The United States Nuclear Regulatory Commission's

Advisory Committee on the Medical Uses of Isotopes

April 20-21, 2005 Meeting

Bethesda North Marriott Hotel and Conference Center
North Bethesda, Maryland

ADAMS Copy

SPEAKERS and PARTICIPATING NRC STAFF
ACMUI MEETING
APRIL 20-21, 2005

Roger W. Broseus, PhD, NMSS/IMNS/RGB

Leon S. Malmud, MD, ACMUI Chairman

Douglas F. Eggli, MD, ACMUI

Thomas H. Essig, NMSS/IMNS/MSIB, Designated Federal Official

Douglas Kondziolka, MD, International Radiosurgery Association

David Larson, MD, American Society of Therapeutic Radiology and Oncology

Angela R. McIntosh, NMSS/IMNS/MSIB

Charles L. Miller, PhD, NMSS/IMNS

Gary Purdy, NSIR

Sami Sherbini, PhD, NMSS/IMNS/MSIB

Orhan Suleiman, PhD, ACMUI

Richard J. Vetter, PhD, ACMUI

Jeffrey F. Williamson, PhD, ACMUI

AGENDA
ACMUI MEETING
APRIL 20-21, 2005

WEDNESDAY APRIL 20, 2005, MARRIOTT BETHESDA, NORTH, ROCKVILLE, MARYLAND
(Room location to be announced in reader boards throughout the hotel)

1)	8:00 – 8:05	Opening Remarks (Open Session) (Presenter: T. Essig, NRC) Mr. Essig will formally open the meeting.
2)	8:05 – 8:10	Opening Remarks (Open Session) (Presenter: C. Miller, PhD, NRC) Dr. Miller will provide opening remarks.
3)	8:10 – 9:00	Commission Briefing Preparation (Open Session) (Presenters: Dr. Eggli, Dr. Vetter, and Dr. Williamson) Presenters will use this time to will review their briefing to the Commission.
4)	9:00 - 10:00	ACMUI Review of Medical Events Involving I-131 (Open Session) (Presenter: Dr. Eggli, ACMUI) The ACMUI will provide the NRC staff its advice, recommendations, and insights regarding the cause of medical events involving I-131, and possible methods to reduce them.
	10:00 – 10:15	*****BREAK*****
5)	10:15 - 11:00	Case Experience Using I-125 Seeds as Markers (Open Session) (Presenter: R. Vetter, PhD, ACMUI) Dr. Vetter will present some actual findings from the use of I-125 seeds as markers for tumors, as experienced by Mayo Clinic.
6)	11:00 – 12:00	FDA Radiation Dose Limits for Human Research Subjects Using Certain Radiolabeled Drugs: Adults and Children (Open Session) (Presenter: Orhan Suleiman, PhD, ACMUI) Dr. Suleiman, the Food and Drug Administration representative to the ACMUI, will give a briefing designed to explain the the current FDA thinking in terms of human research issues; specifically radiation dose limits, for a certain class of radio labeled drugs.
	12:00 – 1:00	*****LUNCH*****

7) 1:00 – 2:00 Establishing Guidance on Exceeding Dose Limits for Members of the Public (Open Session)
(Presenters: S. Sherbini, PhD, NRC; Ralph Lieto, ACMUI)
Dr. Sherbini will present the staff's proposed guidance that will allow members of the public to exceed the regulatory dose limit in instances where a family member is caring for an ill relative. Mr. Lieto will also present his views.

8) 2:00 – 2:30 Status of Rulemaking, Part 35 - Training and Experience (Open Session) (Presenter: R. Broseus, Phd.,NRC)
Dr. Broseus will update the ACMUI on the progress of the Pt. 35 rulemaking.

9) 3:15 – 4:45 Commission Briefing (Open Session)
(Presenters: Dr. Eggli, Dr. Vetter, and Dr. Williamson)
Presenters will provide the Commission with a status update on the efforts of the ACMUI to recommend changes to the medical event criteria definition (Williamson); provide ACMUI opinions on the recently revised training and experience criteria for specialty board recognition (Eggli); provide an overview of its recommendations to the ICRP 60's 2005 recommendations (Vetter); and provide ACMUI opinions on the staff's report on dose reconstruction, as reported in SECY 04-0107 (Williamson).

4:45 ADJOURN***

Revised 4/11/05
Revision 7

THURSDAY APRIL 21, 2005 MARRIOTT BETHESDA, NORTH, ROCKVILLE, MARYLAND
(Room location to be announced in reader boards throughout the hotel)

10)	8:00 - 8:30	ACMUI Biennial Self-Evaluation (Closed Session) The ACMUI will formulate responses to its required biennial self-evaluation.
11)	8:30 - 9:00	Personnel Matters (Closed Session)
12)	9:00 - 10:00	Protective Measures for Control of Sources:(Closed Session) (Presenter: Gary Purdy, NSIR) Mr. Purdy, NRC/NSIR, will provide the ACMUI with an update on the Agency's security measures for the control of radioactive sources.

NOTE: The above session may be closed pursuant to See 5 U.S.C. 552b (c) (3) to discuss unclassified safeguards information

	10:00 - 10:15	*****BREAK*****
13)	10:15 - 12:00	Status and Update: Redefining Medical Events (Open Session) (Presenter: Dr. Williamson, ACMUI) Dr. Williamson will lead the discussion that will forward to NRC staff the ACMUI's recommendation(s) and risk insights regarding updating the definition of medical events in 10 CFR Part 35.
	12:00 – 1:00	*****LUNCH*****
14)	1:00 – 2:00	Patient Safety Issues with Gamma Stereotactic Radiosurgery (Open Session) (Presenter: Douglas Kondziolka, MD; International Radiosurgery Association (IRSA)) Dr. Kondziolka will present IRSA's views and recommendations on physician presence and responsibilities during gamma sterotactic radiosurgery.
15)	2:00 – 3:00	The Importance Of Radiation Oncologist Presence and Authorized User Status for Gamma Stereotactic Surgery Procedures (Open Session) (Presenter: David Larson, MD, ASTRO, former Chairman and Professor of Radiation Oncology and Neurology at the University of San Francisco.) Dr. Larson will present the views of the American Society of Therapeutic Radiology and Oncology (ASTRO) regarding the necessity of the presence of radiation oncologists during gamma stereotactic radiosurgery, to include: the training the radiation oncologist receives to perform these modalities, the added benefits to patient safety with radiation oncologist as the authorized user, and the definition of radiosurgery.
	3:00 – 3:15	*****BREAK*****

16)	3:15 – 4:15	Discussion: Physical Presence During Gamma Stereotactic Radiosurgery (Open Session) Presenters from IRSA and ASTRO, as well as other interested parties in attendance, will use this time to further discuss their recommendations and perspectives on physical presence during gamma stereotactic radiosurgery.
17)	4:15 - 4:30	Administrative Closing/Action Item Review (Open Session) (Open Session) (Presenter : Angela R. McIntosh) The NRC staff and the ACMUI will review staff response to recommendations and action items from the Fall 2004 meeting; will discuss miscellaneous items of interest arising from the April 20-21, 2005 meeting; will review action items arising from the April 2005 meeting; will discuss other non-sensitive administrative matters related to committee business, if any; and will discuss proposed meeting dates for the Fall 2005 meeting.
	4:30	**ADJOURN**

OPENING REMARKS
NO HANDOUT

TAB 4

COMMISSION BRIEFING PREPARATION

NO HANDOUT

COMMISSION BRIEFING

NO HANDOUT

ACMUI Subcommittee Review of I-131 Therapy Incidents

Douglas F. Eggli
Ralph Lieto
Sally Schwarz
Richard Vetter

Subcommittee Charge

- Review I-131 therapy incidents looking for common themes or systematic problems
- Recommend measures which might further reduce I-131 administration incidents

Materials Reviewed

- Summaries of the events from NMED were available for review
- Details were typically absent in NMED summaries
- It was assumed that all pertinent positive observations were included in the summary

Observavions

- The number of incidents is small compared to the total number of therapeutic administrations in the US on an annual basis
  - Fewer than 10 per year
- No institution has more than one error

Errors Reported were Human Errors

- Failure to pay attention to detail
- Failure to follow established policies and procedures
- Miscommunications

Recommendations

Reflect an effort to further reduce human error

Recommendations

- Patient verification procedures similar to blood administration could be considered
- Verbal orders should not be permitted in any step of the therapeutic dosage administration process

Recommendations (continued)

- The dosage to be administered must be verified against the written directive prior to administration
- Re-verify the therapeutic dosage in a dose calibrator on site prior to administration

Recommendations (continued)

- Communication between the Authorized User and the individual administering the dosage should be strengthened
  - The administering technologist should review the treatment plan with the AU prior to dosage administration

Recommendations (continued)

- Documentation in NMED needs to be improved
- Need to know causes/contributing factors:
  - Was AU present?
  - Were multiple dosages on site?
  - Was the dosage assayed on site?
  - Verbal orders?

Informational Briefing to ACMUI Revisions to Part 35 – Recognition of Board Certifications

April 20, 2005

Roger W. Broseus, Ph.D.
Office of Nuclear Material Safety and Safeguards,
Division of Industrial and Medical Nuclear Safety

Final Rule, Revise Part 35
Training and Experience (T&E)

- Published in the Federal Register
  - March 30, 2005 (70 FR 16335)
- Effective 30 days after publication
  - April 29, 2005
- Licensees to implement by October 24, 2005
  - Coincides with extended, effective date of Subpart J
- Agreement States have 3 years to adopt final rule

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Key Changes to Requirements for T&E

- Revises requirements for recognition of specialty board certifications by the NRC and Agreement States (AS)
- Applies to qualifications for individuals to serve as
  - Authorized user (AU)
  - Radiation safety officer (RSO)
  - Authorized medical physicist (AMP)
  - Authorized nuclear pharmacist (ANP)
- Also revises some requirements for "alternate pathway"

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More Highlights

- Preceptor statements
  - Changed to *attest* and *attestation* from *certify* and *certification*
  - Required for board and alternate pathways
  - Requirement 'de-coupled:' NOT required for a board's certification to be recognized

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Highlights (cont'd)

- Added requirements for use-specific training
  - For RSOs, AMPs, AUs for high-risk uses
- Removed requirement for experience with elution, etc., of generators (old 35.390(b)(1)(ii)(F))
- Decoupled requirements for experience with oral and parenteral administrations from requirements for recognition of certifications
  - former 35.390(b)(1)(ii)(G)

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Highlights (cont'd)

- New Section 35.396 – parenteral administration of unsealed byproduct material for which a written directive (WD) is required
- Provides pathway for non-AMP, medical physicists to become RSOs
- Final Rule resolves petition PRM-35-17 filed on behalf of the Organization of Agreement States (OAS)

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Resolution of PRM-35-17

- AS recommended requirements for minimum hours of classroom and laboratory training for
  - Nuclear pharmacists (ANPs, 35.55)
  - Authorized Users (AUs)
    - Uptake, dilution and excretion studies, 35.190
    - Imaging and localization studies, 35.290
    - Uses for which a WD is required, 35.390

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Requirements for Classroom and Laboratory Training (hr)

	Total	Classroom + Lab
35.55 (ANPs)	700	200
35.190 (AUs)	60	8
35.290 (AUs)	700	80
35.390 (AUs)	700	200

- Applies only to alternate pathway
- "Classroom and laboratory," not "didactic"

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Implementation of Final Rule

- Licensees have until Oct 24, 2005 to implement final rule
- Letter to boards inviting application for recognition of certifications
  - Implemented by Material Safety and Inspection Branch (MSIB)
- Licensing guidance for medical use
  - NUREG-1556, Vol. 9, Rev. 1
- Revised NRC Form 313A, "Medical Use Training and Experience and Preceptor Attestation"

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Implementation – Resources

- NUREG-1556, Vol. 9, Rev. 1 available on the NRC's web site via the Medical Uses Licensee Toolkit
  - http://www.nrc.gov/materials/miau/med-use-toolkit.html
- Federal Register Announcement and related documents
  - http://www.nrc.gov/what-we-do/regulatory/rulemaking.html
- Red-line / strike-out comparison – highlights changes

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TAB 7

Federal Register

Wednesday,
March 30, 2005

Part II

Nuclear Regulatory Commission

10 CFR Part 35
Medical Use of Byproduct Material—Recognition of Specialty Boards; Final Rule

10 CFR Part 35, Draft-final Rule
Changes Highlighted with Red-line / Strike-out Markings

This document was prepared as an aid to assist stakeholders in locating amendments to requirements for training and experience in 10 CFR 35. It is not a substitute for NRC regulations or the final rule published in the Federal Register on March 30, 2005. The comparisons appearing herein are between the final rule and current regulations in 10 CFR Part 35, including amendments to Part 35 to extend the effective date of Subpart J to October 24, 2005 (69 FR 55736, September 16, 2004). Only those sections affected by amendments appearing in the final rule are included herein.

Subpart A--General Information

* * * * *

§ 35.2 Definitions.

* * * * *

Preceptor means an individual who provides ~~or~~, directs ~~the~~, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

* * * * *

Radiation Safety Officer means an individual who–

(1) Meets the requirements in §§ 35.50(a) or (c)(1) and 35.59; or, before October 24, 2005, ~~meets the requirements in~~ §§ 35.900(a) and 35.59; or

* * * * *

§ 35.8 Information collection requirements: OMB approval.

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements in this part under control number 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.396, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.900, 35.910, 35.920, 35.930, 35.940, 35.950, 35.960, 35.961, 35.980, 35.981, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047~~;~~ and 35.3067.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 35.12, NRC Form 313, including NRC Form 313A, which licensees may use to provide supplemental information, is approved under control number 3150-0120.

(2) [Reserved]

* * * * *

§ 35.10 Implementation.

(a) A licensee shall implement the provisions in this part on or before October 24, 2002, with the exception of the requirements listed in paragraph (b) of this section.

(b) A licensee shall implement the training requirements in §§ 35.50(a) and (e), 35.51(a) and (c), 35.55(a) and (b)(1)(i), 35.59, 35.190(a) and (c)(1), 35.290(a) and (c)(1), 35.390(a) and (b)(1), 35.392(a), 35.394(a), 35.396(b) and (c), 35.490(a), 35.590(a), and 35.690(a) and (c) on or before October 25, 2005. A licensee shall implement the requirement in § 35.14(a) to provide to the Commission a copy of written attestation(s), signed by a preceptor, on or before October 25, 2005.

(c) Prior to October 25, 2005, a licensee shall satisfy the training requirements of this

part for a Radiation Safety Officer, an authorized medical physicist, an authorized nuclear pharmacist, or an authorized user by complying with either:

(1) The appropriate training requirements in subpart J; or

(2) The appropriate training requirements in subpart B or subparts D through H.

(d) If a license condition exempted a licensee from a provision of Part 35 on October 24, 2002, then the license condition continues to exempt the licensee from the requirements in the corresponding provision of §§ 35.1-35.4002.

(e) When a requirement in this part differs from the requirement in an existing license condition, the requirement in this part shall govern.

(f) A licensee shall continue to comply with any license condition that requires it to implement procedures required by §§ 35.610, 35.642, 35.643, and 35.645 until there is a license amendment or renewal that modifies the license condition.

* * * * *

§ 35.13 License amendments.

A licensee shall apply for and must receive a license amendment–

(a) Before it receives, prepares, or uses byproduct material for a type of use that is permitted under this part, but that is not authorized on the licensee's current license issued under this part;

(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except–

(1) For an authorized user, an individual who meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), 35.690(a), 35.910(a), 35.920(a), 35.930(a) and 35.390(b)(1)(ii)(G), 35.392, 35.394, 35.940(a), 35.950(a), or 35.960(a) and 35.~~59~~690(c);

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in §§ 35.55(a) or 35.980(a) and 35.59;

(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.59 and 35.51(a) and (c); or §§ 35.59 and 35.961(a) or (b)~~ and 35.59~~;

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist–

(i) On a Commission or Agreement State license or other equivalent permit or license recognized by NRC that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(ii) On a permit issued by a Commission or Agreement State specific license of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(iii) On a permit issued by a Commission master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy; or

(iv) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

(c) Before it changes Radiation Safety Officers, except as provided in § 35.24(c);

(d) Before it receives byproduct material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

(e) Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where byproduct material is used only in accordance with either § 35.100 or § 35.200;

(f) Before it changes the address(es) of use identified in the application or on the license; and

(g) Before it revises procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable, where such revision reduces radiation safety.

* * * * *

§ 35.14 Notifications.

(a) A licensee shall provide the Commission a copy of the board certification and the written attestation(s), signed by a preceptor, the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, or the permit issued by a Commission master material license broad scope permittee for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under § 35.13(b)~~(1) through (b)(4)~~. For individuals permitted to work under § 35.13(b)(4), within the same 30 day time frame, the licensee shall also provide, as appropriate, verification of completion of:

(1) Any additional case experience required in § 35.390(b)(1)(ii)(G) for an authorized user under § 35.300;

(2) Any additional training required in § 35.690(c) for an authorized user under § 35.600; and

(3) Any additional training required in § 35.51(c) for an authorized medical physicist.

(b) A licensee shall notify the Commission no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(2) The licensee's mailing address changes;

(3) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § 30.34(b) of this chapter; or

(4) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200.

(c) The licensee shall send the documents required in this section to the appropriate address identified in § 30.6 of this chapter.

* * * * *

Subpart B--General Administrative Requirements

* * * * *

§ 35.50 Training for Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who–

(a) Is certified by a specialty board whose certification process ~~includes all of the requirements in paragraph (b) of this section and whose certification~~ has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (d) and (e) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its

certification process recognized, a specialty board shall require all candidates for certification to:

(1)(i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

(iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2)(i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics–

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.290, 35.390, or, before October 24, 2005, §§ 35.920, or 35.930; and

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(b)(1) Has completed a structured educational program consisting of both:

(i) 200 hours of ~~didactic~~classroom and laboratory training in the following areas–

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct material involving the following–

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of byproduct material; ~~and~~

~~(2) Has obtained written certification, signed by a preceptor~~or

(2) [Reserved]

(c)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.51(a) and has experience in radiation safety for similar types of use of byproduct material

for which the licensee is seeking the approval of the individual as Radiation Safety Officer~~, that the individual has satisfactorily completed~~ and who meets the requirements in paragraphs (~~b~~d) and (~~1~~e) of this section~~ and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee~~; or

(~~c~~2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities~~.~~
; and,

(d) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (e) and in paragraphs (a)(1)(i) and (a)(1)(ii) or (a)(2)(i) and (a)(2)(ii) or (b)(1) or (c)(1) of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

(e) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

§ 35.51 Training for an authorized medical physicist.

Except as provided in § 35.57, the licensee shall require the authorized medical physicist to be an individual who–

(a) Is certified by a specialty board whose certification process ~~includes all of the training and experience requirements in paragraph (b) of this section and whose certification~~ has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(2) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(2) Have 2 years of full-time practical training and/or supervised experience in medical physics –

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in §§ 35.490 or 35.690, or, before October 24, 2005, authorized users who meet the requirements in §§ 35.940 or 35.960; and

(3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(b)(1) Holds a master's or doctor's degree in physics, ~~biophysics, radiological physics,~~ medical physics, ~~or health physics~~other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in

~~therapeutic radiological~~medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist ~~at a medical institution that includes the tasks listed in §§ 35.67, 35.433, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, and 35.652,~~for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

(iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(2) Has obtained written ~~certification~~attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (2), or (b)(1) and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written ~~certification~~attestation must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51, or, before October 24, 2005, § 35.961, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status~~.~~
; and

(c) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

§ 35.55 Training for an authorized nuclear pharmacist.

Except as provided in § 35.57, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who–

(a) Is certified ~~as a nuclear pharmacist~~ by a specialty board whose certification process ~~includes all of the requirements in paragraph (b) of this section and whose certification~~ has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (b)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(i) ~~Didactic~~200 hours of classroom and laboratory training in the following areas–

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving–

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid medical events in the administration of byproduct material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written ~~certification~~attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in ~~paragraph~~paragraphs (a)(1), (a)(2), and (a)(3) or (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

* * * * *

§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

(a)(1) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002, need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively.

~~(b~~

(2) An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002 and April 29, 2005 need not comply with the training requirements of §§ 35.50, 35.51, or 35.55,

respectively.

(b)(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2002, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D through H of this part.

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee ~~before October 24, 2002~~ who perform only those medical uses for which they were authorized ~~on that date~~between October 24, 2002 and April 29, 2005, need not comply with the training requirements of Subparts ~~D-H~~D through H of this part.

* * * * *

Subpart C--General Technical Requirements

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

[In the final rule, the word "draft" was removed from footnote 1 to paragraph (a).]

Subpart D--Unsealed Byproduct Material - Written Directive Not Required

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is--

(a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920; or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

* * * * *

§ 35.190 Training for uptake, dilution, and excretion studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who–

(a) Is certified by a medical specialty board whose certification process ~~includes all of the requirements in paragraph (c) of this section and whose certification~~ has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and

(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under §§ 35.290, 35.390, or, before October 24, 2005, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements; or

(c)(1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include–

(i) Classroom and laboratory training in the following areas–

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.190, 35.290, 35.390, or, before October 24, 2005, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, involving–

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) ~~Calibrating~~Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written ~~certification~~attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, 35.390, or, before October 24, 2005, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

* * * * *

§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is–

(a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920; or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section;

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

* * * * *

§ 35.290 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who–

(a) Is certified by a medical specialty board whose certification process ~~includes all of the requirements in paragraph (c) of this section and whose certification~~ has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and

(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under § 35.390 and meets the requirements in

§ 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements; or

(c)(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a ~~minimum,~~ minimum–

(i) Classroom and laboratory training in the following areas–

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290, or 35.290(c)(1)(ii)(G) and 35.390, or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements, involving–

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) ~~Calibrating~~Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written ~~certification~~attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.290~~,~~ or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

* * * * *

Subpart E--Unsealed Byproduct Material - Written Directive Required

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§ 35.390 Training for use of unsealed byproduct material for which a written directive is required.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who--

(a) Is certified by a medical specialty board whose certification process ~~includes all of the requirements in paragraph (b) of this section and whose certification~~ has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(1)(ii)(G) and (b)(2) of this section. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs (b)(1)(i) through (b)(1)(ii)(E) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or

(b)(1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include--

(i) Classroom and laboratory training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in ~~§§ 35~~§ 35.390~~(a), 35.390(b)~~, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b) or, before October 24, 2005, § 35.930(b), must also have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)~~(1), (2), (3), or (4)~~) as the individual requesting authorized user status. The work experience must involve--

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) ~~Calibrating~~Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of

unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(F) ~~Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and~~ [Reserved]

(G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status–

(1) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

(2) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131[2];

(3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

(4) Parenteral administration of any other radionuclide, for which a written directive is required; and

(2) Has obtained written ~~certification~~attestation that the individual has satisfactorily completed the requirements in ~~paragraph~~paragraphs (a)(1) and (b)(1)(ii)(G) or (b)(1) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written ~~certification~~attestation must be signed by a preceptor authorized user who meets the requirements in ~~§§ 35~~§ 35.390~~(a), 35.390(b)~~, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), or, before October 24, 2005, § 35.930(b), must ~~also~~ have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)~~(1), (2), (3), or (4)~~) as the individual requesting authorized user status.

* * * * *

§ 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).

Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who–

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section and whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.); or

---

[2] Experience with at least 3 cases in Category (G)(2) also satisfies the requirement in Category (G)(1).

(b) Is an authorized user under §§ 35.390(a), 35.390(b) for uses listed in §§ 35.390(b)(1)(ii)(G)(1) or (2), § 35.394, or, before October 24, 2005~~,~~ §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include–

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(a), 35.390(b), 35.392, 35.394, or, before October 24, 2005~~,~~ §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2). The work experience must involve–

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) ~~Calibrating~~Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation ~~for~~of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written ~~certification~~attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written ~~certification~~attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390~~(a), 35.390(b)~~, 35.392, or 35.394, or, before October 24, 2005, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2).

* * * * *

§ 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).

Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who–

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section, and whose certification has been recognized by the Commission or an Agreement State, and who meets the requirements

in paragraph (c)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.); or

(b) Is an authorized user under §§ 35.390(a), 35.390(b) for uses listed in § 35.390(b)(1)(ii)(G)(2), or, before October 24, 2005, §§ 35.930 or 35.934, or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include–

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(a), 35.390(b), 35.394, or, before October 24, 2005~~,~~ §§ 35.930 or 35.934, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve–

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) ~~Calibrating~~Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation ~~for~~of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written ~~certification~~attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written ~~certification~~attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390~~(a), 35.390(b),~~ or 35.394, or, before October 24, 2005, §§ 35.930 or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2).

* * * * *

§ 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

Except as provided in § 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who–

(a) Is an authorized user under § 35.390 or, before October 24, 2005, § 35.930 for uses listed in §§ 35.390(b)(1)(ii)(G)(3) or 35.390(b)(1)(ii)(G)(4), or equivalent Agreement State requirements; or

(b) Is an authorized user under §§ 35.490 or 35.690, or, before October 24, 2005, §§ 35.940 or 35.960, or equivalent Agreement State requirements and who meets the requirements in paragraph (d) of this section; or

(c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 35.490 or 35.690, or, before October 24, 2005, §§ 35.940 or 35.960; and who meets the requirements in paragraph (d) of this section.

(d)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV; and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include–

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390 or 35.396, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required: A supervising authorized user who meets the requirements in §§ 35.390 or 35.930 must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4). The work experience must involve–

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.396, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390, or, before October 24, 2005, § 35.930, must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4).

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Subpart F-- Manual Brachytherapy

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§ 35.490 Training for use of manual brachytherapy sources.

Except as provided in § 35.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who–

(a) Is certified by a medical specialty board whose certification process ~~includes all of the requirements in paragraph (b) of this section and whose certification~~ has been recognized by the Commission or an Agreement State, and who meets the requirements in paragraph (b)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes–

(i) 200 hours of classroom and laboratory training in the following areas–

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490, or, before October 24, 2005, § 35.940, or equivalent Agreement State requirements at a medical institution, involving–

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material;

(F) Using emergency procedures to control byproduct material; and

(2) Has ~~obtained~~completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490, or, before October 24, 2005, § 35.940, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written ~~certification~~attestation, signed by a preceptor authorized user who meets the requirements in § 35.490, or, before October 24, 2005, § 35.940, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), or (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.

§ 35.491 Training for ophthalmic use of strontium-90.

Except as provided in § 35.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who–

(a) Is an authorized user under § 35.490, or, before October 24, 2005, §§ 35.940 or 35.941, or equivalent Agreement State requirements; or

(b)(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, clinic, or private practice 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; and

(3) Has obtained written ~~certification~~attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.490~~,~~ or 35.491, or, before October 24, 2005, §§ 35.940 or 35.941, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

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Subpart G--Sealed Sources for Diagnosis

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§ 35.590 Training for use of sealed sources for diagnosis.

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) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (b) and (c) of this section and whose certification has been recognized by the Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.); or

(b) Has ~~had~~completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include–

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(5c) ~~T~~Has completed training in the use of the device for the uses requested.

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Subpart H-- Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

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§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Except as provided in § 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under § 35.600 to be a physician who–

(a) Is certified by a medical specialty board whose certification process ~~includes all of the requirements in paragraph (b) of this section and whose certification~~ has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(3) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes–

(i) 200 hours of classroom and laboratory training in the following areas–

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690, or, before October 24, 2005~~,~~ § 35.960, or equivalent Agreement State requirements at a medical institution, involving–

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation ~~oncology~~therapy, under an authorized user who meets the requirements in § 35.690, or, before October 24, 2005, § 35.960, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written ~~certification~~attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) or (b)(1) and (b)(2), and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written ~~certification~~attestation must be signed by a preceptor authorized user who meets the requirements in § 35.690, or, before October 24, 2005, § 35.960, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status~~.~~; and

(c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

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Subpart J--Training and Experience Requirements

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§ 35.980 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who–

(a) Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or

(b)(1) Has completed 700 hours in a structured educational program consisting of both–

(i) Didactic training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised experience in a nuclear pharmacy involving the following–

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(2) Has obtained written ~~certification~~attestation, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150-AH19

Medical Use of Byproduct Material—Recognition of Specialty Boards

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations governing the medical use of byproduct material to change its requirements for recognition of specialty boards whose certifications may be used to demonstrate the adequacy of the training and experience of individuals to serve as radiation safety officers, authorized medical physicists, authorized nuclear pharmacists, or authorized users. The final rule also revises the requirements for demonstrating the adequacy of training and experience for pathways other than the board certification pathway. This final rule grants, in part, a petition for rulemaking submitted by the Organization of Agreement States (PRM-35-17) and completes action on the petition.

DATES: *Effective Date:* This final rule is effective on April 29, 2005.

FOR FURTHER INFORMATION CONTACT: Roger W. Broseus, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone (301) 415-7608, e-mail *rwb@nrc.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background

During development of revised 10 CFR Part 35, published as a proposed rule on August 13, 1998 (63 FR 43516) and as a final rule on April 24, 2002 (67 FR 20249), there was a general belief that the boards, whose certifications were recognized by the NRC, would meet, or could make adjustments to meet, the new requirements established by that rulemaking governing recognition of specialty boards by the NRC and that the certifications of these boards would continue to be recognized by NRC. However, when applications for recognition were received, the NRC staff determined that, except for one board, the boards did not meet all the requirements specified in the final rule. Specifically, the boards' certification programs failed to meet the requirements in the final rule regarding preceptor (*i.e.*, an individual who provides, directs, or verifies training and experience) attestation and work experience. The only board that currently meets the revised requirements is the Certification Board of Nuclear Cardiology (CBNC) because it developed its certification program based on the final rule (published on April 24, 2002 (67 FR 20249)).

The current regulations in 10 CFR Part 35 offer three pathways for individuals to satisfy training and experience (T&E) requirements to be approved as a radiation safety officer (RSO), authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), or authorized user (AU). These pathways are: (1) Approval of an individual who is certified by a specialty board whose certification has been recognized by the NRC or an Agreement State as meeting the NRC's requirements for training and experience (a "recognized board"); (2) Approval based on an evaluation of an individual's training and experience; or (3) Identification of an individual's approval on an existing NRC or Agreement State license. For this discussion, pathway (1) will be referred to as the certification pathway, and pathway (2) as the alternate pathway.

On February 19, 2002, in a briefing of the Commission, the Advisory Committee on Medical Uses of Isotopes (ACMUI [1]) expressed concern about requirements for T&E in the revised 10 CFR Part 35, approved by the Commission on October 23, 2000 (SRM-SECY-00-0118). The ACMUI was concerned that if the requirements for recognition of specialty board certifications were to become effective as drafted, there could be potential shortages of individuals qualified to serve as RSOs, AMPs, ANPs, and AUs because they would no longer meet the requirements for T&E under the certification pathway. The ACMUI indicated that, without changes to the requirements for T&E in the final rule approved by the Commission in October 2000, the boards would no longer be qualified for recognition by NRC and, therefore, a board's future diplomates could no longer be approved as RSOs, AMPs, ANPs, or AUs.

The ACMUI also expressed the concern that the boards might be "marginalized." Specifically, under the draft final rule, to gain approval via the certification pathway, a candidate for certification would have been required to meet all of the requirements in the alternate pathway, thereby imposing more requirements beyond those already required by boards, on candidates using the certification pathway for approval. The extra requirements of concern to the ACMUI, incorporated from the alternate pathway by reference, include a specification for length-of-training as well as obtaining a written attestation signed by a preceptor. Taken together with other requirements of boards, such as requiring candidates for certification to take written and/or oral examinations, the concern was that candidates seeking approval might bypass the board certification pathway and select the alternate pathway.

Based on these concerns, the ACMUI urged the Commission to implement measures to address the training and experience issues associated with recognition of specialty boards by the NRC in the draft final rule and to find a permanent solution after publication of the final rule. Subsequently, the NRC modified the final rule by reinserting Subpart J (as contained in the proposed rule before publication of revised Part 35 in April 2002) for a 2-year transition period. Subpart J provides for continuing recognition of the specialty boards listed therein during the transition period. The final rule was published in the **Federal Register** on April 24, 2002 (67 FR 20249), and became effective on October 24, 2002. As specified in § 35.10(c), the 2-year transition period ended on October 24, 2004. In a Staff Requirements Memorandum (SRM-COMSECY-02-0014) dated April 16, 2002, the Commission directed the NRC staff to develop options for addressing the training and experience issue. The intent was to have this final rule in place before the end of the 2-year transition period. Public comment on

[1] The Advisory Committee on the Medical Uses of Isotopes (ACMUI) advises NRC on policy and technical issues that arise in the regulation of the medical uses of radioactive material. the ACMUI membership includes a representative of Agreements States and health care professionals from various disciplines who comment on changes to NRC regulations and guidance; evaluate certain non-routine uses of radioactive material; provide technical assistance in licensing, inspection, and enforcement cases; and bring key issues to the attention of the Commission for appropriate action.

the proposed rule led the NRC to conclude that the transition period should be extended for 1 year to October 24, 2005, to allow time for implementation of amendments to requirements for recognition of specialty board certifications. This extension was effected through a separate rulemaking (69 FR 55736; September 16, 2004).

The issue in question concerns the requirements in the rule governing the recognition of specialty boards by the NRC. These requirements are located in the current regulations at §§ 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590, and 35.690.

The ACMUI submitted a report to the NRC on August 1, 2002 related to the T&E requirements. The NRC staff presented three options to the Commission in a Commission paper, SECY-02-0194, dated October 30, 2002, which included the recommendations of the ACMUI in an attachment. The three options were: (1) Retain the existing requirements in the current regulations; (2) Prepare a proposed rule to modify training and experience requirements based on the recommendations submitted by the ACMUI; and, (3) The same as Option 2 with a minor modification (*i.e.*, listing all specialty boards' certifications recognized by NRC on the NRC's Web site rather than, as recommended by the ACMUI, listing some boards in the regulation and others on the Web site). In SRM-02-0194, dated February 12, 2003, the Commission approved Option 3, directing the NRC staff to prepare a proposed rule based on the ACMUI's recommendations with certain exceptions. The Commission directed that a list of recognized board certifications be posted on the NRC's Web site, that the preceptor statement remain as written in the current regulations (published April 24, 2002; 67 FR 20249), and that the staff should clarify that the preceptor language does not require an attestation of general clinical competency, but does require sufficient attestation to demonstrate that the candidate has the knowledge to fulfill the duties of the position for which certification is sought. This form of attestation should be preserved both for the certification pathway and the alternate pathway.

During a teleconference with the ACMUI, conducted on July 17, 2003, the ACMUI members continued to voice concern about having recognition of board certifications conditioned on requiring candidates for certification to obtain written attestation of competency signed by a preceptor. The ACMUI recommended that if the Commission still maintained that it was necessary to include a preceptor statement for all authorized positions named in 10 CFR Part 35, this requirement should be separated from the criteria for recognition of board certifications, as well as for the alternative pathway. Agreement State representatives participated in the teleconference and agreed with this recommendation. In a letter, dated July 23, 2003, the ACMUI recommended that the requirements for a preceptor statement be removed from the certification pathway; however, if the Commission still believed it necessary to include a preceptor statement for all "authorized positions" named in 10 CFR Part 35, the ACMUI recommended that this requirement be separated from the board certification pathway and that it be specified separately as a new paragraph in each training section.

The NRC staff submitted a proposed rule to the Commission on August 21, 2003 (SECY-03-0145). The Commission approved the NRC staff's recommendation to publish the proposed rule, with certain changes directed by the Commission, in SRM-03-0145, dated October 9, 2003. The Commission approved the recommendation of the ACMUI that the requirement for a preceptor statement be removed from the requirements for recognition of specialty board certifications. The Commission also indicated it should be made clear in the proposed rule language that a preceptor statement is required regardless of which training pathway is chosen. The proposed rule was published for a 75-day comment period on December 9, 2003 (68 FR 68549). The NRC staff posted a comparison document, with differences between the current and proposed rule highlighted, on the NRC's rulemaking forum on December 19, 2003, to facilitate public understanding and stakeholder review of proposed changes to 10 CFR Part 35.

The ACMUI provided comments on the proposed rule at its meeting on March 1-2, 2004. The ACMUI also conducted a public meeting via teleconference on March 22, 2004, to discuss, in part, additional recommendations related to the proposed rule. Following receipt of public comments, the NRC staff distributed a draft final rule to ACMUI and Agreement States for their 30-day review and comment. The NRC considered the additional comments received in developing the final rule. These comments are discussed in Section IV, "Summary of Public Comments and Responses to Comments."

II. Petition for Rulemaking

The Organization of Agreement States (OAS) (petitioner) filed a Petition for Rulemaking (petition) dated September 3, 2004 (PRM-35-17) requesting that the NRC amend §§ 35.55, 35.190, 35.290 and 35.390 to define and specify the minimum number of "didactic" training hours for Authorized Nuclear Pharmacists and Authorized Users identified in these sections. Notice of receipt of the petition was published in the **Federal Register** on October 28, 2004 (69 FR 62831). The terms "didactic training" and "classroom and laboratory training" were used interchangeably by the Agreement States in their comments and both terms are used in the current regulations in Part 35. The term "classroom and laboratory" will be used hereinafter to refer to this type of training.

The petitioner states that, in the current regulations in these sections, the minimum numbers of hours of classroom and laboratory training in radiation safety are not specified or separated from the total training hours. The petitioner notes that Subpart J does include a requirement for a minimum number of classroom and laboratory training hours as well as supervised work experience.

The petitioner asserts that the T&E requirements have been designated as "Category B" for Agreement State compatibility to provide nationwide consistency and uniformity of authorized user credentialing, and that the lack of clearly defined classroom and laboratory training hours for these authorized users weakens the consistency and uniformity of the rule. The petitioner also believes that the need for specified classroom and laboratory training hours is a radiation safety issue rather than a "practice of medicine" issue in that radiation safety for the patient and the occupational radiation workers may be compromised, and that a majority of radiation safety principles and procedures are learned during classroom and laboratory training.

As discussed further in subsequent sections of the **SUPPLEMENTARY INFORMATION**, during the 75-day public comment period for the proposed rule, ending on February 23, 2004, the NRC received comments which raised the same issues as those raised by the petitioner. Because of the similarity in issues raised, the NRC has determined to consider the OAS petition as part of this rulemaking.

During resolution of the comments, the NRC staff consulted with the ACMUI and Agreement States on how to

ensure adequacy of T&E in radiation safety and consistency of requirements for T&E between Agreement States and between Agreement States and the NRC. Agreement State representatives served as members on an NRC working group to develop this rule. A steering group was formed to provide recommendations to resolve the issue raised by the Agreement States, during comments on the proposed rule, on requirements for classroom and laboratory training. The working group addressed issues raised in the petition related to specifying hours of classroom and laboratory training in 10 CFR Part 35. The NRC staff consulted with and received comments from the ACMUI via a public teleconference on the issue on October 5, 2004, with participation of Agreement States, and during its meeting on October 13–14, 2004. After consideration of the input from these sources, as well as review and analysis of the issue by the working and steering groups, the NRC has determined to grant the petition in part, and is revising §§ 35.55, 35.190, 35.290, and 35.390, in the final rule, to establish a requirement for minimum number of hours of classroom and laboratory training for the alternate pathway. The petition is denied, in part, in so far as the NRC is not requiring a minimum number of hours of classroom and laboratory training for the certification pathway. The NRC staff believes that such a requirement would unnecessarily limit the flexibility of boards to determine their certification requirements. The rationale for this change to requirements for T&E is explained in the NRC's response to comments on the proposed rule in Section IV. Summary of Public Comments and Responses to Comments, under Part II—General Issues (Issue 1), and Part IV—Implementation by Agreement States—Timing and Compatibility (Issue 2).

This completes action on PRM–35–17.

III. Discussion

The principal changes in the final rule involve revising the criteria for recognizing the certifications of specialty boards. These changes relate to the requirements for T&E that boards would place on candidates seeking board certification. The NRC staff reviewed board certification procedures and made a determination that, with one exception, the boards' certification programs failed to meet the requirements in the current regulations regarding preceptor certification (attestation) and work experience. This assessment[2] resulted from a detailed comparison, performed by the NRC staff, between requirements in the regulations (in Subparts B and D through H) and specialty board requirements for certification. The changes resulting from adoption of the final rule will resolve the issues related to recognition of board certifications by instituting requirements that are less prescriptive, while maintaining public health and safety. These changes will ensure that a clear regulatory determination can be made that specialty boards, both new and existing, meet the relevant criteria for recognition by the NRC or an Agreement State. Changes have also been made to the T&E requirements for the alternate pathway. The final rule provides a more flexible and performance-based approach to specifying requirements for training and experience, using a graded approach to ensure that training in radiation protection is consistent with the need for adequate understanding and skills.

The changes to T&E requirements are intended to address issues raised by the ACMUI. However, the NRC disagrees with the ACMUI's belief that the T&E criteria in the current rule would result in candidates bypassing board certification. The NRC believes that board certification has been, and will continue to be, essential for physicians, including AUs, to practice medicine. While health physicists, medical physicists, nuclear pharmacists, and physicians can serve in the respective categories of RSO, AMP, ANP, and AU by satisfying T&E requirements under the alternate pathway, the NRC believes that individuals who would have sought certification are likely to continue to do so because certifications are useful to individuals for reasons other than satisfying requirements in 10 CFR Part 35, *e.g.*, measuring areas of competence that go beyond regulatory requirements established under the Atomic Energy Act. Furthermore, some State agencies now require that individuals be certified by specialty boards before they can practice in some specialties, *e.g.*, as medical physicists and nuclear pharmacists.

Changes to the Certification Pathway

For the certification pathway, the current regulations incorporate the more prescriptive requirements from the alternate pathway. This final rule establishes less prescriptive criteria board certifications to be recognized the NRC or an Agreement State.

For the RSO, AMP, and ANP, the revised criteria include a degree from an accredited college or university, professional experience, passing an examination administered by the board, and in some cases, additional training related to the type of use for which an individual would be responsible. The requirement for passing an examination reflects the current practice of certification boards.

The addition of a requirement in § 35.50(a) for candidates for RSO to have a degree is consistent with current standards of certification boards to require a minimum of a baccalaureate degree. The NRC believes that this requirement helps ensure that a candidate for RSO has the level of knowledge necessary to fulfill the duties of an RSO. However, this final rule retains current regulatory provisions that allow candidates who do not hold a degree required under revisions to § 35.50(a) to qualify for positions as RSO under provisions in § 35.50(b). Requirements for T&E of candidates to serve as AMPs have been revised for the board certification pathway, in § 35.51(a)(2), to require 2 years of ful time practical training and/or supervised experience under the supervision of a medical physicist certified by a specialty board, whose certification is recognized by the NRC or an Agreement State, or in clinical radiation facilities providing high-energy, external beam therapy and brachytherapy services under the direct supervision of physicians who meet the requirements for AUs in §§ 35.490 or 35.690 or under supervision of a certified medical physicist in clinical radiation facilities. This T&E will help ensure that candidates have the level of knowledge necessary to fulfill the duties of an AMP.

The current regulations in 10 CFR Part 35 provide for a preceptor, defined in § 35.2, to certify that individuals have satisfactorily completed requirements for T&E and have achieved a level of radiation safety knowledge sufficient to function independently as RSOs, AMPs, ANPs, and AUs. In response to public comments, as discussed under the heading "IV. Summary of Public Comments and Responses to Comments," the NRC is now using "attestation" and "attest" in place of "certification" and "certify" in 10 C' Part 35. A preceptor attestation is commonly referred to as a "preceptor statement," and this term is used

[2] "Comparison between NRC requirements and boards' certification programs," attachment 2 to SECY–02–0194, "options for addressing Part 35 Training and Experience Issues Associated With Recognition of Speciality Boards by NRC." SECY–02–0194 is available on the NRC's Web site, *http://www.nrc.gov*, in the "Electronic Reading Room."

interchangeably with the term "preceptor attestation" in the SUPPLEMENTARY INFORMATION, particularly in the summary of public comments, to reflect this usage by commenters.

The requirement that boards must have candidates for certification obtain a preceptor attestation as a condition for NRC recognition of certifications has been removed in the final rule; however, individuals are still required to obtain preceptor attestations, and licensees are required to submit them to the NRC (except as provided in § 35.15(d)). This is an addition to the current requirement in § 35.14(a) to provide a copy of board certifications to the NRC. Further discussion of the requirement for a preceptor attestation appears under the heading "Preceptor Attestation." The certification pathway also includes a specification for the number of hours of training and experience for ANPs and AUs for certain uses of byproduct material under §§ 35.100, 35.200, 35.300 (in §§ 35.390, 35.392, 35.394, and 35.396 for uses under § 35.300), and 35.500. The ACMUI recommended, for the proposed rule, that the requirement for 200 hours of classroom and laboratory training, now required in §§ 35.490 and 35.690, be removed because it believes that the combination of degree, practical experience, and examination in the criteria for recognizing certifying boards is equivalent to the number of hours of classroom and laboratory training specified for the alternative pathway. A detailed analysis of T&E requirements was performed by NRC staff and appears as Attachment 1 to SECY–02–0194, "OPTIONS FOR ADDRESSING PART 35 TRAINING AND EXPERIENCE ISSUES ASSOCIATED WITH RECOGNITION OF SPECIALTY BOARDS BY NRC." The NRC believes that, although the requirements are not identical, the T&E standard for recognizing certifying boards will be equivalent to the standard for the alternate pathway. The board certification process requires a candidate to have an academic degree, complete practical experience or a residency program, and pass an examination. Examinations test the knowledge and skills required to perform the applicable activities, including those in §§ 35.490(a)(2) and 35.690(a)(2), to ensure radiation safety. The NRC believes that the combination of a degree, practical experience, and an examination, in the criteria for recognizing certifying boards, will be equivalent to the number of hours of classroom and laboratory training specified for the alternate pathway. Further, the requirement in the certification pathway for §§ 35.490 and 35.690 for completion of an approved residency program, provides added assurance that T&E is sufficient. Therefore, the requirement for 200 hours of classroom and laboratory training does not apply to the criteria for recognition of board certification processes in §§ 35.490, and 35.690 of the final rule.

The ACMUI's recommendations included the addition of the Royal College of Physicians and Surgeons of Canada (RCPSC) in listings of entities which approve residency training to satisfy requirements for the board certification pathway for uses under §§ 35.300, 35.400, and 35.600. While the RCPSC was named in Subpart J of the current rule, it is not named in other subparts. There are reciprocal arrangements between U.S. entities and the RCPSC regarding approval of residency programs. Thus, the NRC finds these reciprocal agreements to be a sufficient basis to provide that RCPSC be included in various sections of 10 CFR Part 35.

The final rule provides the boards more latitude in making the determination that individuals are fully trained and capable of performing their duties involving radiation safety. These changes to the certification pathway continue to ensure the safe use of byproduct material by medical licensees by establishing criteria for specialty boards to use in granting certifications. The NRC made a determination that, with the exception of one specialty board, the boards do not meet the requirement in the current rule regarding preceptor certification and work experience. With more latitude under the certification pathway in the final rule, the NRC believes that boards will be able to meet the revised requirements for recognition of board certification processes.

Changes to the Alternate Pathway

The final rule also contains revised requirements for some of the alternate pathways. Some of these changes are minor and clarify the requirements for T&E.

The ACMUI's recommendations for approval as an AU in the alternate pathway in §§ 35.490(b) and 35.690(b) include the addition of the RCPSC to the listings of organizations that approve residency programs. The NRC finds that RCPSC should be included in the listing for the reasons previously discussed under the heading, "Changes to the Certification Pathway."

In comments on the proposed rule, Agreement States recommended that a minimum number of hours of "didactic" training in basic radionuclide handling techniques should be specified for individuals to qualify as ANPs under § 35.51 and as AUs under §§ 35.190, 35.290, and 35.390. The NRC understands that references by Agreement States to "didactic training" refers both to the "didactic training," currently required to qualify as an authorized nuclear pharmacist under current regulations in § 35.55(b)(1)(i), as well as the "classroom and laboratory training" required to qualify as an authorized user in §§ 35.190(c)(1)(i), 35.290(c)(1)(i) and 35.390(b)(1)(i). The term "classroom and laboratory training" will be used hereinafter to refer to this type of training. As discussed in Part II, Issue 1, and Part IV, Issue 2, of the Summary of Public Comments, the final rule specifies minimum number of hours of classroom and laboratory training for the alternate pathway.

Training Specific to Type of Use

The ACMUI recommended that, in addition to meeting minimum T&E requirements, authorized individuals should have training or experience in the use of byproduct material or specific modalities (types of use), as appropriate, for which a licensee is authorized. The ACMUI also recommended that the requirement apply to newly hired, authorized individuals and when a new type of use is added to the licensee's program. The NRC supports these changes, believing that they will ensure that a licensee's staff has adequate knowledge and experience to fulfill the duties for which they are responsible. The final rule includes new paragraphs that add this requirement in § 35.50(e) for RSOs, § 35.51(c) for AMPs, and for AUs in § 35.690(c) for remote afterloader, teletherapy and gamma stereotactic radiosurgery units. For uses under § 35.300, requirements in §§ 35.390(b)(1) and 35.396(d) provide for training specific to type of use which applies to both the board certification and alternate pathways.

Other Changes

In the current regulations, § 35.390(b)(1)(ii)(G) specifies that work experience for uses of byproduct material in unsealed form, for which a written directive (WD) is required, must include administering dosages of radioactive drugs involving a minimum of three cases in each of the categories for which the individual is requesting authorized user status. Sections 35.390, paragraphs (b)(1)(ii)(G)(*1*), (*3*) and (*4*) refer to oral and parenteral administration of certain radionuclides.

The final rule clarifies that this training must be with quantities of radionuclides for which a WD is required. The NRC believes these changes are necessary because, without them, an individual might cite experience with low-level dosages to satisfy requirements for work experience; the changes place emphasis on the need for AUs to have work experience with higher level dosages, for which a WD is required. Similar requirements have also been incorporated into new § 35.396(d).

The ACMUI and public commenters on the proposed rule stated that the physicians, who have sufficient T&E to serve as AUs for the medical use of unsealed byproduct material for which a WD is required, are unable to meet the requirements for use in Subpart E. As discussed in response to public comments on § 35.390, this issue was resolved by the inclusion of a new § 35.396, entitled, "Training for the parenteral administration of unsealed byproduct material requiring a written directive." A conforming change was also made to § 35.8, "Information collection requirements: OMB approval," to indicate that an information collection requirement applies to § 35.396.

The ACMUI recommended that the requirements for work experience for authorized users in §§ 35.190, 35.290, and 35.390 be changed to require experience with performing quality control check of instruments rather than with calibrating instruments. In addition to instrument calibration, quality control procedures commonly include checks of parameters such as linearity, constancy, and functionality (including battery checks). The NRC agrees with the ACMUI's recommendation because ensuring proper function of these instruments involves more than periodic calibration. The final rule effects these recommendations with changes to §§ 35.190(c)(1)(ii)(B), 35.290(c)(1)(ii)(B), 35.390(b)(1)(ii)(B), 35.392(c)(2)(ii), and 35.394(c)(2)(ii). Similar requirements have also been incorporated into new § 35.396(d)(2).

Training requirements for authorization as a medical physicist have been changed in § 35.51(b)(1) to remove specific requirements for a degree in biophysics, radiological physics, and health physics, and add the more general, other physical sciences, as well as engineering and applied mathematics. The requirement for 1 year of full-time training in therapeutic radiological physics has been changed to a more general requirement for 1 year of full-time training in medical physics. In § 35.690(b)(2), the requirement for candidates to be approved as AUs has been changed to broaden the requirement that supervised clinical experience be received in "radiation therapy" rather than in "radiation oncology." These changes are needed to allow for the therapeutic use of byproduct material in applications other than cancer therapy.

Current regulations in § 35.50(c) provide that an AMP identified on a licensee's license can serve as an RSO, provided that the individual has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has responsibilities as an RSO. However, current regulations only require services of an AMP for uses under §§ 35.433 and 35.600; a few AMPs are also named on licenses for uses under § 35.1000. Therefore, individuals who may have adequate T&E to serve as AMPs for types of use licensed under §§ 35.100, 35.200, 35.300, 35.400 and 35.500, are not listed on an NRC or Agreement State license under current rules. Medical physicists who are certified by a specialty board whose certification is recognized by the Commission or an Agreement State have training and experience in radiation safety aspects of the use of byproduct material for medical purposes. The regulations in § 35.50 have been changed to allow medical physicists, who are certified by a specialty board whose certification is recognized by the NRC or an Agreement State, to serve as RSOs, while retaining the requirement that these individuals have experience specific to the types of use for which they would be responsible. This change removes an impediment for individuals who have adequate T&E to become approved as RSOs. It also avoids placing a burden on licensees to apply for an exemption to regulations and on NRC and Agreement State staff who would be required to process an application for an exemption to regulations to approve a licensee's request to have a medical physicist, certified by a specialty board whose certifications are recognized by the NRC, serve as an RSO. Comments on the proposed rule indicated that medical physicists generally have adequate T&E to serve as RSOs. As discussed in response to comments on § 35.50, this section has also been amended to provide criteria for medical physicists, other than those who are AMPs, to serve as RSOs.

The term "high-energy" is used in the rule text in §§ 35.51(a)(2)(ii) and 35.51(b)(1) to specify the type of training to be included in T&E for AMPs. High-energy radiation is specified, in §§ 35.51(a)(2)(ii) and 35.51(b)(1) of the final rule, as photons and electrons with energies greater than or equal to 1 million electron volts, which is consistent with the definition of high-energy used by the International Commission on Radiation Units and Measurements in Report 42, *Use of Computers in External Beam Radiotherapy Procedures with High-Energy Photons and Electrons.*

In § 35.75(a), reference is made to "draft" licensing guidance in NUREG–1556, Vol. 9. This guidance was published in final version in October 2002. Therefore, the "draft" designation is being removed.

Preceptor Attestation

Part 35 currently requires a written certification, termed attestation in this final rule (and referred to as attestation in this discussion, when appropriate), that the individual has satisfactorily completed the required training, has achieved a level of knowledge or competency sufficient to function independently, and requires that the written certification be signed by a preceptor who is a radiation safety officer, authorized medical physicist, authorized nuclear pharmacist or authorized user. This requirement applies to both the board certification and alternate pathways.

The ACMUI recommended that, instead of certifying "competency," the preceptor should attest that the individual has satisfactorily completed the required training and experience. It further recommended that a training program director be allowed to sign the written attestation.

As explained previously, the Commission considered recommendations of the ACMUI and determined in SRM–02–0194, "OPTIONS FOR ADDRESSING PART 35 TRAINING AND EXPERIENCE ISSUES ASSOCIATED WITH RECOGNITION OF SPECIALTY BOARDS BY NRC," that the preceptor statement should remain as written in the current regulations. However, the Commission emphasized that the preceptor language does not require an attestation of general clinical competency, but requires sufficient attestation to demonstrate that the candidate has the knowledge to fulfill the duties of the position for which certification is sought.

The ACMUI also recommended that the Commission separate the requirement to obtain a preceptor statement from the certification and alternate pathways, and to specify this requirement as a new paragraph in the sections dealing with T&E for RSOs, AMPs, ANPs, and AUs. The

Commission approved this recommendation of the ACMUI, placing the requirement on licensees to submit the preceptor statements to the NRC. This requirement appeared in the proposed rule. The regulations retain the requirements that individuals obtain preceptor attestations for both the certification and alternate pathways.

The requirement for licensees to submit a preceptor attestation to the NRC appears in revised § 35.14(a).

Listing of Recognized Board Certifications

The NRC will list on its Web site (*http://www.nrc.gov/materials/miau/med-use-toolkit.html*), instead of in its regulations, the names of board certifications for those boards whose certification processes meet the NRC's requirements. This approach has the advantage of eliminating the need to amend 10 CFR Part 35 to effect recognition each time a new board needs to be added to the listing. The ACMUI and specialty board representatives who participated in a public meeting on May 20, 2003, were in agreement with this approach.

Because of the importance of board certification in establishing the adequacy of T&E for individuals to serve as RSO, AMPs, ANPs, and AUs, a clear regulatory determination must be made that all boards, both new and existing, meet the relevant regulatory criteria. Evaluation of board requirements against revised criteria in the final rule is necessary to make this determination. Boards that are currently listed in Subpart J of Part 35 and other boards are required to apply for recognition under this rule. When necessary, the NRC staff will review a board's submittal with the ACMUI before a decision on recognition of a board is made.

The NRC will place the procedures for listing and delisting of specialty boards on its Web site at the time of publication of the final rule. Because of the important role of board certification, the procedures will provide for making a clear regulatory determination that boards, both new and existing, meet the relevant criteria in the revised regulations. The procedures provide for both adding new specialty boards to the listing of recognized certifications and for removal from the list.

The NRC staff does not intend to conduct inspections of the specialty boards whose certification processes it recognizes but will monitor trends in medical events. If the NRC staff determines that a series of medical events is associated with a particular specialty, and the trend can be attributed to inadequate radiation safety training, the staff will determine whether the inadequate training is related to a deficiency in a board's evaluation of the radiation safety competency of the board's diplomates. The NRC conducts a comprehensive regulatory program to ensure safety. This regulatory program is also important to the identification of issues related to T&E that may, in turn, point to issues associated with the certification process of a specialty board. If these activities result in identification of a deficiency in a board's evaluation of the radiation safety competency of the board's diplomates, the NRC staff will review the specialty board's certification program. The assessment will include a determination of whether the board's examination adequately assesses the requisite knowledge and skills in radiation safety. If the staff determines that changes in the board's evaluation of competency in radiation safety are necessary, and the board either cannot or will not make adequate changes to its program to address these needs, then the NRC will withdraw recognition of that specialty board's certification processes and delist that board. The NRC staff will inform the Commission and the ACMUI of an NRC staff decision to withdraw recognition. The NRC has reviewed existing procedures for the conduct of inspections and has determined that they provide for collection of the information necessary to evaluate trends in medical events possibly related to requirements for T&E of specialty boards. The NRC staff provided a copy of draft plans for implementation of the procedures for listing and delisting of board certifications to Agreement States and the ACMUI during the development of the proposed rule. The comments provided by these groups were considered by the NRC staff in developing final procedures for implementation.

Stakeholder Interactions

On May 20, 2003, a public meeting was held to solicit early input on the proposed rule from representatives of professional specialty boards and other interested stakeholders. The NRC staff also made a presentation to the ACMUI on May 20, 2003, regarding the staff's approach to the proposed rule. The ACMUI provided input and a comment was received via e-mail from a participant in the meeting with the boards.

