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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

TELEFAX TRANSMITTAL

DATE: January 22, 2007 NUMBER OF PAGES: 19
(including this page)

SEND TO: Stephen T. Slack, Ph.D. - Radiation Safety Officer

LOCATION: Research Medical Center

FAX NUMBER: (816) 276-3478 **VERIFY BY CALLING
SENDER**

FROM:
(SENDER) **Bill Reichhold**

TELEPHONE NUMBER (630) 829-9839 FAX NUMBER (630) 829-9782
or
(630) 515-1259

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above



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MESSAGE

Please see attached.

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone and return the original to the above address, by U.S. Mail. Thank you.

Your request to add Dr. David Shaeffer was unclear. Please provide the following additional information so we can complete the review of your request.

1. Please clarify if you wish Dr. Shaeffer authorized for the materials in 10 CFR 35.400 and 35.600. Item 1 in the "Medical Use Training and Experience and Preceptor Attestation" form (NRC Form 313A) indicates that the proposed authorization is for HDR Brachtherapy & Gamma knife, 10 CFR 35.690.

If you wish Dr. Shaeffer to use materials in 10 CFR 35.400, you will need to provide the information required by 10 CFR 35.490 and a preceptor attestation for 10 CFR 35.490 as required by 10 CFR 35.490 (a) (3).

2. Please specify the name of the supervising individual(s) in item 6a, "Work or Practical Experience with Radiation". For each supervising individual listed in item 6a, please provide a completed Item 10, "Supervising Individual - Identification and Qualifications".
3. Please specify the number of hours of experience in Item 6a, "Work or Practical Experience with Radiation". The requirement for training using 35.600 materials is 500 hours in the topics described in 10 CFR 35.690 (b) (1) (ii) (A) through (F).
4. Please specify that Dr. Shaeffer received training and work experience in topic (F), "Selecting the proper dose and how it is to be administered" as required by 10 CFR 35.690 (b) (1) (ii) (F).
5. It is unclear if Dr. Shaeffer received training and work experience preparing treatment plans and calculating treatment doses. Please clarify that Dr. Shaeffer received training and work experience in topic (B) "Preparing treatment plans and calculating treatment doses and times" as required by 10 CFR 35.690 (b) (1) (ii) (B).

Please send a facsimile of your response to the above within 7 days and refer to control 315829. Please call me at 630-829-9839 if you have any questions.

From the desk of:

Bill Reichhold

Bill Reichhold

**MEDICAL USE TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**

PART I - TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35)

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

David Shaeffer, M.D. Authorized User HDR Brachtherapy & Gammaknife, 10 CFR 35,690

35.400 ALSO?

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

Missouri Licence Number 2005 013030 Kansas Licence 0527206

3. CERTIFICATION

- a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)
- b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).
- c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.
Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS

- a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)
- b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).
- c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	Indiana University School of Medicine Dept. of Radiation Oncology	227	7-1-01 to 6-30-2005
Radiation Protection	Indiana University School of Medicine Dept. of Radiation Oncology	39.9	7-1-01 to 6-30-2005
Mathematics Pertaining to the Use and Measurement of Radioactivity	Indiana University School of Medicine Dept. of Radiation Oncology	16.5	7-1-01 to 6-30-2005
Radiation Biology	Indiana University School of Medicine Dept. of Radiation Oncology	93.5	7-1-01 to 6-30-2005
Chemistry of Byproduct Material for Medical Use	Indiana University School of Medicine Dept. of Radiation Oncology	13	7-1-01 to 6-30-2005
OTHER		17.9	7-1-01 to 6-30-2005

Name of Supervising Individual(s)

HOURS? NEED 500 hrs 35.690

NRC FORM 313A (10-2005)

