



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. STE 210
LISLE, IL 60532-4352

Imad Issawi, M.D.
Radiation Safety Officer
Advanced Cardiovascular Clinic
5084 Villa Linde Parkway #6
Flint, MI 48532

MAY 12 2016

Dear Dr. Issawi:

This refers to the letter dated March 16, 2016, signed by Mohammad Luay Alkotob, M.D. requesting a new location of use to be added to your NRC Material License No. 21-35275-01.

We have reviewed your correspondence above and find that we need the information below in order to continue our review.

1. The facility diagram accompanying your letter above is of such poor quality that we cannot determine what it depicts. Please submit a replacement facility diagram that clearly shows the facility you wish to add. Please include larger fonts for the wording and sharper contrast as well.
2. Please confirm that you will extend all of the radiation safety elements in your existing licensed program to include the new facility when it is approved.
3. We noted that the letter above was signed by Mohammad Alkotob, M.D. and that Aubrey Gilbert is listed as the point of contact on the NRC Form 313 that accompanies the letter. Neither individual is the Radiation Safety Officer (RSO) of record or a senior management official, so far as we know. Dr. Alkotob is an authorized user on the license but Aubrey Gilbert is unknown to us.

Normally, the RSO and a senior management official sign licensing correspondence directed to us for changes to be made to the NRC license. We then normally address our correspondence and the finalized amendment to the attention of the RSO.

Please explain who Aubrey Gilbert is and advise us as to who should be signing your correspondence to us and serving as a point of contact. The RSO is intended to be a knowledgeable resource person in regulatory affairs who interacts with us, in conjunction with a licensee's senior management.

Please provide the fax number, direct telephone number and business email address for the RSO and point of contact.

Please also note the following information that may assist you in your understanding of our normal business expectations with you and our licensees.

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 licensing requests and subsequently provided information 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.

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.

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, 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>

I. Issawi

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

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.”

Within 15 days of the date of this letter (by May 27, 2016), please provide only one complete, written response to the issues below that is currently dated and signed by a senior management official for this license. Your written response should be addressed to my attention at the above address, as “additional information to control number 590419.” This will help ensure that your response is processed correctly in our offices.

If an alternative timeframe for response is needed please contact me directly. Or, if you have any specific questions concerning this letter or the information we are requesting, 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.

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>.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 21-35275-01
Docket No. 030-38875
Control No. 590419