



CONVERSATION RECORD

11/20/2013

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU Carmen R. Kmety-Stevenson, Ph.D. Radiation Safety Officer (RSO)		DATE OF CONTACT 11/14/2013	TYPE OF CONVERSATION <input type="checkbox"/> E-MAIL <input checked="" type="checkbox"/> TELEPHONE <input type="checkbox"/> INCOMING <input checked="" type="checkbox"/> OUTGOING
E-MAIL ADDRESS ckmety-stevenson@oncure.com		TELEPHONE NUMBER (260) 436-4116	

ORGANIZATION Radiation Oncology Associates	DOCKET NUMBER(S) 030-36814
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LICENSE NUMBER(S) 13-32551-01	CONTROL NUMBER(S) 581689
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SUBJECT
Our review of license amendment request dated September 9, 2013

SUMMARY

We have reviewed your license amendment request and find that we are unable to continue this action until we have received additional information requested below.

Direct any questions you have to me at (630) 829-9892 or sara.forster@nrc.gov.

Submit requested information within 12 days of this record, referencing Control No. 581689, as listed at the top of this memo. Please FAX your response to my attention at (630) 515-1078. You may also scan your response and send to me via email, as a pdf file. As we discussed, include a signed and dated cover letter with your response.

We expect to receive your written response on or before November 26, 2013.

Continue on Page 2

ACTION REQUIRED (IF ANY)

We have requested that the licensee provide additional information as follows:

- Training & Experience Information for Mark C. Ranck, M.D., including HDR cases & Form 313A (AUS) signed by preceptor AU
- Training & Experience Information for Wesley A. Russell, M.D., including HDR cases & Form 313A(AUS) signed by preceptor AU

NAME OF PERSON DOCUMENTING CONVERSATION
Sara A.B. Forster, Materials Licensing Branch, Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532

SIGNATURE
Sara A.B. Forster 11/20/2013

CONVERSATION RECORD (continued)

SUMMARY: (Continued from page 1)

C. Kmety-Stevenson

1. The September 9, 2013, letter requested to add Mark C. Ranck, M.D., as an Authorized User (AU) & included an NRC Form 313A (AUS), signed by Steven Chmura, M.D., Ph.D., but did not include documentation of Dr. Ranck's specific hands-on HDR training and experience (T&E), or of Dr. Chmura's status as a qualified preceptor AU. In addition, submitted documentation of the supervised work experience required under 10 CFR 35.690 omitted total hours of experience, training in several required topics, and the name of the supervising AU. Please resubmit your request to add Dr. Ranck as an AU, including, at a minimum, the following information:

- i. NRC Form 313A (AUS), found at [http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a\(aus\).pdf](http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aus).pdf), documenting Dr. Ranck's completion of 10 CFR 35.690 requirements, for the use of radioactive material in an HDR:
 - (1) at least 200 hours of classroom & laboratory training in topics listed on p. 1, Part I, Item 3.a. of the Form 313A (AUS)
 - (2) at least 500 hours of supervised work experience in topics listed on p. 3, Part I, Item 3.d. of the Form 313A (AUS)
* Note: training dates for each hospital or educational institution should be listed separately, as applicable.
 - (3) name of each qualified supervising AU, at approved training program on p. 4, Part I, Item 3.d., of the Form 313A (AUS)
* Note: for supervising AUs listed on an NRC license, provide that license number. For supervising AUs listed on an agreement state license, provide a copy of that license listing the supervising AU. For supervising AUs authorized for HDR use under a broadscope license permit, provide a letter signed by the broadscope licensee Radiation Safety Officer (RSO) or Radiation Safety Committee (RSC) chairperson, indicating the dates on which the supervising AU was authorized for the use of radioactive materials in an HDR.
 - (4) name of each qualified remote afterloader supervising individual or other qualified training provider, on p. 4, Part I, Item 3.e., of the Form 313A (AUS). As for supervised work experience, training dates for each hospital or educational institution should be listed separately, as applicable. As for supervising AUs, documentation should be provided supporting the training individual's qualifications to supervise and/or train in the use of HDR.
 - (5) qualified preceptor AU name, signature, and date on pp. 5-6, Part II, 2nd-5th sections, of the Form 313A (AUS)
* Note: for preceptor AUs listed on an NRC license, provide that license number. For preceptor AUs listed on an agreement state license, provide a copy of that license listing the preceptor AU. For preceptor AUs authorized for HDR use under a broadscope license permit, provide a letter signed by the broadscope licensee Radiation Safety Officer (RSO) or Radiation Safety Committee (RSC) chairperson, indicating the dates on which the preceptor AU was authorized for the use of radioactive materials in an HDR.
- ii. Sample HDR clinical case log, including date of treatment, and supervising AU for each case. Do not include privacy-protected patient names or other information. As for supervising AUs, documentation should be provided supporting the training individual's AU status on the dates supervising use of HDR.
- iii. Radiation Oncology Residency program completion certificate (okay as submitted originally)
- iv. If submitted HDR T&E was on a device model other than a GammaMed, please indicate the dates on which the proposed AU completed GammaMed device-specific training, or the date by which such training will be completed.

2. The September 9, 2013, letter requested to add Wesley A. Russell, M.D., as an AU included an NRC Form 313A (AUS), signed by Julius S. Turian, Ph.D., and included an outline of Dr. Russell's specific hands-on HDR T&E, but did not include documentation of either Dr. Turian's status as a qualified preceptor AU, or of the supervising individuals' status as HDR AUs. In addition, submitted documentation of the supervised work experience required under 10 CFR 35.690 indicated only 70 hours of experience. Please resubmit your request to add Dr. Russell as an AU, including, at a minimum, a completed NRC Form 313A (AUS), his HDR clinical case log (okay as submitted originally), Radiation Oncology Residency program completion certificate (also okay as submitted originally), and GammaMed-specific training documentation or commitment, as requested for Dr. Ranck.

Forster, Sara

From: Forster, Sara
Sent: Wednesday, November 20, 2013 2:00 PM
To: Carmen Kmety-Stevenson (CKmety-Stevenson@oncure.com)
Subject: Additional Information Request for Radiation Oncology Associates, NRC Lic. No. 13-32551-01
Attachments: 02230.581689.13-32551-01 telecon signed.pdf

Dear Dr. Kmety-Stevenson:

As promised in last Thursday's phone conversation, please see the attached file for additional information needed to complete the review of your recent license amendment request. Note that the attached conversation record requests additional information on or before close of business on November 26, 2013.

Please note that submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Do not hesitate to call me with any questions you may have.

Sara A. B. Forster, Health Physicist Licensing Reviewer
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Division of Nuclear Materials Safety
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