



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4352

DEC 22 2004

Richard T. Hurley, DA  
Radiation Safety Officer  
Bellbrook Labs LLC  
505 S. Rosa Rd.  
Madison, WI 53719

Dear Mr. Hurley:

This refers to your application dated September 21, 2004, requesting a new byproduct materials license. The information provided by your application was insufficient to complete my review and I need additional information, as described below.

As we cannot continue to process your request, we have voided your request at this time. This action is without prejudice to resubmission. If you resubmit your request please state that the resubmission is "additional information to Control Number 313765" and reference it to my attention at the above address. Please also advise us of the facsimile telephone number for your licensed program.

1. Please submit a letter, currently dated and signed by you stating that you accept the position as RSO for this license and that you understand the duties and responsibilities associated with this position.
2. Please explain what a "DA" degree is, as I am unfamiliar with this designation.
3. Please have a senior administration official at the University of Saint Francis sign and date your response, and attest to his or her concurrence on the submission of the new license application dated September 21, 2004. This is because we cannot accept you as the signatory for the license at this time, unless you also hold a senior administration position with the University and are authorized to sign documents on behalf of the University.
4. We will require additional detailed information about each of your proposed authorized users (AU) and you, as the Radiation Safety Officer (RSO). To assist you in preparing your response, I am offering the following guidance and suggestions, as well as enclosing a copy of NUREG 1556, Vol. 7, Final.

Generally, the training and experience supporting an applicant should be commensurate with the types, quantities and proposed uses of radionuclides and the associated degree of hazard.

For example, a minimal level of training and experience would be necessary for an authorized user working with microcurie amounts of pre-labelled soft beta emitting radionuclides "in vitro."

Additional training and experience in the safe handling of radioactive materials, appropriate to the type of use, would be necessary for an authorized user working with millicurie amounts of gamma-emitting materials "in vivo" or for an authorized user working with millicurie or curie amounts of tritium, iodine-125, carbon-14 or phosphorus-32 in labelling procedures.

Please refer to section 8.7 in NUREG 1556, Vol. 7, for guidance in preparing your response. Also, the criteria in 10 CFR 33.15(b), excerpt attached, may assist you.

Please do not include extraneous, personal, proprietary information such as resumes, curricula vitae, college transcripts, dates of birth, social security numbers, etc. If appropriate, include a brief narrative statement of explanation on a separate sheet of paper.

Specifically, each applicant should submit information that clearly demonstrates his/her training and experience is commensurate with the proposed possession and use.

It may be useful to describe in greater detail, but concisely what major field of study each applicant obtained his/her degree in, particularly if the degree does not readily appear to be associated with the use of radioactive materials. If the applicant received radiation safety training or supervised radioactive materials work experience as an undergraduate and/or graduate student, please provide details, on-the-job and/or formal coursework training, including the location and duration (hours, days or months) of the training.

Training should consist of at least forty hours and cover:

- 1.1. principles and practices of radiation protection,
- 1.2. radioactivity measurements, standardization, and monitoring techniques,
- 1.3. mathematics and calculations basic to the use and measurement of radioactivity,
- 1.4. biological hazards of exposure to radiation appropriate to the type and form of byproduct material to be used, and
- 1.5. radiation detection instrumentation.

Please describe the typical and maximum activities each applicant used of each isotope and the types of experiments engaged in (bound or unbound, "in vitro" or "in vivo.")

Please provide appropriately detailed information for you, Teresa A. Beam, Ph.D., Jean M. Elick, Ph.D., Sister M. Carol Meyers, D.A., and Warren Pryor, M.S.

5. Certain sections of your application appear to indicate that sealed sources might be obtained under this license, if it is approved. However, no commitment to testing sealed sources for leakage was made and no commitment to handling sealed sources with remote handling tools, as appropriate, was made. Please clarify whether it is your intention to possess sealed sources under the proposed license and if so, please commit to testing the sealed sources for leakage, as described in Section 8.10.7. and Appendix R in NUREG 1556, Vol. 7, and please confirm that sealed sources will be handled with remote handling tools, as appropriate.
6. Regarding your proposed training program for individuals working in or frequenting restricted areas, please enhance your training program to more closely align with the topics in Appendix J, NUREG 1556, Vol.7. It appears that such topics as emergency procedures, NRC regulations, survey requirements, personnel monitoring requirements special lab rules, plexiglas shielding and finger badges for handling phosphorus-32, etc. were not addressed in your application dated September 21, 2004.

Further, please define "biannual" training frequency. Please state whether the assessment test after training will be written and/or oral or practical. Please advise me

as to what a passing grade will be and please confirm that incorrect answers will be reviewed with the trainee to ensure complete understanding of the material presented. It is not necessary nor desirable to submit an exam.

Please submit your revised training program to include the additional elements above.

7. Please describe and show the locations of shielding materials, and describe the types of shielding you will employ for your facility diagram. Also, please describe and show the proximity of radiation sources to unrestricted areas and identify the function of all areas immediately surrounding your proposed laboratory areas.

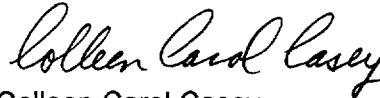
As stated above, we cannot issue your new license at this time and so we are voiding this request in order to enable you to prepare a quality application without time constraints. Please note that a "void" is an administrative procedure that puts your new license request "on hold" (takes it out of our active casework database) until you reactivate it via submission of a written response to the above items. It "buys" you time to prepare a quality response and is generally regarded as a "good thing."

Please direct any questions you may have to me at (630) 829-9841 or (800) 522-3025. My fax numbers are (630) 829-9782 or (630) 515-1259.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS.

The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or [pdr@nrc.gov](mailto:pdr@nrc.gov).

Sincerely,



Colleen Carol Casey  
Materials Licensing Branch

Control No. 313765  
Docket No. 030-36686

Enclosures:

1. 10 CFR Part 33
2. NUREG 1556, Vol. 7, Final