

United States Nuclear Regulatory Commission

Advisory Committee on the Medical Uses of Isotopes

October 27-28, 2008

ADAMS

**MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES**

**October 27-28, 2008
Two White Flint North (T-2B3), Rockville, Maryland**

**Monday, October 27, 2008
CLOSED SESSION**

- 8:00 – 8:15 **1. Opening Statements** **R. Lewis, NRC**
Mr. Lewis will discuss internal Committee business.
- 8:15 – 8:45 **2. Ethics Briefing** **J. Szabo, NRC**
Mr. Szabo will provide annual ethics training for Committee members.

NOTE: The above session may be closed pursuant to 5 U.S.C. 552(b) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACMUI; information the release of which would constitute a clearly unwarranted invasion of personal privacy; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and disclosure of information which would risk circumvention of an agency regulation or statute.

**Monday, October 27, 2008
OPEN SESSION**

- 9:00 – 9:10 **3. Opening Statements** **C. Einberg & R. Lewis, NRC**
Mr. Einberg will formally open the meeting. Mr. Lewis will present opening remarks.
- 9:10 – 10:00 **4. Old Business** **A. Tull, NRC**
Ms. Tull will review previous Committee recommendations and provide NRC responses.
- 10:00 – 10:15 **B R E A K**
- 10:15 – 11:00 **5. Cesium Chloride (CsCl) Subcommittee Report** **B. Thomadsen, ACMUI**
Dr. Thomadsen will provide information from the CsCl Subcommittee Report.
- 11:00 – 11:30 **6. Fingerprinting Subcommittee Report** **R. Vetter, ACMUI**
Dr. Vetter will provide information from the Fingerprinting Subcommittee Report.
- 11:30 – 12:15 **7. Permanent Implant Brachytherapy Rulemaking Subcommittee Report** **S. Nag, ACMUI**
Dr. Nag will provide information from the Permanent Implant Brachytherapy Rulemaking Subcommittee Report.
- 12:15 – 1:15 **L U N C H**
- 1:15 – 2:45 **8. Yttrium-90 (Y-90) Microsphere Licensing Guidance** **R. Salem, SIR**
Dr. Salem will provide information on interventional radiologists as potential Authorized Users for Y-90 microspheres.
- 2:45 – 3:15 **9. Potential Rulemaking and Associated Regulatory Information Summary (RIS) Regarding Multiple RSOs on a Medical-use License** **R. Zelac, NRC**
Dr. Zelac will update the Committee on the status of the RIS and will also provide information on potential rulemaking to allow more than one RSO per license.
- 3:15 – 3:30 **B R E A K**
- 3:30 – 4:15 **10. Status of Technical Basis for follow-up to Petition for Rulemaking (PRM) 35-20 (Ritenour Petition)** **R. Zelac, NRC**
Dr. Zelac will provide an update on the status of the technical basis for PRM 35-20.
- 4:15 – 5:00 **11. Medical Isotope Shortages** **TBD, NRC**
NRC staff is seeking advice from the Committee on the impacts of isotope shortages on the medical community.

Tuesday, October 28, 2008
OPEN SESSION

- 8:00 – 9:00 **12. Revisions to the NRC Radiation Protection Requirements: Potential Impacts to the Medical Community** **D. Cool, NRC**
Dr. Cool will propose changes to 10 CFR Part 20 and seek Committee advice.
- 9:00 – 9:30 **13. Infiltration of Fluorine-18 and Therapeutic Radiopharmaceuticals as Medical Events** **C. Flannery, NRC**
Ms. Flannery will provide information on a recent infiltration and seek input from the Committee on the applicability of the medical event reporting requirements.
- 9:30 – 10:15 **14. Status of Commission Paper for Modifying Training and Experience (T&E) Attestation Requirements** **R. Zelac, NRC**
Dr. Zelac will provide the status of the Commission Paper addressing the Committee's recommendations for modifying the T&E attestation requirements.
- 10:15 – 10:30 **B R E A K**
- 10:30 – 11:00 **15. Status of Current and Future 10 CFR Part 35 Rulemaking** **N. Bhalla & E. Lohr, NRC**
NRC staff will provide information on current and future 10 CFR Part 35 rulemaking.
- 11:00 – 12:00 **16. Potential Changes to 10 CFR Part 35** **DB. Howe, NRC**
Dr. Howe will propose changes to 10 CFR Part 35 and seek Committee advice.
- 12:00 – 1:00 **L U N C H**
- 1:00 – 2:00 **17. Medical Nuclear Materials Events** **DB. Howe, NRC & R. Lieto, ACMUI**
Dr. Howe and Mr. Lieto will provide a summary of recent medical-related events and seek Committee advice, recommendations, and insights.
- 2:00 – 2:45 **18. Intraocular Strontium-90 Eye Applicator** **J. Heier, NeoVista, Inc.**
Dr. Heier will provide information on retinal surgery use of the NeoVista eye applicator in an ambulatory surgery center.
- 2:45 – 3:00 **B R E A K**
- 3:00 – 3:45 **19. Patient Needs, Concerns, and Rights in Radiation Medicine** **D. Fisher, ACMUI**
Dr. Fisher will provide information from a patient's perspective.
- 3:45 – 4:30 **20. Administrative Closing** **A. Tull, NRC**
Ms. Tull will provide a meeting summary and propose dates for the next meeting.

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The Report of the ACMUI Subcommittee on ¹³⁷CsCl Irradiators

Darrell Fisher
Debbie Gilley
Ralph Lieto
Orhan Sulciman
Bruce Thomadsen
Richard Vetter
James Welsh

Purpose of the Subcommittee

- The National Research Council's report made several assumptions that seemed questionable to the ACMUI.
- This subcommittee investigated the concerns raised by the ACMUI

Concerns Addressed

- The need for ¹³⁷CsCl irradiators
- Viable alternatives
- Current Security

The Need for the Irradiators Blood Products

- The original report assumed that approximately 10% of the blood used in the US was irradiated.
- Discussions with hematologists and oncologists indicated that for these practices, the value ranged between 15% and 40%.
- The patients involved have depressed immune systems and need the irradiated blood.
- The lower number probably comes from a higher fraction of trauma cases, where irradiation is irrelevant.

The Need for the Irradiators Animal Irradiation

- Research on stem cells and other systemic therapies increasingly requires whole-body irradiation of the animals (usually mice) before infusion.
- This research is growing and may soon lead to treatments for currently untreatable conditions.

The Need for the Irradiators Summary

- Without irradiators available, hematology and oncology patients would suffer potential death from the lack of irradiated blood.
- Without irradiators available, much of the stem-cell and systemic drug research would not be able to proceed.

Alternatives to $^{137}\text{CsCl}$ Irradiators

- The alternatives are conventional x-ray units or linear accelerators.
- Both have been and are used for blood, animal and material irradiation.

Conventional X-ray Units Blood Irradiation

- For blood irradiation, only one unit is FDA approved.
- The National Research Council listed the price as \$180,000, with \$10,000/y for the service contract.
- The current price is \$250,000 with \$33,000/y for the service contract.
- A replacement tube is extra, as is calibration and quality management.

Conventional X-ray Units Blood Irradiation

- Throughput is lower for the x-ray unit.
- With 48,000 blood-product units / x-ray tube, a 50-unit per day operation would replace the tube every 3.7 years, adding to the cost of running the unit.

Conventional X-ray Units Animal Irradiation

- About 10 x-ray units are available.
- Few provide beams of 200 kV or higher, which limits their use with animals due to lack of penetration.
- Most prices range from \$146k - \$250k, plus the service contracts of about 10% per year.
- One low energy, short distance, small field size units markets for \$43k - \$87k.

Conventional X-ray Units Animal Irradiation

Issues with the x-ray units for animal irradiators, other than price, include:

- The different Relative Biological Effectiveness (RBE) compared with ^{137}Cs – possibly a factor of 2 for the lower energy units.
- The dose rates, which can have an effect on the biological effectiveness as well as make anesthesia more difficult.
- Penetration may require irradiating animals from several directions.

Medical Linear Accelerators

- If the radiotherapy department's accelerator is used, time available for blood or animal irradiation become a problem.
- If not using a radiotherapy department's accelerator, price becomes a problem, at \$1.5M to start.

Security

Since the National Research Council report raising the concerns about the security of these units, several things have changed.

- The security of the users has been enhanced through the required background checks and fingerprinting.
- The security of the facility has been enhanced following directives of the Nuclear Regulatory Commission (sometimes at great costs to the facility.)
- The security of the units are being enhanced through a program of the DOE and DHS.

Security

- Following these three security enhancements, the units present little hazard for unauthorized source removal or disruption.
- The lack of such security was a major factor in the original report.

Summary

- Irradiation facilities are essential for irradiation of blood and in research.
- Forced replacement of $^{137}\text{CsCl}$ -based units would force many facilities to stop irradiations because of the large expense, since most of the facilities are non-profit and have few resources for funding a new x-ray unit or maintaining the unit.
- If not leading to the termination of the irradiations, the replacement would place a large financial burden on facilities which usually have little funding.

Summary

- While x-ray units have been used for blood, animal and material irradiation, the difference in the RBE complicates simple replacement of the ^{137}Cs .
- Finally, with the enhanced security programs for the $^{137}\text{CsCl}$ units, replacement is unnecessary.

Advisory Committee on the Medical Uses of Isotopes's Report on $^{137}\text{CsCl}$ Irradiators

Summary

After studying the issues, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) came to the following conclusions:

1. Irradiators are necessary for medical practice and medical research.
2. It is not clear from the available data that x-ray sources are biologically equivalent to $^{137}\text{CsCl}$ irradiators.
3. Alternatives to the $^{137}\text{CsCl}$ irradiators currently in operation present greatly increased expense to programs that need the functionality and operational reliability of the irradiators.
4. The recommendation of the National Research Council (NRC) of the National Academies to eliminate the use of irradiators that employ $^{137}\text{CsCl}$ was based on the situation at the time of their study. Since that time, security of medical irradiators units has been substantially strengthened in three ways:
 - a. Increased security of persons with access. The December 2005 NRC orders increased the security requirements for all persons having unescorted access to $^{137}\text{CsCl}$ irradiators, including background checks, personal reference checks, and fingerprinting checks against the FBI fingerprint database.
 - b. Increased security of the facilities housing the units, including high-security locks on facility door, multiple doors with locks for access, motion sensors, video cameras monitored by facility security, preplanning with local law enforcement, database encryption, and secured facility schematics, and drawings.
 - c. Increased security of the units themselves, including locks on source access panels and entry points.

Given these changes, we found that the National Research Council concerns do not currently apply as previously stated, and have been superseded by increased safeguards as required by the Nuclear Regulatory Commission and state regulatory authorities. Well-secured $^{137}\text{CsCl}$ irradiators present little security hazard.

Practicality of Alternatives to $^{137}\text{CsCl}$ Self-Shielded Irradiators*

Blood and Blood-Product Irradiation

Based on our survey of the literature and other publicly available information sources, the only medical x-ray irradiator that the U.S. Food and Drug Administration (FDA) has cleared to irradiate blood and blood products to prevent graft-versus-host disease is the

* Content taken from manuscript submitted to *Health Physics* June 17, 2008: Dodd, B and Vetter, R. "Replacement of ^{137}Cs Irradiators with X-Ray Irradiators"

1 Raycell (Best Theratronics 2008) originally manufactured and sold by Rad Source (Rad
2 Source 2007a) as the unit model RS 3000. Other manufacturers may also be developing
3 plans for new irradiators.

4 The first question regarding practicality of an x-ray machine to irradiate blood or
5 blood products is whether there are any technical issues. Although the photon energy of
6 x-ray machines is lower than those of ^{137}Cs , Janatpour et al. (2005) demonstrated that x-
7 ray machines can deliver the necessary 25 Gy dose with sufficient uniformity and
8 stability to meet FDA guidelines. The typical x-ray irradiator generates a filtered energy
9 spectrum with a peak energy of approximately 160 kVp, compared to the monoenergetic
10 662 keV gamma rays from ^{137}Cs . While a radiation weighting factor of 1 is applied to
11 both gamma rays and x rays for radiation protection purposes (NCRP 1993), the
12 biological effectiveness of low energy photons is approximately twice that of 662 keV
13 ^{137}Cs gamma rays (ICRU 1986). Consequently, a dose of 25 Gy delivered by an x-ray
14 irradiator will not produce the same biological effect as 25 Gy from ^{137}Cs gamma rays.
15 The significance of this difference in radiation effectiveness relevant to transfusion
16 medicine and immunological research is unknown.

17 Regarding costs, the NRC study (2008) quoted about \$180,000 for a new x-ray
18 irradiator and an annual service agreement cost of just over \$10,000. However, the actual
19 cost of the x-ray system has increased. In May 2008 this manufacturer quoted a purchase
20 price of \$250,000 and \$66,000 for a 3-year maintenance contract including a routine
21 service call and one set of replacement parts as needed. While the purchase price might
22 be about the same as a ^{137}Cs irradiator, the annual maintenance cost with a service
23 agreement may be much greater unless the owner has engineering capabilities to provide
24 service and maintenance in-house. Also, the service contract does not include physics
25 services. Depending on the number of set-ups, calibration costs may exceed \$10,000 per
26 year if outside physics services are required. In addition, there would be a one-time cost
27 of installing a 240 volt line to the room for most of the x-ray units replacing a cesium
28 irradiator.

29 Based on repair history of clinical x-ray machines, a user of an x-ray irradiator
30 may experience a higher failure rate and require more service and down-time than a
31 $^{137}\text{CsCl}$ irradiator. Since maintenance of an irradiated blood supply is important,
32 purchasers of x-ray blood irradiators find it necessary to purchase an annual maintenance
33 agreement. However, outside service can result in a facility being unable to perform life-
34 saving irradiations for a time. For example, one owner experienced a service response
35 and re-calibration time of two weeks. Both the upper and lower power supplies had to be
36 replaced after a few years of operation. Therefore, blood banks and hospitals may need
37 to plan for an alternative means of irradiation or an alternative supply of irradiated blood
38 components to meet critical demand. Without $^{137}\text{CsCl}$ as an alternative, the facility may
39 have to purchase two units to assure a continuous supply of irradiated blood.

40 Another factor to evaluate for practicality is the throughput of an x-ray irradiator.
41 Two units of blood can be irradiated at one time with the Raycell, and irradiation time is
42 about 5 min. This is sufficient for two blood centers contacted, which do about 30-100
43 units per month, and it is adequate for a clinic doing about 20 units per day. However, a
44 significant workload like that at a large academic medical center with a throughput of 50-
45 60 units per day may exceed the capabilities of a single x-ray unit. While it may seem
46 that the exposure rate with the x-ray would keep up with the demand, the blood

1 irradiation is not continually as with an assembly line. Rather, units are irradiated as
2 needed based on the clinical demand, in irregular intervals. Thus, the duration required
3 for the irradiation becomes an important limiting factor. One potential buyer stated that
4 about 48,000 blood products could be irradiated within the x-ray tubes' 2000-h warranty
5 period (Blood Bank Talk 2007). For a site processing 50 units per day and assuming that
6 procedures requiring irradiated blood happen mostly during normal work days, that
7 would imply the need for a new tube each 3.7 years, adding considerably to the cost of
8 the operation.

9 Since ^{137}Cs has a half-life of 30 years, it is not financially practical to replace
10 those units that were installed within the last 15 years. Ease of use is comparable
11 between the $^{137}\text{CsCl}$ irradiator and the x-ray irradiator.

12 One issue that has not been investigated is whether all the operating cesium
13 irradiators could afford to replace the units, or whether some facilities will cease
14 operation, depriving patients of irradiated blood and researchers a source of radiation.

15 **Biomedical and Small Animal Irradiators**

16 Ten x-ray irradiators are commercially available for cell, tissues and small animals, eight
17 from three U.S. manufacturers and two irradiators from outside the U.S. A few will be
18 discussed as being representative of the issues.

19 The **RS 2000** (Rad Source 2007b) has been sold by Rad Source since 1999, with
20 about 15-20 units placed in Europe and Asia and 50-60 placed in the USA. Several users
21 contacted seem satisfied with the device. The purchase price is little over \$100,000, and
22 a service agreement is around \$10,000 per year. Apparently reliability has been good;
23 however, owners should expect to refurbish or replace the power supply about every 4-5
24 years.

25 The Rad Source RS 2400 (Rad Source 2007c), operating between 80 and 160 kV,
26 delivers a higher dose rate using a new technology emitter. This 4-pi x-ray source may
27 have the capability of eventually delivering about 300 Gy min^{-1} , but the two RS 2400s
28 operated considerably lower than this. The International Atomic Energy Agency is
29 testing one of these units for its sterile insect programs. The dose rate and irradiation
30 volume of the RS 2400 are much larger than those for the RS 2000 and may allow five
31 450-ml blood bags to be irradiated simultaneously at a dose rate about 45 Gy min^{-1} .
32 However, the canister loading methodology may need some redesign before it would be
33 practical for irradiation of blood. Rad Source expects to submit its application for FDA
34 approval for irradiation of blood products with this device in 2008. The RS 2400 is
35 expected to sell for about \$200,000 - 250,000 with an annual service contract of about
36 \$20,000. To ensure a high degree of reliability and minimal down time, the service
37 agreement will include a tube replacement every 2000 h.

38 **Faxitron** (2008) sells two irradiation systems, the RX-650 and the CP-160, with
39 prices around \$43,000 and \$87,000 respectively. The Faxitron RX-650 operates at a peak
40 energy of only 130 kVp. To achieve adequate uniformity of dose, Kennedy et al. (2004)
41 had to irradiate the mice from several directions because of the attenuation of the lower
42 energy radiation in the bodies of the mice. Woo and Nordal (2006) concluded that the
43 Faxitron CP-160 could be useful for small animal research if radiation was delivered
44 carefully to ensure accurate and uniform radiation dose. The authors stated that at a
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1 distance of 33 cm the indicated beam diameter on the tray was 26 cm, whereas the part of
2 the beam where the uniformity as within 10% was confined to a diameter of 16 cm.

3 **Precision X-Ray Inc.** (2005) sells four different biomedical and small animal x-
4 ray irradiators with energies ranging from 160 kVp to 320 kVp. With 0.5 mm Cu and
5 operating at 320 kV, the unit delivers a dose rate of 2 Gy/minute. The higher tube
6 potential brings the RBE to the same value as the ^{137}Cs gamma ray beam. The price runs
7 around \$170,000, exclusive of the service contract.

8 **Kimtron** markets units similar to the Precision X-ray units, with four units
9 operating between 160 kV and 450 kV. The prices appear comparable to similar units.

10 **Gilardoni**, an Italian company, sells the Radgil (Gilardoni 2000) with an energy
11 of 200 kVp and a dose rate of about 1 Gy min⁻¹ at a cost of about 94,000 Euros
12 (~\$146,000).

13 **Hitachi** (2008) manufactures the MBR-1520-3, which is a 150-kVp blood
14 irradiator that can deliver doses from 15 to 35 Gy in 5-Gy increments. However, there is
15 no indication of FDA approval for human use.

17 **AAPM Survey of Users**

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19 The American Association of Physicists in Medicine (AAPM) conducted a survey of its
20 members in August to assess their experience with irradiators. The results of the survey
21 would be skewed toward hospital-based or university-based irradiators; however, for the
22 information gathered, that should not affect the conclusions. The survey, since it was
23 targeted at medical physicists and some health physicists, represents only a small part of
24 the irradiators in use. Of the 363 respondents, 297 had irradiators, 84.6% of those used
25 ^{137}Cs as the source, 9.3% used conventional x-ray units and 6% used medical linear
26 accelerators (linacs). The $^{137}\text{CsCl}$ units represented the major vendors. Only 10% were
27 purchased within the last two years, with 7% planning on replacing the units within the
28 next 5 years.

29 A quarter of the $^{137}\text{CsCl}$ units had had some malfunction but most were repaired
30 in less than 7 days. Of the x-ray units, 35% had malfunctions, with 44% being repaired
31 within 7 days.

32 Only 40% of the cesium units were used for blood irradiation, with about 25%
33 used for material irradiations and another 25% for animal irradiations. Of the x-ray units,
34 half were for blood irradiation, while 19% were for material irradiation and 32% for
35 animals. Forty percent of the medical linacs for the respondents were used
36 predominantly for blood irradiation and 11% for animals.

37 This survey indicates that, while fairly reliable, conventional x-ray units and
38 medical linacs account for a small minority of the irradiators in the field. They had
39 slightly more downtime than $^{137}\text{CsCl}$ units. The cesium units have also been reliable and
40 their users, in general, have no plans to replace them. Forced removal of the cesium
41 irradiators would result in a very large loss of resources, both radiation sources and funds,
42 not only for blood banks but research institutions as well.

1 **Linear Accelerators**

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3 Medical linear accelerators (linacs) can and do provide irradiation for blood
4 products and materials. While linacs can serve for animal irradiation, their use with mice
5 presents some difficulties because of the build-up region in the dose that is on the order
6 of the thickness of a mouse. Most facilities that use linacs for irradiation either are part
7 of larger processing facilities (for example, medical product sterilization companies) or
8 find time between patients (creating problems in scheduling and staffing) in a
9 radiotherapy clinic because of the extremely large initial investment, about \$2,000,000
10 for these units and the cost for maintenance of \$200,000 per year. Night time irradiations
11 pose additional staffing issues. Because of the costs, linacs are not a viable replacement
12 for $^{137}\text{CsCl}$ irradiators for the vast majority of facilities.

13 **Alternative Radionuclides**

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16 At the time of writing, the only reasonable alternative radionuclide source for
17 irradiators would be ^{60}Co . This radionuclide is used in large industrial irradiators, but is
18 not currently available for blood or research irradiators. The use of ^{60}Co would require
19 frequent source change due to the much shorter half-life compared with ^{137}Cs (5.27 years
20 compared with 30 years), and higher initial source activities to extend the useful life of
21 the sources. The ^{60}Co also requires thicker shielding because of the higher energy (1.2
22 cm half-value layer in lead compared with 0.6 cm.) Since the half-value layer enters into
23 shielding as an exponent, the difference in the thickness of shield required due to the
24 differences in the values multiplies rapidly. These two considerations would lead to high
25 initial costs for a unit and frequent, repetitive costs for source replacement. Finally, there
26 is no convincing evidence that the ^{60}Co sources of any form would pose less of a hazard
27 than the $^{137}\text{CsCl}$.

28 **Further Considerations for Blood Irradiation**

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31 The subcommittee consulted 10 hematologists or oncologists and one clinical laboratory
32 director. These included researchers at one of the nation's most prestigious blood
33 disorder and hematologic cancer research centers having extensive use of $^{137}\text{CsCl}$ blood
34 and small animal irradiators.

35 Most of the previous information, such as in the National Research Council
36 report, focused use of irradiators at central blood banks.

37 Five of the 10 hematologists/oncologists reported that they regularly prescribe
38 irradiated blood for transfusions. Of these, one said that up to 40% of all blood he
39 prescribed was irradiated. The others estimated that 15% to 33% of all blood for
40 transfusion was irradiated. They all mentioned that their patient population was the
41 reason why they tended to prescribe more irradiated blood products than the nominal
42 10% that often is used for planning. Patients who are post transplant are one such
43 category, although none of these physicians had many patients in this subset. The more
44 common reason was the use of certain chemotherapeutics that severely affect the host
45 immune system.

1 Although no surveyed physicians were aware of difference between ^{137}Cs
2 irradiated blood vs. x-ray, all ten (including one physician who doesn't presently
3 routinely give irradiated blood transfusions) stated a regulation to eliminate or reduce the
4 availability of irradiated blood products, or access to $^{137}\text{CsCl}$ irradiators would represent
5 a severe drawback in the hematology/oncology field of medical practice and research.
6 One physician who prescribes irradiated blood 40% of the time said that hematologists
7 and oncologist prescribe irradiated blood about 33% of the time and that figures which
8 say that only around 10% of all transfused blood is irradiated are skewed by the trauma-
9 related transfusions in hospital emergency rooms and for surgery-related transfusions.
10 Oncologists might rely more on irradiated blood than other medical professionals.

11 One institution specializing in research on hematologic malignancies reported that
12 four $^{137}\text{CsCl}$ irradiators are used by 250 authorized users at a frequency of about 30 to 40
13 times per day in support of about 20 research projects and eight active clinical trials.
14 Although comparable x-ray systems could be obtained to replace the $^{137}\text{CsCl}$ irradiators,
15 four physician/PhD researchers indicated that the change would require more than a year
16 to develop the radiation response relationships between the radionuclide-source and x-ray
17 source irradiators, and that impacts on ongoing funded research would be enormous.

18 None of the physicians or the lab director had knowledge of the radiobiological
19 differences between samples irradiated by x-rays or monoenergetic photons from ^{137}Cs
20 sources. Four of six hematologists had experience with both irradiator systems. Three
21 also had experience also with linac irradiated blood before their institutions obtained
22 dedicated blood irradiators.

23 $^{137}\text{Cesium Chloride Irradiator Security}$

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26 Prior to the publication of the National Research Council report the U.S. Nuclear
27 Regulatory Commission (NRC) has disseminated orders to licensees for increased
28 controls on sources of radioactive material in quantities of concern. The "Orders
29 Imposing Increased Controls" issued in December 2005 contain requirements based on
30 the International Atomic Energy Agency Code of Conduct. These measures were
31 required to safeguard radioactive sources from theft or other unauthorized use. These
32 requirements include:

- 33 1. Limit access to approved individuals who need to use radioactive materials in
- 34 performing work activities.
- 35 2. Perform background and trustworthiness checks on all employees with access.
- 36 3. Escort all service providers who need to access the radioactive source.
- 37 4. Document the monitoring of sources with means for detecting source removal.
- 38 5. Increase source monitoring during source delivery or shipment.
- 39 6. Respond immediately to any attempted theft, sabotage, or diversion of sources.
- 40 7. Develop a plan for assistance from supporting authorities in the event of theft,
- 41 sabotage, or diversion.
- 42 8. Provide means for transmitting information between personnel and components used
- 43 to detect an intrusion.
- 44 9. Notify the NRC Operations Center of any attempted theft of radioactive material.
- 45 10. Document any attempt at theft or diversion of radioactive material.

- 1 11. Use trusted carriers with package tracking systems, who maintain constant control
- 2 during transit, and who maintain communication for response or assistance.
- 3 12. Notify the NRC 90 days prior to certain shipments.

4 To review the changes resulting from the NRC orders for increased controls, a site
5 visit for one of the members of this subcommittee was arranged to a major medical center
6 with four ¹³⁷CsCl blood irradiators. The visit found that the licensee maintained access
7 control to the irradiators by the means required in the Order, including:

- 8 1. Allowing access only to approved personnel who had undergone a thorough FBI
- 9 background check, fingerprinting, work history review, psychological review, and
- 10 local law enforcement background check.
- 11 2. Allowing access only to persons needing and trained to use the irradiators properly.
- 12 3. Providing redundant enforced doors, locks, heavy walls, computer-coded key-card
- 13 access, and continuous video monitoring of the halls, entry, and workspace occupied
- 14 by the irradiator units.
- 15 4. Presenting documented procedures to ensure that authorized users support the
- 16 institutions system to prevent unauthorized access and protect access information,
- 17 drawings, schematics, maps, and facility floor plans from unauthorized use.
- 18 5. Coordinating with local law enforcement agencies for rapid response to any
- 19 attempted intrusion or theft of radioactive material.

20 In addition, we found the irradiator systems to be outfitted with additional
21 padlocks and security measures for preventing unauthorized access to radioactive sources
22 inside the irradiators. The irradiators weigh 4000 to 5000 pounds and do not have
23 wheels.

24 In summary, we found highly increased security of ¹³⁷CsCl irradiators and
25 increased controls over access by authorized personnel at the institution. It would be
26 very difficult, even for personnel with access permission, to attempt theft, diversion, or
27 misuse of the ¹³⁷CsCl irradiator systems. The institution had implemented all
28 requirements to enhance the security of ¹³⁷CsCl irradiator systems in a manner typical of
29 such irradiators.

30 In addition to the increased security enhancements required by the NRC, an
31 initiative by the Department of Energy (DOE), the Department of Homeland Security
32 (DHS), and the Domestic Nuclear Detection Office will harden ¹³⁷CsCl irradiators
33 throughout the United States to delay unauthorized access to ¹³⁷Cs sources. This has
34 been a cooperative effort for the past 18 months. The demonstration project was
35 completed in March of 2008 and the pilot project is currently being conducted in nine
36 facilities. DOE and DHS anticipate that this pilot program will be completed later this
37 year.

38 The pilot project is the actual enhancement of the irradiators in the field. The
39 manufacturer will install additional material and make minor changes to the exterior of
40 the irradiator to make it more difficult to remove the source(s). There are nine facilities
41 that have volunteered to participate. The pilot will have two of the manufacturers visit
42 the facility and add the enhancements to the irradiators. The pilot will demonstrate the
43 ease and ability of performing these tasks in a "real world" environment. The pilot will
44 also validate the costs to perform the retrofit. It is estimated that the cost will be \$2,000
45 to 4,000 for each device. The DHS and the DOE will pay the manufacturers for the

1 enhancements. It is expected that the pilot will be successful and the project will be open
2 to all of the devices currently licensed in the United States.

