NRC FORM 699
(03-2013)

U.S. NUCLEAR REGULATORY COMMISSION

CONVERSATION RECORD

DATE OF SIGNATURE: 3/23/2016

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU: Richard D. Siska, NMAA, MIS

DATE OF CONTACT: 3/23/2016

TYPE OF CONVERSATION: [✓] E-MAIL [ ] TELEPHONE [ ] INCOMING [✓] OUTGOING

E-MAIL ADDRESS: richard.siska@mercy.net

TELEPHONE NUMBER: (573) 458-6614

ORGANIZATION: Mercy Hospital Lebanon Imaging Services - Rolla

DOCKET NUMBER(S): 03037188

LICENSE NUMBER(S): 24-32615-01

CONTROL NUMBER(S): 590412

SUBJECT: Request for additional information

SUMMARY

We have reviewed your application dated March 4, 2016, requesting renewal of your NRC license and find that we will need additional information as follows:
Although we received your NRC Form 313, there was no renewal application attached to it. This form directs the user to submit the information in items 5 through 11....as described in the license application guide. We are unable to work with the form you submitted.
Please submit a complete application, including all of the information requested, in order for us to consider renewing your license. Please refer to the attachments enclosed regarding appropriate signatories for your application; some advice on how to prepare the renewal; and an excerpt from NUREG 1556, Vol. 9, Rev. 2, our primary guidance document for medical programs, pertaining

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ACTION REQUIRED (IF ANY)

Please submit a written response within 30 days of the date of this record (by April 24, 2016) 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 590412."

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.

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NAME OF PERSON DOCUMENTING CONVERSATION: Colleen Carol Casey

SIGNATURE: Colleen Carol Casey

CONVERSATION RECORD (continued)

SUMMARY: (Continued from page 1)

to renewing the license.

When you have reviewed this information, please contact me to discuss it, which will enable us to ensure that your response is appropriate and complete. Please also use the "Medical Licensing Toolkit" webpages on our website, which contains a wealth of information to assist you.

Please have a senior management official sign your response and the "Delegation of Authority" for you, as the RSO.

In addition, we noted that your signature on the NRC Form 313 was illegible. Please ensure that all signatures on NRC correspondence going forward are legible. This helps us protect the integrity of your license.

We are also unclear as to what the letters following your name refer to, "NMAA, MIS." Please explain so we may determine whether it is appropriate for us to include them in your designation as RSO on the license.

Please only submit one complete and signed response, not duplicate copies, and not one copy sent by one transmission form and another copy sent via a different transmission form. Only one complete copy is needed. A duplicate or second copy can interfere with the timely review of your response and delay it.

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 record and its attachments 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.

Additional Note: Richard Sorka called me @ 4:13 PM on 3/24/16 to discuss this record. He misunderstood things. We also discussed why there are 2 LOCs on license when he said there should only be one. I could not find licensee's request to delete former LOC but Richard insists close-out survey was done + he thought it had been submitted. Former LOC is empty + still under licensee's control. They will re-request taking it off license in this renewal.

Colleen Carol Casey
3/24/16

36 min. phone call

(573-458-6600)

Colleen
Colleen Carol Casey
Materials Licensing Reviewer
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352
Colleen.Casey@nrc.gov
(630) 829-9841 Direct, Central time zone
(630) 515-1078 Fax
NRC 24 HR Operations Center
(301) 816-5100, Eastern time zone

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.
Ensuring the health and safety of
our people, our nation and
our environment
http://www.nrc.gov/

Signatures required for Materials Licensing Correspondence and Best Practices

To help ensure that an application for a new, amendment or renewal materials licensing request is complete and may be acted upon by NRC, all incoming licensing correspondence must be signed by an appropriate certifying officer for the materials licensee in question.

An applicant's or licensee's legal representative, administrative assistant, outside consultant, etc. will not suffice as a certifying officer.

As enumerated below, for all materials applicants and licensees, and as noted for medical/human use applicants and licensees, all initial requests for licensing requests must be signed, in order to comply with the regulatory requirements listed below.

