

From: [Gallagher, Robert](mailto:Gallagher.Robert)
To: jseibyl@mnimaging.com
Cc: pgenakos@invicro.com
Subject: Request for Additional Information - Mail Control No. 609594
Date: Wednesday, September 12, 2018 1:13:00 PM
Attachments: [image001.png](#)

PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL

License No. 06-30624-01
Docket No. 03035657
Control No. 609594

Dear Dr. Seibyl;

This letter is in response to your request to amend Radioactive Materials License No. 06-30624-01 to change the radiation safety officer (RSO) and add an authorized user (AU). In order to continue our review additional information is necessary. Please provide the following information:

1. It appears from your letter that a possible change of name has occurred. Please respond whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who NRC may contact if more information is needed. Your last letter to the Commission, dated February 1, 2018 (signed by Kiyotaka Fujii, Senior Executive Officer, Konica Minolta, Inc. and Jack Hoppin, Chief Executive Officer, InviCRO, LLC) confirmed that the transaction (the indirect transfer of control of Molecular Neuroimaging to Konica Minolta) resulted in no change to Molecular Neuroimaging, LLC's name.
2. You have requested Jennifer Madonia, MS, PA-C replace John Seibyl, M.D. as the RSO (Dr. Seibyl will remain as an AU). In support of this request you provided a copy of a Certificate of Achievement for her completion of a 40 hour Radiation Safety Officer Training offered by Radiation Safety Associates, Inc. 10 CFR 35.50 Training for Radiation Safety Officer requires, in part, except as provided in 10 CFR 35.57, the licensee shall require the individual fulfilling the responsibilities of the Radiation Safety Officer as provided in 10 CFR 35.24 to be an individual who-
 - (a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State; or
 - (b) Has completed a structured educational program consisting of both:
 - (i) 200 hours of classroom and laboratory training in the following areas:
 - (A) Radiation physics and instrumentation;
 - (B) Radiation protection;
 - (C) Mathematics pertaining to the use and measurement of radioactivity;
 - (D) Radiation biology; and
 - (E) Radiation dosimetry; and
 - (ii) One year full time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer or a Commission or Agreement state license.

Please complete NRC Form 313A (RSO) RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION in support of Jennifer Madonia. The form and associated may be found in Appendix B of NUREG-1556, Vol. 9, Rev. 2 "Consolidated Guidance About Materials Licenses; Program-Specific Guidance About Medical Use Licenses." The NUREG may be found at <https://www.nrc.gov/docs/ML0734/ML073400289.pdf>.

We will continue our review of your request upon receipt of the above requested information. Please contact Robert Gallagher at (610) 337-5182 or at Robert.gallagher@nrc.gov with any questions.

Sincerely,

Robert L. Gallagher
Health Physicist
U.S. NRC, Region I
2100 Renaissance Blvd.
King of Prussia, PA 19406
(610) 337-5182 office
(610) 337-5269 fax

