



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 9/6/08

NUMBER OF PAGES: 9
(including this page)

SEND TO: Terri Wade / Zhongshan (John) Zheng, MSc.

LOCATION: Oncology Hematology Associates

FAX NUMBER: 812-485-5719 **VERIFY BY CALLING SENDER**

FROM: COLLEEN CAROL CASEY
(SENDER)

TELEPHONE NUMBER: 630-829-9841 FAX NUMBER: 630-515-1078

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

MESSAGE

*I will be out of the office 9/8-12/08.
If you would like to schedule a Conference call to discuss these matters further, please call me + leave a message as to which date + time is best for you, between 9/15 (afternoon) - 9/19, or thereafter.*

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.

COLLEEN CAROL CASEY
MATERIALS LICENSING BRANCH
UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352
OFFICE: (630)-829-9841 FAX: (630) 515-1078

CONVERSATION RECORD

|TIME

|DATE

ACTUALLY FAXED? YES.

September 6, 2008

NAME OF PERSON(S) CONTACTED

ORGANIZATION

TELEPHONE Nos.

Terry Wade or

Zhongshan (John) Zhang, MSc., DABR, proposed AMP for
Oncology Hematology Associates of Southwest Indiana

573-406-5814

FAX: 812-485-5719

SUBJECT

License No.: PENDING

Control No.: 317233

SUMMARY

We have reviewed your application dated June 2, 2008, and your fax dated August 26, 2008, requesting a new byproduct materials license and find that we need additional information as follows:

At this time I was unable to approve your request to issue a new byproduct materials license for the use of certain diagnostic materials, sealed and unsealed, and an HDR remote afterloading brachytherapy device because the information provided in your application dated June 2, 2008, and your fax dated August 26, 2008, was insufficient to complete my review.

- 1. The Sealed Source and Device Registry (SSDR) certification authorizes two different HDR devices for the use of the source VS 2000 you requested. Your application in Attachment A1 was unclear as to which model of Varian HDR device you wanted to be licensed for. Please make explicit commitments describing which model of HDR device you want to become licensed for.**

In addition, your fax changed your total requested possession of Ir-192 to 20 Ci but you did not specify how you wanted that authorized. I would suggest that one source be no greater than 12 Ci for receipt (so it can decay to 10 by installation date) and that one source be no greater than 8 Ci. Please confirm this authorization or propose an alternative.

- 2. Your application in Attachment A1 was also unclear as to what you wanted to be licensed for in terms of diagnostic materials, both sealed and unsealed, i.e., materials in 10 CFR 35.200 or F-18 and materials in "10 CFR 35.500, Ge/Ga-68." Also, the model no. of the sealed source is given as "A34 series," which is unacceptable as it applies to different devices. Please determine exactly which sealed sources**

your want, by model no. and specify which device, by model no. you wish to be licensed for.

3. As your diagrams consisted of copies of blueprints, which we strongly discourage submitting, I was unable to gain a full understanding of your proposed HDR facilities. Please provide revised diagrams (simple, hand-drawn diagrams are good) that clearly show the HDR treatment room and the location and functional identity of all contiguous rooms, areas and/or spaces surrounding it, especially the areas above and below the room. Some of this information was included in your letter but some of it was not or was difficult to decipher.

Your diagrams should be either drawn to scale or actual dimensions given; room numbers provided; show the direction of north; the functional identity of each room, space or area; the elevation/grade clearly described; indicate where you anticipate the patient to be located; the composition and thickness of each barrier in each direction; whether each area is restricted or unrestricted; and the distances from the source to the barriers/walls in all directions.

Please do not submit blueprints or copies of blueprints for HDR facilities. Simple hand-drawn diagrams containing only the information requested in NUREG 1556, Vol. 9, Rev. 2, sections for HDR are best. (Note Rev. 2 is on our website for Pt. 35 medical licensing.)

Please indicate clearly whether persons may gain access to an area above or below the proposed HDR treatment room. If this area may be occupied during treatment, please either submit exposure rate calculations to demonstrate that the doses received will not exceed the limits in 10 CFR 20.1301 or describe the administrative controls (training, posting, surveillance, lock-out, etc.) that will be put in place to prevent occupation during HDR treatment.

Please note that it is my understanding that you will not be permitted to install a sealed source containing greater than 10 curies of iridium-192. Please explain and justify your request to install greater than 10 curies of iridium-192 in the HDR device or confirm that you will only install and use the device when it contains a sealed source less than or equal to 10 curies.

Please provide revised and simple shielding calculations, showing your work, detailed assumptions, defined terms, equations, constants, substitutions, parameters, and diagrams to demonstrate that radiation levels in all adjacent areas, including above and below the room, will not exceed levels in 10 CFR 20.1301.