U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Ordering receiving and unpacking radioactive materials safely and performing the related radiation surveys	Radiation Safety Office	13-02752-03	7-01-01 to 6-30-05
Checking survey meters for proper operation and performing measurements	Radiation Safety Office, Rad Onc. Medical Physics Staff	13-02752-03	7-01-01 to 6-30-05
Preparing, implanting, and removing sealed sources	Radiation Safety Office, Rad. Onc. Medical Physics Staff, Rad Onc. Authorized Users	13-02752-03	7-01-01 to 6-30-05
Maintaining running inventories of material on hand	Rad. Onc. Medical Physics Staff	13-02752-03	7-01-01 to 6-30-05
Using administrative controls to prevent a medical event involving byproduct material	Radiation Safety Office, Rad. Onc. Medical Physics Staff, Rad Onc. Authorized Users	13-02752-03 13-02752-08	7-01-01 to 6-30-05
Using/implementing emergency procedure a medical control byproduct material and/or respond to abnormal operation of a medical device	Radiation Safety Office Rad Onc. Medical Physics Staff, Rad Onc. Authorized Users Device Vendors	13-02752-03 13-02752-08	7-01-01 to 6-30-05
Review of the full calibration measurements and periodic spot-checks	Rad Onc. Medical Physics Staff	13-02752-03 13-02752-08	7-01-01 to 6-30-05
Preparing treatment plans and calculating treatment times	Rad. Onc. Medical Physics Staff Rad. Onc. Authorized Users.	13-02752-03 13-02752-08	7-01-01 to 6-30-05

6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Ir-192	HDR-intracavitary	14	Dr. Zimmerman, Langer, Rendell, Memphis, Cardenas, DesFosses, McGarry, La, Shidris	13-02752-03	7-01-01 to 6-30-05
Ir-192	LDR Interstitial	16	Dr. Zimmerman, Langer, Rendell, Memphis, Cardenas, DesFosses, McGarry, La, Shidris	13-02752-03	7-01-01 to 6-30-05
Ir-192	HDR Interstitial	1	Dr. Zimmerman, Langer, Rendell, Memphis, Cardenas, DesFosses, McGarry, La, Shidris	13-02752-03	7-01-01 to 6-30-05
Co-60	brain stereotactic stereotactic	8	Dr. Zimmerman, Langer, Rendell, Memphis, Cardenas, DesFosses, McGarry, La, Shidris	13-02752-03	7-01-01 to 6-30-05
	radiosurgery		Dr. Zimmerman, Langer, Rendell, Memphis, Cardenas, DesFosses, McGarry, La, Shidris	13-02752-03	7-01-01 to 6-30-05
Cs-137	LDR Intracavitary	26	Dr. Zimmerman, Langer, Rendell, Memphis, Cardenas, DesFosses, McGarry, La, Shidris	13-02752-03	7-01-01 to 6-30-05
			See attachment		

Item F - SELECTING THE PROPER DOSE AND HOW IT IS TO BE ADMINISTERED?
Item B - Preparing treatment plans and calculating treatment doses?

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)

Training Element	Type of Training *	Location and Dates
HDR Brachytherapy Device (Ir 192)	Supervised, Didactic and Vendor	Indiana University School of Medicine Radiation Oncology 7-01-01 to 6-30-05
LDR Brachytherapy Device (Cs 137)	Supervised, Didactic and Vendor	Indiana University School of Medicine Radiation Oncology 7-01-01 to 6-30-05

* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
Indiana University School of Medicine Radiation Oncology Residency Program	13-02752-03 13-02752-08	7-01-01 to 6-30-05	Accreditation Council for Graduated Medical Education

8. RADIATION SAFETY OFFICER (RSO) – ONE-YEAR FULL-TIME EXPERIENCE

- YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.
- N/A of _____ the RSO for License No. _____

9. MEDICAL PHYSICIST – ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

- YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of _____
- N/A who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

and

- YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) _____
- N/A under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) _____

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. SUPERVISING INDIVIDUAL - IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR Part 35, provide the following information for each) :

A. Name of Supervisor

See Attached

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) See Attached

for medical uses in Part 35, Section(s) See Attached

D. Address

Indiana University Medical Center
541 Clinical Drive
Indianapolis, In. 46202-5111

E. Materials License Number

13-02752-03 13-02752-08

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet training requirements in 35.590 or Part 35, Subpart J (except 35.980).

I attest the individual named in Item 1:

11a.

has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) subpart F, H 35.690, as documented in section(s) 5,6,7 of this form.