4 **Alternative Forms for ¹³⁷Cesium Sources**

5
6 The subcommittee considered whether this report should recommend to
7 manufacturers of ¹³⁷CsCl irradiators that alternatives to the powder form of the source be
8 pursued. However, as of this time, there is no convincing evidence that another form,
9 particularly a solid form, would be safer. While a powder may be dispersed by a bomb, a
10 solid poses a radiation hazard much greater than the dispersed powder. In addition, the
11 manufacture of a solid source could pose a hazard to the workers making the sources.

13 **Conclusions**

- 15 1. Cesium-137 irradiators are used in a number of important medical and research
16 applications. As the population of the United States ages, the use of irradiated
17 blood products will escalate, producing an increased demand for the availability
18 of this technology for patient safety. The need for medical irradiators is
19 unquestionable.
- 20 2. Some investigators are concerned about the ways that differences in radiation
21 quality between ¹³⁷CsCl irradiators and x-ray systems would affect experimental
22 results on blood samples, small animals, separated T-cells and stem cells, and
23 other biological media.
- 24 3. Alternatives to ¹³⁷CsCl irradiators are expensive, and forcing the switch to x-ray
25 sources would place an unnecessary and great financial burden on blood banks
26 and research institutions.
- 27 4. The ACMUI subcommittee believes that the ¹³⁷Cesium Chloride Irradiator
28 Security Enhancements and Increased Controls and Security Inspections have
29 provided strong measures for ensuring the safety and integrity of ¹³⁷CsCl sources
30 in medical irradiators, have reduced the vulnerability of these devices as material
31 suitable for malicious intent, and should prove to be acceptable as an alternative
32 to removal or prohibition of these devices.

34 **ACMUI ¹³⁷CsCl Irradiator Subcommittee**

35
36 Debbie Gilley^{1,2}
37 Darrell Fisher^{3,4} (Lead of the Security Subgroup)
38 Ralph Lieto²
39 Orhan Suleiman^{2,3}
40 Bruce Thomadsen² (Chair)
41 Richard Vetter¹ (Lead of the X-ray Alternative Subgroup)
42 James Welsh³ (Lead of the Need Subgroup)
43 ¹Member, X-ray Alternative Subgroup
44 ²Member, Security Subgroup
45 ³Member, Need Subgroup
46

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 - 3 Rad Source Technologies, Inc; 2007c, Available at:
 - 4 http://www.radsource.com/irradiation_rs2400.html . Accessed 12 May 2008.
 - 5
 - 6 Woo, M.K., Nordal, R.A., Commissioning and evaluation of a new commercial small
 - 7 rodent x-ray irradiator, Biomed Imaging Interv J 2: e10; 2006.
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Advisory Committee on the Medical Uses of Isotopes (ACMUI)
Fingerprint Efficiency Subcommittee Report
August 1, 2008

Team Members: R. Lieto, M.S., B. Thomadsen, Ph.D., R. J. Vetter, Ph.D., Chair

Charge: The Subcommittee was charged with examining fingerprinting options for improving efficiency & reducing costs for licensees. This report briefly describes optional mechanisms for licensees to use in satisfying the requirement to submit fingerprints of workers who need access to radioactive materials that require increased controls. The report provides options for improving efficiency and reducing cost without judging which option(s) might be best for a particular licensee. Small licensees might find that the best option for them is not the best option for larger licensees and vice versa. Also, the technology used by local law enforcement or the licensee's own Security work unit may dictate which option a licensee uses. Finally, suggestions are provided on actions licensees may take to decrease costs and increase efficiency and actions the NRC should consider to remove obstacles for licensees.

Methods: The Subcommittee discussed numerous processing and fingerprinting options with security specialists and members of local law enforcement. Comments were also received from a number of licensees. Processing options considered were: processing fingerprints in-house, using an outside vendor who could collect fingerprints and send them to NRC, and using law enforcement either on-site or at law enforcement headquarters.

Costs (excluding fingerprinting labor and employee time away from work):

The cost of fingerprinting by local law enforcement or by a vendor is usually a per-person fixed price. Licensees who want to perform their own fingerprinting in-house need to purchase equipment to do so. The cost of equipment and supplies is dependent on the sophistication of the process selected. Following are approximate costs for equipment and supplies for three common processes.

1. Hand-written, hand rolled:

Fingerprinting station	\$150
Hand cleaner	\$ 40
Total	~ \$200

2. Computer-printed, hand rolled:

Fingerprinting station	\$150
Hand cleaner	\$ 50
Laptop computer	\$600
Laser printer	\$400
Misc. connectors	\$ 50
Equipment cart	\$200
Total	~ \$1500

3. Automated Fingerprint Identification System (AFIS): ~ \$30,000
 - Printrak (Motorola)
 - Cogent (Motorola)
 - Morpho
 - NEC

Enclosure

Outcomes:

Processing Options: Internal processing (i.e. fingerprinting in-house) is convenient, allows complete control of scheduling and rapid re-printing of unclassifiable fingerprints when using an AFIS and is good for ongoing fingerprinting needs. However, it requires registration with State Department of Public Safety, and currently, cards could be rejected by FBI for not being processed by an "official" law enforcement agency. Vendor processing offers guaranteed quality, and information privacy liability is passed on to the vendor. Most vendors use AFIS, so processing is fast. However, it may be expensive depending on the number of persons to be fingerprinted. Most law enforcement agencies use AFIS so processing is fast, and information privacy liability is passed to the agency. However, current jurisdictional issues require that the fingerprints be submitted to NRC rather than directly to the FBI.

Options for processing fingerprints in-house: Fingerprinting with hand-written, hand-rolled fingerprint cards is fast and inexpensive (e.g. Fingerprinting station costs approximately \$200). No electronic technology is required and technician training is minimal. However, inaccurate or illegible entries and poorly rolled fingerprints may result in a high rate of rejected (unclassifiable) cards. Computer-printed, hand-rolled fingerprint cards offer fast generation of multiple cards, accurate and legible entries, standardized abbreviations, a permanent data record, and less risk of unclassifiable cards. Fingerprints still can be poorly rolled, however. An AFIS provides fast generation of multiple cards, accurate and legible entries, standardized abbreviations, a permanent data record, and the possibility of electronic submission. The system quickly identifies unclassifiable fingerprints, so employees can be reprinted on the spot. However, AFIS is expensive and requires regular calibration and upgrades and network requirements to NRC, FBI, or State Department of Public Safety.

IV. Summary

- | | |
|---------------------------------|--|
| 1. Best price: | Hand written, hand rolled, internal processing |
| 2. Best quality: | AFIS, vendor processing |
| 3. Most Convenient to use: | AFIS, internal processing |
| 4. Highest customer throughput: | Computer printed, hand rolled, internal or vendor processing |
| 5. Highest data security: | Hand written, hand rolled, internal processing |
| 6. Govt. preference: | AFIS, Law Enforcement processing |
| 7. Govt. processing: | AFIS, Law Enforcement processing |
| 8. Best search capabilities: | AFIS, internal processing |

How to Decrease Costs and Increase Efficiency

1. Actions that licensees should consider:
 - a. Use fingerprints submitted under other state or federal regulatory requirements such as select agents or medical licensing (see Attachment 3, Par. 3 of order)
 - b. Reduce the number of people approved for unescorted access by pairing up or by designating a few people to escort others or to perform the irradiations. This may not be practical for all licensees, especially for blood banks or transfusion medicine laboratories that operate 24/7 but may be workable in a research setting.
 - c. Isolate irradiator in a small room to reduce the number of people who need access. In small blood banks and hospital transfusion medicine departments, this may not increase safety if the laboratory is already secured. In large transfusion medicine departments it may be justifiable but still costly.

Enclosure

- d. Research facilities establish a core facility where samples are irradiated by a small staff. This option would be expensive if staff must be hired for this purpose only but may reduce costs if incorporated into a few designated technologists' duties.
 - e. Order allows relaxing certain requirements including requesting that certain parts of order not apply to a specific individual, e.g. someone with an active federal security clearance. However, this may be rarely applicable, and the paperwork may be onerous. (See Attachment 3, Par. 3 of order).
 - f. If employees must travel some distance, e.g. 20 miles, for fingerprinting, arrange for licensee Security or local law enforcement to do the fingerprinting on site.
2. Actions that NRC or others should consider to remove obstacles for licensees:
- a. Licensees have experienced many unclassifiable fingerprint cards (some say as high as 25%). However, when fingerprinting physicians for licensing purposes, they seldom experience unclassifiable cards submitted to FBI through local or state law enforcement. Thus, it appears that NRC's handling of fingerprint cards causes many unclassifiable errors. The NRC should address jurisdictional issues to allow licensees to submit directly to the FBI which would decrease opportunities to degrade the quality of fingerprint cards and may increase the number of acceptable agencies or vendors that provide this service. The NRC should also more specifically identify acceptable agencies and vendors to facilitate fingerprinting. The list could be referenced on the NRC website.
 - b. The NRC should address portability of results, i.e. transfer of trustworthy and reliability (T&R) determinations, from one licensee to another to avoid the additional cost associated with repeating the T&R determination including fingerprinting. This process could be analogous to exposure history requests. Alternatively, the NRC could establish a national registry that would allow T&R radiation workers to transfer to another licensee without repeating the fingerprinting and criminal records check.

Permanent brachytherapy subcommittee (PBSC) report

NRC Proposed
Rules published:
Federal Register
Vol. 73, No. 152
Pages 45635 - 45644
August 6, 2008

PBSC Members:

- Subir Nag (Chair)
- Bruce Thomadson
- James Welsh
- Ralph Lieto

Teleconference held 09/12/08, 1-3 pm EST

PERMANENT IMPLANT BRACHYTHERAPY NRC proposed rules

- § 35.40 (6) Written directive (WD) for permanent implant brachytherapy to be source strength-based rather than dose-based
- PBSC supports this proposed rule
- Comment: the word "activity" should be replaced by the correct term: "source strength" whenever it is applied to permanent brachytherapy in the document

PBSC concerns

- While these rules were developed with prostate brachytherapy in mind, they will nevertheless apply to all types of permanent brachytherapy in any organ of the body.
- Unintended consequences: The proposed language in some parts of §35.3045(a)(2) could result in inadvertently and inappropriately categorizing some properly executed, medically acceptable, implants as "medical events" (ME)

PBSC concerns

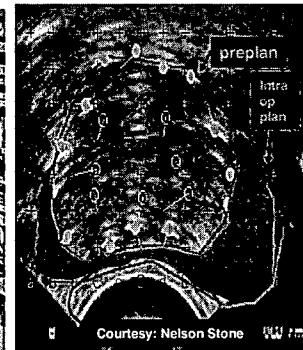
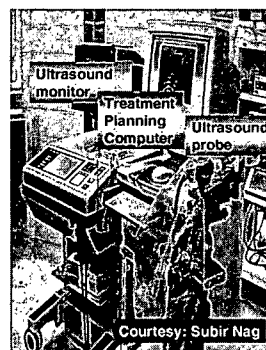
- § 35.3045(a)(2) (i) would deem it a medical event if the total source strength administered differed by 20 percent or more from the total source strength documented in the pre-implantation written directive.
- Further, NRC states pre-implantation WD cannot be changed since pre-implantation WD serves as basis for determining if an ME has occurred

PBSC clarifications

- Many Authorized Users (AU) perform real-time adaptive interactive planning
- WD and source strength implanted based on actual volume dynamically obtained during the procedure
- Not based on the pre-implant volume
- Real-time planning is more accurate
- Takes into account any alterations in the prostate volume and shape
- Plan constantly and dynamically updated as changes occurs during the procedure
- Even those performing preplanned techniques often modify their plan if intraoperative gland volume differs markedly from pre-implant volume

Ref: Nag S et al: ABS Report. JROBP 2001;51:1422-30

Intraoperative planning/dosimetry – O.R. setup



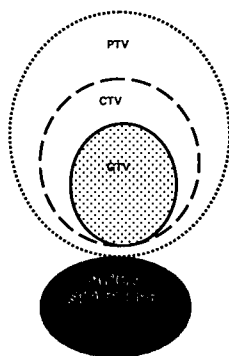
PBSC RECOMMENDATION

- In section § 35.3045 (a)(2)(i), basis for ME should be total source strength implanted after administration (but before patient leaves post-procedural recovery area)
 - Not be based on “pre-implantation” WD
 - Will allow intraoperative adaptation, if needed
 - Will apply both to preplanned technique and real time adaptive technique
- Similarly, the word “pre-implantation” be deleted from “pre-implantation written directive” in sections § 35.3045 (a)(2)(ii), (iii) and (iv) as well

PBSC concerns

- § 35.3045(a)(2) (ii) would deem it a ME if the total source strength implanted outside the treatment site and within 3 cm of the boundary of the treatment site exceeded 20 percent of the total source strength documented in the pre-implantation WD
- Definition of treatment site as “the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive” leads to ambiguity regarding the exact volume referred to

Standard radiation oncology volumes defined (ICRU report #50)



- GTV = gross tumor volume - palpable or visible extent and location of tumor
- CTV = clinical target volume - margins added to the GTV to account for the subclinical microscopic spread of tumor
- PTV = planning target volume - additional margin to account for uncertainties in source positioning, tumor boundaries, isodose constrictions, etc.
- Expansion margins not constant nor uniform - vary for different clinical situations
 - Larger margin if high degree of uncertainty and/or if no adjacent critical structures
 - Margins smaller if boundary is distinct and/or if adjacent critical structures

PBSC concerns

- Determination of margins and source strength to be placed in the margin is a clinical decision
- NRC will be interfering with medical judgment if it dictates source strength AU can place in margin
- Unclear whether “treatment site” refers to
 - gross tumor volume or
 - includes margins as in clinical target volume or
 - includes margin as in planning target volume

PBSC RECOMMENDATION

- Clarify that to be considered a ME , total source strength implanted outside the treatment site (including the gross tumor, the clinical target volume plus a variable planning margin as defined by the AU) exceed 20 percent of the total source strength documented in the WD
- With this definition, NRC will not be interfering with clinical judgment but will be able to identify poor implants that need to be reported as MEs

PBSC concerns

- § 35.3045 (a)(2)(iii) would deem it a ME even if a single brachytherapy source were implanted beyond 3 cm from outside boundary of the treatment site....
- However, in normal course of brachytherapy properly executed implants, a few seeds end up beyond 3 cm from the outside boundary of the treatment site:

PBSC concerns

- Seeds can be deposited into periprostatic blood vessels and migrate to distant organs such as the lung (correctly recognized by the NRC not to be an ME)
- Deposited seeds could also travel to the adjacent pelvic area via the pelvic vessels and be more than 3 cm away from the prostate
- A few seeds can sometimes be implanted into the urethra or adjacent bladder - and normally are excreted in the urine
- Sometimes they move within the bladder or urethra and lodge more than 3 cm from the prostate
- In permanent implants of any organ, some seeds can be unknowingly sucked along the needle track while the needle is being retracted
- May end up more than 3 cm from the organ in the direction of the needle track (eg in prostate, >3 cm inferior to prostate)
- Patients inadvertently move during needle retraction - causing some seeds to be deposited more than 3 cm from treatment site

PBSC concerns

- While most permanent brachytherapy done in prostate, these rules will apply to other sites of permanent implant (eg. tumor beds after resection, deep seated liver tumors)
- At other sites, margins can be indistinct and have greater uncertainties
- After tumor resection no tissues to anchor the seeds - so seeds placed in gelfoam or vicryl mesh and attached to the tumor bed
- Some of these seeds can dislodge and travel in adjacent free cavity (e.g., abdominal, pelvic, or thoracic cavity)
- Finally deposited more than 3 cm away
- Virtually impossible to determine whether they were implanted there or were dislodged and migrated there
- Could be deemed to be an ME

PBSC RECOMMENDATION

• § 35.3045(a)(2) (ii) be modified to: ME if total source strength implanted outside the treatment site (including the GTV, CTV, plus a variable planning margin as defined by the AU) exceed 20 percent of the total source strength documented in the WD

—would take into account source migrations, seeds being dislodged, etc, but would still hold accountable cases in which target organ grossly misidentified and wrong area implanted

• § 35.3045 (a)(2)(iii) will become superfluous and therefore should be eliminated

PBSC concerns

- §35.3045(a): "A licensee shall report as a medical event any administration requiring a written directive if a written directive was not prepared ..."
- Not having a WD prior to administration of byproduct material is already a violation of NRC regulations
- Creating ME situations that are already regulatory violations serves only to add the number of reported MEs (i.e. adding to the reporting burden without adding to safety)
- The proposed rule change will only add MEs that are rule violations but are not harmful to the patient
- Administrations done without required WD should be cited as regulation violation

Summary

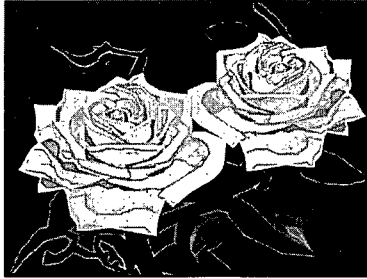
- PBSC very much concerned that, with the proposed rules, above situations may be inappropriately deemed to be medical events when, in reality, they sometimes occur in the course of some normal, properly executed, brachytherapy implants and are beyond the control of the AU.
- PBSC is concerned that some practitioners will simply abandon permanent brachytherapy procedures rather than risk having medical events
- This will be detrimental to patient care

PBSC specific recommendations - summary

- In sections § 35.3045 (a)(2) (i), (ii), (iii) and (iv) "pre-implantation" should be deleted from "pre-implantation written directive"
- In § 35.3045(a)(2) (ii) clarify that "treatment site" includes the gross tumor, the clinical target volume, plus a variable planning margin as defined by AU.
- § 35.3045 (a)(2)(iii) will become superfluous and therefore should be eliminated
- "Activity" should be replaced by "source strength" whenever it is applied to permanent brachytherapy
- Administrations without WD should be cited as regulation violation and are not MEs *per se*.
- NRC should allow ACMUI to review and comment on any proposed rules BEFORE the proposed rules are published

Thanks to:

- **ASTRO**
- **ACRO**
- **ABS**



members for their input

ACMUI permanent brachytherapy subcommittee (PBSC) report of teleconference
held 09/12/08, 1-3 pm EST

Members present:

Subir Nag (Chair)
Bruce Thomadson
James Welsh
Ralph Lieto

Background:

The PBSC reviewed the proposed rule on medical use of byproduct material for permanent implants published in the Federal Register Vol. 73. No. 152 issued on August 6, 2008. The PBSC concurs with many of the proposed rules drafted by the NRC for permanent brachytherapy, which are in accordance with the recommendations of the ACMUI. The PBSC notes that while these rules were developed with prostate brachytherapy in mind, they will nevertheless apply to all types of permanent brachytherapy in any organ of the body. In this regard, the PBSC wishes to reiterate to the NRC the following recommendations that the previous ACMUI Medical Event Subcommittee had made on 6/21/2003 under Section B 2) c) "The technology for image-guided seed positioning and verification is most developed and mature for prostate brachytherapy. However, even in this clinical setting, the precision with which the fraction of seeds implanted in the prostate can be determined from post-implant CT or intraoperative ultrasound imaging maybe limited, due either to image artifacts or operator variability in defining the treatment site. For some treatment sites, e.g., postoperative brachytherapy of a tumor bed, there is no well-encapsulated or radiographically visible target volume that can be used to precisely determine whether the implant is a treatment-site accuracy ME. In such cases, only grossly erroneous MEs can be determined with certainty. NRC enforcement policy must be based upon realistic expectations of the precision that can be achieved in ME determination in different clinical settings." The PBSC also notes that although the proposed rules were based on the recommendations of the ACMUI, the ACMUI was not offered an opportunity to review the proposed rules before the proposed rules were published in the Federal Register. The PBSC feels that some of the unintended consequences could have been avoided if the ACMUI had been able to review the proposed rules before publication.

Specific concerns:

The PBSC is concerned that the proposed language in some parts of §35.3045(a)(2) could result in inadvertently and inappropriately categorizing some properly executed, medically acceptable, implants as "medical events" as follows:

1. The proposed language for § 35.3045(a)(2) (i) on page 45643, column 3 would deem it a medical event if the total source strength administered differed by 20 percent or more from the total source strength documented in the

preimplantation written directive. Further in page 45637 column 3 it is noted *that* the preimplantation WD cannot be changed since the preimplantation WD serves as the basis for determining if an ME has occurred.

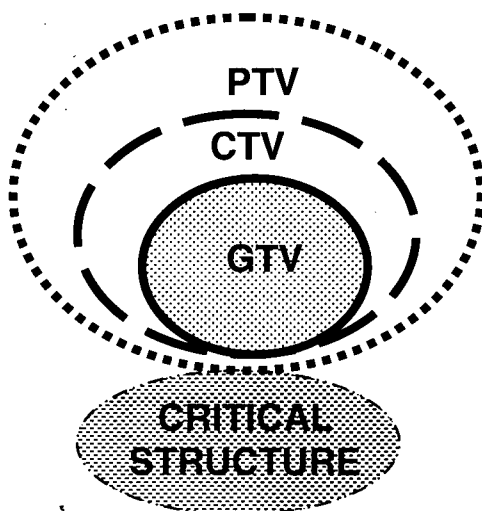
The PBSC wishes to clarify that many AU perform real-time adaptive interactive planning whereby the written directive and the source strength to be implanted are based on the actual volume dynamically obtained during the procedure rather than be based on the preimplant volume (Reference: Nag S, Ciezki JP, Cormack R, Doggett S, DeWyngaert K, Edmundson GK, Stock RG, Stone NN, Yu Y, Zelefsky M. Intraoperative Planning and Dosimetry for Permanent Prostate Brachytherapy: Report of The American Brachytherapy Society. Int J Radiat Oncol Biol Phys 2001;51:1422-30). Real-time planning is a more accurate method of implantation as it takes into account any alterations in the prostate volume and shape that occur between the time of the preplan and the implant procedure and therefore represents the actual prostate volume and implant situation. Hence for those performing real-time adaptive planning implantation, the total source strength to be implanted is determined intraoperatively during the implantation procedure and not preimplant. Further, even those performing permanent brachytherapy using preplanned techniques will often modify their plan if, intraoperatively, they find that the gland volume differs markedly from the volumes determined during the preplan. This is also reflected in the ACMUI directive (page 45636 column 3, sec.6) that "The AU is to complete any revisions to the WD for permanent implants to account for any medically necessary plan adaptations before the patient is released from licensee control after the implantation procedure and immediate post-operative period." Hence the basis for medical event should be the total source strength implanted after administration but before the patient leaves the post-treatment recovery area.

The PBSC recommends that: § 35.3045 (a)(2)(i) be modified to read "The administration of byproduct material or radiation from byproduct material for permanent implant brachytherapy (excluding sources that were implanted in the correct site but migrated outside the treatment site) results in the total source strength administered differing by 20 percent or more from the total source strength documented in the written directive." {ie delete "preimplantation"} It should be clarified that, in the written directive, the source strength implanted refers to the source strength implanted after administration but before the patient leaves the post-treatment recovery area. This wording would therefore apply both to those using the preplanned technique and those using real time adaptive technique. Similarly, the word "preimplantation" should be deleted from "preimplantation written directive" in sections § 35.3045 (a)(2)(ii), (iii) and (iv).

2. The proposed language for § 35.3045(a)(2) (ii)) on page 45643, column 3 would deem it a medical event if the total source strength implanted outside the treatment site and within 3 cm (1.2 in) of the boundary of the treatment site

exceeded 20 percent of the total source strength documented in the preimplantation written directive.

The PBSC wishes to point out that the definition of treatment site as described in § CFR35.2 as "the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive" leads to some ambiguity regarding the exact volume of the treatment. ICRU report #50 has defined various standard volumes to be used in radiation oncology. These include the gross tumor volume (GTV), which is the gross palpable or visible extent and location of tumor. There are also two margins added to the GTV during the brachytherapy planning process. There is a margin added to account for the subclinical microscopic spread of tumor, which is termed the "clinical target volume" (CTV). There is an additional margin added to account for uncertainties in source positioning, tumor boundaries, isodose constrictions etc., which is termed the "planning target volume" (PTV). These expansion margins are neither constant nor uniform and vary for different clinical situations. Radiation oncologists use a larger margin if there is high degree of uncertainty and/or if there are no adjacent critical structures. Conversely, the margins are smaller if the boundary is distinct and/or if there are adjacent critical structures as illustrated in the following diagram.



Volume abbreviations:

GTV = gross tumor volume

CTV = clinical target volume

PTV = planning target

The determination of margins and the source strength to be placed in the margin is a clinical decision. The NRC will be interfering with medical judgment if it dictates the amount of source strength the authorized user can place in the margins. Using § 35.2 definition of treatment site as "the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive" leads to ambiguity since it is unclear whether the "treatment site" refers to the gross tumor volume or includes the margins as in the clinical target volume or includes the margin as in the planning target volume.

For clarification, the PBSC recommends that to be considered a medical event, the sentence "The total source strength implanted outside the treatment site and within 3 cm (1.2 in) of the boundary of the treatment site exceeding 20

percent of the total source strength documented in the preimplantation written directive" be replaced by "The total source strength implanted outside the treatment site (including the gross tumor, the clinical target volume plus a variable planning margin as defined by the AU) exceeding 20 percent of the total source strength documented in the written directive". With this clarification of the treatment site and deletion of "preimplantation", the NRC will not be interfering with clinical judgment but will still be able to identify poor implants that will need to be reported as medical events.

3. The proposed language for § 35.3045 (a)(2)(iii) on page 45643, column 3 would deem it a medical event if any brachytherapy source(s) were implanted beyond 3 cm (1.2 in) from the outside boundary of the treatment site, except for brachytherapy source(s) at other sites noted in the preimplantation written directive. Further in page 45638 column 2 it is noted that with the exception of sealed sources that migrate after implantation, even a single brachytherapy source implanted beyond 3 cm from the outside boundary of the treatment site would constitute an ME.

The PBSC wishes to emphasize that in the normal course of some brachytherapy implants, a few seeds can end up beyond 3 cm (1.2 in) from the outside boundary of the treatment site due to a number of factors.

- a. In the prostate, seeds can be deposited into the periprostatic blood vessels and then travel to distant organs such as the lung. This is correctly recognized by the NRC, which excludes sources that were implanted in the correct site but have migrated outside the treatment site from medical event criteria. However, the deposited seeds could also travel to the adjacent pelvic area via the pelvic vessels and be more than 3 cm away from the prostate. This case could be determined to be a medical event as it would be impossible to distinguish whether it was wrongly deposited there or was correctly placed but migrated there.
- b. In prostate implants, a few seeds can sometimes be implanted into the urethra or adjacent bladder. Most of these seeds normally are excreted in the urine. However, sometimes they move within the bladder or urethra and lodge more than 3 cm from the prostate.
- c. In permanent implants of any organ, some seeds can be unknowingly sucked along the needle track while the needle is being retracted and may end up more than 3 cm from the organ in the direction of the needle track. In the prostate, they would end up inferior to the prostate.
- d. In permanent implants of any organ, patients could inadvertently cough or otherwise move during the needle retraction causing some seeds to be deposited more than 3 cm from the treatment site.
- e. While most permanent brachytherapy is done in the prostate, these rules will apply to other sites of permanent implant in addition to prostate. At other sites, for example the tumor beds after resection and deep seated liver tumors, the margins are indistinct and there are greater uncertainties. Therefore clinicians routinely implant beyond the tumor or tumor bed if

there are no critical structures in that area. Further, sometimes (especially after tumor resection) there may be no tissues to anchor the seeds to and so they are placed in gelfoam or vicryl mesh and attached to the tumor bed. Some of these seeds do dislodge and then can travel in an adjacent free cavity and be deposited more than 3 cm away (e.g., in the abdominal, pelvic, or thoracic cavity). It would be virtually impossible to determine whether they were implanted there or were dislodged and migrated there and therefore could be deemed to be a medical event.

The PBSC recommends that section § 35.3045(a)(2) (ii) be modified to "The total source strength implanted outside the treatment site (including the gross tumor, the clinical target volume plus a variable planning margin as defined by the AU) exceeding 20 percent of the total source strength documented in the written directive". This would take into account source migrations, seeds being dislodged, sucked out, etc, but would still hold accountable cases in which the target organ was grossly misidentified and the wrong area was implanted. Accordingly, § 35.3045 (a)(2)(iii) will become superfluous and therefore would be eliminated.

Other comments:

1. In addition to the above specific recommendations, the PBSC recommends that the word "activity" should be replaced by the term "source strength" whenever it is applied to permanent brachytherapy in the document.

2. Further, in the course of the review of these proposed rule changes, the PBSC wishes to comment on new wording that potentially affects any administration of byproduct material requiring a written directive (WD). The proposed language for §35.3045(a) on Federal Register, page 45643, column 2 currently reads, "A licensee shall report as a medical event any administration requiring a written directive if a written directive was not prepared or any event..."

The PBSC recommends that "...if a written directive was not prepared or..." be deleted from the proposed rules for the following reasons.

Not having a written directive prior to administration of byproduct material is already a violation of NRC regulations. 10 CFR §§35.40(a) and 35.41 require having a written directive prior to administration and the program and procedures to provide "high confidence" for verifying the written directive is done.