The proposed rule was published in the Federal Register on December 9, 2003 (68 FR 68549). The NRC staff briefed the ACMUI on the proposed rule during its meeting on March 2, 2004, and received comments from the ACMUI on the proposed rule during this meeting and a public teleconference conducted on March 22, 2004. Comments of the ACMUI, Agreement States, board members, and members of the public provided useful information to the NRC in preparing the proposed and final rule. A person from the State of Alabama, nominated by the Organization of Agreement States, participated as a member of the working group with the NRC staff in the development of the proposed and final rule. A person from the State of New York, nominated by the CRCPD, was added to the working group and participated in the resolution of comments on the proposed and draft final rule. The NRC staff distributed a draft final rule to the Agreement States and the ACMUI for 30-day review, ending on October 18, 2004. During this time, the ACMUI held a publicly announced meeting, via teleconference, on October 5, 2004, with Agreement State participation, to discuss requirements for a minimum number of hours of classroom and laboratory training in §§ 35.55, 35.190, 35.290, and 35.390. The meeting was announced in the Federal Register on September 28, 2004 (69 FR 57977). Approximately 37 representatives of 22 Agreement States participated in the meeting. The ACMUI also discussed the draft final rule, and made recommendations to the NRC, during its meeting on October 13–14, 2004. These comments are discussed in Section IV. Summary of Public Comments and Responses to Comments.

Additional Recommendations of the ACMUI

At the teleconference held on July 17, 2003, the ACMUI discussed the draft proposed rule; Agreement State representatives also participated in the teleconference. During the teleconference, the ACMUI agreed with the NRC staff recommendation to broaden the requirement that supervised clinical experience be received in a "radiation facility" rather than in a "radiation oncology facility" for individuals to qualify as AMPs, in § 35.51(b)(1) of the proposed rule, and to change the requirement for experience in "radiation oncology" in § 35.690(b)(2) to allow for experience in "radiation therapy." Parallel changes were made to the certification pathway for AMPs in the proposed rule in § 35.51(a)(2)(ii) and in § 35.690(a)(1) for uses under § 35.600. These changes were retained in the final rule.

The ACMUI recommended that the requirements for experience, described

in the current rule in § 35.390(b)(1)(ii)(G), not be included in criteria for recognition of specialty board certifications, but that they continue to be required for AUs meeting T&E requirements for both the certification and alternate pathways. This recommendation was not incorporated into the proposed rule, because the NRC staff believed that the requirements for work experience in § 35.390(b)(1)(ii)(G) are essential for an individual to be able to function independently as an AU for administration of byproduct material for which a WD is required. As discussed in the response to public comments on the proposed rule, the ACMUI raised this recommendation again, indicating that many individuals obtain the experience required in § 35.390(b)(1)(ii)(G) after they have obtained their board certification. After further consideration, the requirement for this experience was removed from requirements for recognition of board certifications in the final rule but retained as a requirement for individuals to be AUs.

At the teleconference held on March 22, 2004, the ACMUI recommended removal of requirements, in § 35.390(b)(1)(ii)(F), for experience with elution of generators and measuring, testing, and preparation of radiolabeled drugs. As indicated in the discussion of public comments on § 35.390, this requirement has been removed from this section in the final rule but retained in other sections when individuals qualify as AUs by virtue of being approved as an AU under § 35.390. Additional recommendations, made by the ACMUI during the meeting on October 13–14, 2004, are discussed in Section IV. Summary of Public Comments and Responses to Comments.

Timing of Agreement State Implementation

Normally, Agreement States have 3 years in which to adopt a compatible rule. Agreement States have until October 24, 2005, to adopt the revised 10 CFR Part 35 published on April 24, 2002. It was noted in the SUPPLEMENTARY INFORMATION for the proposed rule that, for Agreement States to adopt the proposed training and experience requirements and have them in place by October 24, 2005, the Agreement States would have a shortened time frame for developing compatible requirements. Because Agreement States had voiced concern regarding this shortened time frame, the NRC invited public comment on this issue. As indicated in "IV. Summary of Public Comments and Responses to Public Comments," the NRC is allowing 3 years for adoption of this final rule.

Revision of Guidance for Licensing of Medical Use of Byproduct Material

Licensing guidance for medical uses of byproduct material is available in NUREG–1556, Vol 9, "Consolidated Guidance About Materials Licenses. Program-Specific Guidance About Medical Use Licenses." The NRC has revised this guidance to conform to the revisions in this final rule and is making it available to the public coincident with publication of the final rule.

Extension of Subpart J to October 24, 2005

The NRC has extended the expiration date for Subpart J to October 24, 2005, through a separate rulemaking (69 FR 55736, September 16, 2004).

IV. Summary of Public Comments and Responses to Comments

The NRC received 27 comments on the proposed rule. The commenters included members of the general public and the ACMUI as well as representatives of Agreement States, professional societies, and certification boards. Additional comments from Agreement States were received on a draft of the final rule distributed made available to Agreement States for a 30 day comment period, ending on October 18, 2004. Copies of the public comments are available for review in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD.

This section summarizes the written and oral comments received and provides responses to these comments. Part I contains a list of the acronyms used in this section. Part II contains a discussion of general issues that were considered during the rulemaking. Part III contains a discussion of comments on specific sections in the proposed rule. Comments on timing of adoption of the rule by Agreement States and compatibility are discussed in Part IV.

The NRC posed three questions in the "Invitation for Public Comment on Specific Issues" section of the proposed rule. These questions were:

1. Do the proposed revisions to requirements for training and experience provide reasonable assurance that RSOs, AMPs, ANPs, and AUs will have adequate training in radiation safety? (This question is discussed in Part II—General Issues, Issue 1.)

2. Should Agreement States establish the requirements to conform with this proposed rule by October 24, 2005, or should they follow the normal process and be given a full 3 years to develop a compatible rule? (This question is discussed in Part IV—Implementation by Agreement States—Timing and Compatibility.)

3. Should the word "attestation" be used in place of the word "certification" in preceptor statements? (This question is discussed in Part II—General Issues, Issue 2.)

Part I—Acronyms

The following acronyms are used in the discussion of both the general and specific comments.

ACGME—Accreditation Council for Graduate Medical Education
ACMUI—Advisory Committee on the Medical Uses of Isotopes
ACPE—American Council on Pharmaceutical Education
ABMS—American Board of Medical Specialties
AMP—Authorized medical physicist
ANP—Authorized nuclear pharmacist
AU—Authorized user
FPGEC—Foreign Pharmacy Graduate Examination Committee
NMED—Nuclear Materials Events Database
OAS—Organization of Agreement States
RSO—Radiation safety officer
T&E—Training and experience
WD—Written directive

Part II—General Issues

Several commenters expressed general support for the proposed rule as well as offering comments on specific aspects of the proposed rule, which are discussed further in succeeding sections. Support was also voiced for the listing of recognized board certifications on the NRC's Web site rather than in regulations.

Issue 1: Do the proposed revisions to requirements for training and experience (T&E) provide reasonable assurance that RSOs, AMPs, ANPs, and AUs will have adequate training in radiation safety?

Comment: One commenter suggested that the NRC should go back to its original preceptor concept, under which no board certifications were required, but the preceptor (mentor) had the responsibility to ensure that training was adequate to ensure health and safety and medical efficacy. The commenter expressed concern that applicants could receive certification without complete knowledge and skills in a particular discipline, *i.e.*, board certification may omit or excuse lack of knowledge and skill (if the applicant passes the requisite examination with a score of less than 100 percent) where the alternate pathway would require demonstration of 100 percent in a given discipline.

Response: The NRC believes that RSOs, AMPs, ANPs, and AUs should have T&E sufficient to ensure radiation safety in the medical use of byproduct material. The NRC believes that it is necessary to specify requirements for T&E to accomplish this objective, either by requiring that candidates for approval as RSOs, AMPs, ANPs, or AUs are certified by a board which has a certification process that has been recognized by the NRC, or by meeting the requirements for T&E for the alternate pathway, combined with attestation by a preceptor that the individual has satisfactorily completed these requirements and has achieved a level of competency sufficient to function independently in the position for which approval is sought. The NRC believes that requirements for both pathways are similarly and sufficiently rigorous, and, that by passing a board examination, together with meeting the other requirements in the board certification pathway, a candidate will have demonstrated the knowledge and skill necessary to safely handle byproduct material. The NRC believes that this combination of requirements will ensure the safe medical use of byproduct material and has retained the option for AUs to meet requirements for T&E via the certification pathway.

Comment: One commenter indicated, given that new problems consistently arise, specialty board training should only be accepted if it can be shown that there is a recertification/required continuing education every 10 years or less and that the recertification/continuing education process can be shown to encompass the radiation protection aspects of newer technologies.

Response: The NRC plans to periodically review the requirements of boards for certification to accommodate changing needs for T&E. However, the NRC does not depend solely on board certification to ensure adequacy of T&E. The regulations also provide, in § 35.59, that T&E must have been obtained within 7 years preceding the date of an application to the NRC or that the individual had related continuing T&E. They also provide, in § 35.57, for accommodating experienced AUs (*e.g.*, individuals identified on a license), allowing those who serve as AUs under existing licenses and permits to continue medical uses for which they have been authorized. NRC regulations also provide requirements for licensing of new medical uses of byproduct material, including assessment of the adequacy of T&E of AUs for proposals for new uses in requests for amendments to licenses.

Comment: One Agreement State commenter on the draft final rule stated that the NRC appears to want only limited submittal of the training programs for review and approval from medical boards and does not plan to conduct inspections of specialty boards to insure that they meet the latest certification requirements. Rather, the intent is to wait and see if specific medical events related to training occur in the field before investigating. The commenter does not believe this is acceptable, especially when considering the number of hospital staff and patients that may be at risk before this type of link to training can or will be made once an incident occurs.

Response: In order to have their certification processes recognized, specialty boards must demonstrate that their certification processes meet the specific criteria established in the regulations. The NRC will carefully review the documentation submitted before recognizing a board's certification program. The NRC believes that this process for board recognition, taken together with the NRC's coordination with ACMUI, its inspection of licensed facilities, and its continued monitoring of medical events, will be sufficient to ensure public health and safety.

Comment: Commenters from Agreement States expressed concern that the regulations no longer specify the number of classroom and laboratory or supervised clinical and work hours necessary for the various types of use. One commenter indicated that this could jeopardize radiation safety, and recommended that the NRC include a minimum acceptable number of hours of classroom and laboratory training in the SUPPLEMENTARY INFORMATION for the final rule (*i.e.*, a minimum of 200 hours of classroom and laboratory training out of the total of 700 hours for those types of use for which a WD is required (§ 35.390); 80 hours of classroom and laboratory training for those uses for which a WD is not required but for which 700 hours is still required (§ 35.290); and a minimum of 8 hours of classroom and laboratory training for types of use for which 60 hours of training is required (§ 35.190)), based on the risk to patients, occupational workers, and the public, for each type of use, and assuming class days are 8 hours. Three other commenters from Agreement States recommended that regulatory agencies should specify a minimum number of hours of classroom and laboratory training under §§ 35.190, 35.290, and 35.390. One commenter suggested that individuals qualifying as ANPs under § 35.55 and as AUs under § 35.390 should be required to have 200 hours of classroom and laboratory training. Also, the Organization of Agreement States (OAS) (petitioner) filed a Petition for Rulemaking (petition) dated September 3, 2004 (PRM–35–17) requesting that the NRC amend §§ 35.55, 35.190, 35.290 and 35.390 to define and specify the minimum number of didactic training hours for Authorized Nuclear Pharmacists and Authorized Users identified in these sections.

Response: The NRC agrees with the Agreement States' assertion that the inclusion of a requirement for minimum number of hours of classroom and laboratory training (in §§ 35.55, 35.190, 35.290, and 35.390) for the alternate pathway only, will ensure safety and consistency of regulation on a national basis. Therefore, requirements for a minimum number of hours of classroom and laboratory training have been included in §§ 35.55(b)(1)(i), 35.190(c)(1), 35.290(c)(1), and 35.390(b)(1) of the final rule. However, the added requirements, specifying a minimum number of hours of classroom and laboratory training, were not added to the requirements for recognition of specialty board certifications because the NRC believes that it is important to provide flexible options for boards to evaluate the adequacy of T&E related to radiation safety. This flexibility is provided by a combination of evaluation through examinations, and academic and practical T&E. The NRC believes that the requirements of certifying boards, including requirements for examinations, whose certification processes have been recognized by the Commission or an Agreement State, will ensure the adequacy of radiation safety training. As part of their application for recognition of certifications, boards will be asked to provide information on how their examination process assesses the candidates' knowledge related to radiation safety as it pertains to the subject areas enumerated in the regulations. The NRC believes that specifying a minimum for the number of hours of classroom and laboratory training, in the alternate pathway, will help to ensure that training programs are of adequate length to properly cover the topics important to safe medical use of byproduct material, supplementing the T&E gained during supervised clinical training. Doing so will increase the rigor of the alternate pathway and provide useful and consistent standards for developing training programs. Specifying a minimum number of hours of classroom and laboratory training will also be useful to States in reviewing the adequacy of training programs and assist Agreement States in developing

their T&E regulations to be consistent with the compatibility category B designation for T&E regulations.

The draft final rule, circulated to Agreement States for a 30-day comment period, ending on October 18, 2004, included requirements for a minimum number of hours of classroom and laboratory training (applicable to the alternate pathway only) as follows: § 35.55—200 hours, § 35.190—8 hours, § 35.290—80 hours, and § 35.390—200 hours. Twelve Agreement States provided comments on this issue, with nine of them being in favor of a minimum of 200 hours of classroom and laboratory training for § 35.390. Two Agreement States recommended minimums of 120 and 160 hours of classroom and laboratory training, respectively, for § 35.390. Eight Agreement States supported the proposed number of hours for §§ 35.55, 35.190 and 35.290, and two States suggested requirements ranging from 120 to 200 hours for these four sections. One commenter from an Agreement State stated that the risks associated with uses under § 35.200 is similar to those for uses under § 35.300 because the higher frequency of uses under § 35.200 results in more risk and that, therefore, the number of hours of classroom and laboratory training should be the same (200 hours) in §§ 35.290 and 35.390. This commenter suggested that, for clarity, the term "classroom and laboratory training" be used in place of the term "didactic training" in sections where the latter term appears. The commenter also stated that the way the draft revisions to the regulations are now written, the preceptor statement seems to apply only to the alternate pathway, and that they should be restructured to ensure that information is provided in preceptor statements about hours of training and experience, including classroom and laboratory training. The commenter suggested restructuring the regulations and re-designating paragraphs so that paragraph "(d)" always included the requirements for preceptor statements.

During the ACMUI meeting on October 14, 2004, the ACMUI passed a motion recommending that the requirement for classroom and laboratory training, in § 35.390, be 80 rather than 200 hours. The ACMUI believes that the requirements for training in radiation safety and safe handling for medical uses under §§ 35.200 (no written directive required) and § 35.300 (written directive required), including the use of beta emitters, are similar. The total hours of training (classroom and laboratory, combined with work experience) is the same (700 hours) in §§ 35.290 and 35.390. Therefore, the ACMUI recommended that the number of hours required for classroom and laboratory training be the same as that required for § 35.290, *i.e.*, 80 hours, because the knowledge required for radiation safety is similar for uses under both §§ 35.290 and 35.390. The ACMUI was also concerned that time taken for classroom and laboratory training required under § 35.390(b)(1)(i) would detract from time needed for training in other areas required of clinicians.

After consideration of both the ACMUI's and Agreement States' recommendations, the NRC staff analyzed the issue to determine the appropriate amount of classroom and laboratory training for approval of AUs under § 35.390. The NRC is adopting a requirement for 200 hours of classroom and laboratory training for the alternate pathway in § 35.390 because more knowledge is necessary in the topic areas listed in § 35.390(b)(1)(i)(A) through (E), as enumerated below, to ensure the safe use of byproduct material for which a written directive is required.

1. Radiation physics and instrumentation—a wider variety of radionuclides, having a wider range of energies, both for beta and gamma emitters, is used. This affects understanding of how radiation interacts with matter, which impacts understanding of shielding as well as the effects of radiation, and choice and use of instrumentation to detect and measure radiation and to measure quantities of radionuclides.

2. Radiation protection—more knowledge of principles and practices of radiation protection is needed because of the wider variety of radionuclides and associated types and energies of radiations used under § 35.300. Because greater quantities of byproduct material are commonly used for therapeutic purposes, risks are greater for patients and patient care personnel as well as for the public after the release of patients. Evaluation of these risks and associated protective measures and practices necessitates more knowledge for uses under § 35.300 than for uses under § 35.200. More knowledge of principles and practices in radiation protection is needed because of a wider variety of modes of administration and physical forms of byproduct material, *e.g.*, intravenous, intra-peritoneal, oral and liquids in catheters. Each of these factors necessitates different radiation safety considerations for patients, occupationally exposed personnel and members of the public. Radiation safety considerations relate both to the preparation and use of byproduct material for medical purposes, and may extend to the treatment of patients in the operating room and to the pathology staff.

3. Mathematics pertaining to the use and measurement of radioactivity—Mathematics related to dosimetry is more complex for the wider variety of radionuclides, greater quantities, different types of radiation, and the broader purposes of use. Whereas byproduct material is used for diagnostic purposes under § 35.290, uses under § 35.390 are common for various therapeutic purposes.

4. Chemistry of byproduct material for medical use—a wide variety of chemical forms of byproduct material is used under § 35.300. These forms include ionic, bound-to-antibodies, and simpler chemical species, resulting in differences in uptake in the body and various organs and tissues (biodistribution), and elimination. Agents are used both for diagnostic and therapeutic purposes.

5. Radiation biology—more knowledge of radiation biology is needed because byproduct material are administered in greater quantities, both for diagnostic and therapeutic purposes, resulting in the potential for a greater variety of radiation effects and greater potential for harm. Risk assessments sometimes involve consideration of immediate biological effects whereas this is not usually a consideration in diagnostic applications under § 35.200.

In addition to these considerations, the NRC notes that new medical applications of byproduct material are evolving under § 35.300. Examples include more common use of byproduct material for alleviation of bone pain and for treatment of metastatic disease. This results in a need for additional knowledge of a wider variety of applications of physical and chemical forms of byproduct material.

The NRC determined that the minimum amount of classroom and laboratory training should be 200 hours by reviewing the content of training courses that an individual might attend to satisfy the requirements in § 35.390(b)(1)(i). This training involved 200 hours of classroom and laboratory training.

The requirement for 200 hours of classroom and laboratory training is also incorporated into the final rule for individuals to qualify as ANPs because nuclear pharmacists may be involved in the preparation of dosages of byproduct material for uses under § 35.300 as well as under §§ 35.100, 35.200 and other uses specified in 10 CFR Part 35. Therefore, these individuals will be

involved in high-risk activities related to use of byproduct material, including wet chemistry. Their work may also involve greater quantities of byproduct material because they may dispense dosages from stock-quantities. Greater quantities are also used for short half-life radionuclides which decay between preparation and administration to patients.

The minimum number of hours of classroom and laboratory training for uses under § 35.200 is 80 hours because the complexity and level of knowledge required is less than for uses under § 35.300. The NRC believes that the frequency of use of byproduct material should not be considered in evaluating the risk to individuals from uses of byproduct material under § 35.200, for the purpose of determining the requirement for hours of classroom and laboratory training to be required for such uses. Rather, the NRC believes that other factors should be considered in this regard, *e.g.*, adequacy of size and scope of a radiation safety program to ensure safe uses of byproduct material. However, because procedures such as elution of radionuclide generators and preparation of drugs labeled with byproduct material are conducted under § 35.200, the minimum was set at a greater level than for uses under § 35.100, for which risks are significantly less and for which the minimum requirement was set at 8 hours of classroom and laboratory training, in § 35.190.

The NRC recognizes that the minimum number of hours of classroom and laboratory training for uses of licensed byproduct material specified in these sections differs to some extent from the minimum number of hours of classroom and laboratory training specified for similar uses of such material in Subpart J. However, in determining the minimum number of hours of classroom and laboratory training to be required for each use, the NRC also recognized that the uses specified in sections of Subpart J are different from those covered in Subparts D through H and that the medical use of byproduct material has evolved and changes have taken place in the available technology for use in each of these areas since the promulgation of Subpart J. The NRC has considered these factors in determining the minimum number of hours of classroom and laboratory training to be required for uses in Subparts B and D through H.

The NRC also agrees with the comment that the term "classroom and laboratory training" should be used in place of the term "didactic training." The regulations in §§ 35.50(b)(1)(i) and 35.55(b)(1)(i) have been revised to use the term "classroom and laboratory" in place of "didactic training."

The NRC has revised the language in the final rule so that the requirement for a preceptor attestation, for individuals to be approved as RSOs, AMPs, ANPs and AUs, now appears in §§ 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390 (a), 35.392(a), 35.394(a), 35.396(a), 35.490(a), and 35.590(a). This approach helps make it clear that a preceptor statement is required for both the certification and alternate pathways. The NRC did not re-designate paragraphs to have the requirement for preceptor statements appear in paragraphs "(d)" in order to avoid extensive renumbering that would be necessary for other paragraphs.

Comment: One Agreement State commenter stated that there is too great of a reliance on a preceptor's attestation/certification for physicians who qualify as AUs under the alternate pathway to provide adequate assurance that the individual will have obtained adequate radiation safety training. The criteria used by preceptors must be specifically and clearly defined and the qualifications for preceptors should be defined as well. Otherwise, AUs may give undue weight to the clinical aspects of training rather than to safety, and a clinically competent AU who has a poor radiation safety compliance history may provide a strong statement for an individual for whom radiation safety training was minimal.

Response: The criteria to be used by preceptors are stated in the regulations, including the qualifications required for an individual to serve as an AU. The NRC believes that competency of candidates to function independently as AUs is best assessed by AUs who have experience performing the duties of an AU. The definition of "preceptor" appears in § 35.2. The qualifications for an individual to serve as a preceptor are specified in the requirements for preceptor statements in Subparts B and D through H. In general, they require that the preceptor be an individual who serves in the same capacity as the candidate for approval as RSO, AMP, ANP, or AU. The criteria for evaluation of T&E by preceptors are specified in each section of Subparts B and D through H. These criteria were chosen to ensure that they are risk-informed and performance-based and not unduly prescriptive in relation to the degree of risk associated with various types of use. Moreover, reflecting a performance-based approach, an AU is considered qualified to serve as a preceptor as long as his or her authorized status remains current. However, if an individual's status as an RSO, AMP, ANP, or AU, is revoked for non-compliance with the NRC's regulations, that person could no longer serve as a preceptor.

Issue 2: Should the word "attestation" be used in place of the word "certification" in preceptor statements? Should other changes to the wording or preceptor statements be made?

Comment: One commenter observed that "attest" and "certify" mean the same thing, and, because preceptors have been "attesting" for years, questioned changing terminology. Other commenters expressed support for making the change, with two commenters noting that the word "certification" should only be used in connection with the board process. Another commenter believes that the use of the word "attest" in place of "certify" would alleviate certain obstacles to individuals willing to serve as proctors.

Response: The NRC agrees that the use of the word "attest" and its various other forms (attestation, attesting) is more appropriate than the use of the word "certify" and would lead to more clarity in the regulations. Therefore, appropriate changes were made in the definition of "preceptor" and in the requirements for preceptor attestations in the regulations. This change was also made, as a conforming change, in § 35.980(b)(2) of Subpart J to maintain consistency with other Subparts of 10 CFR Part 35.

Comment: The preceptor statement should be reworded to indicate that a preceptor "attest[s] to the candidate's knowledge and ability to handle radioisotopes in preserving the health and safety of the patient and the provider." The preceptor should not be required to attest to the general clinical competency of the candidate.

Response: The NRC agrees with the suggestion that the word "attest" should be used in place of "certify" in preceptor statements and has made these changes in the final rule. However, the other changes to the preceptor statements suggested by the commenter would result in the elimination of essential elements of a preceptor statement that the NRC continues to rely on to determine if an individual has satisfactorily completed requirements for T&E and has a level of competency sufficient to function independently as an RSO, AMP, ANP, or AU. The NRC clarified the meaning of the word "competency" in the section of the SUPPLEMENTARY INFORMATION entitled "Preceptor Attestation," by indicating that preceptors are not attesting to the general clinical competency of the

candidate; this interpretation represents a restatement of the NRC's intent stated in the SUPPLEMENTARY INFORMATION for the current regulations, published on April 24, 2002 (67 FR 20249). Therefore, the other changes suggested by the commenter were not adopted in the final rule.

Comment: One Agreement State commenter believes that preceptors are not certifying "individuals," but they certify that the training received by an individual meets regulatory requirements. Otherwise, there may be an implication that organizations which provide training are relieved of any responsibility.

Response: The NRC agrees with the commenter's statement that preceptors do not "certify individuals." The purpose of preceptor attestations is stated in the regulations (*e.g.*, in the case of RSOs), to attest to the satisfactory completion of requirements for T&E to serve as an RSO and to an individual's having achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee.

Comment: An Agreement State commenter on the draft final rule stated that the definition for preceptor should confirm that the individual verifying training for another authorized user, medical physicist, nuclear pharmacist or RSO is also a licensed user/RSO on a specific medical license. The commenter indicated that it is also important for the preceptor to know that his or her own authorization on a medical license is at risk when signing a preceptor attestation.

Response: As stated above, the qualifications required for an individual to serve as preceptor are specified in the requirements for preceptor statements in Subparts B and D through H, and require that the preceptor be an individual who serves in the same capacity as the candidate for approval as RSO, AMP, ANP, or AU. Therefore, the NRC does not believe that the definition for preceptor should be revised. The NRC notes that a preceptor's authorization on a medical license is not, per se, "at risk" for signing a preceptor attestation. However, under Section 186 of the Atomic Energy Act, as well as the Commission's regulations in 10 CFR 30.10, a licensee, or applicant for a license, who deliberately submits to the NRC information that a person submitting the information knows to be inaccurate in some respect material to the NRC, may be subject to enforcement action. Under 18 U.S.C. § 1001, any person who makes a willful false statement to the NRC may be subject to criminal sanctions.

Issue 3: Comments on other requirements related to preceptor statements.

Comment: Some commenters stated that the wording of the requirements for preceptor statements in the proposed rule implies that the preceptor has knowledge that an individual meets all of the requirements for board certification, including passing of a certification examination, thereby establishing an unintended link between preceptor statements and examinations administered by boards. This may or may not be true, since, in some cases, a preceptor statement may be signed before the individual sitting for the board examination.

Response: The NRC agrees that preceptors should not be required to certify that individuals have completed all of the requirements that candidates for certification by a specialty board would be required to meet to obtain certification. The requirements for preceptor statements have been reworded in Subparts B and D through H of the final rule to remove requirements to attest to candidates having passed board administered examinations.

Comment: While agreeing that the change from certification to attest should be made, other commenters recommended that the following be inserted in place of the first sentence of all preceptor paragraphs in the December 9, 2003, draft: "Has obtained written attestation that the individual has satisfactorily completed the required training in paragraph (a)(1) or (b)(1) of this section and has achieved a level of knowledge and demonstrated the ability to safely handle radioisotopes to ensure adequate protection of public health and safety. The written attestation must be signed by a preceptor. * * *"

One commenter indicated that the word "competency" should be dropped from the suggested preceptor statement because the phrase "has achieved a level of knowledge and demonstrated ability" is a demonstration of competency.

Response: As noted in the Discussion section of the SUPPLEMENTARY INFORMATION, the Commission directed the NRC staff, in SRM–02–0194 (dated February 12, 2003), that the preceptor statement remain as written in the current regulations (published April 24, 2002), and that the staff should clarify that the preceptor language does not require an attestation of general clinical competency but does require sufficient attestation to demonstrate that the candidate has the knowledge to fulfill the duties of the position for which certification is sought. Further, this form of attestation should be preserved both for the certification pathway and the alternate pathway. Therefore, the suggestion related to the use of the word "competency" was not adopted in the final rule.

Comment: One Agreement State commenter stated that the proposed language regarding the requirement for obtaining preceptor statements is not the same in different sections. For example, § 35.290(a) reads, "meets the requirements in paragraph (c)(2) [has obtained a preceptor statement] and is certified." But § 35.390(a) reads, "is certified by a medical speciality board * * *" and "(c) has obtained written certification (from a preceptor)." While this accomplishes the same purpose, at first glance it appears that some boards do not require preceptor statements while others do. The language should be made more uniform for each discipline.

Response: The NRC agrees that parallel construction should be used in the language for requirements for preceptor statements for individuals who are board certified, and this approach was taken in the final rule. The requirement for a preceptor attestation for individuals to be approved as RSOs, AMPs, ANPs, and AUs now appears in §§ 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.396(a), 35.490(a), and 35.690(a). This approach also helps make it clear that a preceptor statement is required regardless of which training pathway is chosen.

Comment: One Agreement State commenter agreed that a preceptor statement should continue to be required for board certified individuals, stating that it is important for a person who knows a candidate to attest to the individual's competence in radiation safety.

Response: The NRC agrees with this comment. The NRC continues to rely on preceptor statements to determine if an individual has satisfactorily completed requirements for T&E and has a level of knowledge sufficient to serve as an RSO, AMP, ANP, or AU.

Comment: Several commenters expressed the opinion that the change in the requirements that de-couples requirements for a preceptor statement from requirements for recognition of board certifications will result in a shift of burden for obtaining the statement from boards to individuals. One Agreement State commenter supported placing the responsibility for obtaining preceptor statements on individuals rather than on certification boards as a prerequisite to the certification process.

Other commenters recommended that the NRC retain the preceptor letter requirement as a prerequisite to recognition of board certifications. They questioned what is gained by dropping requirements for preceptor statements from requirements for recognition of board certifications. An Agreement State commenter opposed separating requirements for preceptor statements from requirements for recognizing board certifications on the grounds that it integrates less uniformity and reliability into the training process. According to the commenter, a large number of physicians are currently denied authorizations because of inadequate preceptor statements, and this will only increase if these statements are not reviewed and issued by a valid source such as approved certification boards, thereby increasing the shortage of approved AUs.

Response: The NRC believes that individuals will continue to be involved in the process of documenting T&E and that the shift in responsibility is primarily from the involvement of boards in the process to licensees, which will be subject to the new requirement for submitting the preceptor statement to the NRC under § 35.14(a). The NRC removed the requirement for boards to obtain preceptor attestations, as a condition of recognition of board certifications, upon the recommendation of the ACMUI, which indicated that the requirement should be de-coupled from requirements for recognition of board certifications because individuals may obtain the preceptor statement required by the NRC after they have obtained their board certifications. This approach will enable a more flexible approach to satisfying the requirement for preceptor statements. The NRC believes removal of the requirement for a preceptor statement from requirements for recognition of specialty board certifications will not result in less uniformity in the process of training or decrease the number of individuals who are approved as AUs because the responsibility for obtaining preceptor statements will still rest with individual candidates for approval as AUs, and the statements now must be submitted to the NRC or an Agreement State, rather than to a certification board. The NRC also notes that the final rule does not prevent specialty boards from requiring preceptor statements.

Comment: One commenter stated that the NRC should not require written preceptor certifications for the certification pathway because certification boards already require letters of endorsement to verify candidates' work experience and qualifications, and candidates must also pass a multi-part examination to assess knowledge and fitness to practice in a particular medical specialty. Therefore, it is redundant for the NRC to require preceptor statements. Furthermore, preceptors who are not involved in a specialty board's certification practice can only verify that an individual possesses a valid certificate. In addition, the commenter questions the justification for this new requirement.

Some commenters stated that the requirement for preceptor statements should be eliminated for board certified AUs, AMPs, and ANPs; they should only be required for those requesting authorization via the alternate pathway and for RSOs. Board certification and continued experience are satisfactory demonstration for meeting the radiation safety requirements to perform those authorized activities as AU, AMP, or ANP. The commenters believe that there is no evidence to support that any added benefit would be provided by requiring a preceptor statement for these individuals. Removing requirements for obtaining preceptor statements would also minimize the delay in approval of these individuals by the appropriate regulatory agency or the Radiation Safety Committee.

Response: The NRC continues to rely on preceptor statements to determine if an individual has satisfactorily completed requirements for T&E and has a level of knowledge sufficient to serve as an RSO, AMP, ANP, or AU. The NRC believes that it is essential to have individuals who are familiar with the duties of RSOs, AMPs, ANPs, and AUs, through personal experience, to serve as preceptors. Individuals who serve in these positions are best qualified to attest that an individual has achieved a level of competency sufficient to function independently as an AMP, ANP, AU, or RSO. The concern expressed about the unavailability, or inability, of an authorized individual to complete a preceptor statement for an individual seeking authorized status was addressed in the final rule by modifying the definition of a preceptor, in § 35.2, to permit verification by the preceptor of required training and/or experience obtained previously or elsewhere. As indicated under the discussion of comments on the definition of "preceptor," the word "the" was removed from the phrase "the training and experience" in the definition of preceptor to help clarify that more than one individual may serve as a preceptor. The NRC does not agree that removing the requirement to obtain a preceptor statement would minimize the delay in approvals of individuals to serve as RSOs, AMPs, ANPs and AUs because other means would have to be used to evaluate the competency of these individuals, which would increase the amount of time needed for these approvals.

Comment: Some commenters stated that clarification that individuals may submit more than one preceptor statement, as applicable, for all categories of AU, AMP, or RSO, should be provided in the SUPPLEMENTARY INFORMATION for the final rule. Proposed §§ 35.490(c) and 35.690(c) indicate that the preceptor must be an AU of each type of medical unit for which the individual is requesting AU status. The language must be clarified to allow for different preceptors for multiple devices for which AU status is sought.

Response: The NRC recognizes that separate preceptor statements may be needed to document the T&E of individuals, *e.g.*, in the case of an individual who receives training at different times in his or her career or in other circumstances when it may not be possible for only one preceptor to attest to some of the T&E that an individual has received. The NRC accepts multiple preceptor statements from licensees in these circumstances. As indicated under the discussion of comments on the definition of "preceptor" in Part III, the word "the" was removed from the phrase "the training and experience" in the definition of preceptor to help clarify that more than one individual may serve as a preceptor.

Other Issues

Issue 4: Should the NRC continue to recognize the certifications of boards that have been recognized under the current regulations?

Comment: Two commenters believe that the CBNC (Certification Board of Nuclear Cardiology) should not be required to reapply for recognition of its certification because it was the only board that complied with the NRC requirements in 10 CFR Part 35 as promulgated on April 24, 2002 (67 FR 20249).

Response: The NRC believes that, because of the importance of board certification to establishing the adequacy of T&E for individuals to serve as RSO, AMPs, ANPs, and AUs, it is necessary to make a clear regulatory determination that all boards, both new and existing, meet the relevant regulatory criteria. Evaluation of board requirements against revised criteria in the final rule is necessary to make this determination. The NRC notes that, via a separate rulemaking, the expiration of Subpart J was extended for 1 year to

October 24, 2005 (69 FR 55736, September 16, 2004); this will provide time for boards to apply for recognition under the revised regulation in the final rule. During this period, the NRC will continue to recognize the certifications of boards, including the CBNC's, which are recognized under current regulations.

Issue 5: How will the NRC implement procedures for recognition of specialty board certifications? How will the NRC monitor trends in medical events to evaluate whether they are associated with a certification board's requirements for certification?

Comment: In the SUPPLEMENTARY INFORMATION for the proposed rule, the NRC briefly discussed plans for implementation of changes to requirements for recognition of specialty board certifications. One commenter questioned these plans, asking how the NRC will monitor trends in medical events to see if they can be associated with inadequate training in radiation safety and if these trends can be related to a specialty board's requirements for training. The commenter agreed that the NRC should not conduct routine inspections of boards. The commenter indicated that the number of medical events reported by a certain board's diplomates is small, making it difficult to develop associations between trends and a board's requirements. The commenter also asked what statistical methods the NRC would use to make these determinations. One Agreement State commenter stated that the process by which a board would be delisted appears to be ineffective. For example, it is unclear how the NRC will track trends in diagnostic medical events and relate those trends to the adequacy of the radiation safety training component of a specific board certification, considering the fact that most diagnostic medical events are not reportable. The commenter stated that an analysis of current data should have been performed to determine if this approach would be effective.

Response: The NRC conducts a regulatory program to ensure safety. This regulatory program is also important to the identification of issues related to T&E that may, in turn, point to issues associated with the certification process of a specialty board. The NRC also requires that medical events be reported to the NRC and Agreement States. Bi-monthly reviews of events in the Nuclear Materials Events Database (NMED) provide a means for identifying trends in medical events in Agreements States and among NRC licensees that may lead to follow-up and review of adequacy of specialty board certification requirements. The NRC reviewed recent data and determined that radiation safety training related to board certification programs is adequate. The NRC staff has initiated consultations with the ACMUI to review medical events to determine if action is needed when problems arise including trends in medical events reflected in NMED data. The NRC has a broad regulatory framework associated with medical T&E, involving review of specialty board certification processes, licensing and inspections of licensees, and medical event follow up and analysis. The NRC believes that these measures are sufficient to determine the adequacy of training related to a board's certification process.

Comment: One commenter believes that the NRC's plan to review a specialty board's certification program is particularly troubling. The NRC should not expect a certification board to jeopardize the security of its examination by allowing the NRC to review the examination and should not influence the content of a board's examination. The commenter believes that, because of the NRC's lack of expertise concerning the practice of medicine, the NRC is not in a position to determine the content of an examination. Rather, only a specialty board can make this judgement.

Response: The NRC will only review board examinations if it determines that a series of medical events is associated with a particular type of use and if the trend can be attributed to inadequate training in radiation safety. In addition, the NRC has methods to protect proprietary information in examinations; 10 CFR 2.390, "Public inspections, exemptions, requests for withholding," provides procedures for protection and nondisclosure of information that contains trade secrets, commercial or financial information obtained from a person, and privileged or confidential information. The NRC will consult with the ACMUI to seek advice, as necessary. Further, if safety problems are found that relate to the requirements of specialty boards for certifications, the NRC will work with boards to resolve these problems, including inadequacies in examinations if that is identified as a source of the problem.

Comment: One commenter stated that, while it is acceptable that the NRC does not plan to implement the rule by inspecting boards, the entire program for recognition of board certifications is in question unless the NRC reviews copies of training programs used by the boards and has some kind of regulatory basis to implement enforcement of these commitments, if necessary.

Response: While the NRC does not plan to inspect training programs, it believes that specialty boards have a strong incentive to ensure that their certification procedures will ensure the safe use of byproduct material in medicine to protect the integrity of their certifications as well as to gain recognition from the NRC or an Agreement State. The NRC also believes that if a board's certification requirements are deficient, the possibility of delisting and loss of recognition is also a strong incentive for a specialty board to correct deficiencies. Further, as stated in the SUPPLEMENTARY INFORMATION for the current regulations, the NRC will investigate any allegations regarding inadequate training programs on a case-by-case basis.

Comment: One Agreement State commenter stated that, while it appears that posting approved boards on the NRC Web site is appropriate, it is not clear that Agreement States will have input into the review/approval process.

Response: The NRC's current regulations for recognition of specialty board certification processes provide for recognition by either the NRC or Agreement States but do not require consultation between States or between States and the NRC. The regulations provide clear criteria for recognition of board certification processes.

Issue 6: How will revised requirements for T&E affect individuals who are now in training?

Comment: One commenter stated that there has been no requirement for fellows or residents currently in training to document T&E on a case-by-case basis. Therefore, physicians would be adversely affected by this new requirement, which would require a retrospective analysis of data that may not have been kept. Accordingly, the proposed T&E requirements must be applicable only to those who begin training after the date of implementation of the final rule.

Response: The NRC believes that the revisions to requirements for T&E of AUs do not result in such extensive changes from current requirements that it should create difficulty for individuals to document their T&E. The ACMUI noted in its recommendations to the NRC for the development of the proposed rule (see SECY–02–0194) that it expected that the requirements of all boards for certification, that are currently recognized, would satisfy revised requirements. Thus, there should be little change in what an individual would be expected to present to a board to gain certification. Further,

the changes to the requirements for the alternate pathway are relatively few. Thus, these changes will not make the task of documenting T&E significantly more difficult. The NRC believes that these requirements are essential to ensuring adequacy of T&E for medical uses of byproduct material for which a WD is required and, therefore, that they should not apply only to individuals who begin training after the final rule is implemented. Further, under the provisions of § 35.57(b), experienced AUs (*e.g.*, individuals identified on a license) are not required to comply with requirements for T&E in Subparts D through H of Part 35. Therefore, the suggestion offered by the commenter was not adopted.

Issue 7: Should the term "laboratory training" be defined?

Comment: One Agreement State Commenter expressed concern that the meaning of the term, "laboratory training," should be more clearly defined. The commenter expressed concern that "laboratory" time could be interpreted as "clinical lab" which would be patient-care oriented rather than radiation-safety oriented.

Response: The NRC believes that defining the terms "classroom" and "laboratory" would not ensure compliance and would only serve to create a more prescriptive rule. However, the NRC expects that clinical laboratory hours that will be credited toward meeting the requirements for classroom and laboratory training in Subparts B and D through H will involve training in radiation safety aspects of the medical use of byproduct material. The NRC recognizes, for example, that physicians in training may not dedicate all of their clinical laboratory time specifically to the subject areas covered in these subparts and will be attending to other clinical matters involving the medical use of the material under the supervision of an AU (*e.g.*, reviewing case histories or interpreting scans). However, those hours spent on other duties, not related to radiation safety, should not be counted toward the minimum number of hours of required classroom and laboratory training in radiation safety. This type of supervised work experience, even though not specifically required by the NRC, may be counted toward the supervised work experience to obtain the required total hours of training (*e.g.*, 700 hours for § 35.390). Similarly, the NRC recognizes that clinicians will not dedicate all of their time in training specifically to the subject areas described in Subparts D though H and will be attending to other clinical matters. The NRC will broadly interpret "classroom training" to include various types of instruction received by candidates for approval, including online training, as long as the subject matter relates to radiation safety and safe handling of byproduct material.

Part III—Comments on Specific Sections in the Proposed Rule

Subpart A—General Information

Section 35.2—Definitions

Issue 1: Definitions of "authorized medical physicist" and "authorized nuclear pharmacist."

Comment: One Agreement State commenter stated that the current proposed definitions for "authorized medical physicist" and "authorized nuclear pharmacist" did not include individuals who had obtained preceptor statements and met the requirements for the alternate pathway, and that this did not appear to be correct.

Response: The NRC has considered this comment and determined not to change the definitions in § 35.2 for "authorized medical physicist" or "authorized nuclear pharmacist' to include individuals who are not board certified. These definitions clearly specify the individuals who are to be included within their scope and are not the same as the requirements for demonstrating the adequacy of training and experience. The means for a person to become an AMP, ANP, or AU, via the alternate pathway, are provided in Subparts B and D through H.

Authorized medical physicists are defined as individuals who are certified by specialty boards whose certifications are recognized by the NRC or an Agreement State or are identified as authorized individuals on a Commission or Agreement State license or permit. Authorized nuclear pharmacists are similarly defined and also include individuals who have been identified by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists, or are designated as authorized nuclear pharmacists in accordance with the requirements of § 32.72(b)(4). Although not noted by the commenter, the definitions similarly define an authorized user as a physician, dentist, or podiatrist who has been certified by a board whose certification has been recognized by the NRC or an Agreement State, or is identified as an authorized user on a Commission or Agreement State license or permit. These definitions are consistent with the requirements of § 35.13, which provide that a licensee must apply for and receive a license amendment before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license unless they are authorized individuals who either are certified by a board whose certification is recognized or are identified on a Commission or Agreement State license or by a commercial pharmacy authorized to identify authorized nuclear pharmacists. Neither the language of these provisions nor the SUPPLEMENTARY INFORMATION accompanying the initial promulgation of, and modifications to, these sections indicate an intent to include within their scope individuals who are not board certified and who meet the training and experience requirements of the alternate pathway. In fact, there is a clear indication in the SUPPLEMENTARY INFORMATION of a specific intent that before allowing a physician who does not have board certification or is not listed on a license or permit to work as an authorized user, the specific licensee of limited scope must continue to submit a license amendment and obtain NRC approval (58 FR 33401; June 17, 1993).

As these definitions are not intended to parallel the training and experience requirements, the NRC has determined that changing the definitions as the commenter has suggested would be outside the scope of this rulemaking.

Issue 2: Definition of "stereotactic radiosurgery."

Comment: One commenter made a distinction between "stereotactic radiosurgery procedures," which the commenter indicated must be conducted in one session, and "stereotactic radiotherapy," which is conducted over extended periods of time with a linear accelerator. The commenter recommended amending the definition of "stereotactic radiosurgery" to include the words "in one session," and to add a new definition of "stereotactic radiotherapy" as "the use of external radiation in conjunction with a stereotactic guidance device to deliver partial therapeutic dose to a tissue volume over a series of sessions."

Response: The NRC believes that it is not necessary to qualify the definition of stereotactic radiosurgery as suggested by the commenter, or to add a new definition, because the more general term used, "stereotactic radiosurgery," is sufficient to include both types of treatments, and addition of the qualifiers could be unduly restrictive in the future.

Issue 3: Definition of "preceptor." As currently defined, "preceptor" means an individual who provides or directs the training and experience required for an individual to become an authorized

user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

Comment: One commenter suggested that the NRC revise the definition of "preceptor" to read "an individual who provides, directs, or has knowledge of training and experience required for an individual to become. * * *" Deleting the definite article "the" before "training" would clarify that more than one person may serve as a preceptor, and would clarify that the preceptor does not need to be the individual who trained the applicant. Addition of the phrase "or has knowledge of," allows preceptors to address T&E that was not received under the supervision of the preceptor, *e.g.*, training for new uses for which no AU exists, such as those that might be licensed under § 35.1000. Other commenters supported removal of the word "the" in the phrase, "the training and experience," in the current definition. Another commenter also recommended rewording the definition of preceptor to include individuals who verify the training because, in some cases, the person who provides training, such as a vendor, may not meet the definition of a preceptor who provides or directs training and experience.

Response: The NRC agrees with the commenters and has removed the word "the" from the phrase "the training and experience" in the definition of preceptor. This change helps clarify that more than one individual may serve as a preceptor and that the regulations do not require the preceptor to be the same person who provides or directs training for an individual to be approved as an RSO, AMP, ANP, or AU. The NRC also agrees that there may be cases when the person who serves as preceptor may be able to verify that the training and experience meet requirements for T&E in the regulations (for example, training provided by a vendor for a specific type of use) and the definition of preceptor has been changed accordingly in the final rule.

Section35.10—Implementation

Comment: One commenter stated that the current transition period, which ends on October 24, 2004, must be extended to allow time for boards to prepare applications and for processing of applications by the NRC, including review by the ACMUI.

Response: The NRC agrees that additional time for the changes to T&E should be allowed beyond October 24, 2004. Therefore, by way of a separate rulemaking, the NRC has amended 10 CFR Part 35 to extend the expiration of Subpart J for 1 year beyond the current expiration date to October 24, 2005 (69 FR 55736, September 16, 2004). This will allow time for specialty boards to prepare and submit applications for recognition under the revised regulations.

The final rule also contains amendments to requirements for T&E that relate to the alternate pathway and the submission of preceptor statements for board certified individuals under § 34.14(a). The NRC is providing, in § 35.10, for implementation of these requirements, on or before October 25, 2005, to allow time for licensees and license reviewers to adopt revisions to requirements for T&E.

The NRC also notes that those board(s) whose certifications have been recognized by the NRC will continue to be listed on the NRC's Web site until Subpart J expires on October 24, 2005; only those boards whose certifications are recognized under the provisions of this final rule will be listed after October 24, 2005.

Section35.14—Notifications

Section 35.14(a) is being amended to require the submission of statements, signed by preceptors, in addition to a copy of a board's certification (required under current regulations). This change was made as a conforming change necessitated by amendments to requirements in Subparts B and D through H of Part 35 which removed the requirement for specialty boards to obtain preceptor statements as a condition of recognition of their certifications and, instead, requires applicants for licenses to submit preceptor statements, effected by the amendment to § 35.14(a).

Comment: One Agreement State commenter noted that it is unfortunate that certification by an accepted board alone will no longer be adequate to become an AU, AMP, RSO, or ANP. Initially this could be confusing to licensees who will need to become accustomed to submitting copies of valid preceptor statements and board certificates with the notification required by § 35.14.

Response: The NRC removed the requirements for boards to obtain preceptor attestations, as a condition of recognition of board certifications, upon the recommendation of the ACMUI, which indicated that the requirement should bo de-coupled from requirements for recognition of board certifications. The revised regulations require applicants to submit preceptor attestations along with copies of board certifications. The NRC believes that the regulations, as amended, clarify this change, and the NRC staff will work with applicants to resolve questions, should they arise.

Comment: One commenter stated that the requirements in § 35.14(a) should call for written attestation, not a written certification.

Response: The NRC agrees with the comment and made this change in the final rule. This change also brings the paragraph into conformance with changes made in requirements for preceptor statements in Subparts B and D through H of Part 35.

Subpart B—General Administrative Requirements

Section 35.50—Training for Radiation Safety Officer

Comment: One commenter suggested that the NRC should define "professional experience in health physics" and "at least 3 years in applied health physics" in § 35.50(a)(2), expressing concern that, if full-time experience is required in the practice of health physics, then most radiologists would not qualify as RSOs.

Response: The NRC believes that these terms are in common usage and that it is not necessary to define the terms. The NRC believes that it is appropriate to require 1 year of full-time experience under the supervision of an RSO for candidates to meet requirements for T&E, via the alternate pathway, to ensure that they are able to serve independently as RSOs. Therefore, the NRC has retained the requirement for 1 year of full-time, supervised experience, with the exception of the new provisions in § 35.50 for approval of medical physicists as RSOs, for which a requirement for 2 years of full-time experience is required.

Comment: After stating support for proposed changes to § 35.50 that would permit medical physicists who are not AMPs to serve as RSOs, some commenters also indicated that the phrase referring to certification by a board whose certification process has been recognized "under § 35.51(a)" should be deleted from § 35.50(d)(2)(i). These commenters believe that including the connection would limit RSO medical physicists to medical physicists practicing in therapy. These commenters believe that it is critical that qualified medical physicists other than AMPs be able to serve as an RSO. Medical physicists, who are certified in diagnostic radiology or nuclear medicine, need to continue to be able to serve as an RSO.

Response: The NRC agrees that certain medical physicists may be well qualified to serve as RSOs. AMPs may now serve as RSOs. Therefore, § 35.50

has been amended to provide additional criteria for a medical physicist to qualify as an RSO. The new requirement for certification in medical physics by a specialty board that is recognized by the NRC or an Agreement State appears in § 35.50(c)(1), with requirements for recognition set out in § 35.50(a)(2). The criteria for NRC recognition of certification in medical physics for RSOs does not include a requirement for examination in "clinical radiation therapy," but provides a pathway for approval as RSOs of medical physicists certified in diagnostic radiology or nuclear medicine. The adequacy of T&E for individuals to serve as RSOs is ensured by requirements in the final rule for a preceptor statement and for training in radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. The NRC agrees with the commenters and believes that these requirements are appropriate to demonstrating the adequacy of T&E in radiation safety for individuals to serve as RSOs.

Section 35.51—Training for an Authorized Medical Physicist

Issue 1: The requirements for T&E for AMPs include, in § 35.51(b)(1), that the training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy and brachytherapy services.

Comment: Two Agreement State commenters questioned the use of the term "high-energy" in the requirement for training of AMPs, suggesting that there is no definition for the term and that it might be interpreted differently by different States and individuals. The commenter asserted that, because experience with high-energy, external beam therapy is essential for approval of a medical physicist, it would seem appropriate that the term be understood.

Response: The term "high-energy" is used in the rule text in §§ 35.51(a)(2)(ii) and 35.51(b)(1) to specify the type of training to be included in T&E for AMPs. The NRC revised §§ 35.51(a)(2)(ii) and 35.51(b)(1) to indicate that high-energy radiation is considered to be photons and electrons with energies greater than or equal to 1 million electron volts, which is consistent with the definition of high-energy used by the International Commission on Radiation Units and Measurements in Report 42, *Use of Computers in External Beam Radiotherapy Procedures with High-Energy Photons and Electrons.*

Issue 2: During the transition from previous regulations and changes under the final rule on T&E, should medical physicists, serving in functional roles as AMPs but not named on licenses, be allowed to continue serving as AMPs?

Comment: The ACMUI suggested that the rule grandfather those medical physicists, who serve as authorized medical physicists for intravascular brachytherapy, high-dose rate brachytherapy, cobalt-60 teletherapy, and cobalt-60 gamma knife therapy, to allow them to serve as AMPs in these respective categories regardless of whether they are currently listed on Agreement State or NRC licenses. Other commenters agreed, expressing concern that some Agreement States have not established processes for credentialing physicists authorized to perform critical QA and safety checks for intravascular brachytherapy, or gamma stereotactic treatments, and that some Agreement States, which have established requirements for T&E for these AMPs, do not explicitly list them on licenses. Therefore, this issue should be clarified so there could be an initial pool of AMPs to serve as preceptors and any physicist who meets the requirements of the board certification or alternate pathway under § 35.51, and has clinical experience performing AMP duties in the past 7 years, should be grandfathered.

Response: Prior to the implementation of current regulations in Part 35 (published on April 24, 2002; 67 FR 20249), the NRC staff evaluated, on a case-by-case basis, the qualifications of individuals to perform the functions of medical physicists and identified them as AMPs on NRC licenses. These individuals are "grandfathered" under § 35.57(a). Hence, the concern of the ACMUI would relate primarily to those medical physicists performing functions for licensees of Agreement States but who are not identified on Agreement State licenses. To "grandfather" (approve as AMPs) these medical physicists in Agreement State, it is necessary to evaluate the training and experience of these individuals to serve as AMPs to ensure that they have achieved a level of radiation safety knowledge sufficient to function independently as an AMP for each type of medical unit for which the individual would be responsible. The NRC staff does not believe that it is appropriate to "grandfather" medical physicists to allow them to serve as AMPs, absent such an evaluation having been conducted. Regulatory agencies in Agreement States, that have not been identifying on licenses those individuals who have been authorized to serve as medical physicists for the types of use and of concern to the ACMUI should identify (approve) medical physicists on licenses and amendments for types of use for which status as an AMP is required under revised regulations, including previously authorized medical physicists. These individuals, who have been identified on a license, would also be able to serve as preceptors for individuals to become AMPs.

Issue 3: Requirements for clinical experience to serve as an AMP.

Comment: Some commenters believe that proposed § 35.51(a)(2)(i) would allow individuals with no clinical experience (*e.g.*, research post-doctoral candidates supervised by a boarded physicist), to sit for board certification examinations. Therefore, they suggested the following change to § 35.51(a)(2): "Have 2 years of full-time practical training and/or experience in a clinical radiation oncology facility providing high-energy external beam therapy and brachytherapy services under the supervision of (i) a medical physicist who is certified by a board recognized by the Commission or an Agreement State, or (ii) physicians who meet the requirements for §§ 35.490 or 35.690 authorized users."

Response: As in the proposed rule, the regulations in the final rule for recognition of specialty board certifications for AMPs require candidates for certification to have 2 years of practical training and/or supervised experience in medical physics and to pass an examination which assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery. The NRC believes that these requirements, in combination with the requirements for type of use specific training and for a preceptor attestation that a candidate for AMP has achieved a level of competency sufficient to function independently as an AMP, are adequate to assess the T&E of candidates for status as AMPs.

Section 35.57—Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist

Comment: The ACMUI suggested that licenses should be amended to provide that current authorized users of sodium iodine-131 for imaging and localization, involving greater than 30 microcuries, continue to be authorized for these uses.

Response: Section 35.57(b)(1) provides that AUs who are identified on a license or permit are not required to comply with the training requirements

in Subparts D through H to continue performing those medical uses for which they were authorized before October 24, 2002 (the effective date of the current regulations). Under § 35.57(b)(2), the same provision applies to AUs authorized between October 24, 2002 and the effective date of this final rule, (April 29, 2005). NRC licenses are being amended accordingly.

Subpart D—Unsealed Byproduct Material—Written Directive Not Required

Section 35.290—Training for Imaging and Localization Studies

Comment: The ACMUI suggested that the revised regulations should, in the future, allow § 35.200 practitioners to conduct any I–131 imaging and localization involving greater than 30 microcuries, excluding sodium iodine, without further training and experience.

Response: Section 35.57(b)(1) provides the exception sought by the commenter by not requiring AUs to comply with the training requirements in Subparts D through H and to continue performing those medical uses for which they were authorized before October 24, 2002 (the effective date of the current regulations). Section 35.57(b)(2) allows AUs, authorized between October 24, 2002 and the effective date of this final rule (April 29, 2005) to continue performing those medical uses for which they were authorized during this period. NRC licenses are being modified accordingly.

Comment: The ACMUI recommended that the NRC provide a clarification that, for the diagnostic use of I–131 as sodium iodide which falls under § 35.392 for diagnostic use only, the training which an individual may cite for uses under § 35.392 may also serve as credit as part of the 700 hours of training for uses under § 35.200.

Response: The NRC requirement for 80 hours of training for uses under § 35.392 may be credited towards the 700 hours of training for uses under § 35.200 under the current regulations in § 35.290 and under the final rule.

Subpart E—Unsealed Byproduct Material—Written Directive Required

Section 35.390—Training for Use of Unsealed Byproduct Material for Which a Written Directive Is Required

Comment: A commenter indicated that the NRC is imposing a new requirement in its regulations for 700 hours of training for uses for which a WD is required. The commenter indicated that this is 620 hours more than is required for the use of sodium iodide I–131 in quantities up to 1.2 GBq (33 millicuries) for therapeutic applications, for which 80 hours of training is required under § 35.392. Further, an examination is required for recognition of certifications of specialty boards under § 35.390, but not under § 35.392. The commenter stated that risk-based regulations could not be used to justify the requirement for 620 more hours of training given that only 80 hours of training are required for the use of I–131 for treatment, and that virtually all medical events related to the use of unsealed sources are due to the use of I–131. Another commenter expressed similar views and added that it is inconsistent to have minimal requirements for alternate training pathways while placing more prescriptive requirements for training on specialty boards that already require far more than the alternative pathway. The commenter stated that the NRC should reconsider the requirements for the alternate pathway to remove these inconsistencies.

