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. **November 8, 2005**

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
Mark Gates, M.D. or Gail Allen	Saint Francis Medical Center	573-334-5955 ~~314-275-8224~~

SUBJECT
License No.: 24-00158-03 Control No.: **314782**

SUMMARY
We have reviewed your letter dated August 19, 2005, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

1. Please note that Dr. David Croyle's board certification was obtained in June 1993, which is more than 7 years preceding the date of application, August 19, 2005, and he must demonstrate compliance with 10 CFR 35.59, "Recentness of training."

   As noted in the enclosed excerpts taken from NRC's Regulatory Issue Summary 2003-17, copy enclosed and available at:

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

   "In evaluating the adequacy of "related continuing training and experience" to determine compliance with 10 CFR 35.59, the NRC staff considers the training and experience criteria specified in the applicable regulations, and whether the continuing training and experience would further competency in those areas.....Whether the number of hours and types of continuing education and clinical experience are adequate will depend on the period of time the individual has not been involved in licensed activities and how closely the individual's recent educational and work experience are related to the proposed area of medical use....When reviewing the description of the continuing training and experience of an individual, NRC considers the individual's recent training and experience with respect to the following....Each topic for the appropriate medical use in 10 CFR 35.390(b)(1); 35.930(b)....."

   Please submit information demonstrating that Dr. Croyle has obtained related continuing education and/or work experience since the required training and experience, i.e., specialty board certification, was completed in 1993.

   Please show sufficient detail to clearly correlate Dr. Croyle's related continuing education and/or work experience with the guidance excerpted above from RIS 2003-17. To facilitate proper handling, address your response to my attention as "additional information to control number 314782."

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.

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

2. From your letter it appears that you intended to name all five proposed authorized users for the use of materials in 10 CFR 35.300, although none of them presented qualifications to use these materials.

Please refer to 10 CFR 35.390, and, as appropriate, 10 CFR 35.59 also, to submit information to demonstrate that Drs. Johnson, West, Croyle, Macfarlane and Strange each meet the regulatory requirements in 10 CFR 35.390. Please also be advised that 10 CFR 35.390 was significantly revised, effective April 29, 2005.

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.

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

Submit the requested information within 10 calendar days (by November 20, 2005) by referencing control number 314782 to facilitate proper handling. If we do not receive an adequate response by this date, we will **VOID** the current action without contacting you again. This will be done without prejudice to the resubmission of your request at a later date. **In the alternative, please call me to discuss alternative ways to address the requests in the letter dated August 19, 2005.** 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 GENERALLY 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	November 8, 2005

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

October 3, 2003

NRC REGULATORY ISSUE SUMMARY 2003-17: COMPLYING WITH 10 CFR 35.59, "RECENTNESS OF TRAINING," FOR BOARD-CERTIFIED INDIVIDUALS WHOSE TRAINING AND EXPERIENCE WERE COMPLETED MORE THAN 7 YEARS AGO

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC master materials license medical-use permittees.

INTENT

NRC is issuing this Regulatory Issue Summary (RIS) to provide guidance for licensees and permittees seeking to have individuals identified as authorized users (AUs), authorized medical physicists (AMPs), and authorized nuclear pharmacists (ANPs), under the following conditions:

1. The individual is certified by a specialty board recognized by NRC, but the board certification was received beyond the 7-year time frame allowed in 10 CFR 35.59; and

2. The individual is not currently identified on a medical-use license nor permit as an AU, AMP, or ANP, as appropriate in 10 CFR 35.13(b)(4).

This RIS: (1) clarifies that for limited-specific, Type B broad-scope, and Type C broad-scope medical-use licensees, only NRC with input from the Advisory Committee on the Medical use of Isotopes (ACMUI), as necessary, may determine what constitutes adequate "related continuing training and experience," for purposes of complying with 10 CFR 35.59, "Recentness of Training"; (2) describes the criteria NRC uses to evaluate "related continuing training and experience," under 10 CFR 35.59; (3) describes the information NRC reviews to make the determination; and (4) describes NRC's expectations for Type A broad-scope medical-use licensees. No specific action nor written response is required.

