NRC FORM 699 (03-2013)

U.S. NUCLEAR REGULATORY COMMISSION

CONVERSATION RECORD

DATE OF SIGNATURE: 05/13/2015

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	DATE OF CONTACT	TYPE OF CONVERSATION
Christina Pearson	05/13/2015	☑ E-MAIL ☐ TELEPHONE ☐ INCOMING ☑ OUTGOING
E-MAIL ADDRESS: christina.pearson@mymlc.com	TELEPHONE NUMBER: (816) 271-6460	

ORGANIZATION	DOCKET NUMBER(S)
Heartland RMC - Mosaic Life Care (new name)	03014791
LICENSE NUMBER(S): 24-18287-01	CONTROL NUMBER(S): 585378

SUBJECT

Request for additional information to complete renewal review

SUMMARY

We have reviewed your letter dated November 25, 2014 (with attachments), requesting renewal of your license and the addition of two new authorized users. To complete our review, we find that we will need the following additional information:

1. Your renewal application failed to include diagrams/description show where your brachytherapy source storage room was located. Please submit both a description of and diagram for this room. Please do not submit blueprints or copies of blueprints. "Consolidated Guidance About Materials Licenses: Program - Specific Guidance About Medical Use Licenses," NUREG 1556, Vol. 9, Rev. 2, section 8.16 Item 9 and Figure 8.1 will assist you in preparing your response. This guidance document is available on our website at: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/

Please see page 3 for minor revision and disregard the first version sent. Thank you. CCC

Continue on Page 2

ACTION REQUIRED (IF ANY)

Please submit a written response within 7 calendar days of the date of this record (by May 20, 2015) or contact me to make alternative arrangements. Address your response to my attention at the address below in my signature block and reference it as "additional information to control number 585378."

Please respond directly to me for this case only; future new licensing requests should be addressed to the "Materials Licensing Branch Chief." Upon receipt of your written response we will continue our review.

Thank you very much.

Continue on Page 3

NAME OF PERSON DOCUMENTING CONVERSATION

Colleen Carol Casey

SIGNATURE

Colleen Carol Casey

CONVERSATION RECORD (continued)

SUMMARY: (Continued from page 1)

You should also have a hard copy of this guidance document already.

We also noted that your renewal application/letter made several references to the wrong version of this guidance document. You referred to the original version from 2002; the second revision has been in use since 2008 and should be used for your responses.

2. Your renewal application/letter also failed to describe the "Other Equipment and Facilities" requested in the guidance document above, in section 8.20 Item 9. This would include, but not be limited to, remote handling tools, shielded containers, etc. used for manual brachytherapy, materials in 10 CFR 35.400. Please submit a description of the equipment referred to in this section for your manual brachytherapy program.

3. Since your renewal application/letter makes no mention of the use of PET materials, we assume that you are not using them and we will exclude them from 10 CFR 35.200 in your renewed license. Please advise us promptly if this is not the case as there will be other additional information needed from you in order to authorize PET materials on your license.

4. Your renewal application/letter referred to Bonnie K. Goins, M.D. as an authorized user (AU) for the use of materials in 10 CFR 35.200 and 35.500. Dr. Goins is now and has always been an AU for the use of materials in 10 CFR 35.400 (manual brachytherapy) on your license. She has never been an AU for materials in 10 CFR 35.200 (diagnostic imaging and localization studies.) Please confirm our assumption and understanding that this was a typo and that you wish to continue Dr. Goins' authorization in 10 CFR 35.400 and not as an AU for 35.200 materials.

5. Item 5, page 1 of your renewal application/letter referred to "I-123" as a sealed source under 10 CFR 35.400. We believe you meant "I-125" sealed sources. Please confirm our assumption and understanding that this was a typo and that you wish to continue to be authorized for "I-125" sealed sources under 10 CFR 35.400.

6. Your renewal application/letter requested approval for two new proposed AUs, Brett R. Nielson, D.O. and Brandon James Massin, M.D., who both wish to be authorized for the use of materials in 10 CFR 35.100, 35.200 and 35.300, limited to sodium iodide I-131 in quantities less than or equal to 33 millicuries. Both presented acceptable specialty certification board certificates.

However, neither physician included required written preceptor attestations, pursuant to 10 CFR 35.290 (c)(2): "... (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 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 10 CFR 35.100 and 35.200."