Response: The NRC did not propose to change requirements for the number of hours of T&E for individuals to qualify as AUs via the alternate pathway under §§ 35.390, 35.392, or 35.394. The issues raised by the commenter were discussed extensively in the SUPPLEMENTARY INFORMATION for the current rule in response to public comments in Part II, General Issues, Section E, Training and Experience, published in the Federal Register on April 24, 2002 (67 FR 20249). That discussion indicates that the NRC agreed with comments indicating that the T&E requirements should be increased for individuals who wish to use byproduct material for which a WD is required. The number of hours required were increased from 80 to 700 hours in § 35.390 for uses of unsealed byproduct material for which a WD is required. In addition, the work experience in the administration of such dosages to patients must include at least three cases in each of the following categories for which the individual is requesting AU status: (1) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I–131, for which a written directive is required; (2) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I–131; (3) Parenteral administration of any beta-emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or (4) Parenteral administration of any other radionuclide, for which a written directive is required. Physicians who are authorized under § 35.390 for all of these types of administrations also meet the requirements in §§ 35.190, 35.290, 35.392, and 35.394. The NRC continues to believe that the increase in T&E hours was needed because these physicians are authorized to elute generators and prepare radioactive drugs, as well as to administer a wide variety of radionuclides for which WDs are required. Thus, the associated radiation risks of the use could be greater. The discussion in the SUPPLEMENTARY INFORMATION for the current rule also indicates that requirements for T&E were carried forward into the current rule, in § 35.392, for AUs to perform oral administration of sodium iodide I–131 in dosages less than or equal to 1.22 gigabecquerels (GBq) (33 millicuries (mCi)), if they do not prepare radioactive drugs using generators and reagent kits. To qualify as an AU under this limited authorization, an individual must have 80 hours of classroom and laboratory training and supervised work experience that includes 3 cases involving the oral administration of sodium iodide I–131 in dosages less than or equal to 1.22 GBq (33 mCi). Finally, the discussion indicated that requirements were carried forward to the current rule, in § 35.394, for AUs to perform oral administration of sodium iodide I–131 in dosages greater than 1.22 GBq (33 mCi), and do not prepare radioactive drugs using generators and reagent kits. To qualify as an AU under this limited authorization, an individual must have 80 hours of classroom and laboratory training and work experience that includes 3 cases involving the oral administration of sodium iodide I–131 in quantities greater than 1.22 GBq (33 mCi). Physicians authorized under § 35.394 also meet the T&E criteria in § 35.392. Based on licensee use, NRC inspections, and experience with medical events reported since the current rule became effective, on October 24, 2002, the NRC continues to believe that the requirements in §§ 35.390, 35.392, and 35.394 are necessary and sufficient.

Comment: One commenter suggested that the NRC add "diagnostic radiology" to the description of residency programs, which now includes "residency training in radiation therapy or nuclear medicine training program or a program in a related medical specialty."

Response: The NRC believes that the description of "residency programs" should be limited to those which have direct applicability to the use of byproduct material for which a WD is required. Use of the general term

"related medical specialty," allows for training in diagnostic radiology.

Comment: Some commenters believe that to recognize radiation therapy and nuclear medicine residency programs as they now exist, the T&E criteria in § 35.390(a)(1) should be changed to allow for a 2-year nuclear medicine residency program as an alternative to a 3-year residency program in radiation therapy.

Another commenter indicated that the requirement for a 3-year residency should be removed from § 35.390 because it is inappropriate for the NRC to specify training requirements related to the practice of medicine.

Response: The NRC agrees that the requirement for residency programs to be 3 years in duration should be removed from § 35.390. In the final rule, this section no longer refers to the duration of residency programs.

Comment: Two commenters requested that the requirements in § 35.390 be changed to permit individuals trained in radiation oncology residency programs to use unsealed sources under § 35.300. The totality of all work experience possessed by individuals who have completed an accredited residency program in radiation oncology should be considered. The rule should exempt these individuals from requirements in § 35.390(b)(1)(ii) because radiation oncologists have unique experience that qualifies them to perform therapeutic procedures using unsealed sources. Another commenter stated that the American Board of Medical Specialties (ABMS) certified nuclear medicine physicians, radiologists, and radiation oncologists have unique training, experience, and examinations that go well beyond the minimum requirements of the alternate pathway. Therefore, the NRC should only require in § 35.390 that any ABMS medical specialty board meet the same minimal requirements specified for the alternate pathway in proposed § 35.390(b)(1)(ii). The commenter also suggested removal of any additional requirements for an ABMS board such as an examination, and approval of ABMS boards based upon their formal training and examination procedures which would be outlined by the boards in their applications for approval.

Response: The NRC agrees that physicians trained in radiation oncology may have adequate T&E for certain medical uses of unsealed byproduct material for which a WD is required. One pathway now exists (*i.e.*, licensees may apply for approval of physicians to serve as AUs for use under § 35.300 via the alternate pathway), which includes a requirement for completion of a residency program that includes 700 hours of training and experience in basic radionuclide handling techniques, applicable to the medical use of unsealed byproduct material for which a WD is required, as specified in § 35.390(b)(1). The NRC understands, however, that there are classes of physicians who may be well qualified but do not meet the requirement for 700 hours of T&E for unsealed byproduct material. For example, physicians who meet the requirements for T&E for uses under §§ 35.490 or 35.690 have a good understanding of radiation which applies to the use of sealed sources that is common to the use of unsealed sources. However, the NRC believes that, because of the increased risk associated with the use of unsealed sources for which a WD is required, it is essential to ensure that AUs have adequate T&E for this use. Commenters suggested removing requirements for 700 hours of T&E for uses under § 35.300, but that would remove essential requirements for T&E for use of unsealed byproduct material for which a WD is required. Therefore, the NRC has included a new § 35.396 in the final rule to provide a pathway for becoming a AU for uses of byproduct material under § 35.300, for individuals who may have acquired adequate T&E other than that specified in § 35.390 and other sections of Subpart E. This new § 35.396, "Training for the parenteral administration of unsealed byproduct material for which a written directive is required," specifies requirements for T&E that relate to the use of unsealed byproduct material for which a WD is required. These requirements were modeled after the requirements in other sections of Subpart E and include 80 hours of T&E specific to the use of unsealed sources and experience with at least three cases involving parenteral administration of byproduct material for which a WD is required. Section 35.396 allows for individuals to take credit for T&E associated with other medical uses of byproduct material that may be applicable to the uses of unsealed byproduct material, *e.g.*, individuals who are certified by boards who meet the requirements of §§ 35.490 or 35.690 for the use of sealed sources. The NRC believes that this new section will provide the flexibility needed to allow individuals, who do not meet other requirements in Subpart E, to serve as AUs for parenteral administration of byproduct material for which a WD is required while ensuring adequacy of T&E for these uses to be safe.

Comment: One commenter stated that § 35.390(b)(1)(ii)(G) deals with the therapeutic administration of certain unsealed sources orally and by parenteral administration, *i.e.*, by way of the intestines. The commenter stated that, because radiopharmaceutical therapies are now delivered by a variety of routes, the term "parenteral administration" should be changed to "administration by any route."

Response: The NRC believes that the hazards and precautions associated with parenteral administrations of unsealed byproduct material are significantly different from those associated with oral administrations and that the requirements in § 35.390(b)(1)(ii)(G) are sufficiently broad as to cover the various uses for which a WD is required. Therefore, the NRC has retained requirements for experience with both oral and parenteral administrations for which a WD is required. The NRC also notes that the medical use of byproduct material under § 35.300 is not limited to "therapeutic" administrations, but applies to uses for which a WD is required (*see* § 35.40 for related requirements).

Comment: The ACMUI recommended removing the requirement for work experience with elution of generators and measuring, testing, and processing of eluates for preparation of radiolabeled drugs in § 35.390(b)(1)(ii)(F). The ACMUI believes that it is not necessary to require all users of byproduct material, under § 35.300, to have experience with elution of generators and, further, that it is sufficient to require, in § 35.390(b)(1)(ii)(C), work experience with safely preparing patient or human research dosages. However, the ACMUI recommended that the requirement for elution of generators be retained for training in the use of byproduct material for individuals who may become AUs under provisions of § 35.290(b) by virtue of having been approved as an AU under § 35.390. A conforming change was recommended for § 35.100(b) for those AUs who qualify to prepare dosages if they meet the requirements in § 35.390, and in [revised] § 35.290(c)(2) for requirements for preceptors who meet the requirements of § 35.390.

Response: The NRC agrees with the recommendation of the ACMUI to remove the requirement for elution of generators and eluates in § 35.390(b)(1)(ii)(F) because this should not be required for AUs who do not need to use generators for uses of byproduct material under § 35.300 and because there is a requirement for safely preparing dosages in § 35.390(b)(1)(ii)(C). This change was made in the final rule along with conforming changes to retain the

requirement for this experience in §§ 35.100(b), 35.200(b) and 35.290(b).

Comment: One commenter stated that the Accreditation Council for Graduate Medical Education (ACGME) was incorrectly referred to as the "Accreditation Council on Medical Education."

Response: References to the ACGME have been corrected in the discussion of changes to §§ 35.390, 35.490, and 35.690.

Section 35.392—Training for The Oral Administration of Sodium Iodide I–131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicuries)

Comment: One commenter suggested that there should be a grandfathering clause in § 35.392 to allow AUs who were permitted to perform diagnostic total body imaging scans, previously under § 35.200, when the scans were classified as "diagnostic" and "therapeutic" rather than as procedures for which WD is required, to continue to perform these procedures.

Response: Section 35.57(b) provides that experienced AUs, identified on a license or permit, are not required to comply with the training requirements in Subparts D through H to continue performing those medical uses for which they were authorized before October 24, 2002 (the effective date of the current regulations). This provides the "grandfathering" requested by the commenter.

Subpart H of Part 35—Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Section 35.690—Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Comment: One commenter stated that AUs should be required to be neurosurgeons for use of gamma stereotactic radiosurgery treatments because a neurosurgeon is the only trained physician who has the knowledge unique to understanding the neuroanatomy of the brain. The commenter also suggested other changes to regulations, including a recommendation that the NRC require that WDs for gamma stereotactic radiosurgery be signed by both a treating neurosurgeon and radiation oncologist and that a neurosurgeon should be required to be physically present during treatments involving the gamma unit, with the radiation oncologist also present during the initiation of treatment.

Response: The NRC believes that it would be an unwarranted intrusion into the practice of medicine to specify that only neurosurgeons may serve as AUs for the use of byproduct material in stereotactic radiosurgery. The NRC believes that sufficient protections are included in Subpart H of Part 35 and other applicable sections of 10 CFR Part 35 to ensure that licensees develop safety procedures and training to ensure safety. They include several requirements for safe use of byproduct material specific to high dose rate units in § 35.615(a)–(g) as well as requirements for the physical presence of an authorized user and authorized medical physicist (in § 35.615(f)(3)).

Part IV—Implementation by Agreement States—Timing and Compatibility

Issue 1: Should Agreement States establish the requirements to conform with this proposed rule by October 24, 2005, or should they follow the normal process and be given a full 3 years to develop a compatible rule?

Comment: Agreement State commenters were generally in agreement that they should have 3 years to adopt the final rule. One commenter stated that there is not a basis for considering emergency action, and that time is needed to allow for States to develop implementation procedures as well as revising their regulations. Another commenter noted that a requirement to adopt the final rule by October 25, 2005, would result in that State not meeting Compatibility B requirements.

Other commenters indicated that it may take a full 3 years for some Agreement States to adopt comparable regulations, but they should be urged to do so as soon as practical, and the compatibility level for these regulations should remain as compatibility B. One commenter states that Agreement States can and should meet the October 24, 2005, deadline for developing a compatible rule. The commenter believes there is much confusion and misunderstanding on the part of applicants seeking AU status as they have one [or more] sets of requirements in Agreement States and another in non-Agreement States. In some States, these changes will require legislative action and the process needs to be started immediately to achieve compliance with the NRC's requirements. The commenter opposed this delay in the final implementation, indicating that extension of the deadline is quite unreasonable and unnecessary.

Response: The NRC acknowledges that the adoption of the final rule may take legislative action in some Agreement States and that some legislative cycles are up to 2 years in length. To allow adequate time for all Agreement States to adopt the final rule, and help avoid transboundary issues relating to differing standards between States, the NRC has determined that 3 years will be allowed for adoption of this Compatibility B final rule.

Comment: One commenter stated that obstacles to obtaining licensure in individual States discourage endocrinologists from providing treatment with I–131 when, in fact, endocrinologists, with their broad base of experience and training in all forms of thyroid disease and access to various forms of thyroid testing, are in the best position to judge the timing and appropriateness of radioiodine treatment.

Response: Current regulations, in §§ 35.392 and 35.394, include requirements that are specifically intended to enable endocrinologists (and other physicians) to obtain authorized user status for oral administration of sodium iodide I–131 for which a written directive is required. The requirements include 80 hours of classroom and laboratory training in subjects applicable to this usage plus work experience covering procedures important to this usage, including administering dosages to at least 3 patients or human research subjects. Preceptor statements required in the regulations can be completed by users authorized under these sections. The revised rule maintains these provisions. Because requirements for T&E are designated as compatibility category B, Agreement States must establish requirements that are essentially identical to NRC's.

Comment: One commenter suggested that the NRC enforce the compatibility requirements for Agreement States to comply with the requirements for T&E, published in the revised 10 CFR Part 35 on April 24, 2002, by October 25, 2005. The issues in the proposed rule are limited and do not affect the core of the training and experience requirements. The commenter indicated that progress on implementing compatibility in the Agreement States has been very slow. In some States, the regulatory changes must be implemented by legislative action, and the process should be started immediately to achieve compliance with the Federal mandate. Further delay in the adoption of the T&E requirements will inject added uncertainty into the process and delay unnecessarily the final resolution of the T&E issue.

Response: The NRC disagrees with the commenter's assertion that the

amendments proposed do not affect "core" requirements for T&E. Changes between current regulations and the final rule are substantial and Agreement States will need time to adopt the regulations, as noted in the commenter's observation that, in some States, legislative action will be required to adopt revised requirements for T&E. Therefore the NRC is allowing the full three years for adoption of the final rule.

Issue 2: Additional issues relating to implementation by Agreement States: Consistency of requirements.

Comment: Three commenters indicated that the regulations on T&E should remain classified as Compatibility B.

Response: The NRC has not changed its compatibility designation for requirements for T&E in the final rule; they remain classified as Compatibility B.

Comment: Some Agreement State commenters stated that T&E requirements are designated as Compatibility B because of transboundary issues. However, consistency will not be ensured unless a minimum number of classroom hours are specified for AUs in §§ 35.190, 35.290, and 35.390, and for nuclear pharmacists in § 35.55. Each Agreement State will either accept whatever is submitted by an applicant or will designate a minimum number of hours that will be accepted. In either situation, inconsistency will exist.

Response: The NRC's designation of requirements for T&E as Compatibility B is intended to establish uniformity regarding requirements to ensure consistency of requirements for T&E between Agreement States and between the NRC and Agreement States. The NRC agrees with the assertion of the Agreement States that a specification for a minimum number of hours of classroom and laboratory training will promote consistency of regulations between Agreement States, and between the NRC and Agreement States when applied to the alternate pathway. However, this requirement need not be added to requirements for recognition of specialty board certifications to ensure consistency. For these reasons and those discussed in Part II, Issue 1, of the Summary of Public Comments, requirements for a minimum number of hours of classroom and laboratory training have been included in §§ 35.55(b)(1)(i), 35.190(c)(1), 35.290(c)(1), and 35.390(b)(1) of the final rule. These amendments to the regulations will also help ensure that Agreement States maintain Compatibility B status of their regulations for T&E.

Comment: A commenter for OAS indicated that, in response to a poll, some Agreement State commenters argued against categorizing requirements for T&E as Compatibility B. Comments included the argument that this has diminished safety for certain uses of byproduct material, *e.g.*, for oral administrations of I–131 under §§ 35.392 and 35.394. One commenter also noted that a national standard for T&E makes sense because some States use the T&E evaluation of other licensing jurisdictions as part or all of their review of qualifications of applicants to become AUs. One commenter noted, however, that some Agreement States have, in the past, disagreed with the NRC's requirements for T&E and have effectively licensed users with differing qualifications, and recommended a change of designation for T&E regulations to Compatibility C.

Response: The issue of adequacy of T&E for oral administration of I–131 sodium iodide was thoroughly reviewed by the NRC in the SUPPLEMENTARY INFORMATION when the current regulations for medical use of byproduct material were developed for the revision of 10 CFR Part 35, published on April 24, 2002 (67 FR 20249). This analysis included a careful consideration to numerous public comments in relation to adequacy of T&E. Many of the issues raised by the commenters to justify a redesignation of T&E requirements as Compatibility C were also given considerable review during the development of the current regulations and the conclusion was reached that the assignment of the specific compatibility categories to the requirements in the current regulations was necessary to assure that byproduct material is used with a uniform level of radiation safety nationwide. Therefore, a basis for redesignation of Compatibility is unnecessary. Further discussion of the Compatibility designation for requirements for T&E appears above.

V. Summary of Final Revisions

Section 35.2—Definitions

The definition of "preceptor" is changed from "Preceptor means an individual who provides or directs the training and experience * * *." to read "Preceptor means an individual who provides, directs, or verifies training and experience * * *." The definition of "Radiation Safety Officer" is changed to include individuals who qualify as RSOs by meeting the new requirements in § 35.50(c)(1).

Section 35.8—Information Collection Requirements: OMB Approval

This section is amended to incorporate a conforming change related to the addition of § 35.396 to Subpart E of Part 35. The information collection related to this new section is noted in paragraph (b) by the addition of "§ 35.396" to the list of sections appearing therein.

Section 35.10—Implementation

This section is amended to incorporate a conforming change necessitated by the amendment of other sections. Paragraph (b) is amended to require implementation, on or before October 25, 2005, of §§ 35.50(a) and (e), 35.51(a) and (c), 35.55(a), 35.55(b)(1)(i), 35.190(a), 35.190(c)(1), 35.290(a), 35.290(c)(1), 35.390(a), 35.390(b)(1), 35.392(a), 35.394(a), 35.396(a), 35.396(c), 35.490(a), 35.590(a) and (c), and 35.690(a) and (c) and the requirement, in § 35.14(a), to provide a copy of written attestations to the Commission.

Section 35.13—License Amendments

This section is amended to incorporate conforming changes necessitated by amendments of other sections. Paragraph (b)(3) is amended to reference requirements for training specific for types of use specified in new § 35.51(c).

Section 35.14—Notifications

This section is amended to add a requirement to paragraph (a) to submit a copy of a written attestation, signed by a preceptor, in addition to a copy of the board certification now required in this paragraph. The section is also amended to require licensees to provide verification of completion of relevant training for individuals permitted to work as authorized individuals under § 34.13(b)(4).

Section 35.50—Training for Radiation Safety Officer

This section is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board's certification to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway (§ 35.50(b) in the current regulations), paragraph (a) is amended to provide separate requirements for a specialty board's certification process. This includes a requirement to pass an examination, administered by diplomates of the specialty board, that evaluates knowledge and competency in areas that are important to functioning

as an RSO. Requirements for training are changed to add requirements for a bachelor's or graduate degree from an accredited college or university in physical science, engineering, or biological science with a minimum of 20 college credits in physical science. Training requirements also include a minimum of 5 years of professional experience in health physics, including at least 3 years in applied health physics (graduate training could be substituted for up to 2 years of experience). Paragraph (a) is amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certifications. This requirement appears in paragraph (d) and applies to individuals for both the certification and alternate pathways. New paragraphs (a)(2) and (c)(1) are added that specify requirements for medical physicists to serve as RSOs. The term "classroom and laboratory training" is substituted for the word "didactic" in paragraph (b)(1)(i) to be consistent with usage in other sections. A new paragraph (e) is added to require training in radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks authorization. Paragraph (e) applies to all pathways. The requirement for a "written certification," signed by a preceptor, is changed to a requirement for a "written attestation," signed by a preceptor, in paragraph (d).

Section 35.51—Training for an Authorized Medical Physicist

This section is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board's certification to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) is amended to provide separate requirements for a specialty board's certification process. This process includes a requirement to pass an examination, administered by diplomates of the specialty board, that evaluates knowledge and competency in areas that are important to functioning as a medical physicist. Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certifications and now applies to each individual seeking approval as an AMP via either the certification or alternate pathway and is added to paragraph (a). A new paragraph (c) is added to require training related to the type of use for which authorization is sought that includes "hands on" device operation, safety procedures, clinical use, and operation of a treatment planning system. Paragraph (c) applies to the certification and alternate pathways. In addition, for the alternate pathway (paragraph (b)(1)), the acceptable areas of concentration for degrees are expanded, and a requirement that the degree be from an accredited college or university is added. Paragraph (b)(1) is also amended to list the specific areas for which the individual needs to have training and work experience, instead of referring to other sections of 10 CFR Part 35, and allows for the T&E to be received in clinical radiation facilities that provide high-energy, external beam therapy with photons and electrons with energies greater than or equal to 1 million electron volts and brachytherapy services. The term "written certification" in paragraph (b)(2) is changed to "written attestation."

Section 35.55—Training for an Authorized Nuclear Pharmacist

This section is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board's certification to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) is amended to provide separate requirements for a specialty board's certification process. This certification process includes a requirement to pass an examination, administered by diplomates of the specialty board, that evaluates knowledge and competency in areas that are important to functioning as an ANP. Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The requirement for didactic training in paragraph (b)(1)(i) is changed to specify that 200 hours of the 700 hours of training required under paragraph (b)(1) must be classroom and laboratory training; the term "classroom and laboratory training" is substituted for the word "didactic" to be consistent with usage in other sections. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certifications and now applies to each individual seeking approval as an AMP and is referenced in paragraph (a). The term "written certification" in paragraph (b)(2) is changed to "written attestation."

Section 35.57—Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist

This section is amended by adding two paragraphs, (a)(2) and (b)(2), to provide that (1) individuals identified as RSO's, AMPs or ANPs on a Commission or Agreement State license or permit, after the effective date (October 24, 2002) of the current requirements in Subpart B, and before the effective date of this final rule, may continue to serve in these positions; and (2) physicians, dentists or podiatrists identified as AUs on a Commission or Agreement State license or permit, who perform only those medical uses for which they were authorized between October 24, 2002, and the effective date of this final rule, need not comply with the training requirements of Subparts D through H.

Section 35.75—Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material

Paragraph (a) is amended to remove "(draft)" from footnote 1.

Section 35.100—Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required

A conforming change is made in § 35.100(b)(2) to add, and thereby retain, a requirement, formerly incorporated by reference to § 35.390(b)(1)(ii)(F), for work experience with elution of generators and the measuring, testing, and preparation of labeled radioactive drugs for those individuals who qualify for preparation of dosages for use under § 35.100 as AUs approved under § 35.390. The addition is accomplished by adding a reference to § 35.290(c)(1)(ii)(G) in § 35.100(b).

Section 35.190—Training for Uptake, Dilution, and Excretion Studies

Paragraph (a) is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board's certification to be recognized by the Commission or an Agreement State for uses under § 35.190. A requirement is added that candidates must pass an examination administered by diplomates of the specialty board. The requirement for obtaining a preceptor statement is removed from the

requirements for recognition of specialty board certifications and now applies to each individual seeking approval as an AU under § 35.100 and is referenced in paragraph (a). Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The introductory text of paragraph (c)(1) is amended to provide that a minimum of 8 hours of the 60 of training and experience, required in this paragraph, must be classroom and laboratory training. Paragraph (a)(1) is amended to clarify that this requirement does not apply to the certification pathway. The introductory text of paragraph (c)(1)(ii)(B) is amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments. The term "written certification" is changed to "written attestation" in paragraph (c)(2).

Section 35.200—Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive Is Not Required

A conforming change is made in §§ 35.200(b) to add, and thereby retain, a requirement, formerly incorporated by reference to § 35.390(b)(1)(ii)(F), for work experience with elution of generators and the measuring, testing, and preparation of labeled radioactive drugs, for those individuals who qualify for use under § 35.200 as AUs approved under § 35.390. The addition is accomplished by adding a reference to § 35.290(c)(1)(ii)(G) in § 35.200(b)(2).

Section 35.290—Training for Imaging and Localization Studies

Paragraph (a) is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board's certification to be recognized by the Commission or an Agreement State for uses under § 35.290. A requirement is added that candidates must pass an examination administered by diplomates of the specialty board. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certifications and now applies to each individual seeking approval as an AU under § 35.200. Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The introductory text of paragraph (c)(1) is amended to provide that a minimum of 80 hours of the 700 hours of training and experience, required in this paragraph, must be classroom and laboratory training. Paragraph (a)(1) is amended to clarify that this requirement does not apply to the certification pathway. Paragraph (c)(1)(ii)(B) is amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments. The term "written certification" is changed to "written attestation" in paragraph (c)(2). A conforming change is made in §§ 35.290(b) and 35.290(c)(1)(ii) to add a requirement for work experience with elution of generators and the measuring, testing, and preparation of labeled radioactive drugs for those individuals who qualify for use under § 35.290 as AUs approved under § 35.390. These requirements are also applicable to individuals serving as preceptors under § 35.290(c)(2).

Section 35.390—Training for Use of Unsealed Byproduct Material for Which a Written Directive Is Required

This section is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board's certification process to be recognized by the Commission or an Agreement State for uses under § 35.390. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) is amended to provide separate requirements for a specialty board's certification process. The requirement for experience with administration of dosages in paragraph (b)(1)(ii)(G) is no longer included in requirements for recognition of board certifications, but is retained as a requirement for individuals to become AUs for uses for which a WD is required by adding a reference, in paragraph (a), to paragraph (b)(1)(ii)(G). In paragraph (a)(1), the training and experience required for the certification pathway is changed to include a requirement that individuals complete residency training in a radiation therapy, nuclear medicine, or a related medical specialty training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association. A requirement is added that candidates must pass an examination administered by diplomates of the specialty board. Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certifications and now applies to each individual seeking approval as an AU under § 35.390 and is referenced in paragraph (a). The introductory text of paragraph (b)(1) is amended to provide that a minimum of 200 hours of the 700 hours of training and experience, required in this paragraph, must be classroom and laboratory training. Paragraph (b)(1)(ii)(B) is amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments. Paragraphs (b)(1)(ii)(G)(*1*), (*3*) and (*4*) are amended to revise requirements for work experience involving parenteral administration of dosages, clarifying them to indicate that the experience is to be with cases for which written directives are required. Paragraph (a)(2) is amended to clarify that candidates must pass an examination that tests knowledge and competence in use of unsealed byproduct material for which a WD is required. Paragraph (b)(1)(ii)(F) is removed to eliminate the requirement for work experience with elution of generators and the measuring, testing, and processing of eluates for preparing labeled radioactive drugs. The term "written certification" in paragraph (b)(2) is changed to "written attestation."

Section 35.392—Training for the Oral Administration of Sodium Iodide I–131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicuries)

Paragraph (a) is amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certifications and now applies to each individual seeking approval as an AU under § 35.392 and is referenced in paragraph (a). Paragraph (c)(2)(ii) is amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments. The term "written certification" in paragraph (c)(3) is changed to "written attestation."

Section 35.394—Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries)

Paragraph (a) is amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certification processes and now applies to each individual seeking approval as an AU under § 35.392 and is referenced in paragraph (a). Paragraph (c)(2)(ii) is amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments. The term "written certification" in paragraph (c)(3) is changed to "written attestation."

Section 35.396—Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive

A new § 35.396 is added to Subpart E. The section establishes T&E requirements applicable to AUs for the parenteral administration of unsealed byproduct material for which a written directive is required. The following individuals may serve as AUs under this section if they meet specified T&E requirements—

- Under paragraph (a), AUs under § 35.390 or, before October 24, 2005, § 35.930 for uses listed in §§ 35.390(b)(1)(ii)(G)(*3*) and 35.390(b)(1)(ii)(G)(*4*), or equivalent Agreement State requirements.
- Under paragraph (b), AUs for uses under §§ 35.400 or 35.600 or, before October 24, 2005, §§ 35.940 or 35.960, or equivalent Agreement State requirements.
- Under paragraph (c), physicians certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 35.400 or 35.600 or, before October 24, 2005, §§ 35.940 or 35.960.

The specified requirements for AUs under § 35.396 are as follows:

- T&E specific to the use specified in paragraphs (d)(1) and (d)(2), including 80 hours of classroom and laboratory training that includes topics and experience necessary for the safe use of unsealed byproduct material for parenteral administrations for which a written directive is required, and;
- Preceptor statements as specified in paragraph (d)(3).

Section 35.490—Training for Use of Manual Brachytherapy Sources

This section is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board's certification processes to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) provides separate requirements for a specialty board's certification process. In paragraph (a)(1), the training and experience required for the certification pathway is changed to include a requirement that individuals complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association. A requirement is added that candidates must pass an examination administered by diplomates of the specialty board. Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certification processes and now applies to each individual seeking approval as an AU under § 35.490 and is referenced in paragraph (a). The term "written certification" is changed to "written attestation" in the requirements for preceptor attestation in paragraph (b)(3). Paragraph (b)(2) is amended to include the Royal College of Physicians and Surgeons of Canada in the listing of organizations that can provide approval of the formal training program.

Section 35.491—Training for Ophthalmic Use of Strontium-90

Paragraph (b)(3) is amended to change the term "written certification" to "written attestation."

Section 35.590—Training for Use of Sealed Sources for Diagnosis

Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. Paragraph (c) was added and applies to both the certification and the alternate pathways. This revision separates the requirement for training in the use of the device for the uses requested from the requirement for 8 hours of classroom and laboratory training in basic radionuclide handling techniques.

Section 35.690—Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

This section is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board's certification processes to be recognized by the Commission or an Agreement State for uses under § 35.600. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) is amended to provide separate requirements for a specialty board's certification process. Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. In paragraph (a)(1) the training and experience required for the certification pathway is changed to include a requirement that individuals complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association. A requirement is added, in paragraph (a)(2), that candidates must pass an examination administered by diplomates of the specialty board. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certifications and now applies to each individual seeking approval as an AU under § 35.690. Additionally, for the alternate pathway, paragraph (b)(2) is amended to include the Royal College of Physicians and Surgeons of Canada in the listing of organizations that can provide approval of the formal training program. The requirement for experience in "radiation oncology" in paragraph (b)(2) is changed to require experience in "radiation therapy." The term "written certification" is changed to "written attestation" in the requirements for preceptor attestation in paragraph (b)(3). A new paragraph (c) is added to require training in device operation, safety procedures, and clinical use for the type(s) of use for which approval as an AU is sought. Paragraph (c) applies to all pathways.

Section 35.980—Training for an Authorized Nuclear Pharmacist

Paragraph (b)(2) is amended to change the term "written certification" to "written attestation," a conforming

change made to maintain consistency with other subparts of 10 CFR Part 35.

VI. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the Federal Register on September 3, 1997 (62 FR 46517), this final rule is a matter of compatibility between NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. The Compatibility classifications for sections amended in the final rule are unchanged. The new § 35.396 is classified as Compatibility Category B. A summary of compatibility classifications for amended sections in the final rule appears below.

Compatibility: Section.

Compatibility Category B: § 35.2, Definitions: Preceptor, radiation safety officer; §§ 35.50, 35.51, 35.55, 35.57, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, 35.590, 35.690.

Compatibility Category C: §§ 35.11, 35.75(a).

Compatibility Category H&S: §§ 35.100, 35.200.

Compatibility Category D: §§ 35.8, 35.10, 35.13, 35.14, 35.980.

A Compatibility Category B designation means the requirement has significant direct transboundary implications. Compatibility Category B designated Agreement State requirements should be essentially identical to those of NRC.

A Compatibility Category C designation means the essential objectives of this section should be adopted by the State to avoid conflicts, duplications, or gaps. The manner in which the essential objectives are addressed need not be the same as NRC, provided the essential objectives are met.

A Compatibility Category H&S designation means program elements are not required for purposes of compatibility; however, they do have particular health and safety significance. The State should adopt the essential objectives of such program elements to maintain an adequate program.

A Compatibility Category D designation means that the essential objectives of the section are not required for purposes of compatibility and do not need to be adopted by the Agreement States.

VII. Implementation

The revised regulations in 10 CFR Part 35 become effective on April 29, 2005. The Commission provides, by amendments to § 35.10(b), that licensees will have until October 24, 2005, to comply with the training requirements for authorized users, authorized medical physicists, authorized nuclear pharmacists, and Radiation Safety Officers. During this period, licensees will have the option of complying with either requirements of Subpart J, the expiration of which was extended by a separate rulemaking to October 24, 2005 (69 FR 55736, September 16, 2004), or the requirements in Subparts B and D through H of Part 35. The transition period will allow additional time for other specialty boards to seek NRC recognition of certifications as provided in §§ 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a). The transition period will also allow individuals from Agreement States time to satisfy the training requirements to work in NRC jurisdictions. The Commission also provides, by amendment to § 35.57, that individuals who have been named on existing Commission or Agreement State licenses and permits, between the October 24, 2002 (the effective date of current requirements for T&E, revised on April 24, 2002) and the effective date of this final rule, are exempt from the new requirements in Subparts D through H. The effect of this change to the regulations is to "grandfather" those individuals named on an existing Commission or Agreement State license or permit, for those use(s) for which they have been approved to serve as an RSO, AMP, ANP, or AU.

VIII. Voluntary Consensus Standards

The National Technology Transfer Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is modifying the training and experience requirements for radiation safety officers, authorized medical physicists, authorized nuclear pharmacists, or authorized users. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

IX. Finding of No Significant Environmental Impact: Environmental Assessment

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required. The environmental assessment is presented below.

Introduction

The NRC is amending its regulations governing the medical use of byproduct material to change its requirements for recognition of specialty boards whose certification may be used to demonstrate the adequacy of the training and experience of individuals to serve as radiation safety officers (RSOs), authorized medical physicists (AMPs), authorized nuclear pharmacists (ANPs), or authorized users (AUs). The final rule also revises requirements for demonstrating the adequacy of training and experience for pathways other than the board certification pathway. This rulemaking is necessary to address the training and experience issue for recognition of specialty board certifications.

The Final Action

This action amends the Commission's regulations governing the medical use of byproduct material (10 CFR Part 35). The final rule changes the requirements for recognition of specialty boards whose certification may be used to demonstrate the adequacy of the training and experience of individuals to serve as an RSO, AMP, ANP, or AU. This action also amends certain requirements for the training and experience of individuals who do not choose the board certification pathway.

During its revision of 10 CFR Part 35, the Commission became aware that, as a result of the changes to its training and experience requirements, specialty board certifications recognized by the NRC under the former regulations no longer would be qualified for recognition, and that this could result in a shortage of authorized individuals. As a temporary measure to address this issue, the Commission reinserted Subpart J to Part 35 into the final rule which was published in the Federal Register on April 24, 2002 (67 FR 20249). Subpart J to Part 35 was effective for a 2-year transition period, which would have expired on October 24, 2004. This action addresses the issue relating to recognition of board certifications after expiration of Subpart J on October 24, 2005.

Need for the Action

This rulemaking is needed to address the training and experience issue for recognition of certifications of specialty boards by the NRC for approval of individuals to serve as RSOs, AMPs,

ANPs, or AUs. Without this rulemaking, the issue of board recognition would not be addressed. Subpart J to Part 35 expires on October 24, 2005, and without this rulemaking, there could be a potential shortage of individuals authorized to perform medical procedures involving the use of byproduct material.

Alternatives to This Action

An alternative to this final rule would be to take no action. Subpart J to Part 35 would expire on October 24, 2005. The no-action alternative is not favored because the issues related to training and experience, as they relate to NRC's recognition of specialty boards, would not be resolved, and this could result in a shortage of RSOs, AMPs, ANPs, and AUs.

Environmental Impacts of the Final Action

The NRC prepared an environmental assessment as part of the development of the Part 35 final rule published in the **Federal Register** on April 24, 2002 (67 FR 20249). The conclusion from this environmental assessment was that the 10 CFR Part 35 amendments would have no significant impact on the public and the environment. Specifically, pertaining to the training and experience requirements, the environmental assessment stated: "The amendments to the training and experience requirements in 10 CFR Part 35 focus on knowledge and experience that is integral to radiation safety. These changes are expected to have no significant impact on public health and safety, occupational health and safety, and the environment." The NRC finds that the conclusion is still valid for the revisions to the training and experience requirements in this final rule. The revisions also focus on the knowledge and experience that is integral to radiation safety. The amendments to 10 CFR Part 35 are expected to have no significant impact on the public health and safety, occupational health and safety, and the environment.

Agencies and Persons Consulted and Sources Used

The environmental assessment for the final 10 CFR Part 35 rulemaking (67 FR 20249; April 24, 2002), was used in the preparation of this environmental assessment. The draft environmental assessment was sent to Agreement States and the Advisory Committee on the Medical Use of Isotopes for review and comment. The NRC staff has determined that this final action will not affect listed species or critical habitat. Therefore, no further consultation is required under Section 7 of the Endangered Species Act (16 U.S.C. 1531 *et seq.*). The NRC staff has determined that this action is not the type of activity that has potential to cause effects on historic properties. Therefore, no further consultation is required under Section 106 of the National Historic Preservation Act (16 U.S.C. 470 *et seq.*).

Finding of No Significant Impact

Based on the foregoing environmental assessment, the NRC concludes that this rulemaking will not have a significant effect on the quality of the human environment. Therefore, the NRC has determined that an environmental impact statement is not necessary for this rulemaking.

The determination of this environmental assessment is that there will be no significant impact to the public from this action.

X. Paperwork Reduction Act Statement

This final rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). These requirements were approved by the Office of Management and Budget, approval numbers 3150–0010 and 3150–0120.

The burden to the public for these information collections is estimated to average 1.4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Records and FOIA/Privacy Services Branch (T–5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by Internet electronic mail to *INFOCOLLECTS@NRC.GOV;* and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202, (3150–0010/3150–0120), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XI. Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. Single copies of the regulatory analysis are available from Roger W. Broseus, Office of Nuclear Material Safety and Safeguards, telephone (301) 415–7608, e-mail *RWB@nrc.gov.*

XII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the NRC certifies that this rule will not have a significant economic impact on a substantial number of small entities. This final rule amends the regulations governing the medical use of byproduct material to change its requirements for recognition of specialty boards whose certification may be used to demonstrate the adequacy of the training and experience of individuals to serve as radiation safety officers, authorized medical physicists, authorized nuclear pharmacists, or authorized users. This rule also revises the requirements for demonstrating the adequacy of training and experience of individuals who do not choose pathways other than the board certification pathway. This rule will have no burden or economic impact on licensees because it does not add new requirements; it provides a revision to an existing option. Therefore, it does not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 10 CFR Part 121.

XIII. Backfit Analysis

The Commission has determined that a backfit analysis is not required for this final rule because these amendments do not include any provisions that would require backfits as defined in 10 CFR Chapter 1.

XIV. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety

and health, Radiation protection, Reporting and recordkeeping requirements.

■ For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR Part 35.

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

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

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); Sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

■ 2. In § 35.2, the definition "Radiation Safety Officer" is amended by republishing the introductory text and revising paragraph (1) of the definition, and the definition of "Preceptor" is revised to read as follows:

§ 35.2 Definitions.

* * * * *

Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

* * * * *

Radiation Safety Officer means an individual who—

(1) Meets the requirements in §§ 35.50(a) or (c)(1) and 35.59; or, before October 24, 2005, §§ 35.900(a) and 35.59; or

* * * * *

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

§ 35.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.396, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.900, 35.910, 35.920, 35.930, 35.940, 35.950, 35.960, 35.961, 35.980, 35.981, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047 and 35.3067.

* * * * *

■ 4. In § 35.10, paragraph (b) is revised to read as follows:

§ 35.10 Implementation.

* * * * *

(b) A licensee shall implement the training requirements in §§ 35.50(a) and (e), 35.51(a) and (c), 35.55(a) and (b)(1)(i), 35.59, 35.190(a) and (c)(1), 35.290(a) and (c)(1), 35.390(a) and (b)(1), 35.392(a), 35.394(a), 35.396(b) and (c), 35.490(a), 35.590(a), and 35.690(a) and (c) on or before October 25, 2005. A licensee shall implement the requirement in § 35.14(a) to provide to the Commission a copy of written attestation(s), signed by a preceptor, on or before October 25, 2005.

* * * * *

■ 5. In § 35.13, paragraphs (b)(1) and (b)(3) are revised to read as follows:

§ 35.13 License amendments.

* * * * *

(b) * * *

(1) For an authorized user, an individual who meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), 35.690(a), 35.910(a), 35.920(a), 35.930(a) and 35.390(b)(1)(ii)(G), 35.392, 35.394, 35.940(a), 35.950(a), or 35.960(a) and 35.690(c);

* * * * *

(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.59 and 35.51(a) and (c); or §§ 35.59 and 35.961(a) or (b);

* * * * *

■ 6. In § 35.14, paragraph (a) is revised to read as follows:

§ 35.14 Notifications.

(a) A licensee shall provide the Commission a copy of the board certification and the written attestation(s), signed by a preceptor, the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, or the permit issued by a Commission master material license broad scope permittee for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under § 35.13(b). For individuals permitted to work under § 35.13(b)(4), within the same 30 day time frame, the licensee shall also provide, as appropriate, verification of completion of;

(1) Any additional case experience required in § 35.390(b)(1)(ii)(G) for an authorized user under § 35.300;

(2) Any additional training required in § 35.690(c) for an authorized user under § 35.600; and

(3) Any additional training required in § 35.51(c) for an authorized medical physicist.

* * * * *

■ 7. In § 35.50, paragraph (a), the introductory text of paragraph (b)(1)(i), paragraphs (b)(1)(ii)(G), and (c) are revised, paragraph (b)(2) is removed and reserved, and paragraphs (d) and (e) are added to read as follows:

§ 35.50 Training for Radiation Safety Officer.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (d) and (e) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1)(i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

(iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2)(i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics—

(A) Under the supervision of a medical physicist who is certified in

medical physics by a specialty board recognized by the Commission or an Agreement State; or

(B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.290, 35.390, or, before October 24, 2005, §§ 35.920, or 35.930; and

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(b) * * *

(1) * * *

(i) 200 hours of classroom and laboratory training in the following areas-(ii) * * *

(G) Disposing of byproduct material; or

* * * * *

(c)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.51(a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in paragraphs (d) and (e) of this section; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and,

(d) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (e) and in paragraphs (a)(1)(i) and (a)(1)(ii) or (a)(2)(i) and (a)(2)(ii) or (b)(1) or (c)(1) of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

(e) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

■ 8. In § 35.51, paragraphs (a) and (b) are revised, and paragraph (c) is added to read as follows:

§ 35.51 Training for an authorized medical physicist.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(2) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(2) Have 2 years of full-time practical training and/or supervised experience in medical physics—

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in §§ 35.490 or 35.690, or, before October 24, 2005, authorized users who meet the requirements in §§ 35.940 or 35.960; and

(3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(b)(1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

(iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (2), or (b)(1) and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51, or, before October 24, 2005, § 35.961, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(c) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

■ 9. In § 35.55, paragraphs (a), (b)(1)(i) introductory text, and (b)(2) are revised to read as follows:

§ 35.55 Training for an authorized nuclear pharmacist.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (b)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its

certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(b) * * *

(1) * * *

(i) 200 hours of classroom and laboratory training in the following areas—

* * * * *

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), (a)(2), and (a)(3) or (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

■ 10. Section 35.57 is revised to read as follows:

§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

(a)(1) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002, need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively.

(2) An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002 and April 29, 2005 need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively.

(b)(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2002, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D through H of this part.

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002 and April 29, 2005, need not comply with the training requirements of Subparts D through H of this part.

§ 35.75 [Amended]

■ 11. In § 35.75, paragraph (a), footnote 1, remove "(draft)".

■ 12. In § 35.100, paragraph (b)(2) is revised to read as follows:

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

* * * * *

(b) * * *

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920; or

* * * * *

■ 13. In § 35.190, paragraphs (a), the introductory text of (c)(1), (c)(1)(ii)(B) and (c)(2) are revised to read as follows:

§ 35.190 Training for uptake, dilution, and excretion studies.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and

(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

* * * * *

(c) * * *

(1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include—

(ii) * * *

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

* * * * *

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390, or, before October 24, 2005, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

■ 14. In § 35.200, paragraph (b)(2) is revised to read as follows:

§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

* * * * *

(b) * * *

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, or 35.390 and

35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920; or

* * * * *

■ 15. In § 35.290, paragraphs (a), (b), the introductory text of (c)(1) and (c)(1)(ii) introductory text, (c)(1)(ii)(B), and (c)(2) are revised to read as follows:

§ 35.290 Training for imaging and localization studies.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and

(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under § 35.390 and meets the requirements in § 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements; or

(c)(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum—

* * * * *

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290, or 35.290(c)(1)(ii)(G) and 35.390, or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements, involving—

* * * * *

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

* * * * *

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

■ 16. In § 35.390, paragraph (a), the introductory text of paragraphs (b)(1) and (b)(1)(ii) introductory text, paragraphs (b)(1)(ii)(B), (b)(1)(ii)(G)(1), (3) and (4), and (b)(2) are revised, and paragraph (b)(1)(ii)(F) is removed and reserved.

§ 35.390 Training for use of unsealed byproduct material for which a written directive is required.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(1)(ii)(G) and (b)(2) of this section. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs (b)(1)(i) through (b)(1)(ii)(E) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or

(b)(1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include—

* * * * *

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b) or, before October 24, 2005, § 35.930(b), must also have experience in administering dosages in the same dosage category or categories (*i.e.*, § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involve—

* * * * *

(B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

* * * * *

(G) * * *

(*1*) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131, for which a written directive is required;

* * * * *

(*3*) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

(*4*) Parenteral administration of any other radionuclide, for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) and (b)(1)(ii)(G) or (b)(1) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in § 35.390, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), or, before October 24, 2005, § 35.930(b), must have experience in administering dosages in the same dosage category or categories (*i.e.*, § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status.

■ 17. In § 35.392, paragraphs (a), (c)(2)(ii) and (c)(3) are revised to read as follows:

§ 35.392 Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).

* * * * *

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section and whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

* * * * *

(c) * * *

(2) * * *

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

* * * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.392, or 35.394, or, before October 24, 2005, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*1*) or (*2*).

■ 18. In § 35.394, paragraphs (a), (c)(2)(ii) and (c)(3) are revised to read as follows:

§ 35.394 Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).

* * * * *

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section, and whose certification has been recognized by the Commission or an Agreement State, and who meets the requirements in paragraph (c)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

* * * * *

(c) * * *

(2) * * *

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

* * * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390 or 35.394, or, before October 24, 2005, §§ 35.930 or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*).

■ 19. Section 35.396 is added to read as follows:

§ 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

Except as provided in § 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who-(a) Is an authorized user under § 35.390 or, before October 24, 2005, § 35.930 for uses listed in §§ 35.390(b)(1)(ii)(G)(*3*) or 35.390(b)(1)(ii)(G)(*4*), or equivalent Agreement State requirements; or

(b) Is an authorized user under §§ 35.490 or 35.690, or, before October 24, 2005, §§ 35.940 or 35.960, or equivalent Agreement State requirements and who meets the requirements in paragraph (d) of this section; or

(c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 35.490 or 35.690, or, before October 24, 2005, §§ 35.940 or 35.960; and who meets the requirements in paragraph (d) of this section.

(d)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390 or 35.396, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in §§ 35.390 or 35.930 must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(*3*) and/or 35.390(b)(1)(ii)(G)(*4*). The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.396, or, before October 24, 2005, § 35.930, or equivalent Agreement State

requirements. A preceptor authorized user, who meets the requirements in § 35.390, or, before October 24, 2005, § 35.930, must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(*3*) and/or 35.390(b)(1)(ii)(G)(*4*).

■ 20. In § 35.490, paragraphs (a), (b)(2) and (b)(3) are revised to read as follows:

§ 35.490 Training for use of manual brachytherapy sources.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State, and who meets the requirements in paragraph (b)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(b) * * *

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490, or, before October 24, 2005, § 35.940, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in § 35.490, or, before October 24, 2005, § 35.940, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), or (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.

■ 21. In § 35.491, paragraph (b)(3) is revised to read as follows:

§ 35.491 Training for ophthalmic use of strontium-90.

* * * * *

(b) * * *

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.490 or 35.491, or, before October 24, 2005, §§ 35.940 or 35.941, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

■ 22. In § 35.590, paragraphs (a) and (b) are revised and paragraph (c) is added to read as follows:

§ 35.590 Training for use of sealed sources for diagnosis.

* * * * *

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (b) and (c) of this section and whose certification has been recognized by the Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

(b) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include—

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(c) Has completed training in the use of the device for the uses requested.

■ 23. In § 35.690, paragraphs (a), (b)(2) and (b)(3) are revised, and paragraph (c) is added to read as follows:

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(3) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(b) * * *

(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in § 35.690, or, before October 24, 2005, § 35.960, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) or (b)(1) and (b)(2), and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in § 35.690, or, before October 24, 2005, § 35.960, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

■ 24. In § 35.980, paragraph (b)(2) is revised to read as follows:

§ 35.980 Training for an authorized nuclear pharmacist.

* * * * *

(b) * * *

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Dated at Rockville, Maryland, this 22nd day of March, 2005.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 05–6103 Filed 3–29–05; 8:45 am]

BILLING CODE 7590–01–P

Case Experience Using I-125 Seeds as Markers

Richard J. Vetter, Ph.D.
Radiation Safety Officer

Acknowledgements

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S Krage
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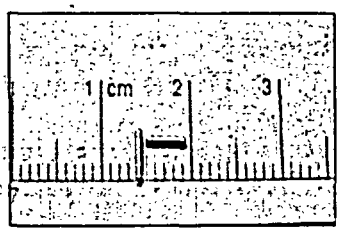
Disadvantages of Wire Localization

- Approach to tumor, radiologist vs. surgeon
- Scheduling conflicts
- Wire limits post-localization mammograms
- Wire migration & transection
- Infection

Alternative to Wire Radioactive Seed Localization (RSL)



The Seed

- Titanium Capsule
- 125-250 µCi ^{125}I
- $T^{1/2}$ 60 days

Advantages of RSL

- RSL up to 5 days before surgery minimizing scheduling conflicts
- Radiologist can approach from any direction
- Bracketing of lesions and post-localization mammograms not impeded by wires

Advantages of RSL

- Seed cost: $15.00
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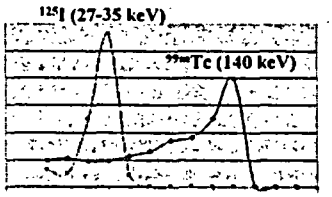

Prospective Comparison Mayo Scottsdale

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- WL same day as surgery
- 68% of RSL at least 1 day prior to surgery
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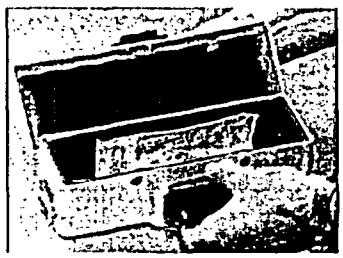
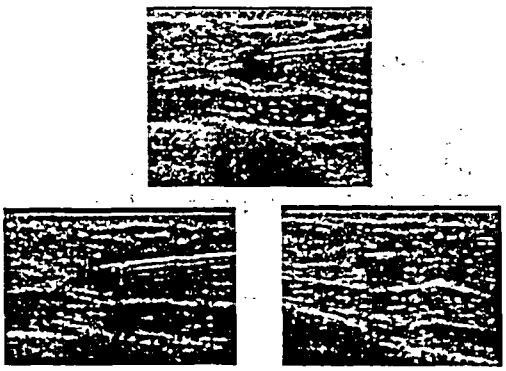
- Patients comfort & convenience

RSL Technique





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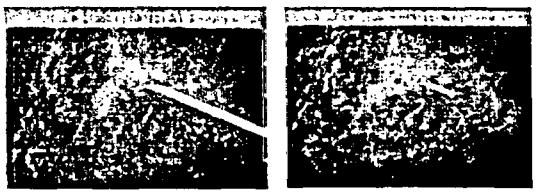
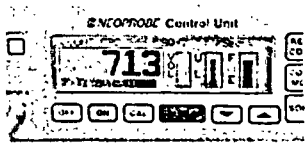
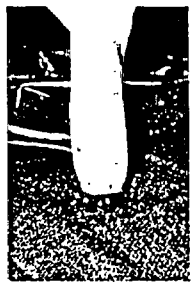


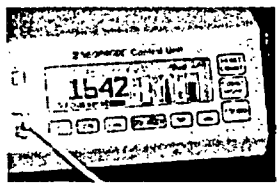
Post-Localization Mammogram



Dissection

Specimen





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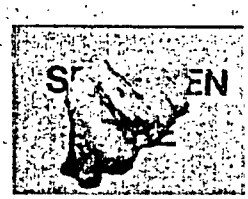

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	RSL	WL	p value
No. of patients	100	100	
Mean age (yrs)	64.1	63.3	0.82
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Mean tumor size (cm)	1.13	1.36	0.22
Margins negative 1st specimen	74	54	0.01
Margins negative 1st operation	90	76	0.01

Breast Dose

cm	rad [a]	rad [b]
1	20.1	
2	4.2	
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[a] 290 μCi ^{125}I for 5 days

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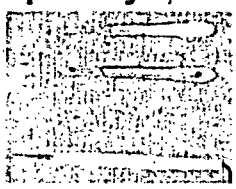
Objective: determine vulnerability of seed to rupture by

- Scalpel
- Cautery



Dummy seeds in pig tissue

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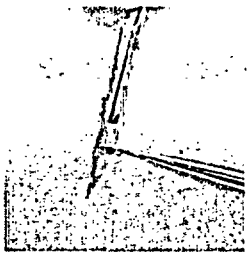

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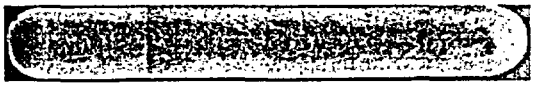

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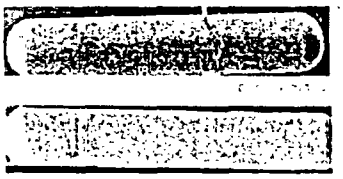

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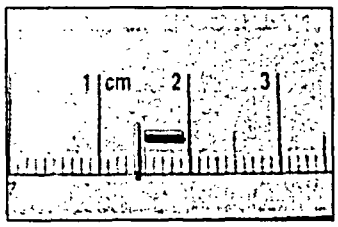

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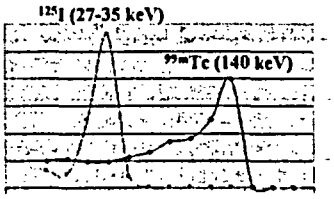

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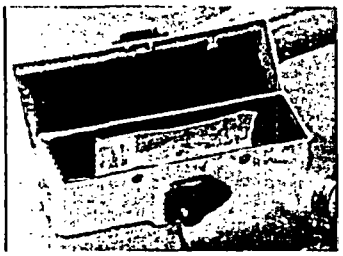

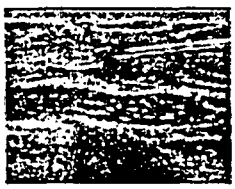

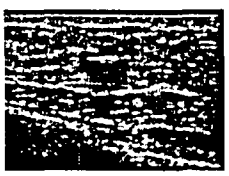

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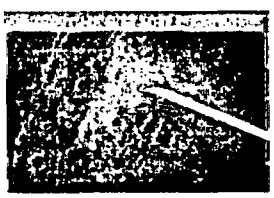

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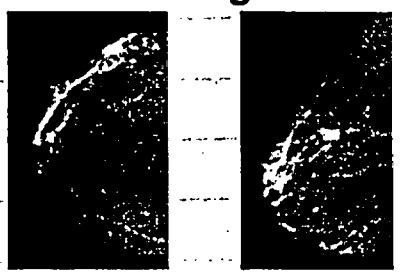

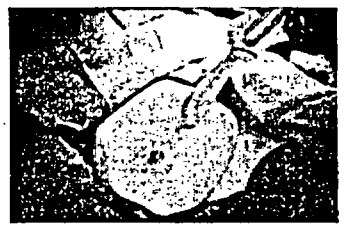

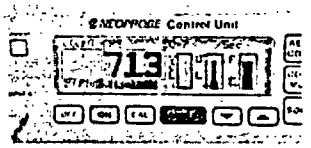

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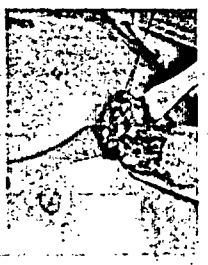

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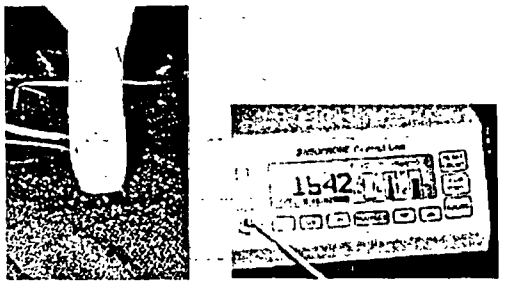

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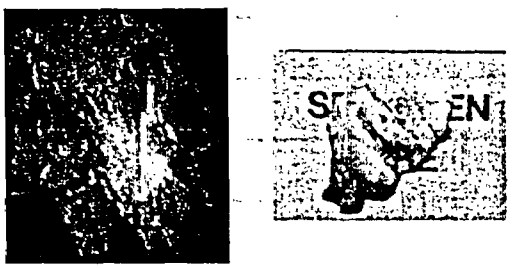

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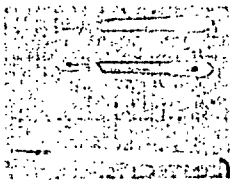

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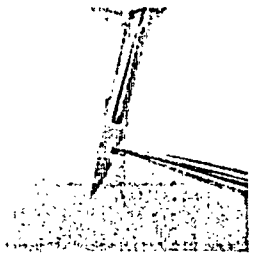

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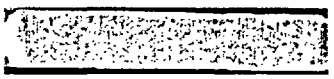

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Questions?

TAB 9

ESTABLISHING GUIDANCE ON EXCEEDING DOSE LIMITS FOR MEMBERS OF THE PUBLIC

Sami Sherbini
U.S. Nuclear Regulatory Commission

The Issue:

- Current dose limit for members of the public is 1 mSv and, under certain conditions, may be raised to 5 mSv
- Occasionally, these limits are not adequate, and higher limits are needed

When are higher limits needed ?