11b. Select one

meets the requirements in 35.50(e) 35.51(c) 35.390(b)(1)(ii)(G) 35.690(c) for HDR & LDR types of use, as documented in section(s) 6c of this form.

N/A

11c.

has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **OR**

has achieved a level of competency sufficient to function independently as an authorized User Radiation Oncology physician for HDR & LDR uses (or units); **OR**

has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee ; **OR**

N/A

11d.

I am an Authorized Nuclear Pharmacist; **OR** I am a Radiation Safety Officer; **OR**

I meet the requirements of section A, 10 CFR 35.57 (bx2) section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor AU or AMP

for the following byproduct material uses (or units): HDR, and LDR (10 CFR 35.600)

A. Address

Indiana University Medical Center
541 Clinical Drive
Indianapolis, In. 46202-5111

B. Materials License Number

13-02752-03, 13-02752-08

C. NAME OF PRECEPTOR (print clearly)

Mark Langer as Residency Program Director on behalf of facility group

D. SIGNATURE - PRECEPTOR

E. DATE

10/12/06

Attachment for NRC Form 313a - Section 10 - Documentation of Supervising Physicians Training and Experience

Applicant:	Shaffer, David M.D.									
Dates of Training:	7/1/03 thru 6/30/05									
Supervising MDs:	Marcus Randall, MD	Higinia Cardenes, MD, PhD	Robert Timmerman, MD	Simon Lo, MD	Paul DesRosiers, MD	Shailaja Reddy, MD	Mark Langer, MD	Ron McGarry, MD, PhD	Homayoon Shidnia, MD	James Morphis, MD
Auth. By Training Under 35.57(b)(2)	X	X	X	X	X	X	X	X	X	X
Auth. Med Uses:										
35.300 - intracavitary, intraperitoneal ³² P only	x	x	x	x	x	x				
35.400 - Manual Brachytherapy	x	x	x	x	x	x	x	x	x	x
35.600 - LDR Brachytherapy	x	x	x	x	x	x	x	x	x	x
35.600 - HDR Brachytherapy	x	x	x	x	x	x	x	x	x	x
35.600 - TBI/Teletherapy	x	x	x	x	x	x	x	x	x	x
35.600 - GSR (GammaKnife)	x		x	x	x					
35.1000 - Gliasite			x							

APPENDIX D

**Documentation of Training and Experience
To Identify Individuals on a License as
Authorized User, Radiation Safety Officer,
Authorized Medical Physicist, or
Authorized Nuclear Pharmacist**

Documentation of Training and Experience to Identify Individuals on a License as Authorized User, Radiation Safety Officer, Authorized Nuclear Pharmacist, or Authorized Medical Physicist

I. Experienced Authorized Users, Authorized Medical Physicists, Authorized Nuclear Pharmacists, or Radiation Safety Officer

An applicant or licensee that is adding an experienced authorized user, authorized medical physicist, authorized nuclear pharmacist, or radiation safety officer to its medical use license only needs to provide evidence that the individual is listed on a medical use 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 broad scope permittee before October 25, 2005 provided that the individual is authorized for the same types of use(s) requested in the application under review, and the individual meets the recentness of training criteria described in 10 CFR 35.59. When adding an experienced authorized nuclear pharmacist to the license, the applicant also may provide evidence that the individual is listed on an NRC or Agreement State commercial nuclear pharmacy license or identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy authorized to identify authorized nuclear pharmacists. For individuals who have been previously authorized by, but not listed on, the commercial nuclear pharmacy license, medical broad scope license, or master materials license medical broad scope permit, the applicant should submit either verification of previous authorizations granted or evidence of acceptable training and experience.

II. Applicants that Include Individuals for New Authorized User, Authorized Medical Physicist, Authorized Nuclear Pharmacist or Radiation Safety Officer Recognition by NRC

Applicants should complete the appropriate sections on NRC Form 313A to show that the individuals meet the appropriate training and experience criteria in 10 CFR Part 35 subparts B, D, E, F, G, H, or J (until October 24, 2005). NRC Form 313A was developed to provide a single location where six different professional groups (physicians, dentist, podiatrist, medical physicist, pharmacist, and radiation safety officer) and ten different medical sub-specialties could document completion of appropriate training and experience requirements. Therefore, some of the sections will not be applicable for each group.