10 CFR 35.392(c)(3) contains essentially the same requirement for a written attestation for the I-131 authorization being sought.

Please refer to Appendix B and Forms 313a AUD and AUT; Appendix D, section III (paragraphs 1 and 2 in particular), section V, Part 1, Item 1 and Part II, Sections IX. and X in NUREG 1556, Vol. 9, Rev. 2, for assistance in preparing your written responses.

Please do not resubmit information you have already submitted to us.

Please only submit the information that we have requested.

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.

If preparation of this information cannot be accomplished in the requested response timeframe, you may respond to the other items within the requested response timeframe and submit the proposed AUs information at a later date, following the same instructions given above.

7. It appears to us that you have two additional locations of use covered by the address in Condition 10.A. Do either or both of these locations of use have addresses different from 5325 Faraon Street or not? It appears more correct for us to list each facility separately according to which materials will be authorized for use.

CONVERSATION RECORD (continued)

ACTION REQUIRED (Continued from page 1)

Please state specifically which materials will be authorized for use at each facility, including the Medical Plaza II and the Heart Center.

8. Your renewal application/letter requested an open ended authorization for materials in 10 CFR 35.500 in Item 5 on page 1, although your license only permits authorization and use of barium-133. No other materials were requested specifically or identified by sealed source manufacturer/model number, device manufacturer/model number and Sealed Source and Device Registry (SSDR) listing. 10 CFR 35.49 restricts your authorization to only materials in the SSDR.

Please confirm that our assumption and understanding are correct in that we will only continue authorization at this time for the barium-133 source currently on your license.

Please direct any questions you may have about these matters to me at 630-829-9841.

Please 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 for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. This is only version made, C. Casey

PLEASE DISREGARD THE FIRST VERSION OF THIS AS IT INADVERTANTLY CONTAINED THE WRONG VERBAGE ABOUT PUBLIC AVAILABILITY. THANK YOU.

Colleen
Colleen Carol Casey
Materials Licensing Reviewer
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352
(630) 829-9841 Direct
(630) 515-1078 Fax
NRC 24 HR Operations Center
(301) 816-5100
Gentle Reminders: Unless previously arranged with or requested by me directly,
please do not submit any licensing requests, responses or correspondence via e-mail.
Please only submit one complete, signed copy of your correspondence to us.
Please prepare your licensing requests in accordance with NUREG 1556 Series Guidance, as appropriate.
Thank you very much!
Please also note that my full-time work schedule includes every other Friday off.
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http://www.nrc.gov/

Casey, Colleen

From: Casey, Colleen
Sent: Wednesday, May 13, 2015 5:43 PM
To: christina.pearson@mymlc.com
Subject: Corrected Version - Please replace
Attachments: Scan001.PDF

Dear Ms. Pearson,

Please destroy the first version of this record I sent over. It has an error on page 3 regarding public availability.

This is the corrected version. Again, please contact me to discuss this. Thank you very much.

Colleen

Colleen
Colleen Carol Casey
Materials Licensing Reviewer
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352
(630) 829-9841 Direct
(630) 515-1078 Fax
NRC 24 HR Operations Center
(301) 816-5100
Gentle Reminders: Unless previously arranged with or requested by me directly, please do not submit any licensing requests, responses or correspondence via e-mail. Please only submit one complete, signed copy of your correspondence to us.
Please prepare your licensing requests in accordance with NUREG 1556 Series Guidance, as appropriate.
Thank you very much!
Please also note that my full-time work schedule includes every other Friday off.
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http://www.nrc.gov/

-----Original Message-----
From: R3-238-DRMA-A@nrc.gov [mailto:R3-238-DRMA-A@nrc.gov]
Sent: Wednesday, May 13, 2015 7:06 PM

To: Casey, Colleen
Subject: Scan from a Xerox WorkCentre Pro

Please open the attached document. It was scanned and sent to you using a Xerox WorkCentre Pro.

Sent by: Guest [R3-238-DRMA-A@nrc.gov]
Number of Images: 3
Attachment File Type: PDF

WorkCentre Pro Location: DRMA
Device Name: R3-238-DRMA-A

For more information on Xerox products and solutions, please visit http://www.xerox.com