- In some hospital settings, and
- Member of the public participating in patient care (caregiver), and
- Resulting dose expected to be higher than 5 mSv

Options for choosing limits:

1. Use the occupational dose limit – 50 mSv

Not adequate because:

- the cost-benefit considerations do not match the caregiver situation
- the annual limit is an apportioned part of a lifetime risk
- may be more than is required

Options for choosing limits:

2. Use the Protective Action Guide for emergency situations of 250 mSv

More closely matches the cost-benefit considerations of the caregiver situation

Not adequate because:

Limit is too high for nearly all situations. May encourage higher caregiver doses than warranted

Options for choosing limits:

3. Consider the caregiver situation as part of the patient's treatment. Case-specific dose limits

Dose needed is formally established by the authorized user or designee for the specific case

This is the preferred option, and the one recommended to the Commission

- How it would work –
  - Treating physician/authorized user establish the need for a caregiver situation
  - Authorized user and radiation protection staff estimate needed dose based on available information/experience
  - NRC regional office contacted to obtain a case-specific license amendment

- How it would work –
  - Caregiver provided instructions and signs consent
  - Caregiver provided with dosimetry
  - Running total dose to date maintained by the radiation protection staff
  - Appropriate action taken if accumulated dose approaches selected limit

- How it would work –
  - A new limit established and reasons documented
  - NRC will issue guidance on the details of this process, including procedures for requesting exemptions, documentation to be maintained, monitoring requirements, and other details
  - The guidance will be used by the regional offices as well as by the Agreement States

- Regulatory Considerations
  - No rulemaking involved. There are not enough cases to justify rulemaking
  - Notification of regional office and obtaining amendment is necessary because the selected caregiver dose limit would not be in compliance with regulatory requirements
  - Experience with this approach may indicate the need for some modifications

END

TAB 10

RDRC Radiation Dose Limits for Human Subjects Using Certain Radiolabeled Drugs: Adults and Children

Orhan H Suleiman, MS, Ph.D., FAAPM
Senior Science Policy Advisor
Center for Drug Evaluation and Research (HFD-103)
Food and Drug Administration

Presented at Nuclear Regulatory Commission Advisory Committee on Medical Use of Isotopes
April 20, 2005
Marriott Bethesda, North
Rockville, Maryland

1

FDA Public Meeting Radioactive Drugs for Certain Research Uses November 16, 2005

- In 1975 authority for radioactive drugs transferred to FDA from NRC
- FDA promulgated 21 CFR 361.1* Radioactive Drug Research Committee (RDRC)

Meeting transcript and presentations available at:
www.fda.gov/cder/meeting/clinicalResearch/default.htm

* 40 FR 31308, July 25, 1975

2

Provisions within 21 CFR Part 361.1

- Pharmacological dose limits
- Radiation dose limits
- Qualifications of investigator
- Licensed radioactive materials
- Selection and consent of research subjects
- Quality of the radioactive drug
- Protocol design
- Report of adverse reactions
- Approval of IRB

3

Why do we need to revisit radiation dose limits?

- Based on 1975 occupational dose limits
- Evolving Metrics
- New radiation risk concepts - E
- New scientific data
- New pediatric human research regulations

E, effective dose

4

RDRC Radiation Dose Limits*

Organ or System	Single Dose	Annual and Total Dose
Whole body	0.03 Sv (3 Rem)	0.05 Sv (5Rem)
Active blood-forming . . organs	0.03 Sv (3 Rem)	0.05 Sv (5 Rem)
Lens of the eye	0.03 Sv (3 Rem)	0.05 Sv (5 Rem)
Gonads	0.03 Sv (3 Rem)	0.05 Sv (5 Rem)
Other organs	0.05 Sv (5 Rem)	0.15 Sv (15 Rem)

For research subjects under 18 years of age at his last birthday, the radiation dose does not exceed 10 percent of adult dose.

Radiation doses from x-ray procedures that are part of the research study shall also be included.

*21 CFR 361.1 (b) (3)

5

Rationale for adopting Occupational Dose Limits

- "An informed potential research subject is able to make a decision...and assume a risk in the same sense as does a radiation worker."
- "...that the radiation dose, even though it is within the limit, should be the smallest amount needed to carry out the study"* (ALARA – as low as reasonable achievable)

*Federal Register 31298 Volume 40 Number 144 (July 25, 1975)

6

RDRC Radiation Experience*

- Organ doses are the limiting constraint, not whole body limits.
- Reports suggest general compliance with radiation dose limits.

* Review of RDRC Annual reports

7

Evolving Metrics

1975 RDRC Dose limits- rem
1977 ICRP* promulgates effective dose equivalent, H.
1980's rad to Gray; rem to Sievert; mCi to MBq.
1991 NRC** adopts H for radiation dose
1991 ICRP replaces H with effective dose, E.
1993 NCRP*** adopts E.
2004 ICRP proposes modification of E.

*International Commission on Radiological Protection
**Nuclear Regulatory Commission
*** National Council on Radiation Protection and Measurements

8

Effective dose (E): A homogenized single metric of radiation risk

Risk based metric, relating partial body irradiations (individual organ or tissue, limited x-ray field) to uniform whole body irradiation.

The effective dose (E) is the sum of the weighted equivalent doses in all the tissues and organs of the body.

$$E = \Sigma_T \, w_T H_T$$

W_T is the weighting factor for tissue T, and
H_T is the individual tissue or organ dose for tissue T

*International Commission on Radiological Protection ICRP Report 60, (1991)

9

Effective Dose (E)

Tissue Weighting Factors (w_t)

Organ (Tissue)	ICRP 26 1977	ICRP 60 1991	ICRP-DRAFT 2004
Gonads	0.25	0.20	0.05
Breast	0.15	0.05	0.12
Red BM, lung	0.12	0.12	0.12
Thyroid	0.03	0.05	0.05
Bone surfaces	0.03	0.01	0.01
Colon, stomach	NC	0.12	0.12
Bladder, liver, esophagus	NC	0.05	0.05
Skin	NC	0.01	0.01
Salivary glands, brain	NC	NC	0.01
Remainder	0.30	0.05	0.10

10

Adult Effective dose (E)

Radiation Source	Effective Dose (E)	Equivalent to # of chest x-rays	Equivalent time	Lifetime* Cancer Mortality Risk
Background				
U.S. - 1 year	3 mSv	150	1 year	1.5×10^{-4}
Medical				
Chest x-ray	0.02 mSv	1	2.4 days	1.0×10^{-6}
Upper GI II	3 mSv	150	1 year	1.5×10^{-4}
CT- abdomen	10 mSv	500	3.3 years	5.0×10^{-4}
Tc-99m-lung perf	1 mSv	50	4 months	5.0×10^{-5}
Tc-99m-bone	4 mSv	200	1.3 years	2.0×10^{-4}
PET-FDG	10 mSv	500	3.3 years	5.0×10^{-4}
Regulatory Limits				
Individual Gen pop	1 mSv	50	4 months	5.0×10^{-5}
Worker	50 mSv	2500	16.7 years	2.5×10^{-3}
Emergency Worker	500 mSv	25,000	167 years	2.5×10^{-2}
NCRP Limits				
Whole body	50 mSv	2500	16.7 years	2.5×10^{-3}
RBM** (0.0 x .12) =	6 mSv	300	2.0 years	3.0×10^{-4}

*ICRP risk coefficients
**RBM = Red Bone marrow; ($H_{RBM} \times w_t$)= E

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We ask...

- Are current dose limits for adults still appropriate for research conducted under 361.1 ?
- If not, what dose limits are appropriate?
- Should there be different dose limits for different adult age groups?

12

Pediatric Effective Dose (E)

Radiation Source	Effective Dose (E)	Equivalent to # of chest x-rays	Equivalent time	Lifetime* cancer Mortality Risk
		Background		
U.S. - 1 year	3 mSv	150	1 year	$1.5\ 10^{-4}$
		Medical		
Chest X-ray -child	0.02 mSv	1	2.4 days	$1.0\ 10^{-6}$
PET FDG adult**	8 mSv	400	2.67 years	$4.0\ 10^{-4}$
PET 5 year old**	6.4 mSv	320	2.13 years	$3.2\ 10^{-4}$
PET 10 year old**	5.6 mSv	280	1.87 years	$2.8\ 10^{-4}$
		Regulatory Limits		
Individual Gen pop	1 mSv	50	4 months	$5.0\ 10^{-6}$
Pediatric RDRC Limits				
Whole body	5 mSv	250	1.67 years	$2.5\ 10^{-4}$
RBM*** (5 x .12) =	0.6 mSv	30	2.4 months	$3.0\ 10^{-6}$

*ICRP risk coefficients
**Stabin MG, Gelfand MJ. Q J Nuclear Med 1998 42 93-112.
***RBM = Red Bone marrow; $(H_{RBM} \times w_t) = E$

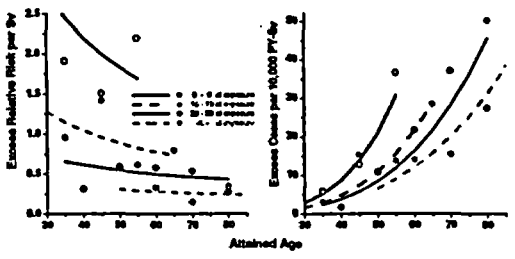
13

Pediatric ethics and risks

- Pediatric Ethics* - 21 CFR Part 50 Protection of Human Subjects
  Subpart D Additional Safeguards for Children in Clinical Investigations
- Higher risk for children
  "... a new finding is that relative risks decline with increasing attained age, as well as being highest for those exposed as children as noted previously."
- Noncancer risk
  "The evidence for radiation effects on noncancer mortality remains strong, with risks elevated by about 14% per sievert during the last 30 years of follow-up. Statistically significant increases are seen for heart disease, digestive diseases, and respiratory diseases."**
- Work in progress
  "People exposed prior to age 20 comprise the largest portion (41%) of the cohort and most of these are still alive...". "Because our risk models suggest that excess rates (particularly for cancer) are highest for those exposed as children, we anticipate that 60 to 70% of the radiation-associated deaths in the LSS cohort have yet to occur."**

*[illegible]
**[illegible]

14



From Preston et al. Radiat. Res. 160, 381-407 (2003)

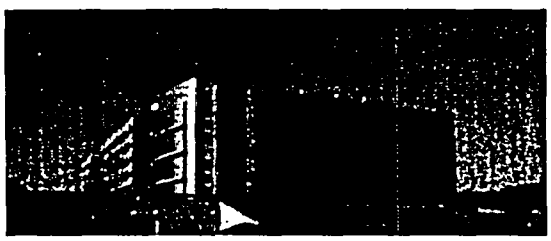
15

We ask...

- Does 361.1 provide adequate safeguards for pediatric subjects? If yes...
- Do current radiation dose limits for pediatric subjects pose a significant risk?
- If not, what dose limits would be appropriate to ensure no significant risk?
- Should there be different dose limits for different pediatric age groups?

18

FDA Campus @ White Oak,
Silver Spring, Maryland



Establishing Guidelines on Exceeding Dose Limits for Members of the Public

Ralph P. Lieto, MSE
ACMUI Member
April 20, 2005

Background/Purpose

- Commissioners Meeting
  - April 2, 2004
- ACMUI Meeting
  - April 8, 2002
- SECY 04-0107

Issue

- Allowing immediate family members or external caregivers to exceed 100 mrem (0.1 mSv) annual limit for members of the general public
  - Hospitalized patient with therapeutic amount of RAM
- 500 mrem (0.5 mSv) applies to released patients (10 CFR 35.75)

Assumptions

- Rare occurrence for any individual licensee
- The initiating event could occur within an extremely short time period (<24hrs)
- Licensee resources available because existing authorization for hospitalized patients

Guidelines Content

- What dose limit should be allowed
- Who
  - Patient
  - Family Caregivers
- Process
- Where should guidelines reference be

Guidelines Reference

- Regulation
- License Amendment
- Regulatory Guidance
- Regulatory Issue Summary
- Other?

Allowable Dose Limit

Two-tiered (annual dose)

1) >0.1 - 0.5 rem (5 mSv)
   - Immediately notify NRC Regional office (&/or Agreement State?) only
2) 0.5 - 5 rem (50 mSv)
   - Immediately notify NRC Regional office (&/or Agreement State?)
   - Fulfill criteria/commitments

Allowable Dose Limit

- 5 rem (50 mSv) justification
  - NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients", 1995
  - National occupational dose limit for radiation workers
  - FDA dose limits for research subjects of agents "generally recognized as safe", [21 CFR 361.1]

Who

- Patients
  - Life threatening (compassionate)
  - Medical care would be adversely affected (e.g. pediatrics)
  - Determined by patient's physician (& AU?)
- Family Caregivers
  - Relative or "extended" family
  - No Minors
  - Willingly accepted

Process Components

For the 5 rem "allowable" dose

- Immediate Notification
  - Hospital Management
  - Licensee RSO
  - NRC Regional office (&/or Agreement State?)
  - Hospital Risk Management

Process Components

For the 5 rem "allowable" dose

- Family caregiver(s) gets:
  - Individual dose monitor
  - Radiation precautions/risk instruction
  - Risk management consult
  - Informed Consent (AU & caregiver)
- Document each of above for regulatory review

Suggested Next Actions

- Review NRC information on any previous events authorized to date
- Draft guidelines with NRC staff addressing various process components
  - Target: Final ACMUI review & approval for October 2005

ACMUI BIENNIAL SELF EVALUATION

NO HANDOUT

PERSONNEL MATTERS

NO HANDOUT

PROTECTIVE MEASURES FOR CONTROL OF SOURCES

HANDOUT PROVIDED AT MEETING

TAB 14

Summary: Medical Event Reporting Issues

Jeffrey F. Williamson, Ph.D.
Chair, ACMUI Medical Event Subcommittee

Subcommittee Charge

- Evaluate 20% Threshold in ME rule
  - Appropriateness and justification
- How best to communicate risk
- permanent interstitial brachytherapy: Identify problems in current ME rule and solutions

Medical Event Subcommittee (MESC) activities

- Membership
  - D. Diamond, MD; S. Nag, MD; R. Lieto, MS; R. Zelec, PhD (liaison)
- Two closed MESC conference calls; two noticed public calls with ACMUI
- Consultant: Louis Potters, MD
- Some recommendations to be presented to ACMUI at April meeting

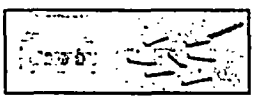
Outline

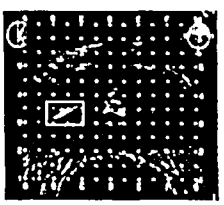
- Review ME issues in prostate permanent seed brachytherapy
- Review MESC consensus achieved to date
- Review issues still under discussion

Image-Guided Source Insertion Procedure

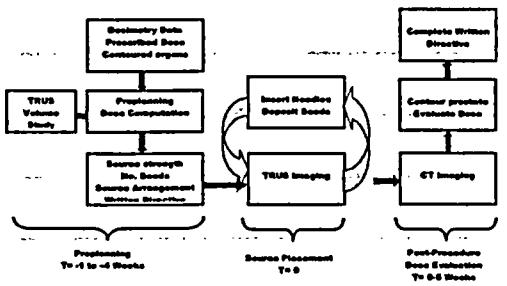
- 18 gauge (1.3 mm diameter) needle for seed placement
- Ultrasound probe in rectum for needle guidance
- TRUS = Trans-rectal ultrasound imaging

TRUS Image Guidance



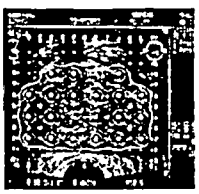


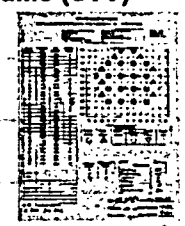
Prostate Brachytherapy Procedure Flow



Preplanning

- TRUS imaging 2 wks before implant
- Dose calculations to find needle loadings & seed strengths that deliver desired dose to clinical target volume (CTV)





Seed Insertion Procedure

- Patient anatomy may differ from preplan
  - Prostate: deformed/displaced/smaller
  - Needle insertion ⇒ prostate swelling
  - Needle insertion constraints
- AU must be free to adapt preplan to anatomy imaged during procedure

Post-Procedure Dose Evaluation

- CT imaging: 0-30 days later
- Contour CTV and organs at risk & calculate doses
- Post-implant doses, e.g., D_{90}, most definitive estimate of delivered dose

Current ME Definition

10 CFR 35.3045

- ME = byproduct material administration, in which
  - |Delivered - Prescribed|> 50 Rem AND > 20% OR
  - Dose to extra-target site > expected (planned) dose by 50 Rem AND 50%

Is 20% Level Justifiable?

MESC consensus

- For temporary implants, 20% is a reasonable regulatory action level
  - Only as a QA performance indicator, not as a patient harm index
- Permanent Implants: No
  - 20% comparable to normal practice variations
  - Dose-based ME definition not workable

Rationale: Prostate

- Variability in Post-Implant CT vs. written directive (WD) dose comparisons
  - CT vs. US CTV: 50% differences
  - Large CT contouring variations
  - Long/variable interval from Implant to dose calculation
  - legitimate preplan modifications

Other Permanent Implant Issues

- WD: 35.40(b)(6)(ii) allows AU to specify No. sources and dose at any time post-Implant
- Wrong site ME: unenforceable
  - Small error in seed position ⇒ Big dose changes to small volumes
  - To cover target, seeds in normal tissue may be needed

MESC Proposal

- Define ME in terms of where sources are implanted rather than dose delivered
- Recommendation 1: For permanent implants, require that WD document total source strength and no. seeds

MESC Proposal

- Recommendation 2: Replace wrong site and target volume ME definitions with:
- A permanent implant is a ME if (a) the total strength implanted exceeds WD by >20% OR (b) the source strength implanted in the target volume deviates from WD by > 20%.

MESC Proposal

- Recommendation 3: For permanent implants amend 35.40(c) and (b)(6)(iii) to require completion and any revision of WD within 1 working day of source insertion

Rationale: Recommendations 1-3

- Determining fraction of seeds in target much less variable than comparing doses
- AU can determine seed fraction intraoperatively, without waiting for post-implant planning
- Limiting WD revisions reduces abuses

Risk Communication

MESC proposals under discussion

- **Recommendation 4: Treat ME strictly as QA performance surrogate divorced from patient harm**
  - **Limit patient/relatives reporting requirement to MEs involving patient harm**
  - **Model NRC ME enforcement response on industry QA practices**

Rationale Rec 4:

- **ME reporting perceived as invitation for regulatory burden, negative public exposure, increased liability**
- **AU dilemma when reporting medically contraindicated: medical need vs. patient confidentiality**

Rationale Rec 4:

- **Industry practice**
  - **Errors alone not grounds for punishment**
  - **Error reports used to improve overall process**
  - **QA deliberations not discoverable**

Unresolved Issues

- Should dose calculation errors affecting source strength WD be exempt from regulatory review?
- Williamson: Add dose-calculation error ME pathway limited to preplanning
  - ME = any calculation ⇒ error in source strength WD > 20%

Other ME issues

- Is current wrong-site ME criterion workable and justifiable for other types of brachytherapy and external beam treatments?

Recommendations of ACMUI subcommittee on Medical Event (ME) Criteria.

Task of subcommittee: The subcommittee was formed during the ACMUI meeting of 13-14 Oct 2004 in response to the commissioners' memo No. M040302B dated March 16, 2004 to provide the ACMUI (and ultimately the NRC Commissioners) with recommendations concerning the current definition of medical event and how to communicate effectively to the public the associated risks, if any. In developing recommendations, the subcommittee should confirm that there was an appropriate basis, for applying the 20% reporting threshold for medical events to each modality, in the final Part 35 rule that became effective in October 2002.

Members: Jeffrey F. Williamson, Ph.D. (Chair), Subir Nag, M.D., David A. Diamond, M.D., Ralph P. Lieto, Ph. D.

Method: The sub-committee met by teleconference on December 7, 2004, January 13, 2005, January 18, 2005, and March 8, 2005. A practicing radiation oncologist, Dr. Louis Potter, provided expert consultation during part of the March 8 meeting. Dr. Nag also solicited the input of expert radiation oncologists at the American Brachytherapy Society Board meeting of March 24th. This report summarizes the combined opinion expressed at these meetings.

Summary of recommendations:

(1). Current regulations (35.40b) require a written directive before implantation stating: treatment site, radionuclide, and dose; and before completion of the procedure: the radionuclide, treatment site, number of sources and total source strength and exposure time or total dose. The subcommittee felt that this requirement was appropriate for **temporary (removable)** implants.

Additional comments: Expert radiation oncologist's comment noted that activity based (mg Ra Eq – hr) written directive is still being used at certain centers even for removable implants and that this method of written directive should not be excluded. Needs brief discussion at ACMUI.

The majority of subcommittee members felt that dose based written directive was problematic for **permanent** implants for two reasons: (a) for permanent implants one cannot define when the procedure is considered to be completed since theoretically the radiation duration is infinite and (b) the authorized user (AU) can control the quantity of the radionuclide implanted but has less control of the final dose which is dependant on many factors including edema, seed movement, migration, volume contouring etc. The vast majority of subcommittee members and practicing brachytherapy experts felt that for permanent implants, the authorized user (AU) should specify in the written directive the treatment site, the radionuclide and total source strength (rather than the dose). It is to be noted that a verbal order can be used to modify the written directive if a significant change from the preplan is observed during the brachytherapy procedure (also see section 3 below). In this way, the radiation oncologist can modify the written directive without breaking the sterile field. Present regulation [35.40(c)] requires the revised written directive to be signed by the AU **within 48 hours** of the verbal order.

A small minority felt that the written directive could be based on prescribed dose. However, it should be noted that if a dose based written directive is used for brachytherapy (eg 145 Gy for I-125 monotherapy) a resultant dose of 115 Gy or 175 Gy will be considered a medical event even if the implant site (prostate) was implanted satisfactorily.

A suggestion was made to replace a single prescribed dose with a dose range for permanent brachytherapy procedures. The subcommittee unanimously rejected this suggestion.

(2) Currently, a medical event results (35.3045a) if the total dose delivered differs from the prescribed dose by 20 percent or more. The 20% figure was originally derived from external beam (Cobalt-60) misadministration data. There were no rigorous evidence-based criteria for retaining the 20% variance threshold in the revision of Part 35. In large part, the 20% threshold was retained because it was in the prior version of the rule. Whether a variance of more than 20% will cause harm to a patient is highly dependent on the site and modality.

The subcommittee felt that 20% dose difference was a reasonable action level for reporting events of QA significance to NRC for temporary implants, external beam treatments, and unsealed radiopharmaceutical administrations **as long as medical event reporting is not automatically treated as an indicator of potential patient harm.**

The subcommittee felt that 20% absorbed dose difference was **not justifiable** as a medical event for permanent implants since the AU has control over the quantity of the radionuclide implanted but has less control of the final dose which is dependant on many factors including edema, seed migration, volume contouring etc. The subcommittee recommended that for permanent implants, medical event be defined (excluding seed migration and patient intervention), if (a) the total source strength implanted anywhere in the patient exceeds the written directive by more than 20% OR (b) the total source strength implanted in the planned target volume (PTV) deviates from the written directive by more than 20%. On discussing the above with practicing brachytherapists, it was felt that the definition was unnecessarily complicated and prescriptive and that we do not need both a and b. They suggested keeping the definition simple: "a medical event results if the total source strength implanted into the treatment site differs from the prescribed source strength by 20 percent or more. It is not considered to be a medical event if the deviation resulted from patient intervention or was due to seeds that were implanted in the

correct site but subsequently migrated outside the treatment site." There was much discussion about how to define treatment site (prostate, margins etc). It should be recognized that "treatment site" is difficult to define precisely and this problem applies both for permanent and removable implants. Some suggested using clinical target volume (CTV) or planned target volume (PTV) instead. The majority view was that the wording is better left as "treatment site" rather than imposing an arbitrary CTV or PTV, which could be subject to varied interpretations.

In addition to the above source-strength based medical events criteria Dr. Williamson asked that the following additional medical event criterion be considered:

"In addition to the above, a medical event is any administration of permanently implanted sealed byproduct material based upon erroneous dose calculations that lead a deviation of 20% or more in the source-strength documented in the written directive relative to a correctly executed dose calculation. Examples of targeted "erroneous dose calculations" would be:

a) Unintended deviations from nationally accepted dose-calculation protocols

b) Use of wrong data and data entry errors

c) Use of wrong units

d) Incorrect application of physician's dose-specification criterion

e) Incorrect entry of the intended pretreatment PTV.

Dr. Williamson's request has not been discussed in the subcommittee. Dr. Nag feels that it is a reasonable request.

(3) Another subcommittee recommendation was: "For permanent implants based on written directives specifying total source strength implanted in the treatment site. 35.40(c) and 35.40(b)(6)(iii) should be amended to require completion of the written directive and

documentation of any written directive revisions within 1 working day of completing the source insertion procedure." Dr. Nag believes that this recommendation came from the subcommittee's misunderstanding that current regulation allowed revisions to be made within one day of the procedure and they wished to change it to "one working day". Current regulation [35.40(c)] actually states: "A written revision to an existing written directive may be made if the revision is dated and signed by an AU before the administration of the brachytherapy dose. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented in the patients chart as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision." Note that there is no section 35.40(b)(6)(iii) in the current regulations.

Also it is to be emphasized that revisions to the written directive is to be made BEFORE the administration of the brachytherapy dose. Oral revisions (which have to be signed within 48 hours) are acceptable only if because of the patient's condition, a delay in the order to provide a written revision to an existing written directive would jeopardize the patient's health.

Dr. Nag believes that the subcommittee made their recommendation due to a misunderstanding. Dr. Nag's opinion is that the current regulation of April 24, 2002 need not be altered. This should be rediscussed before giving any recommendation about this section to the commissioners.

The subcommittee unanimously agreed that written directive revisions should only address legitimate medically indicated revisions of the treatment plan. Dr. Nag's opinion is that the

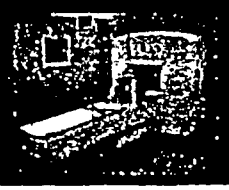
current regulation of April 24, 2002 (see above) already includes this and hence this recommendation is superfluous.

(4) Current regulations (35.3045e) require that the AU notify the patient and the referring physician in writing within 24 hours of discovery of a medical event. A major recommendation of the sub-committee is that the role of the Medical Event reporting rule should be as a technical quality performance indicator and should not be viewed as a potential patient harm index. The subcommittee recommended that NRC staff strive to make the medical event reporting process more like a QA process review that occurs following detection of a delivery error or potential error rather than a trigger for enforcement or penalization. To this end, the patient reporting requirement should be amended to require informing the patient and referring physician ONLY if the licensee determines that the medical event may have harmed the patient, could potentially harm the patient, or is materially relevant to the patients future medical treatment decisions. This was unanimously agreed within the subcommittee and practicing brachytherapists.

(5) Current regulation [35.3045 (a) (3)] requires licensee to report any event (except for an event that results from patient intervention) in which the radiation from byproduct material results in a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site). The subcommittee unanimously agreed that the dose-based wrong-site medical event criterion of 35.3045(a)(3) is completely impractical clinically for permanent implants and that permanent implants should be exempted from the wrong site ME reporting requirement, 35.3045(a)(3)."

The Neurosurgeon in Gamma Knife Radiosurgery: Maintaining Safety and Efficacy

Douglas Kondziolka, MD, MSc, FRCSC, FACS
University of Pittsburgh



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Professor of Neurological Surgery
Professor of Radiation Oncology
MS (thesis in radiobiology)

President, International Stereotactic Radiosurgery Society
Past-President, American Society for Stereotactic and Functional Neurosurgery

Douglas Kondziolka, MD, MS, FACS FRCS

Experience in Gamma Knife Radiosurgery

>3,000 personal cases
>1,000 animal experiments
>200 peer-reviewed journal publications
>100 book chapters
Edited 2 books
Current Editor of *Radiosurgery*

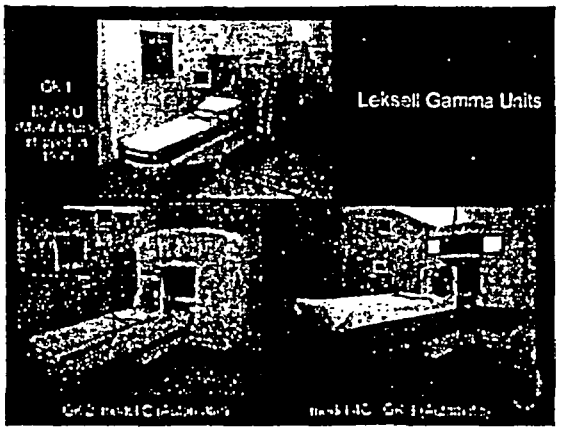
Douglas Kondziolka, MD, MS, FACS FRCS

Course Co-Director, Principles and Practice of
Gamma Knife Radiosurgery
Department of Neurosurgery, University of
Pittsburgh

Neurosurgeries = 2[illegible]
Radiation Oncologists = 233
Medical Physicists = [illegible]

Neurosurgery at UPMC
Technologies

- MRIs: 6
- CTs: 8
- Intraoperative CT 1
- Gamma Knife Units: 3
- Stryker Image Guidance: 2
- MEG: 1*
- Cyberknife: 1
- Synergy Linac: 1*
- PET: 2



The Radiosurgery Team

- Neurosurgeon
- Radiation Oncologist
- Medical Physicist
- Nurse

Adjunct: Neuroradiologist
Medical Oncologist

Stereotactic Radiosurgery

Single session, closed skull, definitive irradiation of a brain target using image-guidance and stereotactic precision

Gamma Knife Radiosurgery
Linear accelerator Radiosurgery
Charged Particle Proton Beam Radiosurgery

Gamma Knife Radiosurgery is Multi-Disciplinary

No neurosurgeon should do this procedure without a trained radiation oncologist (not any radiation oncologist)

A radiation oncologist should work with a trained neurosurgeon (not any neurosurgeon)

[illegible] of how this procedure is performed and what is in the best interest of the public

Neurosurgeons can are being excluded from the procedure as NRC regulations do not require neurosurgeons

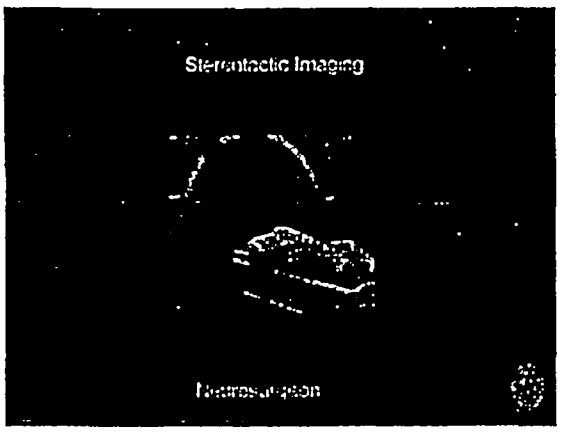
In Pennsylvania, a radiation oncologist used NRC regulations to keep a neurosurgeon out of the procedure

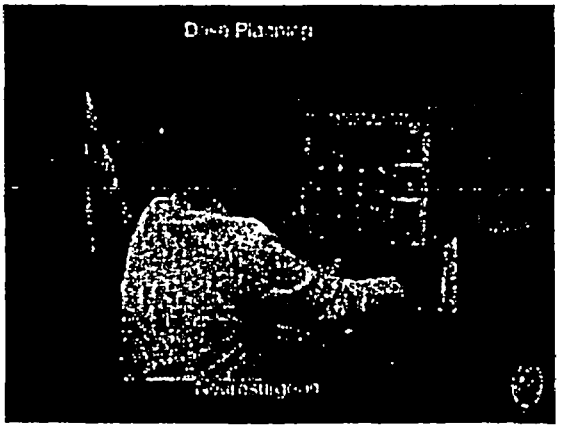
Is this what the NRC wants?

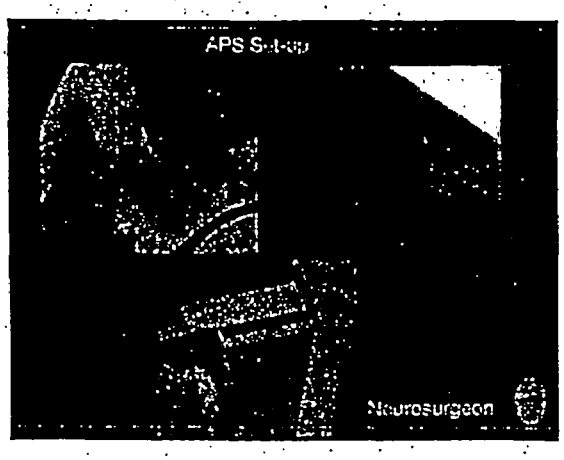
The patient is the one in jeopardy.

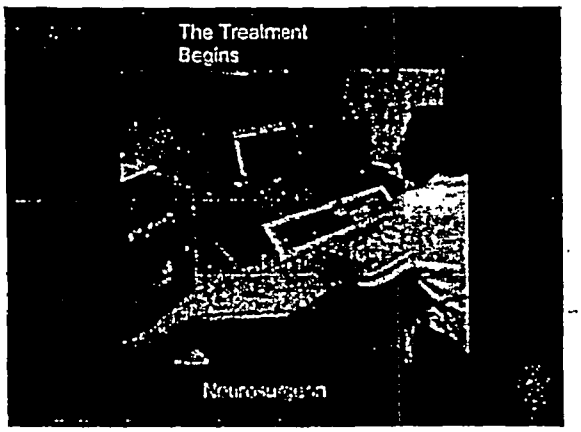
Frame Placement

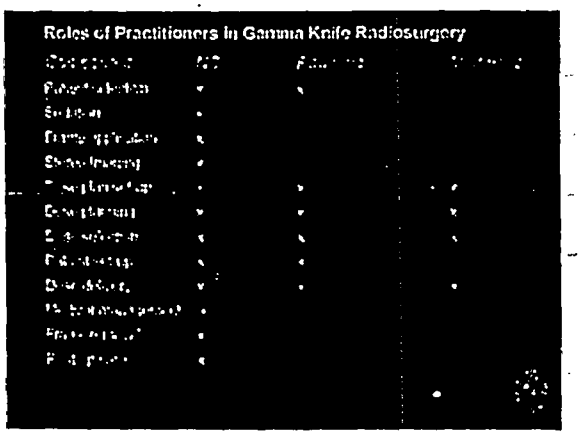
Neurosurgeon


Stereotactic Imaging


Dose Planning


APS Set-up
Neurosurgeon





According to the NRC: Neurosurgeons are not authorized users

(I was an approved NRC authorized user for many years before "losing" this license due to an NRC decision).

The Risk: Safe Patient Radiosurgery

Why is Safe Patient Radiosurgery at Risk?

Radiation Oncologists are not trained in many of the components of radiosurgery.

Not trained in residency.

Not trained in practice.

The neurosurgeon is required by training to remain present during all procedures.

1. Who else will take care of medical emergencies?
2. The neurosurgeon's name is on the hospital chart. It is the neurosurgeon's patient that day
3. The neurosurgeon carries the greatest medical liability risk.

The American Board of Neurological Surgery,

Definition

ACGME/RRC in Neurological Surgery

Clinical Components:

...cases should be appropriately distributed among cranial, extracranial, spinal, and peripheral nerve surgical procedures and should represent a well-balanced spectrum of neurological surgery in both adults and children. This spectrum should include craniotomies for trauma, verified neoplasms, aneurysms, and vascular malformations; extracranial carotid artery surgery; transphenoidal and stereotaxic surgery (including radiosurgery); pain management, and spinal procedures of a sufficient number and complexity using modern techniques that encompass a variety of disorders.

The American Board of Radiation Oncology

Definition

ACGME RRC in Radiation Oncology

Clinical Components

Facilities: There must be 2 or more megavoltage machines, a machine with a broad range of electron beam capabilities, a dedicated therapy simulator, 3dimensional conformal computer aided treatment planning, a system for construction of treatment aids, and equipment to perform interstitial and intracavitary brachytherapy.

The curriculum must provide instruction in the physics, radiation and cancer biology, and clinical applicability of the following areas: radiosurgery, intraoperative radiation therapy, 3D conformal treatment planning and delivery, radioimmunotherapy, unsealed sources, total body irradiation.

Residency Training in Radiosurgery

University of Pittsburgh

Neurosurgery: 4 month rotation for all neurosurgery residents (participation in over 250 cases)

Radiation Oncology: no formal training. Pitt residents see no case from start to finish.

Radiosurgery is Neurosurgery

- JCAHO (Joint Commission on Accreditation of Healthcare Organizations) certifies the service as surgical.
- 90% of all Gamma Stereotactic Units are set up and staffed as separate neurosurgical units within hospitals.
- Insurance Companies approve and pay for the procedure as neurosurgery using a neurosurgery procedure code.
- Medicare Inpatient pays the procedure as neurosurgery.

Why is Safe Patient Radiosurgery at Risk?

Radiation Oncologists are not trained in:

1. Neuroanatomy
2. Stereotactic frame use/imaging
3. Many of the disorders treated with radiosurgery
4. Acute patient care during procedures (ie. Seizures)

Why is Safe Patient Radiosurgery at Risk?

Radiation Oncologists are not trained in:

a. Brain vascular malformations (initially 50% of the cases, now about 5-10%)

b. Trigeminal neuralgia and other functional disorders

c. Movement disorders (Parkinsons disease, Essential tremor, epilepsy, pain)

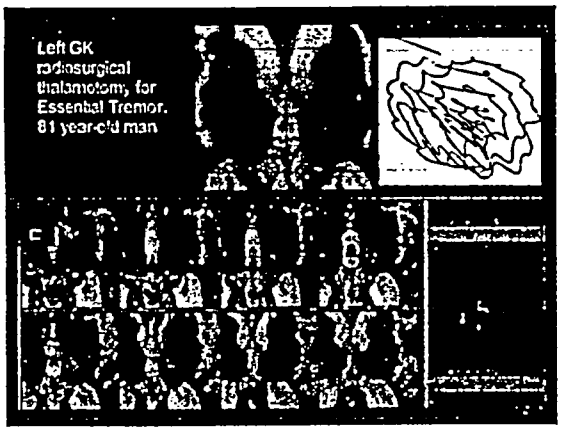
d. High dose, single session irradiation

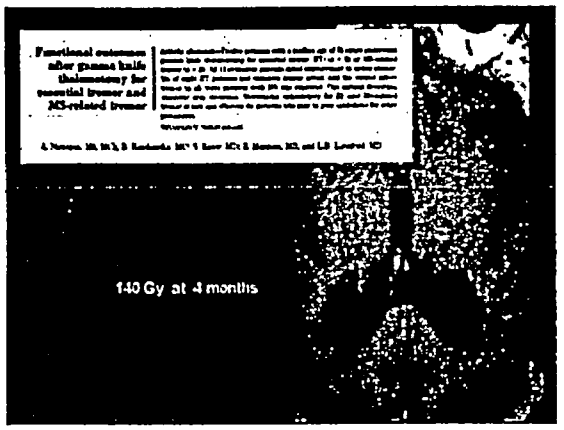
J Neurosurg [illegible]

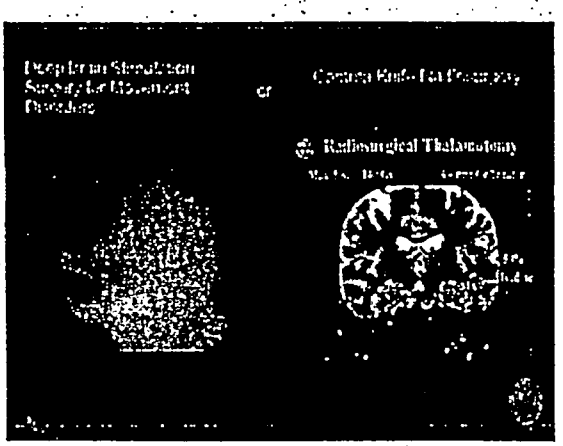
Stereotactic radiosurgery for brainstem arteriovenous malformations: factors affecting outcome

[illegible], M.D., Douglas Kondziolka, M.D., F.R.C.S.(C), Ajay Niranjan, M.Ch., John C. Flickinger, M.D., and L. Dade Lunsford, M.D.

Department of Neurological Surgery and Radiation Oncology, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania


Left GK
radiosurgical
thalamotomy, for
Essential Tremor.
81 year-old man


140 Gy at 4 months


or
Radiosurgical Thalamotomy

Imaging for Thalamotomy

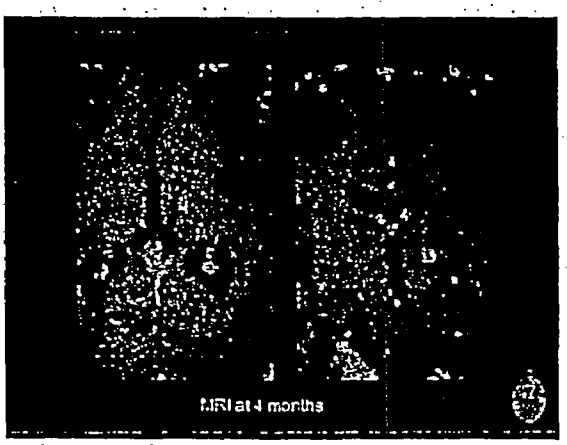
MRI

- Sagittal Scout Images-Fast spin echo
  3mm thick, 1 mm apart
- Axial SPGR contrast enhanced images
  1 mm thick, 0 mm apart
- Coronal or Axial STIR images
  3 mm thick, 0 mm apart

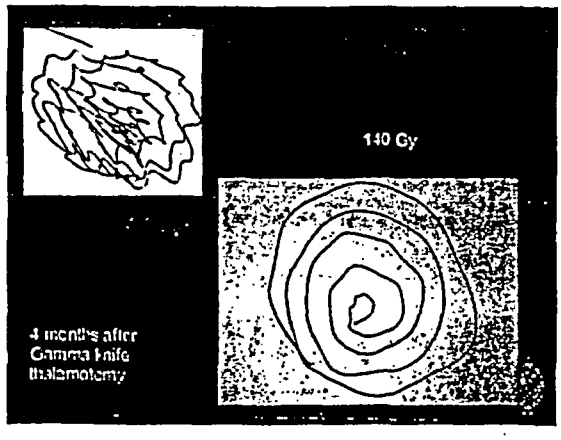
Target Selection: VIM

- A-P = 1/4th of AC-PC distance from PC - plus 1-2mm
- L-R = 1.2 the width of the III rd Ventricle + 11
- S-I = At the level of AC-PC line, or 2 mm above

  (radiosurgery – isocenter placed 2.5 mm above AC-PC line)



MRI at 4 months



What happens with a Poor Target?

Too far	Effect
Lateral	Motor deficit
Posterior	Numbness
Medial	Cognitive
Anterior	Transient benefit

Why is Safe Patient Radiosurgery at Risk?

Radiation Oncologists have limited training in:

a. Acoustic neuromas
b. Skull base meningiomas
c. Pituitary tumors
d. Draining and feeding vessels of AVM
e. Performing complex procedures (surgery)
f. Availability of alternative procedures

73 year-old woman, neurosurgeon's mother-in-law

Acoustic Neuromas

The New England Journal of Medicine

LONG TERM OUTCOMES AFTER RADIOSURGERY FOR ACOUSTIC NEUROMAS

Douglas Kondziolka M.D., L. Dade Lunsford M.D., Mark R. McLaughlin M.D., and John C. Flickinger M.D.

NEJM, 1998

Radiosurgery in Children

General anesthesia under age 12

AVMs and Tumors

Pilocytic astrocytoma is the most common tumor

Only surgeons direct entire procedures under general anesthesia.

Radiation Oncologists "understand" radiation dose selection and delivery.

Wrong.

- Unfortunately...these high single session doses have rarely been taught in radiation oncology training. Radiation oncologists do not deliver such doses routinely.

Is the radiation oncologist really necessary?

Yes

- But the radiation oncologist should be allowed to leave the suite. During administration, the unit can be stopped easily. Problems are RARE (no misadministrations in 7,000 patients at Pittsburgh) We need clear NRC guidelines
- Many GK units report to the IRSA that radiation oncologists routinely leave the suite. This is in keeping with the general practice of radiation oncology where therapists and technicians delivers the treatments and the oncologist is available if needed
- One misadministration (wrong side trigeminal neuralgia) was performed by a radiation oncologist (it was not his patient) since the neurosurgeon did not have to be there
- Neurosurgeon is required by licensure to stay throughout patient procedure as is the general practice of surgery

The neurosurgeon should be required to sign the directive along with radiation oncologists.

The NRC should not allow radiation technicians or therapists to operate gamma knife units. They have no training in this. We have never trained one in 43 didactic courses conducted.

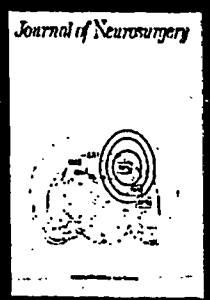
Does only a hospital have oversight?

The NRC should care and not place the patient in jeopardy without a neurosurgeon as an authorized user

Some Gamma knife units

- Are not owned by hospitals
- May be owned by a group of oncologists
- Are no longer located at hospitals
- For-profit ownership is creating pressure on inappropriate use

Who are the Scientific leaders of Gamma Knife Radiosurgery?



Studies in Gamma Knife Radiosurgery

Prospective database

Retrospective reviews

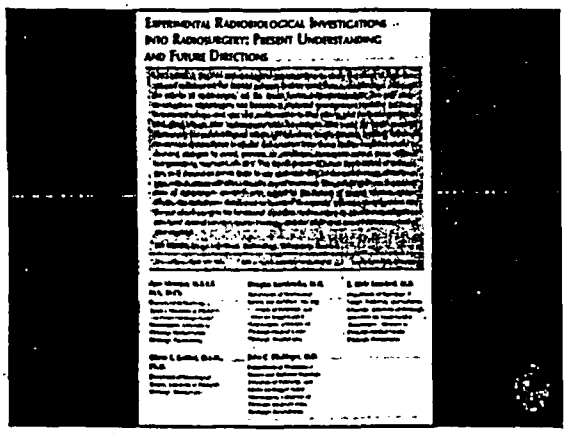
Randomized trials

HIPAA compliance

Who cares about the quality of gamma knife radiosurgery?

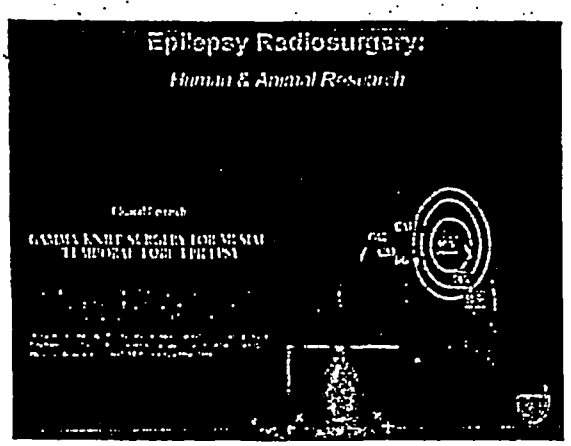
The [illegible] of the peer-reviewed medical literature on gamma knife radiosurgery ...

- Has been published by neurosurgical programs.
- With the neurosurgeon as lead investigator and author
- All animal based radiobiological research in gamma knife radiosurgery has been led by neurosurgeons



Epilepsy Radiosurgery:

Human & Animal Research



Radiosurgery for Epilepsy

Funding NIH

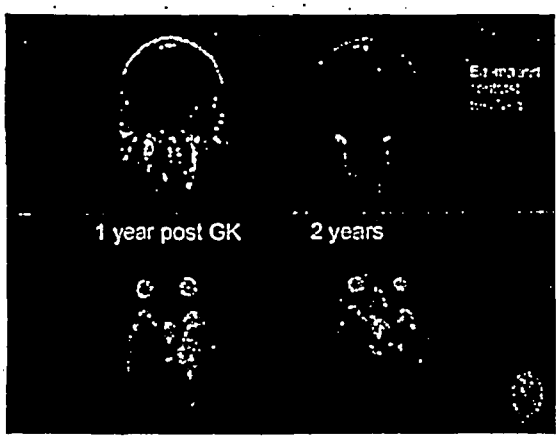
Principal Investigator Nicholas Barbaro MD, UCSF

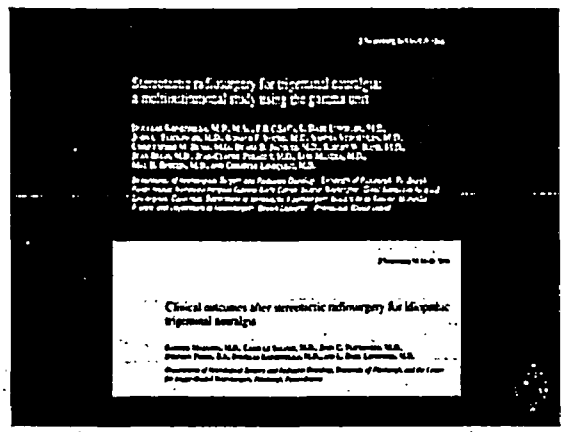
UCSF, Univ of Pittsburgh, Yale, Univ of Virginia, Columbia University, Northwestern University

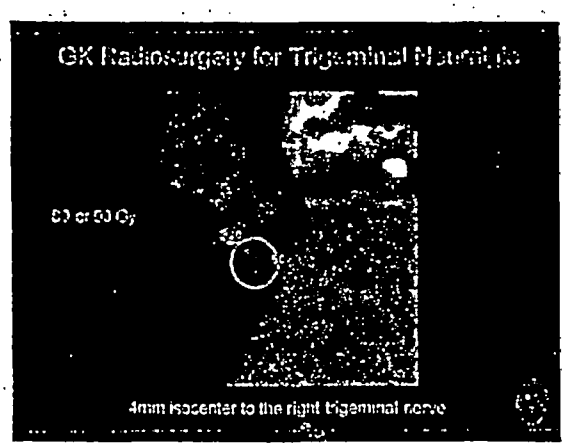
Patient #2 = 48 Gy, 10 months

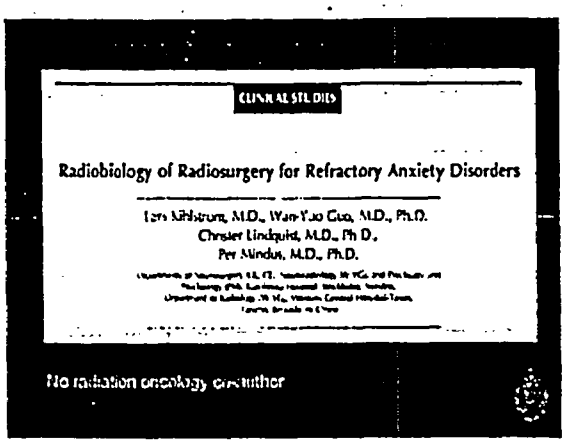
New onset headache

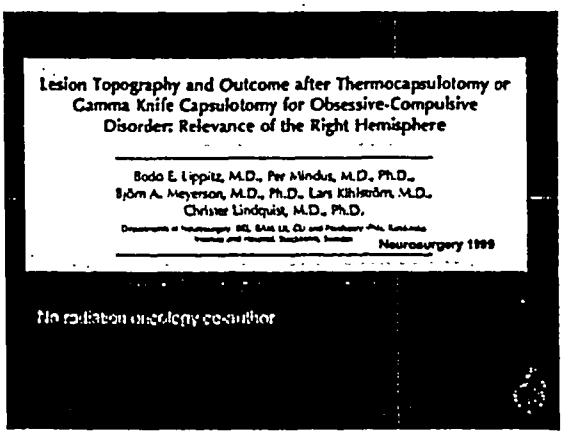
48 Gy, 10 months, headache

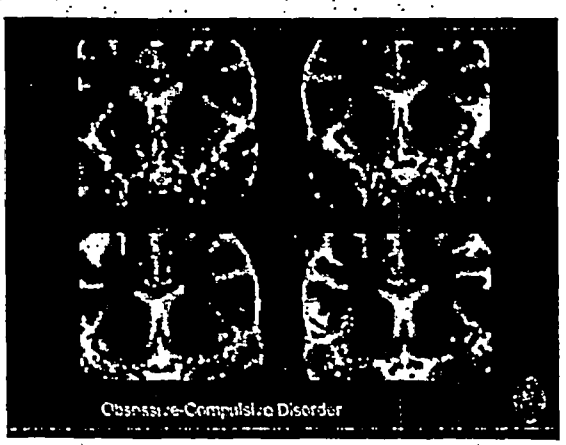

1 year post GK
2 years




GK Radiosurgery for Trigeminal Neuralgia
4mm isocenter to the right trigeminal nerve


CLINICAL STUDIES
Radiobiology of Radiosurgery for Refractory Anxiety Disorders
Christer Lindquist, M.D., Ph.D.
Per Mindus, M.D., Ph.D.
No radiation oncology co-author


Lesion Topography and Outcome after Thermocapsulotomy or Gamma Knife Capsulotomy for Obsessive-Compulsive Disorder: Relevance of the Right Hemisphere
Bodo E. Lippitz, M.D., Per Mindus, M.D., Ph.D.,
Björn A. Meyerson, M.D., Ph.D., Lars Kihlström, M.D.,
Christer Lindquist, M.D., Ph.D.
Neurosurgery 1999
No radiation oncology co-author

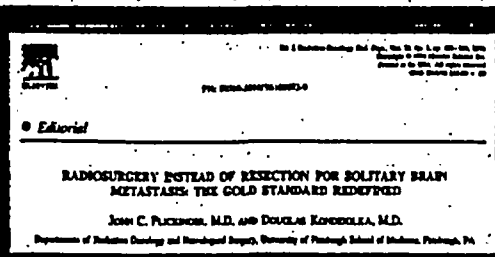

Obsessive-Compulsive Disorder

GK 1 GK 2 GK3

The Gamma Knife is simply an operating room.

Brain Surgery

Radiosurgery
Stereotactic Surgery
Biological treatments
Endovascular Surgery
Guided Resective Surgery



● *Editorial*

RADIOSURGERY INSTEAD OF RESECTION FOR SOLITARY BRAIN METASTASES: THE GOLD STANDARD REDEFINED

JOHN C. PUCCIONE, M.D. AND DOUGLAS KONDZIOLKA, M.D.

The NSC should redefine the Gold Standard

Neurosurgeons and Radiation Oncologists working as equal partners for safety and efficacy

IRSA

www.IRSA.org

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Harrisburg, PA 17110
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January 31, 2005

Thomas H. Essig
Acting Deputy Director, Nuclear Materials Safety Staff
Division: IMNS
U.S. Nuclear Regulatory Commission
11545 Rockville Boulevard, Building 2
Rockville, MD 20852

RE: Gamma Stereotactic Radiosurgery: Patient Safety and Protection of Cobalt Sources Issues

Reference: 10 CFR Part 35: (RIN 3150-AH19) Medical Use of Byproduct Material—Recognition of Specialty Boards, Proposed Rule, December 9, 2003

Dear Mr. Essig:

IRSA (International RadioSurgery Association)[1] appreciates the opportunity to provide additional information on patient safety that has prominently surfaced since we commented in February 2004 to the proposed rule for Medical Use of Byproduct Material (RIN 3150-AH19, Federal Register, December 9, 2003). IRSA has a long-standing position of advocating for the safety of radiosurgery procedures.

In the past, it was not IRSA's practice to monitor the NRC releases that affect gamma stereotactic radiosurgery (GSR). Within the last year we noted that changes within the NRC regulations have impacted the practice of GSR procedures and subsequently the patient safety of GSR procedures. Additionally, it has come to our attention that various professional societies that are involved in radiosurgery have espoused different views as to the training, experience, and responsibilities necessary to ensure safe radiosurgery.

[1] IRSA has operated since 1995 as an association which represents, among others, the gamma stereotactic radiosurgery unit's installation base. Installations of this type are primarily hospital based and specialize in treating brain tumors and brain disorders. The Association's mission is to provide education and guidance on radiosurgery procedures to governments, regulatory agencies, insurers, patients and referring physicians. This is accomplished through providing practice guidelines, position statements, general literature and comments on issues affecting operations or patient safety.

In recent months significant issues of patient safety and lack of oversight have come to the forefront of operations for gamma stereotactic radiosurgery (GSR) centers. Some of these are directly connected to changes in policy by the Nuclear Regulatory Commission (NRC). It is our understanding that the NRC assesses the risks involved in a procedure and then tries to minimize regulations while appropriately weighing those risks and addressing safety for the public. In the last two years, changes in regulations by the NRC, changes in the ownership of GSR units, physician specialty 'ownership' issues and an overall profit motive have given rise to what IRSA believes are serious patient and general public safety issues. We believe these issues may constitute 'absolute risks' to patient safety and protection of the cobalt sources as defined by the NRC.

IRSA believes that these issues require the attention of the NRC and that appropriately revised regulations could be established by the NRC. These revised regulations should provide attention to the operational and safety issues for GSR that would be commensurate with their importance to health and safety. These issues surround the following:

1. Ownership and NRC licensing of GSR units.
2. Authorized user and authorized user (AU) requirements.
3. AU exemption criteria.
4. NRC vendor training criteria.
5. Inappropriate definitions.

IRSA asks your indulgence in presenting an extensive overview of the procedure, the physicians involved and the types of disease indications treated. This in-depth overview is designed to assist in the understanding of the problems that have arisen that we believe jeopardize patient and public safety.

Background:
Professor Lars Leksell, a Swedish neurosurgeon, invented and described stereotactic radiosurgery in 1951. Professor Leksell developed stereotactic radiosurgery due to the risks associated with open craniotomy (brain surgery) and the poor outcomes associated with surgery for neurosurgical patients. Leksell developed the gamma unit to be an 'ablative scalpel-like' dose of radiation that would surgically cure functional brain disorders such as Parkinson's disease, other movement disorders, pain and debilitating cognitive or mood disorders. The gamma stereotactic radiosurgery unit can only be used for brain surgery. The first Gamma Knife was created in 1967.

Since its introduction into the clinical setting the gamma stereotactic radiosurgery unit has become the most widely used, non-invasive, neurosurgical procedure for destroying tumors and vascular malformations, as well as managing a wide variety of non-neoplastic disorders of the brain. Since its U.S. introduction in 1987 at the University of Pittsburgh, GSR currently logs 18,000–20,000 procedures per year using one of the three models of gamma radiosurgery units (A or U, B, or C) in over 90 facilities. The procedure, which is a single surgical procedure, requires the use of a single exposure of up to 201 beams of cobalt^{60} generated photons to achieve the surgical effect. It replaces the need for an open skull craniotomy in patients selected for radiosurgery by the neurosurgeon. Radiosurgery achieves tumor control or AVM obliteration with less risk to the patient than an open skull procedure.

Side effects are relatively rare when performed by an appropriately trained neurosurgeon, in collaboration with a radiation oncologist and medical physicist.

