



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
801 Warrenville Road, Suite 255  
Lisle, Illinois 60532-4351

TELEFAX TRANSMITTAL

DATE: 2/15/05

NUMBER OF PAGES: 9  
(including this page)

SEND TO: ALVIS FOSTER, M.S.

LOCATION: BALL MEMORIAL CANCER CENTER

FAX NUMBER: 765-751-5250  VERIFY BY CALLING SENDER

FROM: (SENDER) COLLEEN CAROL CASEY

TELEPHONE NUMBER: 630-829-9841 FAX NUMBER: 630-829-9782

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

MESSAGE

*Please call me to discuss this.*

*Thank you.*

*Colleen Carol Casey*

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.

TRANSMISSION VERIFICATION REPORT

TIME : 02/15/2005 14:32  
NAME : USNRC  
FAX : 6308299782  
TEL : 6308299782

DATE, TIME : 02/15 14:29  
FAX NO./NAME : 87657515250  
DURATION : 00:03:00  
PAGE(S) : 09  
RESULT : OK  
MODE : STANDARD  
ECM

U-AN-2



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MESSAGE

*Please call me to discuss this.*

*Thank you.*

**COLLEEN CAROL CASEY  
MATERIALS LICENSING BRANCH  
UNITED STATES NUCLEAR REGULATORY COMMISSION**  
REGION III  
2443 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4352  
OFFICE: (630)-829-9841 FAX: (630) 829-9782 or (630) 515-1259

<b>CONVERSATION RECORD</b>	TIME	DATE
<b>ACTUALLY FAXED? YES.</b>		15 February 14, 2005
NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
Alvis Foster, MS., RSO for Ball Memorial Cancer Center		765-747-4440
SUBJECT		
License No.: 13-00951-03	Control No.: 313905	

**SUMMARY**

We have reviewed your letter dated November 9, 2004, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

1. **Please clarify whether Dr. Lin completed 500 hours of supervised work experience performing the tasks specified in 10 CFR 35.490(b)(1)(ii) and 35.690(b)(1)(ii) during her residency program (see attached excerpts, marked).**
2. **Dr. Lin's preceptor forms show she completed only 49.5 hours of actual clinical training, under the supervision of 4 different preceptors, over a four year period. Please note that three years of supervised clinical experience in radiation oncology is required by 10 CFR 35.490(b)(2) and 35.690(b)(2) (see attached excerpts, marked). Please explain this significant discrepancy in actual supervised clinical training hours.**
3. **Dr. Lin's preceptor forms show 4 different preceptor physician's supervised her training. However, only Dr. Ajlouni signed the preceptor form and, as noted in my letter dated June 8, 2004, I cannot verify Dr. Ajlouni as a qualified preceptor because Henry Ford Hospital is a broad scope licensee. Please see attached copy of my June 8, 2004 letter to you, marked section A.1.**

**Each preceptor physician must submit a currently dated and signed form supporting Dr. Lin under the Henry Ford license AND a letter, currently signed and dated by the Chairman of the Radiation Safety Committee at Henry Ford Hospital, attesting that each preceptor physician was an authorized user for the use of materials in 10 CFR 35.490 and 35.690 during the July 1, 2000 to June 30, 2004 timeframe when Dr. Lin was being trained. Please submit these documents.**

4. **Please note again and be reminded of the requirements in 10 CFR 30.9, which states, in part, that "(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the**

**licensee shall be complete and accurate in all material respects.” Your letter dated November 9, 2004, is your second unsuccessful attempt to name Dr. Lin to this license based upon incomplete and inaccurate information. Please ensure that your response is complete and accurate in all material respects.**

5. Please also note, for the sake of accuracy, that Dr. Lin’s first application to be named to this license was not “rejected as it was filed prior to the completion of Dr. Lin’s training.” The first application was not rejected; it simply was not acceptable support of Dr. Lin’s request. I provided several reasons for the unacceptable support in my letter dated June 8, 2004, attached, none of which stated that the cause was Dr. Lin’s not having completed her training. The problem was Dr. Lin appeared to have claimed she completed her training three and a half months before the scheduled completion of her training. This is a significant difference. You do not need to respond to this item.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC’s web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS.

The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or [pdr@nrc.gov](mailto:pdr@nrc.gov).

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ACTION REQUIRED

Please submit your response to my attention at the above address and reference control number 313905 to facilitate proper handling. Note that this is a different control number than the previous one you used.

As we cannot issue an amendment at this time we are voiding this request in order to enable you to prepare a quality application without time constraints. PLEASE NOTE THAT A “VOID” IS AN ADMINISTRATIVE PROCEDURE THAT PUTS YOUR AMENDMENT REQUEST “ON HOLD” (TAKES IT OUT OF OUR ACTIVE CASEWORK DATABASE) UNTIL YOU REACTIVATE IT VIA SUBMISSION OF A WRITTEN RESPONSE. IT “BUYS” YOU TIME TO PREPARE A QUALITY RESPONSE AND IS GENERALLY REGARDED AS A “GOOD THING.”

**PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT 630-829-9841.**

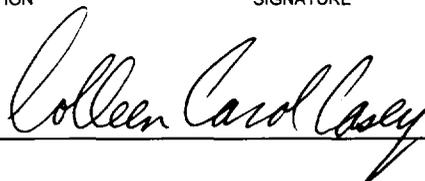
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NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Colleen Carol Casey



February 15<sup>th</sup>, 2005

## PART 35 • MEDICAL USE OF BYPRODUCT MATERIAL

**§ 35.690 Training for use of remote  
reloader 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 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 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 equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

#### Subpart I—[Reserved]

#### Subpart J—Training and Experience Requirements

##### § 35.900 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 the—

(1) American Board of Health Physics in Comprehensive Health Physics;

(2) American Board of Radiology;

(3) American Board of Nuclear Medicine;

(4) American Board of Science in Nuclear Medicine;

(5) Board of Pharmaceutical Specialties in Nuclear Pharmacy;

(6) American Board of Medical Physics in radiation oncology physics;

(7) Royal College of Physicians and Surgeons of Canada in nuclear medicine;

(8) American Osteopathic Board of Radiology; or

(9) American Osteopathic Board of Nuclear Medicine; or

(b) Has had classroom and laboratory training and experience as follows—

(1) 200 hours of classroom and laboratory training that includes—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(v) Radiopharmaceutical chemistry; and

(2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material; or

(c) Is an authorized user identified on the licensee's license.

##### § 35.910 Training for uptake, dilution, and excretion studies.

Except as provided in § 35.57, the licensee shall require the authorized

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## PART 35 • MEDICAL USE OF BYPRODUCT MATERIAL

of 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 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 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 obtained 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 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, 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 (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 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 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;



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REGION III  
2443 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4352

JUN 08 2004

Alvis E. Foster, M.S.  
Radiation Safety Officer  
Ball Memorial Hospital  
2401 W. University Avenue  
Muncie, IN 47303

Dear Mr. Foster:

Enclosed is Amendment No. 68 to your NRC Material License No. 13-00951-03 in accordance with your request. Please note that the changes made to your license are printed in **bold font**.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

- A. 1. Please note that I could not approve Yunjie Xie Lin, M.D. as an authorized user for the use of material in 10 CFR 35.400, 35.600 and 35.1000 because her training and experience do not appear to meet the requirements in 10 CFR 35.490, 35.940 and 35.690.

If you wish to pursue this request, please submit evidence that Dr. Lin's training and experience clearly meets the above regulatory requirements. Please send your response to my attention at the above address as "additional information to control number 313176." You may refer to NUREG 1556, Vol. 9, Section 8.7, Item 11, and Appendices B, D and E for assistance.

We noted that your letter dated March 16, 2004, lists training and experience activities for Dr. Lin projected through June 30, 2004. It is not clear to me how Dr. Lin can claim to have completed training through June 30, 2004, in a letter dated March 16, 2004, three and a half months before the scheduled completion of her training.

Please explain this discrepancy and please be reminded of the requirements in 10 CFR 30.9, which states, in part, that "(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects." A copy of 10 CFR Part 30 is enclosed for your use.

Please also note that we will be unable to verify Dr. Lin's preceptor, Dr. Munther Ajlouni, because Dr. Ajlouni lists a broad scope license at Henry Ford Hospital as the license under which s/he conducted Dr. Lin's training. Broad scope licenses do not list Authorized Users on the license itself. The Radiation Safety Committee evaluates and approves/disapproves Authorized Users internally.

Please provide a letter, currently signed and dated by the Chairman of the Radiation Safety Committee at Henry Ford Hospital, attesting that Dr. Ajlouni was an authorized user for the use of materials in 10 CFR 35.490 and 35.690 during the timeframes when Dr. Lin was being trained by him or her.

2. Your amendment has been prepared in accordance with newly revised 10 CFR Part 35. Since revised 10 CFR Part 35 has become effective and NUREG 1556, Vol. 9, Final, has been issued, please use these new documents to prepare future licensing correspondence. 10 CFR Part 35 and NUREG 1556, Vol. 9, Final, should have been sent to you automatically and are available, respectively, on our website at:

"<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/> " and

"<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/nureg-1556-9.pdf> "

Using the above regulation and guidance, especially the NUREG 1556 series documents, will help ensure that your licensing correspondence is prepared more completely and in a less burdensome manner. You may realize the benefit of a reduced regulatory burden while enhancing safety and maintaining compliance and efficiency if you establish your license in this manner.

3. If you have further questions concerning these matters please contact me at (630) 829-9841 or (800) 522-3025.

- B. Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations.

In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days, pursuant to 10 CFR 35.14:
  - a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
  - b. When the mailing address listed on the license changes.

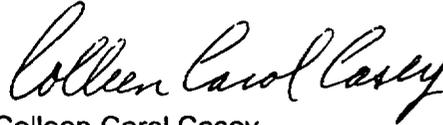
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when a decision is made to terminate all activities involving materials authorized under the license.
4. Request and obtain a license amendment before you:
  - a. Change Radiation Safety Officers, except as provided in 10 CFR 35.24(c);
  - b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
  - c. Add or change the areas of use or the address or addresses of use identified in the license application or on the license, pursuant to 10 CFR 35.13(e), 10 CFR 35.13(f) and 10 CFR 35.14(b)(4); or
  - d. Change ownership of your organization.
5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for an application for medical use must be the licensee's management, as required by 10 CFR 35.12(a).

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

A handwritten signature in cursive script that reads "Colleen Carol Casey".

Colleen Carol Casey  
Materials Licensing Branch

License No. 13-00951-03  
Docket No. 030-01586

Enclosures:

1. Amendment No. 68
2. 10 CFR Part 30
3. 10 CFR Part 35
4. NUREG 1556, Vol. 9