



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 21, 2005

Docket No. 03036120  
Control No. 136722

License No. 19-30771-01

Arnold P. Borsetti, Ph.D.  
Associate Director for Operations  
Department of Health & Human Services  
Center for Food Safety and Applied Nutrition  
Harvey W. Wiley Building  
5100 Paint Branch Pkwy, HFS-003  
College Park, MD 20740

SUBJECT: DEPARTMENT OF HEALTH & HUMAN SERVICES, REQUEST FOR  
ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL  
OF LICENSE, CONTROL NO. 136722

Dear Dr. Borsetti:

This is in reference to your application dated March 30, 2005 requesting to renew Nuclear Regulatory Commission License No. 19-30771-01. In order to continue our review, we need the following additional information:

1. Describe the **criteria** your Radiation Safety Officer (RSO) will use to approve authorized users and uses for activities utilizing licensed material. These criteria should specify the minimum acceptable standards for training and experience of the users, facilities and equipment, and the criteria used for determination of Class I or Class II laboratories. Your application must provide sufficient detail to assure that the RSO evaluations are sufficient in scope and depth to satisfy 10 CFR 33.14(b)(2). You may wish to consider the criteria found on page 8-17 of NUREG-1556, Volume 7, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope." Also consider some of the statements written in Appendix K of NUREG-1556 Volume 7, and classification similar to Appendix K of NUREG-1556, Volume 11, "Program Specific Guidance About Licenses of Broad Scope." The application described the reviews that would be done but more detail is needed in the criteria that is used.
2. Submit a description of the radiation safety training program developed for each group of workers, including: topics covered; qualification of the instructors; method for assessing the success of the training; and the frequency of training and refresher training; or identify the model training program described in an appropriate base NUREG-1556. The model training program in Appendix J of NUREG-1556, Volume 7 may be helpful in formulating your response. The application described basic radiation training topics and method of training but did not give needed detail for each group of workers, qualification of instructors, method to assess training, nor the frequency of refresher training.

A. Borsetti  
Department of Health & Human Services

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3. Provide your procedures for safe use of radionuclides, including security of materials and emergencies. As an alternative, you may state, "We will adopt the procedures for the safe use of radionuclides and emergencies as published in Appendix R of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope."
4. Describe the scope of the activities at temporary job sites. Describe if there will be any limitations placed on temporary job sites that would not be employed at permanent facilities. See Section 8.3 of NUREG-1556, Volume 11
5. Please note that this Radioactive Material License 19-30771-01 is not classified as a Medical License. As such, in-vitro test kits pursuant to 10 CFR 31.11 are not generally licensed to this facility and no exemptions apply. However, you may consider filing NRC Form 483, "Registration Certificate - In Vitro Testing with Byproduct Material Under General License" as stated in 10 CFR 31.11(b)(1). Once approved, in-vitro kits may be purchased under the general license. This paragraph is stated due to the statement on Page 21, section 11.1 which discusses generally licensed material pursuant to 10 CFR 31.11. Additionally it should be noted that the exemptions for in-vitro kits maintain disposal requirements for Mock I-125 reference or calibration sources as required in 10 CFR 30.11(c)(5). No reply from the licensee is required for this paragraph.

Current NRC regulations and guidance are available at the NRC web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html> and <http://www.nrc.gov/who-we-are/governing-laws.html> or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 136722. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5308.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

***Original signed by Todd J. Jackson, CHP***

Todd J. Jackson, CHP  
Senior Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

cc:  
Constance S. Rosser, Radiation Safety Officer



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