The misapplication of GSR procedures, either through mistargeting, overlapping of healthy brain structures or overdosing of vital brain nerves and structures, would be most likely unknown on the day of the procedure and never reported to the NRC. The evidence of injury would erupt over time as the brain nerve or structure began to change due to targeting errors or dose misadministrations. Adverse radiation injury from GSR can include death, blindness, seizures, speech disorders, neurocognitive disorders, weakness of extremities and many other potentially disastrous conditions often permanent in nature.

There are **two manufacturers** of GSR units: Elekta, Inc., the manufacturer of the Gamma Knife® (contains ~6,300 Curies of sealed stationary sources in 201, 30-Curie containers); and American Radiosurgery, Inc., the manufacturer of the Gamma Art 6000 Rotating Gamma system (contains ~900 Curies of sealed rotating sources, in 30, 30-Curie containers). There are a total of 90 active USA units for both companies, with another 9 installations expected in 2005.

The term stereotactic radiosurgery was defined by Professor Lars Leksell to denote the surgically precise closed skull delivery of a single high dose of radiation to a discrete target in the brain in one surgical session using specially constructed rigid head frame fixation devices (stereotactic frames) coupled with high resolution medical imaging designed to define the target tissue during the procedure itself. The high dose of radiation is designed to be an ablative scalpel-like effect that will destroy the affected tissue and spare surrounding healthy tissue. Radiosurgical targets are almost always three-dimensionally complex in shape and are located in critical areas of the brain. Often, these locations are difficult to reach by open skull surgical alternatives and present high risks to patients due to their position next to critical structures and/or sensitive cranial nerves. The dose delivered in radiosurgery is extremely high, and it is of paramount importance to carefully match the dose of radiation delivered to a precise target location, thus limiting the radiation delivered to surrounding normal brain. A therapeutically effective dose of radiation is delivered where the radiation beams converge during the GSR procedure. The procedure is completed in a single surgical session that begins with the rigid application of a stereotactic head frame by a neurosurgeon and concludes with its removal during one day. The frame is attached to the outer table of the skull using local anesthesia injected into the scalp.

The gamma stereotactic radiosurgery unit was specifically developed by neurosurgeons to treat neurological disorders. The training courses for gamma stereotactic radiosurgery are taught by the Department of Neurosurgery at academic teaching centers. Most gamma stereotactic radiosurgery units are established in surgical centers within hospitals. Further:

- 45–55% of treatments are performed on an inpatient basis.
- Medicare groups the procedure under a surgical DRG grouping for reimbursement.
- The Joint Commission on Accreditation of Healthcare Organizations surveys and accredits the units as surgical.
- All commercial insurers (Blue Cross/Blue Shield, Kaiser, United, Aetna, etc.) approve the procedure in lieu of open skull craniotomy utilizing a neurosurgery surgical code for billing and reimbursement.

The same as a craniotomy, the GSR procedure is completed in one surgical session on one day. When using gamma stereotactic radiosurgery, the radiation dose during the surgical session is dependent upon the diagnosis and the desired results. The marginal lesion dose may range from 12–13 Gy to the 50% margin line to as high as 70 Gy to the 50% isodose to small volumes (the central maximal dose will be twice the marginal dose, up to 140 Gy in one session of GSR). This is an extremely large, one time, precisely delivered, unforgiving dose of radiation delivered to a precise structure, nerve or vessels within the brain. The target may be less than 3 mm in size. In comparison, the normal dose given for radiation therapy or IMRT is between 1.8 and 4.0 Gy per day, depending upon hypo-fractionated protocols, and delivered to a target that is usually a minimum of 2 cm or as large as the entire brain. Significant and permanent damage will occur with GSR procedures within the brain if the targeting or dose is misapplied by even 1–2 mm. Damage can include blindness, permanent extremity weakness, loss of hearing, speech problems, depression, seizures and even death, among many other significant side effects that permanently affect a person's continuing quality of life.

For instance: a dose of radiation to a pituitary tumor that is slightly mistargeted or poorly delivered will give a radiation dose to the optic nerve which can result in permanent loss of vision (even complete blindness). The patient will most likely live a normal life span, but may be unable to drive or see objects coming from the side, and will have overall loss of vision with the loss of side vision which will affect the ability to read, work, and even maneuver within the confines of his or her home.

Neurologic morbidity is low when GSR dosing is prescribed at levels established by on-going research. Dosing patterns have lowered over time for some diagnoses as research has found some tumors to be controlled and side effects lowered by lowering the radiation dose. Cognitive side effects are minimal when the targeting is precise and appropriately confined through an understanding of the brain structures and adjacent cranial nerves that might receive radiation and its effect on the cognitive and neurologic future of the patient.

The GSR procedure does not remove tumor material, but serves to halt tumor growth by causing cell death or occludes problem blood vessel walls through blood vessel cell wall proliferation. The reaction to GSR normally works at the rate of growth of the cells, meaning that a highly malignant tumor would react quickly and show effects in a number of months, and a benign blood vessel would react over a much longer time. Since the tumor is not removed, the most common problem is edema (regional brain swelling) caused by the radiation disabling the cells' ability to regulate fluids. Edema requires close medical followup and the use of steroidal medications. Edema has a mass effect and can cause debilitating headaches, temporary loss of eyesight, extremity weakness and other significant issues for the patient. The patient selection for GSR is limited to those whose symptoms do not necessitate immediate open skull surgery and those who are able to wait a significant amount of time for resolution of their conditions.

GSR can never substitute for fractionated radiation therapy as GSR is a precise surgical instrument which allows the surgical ablation of a cranial nerve or tumor. It is not able to treat surrounding tumor spread as radiation therapy instruments can do so in a more

economical fashion with fractionated treatments. GSR is an alternative tool for specific disease indications, almost always in place of conventional brain surgery.

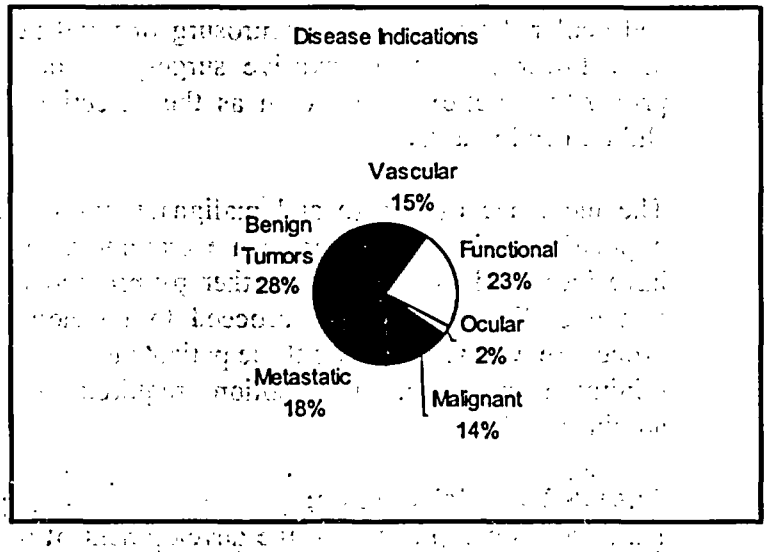
Disease Indications and Utilization:
The typical disease indications treated with GSR do not mirror the general indications treated by radiation oncology but do mirror neurological disorders. The following data was taken from manufacturer's data and from IRSA's survey of its membership for 2003 and 2004. The information given represents over 90% of the installed operations based within the USA.

Disease Indications:

Benign Brain Tumors – 28%

Vascular Brain Disorders – 15%
Functional Brain Disorders – 23%
Ocular and Other Disorders – 2%

Malignant Brain Tumors – 14%
Metastatic Brain Tumors – 18%
(From primary body cancers)



Typical oncology diseases that would utilize GSR are primary malignant brain tumors and secondary (to body cancer) metastatic brain tumors totaling 32% of all GSR procedures. These types of tumors may be treated through a combination of open skull surgery, GSR, chemotherapy and radiation therapy.

Primary benign brain tumors (28%) are generally surgical candidates before GSR or may receive GSR as a first procedure if neurosurgery evaluates that open skull surgery would present extensive harm to the patient.

Functional, ocular and vascular disorders represent 40% of the total treated indications at this time. These disorders are the fastest growing area of treatment for GSR and represent the original intended use of the unit upon development. Functional brain disorders are usually thought to be misfirings of nerves and improper functions of brain structures. Neurosurgeons have always searched to find adequate means to treat these disorders. Functional brain disorders may include: intractable pain, trigeminal neuralgia, Parkinson's disease, tremors, cluster headaches, obsessive-compulsive disorder, epilepsy and other psycho-neuro disorders. Vascular disorders include arteriovenous malformations, aneurysms, cavernous angiomas and other vascular disorders. Ocular disorders include uveal melanoma (of the eye).

Other functional disorders and indications that are currently being treated on a minimal basis or are in the animal research stage are:

- Mesial Lobe Epilepsy
- Dystonia

- Glaucoma
- Endocrine Ophthalmopathy
- Macular Degeneration
- Intractable Depression
- Glossopharyngeal Neuralgia
- Obesity
- Brain Cysts and Abscesses

Clearly, one of the largest developing areas for GSR has continued to be brain dysfunctions and ocular disorders where neurosurgeons and neurologists seek advanced procedures that offer lower risks than invasive surgery. Additionally, vascular indications (which are primarily genetic) have grown as the detection of these disorders has become easier in children and young adults.

The incidence of benign and malignant brain tumors has remained static in the general population and thus has not been a growing area. Metastatic brain tumor GSR procedures have increased as better chemotherapy protocols are seeing patients who live longer with systemic disease and who proceed to develop metastatic brain tumors. The one day procedure with GSR allows these patients to continue active chemotherapy, in contrast to the minimum two-week interruption required when whole brain radiation therapy is administered.

The GSR Physician Team:
IRSA strongly believes that the development of the GSR utilization and procedures and the brain tumors and disorders it treats necessitates the involvement and expertise of both the radiation oncologist and the neurosurgeon. Neither physician alone (radiation oncologist nor neurosurgeon) could competently prepare a targeting or dosing plan without reliance on the other. This is the reason that until recently, both specialties have sought the participation of the other in the procedure during its 50-year history.

The radiation oncologist clearly has the training, experience and education in conventional fractionated radiation therapy management of malignant and metastatic tumors (total 32% of GSR indications) within the brain. Additionally, the radiation oncologist receives over four years of education and training to understand the effects of radiation on cellular structures. The majority of the education and experience with malignant and metastatic brain tumors would be in providing radiation therapy with fractionated treatments over time at a low dose of radiation (2–4 Gy daily) and not with GSR's one session high dosing. We contacted several major academic radiation oncology programs and asked how much time in residency was devoted to central nervous system (brain and spine) tumors or disorders. We were informed by each school that one to three months of the four year residency study is devoted to brain structures and tumors, and little was devoted to understanding functional brain disorders, ocular and vascular indications.

We also contacted several major academic neurosurgery programs which informed us that all neurosurgery students spend one year of a 6–7 year residency studying neuroradiology and radiosurgery for brain disorders and tumors. Additionally, each neurosurgeon receives a minimum of 60 months of training in open skull surgery and neuroanatomy, neurophysiology, neuropathology and neuroradiology.

The American Society for Therapeutic Radiology and Oncology (ASTRO) posts recommended residency requirements for radiation oncologists on its web site. In the guideline, overall stereotactic radiosurgery study and other alternative dose delivery systems are grouped together to receive less than one month of study within a four year residency. A month would not prepare one for the intense radiation dosing levels, the types of brain diseases and disorders, alternative/adjunct procedures and the precise targeting of GSR that are needed to mitigate extreme medical injury and permanent brain damage to a patient.

Hopefully, it is clear that both physician specialties are necessary to perform a safe and effective procedure for the patient. The neurosurgeon could not act as a radiation oncologist during the procedure. The radiation oncologist would not have the skill or knowledge that the many years of open skull surgical procedures performed by the neurosurgeon bring to the understanding of neuroanatomy including glands, nerves and surrounding structures, and the long term permanent beneficial or damaging effects that 'touching' these structures will have, whether with a scalpel or radiation.

Specifically, only a neurosurgeon would have experience in vascular disorders, ocular disorders, brain cysts/abscesses and functional brain disorders which compose 40% of all GSR indications and are the largest growing area of treatment with GSR today. Additionally, there are many unusual types of tumors that are routinely surgically removed that only the neurosurgeon would be able to identify and assess whether GSR in that selected brain region would do more harm than surgical intervention. These are the surgical options that are the alternative to radiosurgery, not fractionated radiation therapy.

The neurosurgeon is vital to appropriate patient selection, the placement of the skeletally fixed frame, sedation and medications during treatments, and anesthesia which is required in the treatment of children and other special cases.

In summary, neither physician specialty can substitute for the other in the GSR procedure, whether it be appropriate patient selection or the GSR procedure itself. Quality GSR centers have two medical directors—a neurosurgeon and a radiation oncologist together.

The American College of Radiology (ACR):
The American College of Radiology (ACR), with more than 30,000 members, is the principal organization of radiologists, radiation oncologists and clinical medical physicists in the United States. The ACR first issued a Practice Guideline for Stereotactic Radiosurgery in 1997. The guideline is not specific to the type of equipment. The guideline was revised effective January 2002 and was most likely reviewed again before being posted on the ACR website on October 31, 2003 (copy attached). The guideline states in part:

> *Imaging, planning, and treatment occur on the same day for single fraction [session] treatments. Treatment delivery should be accurate to within 1 mm. This leaves little room for error in the overall process. Strict protocols for quality control (QC) must be followed using checklists, while double-checking is required at critical junctures. Furthermore, SRS [stereotactic radiosurgery] requires the coordination of a large and diverse team of* ***professionals from***

neurosurgery, diagnostic radiology, and radiation oncology [emphasis added].

The guideline outlined in this document describes a minimal set of criteria [emphasis added] for an SRS quality-assurance program. The reader is also referred to other publications in the literature regarding quality control for stereotactic radiosurgery and its related procedures.

The ACR guideline continues to give a list of 'minimal responsibilities' for staff participating in a radiosurgery procedure. The responsibilities are given under the headings of: Radiation Oncologist, Neurosurgeon, Qualified Medical Physicist and Radiation Therapist. Each professional was given a numbered list of responsibilities with the statement '*specific duties may be reassigned where appropriate.*' Under the heading for 'Neurosurgeon,' the following statements appear:

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL
The following are minimal recommendations for staffing levels and staff responsibilities while participating in an SRS procedure. Specific duties may be reassigned where appropriate.
B. Neurosurgeon
The services of an appropriately trained neurosurgeon in most circumstances are required and may include: [are related to his/her principal role as admitting physician and responsible surgeon]
1. Participating in initial treatment [surgical selection and] management with the radiation oncologist.
2. ...locating and specifying the target volume and relevant critical normal tissues.
3. Participating in the iterative process of plan development [and completion of the radiosurgical dose plan].
4. Ensuring that patient alignment on the treatment unit is appropriate.
5. Following the patient for control of abnormalities and for monitoring potential complications.

Although radiation oncologists contribute to the overall radiosurgery procedure and are a vital part of the clinical team, the neurosurgeon is vested with the responsibility of ensuring appropriate patient selection and serving as the admitting physician to the hospital, direct appropriate treatment if a medical emergency occurs and is required to provide appropriate neurological followup and assess pharmaceutical needs before, during and upon discharge of the patient. This may include long term medications and followup.

Appropriate Patient Selection:
A neurosurgeon is necessary to make the appropriate patient selection for most brain tumors and functional brain disorders. Some requirements for appropriate patient selection by a neurosurgeon are the ability to:

1. Be able to distinguish the difference between central nervous system cysts and tumors. This is done by understanding the effects the cysts would have on hypertension, the congenital nature of cysts and appropriate surgical treatments.

2. Be able to assess and understand when surgery with adjunctive radiosurgery offers the best prognosis with the least morbidity.

3. Be able to examine the patient with an understanding of the 12 cranial nerves, their effects on the body, the assessment of reflexes, pain, eye movement, gait, weakness and intracranial pressure, and understand brain lesions, localization and cause.

For instance, unilateral involvement of the lower face with near normal eye closure would indicate to the neurosurgeon that he or she should look for a contralateral supranuclear lesion, which would then be assessed for possible causation by vascular issues, a tumor, demyelination or infection. It would be inappropriate for a physician that is not a neurosurgeon to decide whether the resulting area on the scan was a tumor and perform radiosurgery with the gamma unit, which would make the patient worse if the cause of the area on the scan was due to a mass of infection or blood buildup. In this case, an open skull craniotomy may be the first line of defense if it is indeed a tumor, with or without a boost from a GSR.

Additionally, what appears to be a tumor on scanning may be caused by developmental disorders: demyelinative disorders (multiple sclerosis); functional disorders (pain, movement, psychological); degenerative disorders (cerebellar degeneration); familial disorders (Von Hippel Lindau disease); neoplastic tumors (medulloblastoma, metastasis); infectious conditions (abscess formation); and vascular conditions (arteriovascular malformations, cerebellar infarction). With the exception of metastasis, the radiation oncologist is not trained in the diagnosis, procedures and medication to control or care for these types of patient indications. Inappropriate diagnosis and inappropriate use of the GSR will place patients in jeopardy.

Acute or long-term morbidity directly related to the radiation may occur. But in contrast to conventional radiation therapy, the higher radiation dosing of gamma stereotactic radiosurgery (26 to 160 Gy) units in one treatment allows for a higher level of absolute risks of acute and long term effects.

Radiation oncologists and medical physicists do not receive training in appropriate patient selection for radiosurgery and alternative surgical or medical neurological disorders or procedures.

Appropriate aggressive patient management, aided by a variety of effective treatments, can often lead to indefinite or extended control of brain tumors and multiple brain metastases in patients with controlled or limited systemic disease. Open skull surgery may be part of a comprehensive management plan where other techniques are brought to bear on brain tumors. Beyond open skull surgery (possibly in conjunction with implantation of chemical wafers) options include stereotactic radiosurgery, intra-arterial chemotherapy with or without blood-brain barrier disruption, newer systemic chemotherapies and a variety of radiation

therapy techniques. Directing the comprehensive medical plan for a patient should be a neurosurgeon.

With functional brain disorders, the neurosurgeon may choose between deep brain stimulators, medications, radiofrequency, injections, open skull surgery and GSR. All of these are dependent upon the current assessment of the patient's condition and evaluation of previous treatment. Defining the candidate for functional GSR procedures is critical as research has taught that some patients will not be viable candidates for positive results. When treating patients with functional disorders, the objective is to use an extremely high dose of radiation (70 to 140 Gy central dose) and to effect a 'surgical strike' into a nerve or an area of the brain to disable it without damage to the adjacent area. With functional disorder patients it is critical that a neurosurgeon evaluate the patient for GSR selection and that the targeting for the GSR plan be completed and approved by the neurosurgeon.

Functional and Vascular Brain Disorders:
Gamma stereotactic radiosurgery units were developed in the late 1960s to treat functional disorders without opening the skull. The unit was made to direct an extremely large dose of radiation to an extremely small target or nerve. As 40% of all GSR procedures are for functional, vascular, and ocular disorders a better understanding of the decision making and dosing of these disorders would be helpful in understanding some of IRSA's concerns with patient safety. While permanent and irreversible damage to the patient may occur in any GSR procedure, we believe the functional, ocular, cystic and vascular areas have a higher risk of patient safety issues. To assist in further understanding concerns for patient safety, we present some current diagnoses treated, the typical dose given, the target areas considered and the permanent neurological side effects that can occur with incorrect targeting or dosing.

Trigeminal Neuralgia: Dose 70–90 Gy; the target area is the terminal end of the trigeminal nerve at the root entry zone of the brain stem. Side effects with mistargeting and overdosing are permanent one-sided facial numbness and tingling (possibly extending to the eye and tongue) which would affect eating, swallowing, blinking and ocular problems such as dry eye. Patient selection is crucial as 'atypical' trigeminal neuralgia patients are not usually good candidates for GSR.

If the brain stem received too much radiation or was accidentally targeted during the GSR procedure, the patient could be expected to have permanent body weakness (paresis or plegia), numbness, dysconjugate gaze (wandering eye with inability to focus), dysphonia and possibly dysphagia (speech problems).

Cluster Headaches: Dose ~90 Gy; the target area may be the centromedian nucleus of the thalamus or intralaminar nuclei. In recent years GSR has been used with some positive results in the treatment of selected patients with cluster headaches who have not found relief through more conventional means. Headaches can be the result of raised intracranial pressure, hemorrhage, or simply be the presenting feature of accelerated hypertension or metabolic diseases. Appropriate selection of patients for treatment and the appropriate target selection and dosing are dependent upon extensive medical evaluation by a multidisciplinary team which includes a neurosurgeon trained in the anatomy of the brain, the sequela of headaches and the full range of treatments available.

Intractable pain: Doses up to 140–160 Gy; the target area could be the centromedian nucleus of the thalamus, pituitary stalk/gland or intralaminar nuclei dependent upon neurosurgical evaluation. Intractable pain may be caused by cancer, stroke to the thalamus or accidental injury.

Parkinson's disease: Dose 120–140 Gy; the target is dependent upon disease progression and may be directed to the thalamus nuclei (thalamotomy) for tremor, dystonia and spasmodic torticollis; or globus pallidus (pallidotomy) for dyskinesia. For spasticity, a lesion in the dentate nucleus or pulvinar might be necessary. Extensive evaluation for the correct patient selection is required with subsequent long term followup using ipsilateral motor scores. Only a physician with extensive training in neurosurgery would be able to select the target and effect a treatment for the nuances of movement disorders.

Essential Tremor: Dose 120–140 Gy; the targeting usually consists of placement of a lesion (using radiation) in the thalamus nuclei. Essential tremor is a genetic disorder that affects the person when movement is enacted, in contrast to the restful tremors of Parkinson's disease. The patient's entire quality of life is affected as they are usually unable to hold cups, forks, tie laces or write legibly. Again, extensive neurological evaluation must be followed to ensure the correct patient selection.

Psychological Disorders: Dose 120 Gy and greater. Obsessive compulsive disorder, chronic debilitating anxiety states or phobias, obsessional neurosis, uncontrolled aggression and intractable depression may be targeted with bilateral cingulotomy, subcaudae tractotomy, limbic leucotomy (smaller subcaudate and cingulated lesions) and amygdalotomy dependent upon condition.

Vascular Disorders: Dose 50 Gy and greater. Vascular disorders are primarily genetic and occur where there is a 'tangled' mass of blood vessels within the brain. Primary to treating these disorders is an understanding of which vessels are the feeding vessels and which are the draining vessels of the abnormality. Targeting the wrong vessels would eventually mean death to a patient. GSR procedures induce endothelial cell proliferation, which produces thickening of the vascular wall and ultimately obliteration of the defect over a period of time (1–3 years). Patients typically present with neurological defects and a detailed assessment must be made as to whether GSR is the procedure of choice for a patient. All treatment with these disorders may result in more neurological deficits for the patient. A neurological assessment of the risks and a long-term plan for management of the patients must be made by a neurosurgeon before any procedure is undertaken with this diagnosis.

Literature and Followup:

GSR patients require long-term followup extending over 10–20 years to evaluate the placement of lesions within the brain, the morbidity rate and the refinement of dosing that results in the lesion or function control while resulting in the lowest morbidity rate for the patient. Today, the majority of this research on GSR (over 2,000 articles) has been printed in neurosurgery journals. The Journal of Neurosurgery has recently dedicated its entire third supplement to GSR research (January 2005). This is not to say that there is not substantial literature in radiation oncology journals. However, much of the research in radiation oncology journals is comparative of different technologies or different modalities (one

surgical session versus fractionated therapy) and is heavily geared toward metastatic and malignant tumors.

Recent research has established that acute (immediate) sequelae occur in as many as 35% of all patients treated with the most common problems being seizures, periorbital edema and headaches.[2] The study concluded that target diameter and prescription dose were associated with early toxicity and problems. Most such complications are not serious, as late effects tend to be more likely to lead to permanent neurological deficits.

Our Association is acutely aware of patients who have permanently lost peripheral vision when treated for pituitary tumors and others who have permanently lost serviceable hearing from treatments of acoustic neuromas. This has occurred when the patient was given greater than 8 Gy to the optic nerve or the targeting for the acoustic neuroma overlapped the hearing nerve excessively. The tolerances of the human brain and its cranial nerves and eloquent structures to high one time dosing are not taught to radiation oncologists in training.

IRSA has been informed by GSR radiation oncologists that they routinely receive referrals from medical oncologists, endocrinologists, neurologists, and neuro-oncologists. Without the required input of a GSR trained neurosurgeon for appropriate patient selection and for treatment planning, significant harm as well as death may result for the patient.

Medical Physicist:
IRSA strongly believes that the medical physicist is not the person who should takes charge of deciding the targeting or dosing with GSR units. Medical physicists may routinely design targeting plans for linear accelerator radiation therapy treatments. The medical physicist is vital to quality assurance and to the operations of the GSR unit but is unschooled in designing targeting and dosing for a brain tumor or brain dysfunction.

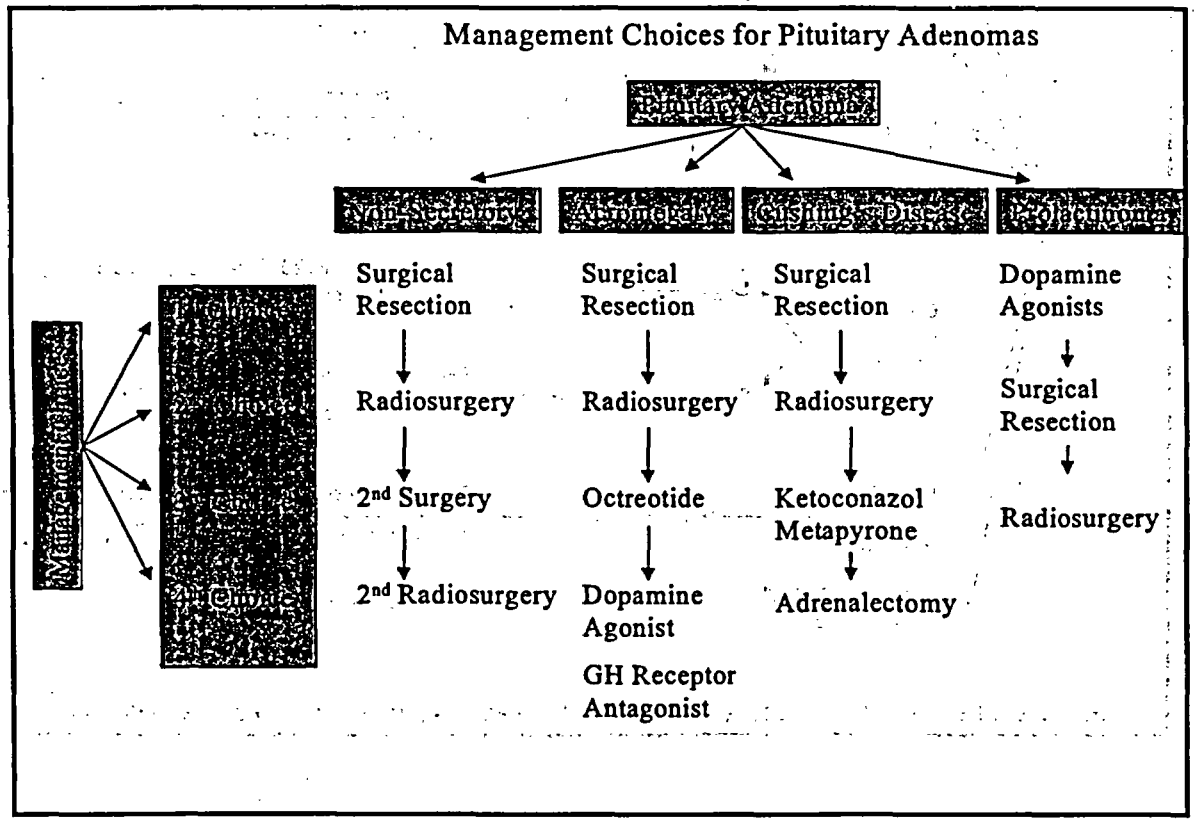
Example Decision Chart:
While we have previously emphasized functional disorders, we believe it is important for the NRC to see that the decision process of whether to use GSR is complex as well for brain tumors, whether malignant or benign. On the following pages, two flowcharts which are part of IRSA's Pituitary Adenomas Practice Guideline are presented as examples of the required knowledge, medical evaluations and decisions that must be made before a patient should be treated with GSR for a pituitary tumor. A pituitary adenoma is normally a benign brain tumor that represents around 15% of all brain tumors. A pituitary tumor is fairly common and the patient usually presents with optic field deficits and endocrine dysfunctions that may affect all aspects of quality of life. The flowcharts provided are but one small aspect of the overall treatment management of the patient with a pituitary tumor. Medical management and monitoring is also required and would be as complex as the charts presented here evaluating open skull surgery and GSR.

[2] Kondziolka D (ed): Radiosurgery. Basel, Karger, 2004, vol 5, pp 38-45.

Reference: Stereotactic Radiosurgery for Patients with Pituitary Adenomas, March 2004.

CLINICAL ALGORITHM(S):

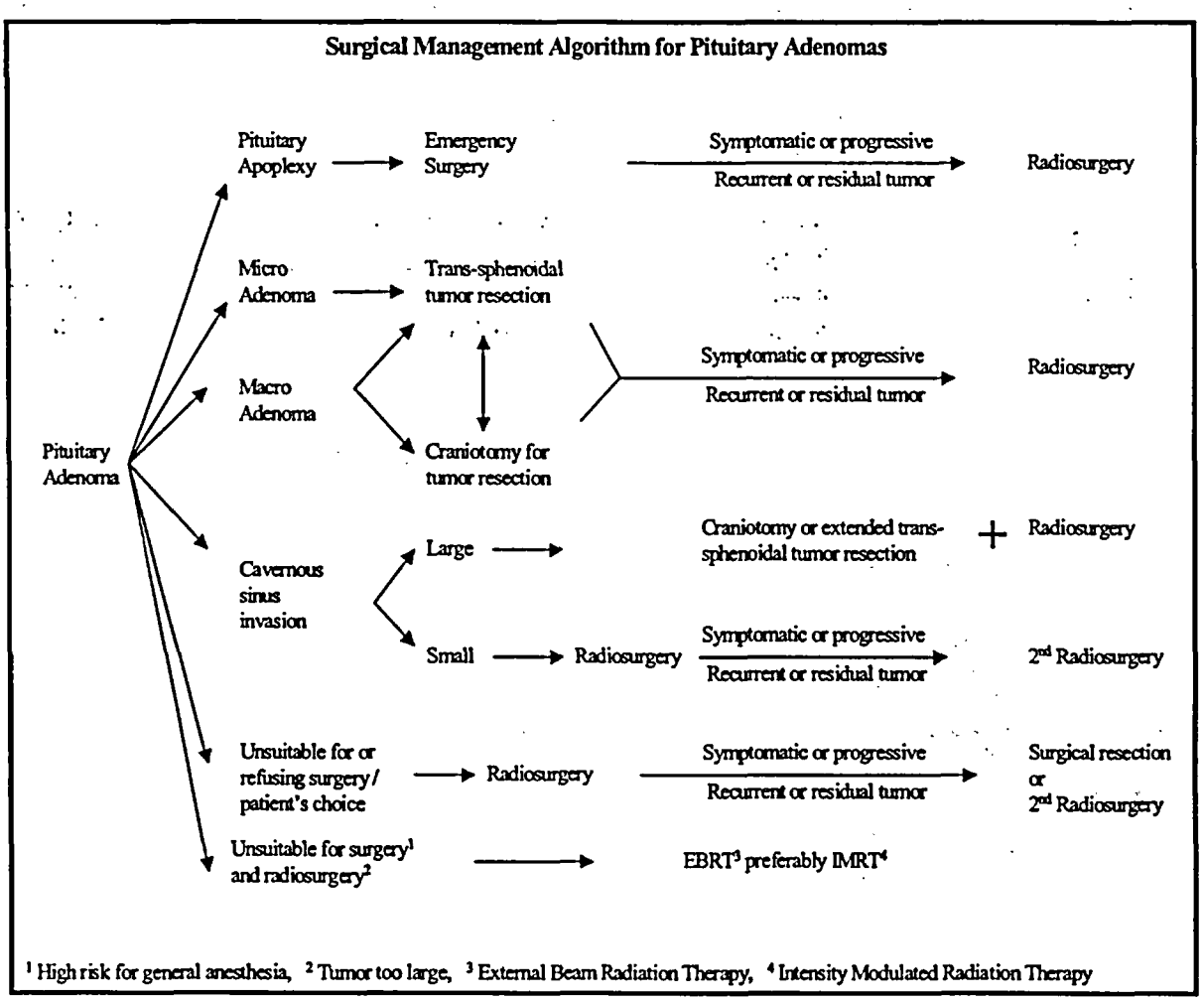
A broad outline of management choices is shown below, however, the final recommendation is usually influenced by the cumulative experience of the medical management team. The choices listed below are not mutually exclusive. Combinations of different treatments may be necessary and/or desired under certain circumstances. Common examples include patients with cavernous sinus involvement present at diagnosis who undergo first stage microsurgery for the extracavernous portion of their tumor followed by second stage radiosurgery for the cavernous sinus component, and patients with secretory adenomas who undergo radiosurgery but are then maintained on their antisecretory medications during the latency period for hormonal normalization after radiosurgery. The common need for staged or tandem treatments with multiple modalities underscores the importance of the presence of a comprehensive and coordinated multidisciplinary team in the optimal management of pituitary adenoma patients.



Reference: Stereotactic Radiosurgery for Patients with Pituitary Adenomas, March 2004 Continued.

A number of factors are considered in making a recommendation regarding surgical management. These factors include:

1. ***Patient's age***
2. ***Hormonal status of the adenoma (secretory or non-secretory)***
3. ***Presenting symptoms and neurological status (vision) of the patient***
4. ***Patient's medical condition (comorbidities)***
5. ***Previous tumor resection (via trans-sphenoidal approach or craniotomy) history***
6. ***Prior radiation exposure***
7. ***Volume of the tumor***
8. ***Proximity to the optic apparatus***
9. ***Response to medical management***



Issue No. 1: Ownership and NRC Licensing of GSR Units.

In the past, hospitals were the primary owners and managers of a GSR center. Additionally, the hospital provided oversight for the procedures and the participation of physicians in the procedure. Private ownership has been increasing by investor groups and radiation oncologists who have purchased GSR units. These centers operate outside of hospital or institutional oversight. IRSA believes this to present a significant problem to:

1. The overall security of the cobalt^{60} sources and the associated safety to the general public.
2. The safety over the patient selection and administration of the GSR procedure and to the possible resulting permanent neurological damage.

IRSA currently knows of nine GSR centers that are licensed by the NRC which exist without proper institutional or hospital oversight because of ownership issues. IRSA firmly believes that all GSR units should be located on hospital grounds and that hospitals should have some ownership in the units and at all times there should be hospital oversight of operations. Some examples of problematic ownership and operations of GSR are provided below.

1. GSR units placed on hospital grounds without oversight, security or management of the hospital. The units are placed on hospital grounds to allow usage of the MRI and CT units for the procedure. In one situation, the center is completely owned and managed by a three-person non-clinical financial investor group. NRC licensed this unit in 2001. This center has a total lack of oversight resulting in significant risk to the patients involved.

2. The same investor group owns a NRC licensed (January 2003) GSR facility that is domiciled in a 'strip mall' within a scanning center owned by the same group. In this situation, a local hospital has a small interest in the GSR unit. However, the total management is operated by the small investor group with oversight for staff, physicians, and medications. Medicare, Blue Cross Blue Shield and the State of Pennsylvania have refused to recognize it in this environment and do not pay for treatments from this center. However, other unaware insurers do pay for treatment. In order to 'mask' where the procedure is performed, the center has transported patients after the GSR procedure to a local hospital and admitted the patient in order to receive payment. IRSA believes this center to be unguarded by security after hours and on weekends as a hospital would be. Additionally, it is possible that a large truck could accidentally drive through its walls in the mall it resides in. Patients are at significant risk during the procedure without any oversight from a medical facility.

3. Recently, two radiation oncologist partnerships have each purchased a GSR unit. We believe that each of these units will be placed on a participating hospital's grounds, but future purchases may reside anywhere there is an MRI and CT scanner. We have no guarantee of the oversight or management of these recently purchased units.

IRSA believes that the NRC is the only regulatory agency that is able to establish policy and guarantee proper oversight for public and patient safety where there is diverse ownership of GSR units outside of hospital ownership. These types of ownerships of GSR units will grow as the treatment is acceptable and the investment in such units is considered highly

profitable. IRSA does not have an issue with the types of GSR ownership, however, we do have concerns over how patient safety and the protections of the cobalt^{60} sources will be secured. We believe the NRC to rely heavily on the oversight of hospital institutions to enforce appropriate operations, require appropriate medical staff in the surgical procedure process and to confirm appropriate training and credentialing. The NRC can no longer rely on hospital ownership or oversight even when hospitals are part of the venture to own a GSR.

Ownership of a GSR unit by private individuals or physicians is motivated by two things. The profits for billing the procedure over and above the professional fees go directly to the investors or the physician ownership group. Also, the new owners are able to operate outside of hospital oversight and credentialing. IRSA believes that this means there is a total lack of accountability especially with the current NRC regulations as they exist.

In particular, the NRC relies heavily on these same hospitals to provide the security and protection of the cobalt^{60} sources 24 hours a day. IRSA is aware of the proposed changes in security measures for GSR units. However we are also concerned that GSR centers that are unmanned for several days at a time (e.g., holiday weekends) and do not have 24 hour security, present difficult issues for the NRC in securing cobalt^{60} sources.

Recommendation:

- NRC should process background checks on all individual owners of GSR units and require the owners by written documents to be personally held responsible for the day to day patient safety as well as the protection of the cobalt^{60} sources.

Issue No. 2: Authorized User (AU) Issues and the Written Directive. The NRC regulations are being used to restrict neurosurgeons from active participation in the GSR procedure, thus affecting patient safety.

In 1987, the first GSR unit in the U.S. was located at the University of Pittsburgh, which fell within the NRC Region 1 area. At that time, and until two years ago (15 years since installation of the first unit), neurosurgeons were required to be listed on the license as an AU and were required to remain present throughout the patient procedure. These requirements are in keeping with appropriate patient safety and the neurosurgeon's responsibilities during the GSR procedure in order to provide for any emergency medical situation that may occur with the patient until the procedure is completed, the head frame removed, and the neurosurgeon has established whether the patient meets the criteria to be released or admitted for observation to the hospital.

The University of Pittsburgh is the primary United States training facility that is approved by the manufacturer in the USA. Attendees of the training at the University of Pittsburgh are taught that the neurosurgeon and radiation oncologist are the procedure team and that the neurosurgeon, as the admitting physician, must remain present throughout the complete GSR procedure, the same as with open skull surgery.

In 2002, the NRC removed the neurosurgeon as an authorized user for GSR and required only the radiation oncologist and medical physicist to be present. The NRC regulations currently state that an AU (radiation oncologist) and AMP (authorized medical physicist)

must be present and that "an" AU must sign the written directive before the administration of dose of radiation from byproduct material. This has meant that the NRC has proposed that only the radiation oncologist would be needed to approve the written directive for the GSR procedure.

Radiation oncologists have begun using the change in the NRC regulation to 'block' the neurosurgeon from the entire procedure. Hospitals have reviewed the change by the NRC and quoted to IRSA that "the NRC removal of the neurosurgeon means that the NRC considers it safe for the radiation oncologist to operate alone and it may be unnecessary for the neurosurgeon to be involved." IRSA does not believe this was the intention of the NRC.

As we stated in the background materials, the radiation oncologist is not trained in neuroanatomy or in the scope of the myriad disorders and tumors that the GSR can treat. While the radiation oncologist plays a **vital role in the GSR procedure**, he or she cannot replace the knowledge of proper patient selection, alternative treatments and the neuroanatomy for targeting within the brain that the neurosurgeon is trained in. Allowing only the radiation oncologist to perform the targeting and dosing without the neurosurgeon is placing the patient in absolute risk of permanent neurological harm.

Recently, an authorized user (radiation oncologist) of a hospital based GSR used the change in the NRC 10 part 35 regulations as justification to exclude the neurosurgeon from patient selection, performing the targeting and planning portion of the treatment (including signing the written directive), and from being present during the procedure.

IRSA is concerned as the hospital in this situation felt compelled to believe that the NRC had only patient safety in mind when changing the regulation.

It is vital to appropriate patient selection, written directive approval and the safety of monitoring the patient during the GSR procedure for the neurosurgeon to be involved and physically present.

The NRC needs to be aware that in the last year, there has arisen a conflict between the professional groups representing the radiation oncologists and the neurosurgeons. This conflict appears to be one of ownership over the GSR procedure whereby ASTRO has proposed that 'radiosurgery' does not exist. As part of this movement, we believe that ASTRO may be trying to eliminate the neurosurgeon's involvement in the procedure and has used the changes in the 10 CFR part 35 ruling, which took effect October 2002, as justification. We have noted letters to the Centers for Medicare and Medicaid from ASTRO where the use of definitions and criteria from 10 CFR part 35 was given as justification to make changes in coding and terminology for GSR. IRSA is aware that ASTRO and the NRC need to work closely together. However, we are concerned over the appropriateness of ASTRO utilizing rulings they assisted the NRC in developing to restrict other physician specialties from the GSR procedure that would result in an absolute risk to patient safety.

In the last month, IRSA has received notice from a radiation oncologist that this physician entered the GSR center and found another radiation oncologist about to treat a patient that should not have been treated. The procedure was discontinued before the radiation had begun and the patient sent home. It was stated to IRSA that the diagnosis and scanning was

misunderstood and the patient would have been harmed as what was seen on the scanning was swelling from a previous open skull procedure and not residual tumor. Additionally this was a pituitary patient that was about to receive an unnecessary dose of radiation next to the optic nerve. Better accountability and regulations requiring the neurosurgeon as an AU are needed from the NRC to avoid these types of situations.

IRSA feels strongly that the NRC must remain objective and place patient safety and protection of the cobalt^{60} sources as its priority. IRSA hopefully has established the need for both professionals to be involved in the procedure.

IRSA provides to its member GSR centers a credentialing criteria for neurosurgeons in radiosurgery. However, IRSA does not have regulatory authority over a center which may or may not decide to utilize the criteria or operate without criteria. With GSR centers also operating outside the oversight of hospitals, there is little if any guidance or oversight other than the NRC's capacity to regulate patient safety. This credentialing document is attached for the NRC's review.

Recently, IRSA was notified by a new hospital based GSR center that one of their prominent neurosurgeons would be using the GSR unit without vendor endorsed training. The hospital felt that the NRC did not require the neurosurgeon to be a part of the treatment, nor to receive formal training; therefore the hospital believes they are operating within applicable standards. Again, IRSA has no regulatory authority and no amount of guidelines or templates on credentialing by any association will enforce a minimum of patient safety. However, the NRC can enforce a level of training and physician involvement of both radiation oncologist and neurosurgeon to ensure a standard of patient safety.

In reading the new proposed 10 CFR part 35, IRSA noted that the requirement of being a radiation oncologist has been eliminated as an AU with GSR, and that a radiation therapist would be allowed to be an AU (Section 35.690 (a)(1), and Section 35.690 ((b)(2)). If we are interpreting this correctly, we believe this to place patients at risk as a radiation therapist does not have the amount of clinical training and expertise that a radiation oncologist has. Further, there is only one state (Ohio) which allows a radiation therapist to be involved in the treatment. All 90 other operating GSR centers do not allow radiation therapists to be a part of the procedure as they do not have the training or education that would enable them to be a part of patient selection, targeting, dosing or implementation of the treatment, even if the therapist operated under the guidance of an AU.

IRSA does not believe the radiation therapist or a radiation technician would have the ability to notice changes in the status of patients that may indicate a change in the medical status of the patient. Indeed, all patients are monitored by registered nurses throughout the GSR procedure while the physicians initiate the treatment. We question who will provide appropriate emergency care and how a radiation therapist can fit into such a specialty. For patient safety, IRSA believes the NRC should specifically bar radiation therapists and radiation technicians in the GSR procedure.

IRSA is aware that NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interest of their patients. However, the NRC has a secondary role when given adequate information, justified

by the risks to patient safety, to establish new regulations to prevent harm to patients. We believe that the information presented in this document has established a real and absolute risk to patient safety and presents to the NRC where its current regulations allow GSR centers to operate without oversight and to deny access to neurosurgeons thus placing the patient in a high risk category of permanent and devastating neurological harm or death.

Recommendations:

- For patient safety, appropriate patient selection, and medical emergencies, the NRC should reinstate the neurosurgeon as an authorized user (AU) for the GSR procedure along with the radiation oncologist and medical physicist, requiring the neurosurgeon to remain present throughout the entire procedure without exemption (10 CFR 35.615 (f)(3)).
- Further, we believe that the qualified neurosurgeon should be required to attend vendor endorsed training and should be listed on the NRC license for the GSR unit so that neurosurgeons that are not properly trained could not be utilized as a substitute for a neurosurgeon trained in the GSR procedure. The neurosurgeon should receive training in the operation and emergency response for the GSR unit, and be trained in radiation safety and biology (Section 35.690(a) (1), part 10 CFR 35).
- For patient safety, the NRC should require that both the neurosurgeon and radiation oncologist approve the written directive and participate in review of the treatment plan (Section 35.40 (b) (3), Written Directives, 10 CFR part 35).
- NRC should require that NRC Agreement States immediately implement these changes for patient safety and not wait up to three years to comply.
- NRC should specifically eliminate the use of radiation therapists and radiation technicians from participation in the GSR surgical procedure as their lower level of training places the patient at risk.

Issue No. 3: AU Exemption Criteria Should Be Established for GSR Centers.

NRC regulations specify for GSR that an 'authorized user' sign the written directive and that an 'authorized user and an authorized medical physicist' be physically present throughout all patient treatments involving the unit. We know of several requests for exemption of the radiation oncologist AU since the previous rule change to 10 CFR part 35 on October 24, 2002. It may be helpful for the NRC to have an understanding of how the majority of GSR centers operate and are trained.

It is common practice for a neurosurgeon, a radiation oncologist and a medical physicist to participate in the GSR procedure until the written directive is reviewed and approved and the initial GSR procedure has been started on a patient. After this time, when the radiation oncologist is needed in the radiation oncology center on the grounds of the hospital, the radiation oncologist may leave when the neurosurgeon remains in the GSR suite with the AMP. With the growing shortage of radiation oncologists in the industry, this has become necessary to adequately cover radiation oncology services. However, the radiation oncologist is always on the hospital grounds and available to be called back to the GSR center.

The medical physicist is not allowed to leave the GSR suite while a procedure is being conducted and is available at all times with the neurosurgeon as well as a registered nurse. The neurosurgeon is necessary and required to stay throughout the procedure for patient safety to handle medical problems and to evaluate the patient. In the past we have seen patients have seizures, begin choking while in the machine (the frame must be removed at once to provide an airway), vomit during a procedure in the machine, have hypertensive problems, diabetic situations, and have heart failure. Additionally, a patient has broken a collar bone and several have severely cut themselves in the machine and needed emergency care.

The following should be noted:

- The GSR unit can be shut down with one button. All personnel involved in the procedure are trained to perform an emergency stop.
- An emergency stop will automatically move the patient couch out of the unit and close the shielded doors to the radiation, thus completely stopping all radiation to the patient.
- The radiation oncologist is not allowed to leave the grounds and can be paged to return.
- With brachytherapy, the NRC allows the radiation oncologists to insert radioactive seeds into a patient's body and then leave the hospital grounds if necessary. Any physician is allowed to cover for the radiation oncologist, regardless of specialty, after the insertion of the radioactive seeds, even a resident. With brachytherapy, the ability to quickly remove the radioactive seeds is limited and there is no quick shut down as with GSR. Brachytherapy presents far greater risks in being able to quickly stop the radiation effects in an emergency than GSR.

IRSA believes that the NRC should establish criteria that are acceptable to meet both patient safety and NRC standards, and that would allow a radiation oncologist AU to leave the GSR suite, while remaining available on grounds if needed. With a neurosurgeon and the AMP present, it is **redundant** to have the radiation oncologist stand in the suite for several hours with the neurosurgeon and AMP when the oncologist is needed in clinic.

Clear exemption guidelines would enable GSR centers to understand how to draft appropriate operational guidelines. The NRC should be made aware that the practice of the radiation oncologist leaving after the written directive is approved and the procedure has begun is commonplace in most large academic medical centers and to our knowledge has gone unreported to the NRC. Nor does a GSR site normally ask for the exemption, as the belief is that the patient is safe and the NRC does not fully understand the safety protocols that are being followed.

IRSA has noted testimony to the ACMUI meeting in May 2003, stating that the GSR procedure involved 'many numbers and mistakes could be made' with coordinates [if the radiation oncologist were allowed to be exempted after the procedure was initiated]. IRSA would like the NRC to know that newer GSR models (since 1999) with automation make this issue moot as the coordinates are positioned by the GSR unit. For older models, the reading of coordinates out loud for patient safety does occur as the testimony stated but only in GSR sites with the oldest GSR units (model U) available in the United States. However, all newer

machines are automated and there will be only 7 GSR model U (older machines) out of 97 machines by the end of 2005. Four of these seven are scheduled for upgrades to the newer automated machines in the next 24 to 30 months, including the unit of the radiation oncologist who gave this testimony. The model U GSR has been obsolete for several years, and the vendor notified all model U installations that they would be unable to guarantee replacement parts for operations in the future as the sub-vendors were no longer producing some replacement parts.

When a machine is older and not automated, two people should read the coordinates out loud to each other during a change of positioning during the GSR procedure to ensure the correct coordinates during the procedure. Reading the coordinates out loud is not highly technical and does not require a radiation oncologist. As long as two competent and purposeful people participate in the safety step, the requirement for a highly trained radiation oncologist to be present to read coordinates is unnecessary.

It should be noted that radiation technologists (the least trained radiation employees) perform this coordinate checking safety procedure by themselves (no person to read out loud to) and without benefit of a radiation oncologist 2–3 times an hour with each patient receiving a radiation therapy treatment on linear accelerator equipment. The radiation oncologist is available somewhere on the grounds if needed, but does not usually participate in this procedure. IRSA does not believe the simple procedure of reading coordinates should be used as justification for a requirement that the radiation oncologist stay present. Certainly, many other radiation oncologists do not see the procedure as vital to their presence or they would not be requesting exemption or leaving the GSR suite without an exemption request.

IRSA is concerned about testimony and input to the NRC that may be politically motivated and not given with concern for patient safety and security. Should it be necessary, our association would be able to provide the NRC with both physician specialties that would provide objective information on patient safety and physician procedures.

IRSA firmly believes that the GSR procedure is a multi-disciplinary area that requires the expertise of both the radiation oncologist and the neurosurgeon. GSR is not a procedure that can be exclusively owned by either specialty and still provide for proper patient selection and patient safety in the procedure.

With the newer GSR machines, the change of coordinates during the procedure is carried out by the machine itself and is automated. There is no room for human error except in drafting the treatment plan. IRSA believes that the NRC should provide clear guidelines of when an exemption is allowable and anyone performing treatment outside the guideline should apply for an exemption. Currently over 63% of all GSR centers have the GSR model C which began installation in 1999. IRSA believes the issue of 'numbers' is made moot by the enhancement of automated technology and qualified and purposeful people performing the GSR procedure.

Recommendations:

IRSA believes the following exemption criteria would provide for patient safety:

1. An appropriately trained neurosurgeon must be allowed to fill the physical presence requirement of the radiation oncologist AU when:

- The treatment plan has been developed and the written directive approved by **both** the neurosurgeon and radiation oncologist (AU), and
- The procedure has been initiated.
- The qualified AMP is to remain present at all times with the neurosurgeon AU.

Further, the addition of a second GSR unit in the same suite is being debated by several centers and exists in one center already. IRSA believes the following would provide for patient safety where a second GSR exists:

1. Both GSR units would have to exist in the same physical surgical suite area.
2. One GSR unit must be an automated unit.
3. An AMP (one person) must be able to monitor concurrent procedures in both GSR units by direct TV oversight and have immediate physical presence in case of an untoward event.
4. The radiation oncologist and neurosurgeon must take part in the treatment planning and both approve the written directive.
5. The radiation oncologist (AU) must be physically present whenever a procedure is being initiated.
6. One neurosurgeon (AU) must remain present throughout the entire procedure and be available to both patients. (This is the same as when a neurosurgeon is in the operating room and overseeing a surgical procedure in the next operating room.)
7. Should patient number 1 require the treatment to be suspended for any reason, the procedure for patient number 2 in the adjoining GSR would be stopped and suspended until the problem is resolved with patient number 1 or the procedure is terminated for patient number 1. After that time, the procedure for patient number 2 could resume.
   - The radiation oncologist (AU) would be paged immediately if a procedure is suspended and would not leave the suite again until the problem is resolved or the procedure terminated.

Issue No. 4: Lack of Proper Training of AU and Vendor Approved Training Issues.

In the proposed language for the RIN 3150-AH19 the NRC has proposed that the GSR AU, as one of the training requirements, "receive training in device operation, safety procedures, and clinical use for the type of use for which authorization is sought (10 Part 35, Subpart H, 35.690)." It further states that this training may be satisfied by:

- Completion of a training program "provided" by the vendor for new users.
- Or by receiving training supervised by an AU or AMP who is authorized to use the applicable type of equipment.

IRSA believes being supervised by an AU or AMP is not a substitute for the GSR training. Recently, we were made aware of a radiation oncologist who spent four hours with an AU and was given a letter to submit to his hospital that he was trained in GSR and could operate the unit. This situation is unsafe for all involved.

Current vendor-endorsed training lasts 40–43.5 hours with 15 hours of hands-on and didactic software target and dosing training and 28 hours of didactic and clinical appropriateness as to patient selection. This training is now taught in two places in the USA with The University of Pittsburgh's **Department of Neurosurgery** and Image Guided Surgery Center providing over 80% of all training for GSR. It should be noted that the training is not being taught in radiation oncology departments.

The University of Pittsburgh's Department of Neurosurgery annually trains approximately 120–140 neurosurgeons, radiation oncologists and medical physicists in the GSR procedure. The training is taught primarily by neurosurgeons as GSR units perform a surgical procedure and it is stressed that the radiation oncologist should work with a neurosurgeon or surgeon trained in neuroanatomy when administering the surgical procedure.

The NRC should be aware that the initial 40-plus hour GSR training is the introductory training. The physician may return and complete more training on functional brain disorders and advanced dose planning. However, we are aware that most physicians do not return but proceed to treat functional disorders and work with advanced dose plans without benefit of additional education.

IRSA understands that one of the reasons the NRC is considering allowing a physician to be trained under another AU, instead of a week-long formal GSR class, is the cost of the training. Training centers do charge a fee to attend the training. This fee is currently around $6,000. However, the vendor provides coverage of the training fee when the GSR unit is purchased (or upgraded to a newer model) and the purchaser may negotiate for training 'slots' to use over a one year period. Additionally, hospitals and other owners of GSR units reimburse professionals who attend training and then work in their GSR centers. We know of no physician who was not reimbursed from either his hospital or his practice for attending the training that is actively working in a GSR center.

The institutions that conduct the training give the trainee a certificate for 40 continuing medical education credits toward renewal of the licensing of the physician. The physician would be required to obtain these credits **at his own personal expense** to renew his medical license. The GSR training provides a way of completing the requirement to maintain a physician's medical license with the expense paid by the vendor upon purchase or upgrade of a unit or by the hospital or practice where the physician works. Therefore, GSR training is merely a substitute in both money and time for another conference or training the physician would have to attend to renew his medical license. IRSA does not believe that working under an AU can substitute for the formal vendor-approved training at a major academic institution.

The NRC should be aware that neither GSR vendor conducts training for GSR. Each vendor approves/endorses a training that is given by an academic medical institution that operates a GSR center. IRSA is concerned about the GSR trainings as there are wide discrepancies in the training criteria. Additionally, vendors may designate a new training center as a 'perk' for the amount of equipment they purchased or the prestigious name of the medical center. This has happened in the United States. Vendors have offered to potential purchasers of equipment that they can be 'training centers' if they buy multiple machines and accessories. IRSA has objected to this type of criteria as a method of providing training as a training

center should have a wealth of experience and be able to provide a high level of patient procedures for the attendees to work with during the week of training.

Another concern IRSA has with GSR training is some physicians may attend a training that is given abroad by another country. We believe these facilities abroad to be incapable of providing the education and knowledge that is required to operate with the USA. Many problems exist with attending training in another country. Some of these problems are:

- A small amount of time spent on software targeting and dosing.
- Patient selection and brain indications treated differ widely from acceptable treatments in the United States.
- A small number of actual patient cases are presented during the training.
- The training is usually substantially less than the 40-plus hours given in the United States.
- There is no education provided on the current and pending NRC regulations concerning patient safety, protection of the cobalt^{60} sources, quality assurance for GSR, radiation safety and acceptance testing.
- There is no education on informed consent and other issues required for patient consent and safety.

IRSA is also aware that at times training centers within the USA have provided only 2–3 patient cases for the entire week of training. We note that the University of Pittsburgh is consistently able to provide 10 cases in a normal week for attendees. We believe that 2–3 patient cases are inadequate to provide appropriate training for GSR procedures during the week of training.

After formal training, proctoring of additional patient cases is required by IRSA and by most hospitals that provide oversight for GSR centers. With the hybrid ownership of GSR centers by physician groups and investor groups, there is no longer a standard or requirement for proctoring. Formal proctoring provides a working clinical environment in which a physician can apply skills under the guidance of another physician that is considered an expert in the GSR procedures.

When a new or upgraded GSR unit is installed, the vendor provides physicians who come to the center to provide a week of guidance and oversight. The vendor-provided physicians see that the GSR team at that center receives proctoring in an additional 6–8 patient cases during the startup week.

The vendor endorsed training and the startup week should allow the physician users of the GSR center to be involved in a minimum of 15 cases. On average, most GSR centers perform 2–3 cases per week after startup; therefore, a minimum of 15 cases would be marginally adequate considering the number of different diagnoses and target and dosing schemes that are available and that must be learned. Fifteen patient cases do not begin to reach the level that IRSA or major academic centers believe would be sufficient to make physicians competent in the procedure. Many academic centers require up to 50 proctored cases within a GSR center before a physician is considered fully trained.

An additional part of the credentialing criteria by most hospital GSR centers and by IRSA is that a physician must participate in one case per month or 12 per year to maintain his

credentialing status to use the GSR unit. Diagnoses, dosing and software targeting upgrades are fast paced in the medical world of GSR. If an AU does not participate regularly in the procedure, he would be a risk to patient safety. This would be the same as having a neurosurgeon that had not performed an open skull procedure for an extended amount of time decide to start operating again. In fact, the changes in the targeting software alone would make some AUs obsolete to the procedure if they had not participated in a six month period.

