



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

TELEFAX TRANSMITTAL

DATE: 4/7/08

NUMBER OF PAGES: 5
(including this page)

SEND TO: KEN WOHLT

LOCATION: JAMES E. CARY CANCER CENTER

FAX NUMBER: 573-466-5832 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 *Please call me to discuss if you have questions.*
Thanks!
Colleen

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.	Afternoon	April 7, 2008

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE Nos.
Kenneth Wohlt, proposed AMP for James E. Cary Cancer Center	573-406-5814	FAX: 573-406-5832

SUBJECT
License No.: 24-02490-03 Control No.: 316786

SUMMARY

We have reviewed your application dated January 15, 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 a HDR (my default assumption, see item 1) remote afterloading brachytherapy device because the information provided in your application dated January 15, 2008, was insufficient to complete my review.

1. The device you propose to obtain can be used for high dose rate remote (HDR) remote afterloading brachytherapy, pulsed dosed rate remote afterloading brachytherapy or both. Your application did not make it clear which of these modalities you wanted to be licensed for. Please make explicit commitments describing the modality you want to become licensed for. (Note that if you are only licensed for ONE modality now, the license will need to be amended at a later date to become licensed for the other modality.)
2. 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 was finalized since your application was submitted, it 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.

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

Please indicate the elevation of your proposed facility.

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. 1 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 only in case you were unaware of it.)

3. 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. viewing and intercom systems; 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.
4. 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.
5. 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.
6. Please note that we are unable to approve you as the RSO for this license at this time. The referenced license submitted in support of your request shows you as RSO for another license but that license did not authorize HDR remote afterloading brachytherapy, so we cannot accept it.

In our telephone discussion on April 7, 2008, you suggested that Mark Bryer, M.D. might become the RSO. It appears he is qualified in accordance with 10 CFR 35.2, "Definitions," as he is a current RSO on another NRC license that authorizes HDR. Please submit supporting information, briefly, for Dr. Bryer in response, including the following:

If Dr. Bryer is to become your new proposed RSO please submit a currently signed and dated "Delegation of authority" for him, including his signature and senior management's signature, in which he agrees to serve as RSO for the license and he accepts and understands the duties and responsibilities associated with the license.

Also as we discussed, this action will be voided for the time being while you research and prepare a response. Please contact me with proposed dates when it will be possible to conduct the pre-licensing site visit. I was reminded that this visit must occur after you submit your responses to this record but we can begin to coordinate scheduling it now.

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.

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		April 7, 2008,

TRANSMISSION VERIFICATION REPORT

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