The requirements throughout Part 35 are more specific for medical use than the general requirements for the use of radioactive material in the other parts, e.g., Part 20 requirements
- A clarifying change was made to exclude reporting medical events that are due to "patient intervention."

36 Issue 3: Are the threshold dose levels for reporting medical events set at appropriate levels [§ 35.3045(a)(1)]?

- Response. We made no change in the proposed threshold reporting levels for medical events. These reporting levels correspond to the annual dose limits in Part 20 for occupational workers and the level for reporting overexposures of occupational workers to NRC
- We believe that applying these same thresholds to reporting exposures to patients is reasonable
- NRC uses the information from the reports of medical events that exceed the dose thresholds to reduce the likelihood of other medical events
- For example, information from a report may indicate a breakdown in the licensee's program for ensuring that byproduct material or radiation from byproduct material is administered as directed by the AU or may indicate a generic issue that should be reported to other licensees

37 Issue 4: Should licensees be required to report events in which the administration of byproduct material or radiation from byproduct material results in a total dose that differs from the prescribed dose by 20 percent or more?

- Comment. Commenters said that the 20 percent difference is arbitrary, and that exceeding this limit presents little or no risk to the patient. The limit should be examined and justified
- Recommendations ranged from the limit should be 100 percent, to maybe there should not be a limit and the physician can decide when to report harm to a patient, to it isinappropriate to have a single criterion for all procedures
- Commenters believe that the 20 percent limit is reasonable for external beam therapy and unsealed therapeutic radiopharmaceuticals, but that it is too restrictive for brachytherapy, gamma stereotactic radiosurgery, and unsealed diagnostic dosages
- Commenters said that they were aware of clinical data that supported the 20 percent level for external beam therapy. However, they were unaware of any brachytherapy or gamma stereotactic radiosurgery data demonstrating that a 20 percent difference between the prescribed dose and delivered dose would result in harm to the patient. In addition, a few millimeters in brachytherapy can make a tremendous difference in the dose
- Some provision should be made to exempt brachytherapy, or to change the 20 percent limit up to 100-120 percent.
- Several commenters questioned the applicability of the 20 percent limit to uses of unsealed byproduct material. Exceeding a radiotherapy dosage by 20 percent may be significant, but reporting an administration of a diagnostic dosage that exceeds the prescribed dosage by 20 percent is overregulation

38 # Response

- Response. We have retained the 20 percent difference that is in the current rule
- According to the Statements of Consideration for the Quality Management Program and Misadministrations (56 FR 34104; July 25, 1991), the 20 percent differences are required to be reported because they could possibly indicate a deficiency in the licensee's program, not because they necessarily indicate a significant risk to the patient
- We agree with this rationale and see no reason to change the threshold
- Licensees should note that they do not have to report an event in which the total dose or dosage delivered differs from the prescribed dose or dosage by 20 percent or more, unless the dose also differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin
- NRC uses the information from the reports of medical events where the administration of byproduct material or radiation from byproduct material results in a total dose that differs from the prescribed dose by 20 percent or more to reduce the likelihood of other medical events
- For example, the difference between the prescribed and administered doses may indicate a breakdown in the licensee's program for ensuring that byproduct material or radiation from byproduct material is administered as directed by the AU

39 Issue 5: Does the proposed rule adequately address wrong treatment site [§ 35.3045(a)(3)]?

- Comment. Commenters both agreed and disagreed on whether the proposed rule adequately addressed wrong treatment site
- Two commenters said that it was unclear how wrong treatment site will be handled for therapy, especially for brachytherapy where a medical event can occur if the patient moves even a small distance
- In addition, commenters questioned how the wrong treatment site criteria will be applied to permanent seed implants that migrate from the prescribed site
- Another comment was that the criteria for a medical event involving the wrong treatment site must be justified
- The criteria of a 0.5 Sv (50 rem) tissue/organ dose and difference of 20 percent from the expected dose defined in the written directive are excessively restrictive
- Justification can be provided that the percentage deviation could be 100 percent
- At a minimum, radiobiological justification can be made for 1 Sv (100 rem) as a significant threshold
- The FDA uses this threshold criteria for evaluating lengthy fluoroscopy studies that could resultin skin injury

