



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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RE: Mail Control No. 136722, Request for additional information concerning application for renewal

Enclosed is the additional information requested in order to continue prompt review of the renewal application for the NRC Type B Broad Scope License No.19-30771-01, issued to the Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, Department of Health and Human Services.

If your staff has questions or need additional information during the review of this response please contact the undersigned at 301-436-2105.

Sincerely,

Constance S. Rosser
Constance S. Rosser
Radiation Safety Officer
Center for Food Safety and
Applied Nutrition

136722

NMSS/RGNI MATERIALS-002

Question 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.

CRITERIA USED FOR APPROVING PROTOCOLS UTILIZING LICENSED MATERIAL. The following criteria will be used to evaluate and approved a request to use radioactive material:

1. Protocol Consideration. The existing license conditions will be evaluated to ensure the request is authorized. The as a minimum the following criteria will be used:

License. The RSO will verify that the existing license conditions authorize the proposed chemical and physical form and the proposed use of the radioactive material. If the license does not authorize the proposed use, a license amendment will be requested. The RSO will not approve a request for radioactive material until the license amendment is granted.

Radionuclide. The RSO will assess the radionuclide to be used, considering whether an alternate, less hazardous radionuclide could be used and whether a radionuclide is necessary or if other technology is available to achieve the same results.

Quantity. The quantity of radionuclide proposed for use will be compared with the amount authorized under the existing license. This comparison will take in consideration both the quantity to be used during the project and the total on-site inventory for the specific radionuclide. The inventory of concern includes both quantities in laboratories and waste generated quantities that are stored for decay and waiting for off-site disposal.

Chemical and Physical Form. If the material proposed for use is volatile, the need engineering controls for volatile form will be assessed. Chemical methods for reducing the volatility of the chemical compound may be used if available.

Work Procedures. The RSO will consider whether there are standard procedures for doing the proposed work; whether the proposed worker understands and complies with the established procedures; whether the procedures can be improved, for example, by reducing the work time; and what type of personal protective apparel should be worn.

2. Personnel Considerations. Personnel considerations in the assessment of authorizing the use of radioactive material include:

Education and Training. Personnel assigned to work on projects involving the use of radioactive materials or radiation-generating sources will be receive site-specific training commensurate with the hazards associated with radiation and trained in the specific skills required for their job. Authorized users should have a college degree at the bachelor level, or equivalent training and experience in physical, chemical, or biological sciences or in engineering. The amount of training and experience will depend upon the type, form, quantity and proposed use of the licensed material requested.

Personnel Monitoring. The RSO will ensure that personnel who will work with radioactive materials are provided with appropriate monitoring devices. Monitoring devices such as whole-body monitors and extremity TLDs shall be worn by all personnel who receive, or may be expected to receive, a radiation dose higher than 10% of the applicable standard.

Pregnant or Declared Pregnant Woman (DPW). The NRC requires that, for declared pregnant woman the maximum equivalent to an embryo-fetus from occupational exposure, during the entire gestation period should not exceed 0.5 rem.

Minors. Individuals under 18 years of age shall not be exposed to more than 10% of the occupational dose limits.

3. Evaluation of Facilities. The facility in which the project will be carried out shall be evaluated to ensure the radioactive materials can be used safely. The information to be considered includes:

Shielding. The amount of shielding required depends on the radionuclide to be used, the quantity of radioactive material to be present and the proposed use of adjacent areas. If shielding already exists, the RSO will assess whether the shielding is sufficient; how much additional shielding will be required, and whether the building can support the required shielding.

Equipment. The working area shall have appropriate equipment prior to beginning a project, which may include chemical fume hoods, glove boxes and air filter systems.

CRITERIA USED FOR DETERMINATION OF CLASS I OR CLASS II LABORATORIES. We will adopt the applicable criteria and classifications for our laboratories as published in Appendix K, NUREG-1556, Volume 7, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope" and Appendix K of NUREG -1556, Volume 11, "Program Specific Guidance About Licenses of Broad Scope."

1. Class I Laboratory.

Type C Workplace. The design, construction and equipment used in a Class I Laboratory are similar to a good quality chemical laboratory. The normal facility ventilation is usually sufficient, and could be complemented with continuous movement of air into a fume hood.

2. Class II Laboratory. This classification is sub-divided into two types of workplace.

Type B Workplace. This laboratory is specifically designed, constructed and equipped for work with radioisotopes. The levels of airborne activity should be kept as low as is reasonably achievable (ALARA) by the use of totally or partially ventilated fume hoods or glove boxes. The workplace should have reduced air pressure relative to the surrounding areas. The ventilation exhaust should be via a fume hood. There should be a space for an absolute filter and for monitoring the negative pressure gradient. Special attention should be given to avoiding the recirculation of air and the dispersion of contamination to other occupied areas. The surfaces of the fume hood and ventilation duct should be smooth and made of non-absorbent material that can withstand the chemicals normally used in the hood. The speed of the air flow be regular, without eddies, and should be such that there can be no escape of air from the fume hood into the workplace under typical operation conditions including the opening of windows and doors and the suction of other fume hoods. The gas, water and electrical outputs should be operated from outside the hood. Fume hoods and glove boxes where "active" work is carried out should be properly marked with the radiation symbol and the appropriate explanatory text. A waste bin with a foot-operated lid should be available for the collection of low activity waste. The bin should bear the radiation warning sign. A plastic bottle which could withstand the effects of the various solvents and the effects of radiation should be provided for the temporary retention of liquid waste.

Type A Workplace. This laboratory is specifically designed, constructed and equipped to handle large quantities of radioactive material. Cases involving risks of air contamination will be carried out in completely enclosed glove boxes or hot cells under negative pressure and provided with filters and transfer boxes. Radioactive substances should be stored only in a special room equipped with suitable shielding and ventilation, and in accordance with waste storage requirements.