If a certifying officer/management representative signs an "initial" licensing request that names someone else as a "point of contact," then the designated point of contact may be the sole signatory for any written responses related to that initial licensing request only, unless the NRC reviewer requests otherwise.

All subsequent "new/initial" licensing requests must then be signed appropriately.

Please always sign every licensing document and communication submitted, even if you sign an email and transmit it to us via email/PDF or fax.

Unsigned email messages, electronically generated or imposed "signatures," stamped signatures, etc. are not acceptable substitutes for an actual, physically hand-written signature.

Submitting any licensing correspondence without a signature, or with an unacceptable signature, may delay the review process until an acceptable signature is obtained on the document(s) in question.

Please be reminded that 10 CFR 30.32(a) and (c) require:

" (a) A person may file an application on NRC Form 313, "Application for Material License," in accordance with the instructions in § 30.6 of this chapter." And,

"(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf."

Please note that the NRC Form 313 requires the typed or printed name and signature of a certifying officer. The NRC Form 313 can be found at:

http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313.pdf

If the NRC Form 313 is not used, then a business letter containing all of the information on the NRC Form 313 may be used instead.

10 CFR 30.9(a) requires:

" (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."

For medical/human use applicants and licensees:

10 CFR 35.12 Application for license, amendment, or renewal requires:

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

10 CFR 35.2, "Definitions" states, in part:

"Management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates."

Please address all licensing correspondence to: "ATTN: Materials Licensing Branch Chief" at the address shown below.

If you have any questions or comments please contact me at either (800) 829-9500, ext. 9841 or (630) 829-9841. My fax number is (630) 515-1078. My email address is colleen.casey@nrc.gov.

Colleen

Colleen Carol Casey
Materials Licensing Reviewer
U.S. Nuclear Regulatory Commission
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Thank you very much!
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Renewing an NRC License

Please note that using the NUREG- 1556 series documents will greatly help ensure that your licensing correspondence is prepared more completely and in a less burdensome manner.

In preparing all future licensing correspondence please focus on providing the information requested in Appendix C to NUREG 1556, Volume 9, Rev. 2. Follow the "Suggested Format.." provided in this Appendix and use the suggested responses and model procedure/appendix references whenever possible, appending descriptive information as appropriate.

It is strongly advisable to read the corresponding text in the front of each NUREG to ensure a complete understanding of the commitments that you make.

IMPORTANT

For an incumbent RSO and incumbent Authorized Users, whose authorization you are not seeking to expand, you only need to provide their names and authorizations. The RSO will need to submit a currently dated, management and RSO - signed "Delegation of Authority" from Appendix I in NUREG 1556, Vol. 9, Rev. 2.

Please do not submit resumes, curricula vitae, college transcripts, any personal, proprietary information, blueprint diagrams, or copies of blueprint diagram and any extraneous, prescriptive information and procedures, unless we specifically request it, which is unlikely.

If you must deviate from a model procedure or suggested response, it may be possible to simply indicate what the deviation is and still use the model procedure/ suggested response as a "basic" commitment.

Descriptive information may be "recycled" from previous documents only so long as it is current, complete information that satisfies the guidance and is equivalent to the model procedure (as appropriate) and does not contain extraneous material.

Do not resubmit information from a previous renewal or new license application under the assumption that it was acceptable then so it should be acceptable now. Always prepare your renewal to conform with the most current guidance and regulations.

DISREGARD THIS SECTION

This advice is particularly relevant to your high dose rate (HDR) remote afterloading brachytherapy program and the significant quantity of procedures, diagrams, commitments, etc. that we need to continue this authorization.

It is in your best interests to only provide those commitments, statements, representations and procedures, in a clear and explicit manner, that we require to issue your license. These documents will form the basis for the license in the last condition of the license, called the "tie-down" condition.

You will realize the benefit of a reduced regulatory burden while enhancing safety and maintaining compliance and efficiency if you establish your license in this manner.

In fact, the easiest way to prepare a renewal, for example, is to take a copy of NUREG 1556, Vol. 9, Rev. 2, Appendix C, especially Tables C.2 and C.3 to your copy machine and copy it out directly.

Read the text in the front of the NUREG that corresponds to each section and simply fill in the checkmarks and blanks on the copied checklist, thereby making your license commitments. We want, and expect that you will, "plagiarize" from this guidance.