Please include your calculations for the barrier transmission factors and indicate whether poured concrete is the only barrier employed.

It appeared to me that the calculations already submitted were based upon assumptions involving a linear accelerator. Please confirm that your shielding calculations, as revised, will be based only upon the HDR device.

Please indicate the thinnest wall/barrier – is it three feet of poured concrete?

Please indicate the elevation of your proposed facility.

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Include the following details in your submission:

- a. expected radiation levels for each adjacent area, under the most adverse and typical source orientations and maximum source activity;
- b. all parameters used to perform the calculations, including: distance to each area of concern, the type and thickness of material(s) used as shields, and the transmission factor of the shields;
- c. the maximum "beam-on time" per hour and per week; the number of patients/treatments (i.e., workload) per week; and occupancy factors used for all adjacent areas; and
- d. demonstrate by calculation the dose received by the individual member of the public likely to receive the highest dose from HDR procedures when present in unrestricted area (in mrem/hr and mrem/yr). These calculations must demonstrate that the limits specified in 10 CFR 20.1301(a) will not be exceeded.
- e. Please include in your shielding calculations sufficient information, in a simple, readily understandable format using traditional units (preferred) to permit us to independently evaluate the adequacy of shielding in your proposed room.

It may be helpful for you to refer to 10 CFR 35.600-35.657 (Subpart H) and corresponding sections in NUREG 1556, Vol. 9, Rev. 2 for assistance.

Please note that we no longer use the HDR licensing guidance that was in place from ~1993 to April 2002 because 10 CFR 35 Subpart H and NUREG 1556, Vol. 9, Final superseded it. (This information is provided because it appeared to me that your application was based largely upon this outdated guidance. Your application contained a significant amount of extraneous information that we do not ask for or need for applications such as yours. The old guidance ceased to be used in April 2002 when revised 10 CFR 35 became effective.)

4. Please specify what you want your proposed Authorized Users to be authorized for, with the exception of Drs. Miller and Kim, whom you already have specified authorization for.

In addition, please clarify the spelling of Dr. Sutkowski's name. His name appears as "Sutkowski" on the referenced license but your application lists his name as "Sutkokski."

5. Please briefly describe the following for your proposed HDR program:
 - a. Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for the proposed HDR treatment room;
 - b. area radiation monitoring equipment;

- c. Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation- producing equipment (e.g., linear accelerator, X-ray machine, etc.) is in the HDR treatment room; and,
- d. Methods to ensure that whenever the HDR device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons.

6x. Please provide the procedures, required by 10 CFR 35.643, "Periodic spot-checks for remote afterloader units," which briefly describe "how you will do things" instead of reiterating the requirements in 35.643. Please see the attached marked up copy of 35.610, which indicates which procedures we need.

7x. Please provide the procedures required by 10 CFR 35.610, "Safety procedures and instructions for remote afterloader units.....," which briefly describe how you will do things, instead of reiterating the requirements in 35.643. Please see the attached marked up copy of 35.610, which indicates which procedures we need.

8x. Please note that we are unable to approve Zhongshan (John) Zhang, MSc, DABR, as the RSO for this license at this time. The referenced license submitted in support of your request shows him as the AMP for that license but we cannot accept that credential alone so make him RSO. Please submit appropriate preceptor attestations, signed and dated by an appropriate RSO, to demonstrate that Mr. Zhang meets the requirements in 10 CFR 35.50 (d) and (e). Since Mr. Zhang appears as an AMP on at least one other current NRC license, this should be reasonably simple to comply with.

9x. Part of your application (Attachment B1) refers to a "Room" without a number given, and part of your application (Attachment B3.VI.) refers to a room number for the HDR device. Please provide the full correct street address and room number for the HDR device.

Please also provide the full correct street address and room numbers for the use of the diagnostic sealed and unsealed materials.

10x. Please withdraw your Quality Management Program (QMP) from Attachment B-6, as we have not had QMP since April 2002, when revised 10 CFR Part 35 became effective.

11x. Please, for future reference, paginate your correspondence to us. This is a "no response item."

12x. In reviewing your website, as part of our pre-licensing verification, I noticed that your website refers to Intraoperative HDR use. You have not requested this authorization. Please clarify this issue and please also clarify whether St. Mary's Medical Center, whose HDR device you plan to acquire, is being used for Intraoperative HDR treatments and whether such use is authorized on the St. Mary's license.

If you have any questions concerning this information above please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is (630) 515-1078.