40 # Response

- In the proposed rule, we attempted to more clearly define when exposure of a wrong treatment site is considered a medical event by including both a 0.5 Sv (50 rem) tissue/organ dose limit and a 20 percent deviation from the expected dose defined in the

written directive

- We believe that the proposed 0.5 Sv (50 rem) tissue/organ dose limit should be retained, but the allowable deviation from the dose in the written directive should be increased to 50 percent
- Therefore, we revised paragraph (a)(3) of this section in the final rule to read "50 percent of the dose expected ..."
- We believe that this change allows for some variation in doses to the wrong treatment site during administrations of radiation from byproduct material, and requires licensees to only report significant doses to the wrong treatment site due to the movement of the patient or source, e.g., during brachytherapy treatments
- In addition, we added a statement that is in the current rule, which was inadvertently not included in the proposed rule, that excludes permanent implants of seeds that were implanted in the correct site, but migrated outside the treatment site

41

Section 35.2067, Records of possession of sealed sources and brachytherapy sources

- Requires the licensee to retain records of the leak tests and inventory required by § 35.67(b) and (g), respectively, for 3 years
- Leak test records are required to show that the leak test was done at the appropriate time interval and that sealed sources are not leaking
- Inventory records are necessary to show that the possession of sealed sources did not exceed the amount authorized by the license
- This section replaces the requirements in the current § 35.59(d) and (g)
- We have deleted the requirement to record the measured activity of each leak test sample and a description of the method used to measure each test sample
- We also revised the rule to require that the name of the individual performing the leak test and inventory be recorded rather than the signature of the RSO

42

FINAL RULE

- We believe this change is needed because recording the name of the individual will ensure future identification of the individual who performed the leak test or inventory
- The record retention period was reduced from 5 years to 3 years to reduce regulatory burden. The Commission does not believe the longer record retention period is warranted
- Leak test records must contain the model number, and serial number if one has been assigned, of each source tested; the identity of each source radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test
- Inventory records must contain the model number of each source, and serial number if one has been assigned; the identity of each source radionuclide and its nominal activity; the location of each source; and the name of the individual who performed the inventory

43

Section 35.2075, Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material

- Requires the licensee to maintain records of patient release required by § 35.75 for 3 years
- This record is needed to show compliance with the requirements in § 35.75
- No changes have been made from the recordkeeping requirements in the current § 35.75 (c) and (d)

44

Medical Event Notification

- The final rule retains the current requirement in § 35.33 that licensees notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of the medical event.
- The final rule also retains the current requirement for licensees to submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the medical event.
- In addition, the licensee is required to notify the referring physician and the individual affected by the medical event, or the responsible relative or guardian, no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful.
- This reporting requirement is needed to ensure that NRC is aware of medical events. Refer to Section III of the Supplementary Information of this document for additional information on the notification requirements in § 35.3045.
- In the current rule, licensees can provide the individual with a brief description of both the event and the consequences as they may affect the individual, if they include a statement that the individual can also obtain from the licensee a copy of the report that was submitted to the NRC.
- In the final rule, the licensee is not required to include this statement. However, licensees are expected to provide the affected individual with a written report that is comprehensive enough to provide the individual with enough information about the effects, if any, of the medical event to enable him or her to make any decisions about remedial or prospective health care. significant from the standpoint of public health and safety, e.g., abnormal