There are two different training and experience routes to qualify an individual as an authorized user, authorized medical physicist, authorized nuclear pharmacist, or radiation safety officer. The first is by means of certification by a board recognized by NRC as provided in 10 CFR 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), 35.396, 35.590(a), or 35.690(a), or until October 25, 2005, a board listed in 10 CFR Part 35 Subpart J. Preceptor attestations must also be submitted for individuals to qualify under Subparts B and D through H.

The second route is by meeting the structured educational program, supervised work experience, and preceptor attestation requirements in 10 CFR Part 35, subparts B, D, E, F, G, and H. Until October 25, 2005 this route also includes the classroom and laboratory training and supervised clinical or work experience requirements in 10 CFR Part 35, Subpart J.

APPENDIX D

III. Recentness of Training

The required training and experience described in 10 CFR Part 35 must be obtained within the 7 years preceding the date of the application, or the individual must document having had related continuing education, retraining, and experience since obtaining the required training and experience. Examples of acceptable continuing education and experience include the following:

- Successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use;
- Practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization;
- Practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization; and
- For therapy devices, experience with the therapy unit and/or comparable linear accelerator experience and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant.

IV. Instructions and Guidance for Filling Out NRC Form 313A

Note: If using NRC Form 313A to document training and experience, individuals who have been certified by boards recognized by the NRC need only complete items 1, 2 and 3 of NRC Form 313A. Information for all other individuals to be listed on the license as an authorized user, authorized medical physicist, authorized nuclear pharmacist or Radiation Safety Officer must be provided in subsequent sections of NRC Form 313A.

Part I. Training and Experience

Provide information for each individual for whom authorization is sought.

Item 1. Name of individual, proposed authorization, and applicable training requirements.

Provide the individual's complete name so that NRC can distinguish the training and experience received from that received by others with a similar name, specify the type authorization being requested (Radiation Safety Officer, authorized user, authorized medical physicist, and authorized nuclear pharmacist), and applicable training requirements.

Note: Do not include personal or private information (e.g., date of birth, social security number) as part of your qualification documentation.

Item 2. State or territory where licensed

NRC requires physicians, dentists, podiatrists, and pharmacists to be licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine, practice dentistry, practice podiatry, or practice pharmacy, respectively (see definition of "Physician" in 10 CFR 35.2).

Item 3. Certification

The applicant should provide a copy of the board certification or provide the complete name of the specialty board and the category (or subspecialty) if the board recognizes more than one certification specialty. Applicants should provide all of the information noted under Item 3, attending to the requirements for different pathways to approval. Data provided about the month and year certified is used to establish recentness of training, to confirm that NRC recognizes¹ that board's certifications, and to verify that the applicant meets the training requirements.

If an individual to be listed on the license as an authorized user, authorized medical physicist, authorized nuclear pharmacist, or Radiation Safety Officer cannot meet requirements for board certification pathway, the applicant must fill out the appropriate remaining sections of NRC Form 313A and must submit a written attestation signed by a preceptor (see Part II of NRC Form 313A).

Item 4. Individuals Identified on a License or Permit as Radiation Safety Officers (RSO), Authorized Users (AU), Authorized Medical Physicists (AMP), or Authorized Nuclear Pharmacists (ANP) Seeking Additional Authorizations.

The applicant should provide a copy of the license or broadscope permit listing his or her current authorization, and also complete the items listed under either 4.b or 4.c, depending on the authorization sought.

Item 5. Classroom and Laboratory Training or Didactic Training, 6a. Work or Practical Experience with Radiation, 6b. Supervised Clinical Case Experience, and 6c. Training for Sections 35.50(e), 35.51(c), 35.590(c), or 35.690(c).

