



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

APR 03 2017

Ray A. Carlson, M.S.
Radiation Safety Officer
ARK Cardiovascular &
Arrhythmia Center, PLC
6050 Greenfield Road
Suite 101
Dearborn, MI 48126

Dear Mr. Carlson:

Enclosed is Amendment No. 3 to your NRC Material License No. 21-35069-01 in accordance with your request.

Please note that this amendment was prepared in our new Web Based Licensing system (WBL). In conjunction with preparing the license in WBL, we also deleted Condition No. 13, as it appeared on Amendment No. 2, in favor of referencing 10 CFR Part 71 in the Preamble at the top of page one of your license. The condition subsequent to the deleted Condition No. 13 has been renumbered as a result of these changes.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078.

We experienced a significant amount of difficulty in obtaining the information needed to process and review the request in this amendment. In order to achieve an improved understanding of our expectations from licensees and facilitate better quality licensing correspondence in the future, we have included the following tips and explanations.

This is not official guidance, it is only a summary of language I have had to use often in deficiency correspondence with our licensees to achieve an improved working understanding of our respective roles in the licensing process.

This is not intended to be "all-inclusive", nor is it a substitute for your reviewing our regulatory requirements and guidance as they apply to your particular license and situation and preparing your licensing requests in accordance with them.

Please be reminded that USNRC is an independent and objective federal government regulator.

The enclosed document contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

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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."

What 10 CFR 30.9(a) means, in part, is that you, as the licensee, are primarily responsible for the quality of your submissions to NRC, as well as the completeness and accuracy of all information provided.

You, the licensee, are responsible for checking and verifying that the information you provide supports the requests you make to your license and that the requests you make to your license are in alignment with our regulations and guidance.

Please do not expect NRC to perform the first check and verification of your licensing requests. We perform the regulatory authority verification that the information needed to consider your requests has been completely provided.

It is understandable and expected that, occasionally, some minor additional information must be solicited from a licensee in the course of the review process.

But such occurrences should be rare and exceptional and address primarily minor issues, information that could not have been foreseen or planned around, etc.

Such occurrences should not be routine and addressing basic issues that have been codified in our regulations for many years and which have been discussed in ample detail in our guidance documents, regulatory issue summaries, information notices, information on our website, and brought to your attention in previous deficiency and cover letter correspondence.

Your assistance in these matters is greatly appreciated and enables us to serve you, and all of our licensees and applicants, better and in a more timely fashion.

Signatures Required for Materials Licensing Correspondence and Best Practices

The following information is provided for future reference "as needed."

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.

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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 physically and legibly hand-sign every licensing document and communication submitted. Electronic signatures, initials, signature stamps, or signatures or initials applied on behalf of someone else are not acceptable.

Sending us an email and/or a fax and/or a hard copy mailed document are simply "means of transmission" and not a substitute for an appropriate signatory on the actual documents being transmitted. Sending us identical information by more than one means of transmission should never be done, as it increases the likelihood of mis-processing and subsequent delays.

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

Submitting any licensing correspondence without a signature, or with an unacceptable signature, will 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-style letter containing all of the "licensee-identifying" 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."

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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 initial licensing correspondence to: “ATTN: Materials Licensing Branch Chief” at the address shown above.

If you are directed to respond to a specific, named reviewer during the review process for a particular action only, then direct your written response to that reviewer by name.

“Expedite” Requests:

A request to “expedite” a licensing action should be a rare and occasional occurrence normally due to circumstances beyond your control, unforeseeable emergencies, medical issues pertaining to the immediate/near-term delivery of care to patients, compelling business situations that could not have been planned around, and so on.

We have in place an internal tracking system and internal timeliness metrics that we have used for a great many years. There is a summary of this information provided with the acknowledgement sent to every applicant/licensee for licensing correspondence we receive.

To assist us in serving you and all of our licensees more efficiently, please contact us by telephone if a circumstance such as those above arises before (best whenever possible), or after you have submitted an amendment request to your license, or new license application, and if you can unambiguously justify and support your asserted need for that particular amendment to be moved up in our normal reviewing queue.

Having this information enables our management to best decide how to handle your expedite request.

Please note that we normally process all licensing actions, including amendment requests, new license applications and renewals, in the order in which they are received, i.e., “first come, first served.”

As stated in our acknowledgment card, sent to all applicants and licensees who submit correspondence for our review, the initial review for amendments and new license applications is normally completed within 90 days of receipt, as an internal goal only.

The initial review for renewals, as an internal goal only, is normally completed within 180 days of receipt.

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The technical quality, accuracy and completeness of your submission are primary factors that only you can control in order to enable us to help you more promptly and minimize delays in the reviewing process.

Please note that your submission should not include extraneous documentation, which only serves to delay the review process.

Please only submit information that our regulations and guidance specifically address. Please completely and concisely answer questions that we ask and provide information that we specifically request.

Preparing your renewal and amendment requests carefully and in accordance with NRC's regulatory requirements and guidance, especially the documents in the NUREG 1556 series, as well as other information on our website at <http://www.nrc.gov>, will greatly help ensure that your correspondence is complete and accurate in all material respects, as 10 CFR 30.9 (a) requires it to be.

Ideally, if you know of an emergent medical situation or compelling business situation impacting your license and you need a licensing action completed by a certain specific date (not "stat" or "as soon as possible," etc.), please advise us of the particulars of the situation, the specific date when the new license or amendment is needed and the specific justification and support for it, which should be briefly summarized.

Please also ensure that an appropriate senior management official (required by 10 CFR 35.12(a)) and/or your Radiation Safety Officer signs and dates the new license application or amendment request letter.

Please include the name of at least one knowledgeable contact person who is familiar with your new license application or amendment request, his or her direct telephone number, and the best fax number to transmit the completed amendment to you. A business email address for the contact person may also be helpful in many circumstances.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system.

Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability.

The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf> and the link for frequently asked questions regarding protection of security related sensitive information may be located at: <http://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document

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system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you.

This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture.

You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 21-35069-01
Docket No. 030-38647

Enclosure:
Amendment No. 3