



24 September 2018

Robert L. Gallagher
U.S. NRC, Region I
2100 Renaissance Blvd.
King of Prussia, PA 19406

Re: Response to Additional Information Request
Licensee: Molecular NeuroImaging, LLC
License No: 06-30624-01
Docket No: 03035657
Control No: 609594

Dear Mr. Gallagher,

Per your email request on 12 September 2018, please see the responses to your inquiries below:

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.

Response: Molecular NeuroImaging, LLC (MNI) is a wholly owned subsidiary of Invicro, LLC and provided a direct transfer of control to the NRC as documented under the Agency's ADAMS package accession # ML16159A106. Additionally, the letter referenced in your request was filed on 01 Feb 2018 to document the transaction of Molecular Neuroimaging to Konica Minolta. In both acquisitions the name of the company, Molecular Neuroimaging, remained a legal entity under Federal EIN #06-1594851 and as a CT business under Business ID # 0661674, per the CT Secretary of State. As a company, we have moved towards a unified branding approach on our letterhead and daily communications, which is Invicro, as you have noted. This branding effort in no way impacts our legal entity name of Molecular Neuroimaging, a wholly owned subsidiary of Invicro, LLC.

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

Rec'd. in HAT-11/21/2018

PROCESSED MATERIAL 0-002



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.

Response: In support of the qualifications for Jennifer Madonia, PA to serve as our site RSO, the NRC Form 313A has been completed and is attached for your review. It should be noted that Jennifer Madonia has been serving a preceptorship under John Seibyl, MD since 2012, who is the site's current Authorized User and Radiation Safety Officer. The specific focus of her training is documented in the attached Form 313A. Additionally, it should be noted that Jennifer Madonia has served as the company Safety Committee Officer from 2012-2017 and as of early 2018 is the Safety Committee Chair, where radiation safety is included within the committee's scope.

If you should have any additional questions or require other information, please do not hesitate to contact me directly at (203) 401-4313 or kfabrizio@invicro.com.

Thank you for your assistance.

Sincerely,

Kimberly Fabrizio
Vice President of Regulatory Affairs and Compliance
Invicro, LLC