Creating medical events (ME) that are already regulatory violations serves only to add the number of reported deviations and establishes a undesirable precedent for making any medical regulation violation a ME. ME reporting is a national public notification within 24 hours that may initiate unneeded public embarrassment and scrutiny. Let us analyze the two scenarios where a non-emergent therapy administration requiring a WD was performed without a WD. A. In the first scenario, the therapy is done following verbal orders/no WD but the patient receives the therapy administration as directed. While this is a clear

violation of regulations as described above, there is absolutely no resultant patient harm.

B. In the second scenario, the therapy is done following verbal orders/no WD but the patient receives more than $\pm 20\%$ of the intended therapy dose/dosage. Clearly, this not only violates regulations but also exceeds the medical event reporting criteria hence would be reported as a medical event anyway.

Therefore, the proposed rule change will only add events that are rule violations but are not harmful to the patient. Administration done without required WD should be handled as any citation of regulations by the regulatory enforcement agency (NRC or Agreement State). Licensees should be encouraged to self-identify such violations and implement documented remedial action with the clear understanding that the action would be reviewed during routine regulatory inspections. In addition, anything that would constitute an incomplete WD as required by the regulations (e.g., missing date or signature) would be considered an invalid directive and thus subject to the proposed ME reporting. This further establishes a precedent for any violation of regulations involving procedures requiring a written directive as being a ME.

The Discussion in the Federal Register (Item F, p. 45637) states that without a WD, "licensees do not have a basis for determining if a ME has occurred." This is not accurate. The NRC medical event database has a number of reported examples where *intended* diagnostic administrations of radioiodines, not requiring a WD, mistakenly received amounts in the therapeutic range. Licensees with quality written directive programs as required in §35.41 will have procedures that require a properly completed WD exists prior to administration, with the exception for already permitted emergent situations.

For almost two decades, overwhelming cause of medical events is human error. This new proposed change will provide only another process to add to MEs that are not harmful, without minimizing this cause. Contrary to the Discussion in the Federal Register, this new requirement will not add or improve to ensure the health and safety of patients is protected. The NRC has provided no justification that this rule violation merits being a reportable ME. This added requirement is not needed and will simply increase the number of reported medical events by creating only another process to add to the ME definition.

The PBSC recommends that the NRC staff issue a RIS emphasizing that administrations without the required WD are violations of regulations and procedures must exist to identify any deviations from this requirement. If violations should occur, the event must be documented with any appropriate remedial action. If the NRC feels this needs to be made more explicit in regulations, then the NRC should amend to §35.41 (a) (1) (Procedures for administrations requiring a written directive) to the effect "...to provide high confidence that: (1) The patient's or human research subject's identity is verified *and a properly written directive is done before each administration;*".

Summary:

The PBSC is very much concerned that, with the proposed rules, the above situations may be inappropriately deemed to be medical events when, in reality, they sometimes occur in the course of some normal, properly executed, brachytherapy implants and are beyond the control of the AU. Further, the PBSC is concerned that some practitioners will simply abandon permanent brachytherapy procedures rather than risk having medical events. This will be detrimental to patient care. Specifically, the PBSC recommends that:

- The word "preimplantation" should be deleted from "preimplantation written directive" in sections § 35.3045 (a)(2) (i), (ii), (iii) and (iv).
- § 35.3045(a)(2) (ii)) be clarified to read "The total source strength implanted outside the treatment site (including the gross tumor, the clinical target volume plus a variable planning margin as defined by the AU) exceeding 20 percent of the total source strength documented in the written directive".
- § 35.3045 (a)(2)(iii) will become superfluous and therefore should be eliminated.
- The word "activity" should be replaced by the term "source strength" whenever it is applied to permanent brachytherapy in the document.
- A RIS be issued emphasizing that administrations without the required WD are violations of regulations and are not ME *per se*. Procedures must exist to identify any deviations from this requirement.
- The NRC should allow the ACMUI an opportunity to review and comment on any proposed rules BEFORE the proposed rules are published in the Federal Register. This will avoid unintended consequences.

Thank you for affording us this opportunity to provide comments on the NRC's preliminary draft rule changes to 10 CFR 35.40 and 35.3045 related to medical events in brachytherapy.

Interventional Radiology: Pathway to Authorized User Status

Riad Salem MD MBA
Director, Interventional Oncology
Section of Interventional Radiology
Department of Radiology
Northwestern University
Chicago, IL



Introduction

- Discuss next steps in evolution of Y90 at NRC guidance level
- Representation
 - Society of Interventional Radiology
 - American Board of Radiology



Review

- Yttrium 90 microsphere therapy
 - Available in the USA since 2000
 - TheraSphere (glass), SIR-Spheres (resin)
 - Steady increase in adoption as treatment option (> 5000 patients treated to date)
- Classified as brachytherapy device
 - Status → 35,490
 - Recent addition of 35,390
 - Intent was for IRs to fall under 35,390



Collaborative Efforts

RECOMMENDATIONS FOR RADIOEMBOLIZATION OF HEPATIC MALIGNANCIES USING YTTRIUM-90 MICROSPHERE BRACHYTHERAPY: A CONSENSUS PANEL REPORT FROM THE RADIOEMBOLIZATION BRACHYTHERAPY ONCOLOGY CONSORTIUM

- Consensus statement, International Journal of Radiation Biology and Physics 2006
- Representation by
 - 3 Radiation Oncologists
 - 5 Interventional Radiologists
 - 1 Surgeon
 - 2 Medical Oncologists
 - 1 Nuclear Medicine
- → RO, NM and IR all qualified to be AUs



Collaborative Efforts

PRACTICE GUIDELINE FOR RADIOEMBOLIZATION WITH MICROSPHERE BRACHYTHERAPY DEVICE (RMBD) FOR TREATMENT OF LIVER MALIGNANCIES

- Consensus statement, ACR Practice Guidelines 2008
- Representation by
 - 4 Radiation Oncologists (ASTRO, ACRO)
 - 4 Interventional Radiologists (SIR, ABR)
 - 6 members of ACR
- ACR Guidelines Radiation Oncology Committee
 - 14 members
- ACR Guidelines Interventional Committee
 - 12 members
- Comments Reconciliation Committee
 - 30 members
- → RO, NM and IR all qualified to be AUs



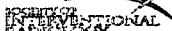
Scope of Issue

- NRC published guidance document
 - Discusses pathway to AU
 - 35,390, 35,490
 - Vendor specific training
- Many states/local RSO/RSC uncertain that IRs fulfill the requirements of 35,390
 - creates confusion
 - impedes ability to gain AU status
 - limits access of patients to therapeutic options



Interventional Radiology Training

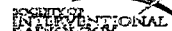
- Diagnostic Radiology: 5 years
 - 700-960 clinical hours in nuclear medicine
 - 80 hours didactic (classroom/laboratory training)
- Formal written radiation physics examination
 - Radiation safety/protection/biology/effects on tissue
- Formal written radiology examination
- Formal oral radiology examination



Interventional Radiology Training

Diagnostic Radiology (80 hours under an AU)

- diagnostic radiologic physics, instrumentation, and radiation biology
- patient and medical personnel safety (i.e., radiation protection)
- the chemistry of by-product material for medical use
- biologic and pharmacologic actions of materials administered in diagnostic and therapeutic procedures
- topics in safe handling, administration, and quality control of radionuclide doses used in clinical medicine



Interventional Radiology Training

Diagnostic Radiology (80 hours under an AU)

- ordering, receiving, and unpacking radioactive material safely
- performing the related radiation surveys
- safe elution and quality control (QC) of radionuclide generator systems
- calculating, measuring, and safely preparing patient dosages
- calibration and QC of survey meters and dose calibrators
- safe handling and administration of therapeutic doses of unsealed radionuclide sources (i.e., I-131)
- written directives
- response to radiation spills and accidents (containment and decontamination procedures)
- radiation signage and related materials
- using administrative controls to prevent medical events involving the use of unsealed byproduct material



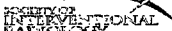
Interventional Radiologists Today: Qualifications for AU

- Perform Y90 safely and effectively
 - institutions with IRs, nonIRs as AUs
- Critical safety and efficacy issue
 - revolve around patient selection for liver directed therapy, safe delivery of treatment using advanced catheterization techniques → realm of IR
- Worked extensively with Y90
 - Courses, workshops, national/international symposia
 - Vast majority of research being performed by IRs
 - Participated in consensus documents
- AUs being proctored and trained by IRs



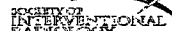
Proposal

- Authorized User Status
 - 35.390 or 35.490
- OR
- 35.290 (Interventional Radiology) + ABR administered examination (primary clinical certificate in Y90)



Society of Interventional Radiology American Board of Radiology Yttrium 90 AU Course/Workshop

- Number of Hours TBD
- Taught by:
 - Interventional Radiologists
 - Radiation Oncologists
 - Nuclear Medicine Physicians
 - Nuclear Medicine Physicists/Health Physics Experts



**Society of Interventional Radiology
American Board of Radiology Yttrium 90:
Course/Workshop Content Part 1**

PATIENT SELECTION AND PREPARATION

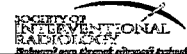
- Identification/screening eligible patients
- vascular mapping and ^{99m}Tc -MAA scanning
- angiographic technique/preparation of hepatic vasculature to administer the therapy
- treatment planning and dosimetry
- radiation safety and monitoring procedures specific to ^{90}Y microsphere dose preparation and administration
- respective technical and clinical aspects unique to the administration of each type of ^{90}Y microsphere therapy
- clinical follow-up and imaging evaluation of patients treated



**Society of Interventional Radiology
American Board of Radiology Yttrium 90:
Course/Workshop Content Part 2**

DOSAGE SELECTION AND PREPARATION FOR ^{90}Y

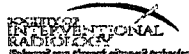
- Radiation physics and instrumentation
- Radiation protection
- Mathematics pertaining to the use and measurement of radioactivity
- Chemistry of byproduct material for medical use
- Radiation biology of beta-isotopes
- Discussion on ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys
- Discussion on performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for operation of survey meters
- Discussion on calculating, measuring, and safely preparing patient or human research subject dosages
- Using administrative controls to prevent a medical event involving the use of the beta-isotope
- Using procedures to contain spilled byproduct material safely and using proper decontamination procedures



VENDOR SPECIFIC TRAINING

VENDOR TRAINING

- Sirtex medical-Introductory presentation/discussion, on-site proctors
- MDS Nordion-Introductory presentation/discussion, training course, on-site proctors



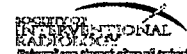
Authorized User: Summary

Pathway 1:

35.390/490 + vendor training per NRC guidance

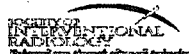
Pathway 2:

35.290 + ABR certificate + vendor training per NRC guidance



Conclusion

- American Board of Radiology
 - Will support an examination for ^{90}Y AU for qualified Interventional Radiologists
 - → primary AU certificate for ^{90}Y
 - Not preclude vendors from onsite support and proctoring as per NRC guidance
- Discussion



Y-90 Microsphere Brachytherapy Licensing Guidance Issue

Yttrium-90 microsphere brachytherapy is a treatment option that continues to show safety and efficacy for the treatment of liver tumors. Patients are treated on an outpatient basis, and the toxicity profile is low. This low toxicity profile is directly attributable to tumor hypervascularity; the microspheres are concentrated within the tumor and emit a local radiotherapeutic effect.

Traditionally, the steps involved in treating patients include a history/physical, review of diagnostic images, planning mesenteric angiogram with Tc-99 MAA, coil embolization of non-target vessels, infusion of the microspheres on treatment day, and clinical follow-up with imaging to assess tumor response. Although ideally there would be an interventional radiologist, a nuclear medicine physician as well as a radiation oncologist involved in the management of the patient, this is not always the case. Because of local factors, it is often not possible to have all members involved. The intensely IR nature of Y-90 microsphere treatments, along with other local factors, has led to an increasing need for the consideration of an IR as an autonomous AU.

Dr. Riad Salem would like to discuss current issues for IRs in obtaining AU status, hurdles that have (and have not) been overcome, as well as possible alternate routes for AU status. In particular, given the nature of the technology, since there are clear guidelines for Nuclear Medicine (10 CFR 35.390) and Radiation Oncology (10 CFR 35.490), there should similarly be a clear and well-defined pathway to AU status for interventional radiologists. Points to be raised in Dr. Salem's presentation include: history of issues encountered by IRs when trying to attain AU status, rationale for Interventional Radiologists as AUs, and possible approaches/solutions suggested by the Society of Interventional Radiology (and the American Board of Radiology). The issues that will be raised are meant to initiate discussion and obtain feedback from the ACMUI.

NO HANDOUT

NO HANDOUT

A copy of a sample letter that is being sent to the boards will be provided to ACMUI members via email prior to the October 27-28, 2008 meeting. Hard copies of the letter will be provided at the meeting.

IMPACT OF ISOTOPE SHORTAGES ON MEDICAL COMMUNITY

BACKGROUND

In response to the recent shortage of Mo-99, Dr. Max Lonneux, General Secretary of the Belgian Nuclear Medicine Society provided the following discussion on the impact of isotope shortages in European medical imaging. [Article taken from Global Nuclear Open Source Information Service (GNOSIS) September 9, 2008: Interview with Dr. Max Lonneux by "R.G." in Brussels; date not given: "There is No Vital Risk to Patients"]

Dr. Lonneux is a nuclear medicine physician employed at the Nuclear Medicine Department at the St. Luc University Hospital in Brussels.

Is the shortage of radioisotopes a cause for concern?

[Lonneux] The problem is certainly serious. The type of tracer affected by the shortage, produced by special reactors with a high neutron flow, is used in about 80% of activities in the nuclear medicine sector. The remaining 20% require the use of tracers that are continuing to be produced in sufficient quantities, in the cyclotrons.

At the time of the previous shortage, in Canada, your colleagues said that about 10% of the patients affected were facing life or death decisions and that in between 30% and 40% of other cases the doctors were in danger of making an insufficient diagnosis and of taking inappropriate decisions in the field of treatment.

[Lonneux] We must not be alarmist. The shortage does not generate a vital risk for patients. It is not as if you were immediately cutting off the electricity supply to an operating theater! We were warned as far back as 29 August. Provisions were made to postpone routine check-ups and reserve the stocks of available radioisotopes for the most urgent cases.

For example?

[Lonneux] This morning, at St. Luc, we received just 15% of the usual radioisotope volume. Appointments for patients who were only to undergo a check-up were postponed. On the other hand, we are carrying out the most urgent examinations, such as the scintigraphy of sentinel ganglions in the case of breast cancer, which makes it possible to determine whether or not a surgical intervention is necessary. In this case the diagnosis is an inherent part of the surgical act. And for this we have no replacement solution.

In other cases, alternatives are envisageable however...

[Lonneux] Some scintigrams carried out normally using a technetium-99 can be carried out using other radioisotopes, less indicated but nevertheless effective, such as thallium. Naturally, to examine the condition of the heart... We can also use a PET scan, for example, to detect certain bone diseases or neurological complaints. With a risk of saturation: The planning for PET scanning is full for the coming week.

How do you explain the shortage?

[Lonneux] It is unbelievable. Europe is in a beneficial situation with three production units out of the six that exist worldwide. How is it possible to shut down for maintenance at the same time two of the three units operating in Europe? The sector suffers from a lack of coordination, between the private and public operators, but also from an evident lack of reinvestment. Investing in nuclear technology, even medical, is no longer politically correct!

Did the temporary shutdown of the IRE aggravate the situation?

[Lonneux] The IRE [Institute of Radioelements] intervenes downstream of the production reactors but its role is vital in the production chain. Ideally the Fleurus processing center, which is continuing to be marked by less than transparent communication, should start up for the latter half of September. If not, the shortage will continue until the Petten unit starts up again and that is not expected until the end of October. But at least they communicate there.

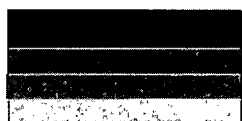
DISCUSSION

The above article discusses the effects of isotope shortages on the medical community in Europe. NRC is seeking advice from the ACMUI on the impact of shortages of isotopes on the practice of medicine in the United States. The following questions may guide the ACMUI in responding:

1. Approximately how many procedures using radioactive drugs are performed in a day? Can you categorize the procedures using these drugs by relative percentages (cardiac, bone, thyroid, lung, etc.)? Can you put this into perspective of the procedures that use Tc-99m? I-131? Xe-133?
2. How many procedures using the fission product radioactive drugs must be performed immediately? How many procedures can be postponed a few days? A week? A few weeks? Note: These estimates can be in percentages for a given procedure, e.g. X% of cardiac studies must be performed immediately. Y% of cardiac studies can be postponed Z number of days.
3. How many patients requiring a procedure using fission product radioactive drugs can receive a different test to achieve the same results? Note: This could include procedures that use accelerator produced byproduct materials. These estimates can be given in percentages for a given procedure, e.g., X% of patients having cardiac studies could have a different examination in lieu of the cardiac study involving fission products and still achieve the same diagnostic objective.
4. Are there other uses of fission radionuclides affecting medicine in short supply that NRC is not focused on?



HEALTH
PHYSICS
SOCIETY



CONGRESS AND FEDERAL AGENCIES MUST TAKE ACTION TO ENSURE A DOMESTIC SUPPLY OF MEDICAL RADIOISOTOPES

POSITION STATEMENT OF THE HEALTH PHYSICS SOCIETY*

Adopted: September 2008

Contact: Richard J. Burk, Jr.
Executive Secretary
Health Physics Society
Telephone: 703-790-1745
Fax: 703-790-2672
Email: HPS@BurkInc.com
<http://www.hps.org>

The Health Physics Society (HPS) believes that strengthening our nation's ability to produce radionuclides (radioisotopes) for the medical sciences must become a national priority. Improving the domestic production of radioisotopes can only be accomplished through timely congressional and federal agency action.

The Health Physics Society encourages research in the radiation sciences, including health-related research that relies on the safe use of radioisotopes. Our nation has long recognized the need for the study of physiological processes, molecular functional imaging, and diagnosis and treatment of diseases using radioisotopes. Modern nuclear medicine has improved the health and welfare of our citizens.

Today, the United States faces a serious shortage of domestically produced medical radioisotopes. With near total dependence on foreign supplies, our nation has lost its competitive edge in the science and technology of radioisotope production for medical applications.

Society members recognize that scientific progress in radiotracer and radiopharmaceutical development, molecular imaging, and targeted radionuclide cancer therapy depends on radioisotope availability. Historically, the domestic production of radioisotopes has been largely a responsibility of the federal government infrastructure and national laboratories managed by the Department of Energy. Today, this is not a priority for the agency. The requirements for applications in medical research are largely driven by the needs of researchers and programs within the various agencies of the Department of Health and Human Services. Domestic private-sector producers are supplying radioisotopes with few incentives at levels far below the need.

The Health Physics Society advocates a federal government commitment to radioisotope production, dedicated production facilities, and the concomitant education and training of scientists. These needs are as described in a report of the National Research Council and the Institute of Medicine of the National Academies (NRC-IOM 2007).

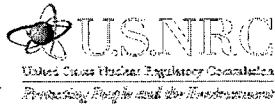
To strengthen the supply of radioisotopes necessary to meet critical national needs and to reduce our nation's dependence on foreign suppliers, the Health Physics Society recommends fundamental changes to federal government programs and policies for radioisotope production:

1. Establish a joint program office of the Department of Energy and the Department of Health and Human Services to focus on national needs, prioritize activities, plan, and coordinate the federal response.
2. Provide adequate congressional funding for radioisotope production, including funds needed to plan, construct, and operate dedicated radioisotope production facilities.
3. Take firm measures to preserve the essential raw (or starting) materials, such as thorium-229, that are needed for radioisotope production.
4. The Department of Energy and the Department of Health and Human Services should engage the private sector and universities by supporting federal-private partnerships and grants to promote radioisotope production, cultivate technology innovation, and foster commercialization opportunities.

Reference

National Research Council and Institute of Medicine (NRC-IOM). Advancing nuclear medicine through innovation. Committee on State of the Science of Nuclear Medicine. Washington, DC: The National Academies Press; 2007.

* The Health Physics Society is a nonprofit scientific professional organization whose mission is excellence in the science and practice of radiation safety. Since its formation in 1956, the Society has grown to approximately 6,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the Department of Defense, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society. The Society may be contacted at 1313 Dolley Madison Blvd., Suite 402, McLean, VA 22101; phone: 703-790-1745; fax: 703-790-2672; email: HPS@BurkInc.com.



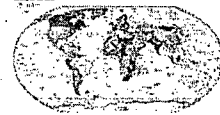
NRC Staff Considerations for Revisions to Radiation Protection Standards

Advisory Committee on Medical Uses of Isotopes

Dr. Donald A. Cool
Senior Advisor
Radiation Safety and International Liaison
Office of Federal and State Materials and Environmental Management Programs

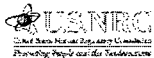
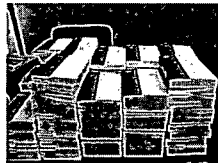
International Developments

- ICRP Recommendations published in December, 2007, ICRP Publication 103
- IAEA revision of BSS underway
- European Union revision of Euratom BSS underway
- Staff reviewing impact as directed by Commission in SRM-SECY-01-0148



Revision of NRC Regulations

- NRC staff developing options for Commission consideration
- Senior Technical Group and Steering Group
- Options due to Commission in December 2008



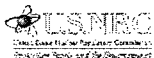
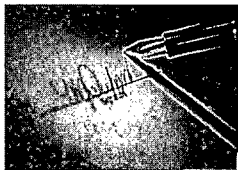
Background

- Considering all parts of regulations, including those not revised in 1991
- Some portions of regulations and guidance date back to ICRP Publication 2 (1959)
- Rationale for action may include adequate protection, updating scientific information, trans-boundary implications, and achieving consistency of approach.



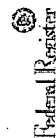
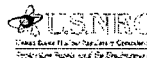
Outline of Options Paper

- Regulatory Options
- Technical Options
- Administrative Options



Regulatory Options

- Status Quo – Make no changes
 - Realign Part 50 and Part 50 Appendix I to Existing Part 20 under the status quo
- Align to ICRP Publication 103 (2007)
 - Revise Part 20 only
 - Revise Part 20, Part 50, and Part 50 Appendix I
 - Revise all 10 CFR Chapter I



Technical Options for Part 20

- Total Effective Dose
- Constraints for occupational exposure
- Dose limits
 - Occupational
 - Public
 - Embryo/fetus of Declared Pregnant Female
- Numerical values of weighting factors and Appendix B



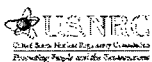
Administrative Options

- Begin Rulemaking Activities Now
- Delay Rulemaking while continuing with Technical Basis Development and Stakeholder Interactions
- Packaging for Actions
 - Part 20 and Part 50 Together
 - Part 20 and Part 50 Separately
 - Timing for other Parts



Points to Ponder

- Changes to the radiation protection framework could be significant, impacting all types of licensees, and Agreement States
- Much of the effort would be guidance and code updates to support regulations.
- Technical basis work still in progress. When is the right time to move to rulemaking?
- How do we effectively gauge benefits and impacts?



Questions?





Infiltration of F-18 FDG and Therapeutic Radiopharmaceuticals

Cindy Flannery, CHP, Team Leader

U.S. Nuclear Regulatory Commission
Office of Federal and State Materials
and Environmental Management Programs
Division of Materials Safety and State Agreements
Radioactive Materials Safety Branch
Medical Radiation Safety Team
October 28, 2008



Background

A report was submitted in January, 2008 as a possible medical event:

3.6 mCi of F-18 fluorodeoxyglucose (FDG) was infiltrated into the antecubital dermis adjacent to the left elbow.

Based on these parameters, the dose to tissue was estimated to range from 0.2 to 96 rem.

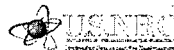
Assumptions: Entire dose infiltrated into tissue within 60 cm³ volume sphere using a soft tissue density of 1.06g/cm³ a range of mean residence time from 0.006 to 2.6 hours



Licensee Estimate

Lacking more information on the residence time of FDG in tissue, it was difficult to further refine the dose value

Residence time (hours)	Estimated Dose (rem)
0.006	0.2
0.5	19
1	37
1.35	49.95
1.5	56
2	74
2.6	96



Outcome

The licensee initially reported the event to the NRC as a possible Medical Event (ME) based on the dose to tissue potentially exceeding 50 rem.

The event was later retracted because NRC staff determined that extravasation does NOT require reporting as a ME under § 35.3045(a)(2)(ii) based on Supplementary Information on the general requirements of 35.3045 based on prior § 35.3045



45 FR 31703, May 14, 1980

"Extravasation is the infiltration of injected fluid into the tissue surrounding a vein or artery. Extravasation frequently occurs in otherwise normal intravenous or intraarterial injections. It is virtually impossible to avoid. Therefore, the Commission does not consider extravasation to be a misadministration."



Questions

Considering the higher doses from the use of NARM, should NRC change its position to now regard infiltrations as MEs if the resulting dose exceeds the dose limits in 10 CFR 35.3045 (i.e., 50 rem)?

How about when an infiltration occurs from a administration requiring a written directive (i.e., therapeutic administration)?

September 17, 2008

(FSME-08-072), September, Program, Medical Use Training and Experience)

ALL AGREEMENT STATES, MICHIGAN, NEW JERSEY, VIRGINIA

**OPPORTUNITY TO COMMENT ON RECOMMENDED CHANGES TO 10 CFR PART 35
TRAINING AND EXPERIENCE REQUIREMENTS, ATTESTATIONS - (FSME-08-072)**

Purpose: To provide an opportunity to comment on recommended changes to training and experience (T&E) attestation requirements in 10 CFR Part 35 from the U.S. Nuclear Regulatory Commission's (NRC's) Advisory Committee on the Medical Uses of Isotopes (ACMUI).

Background: The ACMUI met with the Commissioners on April 29, 2008 and recommended that the attestation requirements that are part of the medical use training and experience requirements in 10 CFR Part 35 be modified.¹ In the Staff Requirements Memorandum (SRM) issued following the meeting,² staff was directed to work with the ACMUI and the Agreement States to provide recommendations to the Commission on amending NRC's requirements for preceptor attestation for both board certified individuals and for individuals seeking authorization via the alternate pathway. Staff was also directed to consider additional methods, such as the attestation being provided by consensus of an authoritative group, e.g., a residency program faculty, represented by a residency program director. This particular additional attestation method was recommended by the ACMUI previously and again in discussion with the Commissioners at the April 2008 meeting.

Discussion: The ACMUI recommended that the attestation requirements be completely eliminated for individuals seeking authorized status via the board certification pathways. ACMUI also recommended that the attestation requirements associated with the more prescriptive alternate pathways to authorized status be modified, to delete text associated with preceptors attesting to individuals' radiation-safety-related competency being sufficient to function independently as authorized persons for the medical uses associated with the authorizations sought. It should be noted that the ACMUI has several times previously recommended these same modifications to the attestation requirements, and that earlier Commissions each time have decided to not implement these specific changes.³

¹ See the presentation for the ACMUI by Douglas F. Eggli, M.D., nuclear medicine physician member, ACMUI, at <http://www.nrc.gov/reading-rm/doc-collections/commission/slides/2008/20080429/080429-slides-eggli.pdf>

² On the NRC public web site at <http://www.nrc.gov/reading-rm/doc-collections/commission/srm/meet/2008/m20080429.html>

³ For explanation, see, on the NRC public web site, at <http://www.nrc.gov/reading-rm/doc-collections/#comm>, the following Commission papers plus their associated SRMs and Commissioner voting records: SECY-02-0194; SECY-03-0145; and SECY-05-0020.

Comments are sought, as follows.

- 1) Do you support the recommended elimination of the attestation requirement for individuals seeking authorized status via the board certification pathways?
- 2) Do you support the recommended modification of the attestation requirement for individuals seeking authorized status via the alternate pathways, to delete text associated with preceptors attesting to individuals' competency being sufficient to function independently as authorized persons for the medical uses associated with the authorizations sought?
- 3) Do you support additional methods for attestations, such as the attestation being provided by consensus of an authoritative group, e.g., a residency program faculty, represented by a residency program director?

We would appreciate receiving any comments regarding the ACMUI-recommended and related changes to the attestation requirements in the Part 35 T&E regulations by Friday, October 3, 2008. Please e-mail your response to the point of contact below.

If you have any questions on this correspondence, please contact me at 301-415-3340 or the individual named below.

POINT OF CONTACT: Ronald E. Zelac
TELEPHONE: 301-415-7635

INTERNET: ronald.zelac@nrc.gov
FAX: 301-415-5955

/RA/

Terrence Reis, Acting Director
Division of Materials Safety
and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

* This information request has been approved by OMB 31 50-0029, expiration 08/31/2010; OMB 3150-0200, expiration 06/30/2009; and OMB 3150-0163, expiration 10/31/2009. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and FOIA/Privacy Services Branch (T-5F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-1 0202 (3150-0029), Office of Management and Budget, Washington, DC 20503. 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.



