



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

December 28, 2004

Docket No. 03030602
Control No. 135937

License No. 37-28218-01

Joan M. Chapdelaine, Ph.D.
Vice President, Immunology
Calvert Laboratories, Inc.
Scott Technology Park
100 Discovery Drive
Olyphant, PA 18447

SUBJECT: CALVERT LABORATORIES, INC., REQUEST FOR ADDITIONAL
INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE,
CONTROL NO. 135937

Dear Dr. Chapdelaine:

This is in reference to your application dated November 29, 2004 requesting to renew Nuclear Regulatory Commission License No. 37-28218-01. In order to continue our review, we need the following additional information:

1. If licensed materials are to be used in animals, please submit:
 - a. a description of the training that will be provided to individuals caring for animals containing licensed materials, and
 - b. a copy of the instructions provided to animal caretakers for handling of animals, animal waste carcasses, and cleaning and decontamination of animal areas and cages.

Appendix H of NUREG-1556, Volume 7 addresses considerations for laboratory animal uses and may be helpful to you in developing a response.

2. You have described your radiation safety training program for laboratory personnel who will work directly with radioactive material. Describe your program for initial training and refresher training for ancillary personnel. This training program must include a review of emergency procedures and response criteria and include topics that are tailored to various types of ancillary workers such as laboratory personnel not working directly with licensed material, personnel receiving licensed material packages, housekeeping, security, maintenance and other ancillary personnel. Include a list of topic(s) covered, the groups of workers to be trained, how you will assess the effectiveness of the training and the method and frequency of the training. The model training program in Appendix J of NUREG-1556, Volume 7 may be helpful in formulating your response.

3. Please provide additional details about your radiation safety survey program. You state that surveys are performed at the conclusion of each study. Please confirm if these are ambient radiation level surveys, contamination surveys or both. Discuss the training and experience an individual will receive before they are allowed to perform surveys. Please clarify what surface area your 200 dpm limit of contamination applies to; 100 cm² is typical. Discuss how you will monitor for potential contamination in unrestricted areas. Confirm that your survey records will include the information listed in Appendix Q of NUREG-1556, Volume 7. This appendix may be helpful in providing more details regarding your radiation safety program.

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 NRC 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 pdrc@nrc.gov.

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. 135937. If you have any technical questions regarding this deficiency letter, please call John Nicholson at (610) 337-5236.

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 Elizabeth Ullrich

Elizabeth Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
10 CFR Parts 19, 20, and 30

cc:
William G. Tuman, Radiation Safety Officer

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