NRC FORM 366 (RIII)
(4-2004)

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

TELEFAX TRANSMITTAL

DATE: 7/1/08

NUMBER OF PAGES: 6
(including this page)

SEND TO: MICHAEL MEADOWS, CEO

LOCATION: STARKE MEMORIAL HOSPITAL

FAX NUMBER: 574-772-5948 ☐ ***VERIFY BY CALLING SENDER***

FROM:
(SENDER) Colleen Carol Casey

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 if you have questions.

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 7/11/08 Sent

ACTUALLY FAXED? YES. **June 30, 2008**

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
Maximo Bleza, D.O., RSO for Starke Memorial Hospital		574-772-6231 574-772-5948

SUBJECT
License No.: 13-15399-02 Control No.: **317039**

SUMMARY
We have reviewed your letter dated march 26, 2008,, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

1. **Please note that I was unable to approve Daniel R. Emig, M.D. as an authorized user for materials in 10 CFR 35.100 and 35.200 at this time because the information in your letter dated March 26, 2008, was insufficient to complete my review.**

   If you wish to pursue this request, please submit the information requested below and address it to my attention as "additional information to control number 317039." We will then continue our review.

   Dr. Emig was not approved for the use of materials in 10 CFR 35.100 and 35.200 because no preceptor attestation, as required by 10 CFR 35.290(c)(2) was attached **provided. This regulation reads as follows:**

   "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 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."

   Please submit the required preceptor attestation form in accordance with 10 CFR 35.290. A copy of this form can be found at :

   http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aud).pdf

   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. 2, for assistance in preparing your response.

In addition, if, you may find the guidance in RIS 2003-17 helpful, found at this link on our website:

http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2003/ri200317.pdf

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 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."

Please also be reminded that a senior hospital management official should sign all correspondence to us as the license is issued to the hospital, in accordance with 10 CFR 35.12:

"35.12 Application for license, amendment, or renewal.

(a) An application must be signed by the applicant's or licensee's management."

2. Your letter dated March 26, 2008, also requested the addition of accelerator produced materials to your license. Please note that this change was "automatically" made for you when 10 CFR 30.4, "Definitions," was amended on October 1, 2007, to expand the scope of materials covered by the term "byproduct materials." Similar changes were made to 10 CFR 35.100, 35.200, etc. on the same date with the same expansion of the scope of covered materials by revision of "Definitions."

Therefore, no amendment of your license for this reason was necessary.

You may wish to consult the "NARM Toolkit" at this link:

http://nrc-stp.ornl.gov/narmtoolbox.html

However, it is incumbent upon you to evaluate your licensed program within the expanded scope of these new authorizations and to request appropriate amendments if or when addresses of use, areas of use, or other program elements change or are expected to change.

Please review NUREG 1556, Vol. 9, Rev. 2 for additional guidance in these matters. It should have been mailed to you as a hard copy already but it is available on our website at:

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/

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.

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 A WRITTEN RESPONSE. IT "BUYS" YOU TIME TO PREPARE A QUALITY RESPONSE AND IS OFTEN REGARDED AS A "GOOD THING."

PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT (630) 829-9841 or (800) 522-3025.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Colleen Carol Casey	Colleen Carol Casey	~~June 30, 2008~~ 7/1/08

§ 35.290 Training for imaging and localization studies.

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 imaging and localization studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) 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 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 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 safely contain spilled radioactive material and using proper decontamination procedures;

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

(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 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; 71 FR 15009, Mar. 27, 2006; 72 FR 45151, Aug. 13, 2007]

TRANSMISSION VERIFICATION REPORT

TIME : 07/01/2008 17:26
NAME : USNRC RIII
FAX : 6308299782
TEL :
SER.# : 000A7J925774

DATE,TIME	07/01 17:24
FAX NO./NAME	85747725948
DURATION	00:01:47
PAGE(S)	06
RESULT	OK
MODE	STANDARD ECM

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