Status of Part 35 Rulemakings

Neelam Bhalla / Ed Lohr
Rulemaking Branch B
DILR/FSME



Part 35 - Medical Event Definitions Proposed Rule

Next Part 35 Rulemaking

2



Part 35 - Medical Event Definitions Proposed Rule

- Adds an ME criterion (reportable under § 35.3045), any administration requiring a written directive (WD) if a WD was not prepared.
- Changes most ME criteria from dose-based to activity-based for permanent implant brachytherapy.
- Clarifies WD requirements for permanent implant brachytherapy.

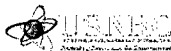
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Part 35 - Medical Event Definitions Proposed Rule

- Proposed Rule published in Federal Register Aug 6, 2008 (73 FR 45635).
- Public comment period ends Nov 7, 2008.
- Staff must review and resolve all public comments.

4



Part 35 - Medical Event Definitions Proposed Rule

- Takes up to a year to develop and publish the Final Rule.
- Very dependent on the number of public comments received.
- Staff may have to do additional analysis or research.
- Final Rule should publish in Aug 2009 pending Commission approval.

5



Legal / Administrative Requirements and NRC Policy that Determines the Length of the Rulemaking Process

- A collaborative, deliberative process.
- Resolution of comments.
- Commission takes very seriously its role in review and approval of regulations.

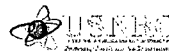
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Next Part 35 Rulemaking

- Will include numerous amendments identified by the NRC Medical Team.
- The proposed changes have been, or will be reviewed by ACMUI.
- Ritenour Petition should be included.
 - Ritenour Petition requested NRC to amend Training and Experience (T&E) requirements for experienced Authorized Medical Physicists and Radiation Safety Officers.
 - NRC resolution (73 CFR 27775, May 14, 2008) to consider the issues in a future rulemaking, pending development of a technical basis.

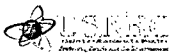
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Next Part 35 Rulemaking Time Line

- Scheduled to begin Summer 2009.
- Proposed Rule – Tentative Summer 2010
- Final Rule – Tentative Summer 2011

8



Status of Part 35 Rulemakings

Questions?

9



Potential Changes to 10 CFR Part 35

ACMUI Meeting

October 28, 2008

Donna-Beth Howe, Ph.D.



10 CFR 30.35(b)

- **Problem:** 30.35(b) requires a certificate of financial assurance for decommissioning for licensees authorized for the possession and use of sealed sources including Co-60 with a half-life greater than 120 days and in quantities exceeding 10,000 but less than 1,000,000 curies for Co-60. Most medical use licensees do not exceed these limits and require financial assurance for sealed sources unless they possess multiple gammaknife units. However, a medical use licensee with a single gammaknife unit that has not gone through a complete half life of decay that changes the sources may exceed the limit for the short period of time that the sources are exchanged or a new replacement unit is installed. The financial assurance requirements should not apply to short term (60 day period) in which the limits are exceeded because of source exchange.

- **Recommend:** Revise 30.35(b) to read:

(b) Each applicant for a specific license authorizing possession and use of byproduct material of half-life greater than 120 days and in quantities specified in paragraph (d) of this section (except licensees that exceed these limits for 60 days due to source exchange) shall either—

2



10 CFR 35.40

- **Problem:** The authorized user (AU) is required to date and sign the written directive. 35.40(b)(6) requires a two part written directive for "all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders." The two part written directive involves before implantation and after implantation but before completion of the procedure. The proposed Part 35 rulemaking clarifies that the AU needs to sign and date the additional information provided after implantation but before completion of the procedure. However, this rulemaking only addressed permanent manual brachytherapy and not all the brachytherapy modalities in 35.40(b)(6).
- **Recommend:** Revise 10 CFR 35.40 to clarify that the AU needs to sign and date both the before administration and after implantation parts of the written directive for all modalities with two part written directives.

3

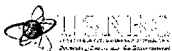


10 CFR 35.65 and 35.590

- **Problem:** 35.65 authorizes medical use licensees to use byproduct material for transmission sources as well as check, calibration, and reference use. All the other sources are used for quality control and quality assurance test when evaluating the function of equipment traditionally found in medical use facilities. These sources are not used to produce radiation for use on humans.

The transmission source on the other hand is used in medical procedures to irradiate patients and human research subjects as part of the imaging process and therefore a medical use. Although a medical use source, it is the only type of medical use source that is not included under one of the types of medical use and associated with a specific type of authorized user. For consistency with other medical uses, the transmission sources when used to irradiate human subjects (as opposed to phantoms) should be moved into 35.500 and authorized for use by AU's meeting the requirements of 35.590 or 35.290.

4



10 CFR 35.65 and 35.590 cont

Recommend:

Revise 35.65 to clarify it does not apply to sources used for medical use, i.e., the intentional external administration of radiation from byproduct material to patients or human research subjects.

"Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use provided the byproduct material is not used to intentionally administer radiation from byproduct material to patients or human research subjects."

Revise 35.590 to permit the use of transmission sources under 35.500 by authorized users meeting the training and experience requirements of 35.590 or 35.290.

Except as provided in §35.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under § 35.500 to be a physician, dentist, or podiatrist who—

- (a) ...; or
- (c) Has completed training in the use of the device for the uses requested; or
- (d) Is an authorized user under §35.290 requesting use of a transmission source administering radiation to a patient or human research subject."

5



10 CFR 35.204(b)

- **Problem:** 35.204(b) permits licensees that elute Mo-99/Tc-99m generators to perform moly-breakthrough measurements on the first generator eluate to demonstrate compliance with the requirement that a licensee may not administer to humans a radiopharmaceutical that contains more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m).

Before the 2002 revision to Part 35, licensees were required to measure moly-breakthrough at each elution to show compliance with the Mo-99 administration requirement. Experience at that time indicated a defective generator would always fail the test on the first elution. However, recent information from a major generator manufacturer shows that there are generator defects that are only detectable by moly-breakthrough measurements performed during later elutions. Therefore, compliance with the limits of Mo-99 that can be administered to humans cannot be made by simply measuring moly-breakthrough on the first elution.

6



10 CFR 35.204(b) cont.

Revise **35.204(b)** to read

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of each eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section.

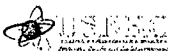
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10 CFR 35.50, 35.51, ..., 35.690

- Problem: All the training and experience requirements in 10 CFR Part 35 that include supervised work experience and attestations require the supervising individual and the attestation preceptor to meet the training and experience requirements of that section. The effect of this is if an individual achieved RSO, AMP, AU, or ANP status under previous requirements they could not technically function as the supervising individual or preceptor.

8



10 CFR 35.50, 35.51, ..., 35.690

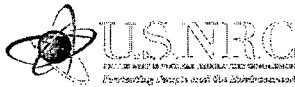
Recommend

Revise each section requiring supervised work experience and preceptor statements to either:

- (1) include individuals meeting the criteria under 35.57 for that particular use, or
- (2) permit individuals identified on a license as an RSO, AMP, ANP, or AU for that particular use

to be the supervising individual or provide the attestation.

9



Status of Medical Events & Other Reported Events

ACMUI Meeting
October 28, 2008

Donna-Beth Howe, Ph.D.

Office of Federal and State Materials
Division of Materials Safety and State Agreements



Status of Medical Events 2006

40 Medical Events reported - FY 2007

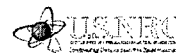
35.200	1
35.300	6
35.400	10
35.600	15
High Dose Rate (HDR)	
Remote Afterloader	13
MAMMOSITE	(4)
Gamma Knife	2
Teletherapy	0
35.1000 Y-90 Microspheres	8



Status of Medical Events

• 31 Medical Events Reported – FY 2008

	FY 2008	Change
35.200	3	+ 2
35.300 (10)	4	- 2
35.400 (109)	10	0
35.600	10	- 5
• HDR	8	
• Breast Balloon (3)		
• Gamma Knife	1	
• Teletherapy	1	
35.1000 Y-90 Microspheres	4	- 8



Diagnostic Medical Events

35.200	3
Communication errors	
Intended I-123 gave I-131	2
Physician did not specify isotope	
Verbal order for I-123, wrote I-123, but scheduled I-131	
Intended 10 mci I-131, wrote 10 μ ci I-131, but delivered 10 mci I-131	1



Therapy Medical Events

35.300	3
3 Nal-131	
Three capsules – gave 1	
Switched patient dosages	
Administered wrong drug to wrong patient – prescribed Bexxar	
Sm-153	
Wrong dose calibrator geometry (8 patients)	



Brachytherapy Medical Events

35.400	8
1 GYN (2 patients)	
Treatment planning magnification error (2 patients)	
9 PROSTATE (109 patients)	
2 – Leaking sources (2 I-125, 1 Pd-103 Mick applicator)	
1 – Treatment Plan Computer failure – went to default dose	
3 – Less than 80% of dose (57, 7, or 3 patients,) or wrong treatment site (35 patients)	
3 – Wrong treatment site (misplacement, misidentification, displacement)	



HDR Medical Events

35.600 HDR

8

Equipment malfunction on 12 of 29 fractions
Manually entered wrong dwell time
Wrong dose reference point
Wrong source wire length and wrong applicator
Gave 1/10 dose each of fraction instead of 10 X dose



HDR Medical Events cont.

HDR Continued

3 Balloon Breast Procedures SenoRx and MammoSite

Source Position Simulator was checked and catheter had kink so wrong source wire length was used

Source placement was dislodged by 2 cm physicist over rode alarm

Attached HDR connector to inflation catheter – saline leaked out



Gamma Knife Medical Events

Gamma Knife

1

MRI set up reversed left and right side
Wrong side of brain treated



Teletherapy Medical Event

35.600 Teletherapy

1

50 % of Dose and Time – Written directive called for 2 approximately equal split times for each anterior-posterior (AP) and posterior-anterior (PA) treatment but only one time per side was given



Y-90 Microsphere Medical Events

35.1000

4

stopcocks

put in backwards caused kink

set erroneously most of dose was collected in the vent vial

Did not turn stopcock on the delivery device dose went to waste vial instead of into the patient

faulty equipment or human error



Other Reported Events

Involving Patients

4

- 5 mCi I-131 after 150 mCi I-131 ablation
- Patient intervention
- Sr-90 eye applicator after calibration
- F-18 infiltration

MEDICAL RADIOACTIVE MATERIAL EVENTS

Ralph P. Lieto, MSE
ACMUI Member
ACMUI Meeting, Oct. 28, 2008

Other Medical Radioactive Material Events

- Nuclear Materials Event Database (NMED)
 - Reported FY 2008 (10/1/2007-10/1/2008)
 - Medical Events (patient) - 30?
 - Other reportable, medical use related
Material Events – 33 events

Other Medical Radioactive Material Events

- Categories
 - Lost sources, sealed & unsealed – 12
 - Leaking sealed sources – 7
 - Fetal/embryo dose - 2

Other Medical Radioactive Material Events

- Categories
 - Landfill Alarms - 4
 - Decay-In-Storage (DIS) waste
 - Unknown origin
 - Released patient (10 CFR 35.75) waste
 - Miscellaneous
 - Equipment Malfunction – 3
 - Packaging - 4
 - Overexposure -1

Lost Sources - Sealed & Unsealed

1. I-131 capsule (0.055 mCi) from thyroid neck phantom
2. Ir-192 seed ribbon (6 mCi) missing from post-treatment inventory ; found 3 days later in off-site laundry
3. I-125 seed (0.157 mCi) for breast tumor localization lost via suction canister after removal.
4. I-125 seed (0.33 mCi) lost when pig of 20 seeds overturned during autoclaving process.

Lost Sources - Sealed & Unsealed

5. 18 I-125 seeds (5 mCi) unused after implant disposed by improperly trained technologist via nuclear medicine decay-in-storage waste.
6. Two I-125 seeds (1 mCi) unused after implant, improperly left in applicator; during cleaning, seeds ejected and flushed down drain.
7. I-123 capsule (200 mCi?) lost when pig not returned to proper storage location .
8. I-125 seed (0.161 mCi) lost after implant removal via general trash.

Lost Sources - Sealed & Unsealed

9. Two Gd-153 transmission sources (194 mCi total) lost when gamma camera disposed to scrap recycler.
10. Five Ir-192 seeds (2.95 mCi) in ribbon lost during temporary implant.
11. 114 Pd-103 seeds (126.5 mCi) unused for implant, lost during storage in area undergoing renovation prior to return.
12. I-125 seed (0.49 mCi) unused for implant missing after inventory of six non-implanted seeds.

Leaking Sealed Sources

Excludes leaking sources reported under medical event (ME)

1. Five seeds unused after implant; wipe testing of storage pig, loading cartridge and one seed found contaminated. Return to vendor for analysis found seed damaged, likely during use in applicator.
2. I-125 seed jammed in applicator. Technician unloaded seed from cartridge with bare hands; survey found cartridge & hands contaminated.

Leaking Sealed Sources

3. Vendor during I-125 seed strand assembly damaged a seed causing contamination of working/ crimping tool.
4. Five I-125 seeds/two different lots unused after implant found leaking & visibly damaged; no patient or work area contaminated. Cause was excessive force on stacked seeds during cartridge loading.
5. I-125 seed ruptured by cauterization tool 3 days after implant. Patient & equipment contaminated; thyroid bioassay < 1 rem (cSv).

Leaking Sealed Sources

6. Vendor reported leaking I-125 seed cross-contaminated potentially 1500 seeds shipped to multiple customers.
7. Licensee reported at least one I-125 seed leaking after survey of group of seeds for removable contamination; found after autoclaving & cartridge loading. Analysis by vendor of returned seeds found surface contamination but no defects (welds, encapsulation).

Fetal/Embryo Dose

1. Patient received 149 mCi I-131 NaI two days after negative HCG pregnancy test. Patient informed pregnant 2 months after administration; 32 cGy (rad) estimated embryo dose. Event discovered during NRC inspection. No adverse effects expected because of stage of pregnancy.
2. Patient received 134 mCi I-131 NaI after two negative HCG pregnancy tests done within 5 days prior to administration. Patient informed pregnant 3 weeks later; 35 cGy (rad) estimated embryo dose. Patient failed to follow instructions.

Landfill Alarms

- Four event reports
 - >2 events – Waste origin unknown
 - >2 events - Improper disposal of hospital LLRW; (source unknown in 1 event)
- All involved I-131
- All events reported from Agreement States (CA, AL)

Miscellaneous - Machine Malfunctions

1. Gamma Knife shielding doors failed to close after treatment; manually closed by medical physicist with negligible dose. No deviation from written directive.
2. High Dose Rate (HDR) source failed to retract properly during testing by manufacturer's field engineer. Source disconnected & top of source capsule clipped off by closing vault door.

Miscellaneous - Machine Malfunctions

3. During HDR source exchange by field engineer, old source failed to enter exchange container. Cause was dummy & active sources extended into same pathway became stuck outside safe. Vendor source recovery team sent to successfully retract source after engineer cuts wrong source (dummy instead of active) wire to place in emergency shielded container.

Miscellaneous - Packaging

1. Inner pig with 51 I-125 seeds opened during shipment. Exposure levels significantly exceed limits; no contamination or loss or overexposures occurred.
2. Three packages of Co-57 flood sources received with removable contamination of the surfaces exceeding reportable limits. Contamination was Tc-99m; source unspecified.

Miscellaneous - Packaging

3. Five packages found with removable Tc-99m contamination exceeding limits. Cause was cross-contamination from radiopharmacy courier who handled empty contaminated containers from previous stop. Significant vehicle and skin contamination.
4. A package of Tc-99m radiopharmaceuticals found with significant removable surface contamination. Package from centralized radiopharmacy.

Miscellaneous - Overexposure

- Two workers for a radiopharmacy received extremity overexposures in the making of I-131 capsules. Doses ranged 53-105 rem (cSv). Lack of written procedures & proper handling tools cited.

Comparison Radioactive Material Events

	FY08	FY07	FY06
Lost sources – sealed & unsealed	12	15	6
Leaking sealed sources	7	3	5
Landfill Alarms	4	6	27
Miscellaneous	8	7	6

Observations

- Multiple search queries needed capture all(?) reported events involving medical use of radioactive material, especially those other than MEs
- Suggested NMED improvement is search capability with multiple key words

35.200

I-123/I-131

NMED Item Number: 080007**Narrative:****Last Updated:** 04/08/2008

Southwest Volusia Healthcare Corporation (dba Florida Hospital Fish Memorial) reported that a patient was administered 81.4 MBq (2.2 mCi) of I-131 for a whole body scan instead of the intended I-123 for a thyroid uptake scan. The doctor ordered an iodine thyroid uptake and scan for the patient without specifying the radionuclide. The facility uses I-123 for that purpose. The administration occurred on 12/17/2007 and the error was discovered on 12/25/2007. The patient and doctor have been notified. Scheduling personnel will be re-educated to verify an order before scheduling patients for a procedure. The technician will also be re-educated to read the script prior to administering a patient.

Event Date: Discovery Date: Report Date:

12/17/2007 12/25/2007 12/28/2007

Licensee/Reporting Party Information:

License Number: FL-2467-1 Name: SOUTHWEST VOLUSIA HEALTHCARE CORP.

Docket Number: NA City: ORANGE CITY, FL

Site of Event:

Site Name: ORANGE CITY, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43872	01/03/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
F-205	04/08/2008		AGREEMENT STATE EVENT REPORT

35.200

I-123/I-131

NMED Item Number: 080053**Narrative:****Last Updated:** 04/08/2008

Southwest Baptist Hospital (dba Baptist Medical Center) reported that the wrong radionuclide was administered to a patient. On 1/14/2008, a physician gave a verbal order to a nurse, who wrote the order for an I-123 uptake scan. The nurse incorrectly scheduled an I-131 uptake scan and the physician never reviewed the order. The patient was administered 173.9 MBq (4.7 mCi) of I-131. On 1/16/2008, the physician reviewed the results and realized that the wrong radionuclide had been administered. The patient was notified. Corrective actions included policy and procedure modifications to require that the physician fill out all orders.

Event Date: Discovery Date: Report Date:

01/14/2008 01/16/2008 01/24/2008

Licensee/Reporting Party Information:

License Number: FL-2213-1 Name: SOUTHERN BAPTIST HOSPITAL

Docket Number: NA City: JACKSONVILLE, FL

Site of Event:

Site Name: JACKSONVILLE, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43930	01/30/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080225	02/25/2008		NRC LETTER
FL08-011	04/08/2008		AGREEMENT STATE EVENT REPORT
LTR080407	04/08/2008		AGREEMENT STATE LETTER

35.200

I-131

NMED Item Number: 080262**Narrative:****Last Updated: 06/25/2008**

Geisinger Wyoming Valley Hospital (GWVH) reported that a patient was administered 0.37 GBq (10 mCi) of I-131 for treatment of a hyperactive thyroid on 2/7/2008, instead of the prescribed 0.37 MBq (10 uCi). The incident was not discovered until 4/25/2008 during a review of written directives administered. GWVH stated that the written directive incorrectly prescribed 0.37 MBq (10 uCi). The authorized user realized his error in prescribing 0.37 MBq (10 uCi) and telephoned the nuclear medicine technician to change the activity to the correct dosage of 0.37 GBq (10 mCi). However, neither a new or revised written directive was issued. The prescribing physician was notified of the incident on the date of discovery. The patient was not notified because it served no beneficial purpose. Corrective actions included counseling the technician on following procedures, revising the written directive form to exclude a choice of units, and enforcing that no telephone requests from an authorized user will be carried out until a new or revised written directive is issued.

Event Date: Discovery Date: Report Date:

02/07/2008 04/25/2008 04/25/2008

Licensee/Reporting Party Information:

License Number: PA-0006 Name: GEISINGER WYOMING VALLEY HOSPITAL
Docket Number: NA City: WILKES-BARRE, PA

Site of Event:

Site Name: WILKES-BARRE, PA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44173	05/05/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PA080010	05/22/2008		AGREEMENT STATE EVENT REPORT
PA080010A	06/25/2008		AGREEMENT STATE EVENT REPORT

35.300

I-131

NMED Item Number: 080024**Narrative:****Last Updated:** 04/17/2008

Hackley Hospital reported that a patient prescribed to receive 3.7 GBq (100 mCi) of I-131 (sodium iodine) for thyroid ablation only received 0.79 GBq (21.39 mCi) on 12/13/2007. The nuclear medicine technologist was unaware that the package contained three capsules, due to lack of visualization and failure to read the vial label. The technologist administered one capsule with an activity of 0.79 GBq (21.39 mCi). The package containing the remaining two capsules was sent back to the pharmacy without a survey. The mistake was recognized the next morning when pharmacy personnel found the two capsules in the returned package. The radiologist was made aware of the situation and the patient was notified. The patient returned the morning of 12/14/2007 and was administered the remaining two capsules totaling 2.58 GBq (69.7 mCi). Therefore, the patient ultimately received a total of 3.37 GBq (91.09 mCi) over the course of 17 hours. No adverse consequences to the patient are anticipated. Corrective actions included disciplining the technician and revising procedures to include verification of the number of capsules received and administered. Personnel were also re-trained on the requirements to survey and wipe test packages prior to any shipment to the nuclear pharmacy.

Event Date: Discovery Date: Report Date:

12/13/2007 12/14/2007 01/04/2008

Licensee/Reporting Party Information:

License Number: 21-04125-01 Name: HACKLEY HOSPITAL
Docket Number: 03002044 City: MUSKEGON, MI

Site of Event:

Site Name: MUSKEGON, MI

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43882	01/10/2008		EVENT NOTIFICATION
ML080460666	02/25/2008		INSPECTION REPORT
ML080460666	02/25/2008		NOTICE OF VIOLATION
ML080460666	02/25/2008		NRC LETTER
ML080500412	02/27/2008		LICENSEE REPORT
ML080730094	04/08/2008		LICENSEE REPORT
ML080840255	04/09/2008		NRC LETTER
LTR080416	04/17/2008		NRC LETTER

35.300

I-131

NMED Item Number: 080555**Narrative:****Last Updated:** 09/17/2008

Lehigh Valley Hospital reported that a patient prescribed to receive 0.74 GBq (20 mCi) of I-131 was administered 2.78 GBq (75 mCi) of I-131 on 7/17/2008. Two patients were scheduled for different I-131 therapy doses and the doses got switched. The patient was given a blocking agent of 130 mg SSKI approximately one hour after the I-131 administration. The next day, measurements indicated a 74 MBq (2 mCi) uptake to the patient's thyroid and a 370 MBq (10 mCi) whole body retention. Both patients and their physicians were notified. Corrective actions included procedure modifications.

Event Date: Discovery Date: Report Date:

07/17/2008 07/17/2008 07/17/2008

Licensee/Reporting Party Information:

License Number: PA-0232 Name: LEHIGH VALLEY HOSPITAL

Docket Number: NA City: ALLENTOWN, PA

Site of Event:

Site Name: ALLENTOWN, PA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
PA080021	09/17/2008		AGREEMENT STATE EVENT REPORT

35.300

Bexxar/NaI-131

NMED Item Number: 080279**Narrative:****Last Updated:** 09/02/2008

Norton Suburban Hospital reported that a patient that was prescribed a dosimetric Bexxar I-131 dosage of 0.19 GBq (5 mCi) for a lymphatic cancer uptake study received an I-131 dosage of 1.65 GBq (44.5 mCi). The received dose was actually intended for another patient. The doctor notified the patient. The patient had taken a thyroid blocking agent prior to the medical event. The patient was subsequently administered a therapeutic dose of I-131, which was adjusted to account for the error. The State of Kentucky Radiation Health Department conducted an investigation and determined that the cause was oversight by the technologist. The administered dose was received for a patient on 4/25/2008. The patient's treatment was canceled and the dose was placed in the hot laboratory to be returned to the radiopharmacy. The intended dose for the patient was not received from the radiopharmacy. The mistake occurred when the call was received to dose the patient on 4/28/2008. The technologist took the dose from the container left from the cancelled procedure. Norton Suburban Hospital changed their process of receiving, handling, and returning doses to the radiopharmacy. A labeling system was instituted on the dose and canister to let staff know the status of the dose. The technologist and nurse are responsible for performing checks.

Event Date: Discovery Date: Report Date:

04/28/2008 04/28/2008 05/08/2008

Licensee/Reporting Party Information:

License Number: KY-202-099-26 Name: NORTON SUBURBAN HOSPITAL
Docket Number: NA City: LOUISVILLE, KY

Site of Event:

Site Name: LOUISVILLE, KY

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44193	05/14/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080821	09/02/2008		AGREEMENT STATE LETTER

NMED Item Number: 080156**Narrative:****Last Updated: 05/29/2008**

The Appleton Medical Center reported patient underdoses to up to eight patients treated with Sm-153 since late 2006. When a nuclear medicine technologist was preparing a recent dose of Sm-153 the activity measured in the dose calibrator did not read as expected. After review, Appleton Medical Center determined that the dose calibrator was set up to measure Sm-153 in a vial, but the technologist had measured the activity in a syringe. The dosage was re-measured properly prior to administration. Further review of previous cases identified up to eight instances where the activity of Sm-153 may have been measured in a syringe instead of in a vial. When the activity is measured in a syringe, the attenuation and volume geometry is estimated to result in administered activities of approximately 30% less than prescribed in the written directives. The Wisconsin Department of Health and Family Services performed a reactive inspection on 3/17/2008. The activity of Sm-153 prescribed to each patient was 37 MBq/kg (1 mCi/kg) patient weight. Since Appleton Medical Center could verify neither the exact dose administered nor which of the eight patients were affected, it was assumed all eight patients were affected. Appleton Medical Center reinstructed their nuclear medicine technologists in the proper method of measuring Sm-153 activity. They also revised several procedures. Four of the eight patients are deceased and the remaining four have not been notified.

Event Date: Discovery Date: Report Date:

03/06/2008 03/06/2008 03/06/2008

Licensee/Reporting Party Information:

License Number: WI-087-1014-01 Name: APPLETON MEDICAL CENTER

Docket Number: NA City: APPLETON, WI

Site of Event:

Site Name: APPLETON, WI

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44045	03/13/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI080005	05/07/2008		AGREEMENT STATE EVENT REPORT
WI080005A	05/29/2008		AGREEMENT STATE EVENT REPORT
LTR080527	05/29/2008		AGREEMENT STATE LETTER

NMED Item Number: 080278**Narrative:****Last Updated: 08/21/2008**

Bridgeport Hospital reported that two patients received underdoses during Cs-137 brachytherapy cervix treatments using a manual afterloader. The medical events were discovered on 5/7/2008. One patient was prescribed to receive 300,100 and 255,200 cGy (rad; right point A and left point B) on 12/10/2007, but was delivered 125,600 and 123,100 cGy (rad; right point A and left point B). On 1/2/2008, that patient was prescribed to receive 188,700 and 202,000 cGy (rad; right point A and left point B), but was delivered 104,200 and 111,600 cGy (rad; right point A and left point B). The second patient was prescribed to receive 227,600 and 267,200 cGy (rad; right point A and left point B) on 1/9/2008, but was delivered 94,800 and 129,600 cGy (rad; right point A and left point B). On 1/30/2008, that patient was prescribed to receive 229,200 and 223,200 cGy (rad; right point A and left point B), but was delivered 87,600 and 98,800 cGy (rad; right point A and left point B). The cause was human error involving incorrect implementation of a new method to input geometric data into the treatment planning computer. This resulted in use of an incorrect magnification factor in the dose calculations. The patient's referring physician and radiation oncologist were informed. The patients were informed and received additional treatment.

Event Date:	Discovery Date:	Report Date:
12/10/2007	05/07/2008	05/08/2008

Licensee/Reporting Party Information:

License Number: 06-01060-01	Name: BRIDGEPORT HOSPITAL
Docket Number: 03001247	City: BRIDGEPORT, CT

Site of Event:

Site Name: BRIDGEPORT, CT

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44192	05/14/2008		EVENT NOTIFICATION
LTR080815	08/21/2008		NRC LETTER

35.400

I-125

Leaking seeds

NMED Item Number: 080169**Narrative:****Last Updated: 09/02/2008**

The Department of Veterans Affairs (VA) reported that two patients were implanted with one or more leaking brachytherapy seeds containing I-125 (Best Medical International model 2301) at the VA Medical Center in San Francisco, California. Each seed contained a nominal activity of 11.1 MBq (300 uCi). Three patients were scheduled for transperineal permanent prostate seed implants on 3/14/2008. Three separate packages of seeds in preloaded needles were received (lots 23017, 23019, and 23018). Surveys showed no surface contamination or contamination outside the inner sterile containers. After 12 of 106 seeds were implanted in the first patient, a survey showed a small amount of contamination on the inside of the sterile packaging. This implantation procedure was stopped and a survey showed contamination on the tips of three of the four needles that had been used, the greatest being 5,000 cpm (420 Bq [0.01135 uCi] assuming a 20% efficiency). A deviation from the pre-implantation treatment plan was authorized by signature of the authorized user and was documented on the written directive. The patient was administered stable iodine to block his thyroid and the seed vendor was notified. To determine if the remaining patients would be implanted, the remaining two packages of seeds were opened to survey the interiors of the sterile packaging. When no contamination was found, the implant procedure was performed on the second patient. The patient was implanted with the prescribed 92 seeds on 3/14/2008, for a total activity of 1.02 GBq (27.6 mCi). At the end of that procedure, surveys of the used needles revealed 1,000 cpm (83 Bq [0.00224 uCi] assuming a 20% efficiency). The seed vendor was again notified. Based on urine and thyroid bioassays of both patients, one or more seeds were determined to be leaking. Both patients were prescribed to receive 14,500 cGy (rad). The implant procedure for the third patient was cancelled. VA is continuing to investigate the incidents. They are also evaluating the dose to the patient's thyroids. It was determined that damage to the seeds did not likely occur during the shipping of the seeds to VA, handling at VA, nor during implantation procedures. However, VA has taken corrective actions and ceased using I-125 seeds from Best Medical International. Corrective actions included procedure modifications and a change in the seed vendor. Best Medical identified a problem with welding fixtures, with a slight distortion in the welding and potential for a microscopic pore not being completely sealed in the welding process. It was determined that that problem was isolated.