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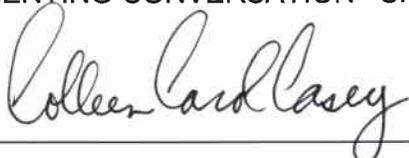
In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

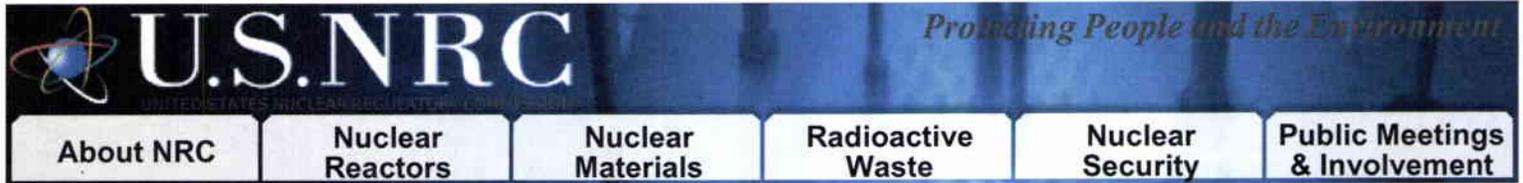
ACTION REQUIRED

As we cannot issue your new license at this time we are voiding this request in order to enable you to prepare a quality response without time constraints. This is done without prejudice to the resubmission of your request at a later date. Upon receipt of your response we will resume our review. Address your written response to my attention at the above address.

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 or (800) 522-3025, ext. 9841.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	Date
Colleen Carol Casey		September 6, 2008



[Home](#) > [Electronic Reading Room](#) > [Document Collections](#) > [NRC Regulations \(10 CFR\)](#) > [Part Index](#) > § 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

§ 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

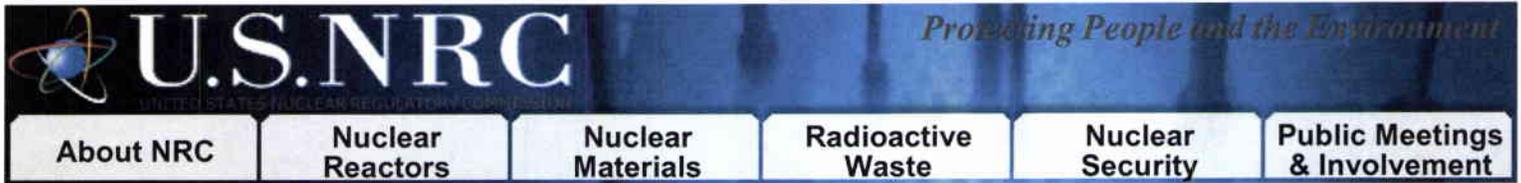
- (a) A licensee shall-- *Please address everything, briefly, unless marked out (marked out means it's already in your application correctly)*
- (1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;
 - (2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);
 - (3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and
 - (4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include--
 - (i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
 - ~~(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and~~
 - ~~(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.~~
- (b) A copy of the procedures required by paragraph (a)(4) of this section must be physically located at the unit console.
- (c) A licensee shall post instructions at the unit console to inform the operator of--
- (1) The location of the procedures required by paragraph (a)(4) of this section; and
 - ~~(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.~~
- ~~(d) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in--~~
- (1) The procedures identified in paragraph (a)(4) of this section; and
 - (2) The operating procedures for the unit.
- (e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.
- (f) A licensee shall retain a record of individuals receiving instruction required by paragraph (d) of this section, in

accordance with § 35.2310.

(g) A licensee shall retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) in accordance with § 35.2610.

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Friday, August 08, 2008

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[Home](#) > [Electronic Reading Room](#) > [Document Collections](#) > [NRC Regulations \(10 CFR\)](#) > [Part Index](#) > § 35.643 Periodic spot-checks for remote afterloader units.

§ 35.643 Periodic spot-checks for remote afterloader units.

Please address all, except as marked out.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit--

(1) Before the first use of a high dose-rate, ~~medium dose-rate, or pulsed dose-rate~~ remote afterloader unit on a given day;

(2) ~~Before each patient treatment with a low dose-rate, remote afterloader unit;~~ and

(3) After each source installation.

(b) A licensee shall perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) To satisfy the requirements of paragraph (a) of this section, spot-checks must, at a minimum, assure proper operation of--

(1) Electrical interlocks at each remote afterloader unit room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

~~(4) Emergency response equipment;~~

(5) Radiation monitors used to indicate the source position;

~~(6) Timer accuracy;~~

(7) Clock (date and time) in the unit's computer; and

(8) Decayed source(s) activity in the unit's computer.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by paragraph (d) of this section and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2643.

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TRANSMISSION VERIFICATION REPORT

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REGION III
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LOCATION: Oncology Hematology Associates

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FROM: (SENDER) COLLEEN CAROL CASEY

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MESSAGE I will be out of the office 9/8-12/08.
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