We are aware of investor centers that require no proctoring of a new AU as the investors want to make the process easy so that new AUs will use the GSR unit faster and thus payment is received for the unit's owners.

IRSA knows of one investor owned GSR center which has over eight AU physicians trained to perform the procedure and yet performs only 100 procedures per year in total. We are also aware of another site that has seven AU physicians and performs around 120 cases per year. When questioned, this center stated that some of the AUs conduct as few as two patient cases per year. This amount of cases is inadequate to allow for proper patient safety and for efficiency with the software. We are concerned that these physician users would more than likely not be aware of the current dosing schedules evidenced in research. It is understandable that private investors and physician owned GSR units may be more concerned with building the patient volume of the GSR centers which will result in more profits and thus allow physicians to complete a minimal level of cases to enhance those profits. However, who will oversee the patient safety of the patients in these environments and with this motivation if not the NRC? As we have previously stated, IRSA is aware of nine GSR units that are privately owned and operated at this time. We are also aware of other groups that are considering the purchase and installation of GSR units.

IRSA believes that the requirement of proctoring additional patient cases and actively working with the GSR unit on a minimal level be a part of NRC criteria along with appropriate academic, USA based, GSR training.

Recommendations:

To ensure appropriate training the NRC should:

1. Specifically remove the proposed section for allowing training under an AU or AMP in proposed section 10 CFR 35.690 (d) as it promotes an absolute risk to patient safety.
2. Further we believe the NRC should establish minimal standards for the vendor 'approved or endorsed' training for GSR to include.
   - GSR vendor approved training should be held in device operation, safety procedures and clinical use composed at a minimum of the following:
     a. Training should occur in the United States.
     b. Minimum 40 hours of training.
     c. Training should be provided in a medical academic teaching institution that has a minimum of five years experience with GSR and where an education department will certify the training and provide oversight as to the quality of the training.
     d. 15 hours of hands on and didactic software training.
     e. Minimum of eight GSR patient cases.

f. Training should be provided on the NRC current and proposed regulations affecting GSR operations.
g. All AUs should retrain if a change in GSR model unit occurs (vendor encourages this but cannot make the physician comply).

3. Require that an additional proctoring of eight cases be completed before an AU can operate without supervision.
4. Require that each AU maintain a minimum level of 12 cases annually, or the AU must return to vendor endorsed training or be proctored for an additional eight cases.

Issue No. 5: Definition of Stereotactic Radiosurgery Should Be Amended.

The blurring of the definition of stereotactic radiosurgery and stereotactic radiotherapy has caused problems for patients seeking treatment (Section 35.2 Definitions, 10 CFR part 35).

Stereotactic Radiosurgery is by definition one-session stereotactic operation, frame on to frame off. **Radiosurgery is not radiation therapy as ASTRO has stated.** Radiosurgery may be gamma or linear accelerator based. The same as open skull surgery, it must be performed in one session and cannot occur over days. Radiosurgery occurs in lieu of surgery and is limited with GSR technology to intracranial locations and diagnoses that are not normally treated by radiation oncology. Radiosurgery always involves a multi-disciplinary team of a neurosurgeon and radiation oncologist when utilizing GSR systems.

Stereotactic Radiotherapy occurs over days or weeks with a linear accelerator or proton generator as the ability to completely immobilize within the spine and body does not exist. In time, radiotherapy may be performed by GSR units also as technology develops. Radiotherapy is neither as precise nor as high dose as radiosurgery. Radiotherapy is more commonly known as XRT (X-Ray Radiation Therapy), and fractionated radiotherapy, among other names. Radiotherapy is primarily directed by a radiation oncologist with a physicist and a radiation therapist without a surgeon or neurosurgeon. Fractionated radiation therapy techniques include IMRT, IGRT, hypo-fractionated stereotactic radiation, and other names.

Recently in a private letter to the Centers for Medicare and Medicaid (dated September 29, 2004), ASTRO **misquoted** the NRC definition of Stereotactic Radiosurgery. Specifically the letter read:

> *The NRC currently defines Stereotactic **radiation therapy** [emphasis added—not 'radiosurgery' as the NRC definition reads] as '...the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume."*

The words 'radiation therapy' in place of the NRC word 'radiosurgery' were used to try to impress upon the Centers for Medicare and Medicaid that the NRC does not acknowledge radiosurgery, only radiation therapy. Because of the total context of the letter to Medicare, IRSA believes this was an intentional misquote to use the NRC for professional gain. We are concerned that patient safety requires that physicians, insurers, and indeed even Medicare, know exactly which procedure is being recommended for a patient. Misrepresenting the

NRC's definition for Stereotactic Radiosurgery to imply it is radiation therapy will eventually result in procedures being performed that are not actually radiosurgery, and thus place patients at extreme risk.

As the organization representing 90% of the USA installed base of GSR units, IRSA finds these attempts to change the accepted clinical 50-year-old definition of radiosurgery for political gain and ownership to be reprehensible. Radiosurgery is a clinically established alternative to open skull surgery and its definition has been supported by research for over 54 years. GSR is not in competition with radiation therapy. All treatments are necessary to properly treat patients, and patients should be offered the type of procedure or treatment that could provide the most benefit to them.

The Journal of Neurosurgery recently published yet another research article reiterating the definition of radiosurgery and radiotherapy and acknowledging them as two separate fields (Radiosurgery and radiotherapy: observations and clarifications, J. Neurosurgery, Volume 101, pages 585-589, October 2004). This article has been attached for your review. On page 586 the article states in part:

> *Because radiosurgery is a multidisciplinary specialty, it is not surprising that there has been some confusion in the use of terms associated with the concept. First, we emphasize the word "surgery." Surgery is the definitive single-session manipulation of a disease or organ system in which energy is used to achieve a specific purpose. The energy may be mechanical (the surgeon's arm moving a scalpel)...or focused radiation (radiosurgery).*

We also note in the previously discussed ACR Practice Guideline for Stereotactic Radiosurgery (attached) that the ACR defines radiosurgery (on the first page) as *"a single, high dose of ionizing radiation..."*

The International Journal of Radiation Oncology, Biology and Physics has monthly articles with titles that are distinguished by the terms "radiosurgery" or "radiotherapy." One term is never substituted for the other in this research journal.

We believe that the NRC should appropriately define the established clinical definitions of radiosurgery and radiotherapy as defined in research so that the NRC is hopefully not used in the future by professional groups seeking to justify a stance against other professional groups.

<u>Recommendation:</u>

1. Amend the definition of Stereotactic Radiosurgery (section 35.2) to include the words "in one surgical session."
2. Add a definition for Stereotactic Radiotherapy defined as "the use of external radiation in conjunction with a stereotactic or image guidance device to deliver a <u>partial therapeutic dose to a tissue volume over a series of treatment sessions.</u>"

IRSA also wishes to suggest the correct language and terminology that applies to gamma stereotactic radiosurgery that should be included in the written directive section. The current descriptors do not apply to GSR technology.

Additional Recommendation:

1. Amend Section 35.40(b)(3) to read: For gamma stereotactic radiosurgery: the total dose, *margin dose and isodose level for each anatomically distinct treatment site* and the target coordinate settings for each anatomically distinct treatment site *must be dated and signed by the neurosurgeon and the radiation oncologist before the administration of...*.

Issue No. 6: A GSR Active Neurosurgeon Should Be Appointed to the NRC's ACMUI Advisory Committee.

IRSA is aware that a GSR radiation oncologist serves on the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI). The GSR center where the advisor works has an older model U GSR unit. IRSA is unaware as to whether this advisor is familiar with the new model C GSR differences and its automation and other technically related issues. We are aware that the radiation oncologist group at this site is looking to purchase the GSR operations from the local hospital, whether wholly or partially, when they upgrade the unit.

In the past IRSA has written and contacted ASTRO to work on some of these issues. ASTRO has refused all contact, and has chosen not to work with the neurosurgeon's professional association over these issues. Recently, at the request of the neurosurgeon's association (AANS) ASTRO has agreed to have a meeting to open discussions. At this time, IRSA believes that the NRC is the only agency that will act responsibly and appropriately to safeguard patients and the general public where GSR is concerned. Indeed, the NRC is the only agency with the authority to regulate patient safety with GSR in such a varied operational environment.

IRSA believes that it would greatly assist the NRC in the future to have a GSR neurosurgeon serve on the ACMUI. We would be pleased to provide assistance with the selection of a GSR neurosurgeon that would be willing to commit to the time and effort needed to serve in such a capacity.

Recommendation:

1. The NRC should appoint a GSR active neurosurgeon to serve as a resource on the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

Summary:

IRSA appreciates the opportunity to make comments and recommendations, and looks forward to working with the NRC to address these important issues in gamma stereotactic radiosurgery operations and patient safety. We would welcome the opportunity to discuss these issues in more detail and would bring the appropriate multi-disciplinary physician team of a radiation oncologist and a neurosurgeon to any meeting. We hope that the issues of safety for patients and operations will allow the NRC to see its way to making appropriate changes in the regulations to ensure that the current and future installation of gamma stereotactic radiosurgery units in untraditional and traditional environments will operate in a safe manner minimizing the risk to patient safety.

IRSA is hopeful that we have presented a detailed analysis and overview of the GSR operations to allow the NRC to make appropriate decisions and changes within its regulatory system to protect the cobalt^{60} sources and the general public and patient safety. The NRC can now look to the risks involved and try to minimize these risks. IRSA believes that the NRC's statutory mandate "to protect health and minimize danger to life" should be focused on high risk procedures like GSR where an extremely high dose of radiation is delivered to an extremely small target within the brain.

NRC regulations are predicated on the assumption that properly trained physicians will make informed decisions. Therefore, IRSA encourages the NRC to reinstate the neurosurgeon as an AU (with immediate compliance by agreement states) and to require vendor endorsed training that is USA based, with sufficient patient case study and software training to ensure an adequate level of competence by the physicians involved in the GSR procedure.

Further, regulations of clarity of when an AU exemption is allowable would be in keeping with current practices in many GSR centers in the USA. IRSA believes this would provide more compliance than is currently seen with regulations that do not speak to current practices or training guidelines.

Finally, a clarification of the definitions of stereotactic radiosurgery and stereotactic radiotherapy that is in keeping with the current research literature would be appropriate. While GSR units treat in one session, we are seeing the discussion of the potential availability of future treatments in multiple sessions (radiotherapy) in the next decade.

If you have any questions regarding our concerns presented in this document, please let us know. Our GSR physicians and hospitals would welcome the opportunity to meet with you at your convenience to discuss our comments on these issues.

Sincerely,

Rebecca L. Emerick, MS, MBA, CPA
Executive Director

Attachments:

1. ACR Practice Guideline for the performance of stereotactic radiosurgery. ACR Practice Guideline, 623–628, 1997, revised 2001, posted to web site 2003.
2. IRSA Neurosurgeon Credentialing Guideline, 2001, revised 2003.
3. Kondziolka D, Lunsford LD, Loeffler JS, Friedman WA: Radiosurgery and radiotherapy: observations and clarifications. **J Neurosurg 101**:585–589, 2004.

Acknowledgments:
IRSA would like to give special acknowledgment to the chairmen of our Medical Advisory Board and Hospital Advisory Board who were involved in editing and reviewing. Dr. L. Dade Lunsford serves as Chairman of the IRSA Medical Advisory Board, Professor and Chairman of The Department of Neurosurgery at the University of Pittsburgh Medical Center, and the Medical Director of the Center for Image-Guided Neurosurgery at the

University of Pittsburgh Medical Center which has three active GSR units and performs over 600 stereotactic radiosurgery procedures annually using GSR units. Dr. Lunsford opened the first GSR center in the USA working with the FDA and the NRC in 1987. The majority of all GSR training in the USA is conducted at his center.

Paul H. Loflin serves as Chairman of the IRSA Hospital Advisory Board and the Administrator at the San Diego Gamma Knife Center located at Scripps Memorial Hospital in La Jolla, California. The center has been open since 1994 and performs over 250 GSR procedures annually.

The IRSA governing board has reviewed and approved this document.

Position Statement: Credentialing for Neurosurgeons in Radiosurgery

Existing standards in credentialing serve the purpose of assuring the basic qualifications and, to some extent, competency of practitioners. The International RadioSurgery Association (IRSA) makes patient referrals to neurosurgical radiosurgery treating sites. It is the intention of IRSA to make patient referrals to qualified treating sites that are staffed by medical professionals who have meet certain standards in credentialing for neurosurgical stereotactic radiosurgery. As a response to growing requests from hospitals for assistance in preparing credentialing standards, IRSA with the assistance of a core group of its medical and hospital advisors has scripted a neurosurgeon credentialing guideline that would act as an inclusive template from which each hospital entity could compose or review their specific credentialing guidelines.

A full review of all available credentialing guidelines was requested and reviewed from IRSA member treating sites. IRSA and its advisors recognize that credentialing is an individual institution decision and as such should be specific to the operations of each center.

General Statement:

Neurosurgical radiosurgery, whether performed with the Gamma Knife or other equipment, is a neurosurgical procedure that requires a board eligible or board certified neurosurgeon to perform. The skills required include training in neurology, neuroanatomy, neuroimaging, neurophsyiology, and radiation biology. Stereotactic technique and knowledge are required, and **are not considered met by attendance** at a one week vendor approved course. Finally, the professional and technical billing coding for radiosurgery falls within the neurosurgical area of the CPT code book under the auspices of the American Medical Association.

General Requirements: It is recognized that competency for the neurosurgeon must be shown in the following area:

- Neurosurgical training
- Stereotactic frame proficiency
- Use and understanding of the specific radiosurgery machine
- Radiation safety and biology
- Competency in radiosurgical neurosurgery treatment
- Knowledge of appropriate clinical indications

Surgical Specialties Other Than Neurosurgery:

Non-neurosurgeons who seek credentialing must be trained CNS surgeons that operate a radiosurgery instrument only within their current operative credentials within the hospital. Appropriate guidelines for this group are also discussed.

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The following terms are defined:
Preceptor: The act of active teaching and training.
Proctor: The act of providing guidance and supervision.

I. Neurosurgeon Privileges

A. General Criteria

To be eligible for clinical privileges in neurosurgical radiosurgery the applicant must meet all of the following criteria:

1. License to practice within the State of _____, AND Active or Consulting/Privilege medical staff privileges at _____Hospital/Medical Center in good standing without encumbrance.

2. The neurosurgeon must be board certified or board eligible in neurological surgery.

2. The neurosurgeon must be proficient in stereotactic neurosurgery as evidenced and documented by one of the following methods.
   - Attendance at a minimum five (5) day course on the use of the Leksell stereotactic frame **AND** a list of fifteen (15) stereotactic cranial surgery cases in which he/she acted as the primary attending surgeon while being proctored AND utilized the Leksell Stereotactic head frame <u>within the preceding 12 months;</u>
   - **OR** The documentation provided of a list of twenty (20) stereotactic cranial surgery cases (within the preceding 12 months) in which he/she acted as the primary attending surgeon, 15 of which utilized the Leksell Stereotactic head frame. The supervising neurosurgeon should provide a written document attesting to the number of cases;
   - **OR** The documentation provided of a list of forty (40) stereotactic cranial surgery cases in which he/she was a participant during residency training, 15 of which utilized the Leksell Stereotactic head frame. The supervising neurosurgeon should provide a written document attesting to the number of cases.

4. Documentation of attendance for a minimum of 40 hours at an approved USA neurosurgical Gamma Knife course (Pittsburgh, Cleveland), or show completion of a minimum four month residency training in a Gamma Knife center with documented participation in a minimum of 40 cases. The supervising neurosurgeon should provide a written document attesting to the number of cases.

   Attendance outside the USA for training is not recommended as the requirements for NRC, coding, billing and physician compliance required within the USA are excluded from training. Additionally, the common acceptability of certain patient criteria and diagnoses are not the same standard as within the USA.

5. Documentation of completion of a basic radiation safety training course. Training should include review of emergency procedures with the machine involved (Gamma Knife, RGS, etc.), risks associated with low level radiation exposure, radiation protection concepts, ALARA, and NRC requirements. Additionally, the understanding of the rate of emission of cobalt when it is fresh and when it is decaying is paramount to mitigating the errors and over-administration of radiation.

6. Candidates must be satisfactorily preceptored for a minimum of 10 one-session neurosurgical radiosurgery cases within a 12 month period. The Gamma Knife Medical Director will have the ultimate authority and discretion to require additional case requirements for credentialing for any physician. **A minimum of two (2) cases must be preceptored in each of the following categories before any candidate has satisfactorily completed this requirement or may treat within these categories:**
   - Vascular lesions
   - Skull based meningiomas
   - Benign tumors
   - Malignant brain tumors
   - Functional disorders

7. The Gamma Knife Medical Director(s) will have ultimate authority and discretion to require additional training and proficiency.

8. Written endorsement of Gamma Knife Medical Director(s) must be obtained after submission and review of all listed criteria.

B. Reappointment Criteria:

1. Complete adherence to the treatment guidelines set forth by the Medical Director(s), Gamma Knife committee and the hospital credentialing department of the facility.

2. All cases treated must be reviewed and receive approval for treatment by the Gamma Knife Committee before treatment. In lieu of a committee, the Medical Director may give approval. In 'open centers' a criteria for treatment acceptance should be established. The criteria should address the treatment of persons who are acceptable upon examination but report for treatment in a debilitated state.

3. Attendance at two-thirds of the Gamma Knife review committee meetings each year.

4. Attendance at a minimum of one national neurosurgery meeting that includes discussion of radiosurgery every two years.

5. Active participation in at least twenty-four cases (24) in a twenty-four (24) month period. Failure to complete at least twelve (12) cases within this period will require the physician to repeat the 40 hour training course at his/her own expense and have an additional 10 cases preceptored before receiving full reinstatement status.

Completion of between 12 and 24 cases will require a minimum of 10 new preceptored cases and the Medical Directors' decision on what attendance (if any) in additional training will be required.

C. Treatment Requirements

The case should be presented and approved before the Gamma Knife committee. Prior to each treatment, the neurosurgeon must take an active part in patient selection with the radiation oncologist. The neurosurgeon is required to appropriately inform patients of **all alternatives** available to the patient and obtain consent to the patient's understanding of alternatives. The neurosurgeon and radiation oncologist must agree on the treatment goals prior to initiation of the procedure. The treatment should conform to the treatment guidelines set forth by the Medical Director and committee. The neurosurgeon is responsible for:

- Appropriate placement of the skull frame
- Selection and approval of the target
- Consultation and agreement with the radiation oncologist and physicist of the treatment plan and prescription radiation dose
- Signature sign-off of the plan before treatment
- Verification of the treatment coordinates during treatment along with the radiation oncologist
- Placement of the patient in and removal from the Gamma Knife unit
- **Immediate availability** during all phases of treatment (may not leave the treatment suite)
- Completion of a prompt operative report
- Follow-up and timely submission of such information to the Gamma Knife center in accordance with the Follow-up Guidelines of the center
- Upon treatment completion the patient and family should be given an understanding in writing of the future scans and examinations that will be required

D. Documentation

Documentation of case requirements will be considered relevant and pertinent when it consists of the following:

- Medical record number (not patient identifier)
- Institution of record
- Diagnosis
- Date of treatment
- Type of instrument utilized
- Evidence of applicant's participation in planning, target definition, interpretation of scan(s), and dose prescription
- Listing of follow-up involvement with patient
- Signature, title and contact information of preceptor or proctor involved

(OTHER CENTRAL NERVOUS SYSTEM SURGEON CRITERIA)

E. Otolaryngologists, Ophthalmologists, ENTs and Non-Neurosurgeon Requirements

Non-neurosurgeons must be surgeons with prior and current surgical operating room privileges and credentialing for the indications treated with the Gamma Knife and more specifically within the central nervous system. This restricts the areas of expertise to surgeons who routinely perform open skull craniotomies and who are licensed as surgeons.

1. Additional completion of the criteria described above for:
   - Section A: Criteria 1, 2, 3, 4, 5, 6, 7, and 8
   - Criteria A-6 must be completed at the Gamma Knife facility for which privileges are being applied

2. Non-neurosurgeons are required to show proficiency with the Leksell stereotactic frame and must strictly adhere to the experience required in Section A-3 above.

4. Alternatively, the possibility of co-surgery with a stereotactic neurosurgeon may be acceptable if training and case requirements (E-1 and E-2) are not met. Co-surgery can exist with a fully privileged Gamma Knife neurosurgeon user and the completion of all criteria in Section E-1 above.

5. **In All Instances: Non-neurosurgeons will only participate in patient cases where the indication for treatment falls within the normal scope of surgical practice for their medical specialty. THE NON-NEUROSURGEON MUST HAVE PRIOR AND CURRENT SURGICAL OPERATING ROOM PRIVILEGES AND CREDENTIALING FOR THE INDICATIONS THAT ARE TREATED WITH THE GAMMA KNIFE WITHIN THE SAME OR A LOCAL HOSPITAL.**

   ADDITIONALLY, THE NON-NEUROSURGEON MUST HAVE PERFORMED A MINIMUM OF TEN (10) OPERATING ROOM PROCEDURES IN THE PRECEDING 12 MONTHS FOR EACH DIAGNOSIS THAT IS DESIRED TO BE TREATED WITH THE GAMMA KNIFE AND PROVIDE WRITTEN PROOF OF SUCH TO THE GAMMA KNIFE MEDICAL DIRECTOR.

6. Non-neurosurgeons will be required to meet all criteria for Sections B, C and D above.

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Originated by: IRSA Physician Advisory Board
Reviewed & Adopted by: IRSA Board of Directors

Radiosurgery Practice Guideline Initiative

Stereotactic Radiosurgery for Patients with Pituitary Adenomas

Practice Guideline Report #3-04

ORIGINAL GUIDELINE: April 2004
MOST RECENT LITERATURE SEARCH: April 2004

This practice guideline, together with a report on "Pituitary Tumors: Overview" is an original guideline approved by the IRSA® (International RadioSurgery Association) Board of Directors and issued in April 2004.

Preface

Summary
The IRSA® (International RadioSurgery Association) Radiosurgery Practice Guideline Initiative aims to improve outcomes for pituitary adenomas by assisting physicians in applying research and clinical evidence to clinical decisions while promoting the responsible use of health care resources.

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KEY WORDS • pituitary adenoma • acromegaly • Cushing's disease • prolactinomas • stereotactic radiosurgery • Gamma Knife® • linear accelerator • proton beam • Bragg peak proton therapy • irradiation

Consensus Statement

Objective
To develop a consensus-based radiosurgery practice guideline for treatment recommendations to be used by medical and public health professionals for patients with the diagnosis of pituitary adenoma.

Participants
The working group included neurosurgeons, radiation oncologists, endocrinologists and physicists, all of whom staff major medical centers that provide radiosurgery treatment.

Evidence
The first authors (LDL/AN) conducted a literature search in conjunction with the preparation of this document and the development of other clinical guidelines. The literature identified was reviewed and opinions were sought from experts in the diagnosis and management of pituitary adenomas, including members of the working group.

Consensus Process
The initial draft of the consensus statement was a synthesis of research information obtained in the evidence-gathering process. Members of the working group provided formal written comments that were incorporated into the preliminary draft of the statement. No significant disagreements existed. The final statement incorporates all relevant evidence obtained by the literature search in conjunction with final consensus recommendations supported by all working group members.

Group Composition
The Radiosurgery Guidelines Committee is comprised of neurological surgeons, radiation oncologists, physicians, endocrinologists and medical physicists. Community representatives did not participate in the development of this guideline but will in future updates.

Names of Group Members: L. Dade Lunsford, M.D., Neurosurgeon, Chair; Ajay Niranjan, M.B.B.S., M.Ch., Neurosurgeon; Tatsuya Kobayashi, M.D., Ph.D., Neurosurgeon; Mark Linskey, M.D., Neurosurgeon; Thomas Witt, M.D., Neurosurgeon; Alex Landolt, M.D., Neurosurgeon; Roman Liscak, M.D., Neurosurgeon; Edward R. Laws Jr., M.D., Neurosurgeon; Mary Lee Vance, M.D., Endocrinologist; John Buatti, M.D., Radiation Oncologist; Jonathan Knisely, M.D., Radiation Oncologist; Paul Sperduto, M.D., Radiation Oncologist; Sammie Coy, Ph.D., Medical Physicist; Tonya K. Ledbetter, M.S., M.F.S., Editor; Rebecca L. Emerick, M.S., M.B.A., C.P.A., ex officio.

Conclusions
Specific recommendations are made regarding target population, treatment alternatives, interventions and practices and additional research needs. Appropriate use of radiosurgery in those patients with pituitary adenoma following medical and/or surgical management may be beneficial.

This guideline is intended to provide the scientific foundation and initial framework for the person who has been diagnosed with a pituitary adenoma. The assessment and recommendations provided herein represent the best professional judgment of the working group at this time, based on research data and expertise currently available. The conclusions and recommendations will be regularly reassessed as new information becomes available.

Stereotactic Radiosurgery

Stereotactic radiosurgery involves the use of precisely directed single fraction (one session) radiation to create a desired radiobiologic response within the targeted tissue volume with minimal effects on surrounding structures or tissues. In the case of pituitary adenoma a single highly conformal dose of focused radiation is delivered precisely to the tumor under the direct supervision of a multidisciplinary radiosurgery team (neurosurgeon, radiation oncologist, physicist, and often a registered nurse).

Pituitary Radiosurgery: Overview

Pituitary tumors are relatively common neoplasms that represent between 10% and 15% of all intracranial tumors (2, 6, 8, 64, 65). Incidental pituitary tumors are found in approximately 10% of patients undergoing brain imaging for other reasons (7). The vast majority of these tumors are benign and grow slowly, but certain factors involved in the genesis of the tumor (G-protein abnormalities, ras gene mutations, p53 gene deletions, mutations) may determine its rate of growth and aggressiveness.

Classification of Pituitary Tumors

Based on size, pituitary adenomas can be divided into microadenomas (≤1 cm diameter) and macroadenomas (>1 cm diameter). They also can be classified on the basis of clinical presentation, serum hormone levels and immunohistochemical staining characteristics. The current prevalent classification (functional) method relies on immunohistochemistry performed on tissue samples obtained at surgery.

Presenting Symptoms

Clinical symptoms result from mass effect on surrounding structures, tumor invasion and symptoms related to elevated or reduced systemic hormone levels. With pituitary macroadenomas, symptoms related to mass effect and pressure on surrounding structures, and occasionally tumor invasion of those structures, tends to dominate the clinical presentation. Fifty to sixty percent of patients with macroadenomas present with visual field abnormalities due to compression of optic nerve structures. Nonspecific headache can be seen, or headache symptoms may be referred to the forehead in the distribution of cranial nerve V1. Compression of the normal pituitary can cause hypopituitarism. Invasion of the cavernous sinus may cause other visual symptoms (ophthalmoplegia, diplopia, ptosis) or facial numbness or pain. Extension into the sphenoid sinuses can cause spontaneous cerebrospinal fluid (CSF) rhinorrhea. In addition to these symptoms resulting from tumor mass effect or invasion of surrounding structures, endocrine dysfunction can result from excess production of pituitary hormones from the tumor (functional or secretory adenoma), or from compression of the stalk or of the normal pituitary gland. The endocrinologic manifestations are dependent on the specific overproduction or underproduction of a hormone or hormones associated with the tumor. Rarely a patient with a pituitary adenoma will present with sudden onset headache, visual loss, and hormonal dysfunction resulting from sudden hemorrhage and/or infarction within the tumor leading to sudden, rapid expansion of tumor size (pituitary apoplexy).

Hormonal Overproduction—Clinical Effects

Prolactin

- Hypogonadism, if hyperprolactinemia is sustained, especially in males
- Women—Amenorrhea, galactorrhea and infertility
- Men—Decreased libido and impotence
- Osteoporosis

Growth Hormone

- Children and adolescents—May result in pituitary gigantism
- Adults—Acromegaly (changes in the size of hands and feet, coarseness of the face, frontal bossing, prognathism, changes in the voice, diabetes mellitus, hypertension, sleep apnea and cardiomyopathy)

ACTH

- Cushing's disease is characterized by weight gain, centripetal obesity, moon facies, hirsutism, violet striae, easy bruisability, proximal myopathy, mood disorder, diabetes mellitus, and secondary cardiac changes

Sex

Symptomatic prolactinomas are found more frequently in women. Cushing's disease also is more frequent in women (female-to-male ratio 3:1). The incidence of acromegaly is equal for men and women.

Age

Most pituitary adenomas occur in young adults, but they may be seen in adolescents and elderly persons. Acromegaly usually is diagnosed in the fourth and fifth decades of life.

Laboratory Studies

Prolactinomas

- Serum prolactin levels are elevated. Levels above 200 mg/L in a patient with a macroadenoma greater than 10 mm in size are diagnostic of a prolactinoma. Levels below that range in a macroadenoma suggest that hyperprolactinemia may be secondary to pituitary stalk or hypothalamic compression (stalk dysinhibition effect). Levels >2000 mg/L are highly suggestive of an invasive growth of a prolactinoma (23).

Growth Hormone Abnormalities

- Growth hormone (GH) levels are elevated in acromegaly but can fluctuate significantly. The oral glucose tolerance test (OGTT) is the definitive test for the diagnosis of acromegaly; a positive result is the failure of GH to decrease to <1 μg/L after ingesting 50-100 g of glucose. A GH level >5 μg/L suggests acromegaly.

- Serum insulin-like growth factor 1 (IGF-1) level is a more practical endocrinologic test for acromegaly. The IGF-1 level reflects GH concentration over the preceding 24 hours.

Cushing's Disease

- Twenty-four hour urine free cortisol is elevated. Usually two baseline values are obtained.

- Low-dose dexamethasone test: Two-day baseline serum and urine cortisol levels are determined. The patient is then given four doses of 0.5 mg dexamethasone at six hour intervals. Normal suppression is a serum cortisol level of <138 nmol/L or a urine level of <55 nmol/L. If cortisol levels are increased abnormally, corticotrophin-releasing factor (CRF) in a dose of 1.0 mg can be given to differentiate between Cushing's disease and other causes of hypercortisolism (i.e., Cushing's syndrome). With pituitary adenomas, cortisol secretion is increased over the baseline.

- High-dose dexamethasone test: Cortisol suppression after high-dose dexamethasone (8 mg) confirms the diagnosis of a pituitary adenoma. It suppresses the pituitary gland even in the presence of an adenoma. If cortisol levels remain unchanged, the cause of increased cortisol is not a pituitary adenoma.

- Serum levels of ACTH: The serum concentration of ACTH is higher than normal (>5.5 pmol/L at 9 am and >2.2 pmol/L at midnight). At times, venous sampling of ACTH from the inferior petrosal sinuses by means of cerebral venography may be valuable in confirming the diagnosis. Inferior petrosal sinus sampling (IPSS) may be used in selected cases to suggest lateralization of the tumor.

Imaging Studies

Pre- and post-gadolinium MRI of the brain and sellar region with multiplanar thin sections (1 mm) is of critical importance, especially in the coronal plane.

Medical Management

The majority of prolactinomas respond to dopamine receptor agonists such as bromocriptine. Medical management can result in improvement in visual field abnormalities, resolution of symptoms associated with hyperprolactinemia (galactorrhea, amenorrhea) and tumor shrinkage. Somatostatin analogues (e.g. octreotide) and a growth hormone receptor antagonist, pegvisomant, can be helpful in the treatment of increased postoperative levels of GH in cases of acromegaly. Dopamine agonists also have been used. Pituitary hormone replacement therapy for decreased or absent hormones should be instituted as needed. For selected patients with Cushing's disease, ketoconazole may be prescribed to reduce cortisol production. Medical management is extremely useful as either first line therapy for secretory adenomas or as an adjunct in a combined multimodal approach to overall patient management. Care must be used when employing these agents peri-operatively for either microsurgical resection or stereotactic radiosurgery. Accumulated clinical experience suggests that these agents can lead tumors to be denser and more fibrotic, thus technically more challenging to remove during microsurgery. Likewise, there are some data to suggest that both bromocriptine and octreotide may confer relative radioresistance to tumors undergoing stereotactic radiosurgery (25–27). As a result, many clinicians suggest stopping these agents four to six weeks prior to any contemplated surgical intervention. These agents can be restarted one week after radiosurgery.

Surgical Management

The primary aim of treatment for clinically hyperfunctioning or nonfunctioning pituitary macroadenomas is tumor removal and preservation of visual function. Transphenoidal surgery is the preferred approach for managing pituitary adenomas (8, 9, 64, 65, 69). For large lesions with lateral suprasellar extension, a craniotomy may be necessary to decompress the visual pathways as well as resect any non-midline suprasellar extension that may have occurred. Adequacy of treatment is assessed by radiological and visual evaluations. Because microadenomas (≤10 mm in diameter) are recognized due to endocrinopathy related to tumor hormonal secretion, the aim of treatment is to correct endocrine dysfunction. This usually requires radical tumor removal. The adequacy of treatment for hypersecreting adenomas is defined by correction of endocrinopathy and preservation of normal pituitary function. Transphenoidal resection is associated with an excellent outcome and successful decompression of the visual pathways. Surgical complications are relatively rare but can include incomplete resection of large adenomas, transient or permanent diabetes insipidus, CSF rhinorrhea, hormonal deficiencies and residual visual field defects. The main endocrine complication after transphenoidal surgery is hypopituitarism. All patients should be assessed for potential need for selective hormone replacement therapy following transphenoidal resection of an adenoma. Failure to achieve permanent remission occurs in at least 5–15% of cases (15), even in the hands of experienced surgeons. The success and complication rates are significantly less favorable with second surgical resection.

Fractionated Radiation Therapy

Fractionated radiation therapy has been used for the treatment of unresectable pituitary adenomas. Rates of tumor control have been reported to vary from 76% to 97%. Fractionated radiation therapy, however, has been less successful (38–70%) in reducing hypersecretion of hormones by hormonally active tumors. It may take years before the full therapeutic effect is exhibited. The delayed complications of fractionated radiation therapy (2–10 years) include a relatively high risk of hypopituitarism (12–100%) and a low but definite risk of optic neuropathy (1–2%) and secondary tumor formation. Some investigators have reported a higher likelihood of cerebrovascular disease in patients treated with radiation therapy for pituitary tumors. In patients with a benign

neoplasm and an otherwise normal expected life span, external beam fractionated radiotherapy (EBRT) leads to exposure of normal surrounding brain to potential long-term cognitive effects of radiotherapy. Newer fractioned radiotherapy techniques such as intensity modulated radiotherapy (IMRT) can minimize the amount of normal brain exposed to radiation compared with conventional or standard 3-D conformal techniques. However, the medial temporal lobes on either side, which are intimately involved in memory processing and learning, often remain exposed as the radiation distribution is shifted away from the optic nerves and chiasm. Minimal long-term outcome data exist for IMRT.

Stereotactic Radiosurgery

The endocrine control aims of radiosurgery are no different from those of surgical resection; namely, normalization of any hypersecretory syndrome without new onset hypopituitarism. Unlike surgical resection, which eliminates the tumor on subsequent neuroimaging, the neoplastic goal of stereotactic radiosurgery is permanent tumor control. This means that a tumor, which has been enlarging, is made incapable of further tumor growth, and this control is confirmed through long-term neuroimaging follow-up. While permanent stabilization of tumor size is the desired goal, the majority of tumors will demonstrate varying degrees of tumor shrinkage over time. Thus the goal of pituitary adenoma radiosurgery is to permanently control tumor growth, maintain pituitary function, normalize hormonal secretion in the case of functional adenomas, and preserve neurological function, especially vision. The small risks of late radiation-induced tumorigenesis and of late cerebrovascular accidents from radiation damage to the internal carotid arteries also exist for patients treated with radiosurgery. Delayed complications are less than that of stereotactic radiotherapy.

Radiosurgery Dose Planning

High-resolution stereotactic magnetic resonance imaging is mandatory for pituitary radiosurgery. Contrast enhanced stereotactic 3D volume acquisition (gradient recalled) is ideal. For patients with a history of trans-sphenoidal surgery a fat suppression sequence is performed. Pituitary radiosurgery planning is usually complex because a highly conformal dose plan is needed to spare the optic apparatus (optic nerves, chiasm and tracts) as well as any remaining normal pituitary gland. Dose selection is based on the tolerance of the adjacent structures. The optic pathway is the most sensitive structure to radiation exposure, and ideally the dose to this structure is kept less than 9 Gy (31, 60). If the goal is close to zero percent risk of permanent optic neuropathy, most radiosurgeons consider 8 Gy to be a safe dose, so long as the patient has not received a prior radiation dose to the area. There are occasions where it is appropriate to deliver higher doses to the optic apparatus, particularly in cases of secretory macroadenomas where higher tumor doses are required to normalize endocrine function. In these cases, a small risk of optic neuropathy is measured against the need for tumor control or hormonal normalization and these differential risks are shared and discussed with the patient pre-operatively. Current data suggest that the risk of permanent optic neuropathy is <2% for doses as high as 12 Gy10Gy delivered with the Gamma Knife®, as long as the patient has not received prior radiotherapy (56). It is however the volume of optic apparatus receiving high dose that determines the rate of optic neuropathy. The optic apparatus may be more vulnerable because of previous compression and prior surgery. Most centers limit the radiosurgical dose to the optic apparatus to < 8 Gy. With current technique a 1–5 mm distance between the tumor and the optic chiasm is enough to safely and effectively perform Gamma Knife® radiosurgery depending on margin dose and target volume. If necessary, selected radiation sources can be blocked to reduce dose fall off to the optic apparatus. A minimum margin dose of 12 Gy is generally considered a safe tumor control dose. Higher doses of at least 15 Gy to ensure reliable and early tumor growth control may be prescribed when distance from the tumor margin to the optic apparatus allows. Although tumor growth control is achieved in most patients, the rate of hormone normalization after radiosurgery is lower with lower doses. Some investigators suggest higher marginal dose (up to 30–35 Gy) whenever possible for treating small volume secretory pituitary adenomas (20, 21). Higher marginal doses are may be associated with a higher rate of hormone normalization.

Tumor Growth Control After Radiosurgery

Non-functioning pituitary adenomas are usually diagnosed late when patients complain of visual dysfunction. Trans-sphenoidal decompression is recommended as the first line of management for these patients. Radiosurgery is often indicated as an adjuvant management after partial resection or later recurrence of pituitary adenomas. However, radiosurgery can be performed as the primary management of non-functioning adenomas in carefully selected patients, including those who are high risk for surgery or consciously choose not to undergo resective surgery. Tumor growth control rates of 90–100% have now been confirmed by multiple centers following pituitary radiosurgery (13, 20, 21, 24, 26, 41). The anti-proliferative effect of radiosurgery has been reported in nearly all patients who underwent Gamma Knife radiosurgery (24, 41). Relatively few patients (who usually had received lower margin doses) eventually required additional treatment (12, 46).

Cavernous Sinus Invasion

Cavernous sinus invasion can occur de novo in patients with large pituitary macroadenomas, but is more commonly seen in patients who develop a recurrent tumor after an attempted microsurgical resection attempt. The cranial nerve complication and cerebrovascular risks of cavernous sinus microsurgery are significantly greater than these risks for routine trans-sphenoidal surgical approaches. As a result, cavernous sinus involvement of a pituitary adenoma is an excellent indication for stereotactic radiosurgery. In many cases, the cavernous sinus mass can be treated while selectively sparing not only the optic apparatus, but also the pituitary stalk and residual pituitary gland within the sella turcica. For secretory adenomas, initial first stage extracavernous microsurgery is often optimal in order to reduce the subsequent tumor volume and create space between the tumor and the optic apparatus, thus allowing safe delivery of the highest dose of radiosurgery possible. For nonsecretory adenomas, the desirability of performing first stage microsurgical extracavernous debulking often depends on overall tumor volume and the space already present between the tumor and the optic apparatus. Microsurgery and stereotactic radiosurgery are now often utilized in a coordinated and planned staged manner for patients with pituitary adenomas that exhibit cavernous sinus involvement at the time of presentation. Adenomas that have invaded the

cavernous sinus and require deliberate high-dose irradiation of tumor contiguous to the carotid may increase the risk for delayed cerebrovascular problems.

Functional Effect of Radiosurgery

Growth Hormone Secreting Adenomas (Acromegaly)
A biochemical remission is defined as GH level suppressed to below 1 μg/L on OGTT and normal age-related serum IGF-1 levels. OGTT remains the gold standard for defining a cure of acromegaly. IGF-1, however, is far more practical. Decrease of random GH to less than 2.5 μg/L is achieved more frequently than the normalization of IGF-1 but it is necessary to obtain the fulfilment of both criteria. Microsurgery results in biochemical remission in 31–80% of patients (1, 5, 19, 53, 59). The suppression of hormonal hyperactivity is more effective when higher doses of radiation are used. Hormonal normalization after radiosurgery was achieved in 29–82% of cases in the published series (3, 4, 11–14, 17, 19, 20, 22, 24, 25, 30, 32, 33, 35, 36, 41, 42, 45, 47–49, 57, 62, 68). Because hormone-suppressive medication during radiosurgery may act as a radioprotective agent, this medication should be discontinued at least six to eight weeks prior to radiosurgery (25, 49) and may be resumed after a week. In a study at the University of Pittsburgh, 38% of patients were cured (GH ≤1 μg/L) and overall, 66% had growth hormone levels ≤5 μg/L, 3–5 years after radiosurgery (44). An important goal of resective surgery is to achieve an immediate postoperative effect, while the results of radiosurgery have a latency of about 20–28 months (18, 28) that must be sometimes temporized through the temporary use of hormone suppressive medications.

ACTH Secreting Adenomas
Cushing's disease: The results to date achieved by radiosurgery (usually used after failed resective surgery) are slightly inferior to those reported after primary surgical resection in regard to secretory normalization. In addition there is a latency of approximately 14–18 months for maximal therapeutic response (18, 28). Patients with Cushing's disease respond to radiosurgery but more than one procedure may be needed. In various published series 63–98% hormone normalization after radiosurgery has been observed (10, 16, 29, 33, 36, 38, 40, 43, 46, 50, 51, 54, 55, 58, 63).

Nelson's syndrome: Maintenance of elevated ACTH levels indicates continued biochemical activity of a pituitary adenoma after prior adrenalectomy for Cushing's disease. Strict hormonal normalization is not as important for the treatment of pituitary adenomas associated with Nelson's syndrome as it is for other secretory pituitary adenomas. The most important task of radiosurgery in the case of Nelson's syndrome is to control the growth of the tumor, which has been achieved in the majority of cases (66).

Prolactin Secreting Adenomas
Most prolactinomas can be controlled successfully by medical treatment. Surgery is indicated for cases of intolerance to medical treatment, in cases where women desire to have children, or when patients are dopamine agonist resistant (5–10% of patients). Some patients prefer microsurgery or radiosurgery to the need for life long medical treatment. In published studies of patients treated with radiosurgery, 25–29% showed normalization (26, 49). The possible radioprotective effect of dopaminergic drugs should be taken into account. In one of the studies patients treated with dopamine agonist had lower remission rates. It is therefore recommended that radiosurgery for prolactinoma be performed during a period of drug withdrawal (26).

Radiation Tolerance of Functioning Pituitary Tissue

The most important factor influencing post-irradiation hypopituitarism seems to be the mean dose to the hypophysis (pituitary stalk). Vladyka et al. observed some worsening of gonadotropic, corticotropic or thyrotropic functions 12–87 months after radiosurgery and usually 4–5 years after radiosurgery (61). There was no post radiation worsening of gonadotropic and thyrotropic functions when the mean dose to the hypophysis did not exceed 15 Gy. The limiting mean dose to the hypophysis for adrenocorticotropic function was 18 Gy (61). In another study, deterioration in pituitary functions was observed when the pituitary stalk received higher doses (10). The risk for hypopituitarism after stereotactic radiosurgery thus becomes a primary function of the anatomy of the tumor and the dose prescribed. For recurrent tumors primarily involving the cavernous sinus, where the pituitary stalk (and even at times the residual pituitary gland) is separate from the tumor, easily visualized, and can be excluded from the treatment volume, the risk of hypopituitarism is extremely small, even when high doses are utilized for secretory adenomas. For adenomas that cannot be visually separated from the normal gland, particularly if they extend upward to involve or compress the pituitary stalk, the risk is predominantly related to the dose necessary to effectively achieve all treatment goals for the functional status of the tumor (higher for secretory than nonsecretory adenomas).

Complications of Pituitary Radiosurgery

Complications of pituitary radiosurgery fall into three categories: hypopituitarism, visual deterioration and hypothalamic damage. The following rates of hypopituitarism have been reported: Levy et al. (32), 33%; Thoren et al. (57), 24%; Rocher et al. (52), 33%; and Lunsford et al. (34), 0%. As discussed in the section above, hypopituitarism risks vary with tumor anatomy relative to the pituitary stalk and gland, and vary with whether the adenoma is secretory or non-secretory (higher dose needed in the former). Stereotactic radiosurgery for residual or recurrent nonsecretory adenomas solely involving the cavernous sinus carries the lowest risk of subsequent hypopituitarism, while secretory tumors close to the median eminence or requiring targeting of the whole pituitary gland carry the highest risk. Future studies must stratify for these variables in order to better predict hypopituitarism risk after stereotactic radiosurgery in an individual patient. Levy et al. (32) reported <1% increase in visual deficit in their large series. Lunsford et al. (34) reported one patient with visual compromise. Using LINAC radiosurgery, Rocher et al. reported a 39% incidence of some visual compromise (6% of patients were blinded) (52). The key to avoiding this complication lies in proper patient selection (adequate space between the optic apparatus and the superior edge of the tumor for the radiosurgery technique you are employing), insisting on strictly conformal planning at the critical structure interface, and accurate dose delivery. Lunsford et al. reported one death due to hypothalamic injury in a patient who had multiple operations, prior pituitary apoplexy and prior fractionated radiation therapy (34). Voges et al. reported one patient who developed a severe hypothalamic syndrome (62). Mitsumori et al., using LINAC radiosurgery for tumor invading the cavernous sinus, reported three cases of temporal lobe necrosis (39). As

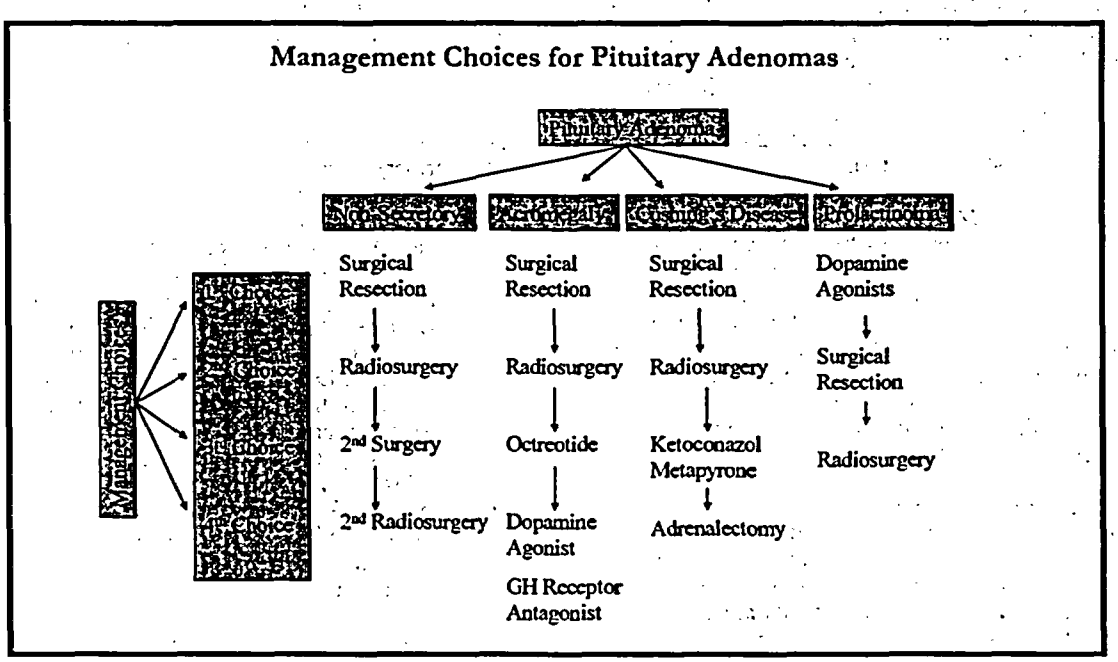
discussed above, there is a theoretical risk of late radiation-induced tumorigenesis for patients receiving radiosurgical treatment. A small risk also exists of late cerebrovascular accidents from the effect of the ionizing radiation on the cerebral circulation passing adjacent to the pituitary gland. Fortunately, while the risk of major morbidity or mortality is not zero with radiosurgery, these occurrences appear to be extremely rare.

Conclusion

Patients with pituitary adenomas are best managed with a multidisciplinary team approach. Multimodal treatment is often necessary, and options include medical management, microsurgery, stereotactic radiosurgery and fractionated radiotherapy. Trans-sphenoidal tumor resection remains the primary recommendation for macroadenomas compressing the optic apparatus or when a rapid reduction in excessive hormone level is required. However about 30% of patients require adjuvant treatment after microsurgery. For residual or recurrent tumors fractionated radiation therapy has been the traditional treatment in the past (37, 67). Fractionated radiation therapy, however, has a prolonged latency up to one decade for its effects and is associated with more frequent side effects: hypopituitarism, visual damage, cerebral vasculopathy, radiation necrosis, potential cognitive effects and radiation induced tumors. While many of these risks have been reduced through improvement in fractionated radiotherapy techniques, the long latency of the effect, and the potential for cognitive effects from exposed normal brain continues to be a significant problem. For many residual or recurrent tumors single session radiosurgery provides growth control and long-term endocrine control that is superior to that of repeat resective surgery. The latency of the radiation response after radiosurgery is substantially shorter than that of fractionated radiotherapy. This short latency can be managed by suppressive medical therapy as a temporizing measure in selected cases. The risk of hypopituitarism is significantly lower with single session radiosurgery as compared to fractionated radiation therapy. The absence of long-term adverse cognitive effects after stereotactic radiosurgery is consistent with technical differences between radiosurgery and fractionated techniques. Stereotactic radiosurgery better limits radiation exposure of the surrounding normal brain. At the present time the major role of pituitary adenoma radiosurgery is as an adjuvant to surgical resection, although it has a primary role for selected cases who are higher medical risk for general anesthesia or microsurgery, for patients with cavernous sinus tumor involvement, and for patients who consciously choose not to undergo microsurgery.

Clinical Algorithms

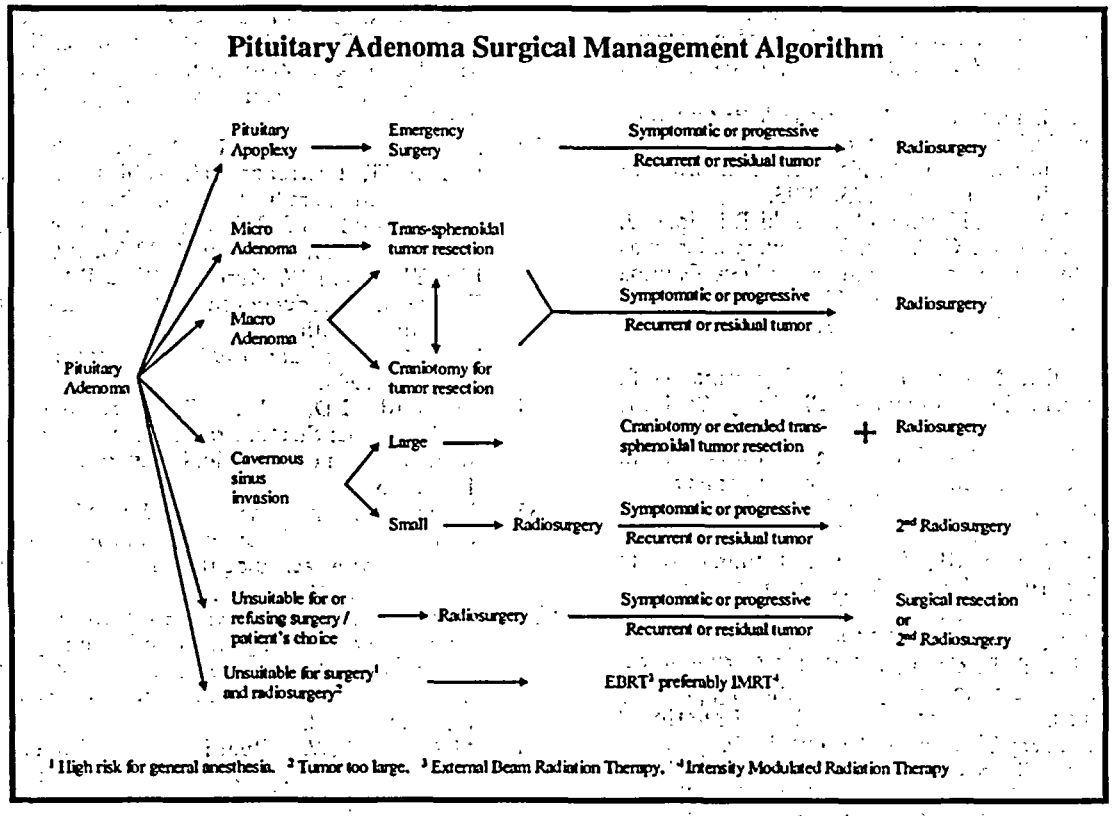
A broad outline of management choices is shown below; however, the final recommendation is usually influenced by the cumulative experience of the medical management team. The choices listed are not mutually exclusive. Combinations of different treatments may be necessary and/or desired under certain circumstances. Common examples include patients with cavernous sinus involvement present at diagnosis who undergo first stage microsurgery for the extracavernous portion of their tumor followed by second stage radiosurgery for the cavernous sinus component, and patients with secretory adenomas who undergo radiosurgery but are then maintained on their antisecretory medications during the latency period for hormonal normalization after radiosurgery. The common need for staged or tandem treatments with multiple modalities underscores the importance of the presence of a comprehensive and coordinated multidisciplinary team in the optimal management of pituitary adenoma patients.



Surgical Management Considerations

A number of factors are considered in making a recommendation regarding surgical management. These factors include:

1. Patient's age
2. Hormonal status of the adenoma (secretory or non-secretory)
3. Presenting symptoms and neurological status (vision) of the patient
4. Patient's medical condition (comorbidities)
5. Previous tumor resection (via trans-sphenoidal approach or craniotomy) history
6. Prior radiation exposure
7. Volume of the tumor
8. Proximity to the optic apparatus
9. Response to medical management



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COMPLETE SUMMARY

TITLE:

Stereotactic Radiosurgery for Patients with Pituitary Adenomas.

RELEASE DATE:

April 2004

DEVELOPER AND FUNDING SOURCE:

IRSA (International RadioSurgery Association)

DEVELOPER COMMENT:

IRSA (International RadioSurgery Association) is a non-profit entity dedicated to promoting the development of scientifically relevant practice guidelines for stereotactic radiosurgery. IRSA is a professional association that works to educate and provide support for physicians, hospitals, insurers and patients.

COMMITTEE:

The IRSA Medical Advisory Board Guidelines Committee and representatives in the industry

GROUP COMPOSITION:

The Radiosurgery Guidelines Committee is comprised of neurological surgeons, endocrinologists, radiation oncologists, and medical physicists.

Names of Group Members: L. Dade Lunsford, M.D., Neurosurgeon, Chair; Ajay Niranjan, M.B.B.S., M.Ch., Neurosurgeon; Tatsuya Kobayashi, M.D., Ph.D., Neurosurgeon; Mark Linskey, M.D., Neurosurgeon; Thomas Witt, M.D., Neurosurgeon; Alex Landolt, M.D., Neurosurgeon; Roman Liscak, M.D., Neurosurgeon; Edward R. Laws Jr., M.D., Neurosurgeon; Mary Lee Vance, M.D., Endocrinologist; John Buatti, M.D., Radiation Oncologist; Jonathan Knisely, M.D., Radiation Oncologist; Paul Sperduto, M.D., Radiation Oncologist; Sammie Coy, Ph.D., Medical Physicist; Tonya K. Ledbetter, M.S., M.F.S., Editor; Rebecca L. Emerick, M.S., M.B.A., C.P.A., "ex officio."

DISEASE/CONDITION:

Pituitary adenomas, acromegaly, Cushing's disease, Nelson's syndrome, prolactinoma.

NUMBER OF REFERENCES:

70

CATEGORY:

Treatment, proposed surgical management

CLINICAL SPECIALTY:

Neurological surgery
Radiation oncology
Neurology
Medical Physics
Endocrinology
Gynecology

INTENDED USERS:

Physicians
Health Care Providers
Hospitals
Managed Care Organizations
Nurses
Utilization Management

OBJECTIVES:

To provide guidelines about the use of stereotactic radiosurgery in symptomatic patients with imaging identified pituitary adenomas with treatment recommendations to be used by medical and public health professionals. Such patients may or may not be candidates for alternative management strategies that include observation, medical management, surgical resection via trans-sphenoidal approach or craniotomy and fractionated radiation therapy.

TARGET POPULATION:

Men and women >2 years old with imaging identified functional or nonfunctional pituitary adenomas.

INTERVENTIONS AND PRACTICES:

Stereotactic radiosurgery of pituitary adenomas is performed using a single procedure or occasionally staged procedure (volume staging) techniques based on intraoperative stereotactic guidance and digitally acquired images (CT or preferably MRI). Minimal tumor margin doses in a single radiosurgical procedure vary from 11 to 16 Gy for non-functional (non-secretory) adenomas. Higher marginal doses (25–35 Gy) are necessary for hormone normalization in cases of functional (secretory) pituitary adenomas. The dose prescription for volumetric conformal pituitary radiosurgery in an individual case is designed to provide maximal dose sparing to surrounding critical structures, especially optic apparatus.

OUTCOMES CONSIDERED:

Long-term growth control (stabilization or regression) of non-functional pituitary adenomas and pituitary hormone normalization in cases of functional pituitary adenomas are the primary end points of interest. Maintenance of quality of life, employability, and prevention of adverse radiation effects are also considered.

METHODS TO COLLECT EVIDENCE:

Hand Searches of Published Literature (Primary Sources); Hand Searches of Published Literature (Secondary Sources); Searches of Electronic Databases

DESCRIPTION OF METHODS TO COLLECT EVIDENCE:

MEDLINE and PUBMED searches were completed for the years 1971 to April 2004. Search terms included pituitary adenomas, acromegaly, Cushing's disease, prolactinoma, stereotactic radiosurgery, Gamma Knife, irradiation, Linac radiosurgery, proton beam radiosurgery, Bragg peak proton therapy, clinical trials, research design, practice guidelines and meta-analysis. Bibliographies from recently published reviews were reviewed and relevant articles were retrieved.