BACKGROUND

Periodically, individuals who at one time met the board certification requirements to be identified as AUs, AMPs, or ANPs, but have not been involved in licensed medical-use activities for extended periods of time (7 years or more) seek to become involved in these activities again as

AUs, AMPs, or ANPs. If these board-certified individuals had remained actively involved in licensed medical-use activities, then the limited-specific, Type B broad-scope, or Type C broad-scope medical-use licensee could have notified NRC, under the provisions of 10 CFR 35.14(a), that it had permitted such individuals to work as AUs, AMPs, or ANPs, without first obtaining license amendments. The Type A broad-scope medical-use licensee's Radiation Safety Committee could also approve the individual who remained actively involved in licensed medical-use activities as an AU, AMP or ANP, as appropriate.

However, to use the provisions of 10 CFR 35.14(a), the individual must meet the conditions specified in 10 CFR 35.13(b)(1) through 10 CFR 35.13(b)(4). Note that for this RIS, 10 CFR 35.13(b)(4) does not apply because, as stated in the "Intent" section, the RIS pertains only to the case where an individual is not listed on a license or permit described in 10 CFR 35.13(b)(4). Section 35.13(b)(1) requires that an individual meet both the board certification training and experience requirements specified in the applicable section of 10 CFR Part 35 [e.g., 10 CFR 35.290(a), 10 CFR 35.920(a), etc.] and the "recentness of training" provisions of 10 CFR 35.59. The "recentness of training" provisions of 10 CFR 35.59 require that an individual must have: (1) completed his/her training and experience within 7 years preceding the date of application; or (2) had related continuing education and experience since the required training and experience were completed. A board-certified individual who did not receive his/her board certification within the last 7 years cannot meet the first criterion.

SUMMARY OF ISSUE

The process for evaluating the "related continuing training and experience" required by 10 CFR 35.59 is not specifically addressed within the regulations. However, the "Supplementary Information" for 10 CFR 35.59 (67 FR 20294 and 20346) clarifies that the continuing training and experience requirements are reviewed by NRC on a case-by-case basis, with input from the ACMUI, as necessary. The provisions of 10 CFR 35.59 apply to all medical uses of licensed material. Therefore, unless exempted by the regulations, a licensee must apply for and receive an amendment before permitting a board-certified individual whose training and experience has not been obtained within the preceding 7 years to work as an AU, AMP, or ANP, when the individual is not currently listed on a license or permit, as described in 10 CFR 35.13(b)(4).

In evaluating the adequacy of "related continuing training and experience" to determine compliance with 10 CFR 35.59, the NRC staff considers the training and experience criteria specified in the applicable regulations, and whether the continuing training and experience would further competency in those areas. The number of hours required of continuing education and clinical experience depends on the period of time the individual has not been involved in licensed activities and how closely the individual's recent educational and work experience are related to the proposed area of medical use.

When reviewing the description of the continuing training and experience of an individual, NRC considers the individual's recent training and experience with respect to the following:

1. Each topic found in 10 CFR 35.51(b) or 10 CFR 35.961(b) for an individual seeking to be recognized as an AMP; or

2. Each topic for the appropriate medical use in 10 CFR 35.190(c)(1); 35.910(b); 35.290(c)(1); 35.920(b); 35.390(b)(1); 35.930(b); 35.392(c)(1) and (2); 35.932; 35.394(c)(1) and (2); 35.934; 35.490(b)(1) and (2); 35.940(b); 35.491(b)(1) and (2); 35.941; 35.590(b); 35.950(b); 35.690(b)(1) and (2); or 35.960(b) for an individual seeking to be recognized as an AU; or

3. Each topic found in 10 CFR 35.55(b)(1) or 10 CFR 35.980(b)(1), for an individual seeking to be recognized as an ANP.

The limited-specific, Type B broad-scope, or Type C broad-scope medical-use licensee should therefore submit an amendment request, to NRC, containing information that would support a determination that the individual's continuing training and education demonstrate competency in the topics specified in the applicable regulation. To facilitate NRC's review, the licensee may also elect to provide a preceptor statement attesting to current competency in the identified radiation safety areas.

The Type A broad-scope medical-use licensee is exempted in 10 CFR 35.15, "Exemptions regarding Type A specific licenses of broad scope," from having to apply for and receive an amendment or notifying NRC when it permits an individual to work as an AU, AMP, or ANP. This type of licensee must have the Radiation Safety Committee approve the individuals using the byproduct material under the license. The Type A broad-scope medical-use licensee is not exempted from meeting the training and experience requirements of 10 CFR Part 35, Subparts B, D, E, F, G, and H, or the recentness of training requirements in 10 CFR 35.59.