Event Date: Discovery Date: Report Date:

03/14/2008 03/14/2008 03/15/2008

License/Reporting Party Information:

License Number: 03-23853-01VA Name: V.A., DEPARTMENT OF
Docket Number: 03034325 City: NORTH LITTLE ROCK, AR

Site of Event:

Site Name: SAN FRANCISCO, CA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44065	03/20/2008		EVENT NOTIFICATION
LTR080821	09/02/2008		NRC LETTER

35.400

Pd-103 Leaking seed

NMED Item Number: 080237**Narrative:****Last Updated:** 04/22/2008

Oklahoma State University Medical Center reported that a patient was implanted on 4/16/2008 with a damaged and leaking Pd-103 seed (TheraSeed model 200) with an activity of 55.5 MBq (1.5 mCi). The prostate treatment prescribed implanting 187 seeds into the patient. During the procedure, it was noted that one of the seeds was sheared off with only 5% of the seed remaining in the Mick cartridge. The piece was identified as leaking and it was assumed that the other part of the seed was injected into the patient. The Medical Center believes that a malfunction in the Mick applicator caused the seed to be out of alignment when the cartridge was inserted or removed. The cartridges were disposed of as biomedical waste immediately after the surgery. The applicator has been taken out of service. Following investigation, the applicator will be returned to the manufacturer for evaluation. The INL has requested additional information for this event.

Event Date: Discovery Date: Report Date:

04/16/2008 04/16/2008 04/16/2008

Licensee/Reporting Party Information:

License Number: OK-05860-01 Name: OKLAHOMA STATE UNIVERSITY MEDICAL CENTER
Docket Number: NA City: TULSA, OK.

Site of Event:

Site Name: TULSA, OK

Reference Documents:

Reference Document Number:	Entry Date: Retraction Date:	Type of Report:
EN44143	04/22/2008	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

35.400

Prostate

NMED Item Number: 070755**Narrative:****Last Updated:** 03/06/2008

The Baptist Hospital reported that a patient received 10,000 cGy (rad) to the prostate gland instead of the prescribed 14,000 cGy (rad) on 12/11/2007. The patient was prescribed to receive 92 I-125 interstitial brachytherapy seeds, each containing an activity of 10.92 MBq (0.295 mCi). A computer failure caused the plan to default to a dose of 10,000 cGy (rad), which went unnoticed. The patient and doctor were notified of the incident. Corrective actions included requiring the document/plan packet be reviewed and signed by a physician and two dosimetrists, requiring a physicist to review and sign the plan prior to surgery, requiring physician approval to update department policy to any original or amended plan, forming a Root Cause Analysis Team to present analysis to the Baptist Hospital Patient Safety Committee, and randomly reviewing 10 charts per month.

Event Date: Discovery Date: Report Date:

12/11/2007 12/11/2007 12/12/2007

Licensee/Reporting Party Information:

License Number: FL-0158-1 Name: BAPTIST HOSPITAL
Docket Number: NA City: PENSACOLA, FL

Site of Event:

Site Name: PENSACOLA, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
3838	12/17/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
FL07-193	01/10/2008		AGREEMENT STATE EVENT REPORT
LTR080303	03/06/2008		AGREEMENT STATE LETTER

35.400

Prostate

NMED Item Number: 080296**Narrative:****Last Updated:** 09/10/2008

The Department of Veterans Affairs (VA) reported that 55 patients prescribed permanent implant prostate brachytherapy procedures using I-125 seeds received administered doses less than 80% of prescribed doses at the VA Medical Center in Philadelphia, Pennsylvania. Each patient was prescribed a dose of 160 Gy (16,000 rad). This event was discovered when the medical center performed an implant on 5/5/2008 using I-125 seeds of a lower apparent activity than prescribed because the wrong seeds were mistakenly ordered and implanted. VA completed a causal analysis and implemented procedural changes to prevent a recurrence. The VA National Health Physics Program initiated a reactive inspection on 5/28/2008. A review of 112 procedures performed since the inception of the cancer treatment program in February 2002 resulted in the identification of 55 procedures as medical events that involved administering an incorrect dose to a patient. The circumstances involved in each incident were similar. The referring physicians and four of the patients determined to have exceeded reportable criteria were notified. The prostate cancer treatment program was suspended by the VA director in June 2008.

Event Date: Discovery Date: Report Date:

05/05/2008 05/05/2008 05/16/2008

Licensee/Reporting Party Information:

License Number: 03-23853-01VA Name: V.A., DEPARTMENT OF
Docket Number: 03034325 City: NORTH LITTLE ROCK, AR

Site of Event:

Site Name: PHILADELPHIA, PA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44219	05/22/2008		EVENT NOTIFICATION
EN44219A	06/09/2008		EVENT NOTIFICATION
EN44219B	06/17/2008		EVENT NOTIFICATION
EN44219C	06/23/2008		EVENT NOTIFICATION
EN44219D	06/26/2008		EVENT NOTIFICATION
EN44219E	07/03/2008		EVENT NOTIFICATION
EN44219F	07/09/2008		EVENT NOTIFICATION
EN44219G	07/14/2008		EVENT NOTIFICATION
EN44219H	07/16/2008		EVENT NOTIFICATION
EN44219I	07/21/2008		EVENT NOTIFICATION
EN44219J	07/23/2008		EVENT NOTIFICATION
EN44219K	07/28/2008		EVENT NOTIFICATION
EN44219L	08/07/2008		EVENT NOTIFICATION
EN44219M	08/14/2008		EVENT NOTIFICATION
EN44219N	08/28/2008		EVENT NOTIFICATION
ML082530237	09/10/2008		NRC NEWS ANNOUNCEMENT

35.400

Prostate

NMED Item Number: 080606**Narrative:****Last Updated: 10/09/2008**

The Department of Veterans Affairs (VA) reported that eight patients prescribed permanent implant prostate brachytherapy procedures using I-125 seeds may have resulted in D90 doses less than 80% of the prescribed doses. The incidents occurred at VA's Medical Center in Jackson, Mississippi. Each patient was prescribed a dose of 160 Gy (16,000 rad). Six of these medical events were discovered on 9/24/2008, and one on 10/7/2008, as a result of an ongoing review of the incident involved in NMED Item 080296. These treatments and their possible effects on the patients are under review by medical experts.

Event Date:	Discovery Date:	Report Date:
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09/24/2008	09/24/2008	09/25/2008
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Licensee/Reporting Party Information:

License Number: 03-23853-01VA	Name: V.A., DEPARTMENT OF
Docket Number: 03034325	City: NORTH LITTLE ROCK, AR

Site of Event:

Site Name: JACKSON, MS

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44522	10/01/2008		EVENT NOTIFICATION
EN44522A	10/09/2008		EVENT NOTIFICATION

35.400

Prostate

NMED Item Number: 080613**Narrative:****Last Updated: 10/02/2008**

The Department of Veterans Affairs (VA) reported that three patients prescribed permanent implant prostate brachytherapy procedures using I-125 seeds may have received D90 doses less than 80% of the prescribed doses. The incidents occurred at VA's Medical Center in Washington, DC. Each patient was prescribed a dose of 160 Gy (16,000 rad). These medical events were discovered on 9/24/2008 as a result of an ongoing review of the incident reported in NMED Item 080296. These treatments and their possible effects on the patients are under review by medical experts.

Event Date:	Discovery Date:	Report Date:
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09/26/2008	09/26/2008	09/26/2008
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Licensee/Reporting Party Information:

License Number: 03-23853-01VA	Name: V.A., DEPARTMENT OF
Docket Number: 03034325	City: NORTH LITTLE ROCK, AR

Site of Event:

Site Name: WASHINGTON, DC

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44524	10/02/2008		EVENT NOTIFICATION

35.400

Prostate

NMED Item Number: 080041**Narrative:****Last Updated: 07/29/2008**

Owensboro Medical Health Systems reported incorrectly implanting 74 I-125 seeds (Isoaid Advantage model IAI-125A, lot #7556), with an average activity of 11.1 MBq (300 uCi), 2.5 cm interior to the base of a patient's prostate gland on 12/20/2007. On 1/10/2008, a four-week follow up CT-based post prostate seed implant plan was performed and reviewed by the prescribing physician. Upon completion of the review, it was determined that the seeds had been implanted in the wrong location. The prescribed dose was 14,500 cGy (rad). The post plan dosimetry revealed that the prostate on received 5,945 cGy (rad). The nearby organs at risk (bladder and rectum) were not affected by the misplacement of the seeds. The prescribing physician notified the attending urologist on 1/11/2008. The urologist will notify the patient. The cause was determined to be human error; the sheath was accidentally partially withdrawn when the needle was pulled from it. Corrective actions included updating procedures to require the use of fluoroscopy, in addition to ultrasound, to check placement during treatment. The State of Kentucky is tracking the incident as number KY082.

Event Date: Discovery Date: Report Date:

12/20/2007 01/10/2008 01/15/2008

Licensee/Reporting Party Information:

License Number: KY-202-161-26 Name: OWENSBORO MEDICAL HEALTH SYSTEMS
Docket Number: NA City: OWENSBORO, KY

Site of Event:

Site Name: OWENSBORO, KY

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43905	01/22/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080409	04/14/2008		AGREEMENT STATE LETTER
LTR080729	07/29/2008		AGREEMENT STATE LETTER

35.400

Prostate

NMED Item Number: 080132**Narrative:****Last Updated: 08/13/2008**

Reid Hospital & Health Care Services (RHHCS) reported that 37 I-125 brachytherapy seeds were implanted approximately 2 cm below the patient's prostate. Each seed contained an activity of 11.66 MBq (0.315 mCi). The patient was prescribed to receive a dose of 11,000 cSv (rem) through the placement of 62 seeds. After 37 seeds were implanted, the location of the implanted seeds was verified to be below the prostate and the procedure was terminated. A dose assessment determined that the region of the perineum where the seeds were implanted received a dose of 5,500 cSv (rem), while the prostate received a dose of 300 to 1,500 cSv (rem). The patient and physicians were notified. This event was caused by misidentification of the patient's prostate due to inadequate procedures. The patient's prostate will be treated with external beam radiation therapy. The patient may develop complications including fibrosis and necrosis of the tissue in the perineum where the seeds were implanted. The NRC contracted a medical consultant, who generally agreed with the dose estimates. Corrective actions included revising the policy and procedure for prostate seed implants to ensure that the location of the needle in the prostate is verified prior to implanting seeds.

Event Date: Discovery Date: Report Date:

02/27/2008 02/27/2008 02/29/2008

Licensee/Reporting Party Information:

License Number: 13-03284-02 Name: REID HOSPITAL & HEALTH CARE SERVICES
Docket Number: 03001614 City: RICHMOND, IN

Site of Event:

Site Name: RICHMOND, IN

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44021	03/04/2008		EVENT NOTIFICATION
ML080730251	04/08/2008		LICENSEE REPORT
ML081200060	05/13/2008		ADAMS DOCUMENT PACKAGE
ML081200121	05/13/2008		CONSULTANT REPORT
ML081200064	05/13/2008		INSPECTION REPORT
LTR080429	05/13/2008		NRC LETTER
ML081200064	05/13/2008		NRC LETTER
ML081480323	06/11/2008		LICENSEE REPORT
ML081960765	08/04/2008		NOTICE OF VIOLATION
ML081960765	08/04/2008		NRC LETTER
ML082240332	08/13/2008		INSPECTION REPORT

35.400

Prostate

NMED Item Number: 070737**Narrative:****Last Updated: 05/05/2008**

Longmont United Hospital reported that a patient receiving I-125 brachytherapy seeds to the prostate gland only received a mean dose of 1,440 cGy (rad), instead of the prescribed dose of 16,000 cGy (rad). In the course of the operative procedure, some of the seeds were placed inferior to the prostate rather than in the prostate gland. A total of 63 seeds (Bard Brachytherapy model STM 1251) were implanted and each seed contained an activity of 13.5 MBq (0.365 mCi). The mean dose to the rectum was 4,470 cGy (rad) and the mean dose to the urethra was 7,340 cGy (rad). Longmont United Hospital determined that the cause of the incident was displacement of the prostate gland, which was not detected by image guidance due to substantial peri-prostatic bleeding and hematoma formation. The tissues adjacent to the prostate provided an image with features mimicking the appearance of the prostate, though with non-distinct borders. Due to the bleeding, even the non-distinct borders were expected. Enough plausible indicators of correct positioning were present, so the surgical team proceeded with the implant until the misplacement of the seeds was discovered. Due to the unusual circumstances of the specific procedure, no underlying deficiencies in the prostate brachytherapy program were indicated. The program has since implemented the use of stabilization needles at initiation of the implantation procedure. The primary element deserving of attention lies in the inherent dependence upon the ultrasound image. The spouse of the patient and the patient were informed of the incident.

Event Date:	Discovery Date:	Report Date:
08/08/2007	08/08/2007	11/29/2007

Licensee/Reporting Party Information:

License Number: CO-073-01	Name: LONGMONT UNITED HOSPITAL
Docket Number: NA	City: LONGMONT, CO

Site of Event:

Site Name: LONGMONT, CO

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43819	12/06/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
CO07M07-02	05/05/2008		AGREEMENT STATE EVENT REPORT

35.600 Teletherapy

NMED Item Number: 080371**Narrative:****Last Updated:** 07/23/2008

Regents of University of California – Los Angeles (UCLA) reported a 50% under dose to a patient prescribed to receive 300 cGy (rad) during whole body irradiation using a Co-60 teletherapy unit (Theratronics model T1000, serial #001) on 6/23/2008. The Co-60 source(s) contained a total activity of 138.08 TBq (3,732 Ci). The prescription was for total body irradiation at 17.12 minutes anterior posterior (AP), then 17.13 minutes AP, then 17.12 minutes posterior anterior (PA), then 17.13 minutes PA. The therapist only treated 17.13 minutes AP and 17.13 minutes PA for a total dose of 150 cGy (rad). The patient was seen by the attending physician on 6/25/2008. There is no plan to re-treat the patient. The attending physician and patient have been notified. The cause of the incident was determined to be human error – the therapist misread the treatment sheet. Corrective actions included revising the treatment sheet to specifically indicate the treatment times from the AP and PA directions, revising the split times per side to include the total treatment time from each side, counseling the therapist, verifying treatment records by two treating therapists, and training all therapy personnel on revised forms and procedures. The State of California is tracking the incident as number 062508.

Event Date: Discovery Date: Report Date:

06/23/2008 06/25/2008 06/25/2008

Licensee/Reporting Party Information:

License Number: CA-1335-19 Name: REGENTS OF UNIVERSITY OF CALIFORNIA - LOS ANGELES
Docket Number: NA City: LOS ANGELES, CA

Site of Event:

Site Name: LOS ANGELES, CA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44321	07/03/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080718	07/22/2008		AGREEMENT STATE LETTER
LTR080722	07/23/2008		AGREEMENT STATE LETTER

35.600 HDR Nucletron

NMED Item Number: 080460**Narrative:****Last Updated: 08/13/2008**

Cleveland Clinic Foundation reported a possible medical event due to an equipment malfunction on 8/7/2008. A patient was being treated for rectal cancer using a Nucletron microSelectron high dose rate remote afterloading brachytherapy unit (model 105.999, serial #31776). The prescribed treatment consisted of the administration of 29 catheter doses of Ir-192. During the 12th catheter dose, an equipment malfunction caused a failure of the administered treatment. The failure mode was code 200; "no radiation detected." The failure mode caused the unit to stop treatment by not proceeding to the next catheter. Nucletron was immediately contacted. A service technician is expected to respond on 8/8/2008 for repair of the unit. Once the unit is repaired, the treatment plan and written directive will be modified and treatment of the patient resumed. The patient and physician have been notified of the incident. The State of Ohio plans to send an inspector to the facility on 8/11/2008.

Event Date: Discovery Date: Report Date:

08/07/2008 08/07/2008 08/08/2008

Licensee/Reporting Party Information:

License Number: OH-02110180013 Name: CLEVELAND CLINIC FOUNDATION
Docket Number: NA City: CLEVELAND, OH

Site of Event:

Site Name: CLEVELAND, OH

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
E 4397	08/13/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

35.600 HDR Nucletron

GYN

NMED Item Number: 070641**Narrative:****Last Updated: 04/09/2008**

The Oncology Institute of Greater Lafayette (aka Clarian Arnett Cancer Care Center) reported a medical event involving a patient receiving three vaginal cylinder HDR treatments on 8/14, 8/28, and 9/11/2007. The incident involved a Nucletron HDR unit (model 105.999, serial #31024). The prescribed dose per fraction was 700 cGy (rad) using a 236.8 GBq (6.4 Ci) Ir-192 source. The treatment was planned with a source dwell position spacing of 5 mm and 13 dwell positions, for a treatment length of 6.5 cm. The electronic transfer of spacing information from the planning console to the treatment console did not function properly, so the source spacing was manually entered into the treatment console. However, the spacing was inadvertently entered as 2.5 mm with 13 dwell positions, for a treatment length of 3.25 cm. In addition, shielding for the posterior vaginal wall and rectum further reduced the dose to the tumor. This resulted in a dose 30% greater than prescribed to the vaginal apex and anterior superior vagina. Additionally, the dose to the inferior posterior vaginal wall (which contained the tumor) was 50 to 96% less than prescribed. An NRC inspection conducted on 10/16/2007 identified the error. The NRC contracted with a medical consultant to review this event. The medical consultant concluded that the overdose to the vaginal vault is unlikely to result in necrosis, but the underdose to part of the tumor area increases the risk of tumor recurrence. The patient will be clinically checked at regular intervals for radiation morbidity and tumor recurrence. Corrective actions included setting the device default dwell spacing at 5 mm, revising procedures, and training personnel.

Event Date:	Discovery Date:	Report Date:
08/14/2007	10/16/2007	10/17/2007

Licensee/Reporting Party Information:

License Number: 13-32087-01	Name: ONCOLOGY INSTITUTE OF GREATER LAFAYETTE
Docket Number: 03034812	City: LAFAYETTE, IN

Site of Event:

Site Name: LAFAYETTE, IN

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43727	10/23/2007		EVENT NOTIFICATION
ML073110149	11/14/2007		NRC LETTER
ML073310366	12/05/2007		CONSULTANT REPORT
ML073180320	01/10/2008		CONSULTANT REPORT
ML073050457	01/10/2008		LICENSEE REPORT
LTR080114	01/14/2008		NRC LETTER
ML080070444	01/15/2008		ADAMS DOCUMENT PACKAGE
ML080070451	01/15/2008		INSPECTION REPORT
LTR080107	01/15/2008		NRC LETTER
ML080070451	01/15/2008		NRC LETTER
ML080840539	04/09/2008		CONSULTANT REPORT
ML080930558	04/09/2008		NOTICE OF VIOLATION
ML080930558	04/09/2008		NRC LETTER

35.600 HDR

GYN

NMED Item Number: 080072**Narrative:****Last Updated:** 02/11/2008

The University of California Davis Medical Center (UCDMC) reported that a patient received two HDR cylinder gynecological treatment fractions of 600 cGy (rad) to 5 mm past the surface of the cylinder on 1/31/2007. The patient was prescribed two fractions of 600 cGy (rad) to the surface of the cylinder. UCDMC believes that the treatment form was filled out by a resident radiation oncologist and was signed by both the attending radiation oncologist and the resident oncologist. When the radiation oncologist typed the official written directive into the Information for Management, Planning, Analysis and Coordination System (IMPAC), her intention was to treat to the surface of the cylinder. However, the treatment was planned according to the written directive to 5 mm past the surface of the cylinder. The plan was checked and signed off by the treating physician prior to administration. The radiation oncologist changed the prescription in IMPAC to reflect the dose that was administered. The treating physician has notified both the referring physician and the patient.

Event Date: Discovery Date: Report Date:

01/31/2008 02/01/2008 02/01/2008

Licensee/Reporting Party Information:

License Number: CA-1334-34 Name: UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER
Docket Number: NA City: SACRAMENT, CA

Site of Event:

Site Name: SACRAMENT, CA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
CA-XCA1211	02/08/2008		AGREEMENT STATE EVENT REPORT
EN43960	02/11/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

35.600 HDR Varian

GYN

NMED Item Number: 080230**Narrative:****Last Updated:** 06/12/2008

The University of Mississippi Medical Center reported an error during a gynecological brachytherapy treatment using a Varian high dose rate (HDR) unit (model Varisource) with a 185 GBq (5 Ci) Ir-192 source (model SL-777V, serial #085). The patient was prescribed to receive five fractional treatments of 600 cGy (rad) each, for a total treatment of 3,000 cGy (rad). The treatments began on 12/11/2007 and were scheduled to occur over six days. Three fractional treatments were administered, but the patient did not return for the final two treatment fractions due to reasons not associated with the HDR treatments. On 3/25/2008, measurements of the tandem and ovoid applicators indicated that the length of the source wire entered into the treatment planning system should have been 128 cm; however, a length of 120 cm had been used. Further inspection revealed that the tandem catheter should have been used with a different applicator. These errors resulted in the dose for the three fractions being delivered 86 mm inferior to the intended treatment site. Therefore, only 470 cGy (rad) of the intended 600 cGy (rad) per fraction was received by the intended treatment site. The vaginal region inferior to the intended treatment site received an unintended dose of 1,300 cGy (rad). The referring physician and the patient were notified. The patient is not expected to experience adverse health effects due to this event. This event was caused by the failure to measure the catheters. Corrective actions included checking all catheters for integrity and length prior to treatment, ordering and using a single set of catheters for the transfer tubes, better verification of the treatment plan and catheters prior to each treatment, and reviewing the existing quality assurance plan and modifying if needed to ensure accuracy. A full time certified medical physicist was also hired.

Event Date: Discovery Date: Report Date:

12/11/2007 03/25/2008 03/26/2008

Licensee/Reporting Party Information:

License Number: MS-MBL-01 Name: UNIVERSITY OF MISSISSIPPI MEDICAL CENTER
Docket Number: NA City: JACKSON, MS

Site of Event:

Site Name: JACKSON, MS

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44137	04/17/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
MS08004	04/18/2008		AGREEMENT STATE EVENT REPORT
LTR080609	06/12/2008		AGREEMENT STATE LETTER

35.600 HDR Varian

Breast

NMED Item Number: 070724**Narrative:****Last Updated: 03/24/2008**

Nuclear Oncology reported that a patient received 34 cGy/fraction (rad/fraction) instead of the prescribed 340 cGy/fraction (rad/fraction) during the first six HDR treatment fractions to the breast. A Varian remote afterloader (model Gammamed Plus, serial #270) was used with 370 GBq (10 Ci) of Ir-192. Patient treatment began on 11/19/2007 and, following six treatments, the patient had received 204 cGy (rad). The original written directive was to have a post surgical total dose of 3,400 cGy (rad) delivered in 10 fractions over the course of five days. The attending oncologist was immediately notified and treatments were suspended. The patient was also notified of the error. It was determined that the treatment provided to date was an ineffective post surgical procedure and the patient should be retreated. A revised treatment plan was prepared and the first six fractions of a revised 10-fraction treatment were completed. Investigation by the treatment team revealed that the dosimetrist who entered the data for the original treatment failed to enter the proper dose per fraction after applying a dose optimization plan. Nor was the error caught during a routine review of the plan by the treatment team prior to loading the plan from the planning system. It was noted that this was the first multi-fractionated treatment that the dosimetrist had prepared. Corrective actions included producing a new procedure, providing additional training to personnel, and improved supervision.

Event Date: Discovery Date: Report Date:

11/19/2007 11/21/2007 11/21/2007

Licensee/Reporting Party Information:

License Number: IL-01641-01 Name: NUCLEAR ONCOLOGY S.C.
Docket Number: NA City: WINFIELD, IL

Site of Event:

Site Name: WINFIELD, IL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43805	12/03/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
IL070062	01/15/2008		AGREEMENT STATE EVENT REPORT
IL070062A	01/21/2008		AGREEMENT STATE EVENT REPORT
LTR080128	01/28/2008		AGREEMENT STATE LETTER
IL070062B	03/24/2008		AGREEMENT STATE EVENT REPORT

35.600 HDR SenoRX

Breast

NMED Item Number: 080406**Narrative:****Last Updated: 09/02/2008**

The University of Wisconsin reported that a patient being treated with high dose rate (HDR) partial breast irradiation to the right breast, using a Contura (SenoRx) balloon, did not receive her first fraction of 365 cGy (rad). The patient was prescribed to receive nine fractions for a total dose of 3,285 cGy (rad) to the planning target volume. After the planning was complete, the length of each of the five catheters was measured using the Nucletron Source Position Simulator. The readings were found to be 1,154 mm each. The treatment file in the HDR treatment console was modified from its default value of 1,500 mm to 1,154 mm and the patient was treated. Her first fraction was intended to be delivered on 7/14/2008 on HDR unit A (Nucletron model V2, serial #31282) using a 222.74 GBq (6.02 Ci) Ir-192 source (model 105.002, serial #D36B-5080). On 7/15/2008, the patient's second fraction was scheduled to be delivered on HDR unit B. Since the Ir-192 sources were different in activity, a total time check was performed and the measured catheter lengths were compared. The Nucletron Source Position Simulator was checked and it was noted that there was an obstruction at the 1,154 mm catheter. Review of the actual delivered dose during the first fraction revealed that the source did not enter the patient's body. A small region of the skin surface received some radiation dose, but the clinical impact was insignificant. Investigation of the Nucletron Source Position Simulator revealed that a welded junction in the cable of the measuring device was kinked. It was immediately replaced with a new one. The University also developed a new quality assurance form, which will be exclusively used for Contura balloons and incorporates the expected length for the five catheters. The patient and referring physician were notified of the incident on 7/15/2008. The Wisconsin Department of Health Services is still investigating the incident.

Event Date: Discovery Date: Report Date:

07/14/2008 07/15/2008 07/16/2008

Licensee/Reporting Party Information:

License Number: WI-025-1323-01 Name: UNIVERSITY OF WISCONSIN
Docket Number: NA City: MADISON, WI

Site of Event:

Site Name: MADISON, WI

Reference Documents:

Reference Document Number:	Entry Date: Retraction Date:	Type of Report:
EN44353	07/23/2008	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI080018	09/02/2008	AGREEMENT STATE EVENT REPORT

35.600 HDR

Mammosite

Breast

NMED Item Number: 080337**Narrative:****Last Updated:** 06/12/2008

Bon Secours Virginia Health Source reported that a patient received doses differing from prescribed during a breast cancer treatment using high dose rate (HDR) mammosite balloon brachytherapy on 5/1/2008. The patient was prescribed 10 fractions using an Ir-192 source with an activity of 165.4 GBq (4.47 Ci). During administration of the first fraction, the physicist received an alarm from the HDR computer. The alarm was overridden based on the judgment of the physicist at the time of the incident and the treatment was completed. The other nine treatments were completed as intended. Subsequent review of the first treatment and cause of the alarm indicated that the source placement was dislodged by 2 cm. The physicist thought that the alarm was indicating the source dislodged by only 2 mm. The dislodgment of the source by 2 cm put it at the skin entry point of the application catheter. That resulted in an under dose to the target site and an overdose to the skin. Preliminary calculations estimate that the skin in a 7 mm diameter around the catheter entry point may have received a dose of 3,700 cGy (rad). The patient will be notified of the incident and the doctor will monitor the skin for ill effects.

Event Date: Discovery Date: Report Date:

05/01/2008 05/01/2008 06/06/2008

Licensee/Reporting Party Information:

License Number: 45-25187-01 Name: BON SECOURS VIRGINIA HEALTH SOURCE
Docket Number: 03032638 City: MIDLOTHIAN, VA

Site of Event:

Site Name: RICHMOND, VA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44275	06/12/2008		EVENT NOTIFICATION

34.600 HDR Mammosite

Breast

NMED Item Number: 070612**Narrative:****Last Updated:** 01/29/2008

Carilion Health System reported that a female patient, receiving a mammosite treatment for a breast lesion using an HDR unit (Varian Medical Systems model Varisource, serial #VS381) with a 225.7 GBq (6.1 Ci) Ir-192 source, received approximately 2,000 cGy (rad) more dose to tissue adjacent to the source than prescribed. The prescribed dose was 340 cGy (rad). There was a 0.5 cm³ site within the treatment volume that received greater than 2500 cGy (rad) and a 1.0 cm³ site that received in excess of 2000 cGy (rad). There was also a radiation exposure of 680 cGy (rad) to an unintended area. The treatment consisted of placing a catheter into the treatment site, inflating a balloon with between 35 and 75 ml saline, and positioning the Ir-192 source inside the catheter into the center volume of the saline balloon. On 8/31/2006, a catheter was inserted and saline was introduced through one of two catheter connections to inflate the balloon. The patient was taken to the HDR unit where the technologist inadvertently connected the HDR unit to the saline instead of the HDR connector. That resulted in draining the saline balloon into the HDR unit. The technologist recognized that the HDR unit was improperly connected, broke the connection, and reconnected to the proper port. When the prescribed 416 second treatment was commenced, the HDR automatically shutdown and retracted the source. During an NRC inspection conducted on 7/26/2007, it was noted that since the saline balloon had been drained, tissue in a 0.5 cm³ volume adjacent to the source received a significantly higher dose than prescribed. Carilion Health informed the prescribing physician and the patient. Corrective actions included revising setup procedures requiring that the catheter not be connected to the HDR unit until after the CT scans are completed and providing training to all personnel on the revised procedure.