METHODS TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE:

Expert consensus (committee)

METHODS TO ANALYZE EVIDENCE:

Review of published meta-analysis

REVIEW METHODS:

External peer review; internal peer review

DESCRIPTION OF REVIEW METHODS:

The recommendations were originally suggested by a core group of two members (LDL/AN). These recommendations were electronically mailed to all committee members. Feedback was obtained in order to revise the proposed guidelines. Committee members

were asked whether the recommendations should serve as a practice guideline. No significant disagreements existed. The final statement incorporates all relevant evidence obtained by the literature search in conjunction with the final consensus recommendations supported by all working group members.

MAJOR RECOMMENDATIONS:

- Patients with pituitary adenomas, defined by modern neurodiagnostic imaging (CT, MRI scan) constitute the study group. Such patients typically present with symptoms related to pituitary hormone imbalance (acromegaly, Cushing's disease, prolactinoma, etc.) in cases of functional adenomas and symptoms of mass effect (headache, visual changes and progressive neurological deficits) in cases of non-functional adenomas. Pituitary adenomas are considered suitable for multimodal management including observation, surgical excision, fractionated radiation therapy and stereotactic radiosurgery. Stereotactic radiosurgery is typically employed in combination with prior surgery but may be employed alone in particular circumstances. The selection of patients suitable for radiosurgery is dependent on the prior treatment history, the age of the patient, existing co-morbidities, anatomic location of the tumor and clinical history. Single session radiosurgery, a minimally invasive, single high-dose, closed skull treatment strategy, may be especially suitable for patients in advanced age groups, those with excessive medical co-morbidity risk factors for surgical excision, and those with adenoma involving the cavernous sinus.

- The optimal dose range for volumetric conformal stereotactic pituitary radiosurgery has been largely established based on tumor anatomy (proximity to visual apparatus), hormonal secretory status, volume, estimated adverse radiation risks, pre-existing neurological conditions and prior history of radiation therapy. Minimum doses to the margin of the non-functional pituitary adenomas typically range from 12– 16 Gy in a single fraction. For secretory adenomas, minimal margin doses as high as 30–35 Gy are optimal if they can be administered safely given the anatomic relationship of the tumor edge to surrounding radiosensitive structures. Stereotactic volumetric imaging (high resolution) is usually necessary for precise conformal dose planning. MRI target imaging is preferred. Depending upon the technology used, the margin of the radiosurgery dose is usually 50–90% of the central target dose within the tumor. Sharp fall-off of the radiation dose outside of the target volume is required. Current radiation delivery technologies for volumetric stereotactic conformal single session radiosurgery include Gamma Knife®, proton beam using Bragg peak effect, and specially modified linear accelerators.

- Patients may receive a single stress dose of corticosteroids at the conclusion of the radiosurgery procedure. It is recommended that hormone suppression therapy (dopaminergic drugs for prolactinomas and octreotide for acromegaly) be discontinued at least 1–2 months prior to radiosurgery. Currently used long acting drugs (e.g. slow release octreotide) should be discontinued 3–4 months prior to radiosurgery. These medications can be restarted one week after the radiosurgery procedure. Patients can continue to take other medications as recommended by their physicians.

- Postradiosurgical clinical examinations and MR studies are requested by referring physicians at six month intervals for the first year and then annually to assess the effect of radiosurgery for 4–5 years. Visual field and acuity testing along with serum and urinary hormone screening are recommended at intervals coinciding with clinical and neuroimaging re-evaluations. Tumors proven to be stable over five years can then be subsequently Stable adenomas can then be reassessed at 2–4 year intervals.

- For non-functional adenomas estimated tumor control rates vary from 90–100%. Stereotactic radiosurgery should not be considered as the panacea for large volume pituitary adenomas, which are better managed initially by surgery. This is particularly true for patients who present with sudden symptomatic mass effect from pituitary apoplexy.

- Causes for failure of stereotactic radiosurgery include inadequate visualization of the tumor, lack of intraoperative stereotactic 3-D (volumetric) imaging, and insufficient dose (due to proximity with optic apparatus) to achieve the growth control response.

- Stereotactic radiosurgery is defined as a relatively high dose of focused radiation delivered precisely, to the pituitary adenoma, under the direct supervision of a medical team (neurosurgeon, radiation oncologist, registered nurse, and medical physicist), in one surgical treatment session.

TYPE OF EVIDENCE:

Type I, II and III evidence (Bandolier) exists in support of stereotactic radiosurgery for pituitary adenomas.

POTENTIAL BENEFITS:

All the published studies have shown a significant tumor control response of stereotactic radiosurgery for non-functioning pituitary adenomas with a low (satisfactory) rate of adverse radiation effect. For functional adenomas normalization of hormone levels is considered necessary in order to define success. Successful outcomes include complete tumor control (stabilization or regression), symptomatic relief, no new neurological deficits, no long-term complications and normalization of pituitary hormone levels.

Literature has documented the cost savings benefit of stereotactic radiosurgery versus invasive surgical procedures and the lower risk potential of bleeding, anesthesia problems, infections and side effects which may include transient or permanent disabilities from open surgery.

SUBGROUP(S) MOST LIKELY TO BENEFIT:

Patients with residual or recurrent pituitary adenoma after resection. Patients with small pituitary adenoma without any previous surgery.

POTENTIAL HARMS:

Major adverse effects of radiosurgery are based on location, volume, and dose, and these risks can be estimated based on published data and experience. Individual risks are related to the anatomic proximity of pituitary adenoma with the optic apparatus and structures of cavernous sinus. Risk of delayed hypopituitarism after single session radiosurgery is low.

SUBGROUP(S) LIKELY TO BE HARMED:

Patients with large volume adenomas causing symptomatic mass effect on optic apparatus who are treated with large doses in a single session radiosurgery as primary management. Patients with functional adenomas treated with low dose will benefit least from radiosurgery.

GUIDELINE STATUS:

This is the full current release of the guideline.

GUIDELINE AVAILABILITY:

Electronic copies: Available in Portable Document Format (PDF) from www.IRSA.org

Print copies: Available from IRSA, 3005 Hoffman Street, Harrisburg, PA 17110

PATIENT RESOURCES:

Patient resources are available on line at www.IRSA.org, by email at intouch@IRSA.org or by calling +717-260-9808.

See "publications" for patient resources for pituitary tumors: www.IRSA.org/publications.html/
Brain Talk® Volume 8, No. 3:
Another Perspective® Volume 4, No. 2; Volume 2, No. 4

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See the Editorial and the Response in this issue, p 573.

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Radiosurgery and radiotherapy: observations and clarifications

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Object. Radiosurgery and radiation therapy represent important but unique treatment paradigms for patients with certain neoplasms, vascular lesions, or functional disorders. The authors discuss their differences.

Methods. Reviewing the authors' experiences shows how the roles of these approaches vary just as their techniques differ. The distinct differences include the method of target localization (intraoperative compared with pretreatment) and irradiation (focused compared with wide-field), their radiobiology (effects of a single high-dose compared with multiple fractions), the physicians and other health personnel involved in the conduct of these procedures (surgical team compared with radiation team), and the expectations that follow treatment. During the last decade, considerable confusion has grown regarding nomenclature, requisite physician training, and the roles of the physician and surgeon. Ten years ago, two task forces on radiosurgery were created by national organizations in neurosurgery and radiation oncology to address these issues of procedural conduct and quality-assurance requirements. At the present time these guidelines are widely ignored. Currently, many patients, payers, and regulatory agencies are bewildered. What are the differences among stereotactic radiosurgery, fractionated radiation therapy, and stereotactic radiation therapy? Radiosurgery is to radiation therapy as microsurgery is to "microtherapy."

Conclusions. In this report the authors discuss terminology, training, and physician roles in this expanding field.

KEY WORDS • radiosurgery • radiotherapy • fractionation • neurosurgery

Things are seldom what they seem; skim milk masquerades as cream.—W. S. Gilbert

The incorporation of stereotactic radiosurgery into neurosurgery and recent improvements in the administration of fractionated radiation therapy represent fundamental paradigm shifts in modern medical care. Neurological surgery has focused on minimal access procedures, searching for the molecular responses of tissues so that they may be eradicated or inactivated, and relying on the multidisciplinary talents and backgrounds of practitioners in neurological surgery, radiation oncology, medical physics, bioengineering, and molecular biology. Radiation oncologists now routinely incorporate high-resolution imaging during treatment planning to spare the central nervous system and contain the tumor. From the patient's point of view, both procedures may be attractive, with no or small incisions, short hospital stays or outpatient care, and a rapid return to full activity. Nonetheless, both techniques remain invasive to the target and surrounding tissues. As greater numbers of clinicians from various disciplines weigh the risks and benefits of radiosurgery and radiation therapy, we believe it is important to reiterate the differences in terminology, techniques, training requirements, and clinician roles during the selection and performance of these procedures. The authors of this report include neurosurgeons and a radiation oncologist who have used LINAC, gamma knife, and proton-beam device and have served as leaders of a multidisciplinary radiosurgery society.

Abbreviations used in this paper: AVM = arteriovenous malformation; LINAC = linear accelerator.

The History of Radiosurgery

Although microsurgical techniques were pioneered in the 1960s and 1970s, radiosurgical techniques developed earlier. The term stereotactic radiosurgery was coined in 1951 by Lars Leksell,[12] a visionary neurosurgeon who practiced at the Karolinska Institute in Stockholm. Leksell was a physiologist, surgeon, and inventor; his use of the term stereotactic radiosurgery was remarkably prescient. He referred to a rigidly fixed skull and a stereotactic guiding device that directed cross-firing ionizing beams of radiation to inactivate or destroy a target identified by the appropriate imaging modality in a single treatment. In partnership with the talented radiobiologist Börje Larsson, Leksell explored methods to destroy intracranial targets by using photons (from LINAC) or protons (from a cyclotron) to inactivate a

deep brain target. Eventually in 1967 Leksell[11] and Larsson developed a dedicated hospital radiosurgical 179-source ^{60}C prototype unit, the Gamma Knife (Elekta Instruments, AB, Stockholm, Sweden). Since that time, hundreds of thousands of patients worldwide have undergone radiosurgery. The refinement of LINAC technologies in the 1980s enabled physicians at additional facilities to perform single-session, small-volume focused radiation treatment of brain targets rather than continue to use multiple-fraction radiation exposures that require weeks of therapy.[4,15]

A redesigned 201-source ^{60}C gamma knife was first used in Pittsburgh, Pennsylvania in 1987.[13] Since that time, refinements in stereotactic methods, dramatic improvements in dose planning, and major improvements in neurodiagnostic imaging have combined to broaden the application of brain and, eventually, radiosurgery of the spine. Current indications for the use of stereotactic radiosurgery include vascular malformations, benign tumors, malignant neoplasms, trigeminal neuralgia, and movement disorders among others. New indications such as epilepsy continue to be evaluated in prospective trials. Extracranial radiosurgery for head and neck cancer and radiosurgery of the spine have emerged as logical progressions from intracranial radiosurgery. A commitment to outcomes studies and the publication of results from numerous centers throughout the world has led to the incorporation of radiosurgical techniques into most neurosurgical centers. Concomitant with this explosion in use has come bastardization of the originally restricted definition of radiosurgery, leading to confusion among patients, physicians, and payers concerning what treatment is actually being performed.

Clarifications on Technique

Because radiosurgery is a multidisciplinary specialty, it is not surprising that there has been some confusion in the use of terms associated with the concept. First, we emphasize the word "surgery." Surgery is the definitive single-session manipulation of a disease or organ system in which energy is used to achieve a specific purpose. The energy used in surgery may be mechanical (the surgeon's arm moving a scalpel), thermal (radiofrequency heat ablation or cryosurgery), chemical (glycerol rhizotomy), light (laser surgery), or focused radiation (radiosurgery). *Webster's Ninth New Collegiate Dictionary* defines surgery as "a branch of medicine concerned with diseases and conditions requiring or amenable to operative or manual procedures" and an operation as "a procedure carried out on a living body usually with instruments for the repair of damage or the restoration of health."

The adjective "stereotactic" refers to a rigidly fixed, precise, accurate, and image-compatible guiding device that is coupled with high-resolution imaging to define a target in three-dimensional space. The noun "radiosurgery" refers to a single-session surgical procedure that uses ionizing radiation to destroy the target.[10] Although brachytherapy also relies on radiation to achieve a desired radiobiological effect, the radioactive sources are surgically implanted to deliver a continuous radiation dose over a period of time (often over many days depending on the source strength). The noun "radiotherapy" refers to an extended treatment course in which external-beam fractionated radiation is delivered, usually by an LINAC. Any treatment may or may not be relatively innocuous; it is the sum of the treatment sessions that leads to an effect. Stereotactic radiosurgery is no more radiation therapy than microsurgery is "microtherapy." The adjective "fractionated" refers to the fact that treatment is divided into multiple fractions or sessions. A reduced number of fractions may be called hypofractionation and a greater number of fractions may be termed extended fractionation or hyperfractionation.[2] Radiosurgery, by definition, cannot be fractionated.

Recently, an administrator for the American Society for Therapeutic Radiation and Oncology sent a letter (dated October 1, 2003) to the Center for Medicare and Medicaid Services, US Department of Health and Human Services. In this letter the administrator stated, "The term stereotactic radiosurgery refers to the precise delivery of radiation to lesions of the brain, head, and upper neck, with sparing of the surrounding normal tissue with the concomitant use of stereotactic localization and planning. It includes therapy that is completed in a single session or therapy that is completed in multiple sessions ('fractionated')." This gratuitous statement sent on behalf of a national medical organization to a government agency uses specious terms, but for what purpose? Are the authors lobbying the Center for Medicare and Medicaid Services to pay for each fraction of irradiation as if it were a separate radiosurgical procedure? Interestingly, this letter states that the two basic methods of radiation delivery are "linear accelerator-based treatment" and "cobalt-60 based treatment," completely failing to mention charged particle irradiation, which has been in use in the US for more than 40 years.

Some open craniotomy surgical procedures are "staged." This may occur during the removal of a large skull base tumor, in which the first stage achieves bone exposure in preparation for a second-stage removal of the tumor. When radiosurgery is staged, and it is done so infrequently, different anatomical components of the target are destroyed.[3] The stages are usually spaced by several months to reduce adverse radiation effects. An example of staged radiosurgery might include irradiation of the anterior half of an AVM in the first procedure, followed by irradiation of the posterior half in the second.[14] In both sessions, a definitive effect is created on the target tissue. The effect on each portion of the AVM is not given in fractions.

As a surgical procedure, radiosurgery follows the paradigm of an entire procedure performed in a single continuous session ("skin to skin," or "frame on to frame off"). The components of patient preparation, stereotactic frame application, intraoperative imaging, dose planning, dose delivery, and frame removal constitute the procedure. In a sense it is completely analogous to open stereotactic brain surgery, in which a probe is inserted into the brain after targeting and trajectory planning. Cross-firing, focused, high-dose beams of photon or proton radiation replace the probe. Computers are used to calculate the attenuation of each beam as the beams silently penetrate the scalp, skull, and intervening tissue before the summed radiation is delivered to the small target volume. The performing of radiosurgery relies on special technologies, trained personnel, and dedicated suites.

"Stereotactic radiation therapy," sometimes called "fractionated stereotactic radiotherapy," refers to an enhanced method to deliver fractionated radiation. The procedure in-

volves daily application of a non-skeleton-affixed guiding device.[5] We prefer the term stereotactic radiation therapy. Although there are no conclusive data to substantiate the value of these approaches over nonstereotactic conventional radiotherapy, such procedures are performed in an attempt to reduce the dose to adjacent critical brain or spine structures and to provide greater dose homogeneity to the target tissue. The principle of stereotactic radiation therapy is quite different from that of radiosurgery. Regardless of whether radiation is delivered by LINACs or proton generators, stereotactic radiation therapy is performed in an attempt to reduce the risks associated with radiation falloff in surrounding normal tissues adjacent to the targeted tissue. The role of the neurosurgeon in a stereotactic radiation therapy procedure can include participation in a preradiotherapy discussion, use of a relocatable stereotactic frame, image interpretation, dose planning, and posttherapy follow up.

The conformality of radiation dose delivery (that is, the matching of the volumetric radiation field to the target volume) is less than the conformality achieved during radiosurgery. Presentations at meetings of the International Stereotactic Radiosurgery Society that show dose plans with radiosurgery or radiotherapy techniques indicate that there is less conformality with radiotherapy and more use of single isocenter plans. In a seminar on the management of vestibular schwannoma in 2001, an oncologist from Staten Island University stated that "conformality does not matter." The accuracy of radiation delivery is also less because rigid fixation is not used. At some centers no attempt is made to conform the radiotherapy volume to the target, but instead simply to provide regional irradiation by using image guidance. This approach may be an improvement over conventional radiotherapy techniques in which frame-based delivery is not used. With "intensity-modulated radiation therapy," an LINAC and microleaf collimators are used to create radiotherapy dose plans that are more conformal than conventional plans, but still use the principal of a standard fractionation regimen. Intensity-modulated radiation therapy may prove to be an important improvement over the techniques of radiation therapy used for the past several decades. In some instances, radiation can be delivered using robotic assistance, as performed using the Model C Gamma Knife (Elekta Instruments, Inc., Atlanta GA) or the CyberKnife (Accuray, Inc., Sunnyvale, CA). The use of a robotic device for movement of the radiation emitter or stereotactic frame does not affect the radiobiological effect of the treatment.

The term "fractionated stereotactic radiosurgery" is oxymoronic and sophistic. Those who use the term desire to speak of the known benefits of radiosurgery for certain indications, but do not actually provide radiosurgery to their patients. Use of this term is confusing to patients, physicians, regulators, and third-party insurance payers who may think they are approving one therapeutic modality, but are paying for another. All radiotherapy requires fractionation. Perhaps the term "radiotherapy" connotes a lesser quality of care to some, but this should not be the case. Radiotherapy is an effective treatment for a wide variety of clinical problems.[1] It is performed differently, with different expectations, and requires the efforts of multiple individuals performing different tasks. Radiosurgery is a single surgical procedure that takes advantage of an energy source that can be focused through tissue without incising it.

Training in Radiosurgery

Does residency training in neurosurgery adequately prepare neurosurgeons to perform radiosurgery? Neurosurgical residency programs provide trainees with knowledge and clinical expertise in neuroanatomy; in the management of a wide variety of neoplastic, vascular, and functional neurological disorders; and in image interpretation. Residency programs provide training in stereotactic surgical procedures and the use of computerized image-guided navigation. The American Board of Neurological Surgery specifically recommends that training programs provide training in radiosurgical procedures. At the University of Pittsburgh and at many other institutions, radiosurgery is incorporated formally into the residency program as part of a specific rotation. Importantly, neurosurgery training focuses on the clinical judgment necessary in choosing between different available treatment options and on the management of complications should they occur.

Does residency training in radiation oncology adequately prepare radiation oncologists to perform radiosurgery? Such residencies do not provide a focused education in neuroanatomy or in the clinical management of many disorders for which radiosurgery may be appropriate. Management of AVMs, cavernous malformations, vestibular schwannomas, trigeminal neuralgia, and movement disorders are not part of the traditional educational experience offered to the radiation oncologist. The principles of steiretactic localization (rigid frame or relocatable frame) are not part of radiation oncology training. Radiation oncologists do learn computer-based planning techniques as well as the principles of radiation administration and safety. They also learn how cumulative radiation administration may interact within the same patient, information of particular value for patients with selected tumors. It is interesting that a nonphysician technician rather than the oncologist actually delivers each fraction of radiation to a patient.

Is the amount of this training received by an individual in each specialty adequate to perform radiosurgery? How should this be determined? Some neurosurgeons receive formal fellowship training (6–24 months) before incorporating radiosurgery into their practice. At one of our centers, all neurosurgical residents spend 4 months on the image-guided neurosurgery rotation, in which they are exposed to approximately 200 radiosurgical procedures. If resident surgeons desire to perform radiosurgery in practice, we recommend that close to the end of their training they spend several more months participating in radiosurgery. Similarly, radiation oncology residents spend one rotation working closely with the oncologist primarily assigned to the radiosurgery program. Such extensive training exposures are uncommon among physicians already in practice who simply start performing radiosurgery. Most centers at which gamma knife technology is used require their neurosurgeons, radiation oncologists, and medical physicists to attend a formal immersion course in radiosurgery, followed by mentored practice at their home institution. Some centers offering LINAC-based radiosurgery request a similar level of commitment, but many do not. We recommend that any physician who has not received formal training in radiosurgery, either during residency or afterward, should seek and receive such training before treating patients. In 1993 the Task Force on Stereotactic Radiosurgery of the American

Association of Neurological Surgeons and the American Society for Therapeutic Radiation and Oncology issued the following statement: "each member of a team initiating a radiosurgical program should have specific, intensive, and documented training in radiosurgery."[8]

Physician Roles

Neurosurgeons, radiation oncologists, and medical physicists each play important roles in a radiosurgical procedure. The decision to use radiosurgery or fractionated radiation therapy is often a group decision and patients may be referred to or by either a neurosurgeon or oncologist. Patients with neoplasms may be referred by their surgeon or oncologist, whereas patients with vascular malformations usually see a surgeon first. Both neurosurgeons and radiation oncologists must provide informed consent. When patients are admitted to the hospital, they are usually assigned to the care of the neurosurgeon.

When the patient arrives in the radiosurgery unit, the neurosurgeon supervises patient preparation, working with nurses who often come from the operating room environment. The surgeon applies the stereotactic frame to the patient's head and should then supervise the acquisition of stereotactic images. Images are transferred to the radiosurgery planning computer, usually by the physicist. In many centers, it is the neurosurgeon who primarily performs the radiosurgical dose planning; in others it may be the radiation oncologist. Nevertheless, final agreement on the radiosurgery plan is made by the team, which then chooses an appropriate radiation dose that has been selected to meet the clinical goals of the patient. The radiosurgical dose is delivered by a physician, rather than by a technician, as occurs in radiation therapy. The surgeon or oncologist should attach the frame to the unit and have the coordinates triple-checked by other members of the team. The Nuclear Regulatory Commission mandates that a responsible and trained surgeon remain present during gamma knife surgery. Stereotactic frame removal is then performed under the supervision of the surgeon, who may be required to suture a pin site in some patients. The immediate postoperative care is given by the surgeon. Patient follow-up visits can be with the surgeon or oncologist, often depending on how the patient was initially referred to the unit. A survey performed by the American Society for Therapeutic Radiation and Oncology found that the average number of specialist hours (M.D. or Ph.D.) required during a radiosurgery procedure was high (> 13 hours).[9] In radiosurgical procedures in which a frame is not used, the neurosurgeon must ensure that an accurate targeting and irradiation technique is in place. For example, when CyberKnife spinal radiosurgery is performed at the University of Pittsburgh, the neurosurgeon is responsible for inserting fiducial markers into the spinal column, which serve as the framework for accurate irradiation, and is expected to participate in the dose planning and irradiation.

Medical physicists have a key role in radiosurgery, beginning with the installation, maintenance, and system upgrades for the hardware and software used. They are involved in meeting regulatory oversight requirements depending on the technology used. Physicists may act to ensure that the images used are of high quality, and they may have obtained experience in radiosurgery dose planning so that they can assist in the creation of the plan. It is important to remember that physicists have not been trained in neuroanatomy, in interpreting images, or in medical decision making. They should not serve as final arbiters of the radiosurgery dose plan. The physicist remains on site for radiation dose delivery and for technical support as needed.

Indications for Radiosurgery

The role of radiosurgery has expanded well beyond its initial application for functional neurosurgery, pain management, AVMs, and selected skull base tumors.[6] The clinical spectrum now includes a wide variety of benign and malignant skull base neoplasms, serves as the primary treatment of metastatic brain cancer, and provides adjuvant management of malignant primary brain tumors. Radiosurgery has or should replace the role of microsurgery in the treatment of skull base tumors located in the cavernous sinus or surrounding critical vascular structures such as the carotid artery or sagittal sinus. Although open surgical techniques are required for removal or decompression of symptomatic large brain masses, radiosurgery can be used as a secondary procedure for the effective management of residual disease. Because of a remarkably low incidence of cranial nerve complications, high long-term tumor control rates, and overall safety, radiosurgery will continue to be practiced on a wide scale. Ten- to 15-year follow-up results in patients with benign intracranial tumors have demonstrated low morbidity rates and high rates of tumor growth prevention.[7] At the same time, we must continue to be diligent about recording clinical outcomes in patients undergoing radiosurgery or radiotherapy and to be mindful of potential long-term adverse effects.

Disclosure

Dr. Kondziolka is the current president of the International Stereotactic Radiosurgery Society. Drs. Lunsford, Loeffler, and Friedman have served as past presidents of the Society.

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The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice guidelines and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice guideline and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice guideline and technical standard by those entities not providing these services is not authorized.

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ACR PRACTICE GUIDELINE FOR THE PERFORMANCE OF STEREOTACTIC RADIOSURGERY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. It should be recognized; therefore, that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

Stereotactic radiosurgery (SRS) has been applied to a number of benign and malignant intracranial conditions. The potential of delivering a single, high dose of ionizing radiation with ±1 mm targeting accuracy that conforms to the shape of the lesion provides the motivation for the development of SRS. Gamma-ray photons, X-ray photons, protons, helium ions, and neutrons have been used for SRS. During irradiation, converging arc beams are usually employed using a conventional medical linear accelerator, or multiple fixed beams are used with a gamma ray or particle beam treatment unit. Despite the variety of stereotactic radiosurgical techniques, many commonalities exist.

For a typical treatment, groups of beams converge on a single point in space, the isocenter. The shape of the beam aperture is usually defined by secondary collimation near the patient to reduce the beam penumbra. After stereotactic localization of the lesion using the appropriate imaging modality, proper placement of one or more isocenters within the lesion can then provide a steep dose gradient close to the periphery of the lesion. Distinct from conventional radiation therapy, special stereotactic

equipment is attached to the patient for accurate SRS imaging and treatment. The patient is rigidly immobilized while being irradiated in order to ensure the required accuracy.

Imaging, planning, and treatment occur on the same day for single fraction treatments. Treatment delivery should be accurate to within 1 mm. This leaves little room for error in the overall process. Strict protocols for quality control (QC) must be followed using checklists, while double-checking is required at critical junctures. Furthermore, SRS requires the coordination of a large and diverse team of professionals from neurosurgery, diagnostic radiology, and radiation oncology.

The guideline outlined in this document describes a minimal set of criteria for an SRS quality-assurance program. The reader is also referred to other publications in the literature regarding quality control for stereotactic radiosurgery and its related procedures.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Guideline for Radiation Oncology where qualifications, credentialing, professional relationships, and development are outlined.

The following are minimal recommendations for staffing levels and staff responsibilities while participating in an SRS procedure. Specific duties may be reassigned where appropriate.

A. Radiation Oncologist

1. Certification in Radiology by the American Board of Radiology of a physician who confines his/her professional practice to radiation oncology, or certification in Radiation Oncology or Therapeutic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec may be considered proof of adequate physician qualifications.

   or

2. Satisfactory completion of radiation oncology residency in an ACGME (Accreditation Council for Graduate Medical Education) approved program.

If the above training did not include SRS, then specific training in SRS should be obtained prior to performing any radiosurgical procedures.

The responsibilities of the radiation oncologist shall be clearly defined and should include the following:

1. Participating in initial treatment decision-making with the neurosurgeon.
2. Overseeing radiation-therapy management of the patient.
3. In concert with the neurosurgeon, and neuroradiologist if necessary, locating and specifying the target volume and relevant critical normal tissues.
4. Prescribing the radiation dose to the target volume.
5. Participating in the iterative process of plan development and approving the final treatment plan in collaboration with a Qualified Medical Physicist.
6. Ensuring that patient alignment on the treatment unit is appropriate.
7. Following the patient for control of abnormalities and for monitoring potential complications.

B. Neurosurgeon

The services of an appropriately trained neurosurgeon in most circumstances are required and may include:

1. Participating in initial treatment management with the radiation oncologist.
2. In concert with the radiation oncologist and neuroradiologist if necessary, locating and specifying the target volume and relevant critical normal tissues.
3. Participating in the iterative process of plan development.
4. Ensuring that patient alignment on the treatment unit is appropriate.
5. Following the patient for control of abnormalities and for monitoring potential complications.

If the above training did not include SRS, then specific training in SRS should be obtained prior to performing any radiosurgical procedures.

C. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The American College of Radiology considers that certification and continuing education in the appropriate subfield(s) demonstrate that an individual is competent to practice one or more of the subfields in medical physics, and to be a Qualified Medical Physicist. The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR).

The appropriate subfields of medical physics for this guideline are Therapeutic Radiological Physics and Radiological Physics.

The continuing education of a Qualified Medical Physicist should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME).

If the above training did not include SRS, then specific training in SRS should be obtained prior to performing any radiosurgical procedures.

The Qualified Medical Physicist is responsible for all technical aspects of radiosurgery and must be available for consultation throughout the entire procedure: imaging, treatment planning, and dose delivery. Those responsibilities shall be clearly defined and should include the following:

1. Acceptance testing and commissioning of the radiosurgery system, thereby assuring its geometric and dosimetric precision and accuracy.[1,2] This includes:
   a. Localization devices used for accurate determination of target coordinates.
   b. The image-based 3-D treatment-planning system.[3]
   c. The radiosurgery external beam delivery unit.
2. Implementing and managing a quality-control (QC) program for the radiosurgery system to monitor and assure its proper functioning:
   a. The radiosurgery external beam delivery unit.
   b. The image-based 3-D treatment-planning system.[4]
3. Establishing a comprehensive QC checklist that acts as a detailed guide to the entire treatment process.
4. Directly planning or supervising the 3-D treatment-planning process.
5. Consulting with the radiation oncologist to determine the optimal patient plan.
6. Using the plan approved by the radiation oncologist to determine and check the appropriate beam-delivery parameters. This includes calculating the radiation beam parameters consistent with the beam geometry.
7. Supervising the beam-delivery process on the treatment unit to assure accurate fulfillment of the prescription of the radiation oncologist.

D. Radiation Therapist

A radiation therapist must fulfill state licensing requirements and should have American Registry of Radiologic Technologists (ARRT) certification in radiation therapy.

The responsibilities of the radiation therapist shall be clearly defined and may include the following:

1. Preparing the treatment room for the stereotactic radiosurgery procedure.
2. Assisting the treatment team with patient positioning/immobilization.
3. Operating the treatment unit after the radiation oncologist and medical physicist have approved the clinical and technical aspects for beam delivery.

E. Other Team Members

A multidisciplinary team should include a neuroradiologist, nursing staff, and, for children and young adults, an anesthesiologist.

III. QUALITY CONTROL OF THE TREATMENT UNIT

The mechanical precision and electronic complexity of the treatment-delivery unit require the implementation of and adherence to an ongoing QC program. The QC program assures that the SRS treatment unit is in compliance with recommendations of the treatment unit manufacturer, the specified clinical tolerances, and, possibly, regulatory requirements. It is recognized that various test procedures, with equal validity, may be used to ascertain that the treatment-delivery unit is functioning properly and safely.

The test results should be documented, archived, and signed by the person doing the testing. Important elements of the treatment-delivery unit QC program are:

1. Radiation-beam alignment testing to assure the beam can be correctly aimed at the targeted tissues.[5]
2. Radiation dose per unit time (or per monitor unit) calculation based on physical

[1] Quality assurance program on stereotactic radiosurgery: report from a quality assurance task group. Hartman GH. Springer-Verlag; 1995.

[2] Schnell MC, Bova FJ, Larson DA, et al. AAPM Report No. 54. Stereotactic radiosurgery report of Task Group 42 Radiation Therapy Committee.

[3] Fraass BA, Doppke K, Hunt M, et al. Quality assurance for clinical radiation therapy, TG-53, AAPM Radiation Therapy Committee,1996.

[4] Ibid. See also the ACR Standard for 3-D External Beam Radiation Planning and Conformal Therapy, 1997.

[5] Hartman GH. Quality-assurance program on stereotactic radiosurgery: report from a quality-assurance task group. Springer-Verlag, 1995.

measurements for the treatment field size at the location of the target.

IV. QUALITY CONTROL OF THE STEREOTACTIC ACCESSORIES

Ancillary instrumentation used to determine the stereotactic coordinates of the target and to immobilize the patient with accuracy and precision should be routinely monitored to assure that it is functioning properly and within specified tolerances.

V. QUALITY CONTROL OF IMAGES

Stereotactic radiosurgery is an image-based treatment. All salient anatomical features of the SRS patient, both normal and abnormal, are defined with computed tomography (CT), magnetic resonance (MR), or angiography. Both high 3-D spatial accuracy and tissue-contrast definition are very important imaging features if one is to utilize SRS to its fullest positional accuracy. Since the imager usually is in the radiology department and not under direct control of the radiation oncology department, considerable cooperation is required for good quality control specific to the needs of SRS.

The medical images used in the SRS are critical to the entire process. They are used for localizing target boundaries as well as generating target coordinates at which the treatment beams are to be aimed. They are used for creating an anatomical patient model (virtual patient) for treatment planning, and they contain the morphology required for the treatment plan evaluation and dose calculation. Accuracy and precision required by SRS are to be assured. This assurance issue is addressed in the QC program for the treatment-planning system. However, general consideration should be given to the following issues:

The targeting of arteriovenous malformations (AVM) for SRS planning may include plain-film angiography, CT angiography, and MR angiography. Digital angiography must be thoroughly investigated for SRS use to correct for potential spatial distortions that may arise from the imaging chain.

Computed tomography is the most useful, nonspatially distorted, and practical imaging modality for SRS. It permits the creation of the 3-D anatomical patient model that is used in the treatment-planning process. However, it too must be thoroughly investigated before use in the SRS treatment-planning process. Some CT considerations are the following: partial volume averaging, pixel size, slice thickness, distance between slices, and image reformatting for the treatment-planning system. Although CT may be the basic imaging dataset for SRS, target tissues and normal tissue structures may be better visualized by MR.

The considerations enumerated for CT also apply to the use of magnetic resonance imaging (MRI). Furthermore, additional caution is warranted in MRI because of magnetic susceptibility artifacts and image distortion. MRI must be thoroughly investigated before use in SRS treatment planning since errors could be unacceptably large and must be verified with a CT. Techniques such as combining MR with CT images via image fusion can be used to minimize geometrical distortions inherent in MR images.

VI. QC FOR THE 3-D IMAGE-BASED TREATMENT-PLANNING SYSTEM

3-D image-based radiation therapy treatment-planning (RTP) systems are very complex. Data from medical imaging devices are used in conjunction with a mathematical description of the external radiation beams to produce an anatomically detailed patient model illustrating the dose distribution with a high degree of precision. Because of the system's complexity, the medical physicist may elect to release the system in stages and the required validation and verification testing will only reflect the features of the system that are in current clinical use at the facility (e.g., testing the system's ability to fuse MR and CT data would not have to be done in a department that only uses CT images). In any case, documentation must exist indicating that the medical physicist has authorized the system for clinical use and has established the QC program to monitor the 3-D system's performance as it relates to the 3-D planning process.

Consequently, the QC program involves elements that may be considered to be dosimetric and nondosimetric in nature. Furthermore, it is recognized that various testing methods may be used, with equal validity, to assure that a system feature or component is performing correctly. It is also noted that the commercial manufacturer may recommend specific QC tests to be performed on its planning systems. For these reasons, the important elements of the QC program for the 3-D image-based RTP system are identified, but the method and testing frequency are not specified. Information with more scientific detail may be found in the AAPM TG-53 report.[6]

A. System Log

Maintain an ongoing system log indicating system component failures, error messages, corrective actions, and system hardware/software changes.

[6] Fraas BA, Doppke K, Hunt M, et al. Quality assurance for clinical radiation therapy. TG-53, AAPM Radiation Therapy Committee, Nov. 1996.

B. System Data Input Devices

Check the input devices of image-based planning systems for functionality and accuracy. Devices include: digitizer tablet, medical imaging data (CT, MR, angiography, etc.) input interface, and video digitizers. Assure correct anatomical registration: left, right, anterior, posterior, cephalad, and caudad from all the appropriate input devices.

C. System Output Devices

Assure the functionality and accuracy of all printers, plotters, and graphical display units that produce, using digitally reconstructed radiographs or the like, a beam's-eye view rendering of anatomical structures near the treatment beam isocenter. Assure correct information transfer and appropriate dimensional scaling.

D. System Software

Assure the continued integrity of the RTP system information files used for modeling the external radiation beams. Confirm agreement of the beam modeling to currently accept clinical data derived from physical measurements. Similarly, assure the integrity of the system to render the anatomical modeling correctly.

VII. VALIDATION OF THE TECHNIQUE AS IMPLEMENTED

Once the individual components of the SRS planning and treatment technique are commissioned, it is recommended that the QC program include an "operational test" of the SRS system. This test should be performed before treating the patient's brain with the single, high radiation dose. The "operational test" should mimic the patient treatment and should utilize all of the same equipment used for treating the patient. An added benefit to the above approach is training of each team member for his/her participation in the procedure.

VIII. FOLLOW-UP

There should be follow-up of all patients treated and maintenance of appropriate records. The data should be collected in a manner that complies with statutory and regulatory peer-review procedures to protect the confidentiality of the peer-review data.

IX. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Guideline for Communication: Radiation Oncology.

X. SUMMARY

The quality of a stereotactic radiosurgery program is only as good as its weakest link. It is a very involved procedure requiring participants from many disciplines. High spatial accuracies are expected, and time constraints are short. Equipment foreign to conventional radiation therapy is used. The treatment is usually given only once, so there is little chance for adjustment afterward. All of the above demands a highly organized and efficient SRS team. Checklists are required to ensure that all aspects of the procedure are completed properly by each team member. The procedure must be appropriately staffed. Adhering to these details and those elaborated above provide the basis for a standard of practice worthy of the American College of Radiology.

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ASTRO
AMERICAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY

Written Testimony

To the

U.S. Nuclear Regulatory Commission's
Advisory Committee on the Medical Use of Isotopes (ACMUI)

RE: Memorandum in Opposition to the Inclusion of Neurosurgeons as Authorized Users for 10 CFR §35.690 Gamma Stereotactic Radiosurgery Units

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Memorandum in Opposition to the Inclusion of Neurosurgeons as Authorized Users for 10 CFR §35.690 Gamma Stereotactic Radiosurgery Units

Introduction

The American Society for Therapeutic Radiology and Oncology (ASTRO)[1] appreciates the opportunity to respond to the comments submitted to the NRC by the International Radiosurgery Association (IRSA) regarding regulation 10 CFR Part 35 governing the medical use of byproduct material, specifically in reference to training and experience associated with the administration of radiosurgery using the Gamma Stereotactic Radiosurgery (GSR) Units.

ASTRO understands that over the past three years, the NRC has worked tirelessly to further redefine the training and experience requirements of these modalities for the inclusion of medical specialty board requirements. The Commission has made a concerted effort to include all stakeholders in this undertaking. The Society looks forward to the publication of the final rule and working with the Commission to ensure the proper implementation of the federal mandate.

Since 1967[2], ASTRO has maintained collegial cordial, and clinically cooperative relationships with neurosurgeons for the administration of GSR. These relationships continue to be maintained by a majority of radiation oncologists and neurosurgeons in the field. Therefore, we felt that there was little need to question the current protocol or to raise issues regarding the definition of radiosurgery. Unfortunately, as a result of the gross misrepresentations made by IRSA, a trade organization, not a medical specialty society, we feel compelled to comment for the record at this time.

The application, submitted by IRSA, contains numerous undocumented anecdotal claims and extremely misleading statements. The NRC has recognized the need for the appropriately trained specialty of radiation oncology to have a primary responsibility for the treatment of patients with sealed sources as Authorized User (AU). ASTRO enthusiastically supports the efforts of the NRC to ensure the safe administration of

[1] ASTRO is the largest radiation oncology society in the world, with more than 8,000 members who specialize in treating patients with radiation therapies. As a leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly changing socioeconomic healthcare environment.

[2] Gamma Stereotactic Surgery was employed clinically in 1967.

medical byproduct materials to all Americans, and we believe that the measures put in place by the Commission promote safety and high quality patient care.

The NRC amended its regulations regarding the medical use of byproduct material in order to: "focus NRC's regulations on those medical procedures that pose the highest risk to workers, patients, and the public, and to structure its regulations to be more risk-informed and more performance-based".[3] We feel that this process of updating and strengthening existing regulations has improved safety for radiation workers and patients. ASTRO disagrees with IRSA's contention that these regulatory changes have had the inverse effect of worsening oversight and have placed patients at risk.

ASTRO's Position

ASTRO strongly agrees with 10 CFR § 35.615[i], which states: "for gamma stereotactic radiosurgery units, the AU (Authorized User) and AMP (Authorized Medical Physicist) must be physically present[4] throughout all patient treatment involving the units." Only radiation oncologists and radiation physicists have the extensive educational training and experience that are necessary to oversee the safe administration and effective delivery of these treatments.

ASTRO agrees that the correct application of dose to the target tissues and protection of normal structures, while always critical, is of particular importance in the administration of single, high dose radiation fractions. We believe a multidisciplinary approach involving radiation oncologists, radiation physicists, neuroradiologists, nurses, technologists and neurosurgeons is critical in the appropriate selection, treatment and follow-up care of patients undergoing radiosurgery, as outlined in the American College of Radiology (ACR) guidelines for radiosurgery[5], as well as the joint guidelines developed and published in collaboration by ASTRO and AANS.[6,7]

Given that tumors or other therapeutic targets in the brain are typically in close proximity to critical normal structures, we agree that precise localization and treatment delivery is absolutely required in the application of stereotactic radiosurgery procedures. Radiation oncologists and radiation physicists therefore work in close collaboration with neuroradiologists and neurosurgeons to identify the appropriate target area.

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[3] The modifications to the rule and the intent of these changes were discussed in the preamble to 10 CFR § 35 Final Rule. 67 Fed. Reg. 20250 (April 24, 2002)

[4] "Physically present" is interpreted by the NRC to mean within hearing distance of a normal voice.

[5] American College of Radiology. "Practice Guideline for the Performance of Stereotactic Body Radiation Therapy." Practice Guidelines & Technical Standards (2004). These guidelines are currently being updated, jointly, by ACR and ASTRO and will be published in ACR's Practice Guidelines & Technical Standards and the International Journal of Radiation Oncology, Biology and Physics in the near future.

[6] Larson DA, Bova F, Eisert D, Kline R, Loeffler J, Lutz W, Mehta M, Palta J, Schewe K, Schultz C, Shaw E, Wilson JF, Lunsford LD, Alexander E, Chapman P, Coffey R, Friedman W, Harsh G IV, Maciunas R, Olivier A, Steinberg G, Walsh J. Consensus statement on stereotactic radiosurgery quality improvement. Int J Radiat Oncol Biol Physics 28:527-530, 1993.

[7] Lunsford LD, Alexander E, Chapman P, Coffey R, Friedman W, Harsh G IV, Maciunas R, Olivier A, Steinberg G, Walsh J, Larson DA Bova F, Eisert D, Kline R, Loeffler J, Lutz W, Mehta M, Palta J, Schewe K, Schultz C, Shaw E, Wilson JF. Consensus statement on stereotactic radiosurgery: quality improvement. Neurosurgery 34:193-195, 1994.

Background

The medical use of radioisotopes is a complex and potentially dangerous process that demands the cooperation of a team of trained professionals in order to ensure high quality and safe administration to the patient and minimal exposure to medical personnel. The radiation oncologist has the principal responsibility to determine the radiation treatment plan and oversee its implementation. The specific parameters include the type and total dose of radiation, the radiation dose-fractionation schedule, the treatment volume, the assessment of radiation treatment effects, and monitoring of potential side effects. For GSR, the radiation oncologist and radiation physicist, in conjunction with the neurosurgeon, determine whether to continue, modify or abort treatment based on variance with any one of these factors related to the radiation treatment plan, which might impact on patient tolerance and response.

This is particularly critical in radiation treatments given in a single setting such as brachytherapy or GSR. In these cases, every factor that could impact response or toxicity must be accounted for in the radiation treatment plan before and during the administration of the radiation for a number of reasons. There is a limited opportunity to correct an error should it occur with these procedures. Radiation complications are directly related to the dose and distribution of radiation given.

IRSA correctly contends "it is of paramount importance to carefully match the dose of radiation delivered to a precise location, thus limiting the radiation delivered to the surrounding normal brain". The radiation oncology resident must be trained in the use of treatment aids and treatment planning to optimize the distribution of the radiation dose and the principles of normal tissue tolerance to radiation and tumor dose response[8]. In addition, radiation oncologists are trained in the diagnosis, follow-up and treatment of acute and long-term radiation side effects, a component not included in the neurological surgery residency program requirements.

IRSA contends that radiosurgery is a procedure performed "in one surgical session." The facts that the term "radiosurgery" is commonly used to refer to a single high dose of radiation, and that a special immobilization device is used to perform radiosurgery with some apparatus (but not all), and that high quality imaging is required for its administration simply do not convert a radiation procedure into a surgical procedure. Radiation oncologists use single dose fractions, accurate immobilization devices and high quality imaging for a large variety of treatment situations. For example, primary or metastatic lesions in bone, lung, spine, liver, brain and other sites are often treated with a single high dose. Immobilization devices are used in nearly every treatment site and in most cases positioned and placed under the supervision of the radiation oncologist. Most of these devices, including various types of stereotactic head frames, have been specifically designed for the immobilization of patients receiving radiation therapy Radiation oncologists routinely use high-resolution imaging including MRI, for target

[8] American Medical Association. "Graduate Medical Education Directory 2004-2005." March 2004: 142-151, 424-429.

localization of nearly every part of the body, another factor not unique to radiosurgery. Finally, stereotactic localization of target tissues is not unique to the region of the brain, but is also used by radiation oncologists to treat the head and neck, lung, pancreas, liver, spine and other sites in the body (stereotactic body radiotherapy SBR) via other types of stereotactic therapy units and immobilization frames.

Radiation oncologists are certainly familiar with Gamma radiation. Radiation oncologists used external beam cobalt-60 for many decades for radiation treatments at all body sites, including the brain, prior to the commercial development of linear accelerator-based radiotherapy. GSR, originally developed by engineers and physicists working with neurosurgeons, is a modification of standard gamma irradiation. Whether GSR carries less risk than neurosurgery is speculative; there has never been a direct comparative study that provides level-one evidence to support or refute this speculation. Radiosurgery does not have a scalpel-like effect as asserted by IRSA.

The general radiobiological principles governing the use of one or multiple fractions of radiation are well understood. For a given type of tissue in isolation from other types, similar biological effects can be obtained with either one or multiple fractions. For two types of tissue being irradiated simultaneously (normal tissue and tumor tissue, for example, with differing alpha/beta ratios), the relative effects in the two types following a single fraction may be different from the relative effects in the two types following multiple fractions. For large targets being irradiated, a wealth of clinical and scientific data indicates more favorable results (better tumor control and less toxicity) with multiple fractions. For very small targets, the volume of normal tissue receiving high dose is often too small to manifest clinically significant toxicity with a single fraction. For a given number of fractions, whether one or multiple, the method of delivery of the ionizing radiation, whether via cobalt-60 source or linac-based photon beam therapy, is largely irrelevant to the development of outcome (control or toxicity). Clearly, sophisticated familiarity with fractionation concepts is required for the selection and safe treatment of patients. Formal radiobiology training is required of all radiation oncology residents, as opposed to neurosurgery residents.

The IRSA statement that gamma radiosurgery is the most widely used technology for radiosurgery is incorrect. There are two main techniques for the delivery of stereotactic radiosurgery in wide use in the United States: the cobalt-60 gamma radiosurgery units (GSR) and linear accelerator-based radiosurgery units. There are many more linac radiosurgery units than GSR units installed in the United States. Both types of units may be used for single dose or fractionated therapy; both may require the placement of an immobilization device (head frame); both require precise delineation and localization of target and normal tissue volumes; and both allow the delivery of highly focused ionizing radiation to spare surrounding normal tissues. There is no clinically demonstrated superiority in either precision or treatment outcomes of the cobalt-60 GSR units over linac-based units, even though many neurosurgeons prefer ease of operation of GSR. Most radiation oncology departments will choose one or the other of these units for the delivery of stereotactic radiosurgery, as they are widely considered to be equivalent

modalities. ASTRO agrees that radiosurgery is a widely utilized alternative to craniotomy, just as it is a widely used alternative to fractionated radiotherapy.

With respect to training requirements, radiation oncology trainees are required to have training and experience treating all sites in the body, including the CNS, and are required to learn about the treatment of both malignant and benign diseases[9]. Topics that are considered integral to comprehensive understanding of each disease site include anatomy, pathology, biology, natural behavior and patterns of spread, in addition to treatment-related radiobiology and physics concepts. Therefore, radiation oncology residents are expected to learn neuroanatomy, neuroradiology and neurological functionality as a routine matter during the didactic portions of their training program. Radiation oncology residents are also expected to demonstrate this knowledge in the application of therapeutic radiation. In a point of fact, anatomy and radiographic appearance of both neoplasm and normal structures is highly emphasized in every radiation oncology-training program throughout the four years of schooling.

In order to become board certified, radiation oncology trainees are specifically tested in the treatment of CNS malignancies and benign disorders, and are required to have experience with one of the available methods of stereotactic radiosurgery, which they are required to log[10]. In addition, radiation oncology trainees, by training program design, receive 200 hours of classroom training in the following areas: radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity and radiation biology. They are also required to complete 500 hours of work experience under the supervision of an authorized user. Both are part of the minimal training requirements under 10 §CFR 35.690[ii].

In addition, the American Board of Radiology (ABR) tests applicants, in written and oral exams, on the planning, delivery, aftercare and implications of radiosurgery. The ABR also tests applicant's knowledge of radiation therapy physics, treatment planning and techniques, radiation biology, and clinical oncology. Candidates in radiation oncology must pass all portions of both examinations, including physics and biology, before receiving certification by the Board.

Discussion

In the January 31, 2005 petition sent to the NRC by IRSA regarding *Gamma Stereotactic Radiosurgery: Patient Safety and Protection of Cobalt Sources*, several issues and questions were raised that we believe are misleading, false, and contradictory, with citation of unsubstantiated references. ASTRO would like to highlight a few of these issues for further discussion.

[9] Id
[10] Id

Issue #1: Ownership and NRC Licensing

The issues of ownership and NRC licensing are totally unrelated. ASTRO objects to IRSA's coupling of the two. The mission of the NRC is not ownership and subsequent physician self-referral prohibitions. The Commission's interests lie solely in ensuring that medical procedures utilizing byproduct material are performed safely so as to minimize unnecessary exposure to patients and workers. The "conflict" that IRSA refers to, from the perspective of the radiation oncologist, is solely related to patient care and not ownership of GSR units or facilities. Indeed, a number of hospital-based GSR facilities are owned by private, for-profit entities, which may include their attending physicians.

ASTRO does not believe that non-hospital based ownership of GSR units is improper, as long as such facilities can meet the same stringent NRC guidelines for appropriately licensed personnel, safety, source security and quality assurance as hospital-based units. ASTRO strongly concurs that units being operated outside the established NRC regulations and those that cannot guarantee the safety of the public, personnel and patients should not continue to be licensed. ASTRO assumes that any non-hospital based centers that have been licensed by the NRC have been inspected and determined to be in proper compliance. Therefore, ASTRO questions the IRSA assertion that such centers lack "proper institutional or hospital oversight". ASTRO asserts that while the radiation oncologist and neurosurgeon already share responsibility for liability regarding radiosurgery treatment, the radiation oncologist is usually the physician responsible for obtaining the informed consent, and the signatory on all treatment-related documentation.

Issue #2: Authorized Users:

ASTRO agrees that the neurosurgeon and radiation oncologist comprise the physician team for patients undergoing radiosurgery. Neurosurgeons are not required to be present throughout the treatment for linac-based radiosurgery, the outcome of which is clinically equivalent to gamma knife therapy. Radiosurgery patients may infrequently require admission, but they can be managed by the radiation oncologist until an admitting physician can evaluate them. Acute emergencies occur rarely, but can be managed initially by the radiation oncologist, while calling for emergency support, exactly as with any other patient who experiences an emergent problem while undergoing radiation therapy.

The IRSA objection to the requirement for an authorized user, a radiation oncologist, to be the responsible physician for signing the written directive is puzzling. The radiation oncologist works closely with the medical radiation physicist, neurosurgeon, neuroradiologist, radiation therapist, dosimetrist, radiation oncology nurse, social worker and dietitian to ensure high quality patient care and safety. In particular, the radiation oncologist has formed a complex and extremely efficient working relationship with the medical radiation physicist to oversee the work of the dosimetrist and to help ensure that complicated treatments are properly tailored for each patient. Therefore, there is no

physician more adequately trained or qualified to sign the written directive than the radiation oncologist.

ASTRO also objects to issues raised that question the vital importance of the Authorized Medical Physicist (AMP) during gamma stereotactic surgery. Ensuring that the dose prescription is adhered to is paramount to patient safety. The medical physicist and radiation oncologist interaction has developed and increased over time with the increased complexity of radiation therapy medical interventions, to ensure safe delivery of radiation treatment. Whether in stereotactic treatment of malignant disease or non-malignant disease, this team is instrumental in minimizing irretrievable errors in the delivery of extremely high doses of radiation.

Most importantly, in the event of a technical failure, the most qualified individual is the medical physicist. Time is paramount in terms of patient safety in such a potential radiation exposure situation and not having a physicist directly present during the procedure could grossly compromise patient safety.

The IRSA assertion that medical physicists are in charge of targeting or dosing the GSR units demonstrates a fundamental lack of knowledge regarding the responsibilities of the AMP and is simply false. The medical physicist does not perform target or dose selection. To the contrary, the medical physicist follows the instructions of the radiation oncologist and neurosurgeon in decision-making related to the treatment plan, performs dosimetric calculations and quality assurance, and provides machine calibration.

While ASTRO concurs that the neurosurgeon is an integral part of the patient selection, treatment and decision-making process, once the patient has arrived for actual treatment administration, the multidisciplinary process of patient selection, discussion of alternative treatments, and target and critical structure delineation has already occurred. The assertion that the risk of permanent neurological harm will be increased if a radiation oncologist administers the treatment, alone, is patently false. Radiation oncologists determine target and normal tissue volumes and prescribe and deliver doses of radiation to every part of the body without the benefit of other specialists' direct oversight, as a matter of daily practice.

The designation of neurosurgeons as authorized users is unnecessary and, we believe, would not be in the best interest of patients. The neurosurgery residency program does not include any required radiation oncology components, clinical or didactic. Furthermore, the neurosurgery residency program lacks radiation physics, normal radiation pathology, radiation biology, and radiation treatment planning in its required curriculum[11]. The American Medical Association's graduate medical requirements state that the neurosurgery program, in its spectrum, "should include stereotactic radiosurgery" but does not delineate any specified number of hours, cases or level of involvement by the trainee[12].

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[11] Id
[12] Id

ASTRO does not assert that radiosurgery does not exist, but that the term radiosurgery merely refers to one modality of radiation therapy, and not surgery, just as externally delivered radiation, whether from linac or isotopic sources, and whether with one or multiple fractions, remain radiation therapy rather than surgery for all body sites. We also dispute the assertion that there is an effort to eliminate neurosurgeons from these procedures. ASTRO recognizes that patient care is optimized by close collaboration between the radiation oncologist and the neurosurgeon in patient selection and in target delineation.

ASTRO recognizes that the NRC has established regulatory procedures for licensing and use of GSR units that places appropriate responsibility for the planning and delivery of targeted radiotherapy with the radiation oncologist. The reference that 10 CFR § 35.690[ii] has been modified in a manner that would allow radiation therapists to become authorized users is incorrect. We interpret this provision to only allow the inclusion of licensed physicians who meet the delineated requisites.

In addition, while ASTRO has provided testimony to the Commission regarding the effect of regulatory changes, the Society has never "utilized rulings they [ASTRO] assisted NRC in developing to restrict other physicians specialties from the GSR procedure that would result in absolute risk to patient safety." The notion that we in some way drafted federal regulations is absurd on its face.

Issue #3: Authorized User Exemption Criteria

ASTRO absolutely disagrees that it is commonplace for the radiation oncologist to leave for other clinical duties during GSR administration. As with other high-risk procedures, the radiation oncologist will remain within a reasonable proximity to the patient undergoing therapy as mandated in the federal regulations[13]. ASTRO knows of no "growing shortage" of radiation oncologists. On the contrary, radiation oncology has become one of the most sought-after and competitive specialties in medicine.

Regarding patient safety under treatment, radiation oncologists, who are not only board certified specialists but also physicians with an unrestricted medical license, are trained and capable of observing and managing such patient problems while undergoing treatment as choking, coughing, vomiting, hypertension and removal of the head frame as well as cardiopulmonary events requiring emergent intervention. Indeed, such events occur regularly among patients undergoing conventional radiation therapy, and are managed by the radiation oncologist without the direct supervision of other medical specialists.

[13] It is mandated in 10 CFR §35.615 that the AU and AMP must be physically present throughout the entire procedure. "Physically present" is interpreted by the NRC to mean within hearing distance of a normal voice.

Issue #4: Training of Authorized User

IRSA argues that vendor-approved courses are the only acceptable training program for use of GSR units. ASTRO disagrees that NRC-licensed AUs cannot provide adequate training in the use of GSR units for new users. ASTRO refutes the statement that radiosurgery training is not being provided in radiation oncology departments. In addition, the training program in radiation oncology is unique in its focus on all of the necessary principles of physics, radiobiology and clinical management issues for proficiency in radiosurgery and other specialized radiation techniques. Since different types of apparatus may deliver radiosurgery, residents learn the specific type of unit at their institution. If they join a practice with a different type of unit, the existing AU (in the case of the GSR unit) or unit director (for linac-based radiosurgery) can readily assure adequate instruction in the appropriate specific operational principles.

ASTRO strongly supports the preceptor statement philosophy instituted by the NRC. The Society believes that the best training in radiosurgery is acquired through the residency program and specialty board certification program. Although ASTRO does not object to vendor-sponsored training classes, the Society believes that the totality of training acquired in a radiation oncology residency program better equips a radiation oncologist to perform radiosurgery procedures. ASTRO believes that vendor-provided and/or supported training has the potential to bring inherent unavoidable and undesirable equipment selection and utilization bias into the training process.