45

Subpart F –Manual Brachytherapy

- Subpart F, "Manual Brachytherapy" is assigned to Compatibility Category "D", with the exception of ten sections
- Section 35.404 (a) and (b) "Surveys after source implant and removal"
- § 35.406(a) and (b), "Brachytherapy sources accountability"
- § 35.410(a), "Safety instruction"
- § 35.415, "Safety precautions"
- § 35.432 (a-e), "Calibration measurements of brachytherapy sealed sources"
- § 35.433(a), "Decay of strontium-90 sources for ophthalmic treatments"
- § 35.457, "Therapy-related computer systems" are assigned to Compatibility Category D/H&S
- Section 35.400, "Use of sealed sources for manual brachytherapy"
- § 35.490, "Training for use of manual brachytherapy sources"
- § 35.491, "Training for ophthalmic use of strontium-90" are assigned to Compatibility Category "C"

46 RECORDS

- Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material,"
- Subpart L, "Records" are assigned to Compatibility Category "D"
- Subpart M, "Reports",
  - Section 35.3045(a) "Report and notification of a medical event"
  - § 35.3047(a), (b),(d), (e), (f), (g) and (h), "Report and notification of a dose to an embryo/fetus or a nursing child"
  - § 35.3067, "Report of a leaking source"
- are assigned to Compatibility Category "C
- Sections 35.3045(b) and (f); and § 35.3047(c) are assigned to Compatibility Category "D"

47 **Subpart A-- General Information**

- 35.1 Purpose and scope.
- 35.2 Definitions.
- 35.5 Maintenance of records.
- 35.6 Provisions for the protection of human research subjects.
- 35.7 FDA, other Federal, and State requirements.
- 35.8 Information collection requirements: OMB approval.
- 35.10 Implementation.
- 35.11 License required.
- 35.12 Application for license, amendment, or renewal.
- 35.13 License amendments.
- 35.14 Notifications.
- 35.15 Exemptions regarding Type A specific licenses of broad scope.
- 35.18 License issuance.
- 35.19 Specific exemptions.

48 **Subpart B-- General Administrative Requirements**

- 35.24 Authority and responsibilities for the radiation protection program.
- 35.26 Radiation protection program changes.
- 35.27 Supervision.
- 35.40 Written directives.
- 35.41 Procedures for administrations requiring a written directive.
- 35.49 Suppliers for sealed sources or devices for medical use.
- 35.50 Training for Radiation Safety Officer.
- 35.51 Training for an authorized medical physicist.
- 35.55 Training for an authorized nuclear pharmacist.
- 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.
- 35.59 Recentness of training.

49

Subpart C-- General Technical Requirements

- 35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material
- 35.61 Calibration of survey instruments
- 35.63 Determination of dosages of unsealed byproduct material for medical use
- 35.65 Authorization for calibration, transmission, and reference sources
- 35.67 Requirements for possession of sealed sources and brachytherapy sources
- 35.69 Labeling of vials and syringes
- 35.70 Surveys of ambient radiation exposure rate
- 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material
- 35.92 Decay-in-storage

50 **Subpart F-- Manual Brachytherapy**

- 35.400 Use of sealed sources for manual brachytherapy
- 35.404 Surveys after source implant and removal
- 35.406 Brachytherapy sources accountability
- 35.410 Safety instruction
- 35.415 Safety precautions
- 35.432 Calibration measurements of brachytherapy sealed sources
- 35.433 Decay of strontium-90 sources for ophthalmic treatments
- 35.457 Therapy-related computer systems
- 35.490 Training for use of manual brachytherapy sources

51 **Subpart L-- Records**

- 35.2024 Records of authority and responsibilities for radiation protection programs.
- 35.2026 Records of radiation protection program changes.
- 35.2040 Records of written directives.
- 35.2045 Records of medical events.
- 35.2047 Record of a dose to an embryo/fetus or a nursing child.
- 35.2061 Records of radiation survey instrument calibrations.
- 35.2067 Records of possession of sealed sources and brachytherapy sources.
- 35.2070 Records of surveys for ambient radiation exposure rate.
- 35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.
- 35.2092 Records of decay-in-storage.
- 35.2310 Records of safety instruction.
- 35.2404 Records of surveys after source implant and removal.
- 35.2406 Records of brachytherapy source accountability.
- 35.2432 Records of calibration measurements of brachytherapy sealed sources.
- 35.2630 Records of dosimetry equipment.