Event Date:	Discovery Date:	Report Date:
08/31/2006	07/26/2007	10/03/2007

Licensee/Reporting Party Information:

License Number: 45-25395-01	Name: CARILION HEALTH SYSTEM
Docket Number: 03034470	City: ROANOKE, VA

Site of Event:

Site Name: ROANOKE, VA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43685	10/09/2007		EVENT NOTIFICATION
LTR071228	01/03/2008		NRC LETTER
LTR080129	01/29/2008		NRC LETTER
LTR080129A	01/29/2008		NRC LETTER

35.600 Gammaknife

NMED Item Number: 070672**Narrative:****Last Updated:** 05/14/2008

Karmanos Cancer Center reported that a gamma knife treatment to a 63-year-old female patient's brain was delivered to the wrong location on 10/24/2007. The patient was being treated for a metastatic brain tumor in the right cerebellum. The gamma knife unit (model 24001, type C, serial #4202) was manufactured by Leksell System and contained Co-60 sources with a total activity of 227.96 TBq (6,161 Ci). While taking an MRI image of the patient's brain in preparation for the treatment, the left and right sides of the brain were reversed in the image due to human error. This resulted in a treatment of 1,800 cGy (rad) being delivered to the wrong location. The left/right image reversal resulted in an 18-mm shift of the isocenter. The collimator size was 18-mm, resulting in some overlap of the delivered 50% isodose volume with the correct target lesion volume. Approximately 9% of the lesion volume received the prescribed dose of 1,800 cGy (rad), rather than the intended 95% of the lesion volume. The patient was informed of the event. The NRC hired a medical consultant to review the consequences of the event, who concluded that no significant deterministic effects were expected. Corrective actions included procedure modification, additional reviews of left/right alignment of MRI images, and personnel training.

Event Date: Discovery Date: Report Date:

10/24/2007 10/24/2007 10/25/2007

Licensee/Reporting Party Information:

License Number: 21-04127-06 Name: KARMANOS CANCER CENTER
Docket Number: 03009376 City: DETROIT, MI

Site of Event:

Site Name: DETROIT, MI

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43746	11/02/2007		EVENT NOTIFICATION
ML073030270	11/02/2007		PRELIMINARY NOTIFICATION
PN307013	11/02/2007		PRELIMINARY NOTIFICATION
LTR071106	11/12/2007		NRC LETTER
LTR080114	01/15/2008		NRC LETTER
ML080100438	01/21/2008		INSPECTION REPORT
LTR080118	01/21/2008		NRC LETTER
ML080100438	01/21/2008		NRC LETTER
ML080420010	02/22/2008		LICENSEE REPORT
ML080580302	03/04/2008		CONSULTANT REPORT
ML080580534	03/04/2008		LICENSEE REPORT
ML081010416	04/14/2008		NOTICE OF VIOLATION
ML080920995	04/14/2008		NRC LETTER
ML081010416	04/14/2008		NRC LETTER
ML080950215	05/14/2008		NOTIFICATION OF SIGNIFICANT ENFORCEMENT ACTION

35.1000 Y-90 Microspheres

NMED Item Number: 080119**Narrative:****Last Updated: 08/06/2008**

Virginia Commonwealth University Medical Center (VCU) reported that a patient being treated for liver cancer on 2/20/2008 only received 42% of the prescribed dose of Y-90 microspheres. VCU calculated that the patient received 0.58 GBq (15.68 mCi) for a dose of 1,600 cGy (rad) instead of the prescribed 1.4 GBq (37.84 mCi) for a dose of 3,800 cGy (rad). The treatment was intended to be performed in three flushes. The first two flushes were intended to deliver the microspheres and the third flush was intended to ensure all prescribed medication was delivered to the patient. The patient received the first flush, but the second flush would not go through the tubing and the treatment was terminated. Both the patient and prescribing physician were notified of the problem. An investigation determined that the cause was the improper assembly of the equipment when the three-way stopcock was put in backwards. This caused crimping of the outlet tubes when the beta shield was inserted, thus restricting flow of the microspheres to the patient during the second flush. While this did not affect the first flush, the additional pressure applied during the second flush was enough to crimp the tubes. VCU reviewed the incident with all personnel involved and staff that might be part of a future procedure. The three-way stopcock was modified, locking it in place. Directional arrows were placed on the device to ensure proper assembly. The patient received the remainder of the treatment on 3/4/2008.

Event Date: Discovery Date: Report Date:

02/20/2008 02/20/2008 02/21/2008

Licensee/Reporting Party Information:

License Number: 45-00048-17 Name: VIRGINIA COMMONWEALTH UNIVERSITY
Docket Number: 03003297 City: RICHMOND, VA

Site of Event:

Site Name: RICHMOND, VA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43999	02/27/2008		EVENT NOTIFICATION
LTR080711	07/16/2008		NRC LETTER
ML081540325	08/06/2008		ADAMS DOCUMENT PACKAGE
ML081840117	08/06/2008		LICENSEE REPORT
ML081640166	08/06/2008		NOTICE OF VIOLATION
ML081640166	08/06/2008		NRC LETTER
ML082140866	08/06/2008		NRC LETTER

35. 1000 Y-90 Microspheres

NMED Item Number: 080146**Narrative:****Last Updated:** 03/10/2008

Skyridge Medical Center reported that a patient treated with Y-90 microspheres was only administered 50% of the prescription. The problem was identified at the conclusion of the procedure when staff noted that 50% of the Y-90 microspheres were still in the application kit. The medical physicist is unsure if the problem was caused by a faulty injection valve or human error. The Colorado Department of Health is investigating the incident. The INL has requested additional information for this event.

Event Date: Discovery Date: Report Date:

03/05/2008 03/05/2008 03/05/2008

Licensee/Reporting Party Information:

License Number: CO-1053-01 Name: SKYRIDGE MEDICAL CENTER

Docket Number: NA City: DENVER, CO

Site of Event:

Site Name: DENVER, CO

Reference Documents:Reference Document
Number:Entry Date: Retraction
Date:

Type of Report:

EN44033

03/10/2008

EVENT NOTIFICATION REPORTED FROM AN
AGREEMENT STATE

35.1000 TheraSpheres Y-90 Microspheres

NMED Item Number: 080380**Narrative:****Last Updated:** 09/18/2008

Baylor University Medical Center (BUMC) reported that a patient being treated with Y-90 Therasphere microspheres (MDS Nordion) on 7/2/2008 for liver cancer only received 49.58 MBq (1.34 mCi) instead of the prescribed 495.8 MBq (13.4 mCi). When the microspheres were delivered, the three-way stopcock was set erroneously and almost the entire dose was collected in the vent vial. Attempts to recover and deliver the misdirected dose were very limited. Post-administration, the residual activity in the original dose vial, the vent vial, and contaminated effects (catheter line, tubing, needles, towels, gauze pads, etc.) totaled 445.85 MBq (12.05 mCi). Therefore, the estimated administered activity was approximately 49.58 MBq (1.34 mCi). That translates to a delivered dose of approximately 870 cGy (rad) instead of the prescribed 10,000 cGy (rad) to the treatment site, or 8.7% of the prescribed dose. Corrective actions included procedure modifications that now require two independent verifications of the correct set-up of equipment prior to administration. BUMC is continuing the investigation.

Event Date:	Discovery Date:	Report Date:
07/02/2008	07/02/2008	07/03/2008

Licensee/Reporting Party Information:

License Number: TX-L01290	Name: BAYLOR UNIVERSITY MEDICAL CENTER
Docket Number: NA	City: DALLAS, TX

Site of Event:

Site Name: DALLAS, TX

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
TX080018	07/09/2008		AGREEMENT STATE EVENT REPORT
TX-I-8522	07/09/2008		AGREEMENT STATE EVENT REPORT
EN44335	07/09/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
TX080018B	09/18/2008		AGREEMENT STATE EVENT REPORT
TX-I-8522B	09/18/2008		AGREEMENT STATE EVENT REPORT

35.1000 TheraSpheres Y-90 Microspheres

NMED Item Number: 080508**Narrative:****Last Updated:** 09/04/2008

The University of Virginia Medical Center reported that a male patient, prescribed to receive 1.83 GBq (49.46 mCi) of Y-90 TheraSpheres (Nordion) to the right liver lobe for liver cancer, only received 37% to that target organ on 8/28/2008. The written directive specified a radiation dose to the right liver lobe of 9,200 cGy (rad). It was determined that the authorized user failed to turn the blue stopcock on the delivery device, which directed the majority of the TheraSpheres into the waste vial instead of into the patient. From waste container measurements, it was stated that 0.68 GBq (16.22 mCi) was implanted into the patient's right liver lobe, with 0.12 GBq (2.7 mCi) going to the patient's lungs. Therefore, 1.03 GBq (27.03 mCi) went into the waste vial. The calculated dose to the patient's liver was 3,430 cGy (rad) and to the lungs was 1,320 cGy (rad).

Event Date: Discovery Date: Report Date:

08/28/2008 08/28/2008 08/29/2008

Licensee/Reporting Party Information:

License Number: 45-00034-26 Name: VIRGINIA, UNIVERSITY OF
Docket Number: 03003296 City: CHARLOTTESVILLE, VA

Site of Event:

Site Name: CHARLOTTESVILLE, VA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44449	09/04/2008		EVENT NOTIFICATION

INTERESTING CASES - NOT MEDICAL EVENTS

Not reportable 35.200

NMED Item Number: 080049**Narrative:****Last Updated:** 04/14/2008

The Department of Veterans Affairs (VA) reported a possible medical event involving the administration of F-18 FDG to a patient using the wrong route of administration. The incident occurred on 1/17/2007 and involved 133.2 MBq (3.6 mCi) of F-18. The referring physician and patient were notified. The incident was retracted on 3/12/2008. The basis for retraction is that infiltration is not considered to be a wrong route of administration. The basis was communicated to the National Health Physics Program by phone on 3/7/2008.

Event Date: Discovery Date: Report Date:

01/17/2008 01/17/2008 01/18/2008

Licensee/Reporting Party Information:

License Number: 03-23853-01VA Name: V.A., DEPARTMENT OF
Docket Number: 03034325 City: NORTH LITTLE ROCK, AR

Site of Event:

Site Name: BOSTON, MA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43917	01/24/2008	3/12/2008	EVENT NOTIFICATION
EN43917A	03/13/2008	3/12/2008	EVENT NOTIFICATION
LTR080409	04/14/2008		NRC LETTER

Not Reportable 35.300

I-131

NMED Item Number: 080297**Narrative:****Last Updated:** 07/25/2008

Baptist Hospital reported that a patient received an unprescribed dose of 0.19 GBq (5 mCi) of I-131 on 5/16/2008. The patient received a prescribed dose of 5.6 GBq (150 mCi) of I-131 on 5/9/2008. However, when the patient returned to the hospital on 5/16/2008 to receive a scan, the nuclear medicine technologist mistakenly administered the unprescribed dose of 0.19 GBq (5 mCi) of I-131. The patient and doctor have been notified of the event. The NRC Medical Radiation Safety Team investigated the incident and determined that it did not meet reportable criteria due to the fact that the patient's thyroid was ablated (totally removed). Therefore, the patient did not receive dose that meets the threshold reporting requirements.

Event Date: Discovery Date: Report Date:

05/16/2008 05/16/2008 05/16/2008

Licensee/Reporting Party Information:

License Number: FL-0158-1 Name: BAPTIST HOSPITAL
Docket Number: NA City: PENSACOLA, FL

Site of Event:

Site Name: PENSACOLA, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44222	05/27/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080625	06/26/2008		NRC LETTER
FL08-079	07/25/2008		AGREEMENT STATE EVENT REPORT

Not Reportable 35.400 Ir-192

GYN

NMED Item Number: 070654**Narrative:****Last Updated: 01/08/2008**

The University of Iowa Hospital reported that a patient intervened during a vaginal treatment using Ir-192 brachytherapy sources. The patient removed one of the needles containing sources from her body. The needle was found by a nurse approximately 30 minutes after it had been removed by the patient. The needle was located at the foot of the bed near the patient's right ankle. The doctor directed the nurse to place the needle into a lead pig. There were six Ir-192 sources in the needle with a total activity of 0.26 GBq (7 mCi). The estimated dose to the nurse's hand was 0.13 mSv (13 mrem). The nurse's whole body dosimeter was sent for processing. The estimated dose to the patient's ankle is between 5 to 165 cSv (rem). The patient was monitored for acute radiation signs to the exposed areas of the legs and ankles. No signs of skin reaction were noted as of 12/5/2007. The patient received the intended therapeutic dose. The University will continue to monitor the patient. The incident was retracted on 1/2/2008.

Event Date: Discovery Date: Report Date:

10/19/2007 10/19/2007 10/19/2007

Licensee/Reporting Party Information:

License Number: IA-37-1-52-AAB Name: IOWA, UNIVERSITY OF
Docket Number: NA City: IOWA CITY, IA

Site of Event:

Site Name: IOWA CITY, IA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43734	10/25/2007	1/2/2008	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
EN43734A	01/03/2008	1/2/2008	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080104	01/08/2008		AGREEMENT STATE LETTER

Not Reportable 35.400

Sr-90 Eye Applicator

NMED Item Number: 080490**Narrative:****Last Updated:** 08/28/2008

The Texas Department of State Health report that Texas Oncology PA Klabzuba was cited for current calibration of a Sr-90 eye applicator. During previous inspection, after calibration, recalculation of recent treatments indicated that three patients received 50% overdose during eye treatments over the past year.

Event Date: Discovery Date: Report Date:

08/19/2008 08/19/2008 08/19/2008

Licensee/Reporting Party Information:

License Number: NR Name: TEXAS ONCOLOGY PA KLABZUBA

Docket Number: NA City: FORT WORTH, TX

Site of Event:

Site Name: FORT WORTH, TX

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
TX-I-8539	08/28/2008		AGREEMENT STATE EVENT REPORT
EN44426	08/28/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

LOST SOURCES

NMED Item Number: 070675

Narrative:

Last Updated: 01/07/2008

Pennsylvania State Milton S. Hershey Medical Center reported the loss of a gel capsule containing 2.04 MBq (55 uCi) of I-131. The capsule was placed into a Leucite thyroid neck phantom on 10/10/2007 for an anterior projection to calibrate the thyroid uptake counting system. The technician then oriented the phantom for a posterior projection, but only background counts were recorded. When the technician checked the neck phantom, the I-131 capsule was missing. The Nuclear Medicine personnel and a Health Physics team searched for the capsule, but it was not found. The local police were notified and responded to investigate. Corrective actions included dismissal of the chief technologist, dismissal of the technologist responsible for the calibration of the thyroid uptake counting system, placing all remaining technologists on probation, increasing the training sessions for all Nuclear Medicine technologists, obtaining additional security cameras, and changing door locks.

Event Date: Discovery Date: Report Date:
10/10/2007 10/10/2007 11/02/2007

Licensee/Reporting Party Information:

License Number: 37-13831-01 Name: PENNSYLVANIA STATE MILTON S HERSHEY MEDICAL CENTER
Docket Number: 03003203 City: HERSHEY, PA

Site of Event:

Site Name: HERSHEY, PA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43766	11/05/2007		EVENT NOTIFICATION
ML073540279	01/07/2008		LICENSEE REPORT
ML073540279	01/07/2008		REGION REPORT

NMED Item Number: 070712

Narrative:

Last Updated: 01/10/2008

On 11/16/2007, Shands Hospital at the University of Florida reported the loss of a brachytherapy seed ribbon, which contained Ir-192 with an activity of 222 MBq (6 mCi). The ribbon was discovered missing following a treatment when only nine of the ten ribbons used were accounted for. A radiation monitor alarm sounded when laundry was placed in the laundry chute; however, personnel ignored the alarm and did not retrieve the ribbon prior to the laundry being shipped off-site to the laundry facility in Lakeland, Florida. The ribbon was recovered from the laundry facility on 11/19/2007. The Florida Department of Health calculated no exposures above the public limit. Corrective actions included further in-house training. In addition, a separate set of instructions concerning the radiation monitor will be placed in the nurse's pass down book and on the patient's room door. The adequacy of the current radiation monitor will be evaluated.

Event Date: Discovery Date: Report Date:
11/16/2007 11/18/2007 11/18/2007

Licensee/Reporting Party Information:

License Number: FL-0031-1 Name: UNIVERSITY OF FLORIDA SHANDS HOSPITAL
Docket Number: NA City: GAINSVILLE, FL

Site of Event:

Site Name: GAINSVILLE, LA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43790	11/21/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
FL07-177	01/09/2008		AGREEMENT STATE EVENT REPORT
LTR080110	01/10/2008		AGREEMENT STATE LETTER

NMED Item Number: 070765**Narrative:****Last Updated:** 12/19/2007

The University of Texas Southwestern Medical Center (UTSMC) reported the loss of an I-125 seed that contained an activity of 5.81 MBq (157 uCi). The seed was used to mark a non-palpable breast tumor and was presumably lost on 10/26/2007 in a suction canister, which was removed from the operating room prior to being surveyed. After the loss was discovered, the patient was returned to the operating room where staff reopened the surgical site in an attempt to locate the seed, then relied on fluoroscopic examination to confirm that the seed was not in the patient. Radiation surveys did not locate the seed. The suction canister was removed immediately following the procedure, treated with microwave sterilization, and then discarded to the general refuse waste stream. The procedure has been modified to ensure positive control of a radioactive seed at all stages of its insertion, surgical recovery, transport, and disposal. Auxiliary detection devices (thin-crystal low-energy gamma detectors) have been acquired and stationed in surgery and pathology rooms. In addition, personnel have been trained in the use of radiation survey instruments at each stage of the procedure.

Event Date: 10/26/2007 **Discovery Date:** 10/26/2007 **Report Date:** 11/13/2007

Licensee/Reporting Party Information:

License Number: TX-L00384-004 Name: UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER
Docket Number: NA City: DALLAS, TX

Site of Event:

Site Name: DALLAS, TX

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
TX-I-8462	12/19/2007		AGREEMENT STATE EVENT REPORT

NMED Item Number: 080071**Narrative:****Last Updated:** 02/07/2008

Memorial Mission Hospital reported the loss of an I-125 brachytherapy seed (IsoAid model IAI-125A) that contained an activity of 12.21 MBq (0.33 mCi). A lead pig containing 20 seeds was taken to be autoclaved. A mesh material was placed over the pig during the autoclave process. Upon completion of the process, the mesh was removed and the pig overturned, spilling the

seeds. Only 19 of the 20 seeds were recovered. Radiation surveys were performed, but the missing seed has not been located. Corrective actions included reviewing procedures.

Event Date: 01/29/2008 **Discovery Date:** 01/29/2008 **Report Date:** 01/30/2008

Licensee/Reporting Party Information:

License Number: NC-011-0091-4 Name: MEMORIAL MISSION HOSPITAL
Docket Number: NA City: ASHEVILLE, NC

Site of Event:

Site Name: ASHEVILLE, NC

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
NC080004	02/07/2008		AGREEMENT STATE EVENT REPORT

NMED Item Number: 080144

Narrative:

Last Updated: 08/21/2008

Marshfield Clinic Minocqua Center (MCMC) reported the loss of 18 I-125 brachytherapy seeds (Oncura model 6733 Echoseed). A permanent prostate seed implant was performed on 12/21/2007. Following the implant, there were 18 unused seeds (three loose and 15 in an unused cartridge). The unused seeds were placed in a container and returned to the nuclear medicine clinic on 12/21/2007. An inexperienced nuclear medicine technologist accepted the container from oncology. The technologist opened the container and identified gauze in the package. She emptied the container including the 18 seeds into a waste bin, defaced the container, and placed it into storage. It was determined that the nuclear medicine waste was disposed of as regular trash on either 1/10/2008 or 2/6/2008. The aggregate activity of the seeds was 186.1 MBq (5.03 mCi) on 1/10/2008 or 136.2 MBq (3.68 mCi) on 2/6/2008. The trash went to the landfill. The State of Wisconsin investigated the incident during an inspection. Corrective actions included updating current written requirements for prostate seed handling and providing additional training to personnel.

Event Date: 01/10/2008 **Discovery Date:** 03/04/2008 **Report Date:** 03/04/2008

Licensee/Reporting Party Information:

License Number: WI-141-1162-01 Name: MARSHFIELD CLINIC MINOCQUA CENTER
Docket Number: NA City: MARSHFIELD, WI

Site of Event:

Site Name: MARSHFIELD, WI

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44031	03/10/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI080004	03/19/2008		AGREEMENT STATE EVENT REPORT
WI080004A	05/07/2008		AGREEMENT STATE EVENT REPORT

NMED Item Number: 080273**Narrative:****Last Updated: 09/23/2008**

Washington University Medical Center (WUMC) reported that two I-125 brachytherapy seeds (IsoAID model IAI-125A), each containing an activity of 19.17 MBq (0.518 mCi), were lost following a prostate implant procedure at 0900 CDT on 5/7/2008. WUMC received 15 seeds from the manufacturer for the procedure, of which 13 were implanted. Following the procedure, a nurse being trained in brachytherapy procedures incorrectly removed the cartridge from the Mick applicator, inadvertently leaving two seeds in the applicator. The applicator was moved to a soap basin for cleaning prior to being placed in storage. It is believed that the seeds were ejected from the applicator during cleaning and went down the drain into the sanitary sewer system. The loss was not identified until 1630 CDT on 5/7/2008 when the medical physicist was planning to use the two remaining seeds for measurements needed to verify the apparent seed activities. Several medical physicists surveyed the operating room used for the procedure and other areas, but did not locate the seeds. A survey of the soap basin's drain trap revealed no increased radiation levels. This event was caused by inadequate training of the nurse and the failure to survey the cartridge or the applicator. Corrective actions included personnel training and procedure modification.

Event Date: 05/07/2008 **Discovery Date:** 05/07/2008 **Report Date:** 05/08/2008

Licensee/Reporting Party Information:

License Number: 24-00167-11 **Name:** WASHINGTON UNIVERSITY MEDICAL CENTER
Docket Number: 03002271 **City:** SAINT LOUIS, MO

Site of Event:

Site Name: SAINT LOUIS, MO

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44194	05/12/2008		EVENT NOTIFICATION
ML081580617	06/12/2008		LICENSEE REPORT
ML081720562	07/01/2008		INSPECTION REPORT
ML081720562	07/01/2008		NRC LETTER
LTR080715	07/21/2008		NRC LETTER
ML082480695	09/09/2008		NOTICE OF VIOLATION
ML082480695	09/09/2008		NRC LETTER
ML082550169	09/23/2008		NRC NEWS ANNOUNCEMENT

NMED Item Number: 080404**Narrative:****Last Updated: 07/22/2008**

Medical Imaging Center of Ocala reported the loss of a 7.4 GBq (200 mCi) I-123 capsule. A technician did not return a pig containing the capsule to its proper storage location on 3/19/2008, but instead left it on a counter within the laboratory. The capsule and pig were determined missing and could not be found. Corrective actions included terminating the technician, installing a key pad lock on the hot laboratory door, and retraining department personnel.

Event Date: 03/13/2008 **Discovery Date:** 03/13/2008 **Report Date:** 03/13/2008

Licensee/Reporting Party Information:

License Number: FL-3335-1 Name: MEDICAL IMAGING CENTER OF OCALA
Docket Number: NA City: OCALA, FL

Site of Event:

Site Name: OCALA, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
FL08-039	07/22/2008		AGREEMENT STATE EVENT REPORT

NMED Item Number: 080413

Narrative:

Last Updated: 08/11/2008

The Mayo Clinic reported the loss of a 5.96 MBq (161 uCi) I-125 brachytherapy seed. The seed had been removed from a patient and then lost. It was suspected that the seed was thrown out in the trash. The clinic interviewed all involved employees, positively determined that the seed was not still in the patient, and surveyed all rooms involved. Corrective actions included procedure modifications that require all tissue specimens be transported from surgery to radiology or pathology in closed containers.

Event Date: 04/04/2008 **Discovery Date:** 04/04/2008 **Report Date:** 04/04/2008

Licensee/Reporting Party Information:

License Number: FL-1812-3 Name: MAYO CLINIC
Docket Number: NA City: JACKSONVILLE, FL

Site of Event:

Site Name: JACKSONVILLE, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
FL08-051	07/23/2008		AGREEMENT STATE EVENT REPORT
LTR080730	08/11/2008		AGREEMENT STATE LETTER

NMED Item Number: 080446

Narrative:

Last Updated: 08/06/2008

Kaiser Foundation Hospital reported the loss of two Gd-153 sources (Isotope Products serial #E2-886 and E2-890), each containing 9.25 GBq (250 mCi) as of May 2007. The sources were contained within lead shielding inside an ADAC Vantage camera that was disposed of in April 2008. This event was discovered on 7/24/2008 when a consultant asked for information regarding the disposition of the sources and it was determined that they had not been removed from the camera prior to disposal. Norcal removed the camera and sent it to Waste Management in San Leandro, California. Waste Management sent the camera to either DC Metals or ALCO Metals. Both companies were contacted, but they did not have the camera and indicated that it would have been recycled to scrap metal very quickly if it had been sent to them.

Event Date: 04/01/2008 **Discovery Date:** 07/24/2008 **Report Date:** 07/30/2008

Licensee/Reporting Party Information:

License Number: CA-2625-43 Name: KAISER FOUNDATION HOSPITAL - SAN JOSE
Docket Number: NA City: SAN JOSE, CA

Site of Event:

Site Name: SAN JOSE, CA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
CA-XCA1284	08/06/2008		AGREEMENT STATE EVENT REPORT
EN44378	08/06/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

NMED Item Number: 080489

Narrative:

Last Updated: 08/28/2008

Greater Baltimore Medical Center reported the loss of five Ir-192 brachytherapy seeds contained in a ribbon. Each seed contained an activity of 21.83 MBq (0.59 mCi). The ribbon was implanted in a cancer patient's neck along with five other strands of seeds. Numerous checks and plain films were obtained to verify correct location. The seeds had been implanted on 8/13/2008 and were checked daily. The loss of a strand of seeds was discovered on 8/17/2008, when the seed strands were being removed. Investigation revealed that the patient was moved to a new room. Extensive monitoring of all linens, surfaces, sink drain, other rooms in the unit, nurse's station, hallways and the loading dock did not locate the ribbon. A relative's car was also surveyed. The Medical Center believes that the ribbon was lost in the toilet while the patient shaved. Preventive action is for two radiation workers to independently check the button crimped on the end of the ribbon strand to insure that the ribbon cannot slide out of the catheter. Further investigation by the Maryland Department of the Environment is pending.

Event Date: 08/17/2008 **Discovery Date:** 08/17/2008 **Report Date:** 08/18/2008

Licensee/Reporting Party Information:

License Number: NR Name: GREATER BALTIMORE MEDICAL CENTER
Docket Number: NA City: BALTIMORE, MD

Site of Event:

Site Name: BALTIMORE, MD

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44424	08/28/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

NMED Item Number: 080544

Narrative:

Last Updated: 09/15/2008

North Okaloosa Medical Center (dba 21st Oncology) reported the loss of 114 Pd-103 brachytherapy seeds, with a total activity of 4.68 GBq (126.5 mCi). 21st Oncology was performing a medical procedure on 7/9/2008, when the source strength was considered too low for the procedure. The seeds were placed into a lock box at the Surgery Center. They were visually checked as present on 7/11/2008, and sent back to Triad Radiopharmaceutical on 7/25/2008. Triad Radiopharmaceutical stated that the shipping container was empty upon receipt at their facility on 8/6/2008. Their facility and dumpster were thoroughly searched with negative results. It was stated that the Surgery Center had been under renovation between 7/11 and 7/25/2008. Some discrepancies were identified between the charge nurse and the medical physicist as to if the lock box was locked after 7/11/2008. The Florida Bureau of Radiation Control will investigate the incident (report number FL08-127).

Event Date: 07/11/2008 **Discovery Date:** 08/06/2008 **Report Date:** 08/06/2008

Licensee/Reporting Party Information:

License Number: FL-3297-1 Name: NORTH OKALOOSA MEDICAL CENTER
Docket Number: NA City: CRESTVIEW, FL

Site of Event:

Site Name: CRESTVIEW, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44477	09/15/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

NMED Item Number: 080548

Narrative:

Last Updated: 09/16/2008

The Missouri Baptist Medical Center reported the loss of an 18.24 MBq (0.493 mCi) I-125 brachytherapy seed. The Medical Center performed a procedure on 8/14/2008 to implant 94 seeds into a patient. A quantity of 100 seeds was taken from inventory for the procedure. Upon procedure completion, a count of non-implanted seeds revealed only five, not six as expected. The Medical Center performed a survey of the operating room on 8/14/2008 and a CT scan of the patient. The missing seed was not located.