Because the applicant is not required to receive the training described in Item 5 at one location or at one time, space is provided to identify each location and date of training. The clock hours must be indicated for those individuals that must meet a minimum number of training and work experience hours. The specific number of hours needed for each training element will depend upon the type of approval sought.

While most applicants will only complete Item 6a, those who must document clinical case experiences (e.g., physicians seeking authorization for uses under 10 CFR 35.300 and strontium-90 eye applicator users) should document this in Item 6b.

Item 6c. should be completed by applicants for Radiation Safety Officer, Authorized Medical Physicist, or for use of sealed sources for diagnosis, or remote afterloader units, teletherapy units or gamma stereotactic radiosurgery units as required in 10 CFR 35.690.

Note: Classroom and Laboratory Training or Didactic Training may be provided at medical teaching/university institutions. In some cases, a course may be provided for that particular need and taught in consecutive days; in others, the period may be a semester or quarter as part of the formal curriculum. The required "structural educational programs" or "training" may be

¹ The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page <<http://www.nrc.gov/materials/miau/med-use-toolkit.html>>.

APPENDIX D

obtained in any number of settings, locations, and educational situations. If the applicant is seeking authorization under the requirements of 10 CFR Part 35 subparts B, D, E, F, G, and H, applicants must submit a written attestation signed by a preceptor, indicating the individual for whom approval is sought meets training requirements of applicable sections and has achieved a level of competency sufficient to function independently. Preceptor statements are also required for ANPs approved under Subpart J (§35.980(a)).

The NRC expects that clinical laboratory hours 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 through 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.

Item 7. Formal Training

This item is completed for individuals qualified to be medical physicists or physicians meeting the requirements in 10 CFR 35.490, 35.690, 35.940, and 35.960.

Item 8. Radiation Safety Officer – One Year Full-Time Work Experience

This item is used to document that the applicant meets the regulatory requirement of one full year of full time work experience in the areas which are listed in Item 6a.

Item 9. Medical Physicist – One-Year Full-Time Training and Experience

This section is used to document that the Medical Physicist has received one full year of full time training and one full year of work experience. Both are required to be under the supervision of an authorized medical physicist but they do not have to be under the same medical physicist.

Item 10. Supervising Individual

Item 10 need only be completed by an applicant seeking to have an individual listed on the license as an AU, RSO, or AMP under Part 35 Subparts B, D, E, F or H. If an applicant is following the training and experience requirements in Subpart J, it is sufficient to identify the supervising individual and licensed facility in Items 6a and 6b. In addition, the use of Item 10 is also dependent on whether information on the identity, qualifications and location (license number) of the supervising individual has already been provided elsewhere on NRC Form 313A (e.g., in Items 8 or 9).

→ *Note: If the individual had more than one supervisor, all supervising individual names must be listed in Items 6a and 6b and Item 10 filled out for each.*

Note: The authorized nuclear pharmacist applicant is required to have supervised practical experience in a nuclear pharmacy but the individual(s) providing the supervision are not specified. Therefore the applicant does not need to identify a supervising individual in Item 6a or complete Item 10.

Part II Preceptor Attestation

The NRC defines the term "preceptor" in 10 CFR 35.2, "Definitions," to mean "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." While the supervising individual for the work experience may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. The preceptor must attest in writing regarding the training and experience of any individual to serve as an authorized user, authorized nuclear pharmacist, authorized medical physicist or radiation safety officer (pursuant to 10 CFR Part 35, Subparts B, C, D, E, F, or H and 10 CFR 35.980) and attest that the individual has satisfactorily completed the appropriate training and experience criteria and has achieved a level of competency or a level of radiation safety knowledge sufficient to function independently. This preceptor also has to meet specific requirements.

The NRC recognizes supervised work experience, such as that described in 10 CFR 35.290(c), conducted under the supervision of an authorized user in a licensed material use program. A supervisor is an AU who provides frequent direction, instruction, and direct oversight of the student as the student completes the required work experience in the use of byproduct material. Supervision may occur at various licensed facilities, from a large teaching university hospital to a small private practice. However, work experience for sealed source therapy, as described in 10 CFR 35.490(b)(1), 10 CFR 35.491(b)(2), and 10 CFR 35.690(b)(1) must have been gained at a medical institution. When the supervised work experience is complete, the applicant should provide documentation of it using NRC Form 313A or equivalent, and written attestation from the preceptor using NRC Form 313A or equivalent that indicates that the applicant has obtained all required experience elements. These documents should be submitted as attachments to NRC Form 313, "Application for Material License."

An applicant requesting authorized nuclear pharmacist status for a pharmacist under 10 CFR 35.980(b) is required to provide a different attestation statement than for a pharmacist under Subpart B, 10 CFR 35.55. Information may be provided in Item 11a needed to meet the requirements under 10 CFR Part 35, Subpart J. Space is provided in Items C and D for the preceptor authorized nuclear pharmacist's name and signature.

Item 11

Item 11 has four components: The information in 11a. attests that the applicant has satisfactorily completed the training and supervised work experience requirements; the information in 11b. attests that the applicant meets the requirements in 35.50(e), 35.51(c), 35.390(b)(1)(ii)(G), 35.690(c) for specified types of uses; the information in 11c. attests that the applicant has the competency to function independently; and the information in 11d. attests that the preceptor is an

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Authorized Nuclear Pharmacist or Radiation Safety Officer or meets the requirements to be a preceptor AU, AMP, and requires the preceptor's signature.

(2) Lodged within the patient following removal of the source applicators.

(c) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible the patient or human research subject has a medical emergency or dies.

§ 35.432 Calibration measurements of brachytherapy sources.

(a) Before the first medical use of a brachytherapy source on or after October 24, 2002, a licensee shall have—

(1) Determined the source output or activity using a dosimetry system that meets the requirements of § 35.630(a);

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(b) Instead of a licensee making its own measurements as required in paragraph (a) of this section, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (a) of this section.

(c) A licensee shall mathematically correct the outputs or activities determined in paragraph (a) of this section for physical decay at intervals consistent with 1 percent physical decay.

(d) A licensee shall retain a record of each calibration in accordance with § 35.2432.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003]

§ 35.433 Decay of strontium-90 sources for ophthalmic treatments.

(a) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432.

(b) A licensee shall retain a record of the activity of each strontium-90 source in accordance with § 35.2433.

§ 35.457 Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine sealed source positions from radiographic images.

§ 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 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 a 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; c

(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 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 completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490 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)(i) of this section; and

✕ (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in § 35.490 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.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003; 69 FR 55739, Sep. 16, 2004; 70 FR 16366, Mar. 30, 2005; 71 FR 15010, Mar. 27, 2006]

§ 35.491 Training for ophthalmic use of strontium-90.

(e) A licensee shall retain a record of each check required by paragraph (b) of this section in accordance with § 35.2647.

§ 35.652 Radiation surveys.

(a) In addition to the survey requirement in § 20.1501 of this chapter, a person licensed under this subpart shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by paragraph (a) of this section in accordance with § 35.2652.

§ 35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing in accordance with § 35.2655.

§ 35.657 Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine sealed source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

§ 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 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 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 therapy, under an authorized user who meets the requirements in § 35.690 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 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.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19326, Apr. 21, 2003; 69 FR 55739, Sep. 16, 2004; 70 FR 16366, Mar. 30, 2005; 71 FR 15011, Mar. 27, 2006]

Subpart I--[Reserved]

Subpart J--[Reserved]

Subpart K--Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

§ 35.1000 Other medical uses of byproduct material or radiation from byproduct material.

A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if--

(a) The applicant or licensee has submitted the information required by § 35.12(b) through (d); and

(b) The applicant or licensee has received written approval from the Commission in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.

Subpart L--Records

§ 35.2024 Records of authority and responsibilities for radiation protection programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by § 35.24(e), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by § 35.24(b), for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

§ 35.2026 Records of radiation protection program changes.

A licensee shall retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

§ 35.2040 Records of written directives.

A licensee shall retain a copy of each written directive as required by § 35.40 for 3 years.

§ 35.2041 Records for procedures for administrations requiring a written directive.

A licensee shall retain a copy of the procedures required by § 35.41(a) for the duration of the license.