52 **Subpart M-- Reports**

- 35.3045 Report and notification of a medical event.
- 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.
- 35.3067 Report of a leaking source.

53 terms

- *Brachytherapy* means a method of radiation therapy in which sealed sources are used

- to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary,
- intraluminal, or interstitial application.
- *Brachytherapy source* means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

54 terms

- *High dose-rate remote afterloader*, as used in this part, means a device that remotely
- delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the
- dose is prescribed.
- *Low dose-rate remote afterloader*, as used in this part, means a device that remotely
- delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface
- where the dose is prescribed.

55 terms

- *Manual brachytherapy*, as used in this part, means a type of brachytherapy in which the radioactive sources (e.g., seeds, ribbons) are manually inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume

56 terms

- *Prescribed dose* means --
- For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive

- *Radiation Safety Officer* means an individual who --(1) Meets the requirements in §§ 35.50(a) and 35.59; or
- (2) Is identified as a Radiation Safety Officer on --

- (i) A specific license issued by the Commission or Agreement State;

- (ii) A permit issued by a Commission master material licensee;

- (iii) A permit issued by a Commission or Agreement State broad scope licensee; or

- (iv) A permit issued by a Commission master material license broad scope permitteewhere that permittee has been given authorization to issue permits designating Radiation Safety Officers

57 terms

- *Sealed source* means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

- *Sealed Source and Device Registry* means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

58 terms

- *Therapeutic dose* means a radiation dose delivered from a source containing byproduct material to a patient or human research

subject for palliative or curative treatment.

59 **§ 35.50 Training for Radiation Safety Officer**

- Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who --
- (a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State

60 **§ 35.50 Training for Radiation Safety Officer.**

- Or (b)(1) Has completed a structured educational program consisting of both:
- (i) 200 hours of didactic training in the following areas--
- (A) Radiation physics and instrumentation;
- (B) Radiation protection;
- (C) Mathematics pertaining to the use and measurement of radioactivity;
- (D) Radiation biology; and
- (E) Radiation dosimetry; and

61 **§ 35.50 Training for Radiation Safety Officer.**

- (ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement Statelicense that authorizes similar type(s) of use(s) of byproduct material involving the following--
- (A) Shipping, receiving, and performing related radiation surveys;
- (B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
- (C) Securing and controlling byproduct material;
- (D) Using administrative controls to avoid mistakes in the administration of byproduct material;
- (E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and
- (F) Disposing of byproduct material; and
- (2) Has obtained written certification, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; or
- (c) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety

62 **§ 35.67 Requirements for possession of sealed sources and brachytherapy sources.**

- (a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.
- (b) A licensee in possession of a sealed source shall --
- (1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the 513 licensee; and
- (2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.
- (c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 µCi) of radioactive material in the sample.
- (d) A licensee shall retain leak test records in accordance with § 35.2067.
- (e) If the leak test reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination, the licensee shall --
- (1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in parts 20 and 30 of this chapter; and
- (2) File a report within 5 days of the leak test in accordance with § 35.3067.
- (f) A licensee need not perform a leak test on the following sources:
- (1) Sources containing only byproduct material with a half-life of less than 30 days;
- (2) Sources containing only byproduct material as a gas;
- (3) Sources containing 3.7 MBq (100 µCi) or less of beta or gamma-emitting material or 0.37 MBq (10 µCi) or less of alpha-emitting material;
- (4) Seeds of iridium-192 encased in nylon ribbon; and
- (5) Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.
- (g) A licensee in possession of sealed sources or brachytherapy sources, except for

gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with § 35.2067.

63 Questions And Concerns

- Thank you for your attention

64 Safety Training

- Presented by Kenith L. Hogue, M.S.
- University of Pennsylvania

This is to acknowledge the receipt of your letter/application dated

7/23/2007, and to inform you that the initial processing which includes an administrative review has been performed.

Amend. 37-05089-01

☑ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

---

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 140861.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader