



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

TELEFAX TRANSMITTAL

DATE: 2/8/06

NUMBER OF PAGES: 6  
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SEND TO: Zafir A. Hawa, M.D., RSO / MARCIA WEST  
816-313-1437

LOCATION: MERITAS HEALTH CORPORATION

FAX NUMBER: 816 - 221 - ~~6150~~ <sup>2335</sup>  VERIFY BY CALLING SENDER

FROM: COLLEEN CAROL CASEY  
(SENDER)

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

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MESSAGE *Please call me if you have any questions.  
Thank you.*  
*Colleen Carol Casey*

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**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) 829-9782 or (630) 515-1259

CONVERSATION RECORD

TIME

DATE

ACTUALLY FAXED? YES.

February 8, 2006

NAME OF PERSON(S) CONTACTED

ORGANIZATION

TELEPHONE NO.

Zafir A. Hawa, M.D., RSO or

Meritas Health Corporation

816-221-6750

Marcia West, consultant

*reached phone ~6:19pm  
fax: 816-313-1437 2/8/06*

FAX: 816-221-6750-2335

SUBJECT

License No.: 24-32275-01

Control No.: 315025

SUMMARY

We have reviewed your letter dated November 1, 2005, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

We cannot approve your request to include Kevin Jones, D.O. as an authorized user at this time because of the following problems and discrepancies with his training and experience as presented on his preceptor forms:

- 26
- Dr. Jones claims he received 100 hours of didactic training in each of two five-day periods, June 15-19, 2005, and September 22, 2004. This translates to Dr. Jones being in an active training status continuously for an average of 20 hours per day for each of the 10 days claimed. As there are only 24 hours in a day, it appears that the training hours claimed per day and per week may have been overestimated. However, it also appears that Dr. Jones' training certificates corroborate these claims.

I find it highly unlikely that Dr. Jones trained actively as claimed in these courses. Please provide an explanation for these discrepancies and, if necessary, please revise Dr. Jones' application and support any changes made. If revised preceptor forms are appropriate, have them currently signed and dated and submit them also.

Please also be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information,"..."(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."

- As I cannot presently accept the 200 hours of didactic training claimed by Dr. Jones and as 10 CFR 35.290(c) requires a minimum of 700 hours total training and experience and as Dr. Jones' preceptors attested to his completion of only 500 hours of clinically supervised training and experience, it therefore appears that Dr. Jones cannot meet the minimum 700 hours total training and experience required.

Please review Dr. Jones' application carefully and submit any updated or current training and experience he may have received.

3. Dr. Jones' supervised clinical training and experience did not appear to include the elements circled on the attached copy of 10 CFR 35.290(c). Please re-submit Dr. Jones' application after he has completed this required training and include revised, currently signed and dated preceptor forms at that time.
4. I am unable to verify the qualifications of Dr. Jones' preceptors, Dr. Henkin and Dr. Dillebey of Loyola University Medical Center, an apparently broad scope medical licensee located in an Agreement State. Please provide a specific, objective letter from the Radiation Safety Committee Chairperson or the Radiation Safety Officer for Loyola and state whether Drs. Henkin and Dillebey were authorized users for the modalities of use they trained Dr. Jones in during the timeframes when Dr. Jones was trained at Loyola.
5. In responding to the above items, please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc. Please do not submit extraneous documents.

Please refer to the above regulatory requirements as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 1, for assistance in preparing your response.

Please also note that a new rulemaking became effective April 29, 2005, which changed many key elements in the training and experience criteria in Part 35. More information on this rule should have been sent to you already and is available on our website at <http://www.nrc.gov>.

6. Your letter directs me to contact your consultant, Marcia West. However, no fax number for her was provided. So I sent this fax to you and you may relay it to Ms. West if you wish. Please always include the name, phone number and fax number of at least one person we can contact if we have questions concerning an amendment. If you name a point of contact other than the RSO, please also provide this information for the RSO as well.
7. I noted that your letter was prepared on letterhead for Northland Cardiology located at the file address for this license. If your license has undergone a name change and/or change of ownership or control, please advise us in response and review and provide appropriate responses to Appendix G, NUREG 1556, Vol. 9, Rev.1.

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

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically 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>.

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ACTION REQUIRED

**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. 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 and reference it as additional information to control number 315025 to ensure proper handling.**

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.**

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NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Colleen Carol Casey



February 8, 2006

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### § 35.290 Training for imaging and localization studies.

3/5025

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

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

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

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

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

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

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

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

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

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

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

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

*missing elements circled*

*C. Casey  
2/8/06*

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

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

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

*missing elements circled.*

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

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

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16364, Mar. 30, 2005]

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Last revised Friday, May 27, 2005

*C. Casey*  
*2/8/06*

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

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MESSAGE

*Please call me if you have any questions.  
Thank you.*

*A. A. A.*

TRANSMISSION VERIFICATION REPORT

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