The Type A broad-scope medical-use licensee's Radiation Safety Committee is expected to review the individual's continuing education and experience similarly to NRC. Therefore, the committee should compare the individual's continuing training and experience with the training and experience criteria specified in the applicable regulations and determine whether the continuing training and experience would further competency in those areas. Whether the number of hours and types of continuing education and clinical experience are adequate will depend on the period of time the individual has not been involved in licensed activities and how closely the individual's recent educational and work experience are related to the proposed area of medical use. The Type A broad-scope medical-use licensee should have sufficient AUs, AMPs, or ANPs to permit the individual to work under the supervision of an appropriate staff AU, AMP, or ANP, before approval by the Radiation Safety Committee.

This RIS requires no specific action nor written response. If you have any questions about this summary, please contact the person listed below or the appropriate regional office.

/RA/

Charles L. Miller, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contact: Donna-Beth Howe, Ph.D., NMSS
(301) 415-7848
E-mail:dbh@nrc.gov

Attachment: List of Recently Issued NRC Regulatory Issue Summaries

LIST OF RECENTLY ISSUED
NRC REGULATORY ISSUE SUMMARIES

Regulatory Issue Summary No.	Subject	Date of Issuance	Issued to
2003-15	Consolidation of the Region I and Region Ii Materials Program	09/05/2003	All materials licensees.
2003-14	Preparation And Scheduling of Operator Licensing Examinations	08/27/2003	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.
2003-13	NRC Review of Responses to Bulletin 2002-01, "Reactor Pressure Vessel Head Degradation and Reactor Coolant Pressure Boundary Integrity"	07/29/2003	All holders of construction permits or operating licenses for nuclear power reactors except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.
2003-12	Clarification of NRC Guidance for Modifying Protective Actions	06/24/2003	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.
2003-11	Reporting Requirements for Distributors of Devices Subject to the General License Requirements of 10 CFR 3.5	07/16/2003	All licensees authorized to distribute devices containing byproduct material under 10 CFR 32.51, or equivalent Agreement State regulation.

Note: NRC generic communications may be received in electronic format shortly after they are issued by subscribing to the NRC listserver as follows:

To subscribe send an e-mail to <listproc@nrc.gov >, no subject, and the following command in the message portion:

subscribe gc-nrr firstname lastname

OL = Operating License
CP = Construction Permit

TRANSMISSION VERIFICATION REPORT

TIME : 11/08/2005 15:43
NAME : USNRC
FAX : 6308299782
TEL : 6308299782

DATE,TIME	11/08 15:40
FAX NO./NAME	85733315018
DURATION	00:02:37
PAGE(S)	09
RESULT	OK
MODE	STANDARD ECM

NRC FORM 386 (RIII)
(4-2004)

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

TELEFAX TRANSMITTAL

DATE: 11/8/05

NUMBER OF PAGES: 9
(including this page)

SEND TO: MARK GATES, MD OR GAIL ALLEN

LOCATION: ST. FRANCIS MEDICAL CENTER

FAX NUMBER: 573-331-5018 ☐ ***VERIFY BY CALLING SENDER***

FROM: COLLEEN CAROL CASEY
(SENDER)

TELEPHONE NUMBER: 630-829-9841 FAX NUMBER: 630-829-9872

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 + leave a message as to when a good time might be.

NRC FORM 386 (RIII)
(4-2004)

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

TELEFAX TRANSMITTAL

DATE: 11/8/05 NUMBER OF PAGES: ~~10~~ 9
(including this page)

SEND TO: MARK GATES, MD OR GAIL ALLEN

LOCATION: ST. FRANCIS MEDICAL CENTER

FAX NUMBER: 573-331-5018 ☐ ***VERIFY BY CALLING SENDER***

FROM:
(SENDER) COLLEEN CAROL CASEY

TELEPHONE NUMBER: 630-829-9841 FAX NUMBER: 630-829-9872

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 + leave a message as to when a good time might be for you + I to speak about this.

Thank you,

Colleen Carol Casey

NOTICE

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