Event Date: 08/14/2008 **Discovery Date:** 08/14/2008 **Report Date:** 09/15/2008

Licensee/Reporting Party Information:

License Number: 24-11128-02 Name: MISSOURI BAPTIST MEDICAL CENTER
Docket Number: 03008325 City: SAINT LOUIS, MO

Site of Event:

Site Name: SAINT LOUIS, MO

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44488	09/16/2008		EVENT NOTIFICATION

LEAKING SOURCES

NMED Item Number: 070640

Narrative:

Last Updated: 12/10/2007

The Carolinas Medical Center reported a leaking Core Oncology (Mills Pharmaceuticals) I-125 brachytherapy seed (model I-125 SL) that contained an activity of 13.32 MBq (0.36 mCi). On 10/12/2007, a patient was implanted with 100 I-125 seeds. Five seeds were left over after the procedure. They were emptied from the loading cartridge into a lead pig. The cartridge was disposed of in the regular trash. The five seeds were assayed on 10/16/2007. The lead pig was surveyed and elevated radiation readings were discovered. Further surveys and wipes revealed removable contamination in the pig. The five seeds were leak tested and one seed showed 29,000 dpm or 740 Bq (0.02 uCi) of removable contamination. The loading cartridge was located and showed removable contamination. The patient returned and a thyroid scan was performed on 10/16/2007; results showed no thyroid uptake. Surveys of the surgeon, surgical staff, surgical suite, and all adjacent areas showed no contamination. The leaking seed was packaged and shipped to Core Oncology. Core Oncology's inspection and review indicated that the seed had an elongated dent from the middle of the seed to the base of an end weld. They noticed a very small hole in the proximity of the weld. They also stated that leak tests prior to being shipped to the Carolinas Medical Center revealed no leakage and or damage. The seed was most likely damaged while loading or unloading the applicator at the medical center.

Event Date: Discovery Date: Report Date:
10/12/2007 10/16/2007 10/17/2007

Licensee/Reporting Party Information:

License Number:	NC-060-0014-3	Name:	CAROLINAS MEDICAL CENTER
Docket Number:	NA	City:	CHARLOTTE, NC

Site of Event:

Site Name: CHARLOTTE, NC

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43726	10/23/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NC070052	11/15/2007		AGREEMENT STATE EVENT REPORT
NC070052A	12/10/2007		AGREEMENT STATE EVENT REPORT

NMED Item Number: 070748

Narrative:

Last Updated: 04/29/2008

Arizona Oncology Services (AOS) reported a leaking brachytherapy seed that contained 0.12 GBq (3.12 mCi) of Cs-131. The discovery occurred at the Scottsdale Radiation Oncology Center (SROC) following a patient prostate implant at AOS. The seed had become jammed in a Mick applicator cartridge at AOS. Using a GM survey instrument, surveys of the linen, operating room, patient's bed, and trash revealed no radiation readings above background. The seed, which was still in the cartridge, was packaged inside the container it had arrived in and shipped to SROC. Upon arrival at SROC, the external surfaces of the package were wipe tested and revealed no radioactive contamination. An SROC technician unloaded the cartridge with her bare hands and the seed was dislodged into a lead container. The cartridge was then surveyed and revealed radioactivity. The empty cartridge was placed in a lead container and the technician

surveyed her fingers. Upon realizing she was contaminated, she informed the assistant RSO. She washed her hands with soap and water for approximately 15 minutes and no residual activity was detected. The seed was placed in a capped glass container and then into a marked lead container. The contaminated shipping container was bagged and will be stored in a locked cabinet for 70 days for decay. All areas and personnel were surveyed with a GM instrument and pancake probe and no contamination was identified. Further wipe tests revealed no contamination. Calculations showed that 15 minutes of exposure to the technician's hands did not exceed limits. Corrective actions included requiring personnel to wear rubber gloves until all cartridges are examined following the return of radioactive seeds.

Event Date: 12/03/2007 **Discovery Date:** 12/07/2007 **Report Date:** 12/07/2007

Licensee/Reporting Party Information:

License Number: AZ-07-161 Name: ARIZONA ONCOLOGY SERVICES
Docket Number: NA City: SCOTTSDALE, AZ

Site of Event:

Site Name: SCOTTSDALE, AZ

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43827	12/12/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR071217	12/17/2007		AGREEMENT STATE LETTER
EN43831	12/17/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080423	04/29/2008		AGREEMENT STATE LETTER

NMED Item Number: 080124

Narrative:

Last Updated: 07/01/2008

Advanced Care Medical reported that during assembly of a brachytherapy seed strand in their production laboratory on 2/27/2008, one I-125 seed (BEBIG Isotopentichnic and Umweltdiagnostik GMBH model 125.S06) was damaged and contaminated the working tool. The damaged seed contained an activity of 14.76 MBq (399 uCi). Contamination levels on the working tool were determined to be 17,224 dpm (287.07 Bq or 7.76 nCi). Decontamination was completed, which restored the working tool to normal background levels. The other 82 seeds that were in the vicinity of the working tool were quarantined. Advanced Care Medical performed a lessons learned analysis and retrained personnel about proper practices to avoid crimping seeds in the future.

Event Date: 02/27/2008 **Discovery Date:** 02/27/2008 **Report Date:** 02/27/2008

Licensee/Reporting Party Information:

License Number: 06-30764-01 Name: ADVANCED CARE MEDICAL
Docket Number: 03036099 City: OXFORD, CT

Site of Event:

Site Name: OXFORD, CT

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44010	02/28/2008		EVENT NOTIFICATION
LTR080616	06/17/2008		NRC LETTER
LTR080617	06/17/2008		NRC LETTER
ML081690631	07/01/2008		OTHER

NMED Item Number: 080170**Narrative:****Last Updated: 05/19/2008**

Carolinas Medical Center identified five leaking brachytherapy seeds (Mills Biopharmaceuticals/Core Oncology model I125SL, lot #81066 and 81069) that were leftover from prostate implant procedures involving two patients. Each seed contained 13.32 MBq (0.36 mCi) of I-125. Four seeds (lot #81066) were from a procedure performed on 3/11/2008 and one (lot #81069) was from a procedure performed on 3/12/2008. Leak test results from the five seeds ranged from 333 to 1,850 Bq (0.009 to 0.05 uCi), and all five had visible damage. There were also two additional seeds from lot #81069 that showed physical damage, but were not leaking. The patients were recalled for evaluation, but showed no iodine uptake. The seeds were manufactured by Mills Biopharmaceuticals (a subsidiary of Core Oncology) of Oklahoma City, Oklahoma, and were preloaded into cartridges, sterilized, and distributed by MedTech Diagnostic Services of Fort Meyers, Florida. An investigation was initiated by the State of North Carolina to determine if the seeds were damaged during manufacture, loading, or unloading. It was determined that the seeds never left the cartridges until unloaded by the dosimetrist. The physician never loaded the cartridges into the Mick Applicator. No radioactive contamination other than the seeds and the storage pig was detected. Carolinas Medical Center reviewed their procedures for handling seeds and does not believe they are doing anything to cause the damage to the seeds. The State of North Carolina asked Oklahoma and Florida for assistance by inspecting Mills and MedTech. The seeds were returned to Mills Biopharmaceutical for disposal. Mills Biopharmaceuticals performed an analysis on the damaged seeds. They confirmed that the seeds were damaged, some severely, and the damage appeared to be the result of stacked seeds impacting one another. They stated that the damage was consistent with that caused by the application of excessive force to the seeds while being stacked horizontally on top of each other, much like being loaded in a seed cartridge. Additionally, the damage more likely occurred at MedTech rather than the other facilities.

Event Date:	Discovery Date:	Report Date:
03/14/2008	03/14/2008	03/17/2008

Licensee/Reporting Party Information:

License Number:	NC-060-0014-3	Name:	CAROLINAS MEDICAL CENTER
Docket Number:	NA	City:	CHARLOTTE, NC

Site of Event:

Site Name: CHARLOTTE, NC

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44069	03/20/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
EN44069A	03/21/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NC080012	04/15/2008		AGREEMENT STATE EVENT REPORT
LTR080402	04/15/2008		AGREEMENT STATE LETTER
NC080012A	05/19/2008		AGREEMENT STATE EVENT REPORT

NMED Item Number: 080171**Narrative:****Last Updated: 05/21/2008**

Whidbey General Hospital reported that an I-125 brachytherapy seed (Best Medical International model 2301) implanted into a patient was leaking. The seed contained less than 12.95 MBq (350 uCi). On 3/10/2008, the patient was implanted with 102 seeds. On 3/11 or 3/12/2008, the patient complained of pain and difficulty urinating. A cauterization was performed via the urethra. Upon removal of the cauterization equipment, some seeds also exited the urethra. One seed was visibly different from the rest. Upon closer observation, the seed was noted to be shorter than the others and had been damaged. The cause of the damage was not definitely determined. However, it is believed to have occurred as a result of the cauterization procedure. Surveys revealed contamination of the equipment and bodily fluids, and an external reading directly over the thyroid showed levels above background. A medical consultant (Pacific Health Physics) was contracted to determine the dose and any potential consequences to the patient. A CT scan performed on 3/19/2008 revealed that 92 seeds remained in the patient. Wipes of the remaining seeds showed contamination levels up to 18.5 kBq (500 nCi). It is believed that those seeds were cross-contaminated while in storage. Bioassays of the patient on 3/19/2008 revealed a thyroid burden of 29.6 kBq (0.8 uCi) and a dose of less than 1 cSv (rem) to the thyroid. Whidbey General stated that while extremely rare, they would consider doing the same cauterization procedure again but with greater screening of the need for that particular procedure as opposed to another, presumably less hazardous procedure, to accomplish the same goal.

Event Date: 03/10/2008 **Discovery Date:** 03/13/2008 **Report Date:** 03/17/2008

Licensee/Reporting Party Information:

License Number: WA-WN-M0217-1
Docket Number: NA

Name: WHIDBEY GENERAL HOSPITAL
City: COUPEVILLE, WA

Site of Event:

Site Name: COUPEVILLE, WA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
WA-08-019	03/20/2008		AGREEMENT STATE EVENT REPORT
EN44073	03/20/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WA-08-019A	03/24/2008		AGREEMENT STATE EVENT REPORT
EN44073A	03/24/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080519	05/21/2008		AGREEMENT STATE LETTER

NMED Item Number: 080176

Narrative:

Last Updated: 03/24/2008

Bard Brachytherapy reported a leaking I-125 prostate seed that cross-contaminated seeds shipped to several clients. The leaking seed contained an activity of 28.86 MBq (0.78 mCi) on 1/2/2008 and was part of some 1,509 seeds in a lot going to the Chicago Prostate Cancer Center and foreign clients. The Chicago Prostate Cancer Center stated that a vial containing a shipment of prostate seeds revealed radioactive contamination. The next day they identified another vial containing seeds as being contaminated. Bard Brachytherapy is in the process of having international shipments (Japan and Germany) from this lot returned for analysis. Corrective actions taken included additional checkpoints and monitoring to look for slow developing leaks and contamination checks immediately before final packaging occurs.

Event Date: 01/21/2008 **Discovery Date:** 01/21/2008 **Report Date:** 01/21/2008

Licensee/Reporting Party Information:

License Number: IL-02062-01

Name: BARD BRACHY THERAPY

Docket Number: NA City: CAROL STREAM, IL

Site of Event:

Site Name: CAROL STREAM, IL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
IL080005	03/24/2008		AGREEMENT STATE EVENT REPORT

NMED Item Number: 080282

Narrative:

Last Updated: 09/08/2008

Chicago Prostate Cancer Center (CPCC) reported that at least one I-125 brachytherapy seed (Best Medical International model 2300), in a shipment containing 87 seeds, was leaking. Each seed had an activity of 15.1 MBq (0.408 mCi). Four vials of loose seeds had been delivered on 4/24/2008. CPCC analyzed them to confirm activity, transferred them to shielded containers to be sterilized by autoclave, and arranged for loading them into needles. Smears of the original vials, the shielded container, the autoclave, and the preparation area revealed negative results. On 4/25/2008, the seeds were again monitored as they were being loaded into cartridges and needles. At that time, one of the trays of seeds showed removable I-125 contamination. Contamination was also identified on the gloves of the technician loading the seeds and on the inner covering of the sterile wrapping. Only seeds from one of the four original vials revealed contamination. Leak test results revealed 370 Bq (0.01 uCi). Best Medical International was contacted and the patient rescheduled. Best Medical International made arrangements for return of the contaminated batch on 5/1/2008 and provided replacement seeds for the treatment. The report from the manufacturer on 6/19/2008 indicated that the seeds exhibited surface contamination. Extended leak tests did not indicate that any of the seeds were defective or exhibit any failure of the weld or encapsulation. As the results from the manufacturer and CPCC were in conflict, the cause may not be determined by the State Agency.

Event Date: 04/24/2008 **Discovery Date:** 04/25/2008 **Report Date:** 04/25/2008

Licensee/Reporting Party Information:

License Number:	IL-02015-01	Name:	CHICAGO PROSTATE CANCER CENTER
Docket Number:	NA	City:	WESTMONT, IL

Site of Event:

Site Name: WESTMONT, IL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
IL080025	05/14/2008		AGREEMENT STATE EVENT REPORT
LTR080703	07/03/2008		AGREEMENT STATE LETTER
IL080025A	09/08/2008		AGREEMENT STATE EVENT REPORT

FETUS/EMBRYO DOSE

NMED Item Number: 080514

Narrative:

Last Updated: 09/11/2008

The U.S. Air Force reported that a pregnant female patient received a therapeutic I-131 dose of 5.52 GBq (149.2 mCi) on 6/4/2008 at the Wilford Hall Medical Center. The NRC first learned of the incident during an unannounced inspection conducted on 9/5/2008. The patient was tested for pregnancy on 6/2/2008 prior to receiving the ablative dose. The serum screening result was negative and the dose was administered with no complications. On 8/13/2008, the patient was informed that she was pregnant. Follow-up consultation with the Radiation Emergency Assistance Center/Training Site (REAC/TS) and calculations determined that the dose to the fetus was approximately 31.5 cGy (rad). However, since the incident occurred early in the zygote phase of development, there are no anticipated adverse consequences. The patient and her physician have been consulted regarding the hospital's conclusions. The NRC is obtaining the services of a medical consultant to assist in its ongoing special inspection of the incident.

Event Date: Discovery Date: Report Date:
06/04/2008 08/13/2008 09/05/2008

Licensee/Reporting Party Information:

License Number:	42-23539-01AF	Name:	AIR FORCE, DEPARTMENT OF THE
Docket Number:	03028641	City:	BROOKS AFB, TX

Site of Event:

Site Name: LACKLAND AFB, TX

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44468	09/08/2008		EVENT NOTIFICATION
ML082530557	09/11/2008		PRELIMINARY NOTIFICATION
PN408009	09/11/2008		PRELIMINARY NOTIFICATION

NMED Item Number: 080550

Narrative:

Last Updated: 09/16/2008

Saint Lukes Hospital reported an embryo/fetus exposure due to a therapeutic administration of I-131 to a patient for thyroid carcinoma. The patient had two negative pregnancy tests on 4/6 and 4/10/2008. She was administered 4.96 GBq (134 mCi) of I-131 on 4/11/2008. Following treatment, the patient suspected she was pregnant and returned to the Hospital on 4/28/2008. Subsequent testing indicated she became pregnant approximately four to six days following treatment. The calculated whole body exposure to the fetus was 35 cGy (rad). The patient and referring physician were notified. The cause of the incident was that the patient did not follow the contraceptive plan outlined in the procedure she signed prior to treatment. Hospital staff followed all procedures. Corrective actions included procedure modifications to over-emphasize the risks associated with becoming pregnant following administration of radioiodine.

Event Date: Discovery Date: Report Date:
04/11/2008 04/28/2008 05/01/2008

Licensee/Reporting Party Information:

License Number:	PA-0073	Name:	SAINT LUKES HOSPITAL
Docket Number:	NA	City:	BETHLEHEM, PA

Site of Event:

Site Name: BETHLEHEM, PA

Reference Documents:

Reference Document Number:

PA080015

Entry Date:

09/16/2008

Retraction Date:

Type of Report:

AGREEMENT STATE EVENT
REPORT

MISCELLANEOUS – EQUIPMENT MALFUNCTIONS

NMED Item Number: 080070

Narrative:

Last Updated: 08/21/2008

Aurora Health Care Metro, Incorporated (AHCM), reported an equipment failure involving an Elekta gamma knife unit (Leksell Gamma System model 24001, type C, serial #9613831) that contained 82.84 TBq (2,239 Ci) of Co-60. A patient treatment plan called for three exposure fractions. The first fraction was initiated on 1/31/2008. After the normal termination time of that treatment, the couch retracted fully and the patient's head was withdrawn from the unit. However, the shielding doors on the unit did not close. An authorized medical physicist entered the treatment room, walked behind the unit, and manually closed the shielding doors. AHCM estimated that the physicist received an exposure of no more than 0.083 uSv (8.3 urem) while closing the doors. The patient was removed from the treatment room and a radiation survey was conducted to verify that the shielding doors had closed completely. Elekta was contacted and a service representative responded and completed an evaluation of the gamma knife unit. Parts were installed in mid-February 2008, following scheduled source replacement. A decision was made by the authorized user to complete the last two exposure fractions to the affected patient. They were completed successfully. The radiation dose received by the patient did not deviate from the written directive.

Event Date: Discovery Date: Report Date:
01/31/2008 01/31/2008 01/31/2008

Licensee/Reporting Party Information:

License Number: WI-079-1281-01 Name: AURORA SAINT LUKE'S MEDICAL CENTER
Docket Number: NA City: MILWAUKEE, WI

Site of Event:

Site Name: MILWAUKEE, WI

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43950	02/07/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI080001	03/19/2008		AGREEMENT STATE EVENT REPORT
LTR080410	04/15/2008		AGREEMENT STATE LETTER
WI080001A	05/30/2008		AGREEMENT STATE EVENT REPORT
WI080001B	08/21/2008		AGREEMENT STATE EVENT REPORT

NMED Item Number: 080087

Narrative:

Last Updated: 05/16/2008

SPEC reported the inability to retract a brachytherapy source into a high dose rate (HDR) unit on 2/9/2008. The incident occurred at the New York Radiation Oncology Associates facility and involved an HDR unit (Oncology Systems model AccuSource 1000, serial #D-101) that contained an Ir-192 source (SPEC model M-19, serial #OSI A011) with an activity of 318.9 GBq (8.62 Ci). A field engineer first performed a systems and software check on the HDR using a dummy source. All quality assurance tests passed during that time. He then loaded the HDR with the Ir-192 source. The engineer performed several successful tests on the HDR unit before extending the source cable, to insure that the inner vault was installed correctly. He then

extended the source and a force error sensor was triggered between the vault and the turret, which triggered an emergency retraction of the source. During the emergency retraction, the vault door closed on the source tip, resulting in a source disconnect and the loss of the top part of the source capsule. The source retracted to the inner vault where it was shielded. The inner vault/spool cartridge, with the source, was packaged in a Type A shipping container provided by SPEC. It was held at the facility in a locked room until it could be shipped to SPEC. SPEC received the container on 2/26/2008. The source capsule tip was not discovered missing until the inner vault was inspected by SPEC on 3/18/2008. Once the package was opened, several wipes were performed. Two areas above background were noted. A wipe of the tip of the cap/wire, where the source capsule was missing, had a count of 327 cpm (background was 37 cpm). The back end of the cable had a count of 101 cpm. Survey results on the side of the vault were 200 mR/hour, with 100 mR/hour at the end of the vault. The inner vault was not open (SPEC wanted the source to decay prior to opening). The inner vault was disassembled on 3/18/2008. The bare Ir-192 pellet was found in the straight exit channel of the front vault slug. The source capsule was not in the inner vault. The shipping package was re-surveyed and the capsule was not found. Wipe tests of the inside of the vault revealed 1.22 MBq (33 uCi). An Oncology Systems field engineer plans to travel to the New York facility during the week of 4/15/2008 to attempt to locate the missing capsule. The City of New York Radiological Health Department was notified by the State of Louisiana of the incident. Initial corrective actions included software changes to ensure the vault door doesn't close until the source is in the appropriate location.

Event Date: 02/09/2008 **Discovery Date:** 02/09/2008 **Report Date:** 02/11/2008

Licensee/Reporting Party Information:

License Number: LA-11598-L01 Name: ONCOLOGY SYSTEMS, INC.
Docket Number: NA City: SAINT ROSE, LA

Site of Event:

Site Name: NEW YORK CITY, NY

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43979	02/14/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080514	05/15/2008		AGREEMENT STATE LETTER
EN43979A	05/16/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

NMED Item Number: 080196

Narrative:

Last Updated: 06/10/2008

Providence Everett Medical Center reported an equipment failure involving their Varian Medical Systems HDR unit (model VariSource iX, serial #600500) that contained an Ir-192 source (model VS2000, serial #02-01-0012-001-011008-11526-58) with an activity of 205.1 GBq (5.543 Ci). A Varian representative was attempting a routine source exchange at the medical center. There were no patients or medical center staff involved in the exchange process. The Varian representative noted some trouble with making the old source enter the exchange container. After several failed attempts, the representative contacted Varian Corporate Headquarters for assistance. The decision was made to cut the source wire near the source and

place the source assembly into the emergency shielded container. After following those directions, the representative performed a radiation survey of the container and noted that levels were lower than expected. The room was locked and barrier tape placed across the door. A Varian recovery team was called and arrived at the medical center on 3/29/2008. A Washington Office of Radiation Protection investigator also responded. Investigation determined that both the dummy wire and the source wire had tried to exit the HDR unit simultaneously. The wires became stuck in the "home switch" section of the HDR. The Varian representative inadvertently cut the dummy source wire and placed the dummy source in the shielded container. The recovery team successfully retracted the radioactive source into the HDR. The highest exposure received by a recovery team member was 0.87 mSv (87 mrem). Several wipe surveys were performed on the source during the course of recovery and no removable contamination was identified. Varian concluded that the cause of the incident was that the representative mistakenly extended the active source wire while the dummy wire was already in the same pathway. That action jammed the dummy and source wires at the home switch and prevented the active wire from properly retracting to the tungsten safe when commanded. Varian also concluded that the likelihood of an operator recreating that type of incident was not possible, because the conditions that allowed it to happen are only present when the factory service engineer is working on the unit.

Event Date: 03/28/2008 **Discovery Date:** 03/28/2008 **Report Date:** 03/29/2008

Licensee/Reporting Party Information:

License Number: WA-WN-M0135-1 Name: PROVIDENCE EVERETT MEDICAL CENTER
Docket Number: NA City: EVERETT, WA

Site of Event:

Site Name: EVERETT, WA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
WA-08-020	04/03/2008		AGREEMENT STATE EVENT REPORT
EN44110	04/03/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WA-08-020A	04/21/2008		AGREEMENT STATE EVENT REPORT
LTR080418	04/21/2008		AGREEMENT STATE LETTER
EN44110A	04/21/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080605	06/10/2008		AGREEMENT STATE LETTER

MISCELLANEOUS – PACKAGING

NMED Item Number: 070691

Narrative:

Last Updated: 06/18/2008

Bard Brachytherapy reported that a package of 51 I-125 seeds (model STM 125), containing a total activity of 1.41 GBq (38 mCi), had been returned to them from Virginia Mason Medical Center with a surface radiation level of 600 mR/hour. The radiation level at one meter was 1.4 mR/hour. Bard Brachytherapy accounted for all of the sources specified on the shipping papers. However, the lid to the pig had become loose during transit due to the failure to properly secure it. The vial containing the seeds was intact with no signs of radioactive contamination or loss of integrity. Bard's RSO contacted the Virginia Mason Medical Center and the courier (Federal Express). No personnel overexposures are suspected. It was stated that at the time the package was prepared, radiation readings were 0.14 mR/hour on contact and 0.015 mR/hour at one meter. Virginia Mason determined that this shipment differed from all previous shipments because it was a sterile shipment. All previous shipments had been non-sterile and had come with different packaging and instructions. Virginia Mason believes that the incident was due to abuse during shipment. All future shipments to clients in the State of Washington will include more tape for sealing the lid and updated repackaging instructions to tape the lid closed.

Event Date: Discovery Date: Report Date:
11/09/2007 11/09/2007 11/09/2007

Licensee/Reporting Party Information:

License Number:	WA-WN-M048-1	Name:	VIRGINIA MASON MEDICAL CENTER
Docket Number:	NA	City:	SEATTLE, WA

Site of Event:

Site Name: SEATTLE, WA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
WA-07-088	11/14/2007		AGREEMENT STATE EVENT REPORT
EN43775	11/14/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
EN43778	11/14/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
IL070058	01/15/2008		AGREEMENT STATE EVENT REPORT
IL070058A	01/21/2008		AGREEMENT STATE EVENT REPORT
IL070058B	03/24/2008		AGREEMENT STATE EVENT REPORT
WA-07-101	06/18/2008		AGREEMENT STATE EVENT REPORT
LTR080617	06/18/2008		AGREEMENT STATE LETTER

NMED Item Number: 080172

Narrative:

Last Updated: 09/24/2008

The Department of Veterans Affairs (VA) reported the receipt of three packages of radioactive material with surface contamination in excess of limits. The packages were received on 3/18/2008 at the VA Medical Center in West Palm Beach, Florida. The packages contained Co-57 flood sources and were received from Isotope Products Laboratories of Valencia, California. Wipe tests indicated removable contamination levels of 24,700, 12,880, and 35,570 dpm/cm², respectively. The final delivery was by common carrier. The final delivery carrier and the vendor

were notified of the contaminated packages. The contaminant was confirmed to be Tc-99m. The medical center provided training to staff regarding survey techniques and notification requirements.

Event Date: 03/18/2008 **Discovery Date:** 03/18/2008 **Report Date:** 03/19/2008

Licensee/Reporting Party Information:

License Number: 03-23853-01VA Name: V.A., DEPARTMENT OF
Docket Number: 03034325 City: NORTH LITTLE ROCK, AR

Site of Event:

Site Name: WEST PALM BEACH, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN44076	03/20/2008		EVENT NOTIFICATION
ML082401006	09/04/2008		INSPECTION REPORT
LTR080824	09/04/2008		NRC LETTER
ML082401006	09/04/2008		NRC LETTER
LTR080919	09/24/2008		NRC LETTER

NMED Item Number: 080312

Narrative:

Last Updated: 06/04/2008

Moore Regional Hospital reported receiving five ammo boxes, each with removable radioactive contamination exceeding 30,000 dpm. The shipment came from Cardinal Health and contained Tc-99m labeled radiopharmaceuticals. The courier was surveyed and his hands revealed a dose rate of 10 mR/hour at a distance of four to six inches. His hands were decontaminated at the hospital to approximately 2 mR/hour. He was sent back to Cardinal Health for further decontamination. A health physicist from the North Carolina Radioactive Materials Branch visited the Cardinal Health facility to investigate the incident. It was determined that the courier had picked up some empty ammo boxes from Womack Army Medical Center prior to the delivery at Moore Regional Hospital. The Womack Army Medical Center containers were radioactively contaminated. The courier had contaminated his hands and then contaminated the five containers delivered to Moore Regional Hospital. Radioactive contamination was also found on the steering wheel of the truck, truck keys, seat belt, door handle, transmission shift lever, and canopy bed cover. The dose to each of the courier's hands was calculated to be 2.32 mSv (232 mrem) shallow dose equivalent. Corrective actions included providing additional training to personnel. The INL has requested additional information for this event.

Event Date: 05/14/2008 **Discovery Date:** 05/14/2008 **Report Date:** 05/15/2008

Licensee/Reporting Party Information:

License Number: 32-04054-04 Name: ARMY, DEPARTMENT OF THE - FORT BRAGG
Docket Number: 03002631 City: FAYETTEVILLE, NC

Site of Event:

Site Name: FAYETTEVILLE, NC

Reference Documents:

Reference Document Entry Date: Retraction Date: Type of Report:

Number:
NC080023
EN44250

06/03/2008
06/04/2008

AGREEMENT STATE EVENT REPORT
EVENT NOTIFICATION REPORTED FROM AN
AGREEMENT STATE

NMED Item Number: 080450

Narrative:

Last Updated: 08/08/2008

The Department of Veterans Affairs reported receiving a package of Tc-99m radiopharmaceuticals with removable surface contamination on the outside on 7/15/2008. The package was received by the Veterans Affairs Medical Center in Fayetteville, North Carolina, and was sent from Cardinal Health in Fayetteville. A wipe test performed on the external surface of the package revealed a removable contamination level of 254 dpm/cm². Surveys inside the package did not indicate elevated contamination. Cardinal Health was notified of the contaminated package.

