

## TRANSMISSION VERIFICATION REPORT

TIME : 01/27/2006 16:12  
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(4-2004)



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

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E.M. CHA, M.D., RSO

LOCATION:

for DAVIES COMMUNITY HOSPITAL

FAX NUMBER:

812-275-1517

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 if you have  
question. I am out of the office  
on 1/30 & 31 ; 2/8 & 9 ; & 2/13-22/06.



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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) 829-9782 or (630) 515-1259

**CONVERSATION RECORD**

	TIME	DATE
<b>ACTUALLY FAXED? YES.</b>	<i>VM msg left 2:51 PM CT on 1/27/06 + Contact made w/ N.M. Dept on 4/26/06 to get fax no.</i>	January 26, 2006
NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
E. M. Cha, M.D., RSO for Daviess Community Hospital		812-275-1515
		fax: 812-275-1517

**SUBJECT**

License No.: 13-16138-01 Control No.: 314962

**SUMMARY**

We have reviewed your letter dated October 24, 2005, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

1. I cannot approve Vasdev Lohano, M.D. as an authorized user for materials in 10 CFR 35.100 and 35.300, limited to I-131 less than 33 mCi, at this time because his/her training and experience does not appear to meet the requirements in 10 CFR 35.190 and 35.392.  
  
If you wish to pursue this request please submit the additional information requested only (i.e., do not resubmit what we already have received from you) and we will continue our review.
2. Item 6a of Dr. Lohano's preceptor forms was marked "N/A." It is applicable, however. Please complete this section to cover the training and experience Dr. Lohano received to meet the requirements in 10 CFR 35.190(c)(1)(ii) and 35.392 (c)(2), as marked on the attached excerpts from Part 35.
3. When providing the information requested in item 2 above, **please provide dates (month/day/year format) and clock hours, not just one or the other - the sixth column of the forms can be misleading in offering applicants a choice in this matter when we need both.**
4. **Please also provide the actual dates (month/day/year format) and clock hours, not just one or the other, for the three cases Dr. Lohano participated in documented in item 6.b. of the forms. Please provide the license number of the facility where Dr. Lohano took this training and experience, as requested in the fifth column of section 6b.**

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."

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. 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



January 26, 2006

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*This was to have been faxed on 1/26/06 but our building experienced a complete power failure just as I was going to send it.  
So I sent it on 1/27/06.*

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

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 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 60 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, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under §§ 35.290, 35.390, or, before October 24, 2005, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements; or

(c)(1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include—

(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; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.190, 35.290, 35.390, or, before October 24, 2005, §§ 35.910, 35.920, or 35.930, 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;

- (D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
- (E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
- (F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390, or, before October 24, 2005, §§ 35.910, 35.920, or 35.930, 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.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16363, Mar. 30, 2005]

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Last revised Friday, May 27, 2005

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## **§ 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).**

Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section and whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(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.); or

(b) Is an authorized user under §§ 35.390(a), 35.390(b) for uses listed in § 35.390(b)(1)(ii)(G)(1) or (2), § 35.394, or, before October 24, 2005, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(a), 35.390(b), 35.392, 35.394, or, before October 24, 2005, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2). The work experience must involve--

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

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

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

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

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.392, or 35.394, or, before October 24, 2005, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering dosages as specified in §35.390(b)(1)(ii)(G)(1) or (2).

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003; 68 FR 75389, Dec. 31, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16364, Mar. 30, 2005]

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