Issue #5: Definition of radiosurgery

ASTRO strongly objects to the IRSA's proposed definition of radiosurgery and its request that the NRC actually move to micro-define a particular medical procedure. To assert that the manipulation of DNA is surgery is patently absurd, and by that definition, many modern drugs and biologicals and non-surgical interventional techniques would fall under the surgery rubric. The fact that the radiation is delivered in one treatment does not justify the designation of surgery. Radiation oncologists have performed single fraction radiation procedures for decades.

Radiosurgery is a form of radiation therapy, as it involves the delivery of external radiation, either with a cobalt-60 unit or a modified linear accelerator. Stereotactic Radiation Therapy (SRT) is the general term for stereotactic-based radiation treatment. This treatment usually consists of one or multiple radiation treatments delivered by a linear accelerator or of one radiation treatment delivered by a cobalt-60 unit (sometimes referred to as a Gamma Knife®) or by a proton machine. The linear accelerator can be contained in a traditional, rotational gantry, as used in a typical course of radiation, or mounted on an industrial robot, as in the Cyber Knife®. With the advent of new technologies for stereotactic treatments to non-cranial areas, the term Stereotactic Body Radiation Therapy (SBRT) is utilized for designation of therapy for extra-cranial targets.

ASTRO refutes the assertion that it is widely or historically accepted that radiosurgery is "surgery". To the contrary, it is our belief that the vast majority of patients, payers and

reasonable practitioners in both neurosurgery and radiation oncology acknowledge that radiosurgery is the precise delivery of radiation, and not actual surgery. The IRSA reference to peer-reviewed journal articles supporting the definition proposed in their petition is spurious, since the articles cited represent essentially self-supporting editorial statements rather than scientifically based manuscripts.

Conclusion

Clearly only authorized users, such as radiation oncologists, meet the requirements set forth in 10 CFR § 35.690[ii]. Furthermore, the rules of procedure for GSR, delineated in 10 CFR §35.615[i], are well and carefully crafted to ensure optimum safety to patients and workers.

It is evident that only radiation oncologists possess the specialized training and experience that is vital to carrying out all procedures governed by the regulations. The educational and training program as set forth by the Accreditation Council for Graduate Medical Education[14] ensures that radiation oncologists are thoroughly trained in all aspects of radiation therapy treatments. To date, there is no other specialty that possesses the skill, knowledge or expertise in the comprehensive implementation and safe application in the totality of radiation therapy procedures that is currently held by radiation oncologists. Therefore, it is imperative that the NRC denies state licensure exemptions that designate an AU other than the radiation oncologist for GSR.

The public impact of such licensure exemptions could prove to be detrimental. The allowance of such exemptions could result in poor quality healthcare, inappropriate radiation exposure, unsafe working conditions and a significant increase in the probability of medical errors. Accordingly, it is in the best interest of public health and safety that a consistent policy be applied. Physicians who are trained in this particular specialty should be the primary care givers.

ASTRO recognizes and welcomes the critical role of our neurosurgical colleagues in gamma stereotactic radiosurgery and this document should in no way be interpreted as a diminution of that role.

ASTRO would like to thank the Commission for its steadfast commitment to ensuring the safe administration of medical procedures utilizing byproduct material and for the opportunity to comment and testify on rulemaking policy and pending petitions.

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[14] American Medical Association. "Graduate Medical Education Directory 2004-2005." March 2004: 142-151, 424-429.

[i] CODE OF FEDERAL REGULATIONS, TITLE 10--ENERGY
CHAPTER I--NUCLEAR REGULATORY COMMISSION
PART 35--MEDICAL USE OF BYPRODUCT MATERIAL
SUBPART H--PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS; 70 FR 9703

§ 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall control access to the treatment room by a door at each entrance.
(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will--
(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
(2) Cause the source(s) to be shielded when an entrance door is opened; and
(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.
(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.
(d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.
(e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.
(f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall--
(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require--
(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and
(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.
(2) For high dose-rate remote afterloader units, require--
(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.
(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.
(4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.
(g) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source--
(1) Remaining in the unshielded position; or
(2) Lodged within the patient following completion of the treatment.

[ii] CODE OF FEDERAL REGULATIONS
Title 10, CHAPTER I--NUCLEAR REGULATORY COMMISSION
PART 35--MEDICAL USE OF BYPRODUCT MATERIAL
SUBPART H--PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS; 70 FR 9703

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Except as provided in § 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under § 35.600 to be a physician who--
(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or
(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes--
(i) 200 hours of classroom and laboratory training in the following areas--
(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity; and
(D) Radiation biology; and
(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690, or, before October 24, 2005, § 35.960, or equivalent Agreement State requirements at a medical institution, involving--
(A) Reviewing full calibration measurements and periodic spot-checks;
(B) Preparing treatment plans and calculating treatment doses and times;
(C) Using administrative controls to prevent a medical event involving the use of byproduct material;
(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
(E) Checking and using survey meters; and
(F) Selecting the proper dose and how it is to be administered; and
(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.690, or, before October 24, 2005, § 35.960, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and
(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690, or, before October 24, 2005, § 35.960, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.
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● *Special Feature*

CONSENSUS STATEMENT ON STEREOTACTIC RADIOSURGERY QUALITY IMPROVEMENT

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INTRODUCTION

Stereotactic radiosurgery is irradiation of an intracranial target localized by an imaging (computed tomography [CT], magnetic resonance imaging [MRI], angiography, magnetic resonance angiogram [MRA], etc.) compatible stereotactic device. Modalities currently used in stereotactic radiosurgery include photon devices such as the gamma knife or modified linear accelerators and cyclotron- or synchrotron-generated particles, such as protons and heavy charged particles.

DISCUSSION

Patient selection

Selection of patients for stereotactic radiosurgery involves a judicious balance of the benefits vs. the risks of radiosurgery relative to the natural history of the disease and to those of alternative therapies. The relative demographic and medical profile of the individual patient as well as the nature, size, shape, and location of the lesion must be considered in assessing the relative risks and benefits of stereotactic radiosurgery. This assessment requires a combination of neurodiagnostic, neurosurgical, radiation oncologic, and medical physics expertise.

Radiosurgery has often been used to treat relatively small, well-circumscribed tumors or vascular malformations readily identified by current high resolution neuroimaging techniques. Selection of radiosurgery in lieu of other treatment modalities involves assessments of its risks and likely benefits in the context of patient preference, the neurological hazards of open surgical resection that requires general anesthesia, the need for precise targeting during irradiation, and the radiobiological efficacy of alternative radiation techniques.

Clinical usage

The indications for stereotactic radiosurgery as for other treatment modalities are evolving as experience is accrued. Worldwide, by mid-1993, more than 18,000 patients have undergone stereotactic radiosurgery. Various diseases have undergone stereotactic radiosurgery under specific circumstances.

Randomized prospective trials have been initiated to evaluate the role of radiosurgery for brain metastases, ocular melanomas, and malignant glioma. Further experience regarding the use of radiosurgery for these and other tumor types is warranted. Therefore, it is imperative that stringent data collection and participation in co-operative studies be considered a prime concern for any ra-

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diosurgical program. Conscientious analysis of patient outcomes after stereotactic radiosurgery will continue to enhance the confidence with which future recommendations regarding radiosurgery can be made.

Stereotactic devices/imaging techniques

The accuracy of the placement of the radiation isocenter to the target must meet stereotactic standards. In general, the mechanical accuracy of stereotactic guiding devices is within ±1 mm. Additionally, the accuracy of stereotactic radiosurgery also depends in part on the imaging modality used to select the target. The most commonly used imaging techniques for target selection during stereotactic radiosurgery are cerebral angiography, CT, and MRI. Magnetic resonance angiography, positron emission tomography (PET), single photon emission computed tomography (SPECT), and digital subtraction angiography (DSA) are also under evaluation.

Stereotactic devices are currently marketed for a wide variety of intracranial indications ranging from biopsy to functional neurosurgery to tumor resection. Such devices have been adapted to be compatible with the multi-source Cobalt Gamma knife, linear accelerators, and particle beam technology. Both re-locatable and conventional (rigid skull fixation) stereotactic devices are currently in use. All such devices must permit low artifact recognition of the target. Most such devices currently have skull fixation under local anesthesia. Re-locatable devices must continue to adhere to stereotactic principles permitting relocation of the frame such that the target coordinates derived during the image acquisition component of the procedure have been demonstrated to be the same coordinates used during the radiosurgical component of the procedure. Stereotactic devices adapted to radiosurgery should adhere to guidelines formulated for the American Society of Testing and Manufacturing (ASTM, Rockville, MD).

Target definition

Interactive computer-based programs using current imaging techniques should define the target in one or more planes; the target should be consistent between these various imaging techniques. Three—dimensional visualization is considered useful. Reliability and reproducibility of target definition should be verified. Potential problems and errors in imaging techniques should be addressed, such as the potential peripheral target distortion associated with DSA and the potential for target or fiducial distortion during MRI arising from magnetic susceptibility artifacts. Proper maintenance of external localization systems of the imaging tools (e.g., laser lights) and maintenance of the imaging tool (e.g., properly shimmed magnets for MRI) are necessary. Reliability and reproducibility of targeting for each imaging device should be confirmed using either external fiducial or internal fiducial measurements.

Dose planning systems

Commercially available dose planning systems require Food and Drug Administration (FDA) approval. Dose planning systems used only at a single institution ("in house") are used without regulatory scrutiny. All centers using such systems should adhere to rigid verification and quality assurance/improvement guidelines.

All radiosurgery dose planning systems should: (a) be compatible with commonly used neuroimaging modalities; (b) be capable of detecting potential inherent errors in the imaging process (e.g., DSA distortion or MRI susceptibility artifacts); (c) be exhaustively tested against accepted dosimetry standards to verify the accuracy of absolute and relative dosimetry for single or multiple isocenters; (d) be of sufficient speed that the dosimetry optimization process is not hindered by lack of computation speed. Using either phantoms, initial port film verification, or other accepted medical physics mechanisms, it should be possible to ensure that the defined target was actually treated by radiosurgery.

Technical standards

Based on the combined expertise of appropriately trained medical physicists, radiation oncologists, and neurological surgeons, supplemented by the manufacturer's data, all radiosurgical systems must meet defined technical standards for a strict program of quality improvement/assurance (QA). Such programs have been evaluated by the Nuclear Regulatory Commission (NRC) for Gamma knife technology and are under evaluation by the FDA for linear accelerator technology. Cyclotron or synchrotron generated particle beams have been under evaluation by the Department of Energy (DOE).

Gamma knife technology

Centers using gamma knife technology must comply with current NRC (including agreement state) guidelines for inaugural use of the gamma knife, and respond to daily, weekly, monthly, and/or yearly requirements of the NRC for quality assurance. Appropriate film dosimetry for confirmation of beam accuracy and beam volume is important prior to initial patient treatment. Some quality assurance (QA) items are checked on a daily basis while others are checked weekly, monthly, or annually. The U.S. U-style Cobalt-60 gamma knife must adhere to the U.S. Code of Federal Regulations, Title 10, Part 35.

Linear accelerator technology

Verification of the exact spatial relationship between the coordinate localization system and the mechanical isocenter of the linear accelerator couch-gantry system is required prior to each treatment session. The integrity of the linear accelerator mechanical isocenter for multiple couch beam entry positions and rotations is also critical for ideal treatment delivery. Therefore, frequent verification of the exact spatial relationship between the co-

ordinate localization system and the mechanical isocenter of the linear accelerator couch-gantry system is required. Linear accelerator QA guidelines addressing these concerns should be individualized at each institution. The American Association of Physicists in Medicine (AAPM) is developing recommendations for linear accelerator QA which may serve as a model for institutional QA programs.

Particle beam technology

Cyclotron- or synchrotron-generated particle beam stereotactic radiosurgery requires an extensive medical physics team to ensure appropriate beam delivery based on particle beam technology. Particle beam stereotactic radiosurgery requires the same stringency of quality assurance (regarding target localization, planning, mechanical positioning of the patient relative to the particle beam, and does verification) as other radiosurgery systems. Extensive quality assurance protocols governing both maintenance of the cyclotron (mandated by the Department of Energy), and its clinical use (developed by an experienced radiosurgery team) are essential.

Supporting medical staff and facilities

The professional staff for stereotactic radiosurgery procedures must include the following members on a multidisciplinary team. All members of the team must receive the appropriate training.

1. Neurological surgeons (board eligible or certified) with commitment to and training in radiosurgery, and with expertise in tumor and vascular malformation management including target definition, the principles of CT, MRI and angiographic imaging, and basic radiation therapy and radiobiology.
2. Radiation oncologist (board eligible or board certified) with commitment to and training in radiosurgery, and with expertise in target definition, the principles of CT, MRI and angiographic imaging, and basic principles of management of CNS tumors and vascular malformations.
3. Medical physicist (board eligible or board certified) with training in radiosurgery.
4. Nursing staff with training in radiosurgery.
5. Diagnostic radiologist (board eligible or board certified) with expertise in neuro-radiology.
6. Technologist staff with training in radiosurgery.

Training guidelines

The multi-disciplinary team performing stereotactic radiosurgery should have broad expertise. The neurological surgeon should have expertise in conventional stereotactic surgery, microsurgery, and selection of target volumes defined by neuroimaging. Neurosurgeons and radiation oncologists should be familiar with the principles of stereotactic imaging and have experience or training with precise single fraction irradiation of small target volumes. Each member of a team initiating a radiosurgical program should have specific, intensive, and documented training in radiosurgery. Such training includes attendance at specific courses or symposia and a site visit and observation of patient planning and treatment at one or more centers currently performing radiosurgery. Education should include analysis of prior results, patient selection guidelines, stereotactic head frame application techniques, stereotactic neurodiagnostic imaging using all pertinent modalities, target selection, dose determination, dose prescription, treatment delivery, and instructions regarding radiation effects, protection, and recognition of complications.

Emergency standards and safety

All stereotactic radiosurgical units should possess the following facilities:

1. Sufficient space for stereotactic coordinate frame application under local control or general anesthesia.
2. Appropriate access to life support mechanisms to handle potential medical emergencies.
3. Appropriate neurodiagnostic imaging facilities to provide high resolution imaging.
4. Emergency safety and technical standards must be defined, posted, and followed at each center.
5. All radiosurgical systems should have redundant methods of measuring radiation output.
6. Linear accelerator based systems should include the following safety features:
   - 12.6.1 Rotate toward non-collision positions whenever possible.
   - 12.6.2 Use interlocks that prohibit rotation into a collision position.
   - 12.6.3 Use interlocks to prevent table motion in any direction during treatment.

CONCLUSION

Follow-up guidelines

Dilligent posttreatment assessment of patients is critical both to the individual patient and to the field of stereotactic radiosurgery in general. Information acquired may prove crucial to the subsequent management of other patients; an incipient radiation induced neurological deficit might be forestalled by medical therapy; a persistent filling AVM might require re-treatment; a recurrent tumor might need microsurgical resection. Similar findings commonly encountered might warrant modification of the criteria for patient selection or changes in treatment parameters. Follow-up evaluations should be timed so as to optimize the chance of detecting both complications of and favorable responses to treatment. Evaluation should be standardized and whenever possible conducted by the treating physician. Results should be compiled, analyzed, and shared with others performing radiosurgery.

APPENDIX I

Table 1. Current radiosurgery studies

Tumor	Stage	Study	Phase	Institution
Single metastases	N	RS + RT vs. RT	III	U Kentucky
Single metastases	N	RS + RS vs. surgery + RT	III	Harvard
Single metastases	N	RT + RS vs. RT + RS with Fluosol	II	U Wisconsin
Single/multiple mets	N, R	RS + RT vs. RS	III	GK Usec Group
Multiple metastases	N, R	RS + RT vs. RT	III	GK User Group
Multiple metastases	N	RS + RT vs. RT	III	U Kentucky
Multiple metastases	N, R	RS + RT vs. RS	III	U Pittsburgh
Two metastases	R	RS vs. RS with SR-2508	III	Harvard
Primary or metastatic	R	RS	I	POG
Primary or metastatic	R	RS	I	RTOG
Primary or metastatic	R	RS with SR-2508	III	RTOG
Supratentorial malignant glioma	N	RS + RT with BCNU vs. RT with BCNU	III	RTOG
Ocular melanoma	N	RS	I/II	GK User Group
Single/multiple metastases	N	RS + RT vs. RS	III	Temple University
Recurrent/persistent glioma	N	RT + RS	I–II	Temple University
Hemangioblastomas	R	RS	-	GK Used Group
Malignant glioma	N	BCNU + Cisplatinum + RT + RS	I/II	U Pittsburgh
Malignant glioma	R	RS + RT	I	GK User Group

RS = Radiosurgery; RT = Fractionated radiation therapy; N = New; R = Recurrent; GK = Gamma knife; POG = Pediatric Oncology Group; RTOG = Radiation Therapy Oncology Group.

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EDITOR'S NOTE

How differences in dose rates and fractionation regimens impact on tumor control, complications, and efficiency and economy of therapy are themes in the lead articles of this issue. From Chandigarh, the capital of the turbulent Punjab region, the most modern city in India, designed by the architect Mies ver Rohe, comes a randomized clinical trial involving 482 cancers of the cervix patients reported by Professor Gupta's team of Patel, Sharma, Negi *et al.* addressing one of the more controversial issues in radiation management, that is, low dose rate (LDR) versus high dose rate (HDR) brachytherapy as to the comparability of tumor control and complications. The results affirm the similarity of end results. Patients are divided into two groups: Group I limited, early Stage I and II cancers with normal anatomy versus Group II advanced disease with distorted anatomy. In both groups, the local control rates and 5-year survival rates were similar for LDR and HDR, that is, 79.7% versus 75.8% and for Stage I, 73% versus 78%, Stage II, 62% versus 64%, and Stage III, 50% versus 43%. Severe grade 3 and 4 rectal and bladder complications were not significantly different, that is, below < 2%. The real advantage for HDR is not a gain in tumor cure, our traditional endpoint, but complete radiation protection for hospital personnel with remote control afterloading, decreased cost due to avoidance of anesthesia and outpatient status, and short treatment times that avoid complications due to bed rest with conventional LDR brachytherapy.

Total body irradiation for hematologic malignancies is widely accepted and cataract complications in long-term survivors is a recognized hazard. Dramatic differences in the cataract incidence is found in comparing instantaneous dose rates and fractionation techniques according to Ozsahin, Belkacemi, Pene *et al.* in a large series of 157 patients with TBI. Treatment was with either a single dose of 10 Gy or 12 Gy fractionated; randomization was to varying dose rates of 6 versus 15 cGy and 3 versus 6 cGy, referred to as low versus high dose rates, respectively. The cataract incidence was 5% versus 15% in low versus high dose rate or 12% versus 34% at 5 years, respectively. Fractionation also decreased cataract formation as compared to single dose, that is, 6% versus 18% and 5-year estimated incidence of 13% versus 39%. Another site of relatively frequent late effects is chronic bowel complications after pelvic irradiation for either colorectal carcinomas and to a lesser degree, endometrial cancers. In a larger series of 153 patients retrospectively analyzed, Sigmon, Randall, Olds *et al.* found an 18% incidence at 12 months with a higher percentage attributed to split course versus continuous fractionation regimens, that is, 23% versus 10%. Suggested biological mechanisms are increased proliferation of mucosal and serosal cells after the split course led to increased desquamation of mucosal lining and serosal loss with the second course of irradiation leading to increased penetration of proteolytic enzymes resulting in ulceration, hemorrhage, fistulas, and adhesions.

Also in this issue are a number of reports reaffirming gains in therapeutic ratios at a variety of sites by utilization of different therapeutic strategies. Theoretically the development of resistance to chemotherapy and radiotherapy should be minimized by using all treatment modalities early in a treatment program. This principle is demonstrated by Canadian investigators, Coy, Hodson, Murray *et al.* in a large randomized study of 308 small cell lung cancer patients with the different timing of radiation therapy (40 Gy in 15 fractions) in either the first or sixth cycle of chemotherapy consisting of cytoxan, doxorubicin, and vincristine. There was a moderate improvement in early versus late use of irradiation, that is, 64% versus 56% complete response, 21 versus 16 months median survival, and survival at 2, 3, and 4 years of 40%, 32%, and 25% versus 33%, 12%, and 15%, respectively. Late local recurrence was 41% versus 39% in early versus late arms, however, pneumonitic rates were only 3%. Intensifying treatment early in combined drug-radiation protocols is recommended and supported by Lee and Hong in their editorial entitled "Timing of Radiotherapy in Small Cell Lung Cancer." Equally interesting is the finding of a high rate of second malignant tumors in long-term survivors—an actuarial accumulative risk of 50% at 8 years, suggesting a role for chemoprevention agents. An advantage for combining modalities and increasing radiation dose can be found in a study of 63 Stage IE primary lymphomas of bone by Fairbanks, Bonner, Inwards *et al.* In a univariate analyses, 5-year disease-free survival was 90% for patients treated with chemotherapy and radiation versus 51% for irradiation alone. However, multivariate analyses indicated only radiation doses greater than 40 Gy to whole involved bone improved overall survival, that is, 81% versus 27% for lower doses. The authors note no attempt to treat regional nodes was made but 22% had developed regional node failure as the first site of failure, suggesting this issue deserves further exploration in future studies.

A controversial topic is the use of elective or prophylactic fields in seminomas and in ependymomas. Lai, Bernstein, Kim *et al.* provide a thorough analysis of 128 patients with testicular seminomas reporting

Stage I 5-year DFS and overall survival (OS) of 97% and 100%, favoring the continued elective use of paraaortic and pelvic fields. However, they question the use of pelvic field extensions since there is only a 2% failure rate in surveillance data as compared to 13% in paraaortic nodes. Even more interesting is questioning the use of inguinal and scrotal fields even when violation of scrotal wall has occurred. There were no mediastinal failures in Stage IIA whether prophylactic mediastinal irradiation was administered or not. Thomas, in her editorial, updates her views on the shape and extent of prophylactic fields in Stage I and II seminomas and addresses alternative treatment options to radiation therapy, namely, surveillance and possible chemotherapy. The value of prophylactic craniospinal fields is challenged in the report by Rousseau, Habrand, Sarrazin *et al.* in a retrospective review of 80 children treated by surgical resection and irradiation. They found no difference in survival on patterns of failure between local field, whole brain, or craniospinal irradiation while severe late effects were noted predominantly in the latter two groups. The only site of failure is the original tumor site leading them to advocate doses greater than 50 Gy. In a Phase I/II study on hyperfractionated craniospinal axis (CSA) radiation therapy for neuro-ectodermal tumors, Prados, Wara, Edwards *et al.* note spinal seeding failures can occur with prophylactic doses of 24 Gy and failures even occur with doses of 30 Gy. Doses greater than 30 Gy make adjuvant chemotherapy difficult to administer. Future studies will pursue dose escalation to 36 Gy CSA and patient stratification as to poor and good risks. Readers should note the usefulness of G-CSF in Hodgkin's disease patients to overcome profound neutropenia by Knox, Fowler, Marquez *et al.* when large extended fields are used. This strategy may be valuable to apply to CSA patients when higher doses are used and chemotherapy needs to be added.

The value of prognostic and predictive factors in breast cancer is a constant source for debate as more cellular and molecular biologic markers are added to clinical staging. In a large review of 795 breast cancers in their database, German investigators Kiricuta, Willner, Kolbl *et al.* found supraclavicular nodes at presentation or at recurrence were similar to M1 disease or presenting distant metastases. The 2- and 5-year survival rates in each of the aforementioned circumstances ranged from 50–56% to 16–34% suggesting supraclavicular nodes appearing at anytime is equivalent to distant metastases. The value of C-ERB B2 overexpression as a predictor of recurrent disease in early breast cancer is not borne out according to Pierce, Merino, D'Angelo *et al.* One of the provocative features in this issue relates to the management of histologically unverified presumed cerebral gliomas with radiotherapy by Rajan, Pickuth, Ashley *et al.* The 5-year survival figures need to be balanced against the lack of precise information as to whether we are dealing with a high-grade or low-grade glioma. In Curran's editorial, he presents the argument for debulking surgery and histologic verification. Brada and Rajan acknowledge that biopsy is considered the gold standard in any oncologic management, however, better imaging techniques "may in the future provide anatomical, pathological and biochemical information superior to that obtained currently from histology alone."

The use of stereotactic radiosurgery is the dominant theme amongst a potpourri of technical innovations, a special feature, and a consensus statement that conclude this issue. The topic of multiple shaped static fields may be better than arcs of single large circular fields in sparing normal vital tissues is presented by Bourland and McCollough, Hartmann, Bauer-Kirpes, Serago *et al.* stress the importance of quality control, and precision of convergent beam techniques should be on the order of 1 mm to accurately conduct stereotactic linear accelerator techniques. A discussion of systematic analysis of spatial errors in target localization with angiography and CT in stereotactic radiosurgery by Yeung, Palta, Fontanesi *et al.* argues for using biplanar treatment portal verification with a fiducial localization frame for therapy set up. In the special feature, current radiosurgery practice is analyzed based on an ASTRO questionnaire by Larson, Bova, Eisert *et al.* They note the labor-intensive and time-consuming nature of the procedure on the day of treatment requiring on the average 3.8 hours by the radiation oncologist and 3.2 hours by the neurosurgeon, and 6 hours by the physicist—emphasizing planning treatment and follow-up in current radiosurgery practice is a team approach. To conclude the issue, a consensus statement on stereotactic radiosurgery quality improvement guidelines has been prepared jointly by ASTRO and AANS (American Association of Neurosurgeons) and has been approved by their respective Boards of Directors. This consensus statement authored by Larson, Bova, Eisert *et al.* from ASTRO and Lunsford, Alexander, Chapman *et al.* from AANS is being published simultaneously in *IJROBP* and *Neurosurgery*. A listing of ongoing studies is also provided for the more than 100 facilities involved in their modality; worldwide it is estimated that more than 18,000 patients have undergone stereotactic radiosurgery by mid 1993. In their editorial, Schell and Kooy provide a perspective on stereotactic radiosurgery methodology.

Philip Rubin, M.D.
Editor-in-Chief

ADMIN CLOSING
NO HANDOUT

UNITED STATES NUCLEAR REGULATORY COMMISSION
CHARTER FOR THE ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES
(Pursuant to Section 9 of Public Law 92-463)

1. **Committee's Official Designation:**

   Advisory Committee on the Medical Uses of Isotopes

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

   The Committee provides advice, as requested by the Director, Division of Industrial and Medical Nuclear Safety (IMNS), Office of Nuclear Material Safety and Safeguards, 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, IMNS

3. **Time period (duration of this Committee):**

   From March 18, 2004, to March 18, 2006

4. **Official to whom this Committee reports:**

   Charles L. Miller, Director
   Division of Industrial and Medical Nuclear Safety
   Office of Nuclear Material Safety and Safeguards
   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:**

   a. $160,000.00 (includes travel, per diem, and compensation)

   b. Total staff-year of support: 1.5 Full Time Equivalent

8. **Estimated number of meetings per year:**

Three meetings per year except when active rulemaking is conducted, then five meetings per year.

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

March 18, 2006

10. **Filing date:**

March 18, 2004

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

TAB 19

ACMUI
February 20, 2002

U.S. NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS

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 Committee's responsibility to provide objective and independent advice to the Commission through the Office of Nuclear Material Safety and Safeguards, 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, tand that the resulting reports represent, to the extend possible, the best of which the Committee 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 regulatins as appropriate.

1.1 Scheduling of Meetings:

1.111 Meetings must be approved or called by the Designated Federal Officer. At least two regular meetings of the Committee will be scheduled each year. A spring meeting will be scheduled in April-May, and a fall meeting will be scheduled in October-November. Additionally, the Committee will meet with the Commission each year in the first or second quarter of each year.

1.1.2 Special 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 Committee 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 Committee 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 Committee (referred to below as "the Chair") in consultation with the Nuclear Materials Safety and Safeguards (NMSS) staff. The Designated Federal Officer must approve the agenda. The Chair will query committee members for agenda items prior to agenda preparation. A draft agenda will be provided to committee 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 committee 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 Designated Federal Officer will preside if the Chair is absent, if the Chair is recused from participating from discussion of a particular agenda item, or if directed to do so by the Commission.

1.3.3 A majority of the current membership of the Committee will be required to constitute a quorum for the conduct of business at a committee 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 committee, 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 committee member may request that any consensus statement be put before the ACMUI as a formal motion subject to affirmation by a formal vote. No committee position will be final until it has been formally adopted by consensus or formal vote, and the minutes written and certified.

2. MINUTES

2.1 The Chair will prepare detailed minutes of each ACMUI meeting (excepting meetings with the Commission for which transcripts are prepared) based on the transcripts of the meeting.

2.2 A draft of the minutes will be prepared by the Chair, assisted by NRC staff, and made available as soon as practicable to the other members. After receiving corrections to the draft minutes from the committee members, the Chair will certify the minutes. By certifying the minutes, the Chair attests to the best of his or her knowledge to the completeness and technical accuracy of the minutes.

2.3 Copies of the certified minutes will be distributed to the ACMUI members. The staff will then forward the minutes to the Public Document Room, with only deletions authorized or required by law.

3. APPOINTMENT OF MEMBERS

3.1 The members of the committee are appointed by the Commission, which determines the size of the committee. 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 Commission. The Commission has the final authority for selection. The term of an appointment to the committee is three years, and the Commission has determined that no member may serve more than 2 consecutive terms (6 years).

3.2 The Chair will be appointed by the Commission. The Chair will serve for a period of two years, and will be eligible for reappointment by the Commission for two additional two-year terms.

4. CONDUCT OF MEMBERS

4.1 If a member feels that he or she may have a conflict of interest with regard to an agenda item to be addressed by the committee, he or she should divulge it to the Chair and the Designated Federal Officer as soon as possible, but in any case before the committee discusses it as an agenda item. Committee 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 committee, 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.

5. ADOPTION AND AMENDMENTS

5.1 Adoption of these bylaws shall require a vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Nuclear Material Safety and Safeguards.

5.2 Any member of the committee or NRC 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 committee meeting.

5.3 The final proposed amendment may be voted on not earlier than the first regular meeting after it has been discussed at a committee meeting pursuant to Paragraph 5.2.

5.4 A vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Nuclear Material Safety and Safeguards shall be required to approve an amendment.

5.5 Any conflicts regarding interpretation of the bylaws shall be decided by majority vote of the current membership of the committee.

[Federal Register: February 28, 2005 (Volume 70, Number 38)]
[Notices]
[Page 9681-9682]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr28fe05-121]

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission will convene a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on April 20 and 21, 2005. A sample of agenda items to be discussed during the public sessions includes: (1) Status of Rulemaking: Pt. 35 Training and Experience; (2) Status and Update: Redefining Medical Events; (3) Case Experience in Using I-125 Seeds as Markers; (4) FDA Radiation Dose Limits for Human Research Subjects Using Certain Radiolabeled Drugs, and (5) Establishing Guidance on Exceeding Dose Limits for Members of the Public who would serve as Caregivers to Persons undergoing Radiopharmaceutical Therapy. To review the agenda, see http://www.nrc.gov/reading-rm/doc-collections/acmui/agenda/ or contact arm@nrc.gov. Furthermore, the ACMUI will brief the Commission regarding its activities, on April 20, 2005.

Purpose: Discuss issues related to 10 CFR 35, Medical Use of Byproduct Material.

Dates and Times for Public Meetings: April 20, 2005, from 8 a.m. to 5 p.m.; and April 21, 2005, from 10 a.m. to 5 p.m.

Address for Public Meetings: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852. The precise room number where the meeting will be held will be announced in reader boards located throughout the hotel.

Date and Time for Closed Session Meeting: April 21, 2005, from 8 a.m. to 10 a.m. This session will be closed so that NRC staff can brief the ACMUI on sensitive information regarding protective security measures, and so that the ACMUI can discuss internal personnel matters.

Address for Closed Session Meeting: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852. The precise room number where the meeting will be held will be announced in reader boards located throughout the hotel.

Date and Time for Commission Briefing: April 20, 2005, from 9:30 a.m. to 11:30 a.m.

Address for Commission Briefing: U.S. Nuclear Regulatory Commission, One White Flint North Building, Commissioners' Hearing Room 1G16, 11555 Rockville Pike, Rockville, MD, 20852-2738.

FOR FURTHER INFORMATION CONTACT: Angela R. McIntosh, telephone (301) 415-5030; e-mail arm@nrc.gov of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Conduct of the Meeting

Leon S. Malmud, M.D., will chair the meeting. Dr. Malmud will conduct the

[[Page 9682]]

meeting in a manner that will facilitate the orderly conduct of business. The following procedures apply to public participation in the meeting:

1. Persons who wish to provide a written statement should submit a reproducible copy to Angela R. McIntosh, U.S. Nuclear Regulatory Commission, Two White Flint North, Mail Stop T8F5, 11545 Rockville Pike, Rockville, MD 20852-2738. Submittals must be postmarked by April 1, 2005, and must pertain to the topics on the agenda for the meeting.

2. Questions from members of the public will be permitted during the meeting, at the discretion of the Chairman.

3. The transcript and written comments will be available for inspection on NRC's Web site (http://www.nrc.gov) and at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852-2738, telephone (800) 397-4209, on or about July 20, 2005. This meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily Section 161a); the Federal Advisory Committee Act (5 U.S.C. App); and the Commission's regulations in Title 10, U.S. Code of Federal Regulations, part 7.

4. Attendees are requested to notify Angela R. McIntosh at (301) 415-5030 of their planned attendance if special services, such as for the hearing impaired, are necessary.

Dated at Rockville, Maryland, this 22nd day of February, 2005.

For the Nuclear Regulatory Commission.
Andrew L. Bates,
Advisory Committee Management Officer.
[FR Doc. 05-3734 Filed 2-25-05; 8:45 am]

BILLING CODE 7590-01-P

ACMUI RECOMMENDATION AND ACTION ITEM TABLE - FY05

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)					Staff Accepted Recommendation?	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	AA	SA	Staff member Assigned	Name and Description of Recommendation or Action Item	Y, N, N/A or Partially		
Oct 2004	2005-01R	X			MRST	**RADIOIMMUNOTHERAPY AND MICROSPHERE THERAPY** Remarks: During the presentation of this topic, the discussion shifted to the Seed Selectron permanent implant remote after loader device, and the ACMUI made a recommendation regarding the Seed Selectron device. No recommendation was made regarding radioimmunotherapy and microsphere therapy. The ACMUI recommended that NRC staff continue to regulate permanent prostate brachytherapy in 10 CFR 35.1000, but use 35.400 as the regulatory framework for creating guidance, while adding elements of 10 CFR 35.600, as necessary, to that guidance.	Y	Staff agrees with the ACMUI and was aligning the guidance for the Seed Selectron closer to the requirements in 35.400 rather than 35.600. However, the development of the guidance is on hold because of lack of licensing requests for this device.	CLOSED

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)					Staff Accepted Recommendation?	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	AA	SA	Staff member Assigned	Name and Description of Recommendation or Action Item	Y, N, N/A or Partially		
Oct 2004	2005-02R	X			MRST	**RADIATION SAFETY ASPECTS OF I-125 THERAPEUTIC SEEDS USED AS MARKERS IN BREAST CANCER TUMORS** That the ACMUI be provided with a copy of the research protocol for review, before making recommendations on guidance regarding the use of I-125 seeds as markers in breast tumors.	N/A	Staff requests that the ACMUI provide a recommendation at the Spring 2005 meeting. Robert Gallaghar provided a copy of the research protocol in an e-mail on 12-2-04. NRC staff forwarded the research protocol to the ACMUI on December 2, 2004. Staff requests that the ACMUI review the protocol and provide a recommendation to staff at the Spring 2005 ACMUI public meeting. April 2005 update: Staff will schedule a teleconference call between the Spring and Fall 2005 meetings, for the ACMUI to forward its recommendations to staff. Mr. Gallaghar will be invited to participate in the teleconference.	

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)					Staff Accepted Recommendation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A	Staff member Assigned	Name and Description of Recommendation or Action Item			
Oct 2004	2005-03R	X			RGB	**DIDACTIC HOURS OF TRAINING** That the number of didactic hours of training in the draft final 10 CFR 35.390 be reduced from 200 to 80, with the total number of hours of training under 35.390 remaining at 700 hours. This motion passed with one abstention.	N/A	Staff will consider this recommendation with all other comments submitted by stakeholders, during the formal comment period.	CLOSED
Oct 2004	2005-04R	X			RGB	**GRANDFATHERING MEDICAL PHYSICISTS IN HDR, IVB, AND TELETHERAPY** That the draft language in 10 CFR 35.57 be modified to read as follows: That physicists who have been authorized to serve the function of authorized medical physicists for high dose rate brachytherapy, gamma stereotactic radiosurgery, and teletherapy be grandfathered to be allowed to serve as authorized medical physicists for those respective modalities.	N/A	Staff will consider this recommendation with all other comments submitted by stakeholders, during the formal comment period.	The discussion that led to this recommendation centered around the appropriateness of grandfathering an AMP working under a broad scope license. Such a person would not be named on the license, but would have been designated an AMP by the local Radiation Safety Committee. The ACMUI believes such individuals are entitled to being grandfathered, in the same manner as AMPs who are named on Type A licenses. CLOSED

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)					Staff Accepted Recommendation?	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	AA	SA	Staff member Assigned	Name and Description of Recommendation or Action Item	Y, N, N/A or Partially		
Oct 2004	2005-05R	X			RGB	**RECOMMENDATION TO IMPLEMENT THE DRAFT FINAL 10 CFR 35** That the staff move toward implementing the draft final 10 CFR 35, except for those items of concern raised in other recommendations during this meeting. (See Recommendation 2005-03R and 2005-04R)	N/A	The Draft Final 10 CFR 35 will move forward in the finalization process in accordance with Agency procedure. All recommendations made in association with the Draft Final 10 CFR 35 will be processed in accordance with Agency procedure.	CLOSED
Oct 2004	2005-06R	X			Mcintosh	**PROPOSED CHANGE TO ABNORMAL OCCURRENCE CRITERIA (FOR MEDICAL EVENTS)** That the staff move forward with the criteria as proposed, with the suggested changes that dose be expressed in "rem" rather than "rad", and the criteria includes language that captures events that involve the medical administration of byproduct material (or radiations therefrom).	N	Staff has given further consideration of the types of anticipated therapies that will be encountered in the future. After consideration of the nature of future therapies, staff has determined it is best to leave the expression of dose in the AO medical event criteria in terms of absorbed dose (rad) rather than dose equivalent (rem). Furthermore, so that the AO criteria is aligned with the medical event criteria in 10 CFR 35, the staff believes it is best that the AO criteria keep its existing language that requires reporting of medical events, rather than "events involving the medical administration" of material.	CLOSED

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)					Staff Accepted Recommendation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A	Staff member Assigned	Name and Description of Recommendation or Action Item			
Oct 2004	2005-07R	X			N/A	**2005 ICRP RECOMMENDATIONS** That the International Commission on Radiological Protection (ICRP) maintain in its recommendations the current occupational exposure of 500 millirem to pregnant occupational workers.	N/A	Dr. Richard Vetter, ACMUI, presented this topic to the ACMUI to gain the committee's perspective on the ICRP's draft recommendations. At the October 19, 2004 meeting to discuss the ICRP recommendations (held at NRC HQ by the Advisory Committee on Nuclear Waste) Dr. Vetter forwarded the ACMUI's recommendation, as stated to the left. No further action is required by NRC staff.	CLOSED
Oct 2004	2005-01A		X		McIntosh	**REQUEST FOR AMP STATUS - NEWARK BETH ISRAEL HOSP.**	Y	ACMUI recommended that staff not grant AMP status to the individual. Staff accepted ACMUI recommendation. TAR is viewable in ADAMS under accession # ML042090505.	E-mailed to R. Lieto and J. Williamson on 10-8-04, with a request for answer by 10-13-04, if possible. Update: Lieto and Williamson responded. TAR is with OGC as of November 23, 2004. TAR closed out 11-30-04.
Oct 2004	2005-02A			X	Sherbini	**DOSE RECONSTRUCTION** That the NRC staff provide the ACMUI a copy of the staff's conclusion of its dose reconstruction effort.	N/A	Staff provided the ACMUI with a copy of the staff's conclusion of its dose reconstruction effort, at the Oct 2004 ACMUI meeting.	CLOSED

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)					Staff Accepted Recommendation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A	Staff member Assigned	Name and Description of Recommendation or Action Item			
Oct 2004	2005-03A		X		Gersey	**MEDICAL EVENT REVIEW OF I-131 MEDICAL EVENTS** The ACMUI should review the medical events, involving misadministrations of I-131, provided at the Oct 2004 meeting and provide feedback on the events by December 2, 2004.			Staff requests that ACMUI limit its review to only those medical events staff provided to ACMUI at the Oct 2004 ACMUI public meeting. Staff notified ACMUI that the new due date is December 28, 2004. Dec 20, 2004 update: ACMUI has agreed to provide a response to staff by January 5, 2005. April 2005 update: ACMUI is scheduled to provide the NRC staff its recommendations to reduce I-131 medical events, at the April 20, 2005 ACMUI public meeting.
Oct 2004	2005-04A		X		McIntsoh	**MEDICAL EVENT REVIEW - ADDITIONAL ACMUI ACTION** Ralph Lieto, ACMUI, will search the NRC's Nuclear Materials Events Database for events related to medical events, and provide feedback that will help structure the ACMUI's review of medical events, and will also participate in an ACMUI subcommittee to review medical event trending.			

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)					Staff Accepted Recommendation?	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	AA	SA	Staff member Assigned	Name and Description of Recommendation or Action Item	Y, N, N/A or Partially		
Oct 2004	2005-A05		X		N/A	**MEDICAL EVENTS CRITERIA DEFINITION-SUBCOMMITTEE FORMATION** The ACMUI will form a subcommittee to more closely review the 20% dose threshold, as applied to medical events. The subcommittee will include Mr. Lieto and Drs. Nag, Diamond, and Williamson, with Dr. Williamson serving as Chair.	N/A	Subcommittee was formed at the Oct 2004 meeting. Members include Mr. Lieto and Drs. Nag, Diamond, and Williamson, with Dr. Williamson serving as Chair.	CLOSED
Oct 2004	2005-A06		X		Zelac	**MEDICAL EVENTS CRITERIA DEFINITION-BACKGROUND DATE AND CONTACT** NRC staff will provide pertinent data for the subcommittee to begins its work (e.g., background data on the genesis of the 20% threshold). Furthermore, NRC will provide a staff member to act as liaison to the subcommittee.	N/A	NRC staff gave the ACMUI pertinent data at the Oct 2004 meeting. Staff will provide further data, as needed, upon ACMUI request. Staff has designated Ronald Zelac, PhD, as liaison to the ACMUI subcommittee. **See also: Action Item 2005-A08**	CLOSED

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)					Staff Accepted Recommendation?	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	AA	SA	Staff member Assigned	Name and Description of Recommendation or Action Item	Y, N, N/A or Partially		
Oct 2004	2005-A07		X		RGB	**REDLINE/STRIKEOUT COPY OF DRAFT FINAL 10 CFR 35** The NRC staff will obtain the Commission's permission to publish a redline/strikeout copy of the draft final rule to the NRC website.	N/A	The deadline for comment submission toward the draft final rule was Oct 18, 2004, only 4 days before ACMUI made this recommendation. Staff was unable to produce the latest version of a redline/strikeout draft rule, approved by the Commission, within such a severe time limit. However, staff anticipates the ability to publish a redline/strikeout version of the draft final rule by (DATE)	CLOSED

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)					Staff Accepted Recommendation?	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	AA	SA	Staff member Assigned	Name and Description of Recommendation or Action Item	Y, N, N/A or Partially		
Nov 2004	2005-A08		X		Zelac	**TELECONFERENCE DISCUSSION: UPDATE TO MEDICAL EVENT CRITERIA DEFINITION** An ACMUI subcommittee will hold an information gathering and discussion (i.e., non-public) teleconference discussion to determine if the 20% dose threshold is an appropriate threshold for medical events. A second charge is to develop a strategy for effectively communicating to the public the risks, if any, associated with all classes of medical events.		The teleconference is scheduled for December 7, from 1-3:00 p.m. Subcommittee will aim to formulate recommendations to be discussed with the full ACMUI during its Spring 2005 meeting. Staff hopes to have final ACMUI recommendations at the Spring 2005 meeting. Staff will forward a Commission paper w/ACMUI recommendations. Deadline: July 31, 2005.	The teleconference held Dec 7. Items discussed and/or needing further investigation include: *permanent implant - when is treatment over? *how criteria is applied to determine when the wrong site is treated (prostate brachytherapy) *20% - can't be viewed as indicator of patient harm *need to close "loop hole" that allows AUs to change the written directive to cover up mistakes. A follow up, non-public teleconference was conducted on Jan 13, 2005, 4-6p.m. A public teleconference has been scheduled for Jan 18, 2005.
Dec 2005	2005-A09		X			**COMMENT ON OPTIONS PAPER: VISITOR RECEIPT OF DOSE IN EXCESS OF REGULATORY LIMITS** Staff e-mailed ACMUI a draft options paper that gives guidance to licensees on allowing certain visitors of patients to receive exposure in excess of regulatory limits.	N/A	Staff requested comments by January 17, 2005.	CLOSED Staff received comments from Drs. Vetter and Malmud, and Ms. Schwarz. Comments supported the staff's position, with further suggestions and considerations.

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)					Staff Accepted Recommendation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A	Staff member Assigned	Name and Description of Recommendation or Action Item			
March 2005	2005-A10		X			**COMMENT ON GENERIC ISSUES PROGRAM** Staff in Nuclear Regulatory Research requested comments from the ACMUI on the revised Generic Issues Program.	N/A	Comments requested by March 23, 2005. ACMUI Coordinator sent e-mail notification on March 14, 2005. Comments were received and forwarded to Nuclear Regulatory Research.	CLOSED

MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

October 13-14, 2004

MEETING SUMMARY

PURPOSE: To discuss issues related to the implementation of the medical regulations in 10 CFR 35, "Medical Use of Byproduct Material."

OUTCOME: The Nuclear Regulatory Commission (NRC) staff gained more understanding of the views and opinions of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), as well as other stakeholders' views and opinions. Staff will consider these views in its continuing effort to make 10 CFR 35 more useful, practical, and not overly burdensome on licensees, while maintaining public health and safety.

WEDNESDAY, OCTOBER 13, 2004

RADIOIMMUNOTHERAPY AND MICROSPHERE THERAPY

Donna-Beth Howe, PhD, NRC, presented this topic to the ACMUI. During this presentation, Dr. Howe discussed current NRC policy, regulations, and the training and experience (T&E) requirements regarding antibody-linked radionuclide therapy and microsphere therapy.

Subir Nag, MD, ACMUI, also made a presentation on this topic to the ACMUI. During this presentation, Dr. Nag discussed his views on issues regarding NRC regulation of these therapies. His general views are as follows:

- The nature of these therapies can make it difficult for the practitioner to contain the dose
- The dose distributes in a non-uniform manner in the liver (the target organ)
- Due to the size of the radioactive seeds, they behave like a liquid although they are solid

Because of the unique nature of microspheres, they are currently regulated in 10 CFR 35.1000, "Other medical uses of byproduct material or radiation from byproduct material." Nevertheless, the permanent prostate brachytherapy afterloader contains characteristics of byproduct material that is regulated under 10 CFR 35.400 as well as 10 CFR 35.600.

ACMUI Recommendation: That NRC staff continue to regulate permanent prostate brachytherapy in 10 CFR 35.1000, but use 35.400 as the regulatory framework for creating guidance, while adding elements of 10 CFR 35.600, as necessary, to that guidance.

REGISTRATION OF BRACHYTHERAPY SOURCES

John Jankovich, PhD, NRC, gave information to ACMUI regarding the background on existing registration of brachytherapy seeds and current guidance for registering seeds. Dr. Jankovich explained the requirement for registration, the standard for acceptance for sources to be placed into the registry, the contents of a registration certificate, and the conditions of normal use for brachytherapy seeds (i.e., permanent or temporary interstitial treatment.) Dr. Jankovich described the conditions of use to prepare the committee for the next presentation, "Radiation Safety Aspects of I-125 Therapeutic Seeds Used as Markers in Breast Cancer Tumors" which describes an off-label use.

RADIATION SAFETY ASPECTS OF I-125 THERAPEUTIC SEEDS USED AS MARKERS IN BREAST CANCER TUMORS

Robert Gallaghar, State of Massachusetts, made a presentation regarding the regulatory issues encountered with the off-label use of I-125 radioactive seeds as markers to delineate tumors in breast cancer patients.

Mr. Gallaghar is the chair of Pilot Project 4 of the NRC's National Materials Program (NMP) He explained that Pilot Project 4 was one of 5 pilot projects within the NMP, and that its goal is to assist the Agreement States assume their responsibility for the development of licensing and inspection guidance for the new use of radioactive material not previously reviewed and approved. The recent use of I-125 seeds as markers in breast cancer tumors is an example of such a use.

Mr. Gallaghar then discussed the genesis of I-125 seeds as markers, and explained that the use of these seeds in this manner is a new use, and therefore, not regulated in NRC's regulations. As the discussion ensued, it was noted that the greatest foreseeable risk regarding this procedure is the inadvertent damage that could be inflicted on these seeds by an electric scalpel.

Mr. Gallaghar informed the ACMUI that the Pilot Project 4 Working Group is creating guidance for the use of these seeds in this manner. Thomas Essig, NRC, asked the ACMUI if it had any specific input toward the guidance. The ACMUI believed it would more appropriate for them to first review the research protocol that demonstrates the specifics of how these seeds are being used.

ACMUI Recommendation: That the ACMUI be provided with a copy of the research protocol for review, before making recommendations on guidance regarding the use of I-125 seeds as markers in breast tumors.

STAFF FINDINGS IN THE DOSE RECONSTRUCTION EFFORT INVOLVING THE ST. JOSEPH MERCY HOSPITAL CASE

Sami Sherbini, PhD, NRC, made a presentation regarding the NRC staff response to the ACMUI's recommendations related to the staff's method of reconstructing doses in the St. Joseph Mercy Hospital case.

Dr. Sherbini explained that, as a result of letters sent to the Commission by the Society of Nuclear Medicine (SNM), the Commission directed NRC staff to engage the ACMUI to perform an evaluation of the NRC's method of dose reconstruction. Included in that review was scrutiny of the SNM's statement that the NRC had greatly overestimated the dose the member of the public received in the St. Joseph Mercy Hospital case.

In response to the Commission's direction, NRC headquarters staff thoroughly reviewed the NRC Region III's dose reconstruction efforts, as well as the ACMUI's evaluation of the case. After review of all these efforts, the NRC headquarters staff concluded that NRC Region III's dose estimate of 15 rem was the most probable estimate of dose received by the member of the public in the St. Joseph case.

The ACMUI commented that it should have been given an opportunity to review the NRC staff's conclusion before it was posted to the NRC website.

ACTION ITEM: **That the NRC staff provide the ACMUI a copy of the staff's conclusion of its dose reconstruction effort. (ITEM CLOSED).**

STATUS OF MEDICAL EVENTS

Thomas Essig, NRC; Linda Gersey, NRC, and Donna-Beth Howe, PhD, NRC, presented this topic to the ACMUI. Mr. Essig began the discussion. He explained that this will be a standing agenda item for discussion at every meeting, as a result of Commission direction that the ACMUI should provide staff with feedback and recommendations to help identify trends and reduce the occurrence of medical events. The staff will provide the ACMUI with lists of events of concern, and will solicit specific feedback from the committee.

Linda Gersey provided ACMUI with the following list of events:

- Several instances where patients received therapeutic doses instead of the prescribed diagnostic doses
- Non-registration of certain devices that have been involved in medical events
  -MICK applicator
  -ReadiStrand

ACTION ITEM: **The ACMUI should review the medical events and provide feedback on the events by December 2, 2004.**

Donna-Beth Howe, PhD, informed the committee that 35 medical events occurred in Fiscal Year 2004. Several of the events involved catheters that developed "kinks" which prevented the radioactive seed from traveling to the desired treatment area.

Ralph Lieto, ACMUI, suggested that ACMUI be allowed to review lists of events that are related to medical events, but are not themselves medical events. (For instance, on occasion, medical byproduct material is involved in transportation incidents.) Mr. Lieto affirmed that he would be willing to spearhead the gathering of data on events related to medical events, and would also be willing to serve on a subcommittee to review medical event trending.

ACTION ITEM: **Ralph Lieto, ACMUI, will search the NRC's Nuclear Materials Events Database for events related to medical events, and provide feedback that will help structure the ACMUI's review of medical events, and will also participate in an ACMUI subcommittee to review medical event trending.**

UPDATE TO MEDICAL EVENTS CRITERIA DEFINITION

Ronald Zelac, PhD, NRC, presented this topic. After a brief definition of medical events, Dr. Zelac explained that the Commission directed the staff to provide recommendations on the appropriateness of the current definition as stated in 10 CFR 35. The Commission further directed the staff to confirm, for each modality, that there is an appropriate basis for the plus or minus 20 percent dose variation threshold, and to involve the ACMUI in any recommended changes.

Some committee members believed that the 20% threshold is acceptable, although at least one member believed that it may not be entirely appropriate when applied to medical events involving brachytherapy. The committee also expressed its opinion that the agency may be overzealous regarding enforcement action against licensees whenever the 20% threshold is exceeded. However, NRC staff clarified that a medical event created by the licensee administering a dose that is above or below 20% of that prescribed, does not automatically result in enforcement action against the licensee.

ACTION ITEM: **The ACMUI will form a subcommittee to more closely review the 20% dose threshold, as applied to medical events. The subcommittee will include Mr. Lieto and Drs. Nag, Diamond, and Williamson, with Dr. Williamson serving as Chair.**

ACTION ITEM: **NRC staff will provide pertinent data for the subcommittee to begins its work (e.g., background data on the genesis of the 20% threshold). Furthermore, NRC will provide a staff member to act as liaison to the subcommittee.**

THURSDAY, OCTOBER 14, 2004

DRAFT FINAL 10 CFR 35 T&E: STATUS OF RULEMAKING

Roger Broseus, PhD, NRC, gave an update on this topic. Dr. Broseus briefed the ACMUI with the status of the training and experience (T&E) draft final rule, which proposes the addition of specified training hours to the T&E in order for a person to obtain Authorized Nuclear Pharmacist (ANP) status or Authorized User (AU) status. Dr. Broseus informed the committee that the formal end date for the comment period on the draft final rule is October 18, 2004.

The committee spent time discussing the tenor of the comments they would like to make

regarding the draft rule. Generally, there was concern regarding the connection between the alternate and the board certification pathway to AU status. The ACMUI stated that the alternate training pathway affects the board certification pathway, although they are supposed to be independent means of attaining AU status.

A related concern was the proposed hours of training a candidate would have to undergo to become a qualified AU. Several committee members expressed their belief that the staff's proposal of 200 hours of training toward the didactic training aspect of the 10 CFR 35.390 alternate pathway to AU status was excessive. All of the ACMUI, with the Agreement State member abstaining, believed that 80 hours of didactic training was sufficient.

ACTION ITEM: **The NRC staff will obtain the Commission's permission to publish a redline/strikeout copy of the draft final rule to the NRC website.**

ACMUI Recommendations:

1. **That the number of didactic hours of training in the draft final 10 CFR 35.390 be reduced from 200 to 80, with the total number of hours of training under 35.390 remaining at 700 hours. This motion passed with one abstention.**

2. **That the draft language in 10 CFR 35.57 be modified to read as follows: That physicists who have been authorized to serve the function of authorized medical physicists for high dose rate brachytherapy, gamma stereotactic radiosurgery, and teletherapy be grandfathered to be allowed to serve as authorized medical physicists for those respective modalities.**

3. **That the staff move toward implementing the draft final 10 CFR 35, except for those items of concern (for which the committee has made recommendations above) the ACMUI has brought forward.**

PROPOSED CHANGES TO ABNORMAL OCCURRENCE CRITERIA

Andrea Jones, NRC, presented proposed changes staff has made to the medical event Abnormal Occurrence criteria. The purpose of the proposed changes is to create criteria that capture events of true safety significance. These changes include:

- The addition of the phrase "unintended permanent functional damage"
- The addition of the term "tissue" to capture events where there was significant tissue damage
- Language that captures events whereby a written directive was required, but one was not prepared

The ACMUI asked the staff to consider the following:

- Amending the criteria to express dose in terms of rem instead of rad, to properly characterize exposures that involve radiation other than gamma and beta.
- Add language that captures events that occur in the medical arena, but are not "medical events," as that term is defined in 10 CFR 35.

ACMUI Recommendation: That the staff move forward with the criteria as proposed, with the suggested changes that dose be expressed in "rem" rather than "rad", and the criteria includes language that captures events that involve the medical administration of byproduct material.

ICRP 2005 RECOMMENDATIONS

Richard Vetter, PhD, ACMUI, lead the discussion on this topic. During this discussion, Dr. Vetter briefed the ACMUI on the International Commission on Radiological Protection's (ICRP) recommendations for 2005. Dr. Vetter sought an ACMUI consensus position on the 2005 recommendations, for presentation to the ACNW Working Group discussion on October 19, 2004.

Highlights of Dr. Vetter's discussion include the following points

- The ICRP intends that their recommendations influence regulatory agencies and management bodies
- ICRP recommendations define safety culture
- ICRP principles of protection require restrictions on dose, which they term "constraints"
- Exposures must be controlled.
  - The government must justify all exposures to the public that are non-medical exposures.
  - The medical profession must justify treatment to patients, by demonstrating that the treatment does more good than harm

Classes of exposure are categorized by the various groups who may encounter exposures. These groups are occupational workers, patients of medical treatments, and members of the public. Each class of exposure is assigned a dose constraint, that either the government or the medical profession should justify.

Regarding occupational radiation workers, Dr. Vetter stated that the ICRP recommended that pregnant radiation workers' limit of exposure be reduced to 100 millirem, from the current 500 millirem. This generated much discussion amongst ACMUI members, who did not agree with this proposal.

ACMUI Recommendation: That the ICRP maintain in its recommendations the current occupational exposure of 500 millirem to pregnant occupational workers.

ADMINISTRATIVE CLOSING

Angela McIntosh, NRC, lead the discussion on this topic. During this discussion, the NRC staff and the ACMUI the recommendations arising from this meeting, and discussed proposed meeting dates for the Spring 2005 meeting.

First, Ms. McIntosh reviewed the recommendations from the October 13-14, 2004 meeting. Next, Ms. McIntosh discussed the dates to hold the Spring 2005 ACMUI public meeting. The ACMUI and NRC staff set the proposed meeting dates for April 11-13, 2005; with alternate dates of April 20-22, 2005.

The meeting was adjourned at 3:20 p.m.

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