



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

JUL 06 2018

Allen D. Soffer, M.D.  
Radiation Safety Officer  
Heart Care Specialists, LLC  
450 North New Ballas Road  
Suite 270 West Wing  
St. Louis, MO 63141

Dear Dr. Soffer:

Enclosed is Amendment No. 2 to your NRC Material License No. 24-35232-01 in accordance with your request.

This amendment changes the name on the license to "Heart Care Specialists, LLC," thus concluding your recent change of ownership and control transaction.

Please also note that we prepared this amendment using our new Web Based Licensing System (WBL). We deleted Condition No. 13, as it appeared on Amendment No. 1, in favor of adding reference to 10 CFR Part 71 in the Preamble language at the top of page 1 of your license.

We also added ADAMS accession numbers for the documents in the last condition of your license, commonly known as "the tie-down condition." ADAMS is the NRC's electronic document system. More information on ADAMS, which NRC has been using since 1999, can be found on our website at: <https://www.nrc.gov/reading-rm/adams.html>.

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. My email address is [colleen.casey@nrc.gov](mailto:colleen.casey@nrc.gov). Magdalena Gryglak worked on this review also. She can be reached at 630-829-9875.

We noticed that there was some confusion experienced in our review of this amendment, with respect to who the authorized point of contact was for the licensee and appropriate signatures for documents, etc. Your attorney, R. Scott Moore, and I discussed some of this in a telephone call on July 3, 2018, and he indicated it was helpful, so I am repeating it here for your benefit also.

To alleviate such confusion going forward, the following information may be useful. This is just some informal advice I've had to use often over the years.

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

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Signatures required for Materials Licensing Correspondence and Best Practices:

(The terms "applicant" and "licensee" are used interchangeably in the following)

Please note 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 identifying information on the NRC Form 313 may be used instead. Please identify your license by name, mailing address and license number; control number, if known; the current date; and a physical and legible signature, as described below.

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 for an initial request. Such persons, if designated in writing by an applicant's or licensee's certifying officer first, may serve as point(s) of contact and/or signatories for responses to requests for additional information to a specific initial request.

However, it is simplest and best to have all licensing correspondence signed by an appropriate certifying officer for the materials licensee in question.

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 NRC's regulatory requirements.

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.

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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 also note that 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 initial (i.e., the first request for a new license, amendment or renewal) licensing correspondence to: "ATTN: Materials Licensing Branch Chief" at the address shown above on our letterhead.

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>.

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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 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. 24-35232-01  
Docket No. 030-38828

Enclosure:

Amendment No. 2