Question 2. Submit a description of the radiation safety training program developed for each group of workers, including : topics covered; qualification of the instructors; methods 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 methods off training but did not give needed detail for each group of workers, qualification of instructors, and method to asses training, nor the frequency of refresher training.

DESCRIPTION OF RADIATION SAFETY TRAINING PROGRAM DEVELOPED FOR EACH GROUP OF WORKERS. The training topics will be consistent with the appropriate procedures for Radiation Safety Training Topics as published in Appendix J of NUREG -1556, Volume 7, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope."

1. Training Program for Authorized Users. All occupationally exposed workers shall receive instruction in accordance with Title 10, Code of Federal Regulation Part 19.12 prior to assuming duties with, or in the vicinity of, radioactive materials; when there are significant changes in duties, regulations, or the terms of the license. The training program will include both initial training and periodic refresher training. The radiation safety training will be commensurate with the assigned duties and specific requirements of the FDA/CFSAN radiation safety program.

a. **Principal Investigator.** The principal investigator's (PI) primary responsibility is to ensure radiation safety through the implementation of the policies and procedures established by the RSO. As a minimum, the training and experience required must be equivalent to that specified in 10 CFR 33.15(b):

(1) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering, and;

(2) At least three years of radionuclide use experience performing work similar to that identified in the user's protocol.

(3) Successful completion of the Basic Radiation Safety Course or equivalent training approved by the RSO. This training will be conducted by the RSO or qualified radiation safety staff/contractor personnel. As a minimum the following topics will be addressed:

- (a) The safe handling of radioactive materials,
- (b) The characteristics of ionizing radiation,
- (c) Units of radiation dose and quantities,
- (d) Radiation detection instrumentation
- (e) Biological hazards of exposure to radiation

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Qualification of the Instructors. The individual conducting the training will meet the qualifications of the RSO or an authorized user on the license and be familiar with the FDA/CFSAN License conditions and duty requirements of the target audience being trained.

Testing. A written assessment will be provided at the end of each training session to ensure satisfactory comprehension of the radiation hazards associated with the ongoing research.

Training Frequency. An initial one day orientation training class will be required and annual refresher training thereafter.

Period of Document Retention. Attendance records and assessment records shall be maintained by Radiation Safety Staff for a period of three (3) years.

b. **Radiation Worker.** A radiation worker is an individual who is approved to conduct research using licensed radioactive material. This individual has demonstrated the appropriate level of knowledge required for safe use of radioactive materials as described in the CFSAN Radiation Safety Program and project protocol. In addition to the 10 CFR 19.12 instruction and prior to handling radioactive material each radiation worker will:

(1) Receive protocol specific training from the PI. The PI will document the radiation worker's completion of his/her instruction and certification.

(2) Be supervised until the PI has confidence in the radiation worker's abilities and understanding of the license conditions and other safety issues governing the protocol.

Qualification of the Instructor. The individual conducting the training will meet the qualifications of the RSO or an authorized user on the license and be familiar with the FDA/CFSAN License conditions and duty requirements of the target audience being trained.

Testing. A written assessment will be provided at the end of each training session to ensure satisfactory comprehension of the radiation hazards associated with the ongoing research.

Training Frequency. The RSO will provide an initial one day orientation training class and annual refresher training thereafter. The PI will provide supervised training until proficiency is demonstrated and recertification as deemed necessary.

Period of Document Retention. Attendance records and assessment records shall be maintained by Radiation Safety Staff for a period of three (3) years.

2. Training Program for Non-Authorized Users. All persons requiring access to FDA/CFSAN licensed facilities restricted areas regulated under the authority of the NRC license shall be provided instruction in radiation safety commensurate with the radiological hazards associated with the areas they are likely to enter or work in the vicinity of in accordance with Title 10, Code of Federal Regulation Part 19.12.

Ancillary Staff. The RSO will develop special programs to instruct ancillary staff, (animal husbandry, maintenance, janitorial, security, shipping and receiving, etc.) commensurate with the radiation hazards in accordance with 10 CFR 19 instructions.

Qualification of the Instructor. The individual conducting the training will meet the qualifications of the RSO or an authorized user on the license and be familiar with the FDA/CFSAN License conditions and duty requirements of the target audience being trained.

Testing. A written assessment will be provided at the end of the initial training session and at least bi-annually thereafter. The assessment will be used to evaluate the individual's level of understanding the radiation hazards associated with their work and the appropriate actions required to prevent unnecessary exposure.

Training Frequency. The RSO will provide an initial one day orientation training class for managers and initial one-half day orientation training for other workers. Annual refresher training will be provided thereafter. The RSO will provide recertification training as deemed necessary, i.e. change in personnel, change in regulatory policy, etc.

Period of Document Retention. Attendance records and assessment records shall be maintained by Radiation Safety Staff for a period of three (3) years.

Question 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."

Response. We have reviewed your comments in Question 3 above and assessed the March 30, 2005 application statements concerning emergency procedures. We believe our initial response has addressed your comments in Question 3. We are requesting that you reevaluation Item 10, RADIATION SAFETY PROGRAM, Subparagraph 10.4, Emergency Procedures of our March 30, 2005 application to verify there are no discrepancies.

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Question 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.

Response. A temporary job site can best be described by a mobile laboratory containing analytical equipment to perform immediate field analysis as required. The authorization to operate a temporary job site will be consistent with the existing NRC License conditions authorized at Muirkirk Road Complex, Laurel, Maryland and Harvey W. Wiley Building, College Park, Maryland.

Question 5. No reply was required from the licensee.