Event Date: 07/15/2008 **Discovery Date:** 07/15/2008 **Report Date:** 08/07/2008

Licensee/Reporting Party Information:

License Number: 03-23853-01VA
Docket Number: 03034325

Name: V.A., DEPARTMENT OF
City: NORTH LITTLE ROCK, AR

Site of Event:

Site Name: FAYETTEVILLE, NC

Reference Documents:

Reference Document Number:
EN44389

Entry Date:
08/08/2008

Retraction Date:

Type of Report:
EVENT NOTIFICATION

MISCELLANEOUS – OVEREXPOSURE

NMED Item Number: 080073

Narrative:

Last Updated: 07/17/2008

Anazao Health Corporation reported extremity overexposures to two individuals on 1/28/2008. Initial determination was on 12/27/2007. During a routine facility audit on 2/6/2008, the Florida Bureau of Radiation Control inspector identified documentation concerning the overexposures. One individual received 105.3 cSv (rem) to his right TLD finger ring and 82.3 cSv (rem) to his left finger ring. The second individual received 53.2 cSv (rem) to his right TLD finger ring and 80.1 cSv (rem) to his left finger ring. Both employees worked with I-131 liquid in the preparation of nuclear medicine capsules. The I-131 stock contained up to 111 GBq (3 Ci) and the individuals removed stock liquid into other vials for diagnostic or therapy capsule production. Operations were conducted within a fume hood. The individuals stood outside the fume hood behind lead shielding, while their forearms and hands were placed inside to perform work. Syringe shields were not used by the individuals. There were no written procedures for those operations and no remote tools were used. Corrective actions included purchasing proper handling tools, hiring a new RSO, improving I-131 handling procedures, and improving and adhering to the radiation safety program. In addition, all finger ring dosimetry will be mailed every non-holiday Monday, at the first of each month.

Event Date: 12/27/2007 Discovery Date: 12/27/2007 Report Date: 01/28/2008

Licensee/Reporting Party Information:

License Number: FL-2975-1 Name: ANAZAO HEALTH CORP.
Docket Number: NA City: TAMPA, FL

Site of Event:

Site Name: TAMPA, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43965	02/11/2008		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080407	04/09/2008		AGREEMENT STATE LETTER
LTR080501	05/07/2008		AGREEMENT STATE LETTER
FL08-018	07/17/2008		AGREEMENT STATE EVENT REPORT

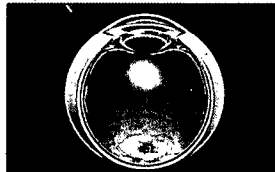
Intraocular Brachytherapy for Neovascular AMD

Wet AMD

- Wet (Neovascular) AMD is the leading cause of irreparable blindness in the elderly
 - Neovascular growth from the underlying vascular system invades the retina.
 - These rapidly growing vessels often leak blood and fluid
 - Damage occurs to the macula leading to loss of central vision
- In the U.S., ~ 200,000 people will develop Wet AMD each year.
- WHO estimates epidemic proportions by 2030

Advances in the Treatment of Wet AMD

- Dramatic advances in last several years
 - Intravitreal therapy with anti-VEGF agents
 - Stability in large majority of treated patients
 - Visual recovery in many



Why Look for More?

- Visual recovery in 30-40% means no significant improvement in 60-70%
- Need for frequent injections and/or frequent visits
 - Physical burden
 - Patients
 - Families
 - Clinicians
 - Financial burden

Why Radiotherapy for Wet AMD?

- Exudative AMD demonstrates characteristics composed of angiogenic, inflammatory and fibrotic components
- Ionizing radiation has proven anti-angiogenic, anti-inflammatory and anti-fibrotic properties
- Demonstrated synergism with pharmacotherapeutic approaches
 - Avastin & Radiation therapy in colon CA

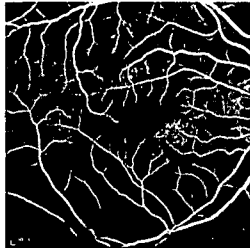
Diagnosis and Treatment of AMD

Patient Evaluation & Treatment Recommendation

Patient Evaluation

- Patient examined by retina specialist
- Diagnostic evaluation
- Discussion of treatment options

Fluorescein Angiography

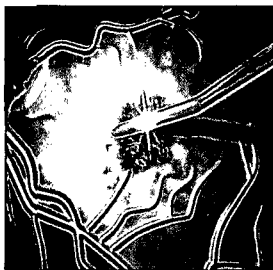


Treatment Approach

- Fluorescein-guided approach
- Decisions based upon lesion
 - Composition
 - Size
 - Location
 - Orientation



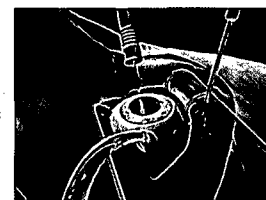
Probe Alignment



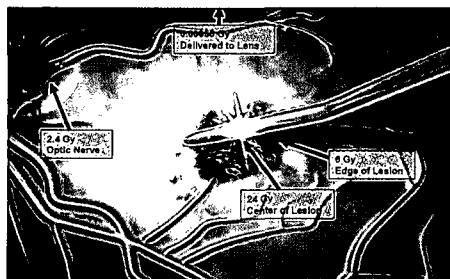
- Device orientation guided by
 - Lesion size
 - Lesion shape
 - Proximity to optic nerve
 - Proximity to normal vasculature

NeoVista Procedure

- Most recent FA image is brought to OR to help retinal surgeon confirm the placement position.
- A posterior vitrectomy procedure is performed.
- The NeoVista device is introduced into the eye and placed in mid-vitreous position.
- The radiation source is delivered to the device tip by sliding the lever down the shaft of the device and locking in place.
- The NeoVista device is then brought to the retina with the tip lightly touching the retina outside the fovea and held in place for the prescribed dwell time.
- At the conclusion of radiation delivery, the NeoVista device is brought back to the mid-vitreous position.
- The radiation source is then returned by sliding the lever back to the original position and the device is removed from the eye.



Radiation Delivery Device Positioned Over Lesion



Threshold For Clinically Observable Damage

Tissue	Effect	Dose for Clinically Observable Damage	Dose Delivered by Epi-Rad90
Cornea	Edema	30-50 Gy	.00039 Gy
Conjunctiva	Conjunctivitis	55-75 Gy	.00040 Gy
Lens	Cataract	2 Gy	.00056 Gy
Retina	Radiation Retinopathy	35-55 Gy	24 Gy
Optic Nerve	Optic Neuropathy	>55 Gy	2.4Gy

Reference: Finger PT, Berson A, Ng T, Szechtel A. Ophthalmic plaque radiotherapy for age-related macular degeneration associated with subretinal neovascularization. Am J Ophthalmol. 1999 Feb;127(2):170-7. Adapted from Bardenstein, Char and Rosenblatt

Retinal Surgeon

- Trained to handle radiation device in the eye
- The NeoVista procedure has basic treatment planning requirements as it pertains to radiation dose
- Placement and orientation of radiation device is the only changing component of the procedure and must be done by a retinal specialist

Scenario in Case of Device Malfunction

- Withdraw the Delivery Device from the eye and move away from all operating suite staff.
- Slide open end of Emergency cap over cannula end of the Delivery Device



- Gently push the Emergency cap and Delivery Device together until a firm seal is achieved



- Place the Delivery Device back into the storage/sterilization tray.
(Note: Radiation personnel may ask that the Delivery Device be put directly into the lead vault storage container for safety.)
- Replace the lid on the storage/sterilization tray and close completely
- Remove the storage/sterilization tray from the sterile field.
- NOTIFY RADIATION SAFETY PERSONNEL IMMEDIATELY OF THE SITUATION.

Listed Concerns from June 2007 NRC Meeting

Listed Concerns from June 2007 Meeting

- Used by ophthalmologists with little or no radiation training
- Little or no radiation oncologist input
- Primitive dosimetry
- Useful technology that may die away if inadequate multi-disciplinary input

Used by Ophthalmologists with Little or no Radiation Training

- 35.491 for "Training for ophthalmic use of strontium-90":
- (1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include—
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) Radiation biology; and
- (2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve—
 - (i) Examination of each individual to be treated;
 - (ii) Calculation of the dose to be administered;
 - (iii) Administration of the dose; and
 - (iv) Follow up and review of each individual's case history

Little or no Radiation Oncologist Input

- Strontium 90 utilization in the NeoVista device is a fixed treatment plan for each and every procedure.
- Far different than treatment planning in ocular tumor therapy.

Primitive Dosimetry

- Previous technique for brachytherapy dosimetry used data based on calculations from either Quimby, Patterson-Parker or Johns – the accuracy was not less than 1 mm.
- NeoVista now utilizes radiochromic film computer algorithms and NIST traceable sources. We can now work in the 100 micron range

Useful Technology That May Die Away if Inadequate Multi-disciplinary Input

- Strontium 90 epiretinal brachytherapy has shown to be promising therapy in previous Phase II studies.
 - Open cooperation between Radiation Oncology/ Medical Physics and Ophthalmology
- Phase III study also requires this cooperation in 45 sites globally

NeoVista Procedure in ASC vs HOPD

- Rapidity of disease onset, coupled with urgency of treatment application, lead to several caveats in the timely delivery of this therapy
 - 1-3 patients with new-onset exudative AMD seen in average busy retina specialist's clinic daily
 - Treatment outcomes believed best if delivered within relatively short period (1-several days)
 - Coordination of retina specialist, radiation oncologist, and OR time in a semi-urgent situation, with regular frequency is extremely unlikely

NeoVista Procedure in ASC vs HOPD

- Procedure best suited for ASC
 - Frequency of cases
 - Potential for cases daily
 - Inability to schedule
 - Easier to "add-on" to ASC than HOPD
 - Need for efficient operation
 - Retina surgeons will need to incorporate this procedure into their "daily" routine
 - Trend towards retina procedures performed in ASC an acknowledgment of this need in all surgeries

Prior Utilization of Strontium 90 Applicators for the Treatment of Ocular Disorders

Post Operative Beta Radiation of Vascularized Pterygium

Safety of Strontium Applicators for the Post Operative Treatment of Vascularized Pterygium

Nishimura Y, et al. Post Operative treatment of 490 lesions with 31-42 Gy. *Int J Radiat Oncol Biol Phys.* 2000

- scleromalacia (scleral thinning) in 4 eyes
- adhesion of eyelids in 3 eyes
- scleral ulcer in 2 eyes

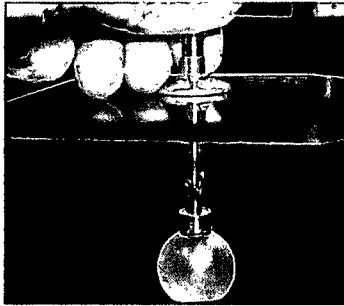
MacKenzie FD, et al. Post Operative treatment of 764 lesions with a mean of 22 Gy. *Ophthalmology.* 1991

- Scleromalacia of varying degrees in 103 (4.5% of the study group had severe thinning)
- endophthalmitis in 2 eyes

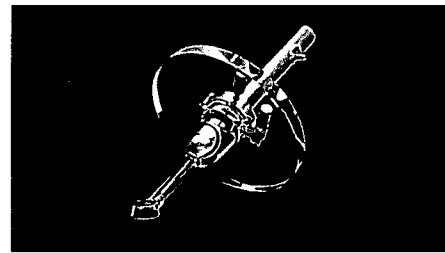
Wilder RB, et al Post Operative treatment of 338 lesions with a mean of 24 Gy. *Int J Radiat Oncol Biol Phys.* 1992

- No severe complications developed
- Ocular irritation in 17 eyes
- decreased visual acuity in 11 eyes
- scleral telangiectasia in 6 eyes
- photophobia in 6 eyes
- granuloma formation in 3 eyes
- cataracts in 3 eyes
- scleral atrophy in 2 eyes

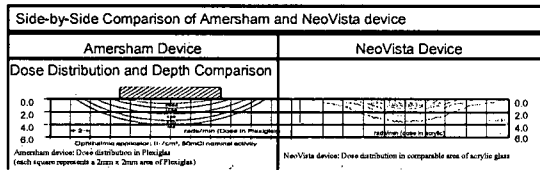
Typical extravitreous Strontium-90 Eye Applicator



NeoVista Pterygium Device



Strontium-90 Applicators for Pterygia Similar Characteristics



Summary

- NeoVista therapy is unique with regards to the interaction between the Specialties of Ophthalmology and Radiation Oncology
 - The application of radiation therapy for ocular tumors has required significant input/planning from both
 - 100% of the planning in this procedure (as it is in the surface applicator) is determined by the eye specialist

Summary

- The Safety of the device has been supported by 30 years of use in thousands of patients
 - The only complications have been ophthalmic in nature, and fully managed by the ophthalmologist
 - The level of recommended training is fully adequate to justify the use of this applicator inside the eye, which by all accounts should be safer with less risk of exposure to surrounding tissue

NeoVista Strontium 90 Device is Almost Identical to Ophthalmic Strontium 90 Surface Applicators

Strontium 90 Surface Applicator	NeoVista Strontium 90 Device
Fixed dosimetry over target area	Fixed dosimetry over target area
Applicator is positioned on cornea	Applicator is positioned on retina
Direct visualization and placement by surgeon	Direct visualization and placement by surgeon
Fixed Dosimetry	Fixed Dosimetry
No radiation management component	No radiation management component
General ophthalmologist must deliver the radiation	Retinal surgeon must deliver the radiation

We believe the NeoVista device should be viewed the same way as the strontium 90 surface applicator



Patients' Needs, Concerns, and Rights in Radiation Medicine

Darrell R. Fisher
Patients' Rights Advocate
Advisory Committee on the Medical Uses of Isotopes
Rockville, Maryland
October 27, 2008



Patient concerns

- Patients want the best possible medical care when faced with illness and disease
 - access to latest scientific advances
- Patients want protection from poor health care practices
- Patients want to understand their options for treatment; they want good information
- Patients want to be treated with dignity and respect
- Patients are concerned about long-term consequences of disease, including quality of life and financial impacts



Role of the Patients' Rights Advocate

- Provide technical advice that helps the NRC develop useful and practical medical regulations (not overly burdensome)
- Provide technical assistance in licensing, inspection, and enforcement cases, if needed
- Provide consulting services *when requested*
- Bring key issues to the attention of NRC staff for appropriate action
- Be cognizant of the impacts of NRC actions on patient access to health care, and represent the concerns of patients' rights stakeholders



Regulation and Patient Access to Best Health Care

Factors that may impact on patients' rights:

- Trade-offs between regulations that restrict or limit availability or patient access to new treatments
- Slow process for new drug or device regulatory approval
- Regulations that restrict hospitals' and physicians' ability to provide most effective treatments



- The history of the NRC Advisory Committee on the Medical Uses of Isotopes dates back to the Manhattan Project.
- The next few slides show the evolution of federal regulations concerning patients' rights in the context of radioisotope research and the practice of medicine



1946: Announcement of Radioisotopes Availability

- Memo: "Specific Proposals for the National Distribution of Radioisotopes Produced by the Manhattan Engineer District"
(January 3, 1946 from the Radioisotope Committee of Clinton Laboratories, Oak Ridge, to Colonel S. L. Warren, Medical Director of the Manhattan Project)
- Journal article: "Availability of Radioactive Isotopes: Announcement from Headquarters, Manhattan Project, Washington, D.C."
(published in *Science* 103:697-705, June 14, 1946)



Historical Context

- 1946: Manhattan Engineering District, Interim Advisory Committee on Isotope Distribution Policy
- Atomic Energy Act of 1946
- 1947: Atomic Energy Commission (AEC), Committee on Isotope Distribution Policy
 - Subcommittee on Allocation and Distribution
 - Subcommittee on Human Applications
- 1950: AEC Advisory Committee on Isotope Distribution



Historical Context (continued)

- 1953: Pres. Eisenhower's "Atoms for Peace" address to the United Nations
- Atomic Energy Act of 1954, with focus on nuclear power and peaceful applications
- Energy Reorganization Act of 1974: split the AEC into the U.S. Nuclear Regulatory Commission and the Energy Research and Development Administration
- Today: The NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) provides advice on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy



1946: Local Isotope Committees

- Two-tiered system: a) local review, and b) federal government oversight
- Experimental protocols reviewed at the local level before being approved by the federal authority to distribute radioisotopes
- Patient safety of "paramount importance"
- Risk-benefit analysis an integral component of policy on use of isotopes in humans
- *"It is not wise in any way to inhibit investigators with ideas--and yet the safety of the patient must come first."*



1949: Patient Informed Consent

1. Responsibility assumed by a special committee of at least three competent physicians belonging to the institution where the work is to be done
2. A subject must consent to the procedure
3. No reasonable likelihood of producing manifest injury by the radioisotope to be employed

(Paul Aebersold, Subcommittee on Human Applications, March 13, 1949)



1951: Federal Codification

- The first federal regulations on isotope use in human subjects were published in 10 CFR 30.50, 1951 supplement to the 1949 edition, and contained
 - administrative, facility, and personnel requirements for receiving and using radioisotopes
 - but did not include dose limits or patient-consent requirements



1956: AEC Guidelines for Use of Isotopes in Terminally Ill Patients

- Use of radioisotopes with half-lives greater than thirty days not permitted without prior animal studies to establish metabolic properties, unless patients have a short life expectancy
- Limited to patients suffering from diseased conditions and life expectancy of one year or less, with no reasonable probability of the radioactivity employed producing manifest injury

(U.S. Atomic Energy Commission, "The Medical Use of Radioisotopes: Recommendations and Requirements by the Atomic Energy Commission," RC-12, February 1956, Isotopes Extension)



1956: Guidelines for Informed Consent

- Required for all use of radioisotopes in normal (healthy) subjects
- The amount of radioactive tracer must not exceed the "permissible body burden" (an ICRP-2 concept)
- Experiments shall not normally be conducted on infants or pregnant women
- Subjects limited to "volunteers to whom the intent of the study and the effects of radiation have been outlined"
- Required that both the purpose and effects of radiation be explained to the volunteer subjects



1956: Medical Isotope Committee

- Three or more physicians plus a qualified radiation physicist
- Review and permit the use of radioisotopes within the institution from the standpoint of radiological health and safety
- Prescribe special conditions such as physical examinations, additional training, designation of limited area or location of use, disposal methods, etc.
- Review records and receive reports from its radiological safety officer
- Recommend remedial action when a person fails to observe safety recommendations and rules
- Maintain committee records



1965: AEC Guide for Medical Use of Radioisotopes

- Described the application process and specific policies for the "Non-Routine Medical Uses of Byproduct Material"
- Reiterated the exclusion of pregnant women
- Required that subject selection criteria be clearly delineated
- Required consent of human subjects or their representatives, except where this is not feasible or where consent is contrary to the best interests of the subjects



1960s: Emerging Role of the FDA

- The Food and Drug Administration developed a more active role in supervising the development of radiopharmaceuticals
- The oversight of radioisotopes research began to change
- The regulatory history of this shift in authority is complex



1997: Patients' Bill of Rights in Medicare and Medicaid

- Pres. Clinton created the Advisory Commission on Consumer Protection and Quality in the Health Care Industry, and charged it with recommending such measures as may be necessary to promote and assure health care quality and value and protect consumers and workers in the health care system
- The President asked the Commission to develop a "Patients' Bill of Rights" in health care



Patients' Bill of Rights: Goals

- Strengthen consumer confidence that the health care system is fair and responsive to consumer needs
- Reaffirm the importance of a strong relationship between patients and their health care providers
- Reaffirm the critical role consumers play in safeguarding their own health



Federal Statement on Patients' Rights

1. **The Right to Information...** to receive accurate, easily understood information needed to make informed decisions about their health plans, facilities and professionals.
2. **The Right to Choose...** to a choice of health care providers; access to appropriate high-quality health care, including access for women to qualified obstetrician-gynecologists and giving patients with serious medical conditions and chronic illnesses access to specialists.
3. **Access to Emergency Services...** the right to emergency health services when needed.
4. **Being a Full Partner in Health Care Decisions...** the right to participate in all decisions related to their health care



Patients' Rights (continued)

5. **Care Without Discrimination...** the right to considerate, respectful care, without discrimination based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.
6. **The Right to Privacy...** to communicate with health-care providers in confidence, with confidentiality of their individually-identifiable health care information protected.
7. **The Right to Speedy Complaint Resolution...** to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that serve them.



Patients' Responsibilities

1. **Maintain Good Health.** In a health care system that affords patients rights and protections, patients must also take greater responsibility for maintaining good health.

Health and Safety Code Section 1288.4; 42 CFR 482.13,
Medicare Conditions of Participation (64 Fed. Reg. 36070-
36089, July 2, 1999)



Summary and Conclusions

- The patients' rights advocate is an integral part of this NRC Advisory Committee
- Concerns for protection of patients' rights are based on historical developments that parallel the evolutionary history of this Committee
- The most important elements of patient's rights are established in federal law

**UNITED STATES NUCLEAR REGULATORY COMMISSION
CHARTER FOR THE ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES**

1. Committee's Official Designation:

Advisory Committee on the Medical Uses of Isotopes

Established Pursuant to Section 9 of Public Law 92-463 as an NRC discretionary committee.

2. Committee's objectives, scope of activities and duties are as follows:

The Committee provides advice, as requested by the Director, Division of Materials Safety and State Agreements (MSSA), Office of Federal and State Materials and Environmental Management Programs (FSME), on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. The Committee may provide consulting services as requested by the Director, MSSA.

3. Time period (duration of this Committee):

Continuing Committee.

4. Official to whom this Committee reports:

Director, Division of Materials Safety and State Agreements
Office of Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555

5. Agency responsible for providing necessary support to this Committee:

U.S. Nuclear Regulatory Commission.

6. The duties of the Committee are set forth in Item 2 above.

7. Estimated annual direct cost of this Committee:

Members are appointed by the Director, Office of Federal and State Materials and Environmental Management Programs as Special Government Employees (SGEs). Approximately 12 members utilize 1 FTE (includes approximately 0.6 FTE for NRC staff and 0.4 FTE for ACMUI member compensation and travel).

8. Estimated number of meetings per year:

Five meetings per year, three of which are teleconferences.

9. **The Committee's termination date.**

Continuing Committee subject to Charter renewal on March 17, 2010.

10. **Filing date:** March 17, 2008 .

/RA/

Andrew L. Bates
Advisory Committee Management Officer
Office of the Secretary of the Commission

ACMUI
OCTOBER 24, 2006

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT
PROGRAMS
ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES
BYLAWS

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PREAMBLE

These bylaws describe the procedures to be used by the Advisory Committee on the Medical Uses of Isotopes (ACMUI), established pursuant to Section 161a of the Atomic Energy Act of 1954, as amended, in performing its duties, and the responsibilities of the members. For parliamentary matters not explicitly addressed in the bylaws, Robert's Rules of Order will govern.

These bylaws have as their purpose fulfillment of the ACMUI's responsibility to provide objective and independent advice to the Commission through the Office of Federal and State Materials and Environmental Management Programs, with respect to the development of standards and criteria for regulating and licensing medical uses of byproduct material. The procedures are intended to ensure that such advice is fairly and adequately obtained and considered, that the members and the affected parties have an adequate chance to be heard, and that the resulting reports represent, to the extent possible, the best of which the ACMUI is capable. Any ambiguities in the following should be resolved in such a way as to support those objectives.

BYLAWS-ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

1. Scheduling and Conduct of Meetings

The scheduling and conduct of ACMUI meetings shall be in accordance with the requirements of the Federal Advisory Committee Act (FACA), as amended, 10 CFR Part 7, and other implementing instructions and regulations as appropriate.

1.1 Scheduling of Meetings:

- 1.1.1 Meetings must be approved or called by the Designated Federal Officer. At least two regular meetings of the ACMUI will be scheduled each year, one in the Spring and one in the Fall. Additionally, the ACMUI will meet with the Commission, unless the Chair or designated Chair declines or the Commission declines.
- 1.1.2 Special meetings (e.g., teleconferences and subcommittee meetings) will be open to the public, except for those meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.
- 1.1.3 ACMUI meetings will be open to the public, except for those meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.
- 1.1.4 All meetings of the ACMUI will be transcribed. During those portions of the meeting that are open to the public, electronic recording of the proceedings by members of the public will be permitted. Television recording of the meeting will be permitted, to the extent that it does not interfere with ACMUI business, or with the rights of the attending public.

1.2 Meeting Agenda:

The agenda for regularly scheduled ACMUI meetings will be prepared by the Chair of the ACMUI (referred to below as "the Chair") in consultation with the Office of Federal and State Materials and Environmental Management Programs (FSME) staff. The Designated Federal Officer must approve the agenda. The Chair, with the FSME staff's assistance, will query ACMUI members for agenda items prior to agenda preparation. A draft agenda will be provided to ACMUI members not later than thirty days before a scheduled meeting. The final agenda will be provided to members not later than seven days before a scheduled meeting.

Before the meeting, the Chair and the Designated Federal Officer for the ACMUI will review the findings of the Office of the General Counsel regarding possible conflicts of interest of members in relation to agenda items. Members will be recused from discussion of those agenda items with respect to which they have a conflict.

1.3 Conduct of the Meeting:

- 1.3.1 All meetings will be held in full compliance with the Federal Advisory Committee Act. Questions concerning compliance will be directed to the NRC Office of the General Counsel.
- 1.3.2 The Chair will preside over the meeting. The Vice Chair will preside if the Chair is absent or if the Chair is recused from participating in the discussion of a particular agenda item. The Designated Federal Officer will preside when both the Chair and the Vice Chair are absent and/or recused from the discussion, or when directed to do so by the Commission.
- 1.3.3 A majority of the current membership of the ACMUI will be required to constitute a quorum for the conduct of business at an ACMUI meeting.
- 1.3.4 The Chair has both the authority and the responsibility to maintain order and decorum, and may, at his or her option, recess the meeting if these are threatened. The Designated Federal Officer will adjourn a meeting when adjournment is in the public interest.
- 1.3.5 The Chair may take part in the discussion of any subject before the ACMUI, and may vote. The Chair should not use the power of the Chair to bias the discussion. Any dispute over the Chair's level of advocacy shall be resolved by a vote on the Chair's continued participation in the discussion of the subject. The decision shall be by a majority vote of those members present and voting, with a tie permitting continued participation of the Chair in the discussion.
- 1.3.6 When a consensus appears to have developed on a matter under consideration, the Chair will summarize the results for the record. Any members who disagree with the consensus shall be asked to state their dissenting views for the record. Any ACMUI member may request that any consensus statement be put before the ACMUI as a formal motion subject to affirmation by a formal vote. No ACMUI position will be final until it has been formally adopted by consensus or formal vote, and the minutes/transcript written and certified.

2. MINUTES/TRANSCRIPTS

- 2.1 Minutes/transcripts of each meeting will be prepared by the ACMUI Chair, with assistance from the FSME staff, in accordance with the requirements in 10 CFR Part 7. The Commission staff will prepare minutes/transcripts of ACMUI meetings with the Commission.
- 2.2 The ACMUI Chair will certify the minutes/transcripts in accordance with 10 CFR Part 7.
- 2.3 In accordance with the requirements of the NRC's Operating Plan, FSME staff will prepare a meeting summary. The FSME staff will e-mail the meeting summary document or web link to the ACMUI members.
- 2.4 Copies of the certified minutes/transcripts will be made available to the ACMUI members, and to the public, not later than 90 days after the meeting.

3. APPOINTMENT OF MEMBERS

- 3.1 The members of the ACMUI are appointed by the Director, FSME, after consultation with the Commission. The Commission determines the size of the ACMUI. The NRC will solicit nominations by notice in the Federal Register and by such other means as are approved by the Commission. Evaluation of candidates shall be by such procedures as are approved by the Director, FSME. The term of an appointment to the ACMUI is four years, and the Commission has determined that no member may serve more than 2 consecutive terms (8 years).
- 3.2 The Chair will be appointed by the Director, FSME, from the membership of the ACMUI. The Chair will serve at the discretion of the Director, FSME.
- 3.3 The Vice Chair will be appointed by the Director, FSME, from the membership of the ACMUI. The Vice Chair will serve at the discretion of the Director, FSME.

4. CONDUCT OF MEMBERS

- 4.1 If a member believes that he or she may have a conflict of interest with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and the Designated Federal Officer as soon as possible, but in any case before the ACMUI discusses it as an agenda item. ACMUI members must recuse themselves from discussion of any agenda item with respect to which they have a conflict of interest.
- 4.2 Upon completing their tenure on the ACMUI, members will return any privileged documents and accountable equipment (as so designated by the NRC) provided for their use in connection with ACMUI activities, unless directed to dispose of these documents or equipment.
- 4.3 Members of the ACMUI are expected to conform to all applicable NRC rules and regulations, and are expected to attend meetings regularly and perform all assigned duties.

5. ADOPTION AND AMENDMENTS

- 5.1 Adoption or approval of an amendment of these bylaws shall require an affirmative vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Federal and State Materials and Environmental Management Programs.
- 5.2 Any member of the ACMUI or FSME staff may propose an amendment to these bylaws. The proposed amendment will be distributed to the members by the Chair and scheduled for discussion at the next regular ACMUI meeting.
- 5.3 The proposed amendment may be voted on as early as the next ACMUI meeting after distribution to the members.
- 5.4 The ACMUI shall consult with the Office of the General Counsel regarding conflicts that arise from the interpretation of the bylaws. After consultation, the ACMUI shall resolve interpretation issues by a majority vote of the current membership of the ACMUI.