

Cassata, James

From: Cassata, James
Sent: Wednesday, October 07, 2015 11:29 AM
To: 'cwatts@clymenvironmental.com'
Cc: 'james.zelinsky@fda.hhs.gov'
Subject: Request for Additional Information Regarding Licensee Renewal Application; NRC Lic No 19-30771-01, Mail Cntrl No 588859

NRC License No. : 19-30771-01

Docket No. : 030-36120

Mail Control No. : 588859

License Name: Department of Health and Human Services, Public Health Service, Food and Drug Administration, CFSAN

RSO: Charles Watts Office 301-694-6000, Business Cellular 410-320-2344, cwatts@clymenvironmental.com

Safety Manager: James A. Zelinsky, Office 240-402-1599, james.zelinsky@fda.hhs.gov

Mr. Watts,

I am working on the review of your license renewal application (letter dated August 24, 2015) and had a few points to clarify as follows.

1. With regard to the purpose for which licensed material will be used (Item No. 6 of NRC Form 313), please state if the animal research will also use licensed material for tracer/field studies. (see page 8-13 of [NUREG-1556 Vol. 7 \(1999\)](#))
2. With regard to the purpose for which licensed material will be used (Item No. 6 of NRC Form 313), please state whether the animal studies will be limited to small animals (e.g., rats, mice, small fish) or will also be used on larger animals (e.g., pigs, dogs, horses) and if the material will be used in pets (cats, dogs) or in farm animals (cattle, horses, pigs). (see page 8-13 of [NUREG-1556 Vol. 7 \(1999\)](#))
3. With regard to training for individuals working in or frequenting restricted areas (Item No. 8 of the NRC Form 313), please indicate if training is provided by person's other than yourself, and if so, please provide a statement of their qualification for instruction. (see Section 8.8 of NUREG-1556 Vol. 7 (1999))
4. With regard to training for individuals working in or frequenting restricted areas (Item No. 8 of the NRC Form 313), please indicate the method of training (for example; classroom, online, handout, etc.) for radiation and ancillary workers. (see Section 8.8 of NUREG-1556 Vol. 7 (1999))
5. With regard to training for individuals working in or frequenting restricted areas (Item No. 8 of the NRC Form 313), please indicate how radiation and ancillary worker training effectiveness is assessed (for example; by on the job work review by RSO, written examination, oral interview by RSO, etc.). (see Section 8.8 of NUREG-1556 Vol. 7 (1999))
6. As an information only item to you, with regard to sealed source and plated foil leak testing (Item No. 10. of the NRC Form 313), please note that although you are not seeking authority to possess specifically licensed sealed sources, license condition 16 of your current license (concerning leak testing) will remain on the renewed license but it will be modified to only allow the **analysis of leak test samples** to be performed by organizations authorized by the NRC or an Agreement State, and not by the licensee. This will specifically change license condition 16 G to read the following:

“Tests for leakage and/or contamination, limited to leak test sample collection, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. **The licensee is not authorized to perform the analysis**; analysis of leak test samples must be performed by persons specifically licensed by U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.”

(Note that the collection of the sample by the licensee would be authorized by this statement but not the analysis of the sample.)

Should you desire in the future to have the ability to perform your own leak test analysis you would need to submit a license amendment and provide the following information for review prior to receiving authorization in a license amendment:

- a. A description of the instrumentation that will be used for analyzing each radionuclide for which you will be performing a wipe test on a sealed source.
- b. The method used to determine the efficiency-of-counting for each instrument for the radionuclides that will be assayed and show the calculation of the efficiency-of-counting for each of the nuclides for which you will be performing a wipe test on a sealed source.
- c. The actual calculation of the minimal detectable activity for each radionuclide to demonstrate the ability to detect 0.005 microcuries.

The reply to this request for additional information must be in the form of a signed and dated reply letter by a management representative/ certifying Officer (an individual who is responsible for the processes for conduct and control of the licensee’s radiation safety program and who has authority to provide necessary resources to achieve regulatory compliance); in this case this person would specifically be **Mr. James A. Zelinsky** (or his designee in writing). Please always include the **Mail Control No. 588859** with all correspondence

For expedience, please make an electronic PDF copy of the signed and dated letter and send it to me at james.cassata@nrc.gov; or alternatively fax it to my attention at 610-337-5269. Once I receive the signed and dated letter you will receive a confirmation of receipt from me.

We will continue our review and processing of your renewal application upon receipt of this information. If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your application.

Please contact me by phone or e-mail if you have any questions.

Thank you for your prompt attention and cooperation.

James R. Cassata, Ph.D., CHP
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