Please do not re-type the checklist as errors and omissions may be introduced, rendering the application incomplete.

As you need to append certain information or provide an alternative procedure, please be sure to incorporate the information in the NUREG, at a minimum, to ensure completeness.

You may "recycle" previously approved diagrams, documents containing procedures, etc., provided they do not contain extraneous details and that they are current and accurate in all material respects.

Please see the Tables C.2 and C.3, NUREG 1556, Vol. 9, Rev. 2, Appendix C. A hard copy of this document should have been sent to you already. It is also available on our website at:

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

9 AMENDMENTS AND RENEWALS TO A LICENSE

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 30.37, 10 CFR 30.38, 10 CFR 35.13.

The NRC now has regulatory authority over sealed sources and devices containing accelerator-produced radioactive material and discrete sources of Ra-226, under the new definition of byproduct material resulting from the EPAct. Licensees may need license amendments for such purposes as to authorize use of these materials, to revise their Radiation Safety Programs to meet new requirements, or to provide new facility diagrams. The NRC issued a waiver on August 31, 2005, that permitted licensees to continue to use the newly defined byproduct material until the waiver was terminated on August 8, 2009. Licensees in Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana who possess and use accelerator-produced radioactive material or discrete sources of Ra-226, or both, may continue to use these materials for medical use or prepare PET radioactive drugs for noncommercial distribution to other consortium members until the date of NRC's final licensing determination, provided the licensee submits an amendment application within 6 months after November 30, 2007. Other licensees should check with the appropriate NRC Regional Office to determine when they have to submit their license amendments.

Licensees are responsible for applying for amendments to licenses and for keeping them up-to-date. Furthermore, to continue a license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date (10 CFR 2.109, 10 CFR 30.36(a)).

Under 10 CFR 35.13, a licensee is required to apply for and receive a license amendment before several activities can occur, including:

- Receipt or use of byproduct material for a type of use permitted by 10 CFR Part 35, but not authorized on the licensee's current Part 35 license;
- Permitting anyone to work as an AU for medical uses, AMP, or ANP, unless the individual meets one of the exceptions listed in 10 CFR 35.13(b) (information required to document training and experience may be provided on the appropriate NRC Form 313A series of forms for change or addition of AU for medical uses, AMP, ANP, or RSO);
- Changing the RSO;
- Receiving byproduct material in excess of the amount, or receiving radionuclides or forms different than, currently authorized on the NRC license;
- Changing an area or address of use identified in the application or on the license. This includes additions and relocations of areas where PET radionuclides are produced or additions or relocations of a radionuclide delivery line from the PET radionuclide production area to a 10 CFR 35.100 or 10 CFR 35.200 medical use area. However, other

changes and additions to the 10 CFR 35.100 and 10 CFR 35.200 medical use area do not require a license amendment and can be made, provided NRC is notified as required by 10 CFR 35.14 within 30 days following the changes, and

- Revising procedures required by 10 CFR 35.610, 35.642, 35.643, and 35.645, when the revision reduces the level of radiation safety.

In case of a medical emergency requiring an expedited license amendment, contact the materials licensing staff at the appropriate NRC Regional Office.

For both renewal and amendment requests, applicants should do the following:

- Use the most recent guidance in preparing an amendment or renewal request,
- Submit ~~in duplicate~~ ONLY ONE COPY OF either an NRC Form 313 or a letter requesting an amendment or renewal, and
- Provide the license number.

Casey, Colleen

From: Casey, Colleen
Sent: Wednesday, March 23, 2016 4:22 PM
To: 'richard.siska@mercy.net'
Subject: Request for additional information - Mercy Hospital License Renewal
Attachments: 0074_001.pdf

Importance: High

Dear Mr. Siska,

Please review the enclosed request for additional information as we are unable to work with the one page form you sent us as a renewal for this license. Please call me or arrange to call me to discuss this information to prevent further misunderstandings. Reaching me via email is usually quickest.

Thank you very much.

Please call me "Colleen."

Colleen

Colleen Carol Casey
Materials Licensing Reviewer
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