L-6

From: Christopher Hott
To: Mtlairmore@optonline.net
Date: Thu, Jun 23, 2005 8:06 AM
Subject: NRC Renewal request for Woodburn Nuclear Medicine, mail control 136820

45-23073-01

03020240

Reference: Woodburn Nuclear Medicine
45-23073-01
03020240
mail control 136820

To: Michael W. Lairmore, Medical Physics Consultant

This is in reference to the application dated March 16, 2005 to renew Nuclear Regulatory Commission license 45-23073-01. Please provide the following information within 30 days. You may fax your response to 610-337-5269.

Please send an e-mail to confirm receipt of this message.

1. Application item five (Radioactive materials)

a) 10 CFR 35.300 amount request is as needed (not to exceed 1.5 Ci of I-131). Current NRC practice is to provide a possession limit that applies to all of 35.300, not just I-131. Please provide a reasonable limit that will include all of your 35.300 activities. When providing this limit, please consider the maximum amount of 35.300 material you might possess at any given time including waste. For a program of your type, the typical authorization is in the range of hundreds of millicuries.

b) You requested authorization for use of materials under 10 CFR 35.311 for clinical in-vitro studies. Please confirm this is a typographical mistake meant to be 10 CFR 31.11 and that you still perform these activities.

c) If you still require 10 CFR 31.11 in-vitro authorization, please provide a limit for the maximum amount of 31.11 material you will maintain on site (including waste) at any given time. 5 millicuries is a typical authorization.

2. The application item seven does not include several of the currently listed authorized users on the license. Please confirm that you wish to remove Dr. Rauth, Dr. Sharma, Dr. Silverman, Dr. Majd, and Dr. Quion as authorized users from your license.

3.The application requested to add Steven K. West as the Radiation Safety Officer (RSO). The credentials submitted for Mr. West do not meet the requirements of 10 CFR 35.900. Attachment 7.2 of the letter provided a certificate for completion of a 40-hour RSO Training course (with no listing of topics covered), two certificates of registry with boards that are not currently recognized by the commission, and a letter from Dr. Eric H. Norby (the current RSO) stating that Mr. West has worked under his supervision for several years to acquire necessary RSO training.

The requirements of 10 CFR 35.900 (b) (Training and experience Requirements for RSO) state:

1) A prospective RSO must have 200 hours of classroom and laboratory training and experience that includes:

i) Radiation physics and instrumentation
ii) Radiation protection
iii) Mathematics pertaining to the use and measurement of radioactivity
iv) Radiation biology

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v) Radiopharmaceutical chemistry

2) A prospective RSO must complete one year of full time experience as a radiation safety technologist under the supervision of the individual identified as the RSO.

Based on these requirements, in order to approve Mr. West as the RSO, you must submit,

1) A summary of classroom and laboratory training that shows a minimum of 200 hours in the topical areas listed above.
2) Confirmation that Mr West completed the equivalent of at least one full-time year as radiation safety technologist while under Dr. Norby's supervision.

4. Please confirm that you will provide treatment authorized under 10 CFR 35.300 only to those persons able to be released under 10 CFR 35.75.

5. Application item 9.3 (dose calibrator calibration) states that you will establish and implement draft report regulatory guide 1556, volume 9, appendix J. NRC draft regulatory guides are not final agency documents and as such cannot be assumed to represent agency position on acceptable ways to meet regulatory requirements. In addition, the agency no longer requires the submission of detailed procedures or commitments to model procedures for the licensed activities that you currently perform. Please confirm that equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

6. Please note that your application included commitments to implement several model procedures that are no longer required to be submitted for the licensed activities you perform. The NUREG-1556 volume 9 model procedure appendices and Reg Guide 10.8 model procedures listed below were not reviewed and will not be considered part of your license:

1) Appendix J - Model Training Program
2) Appendix I - Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority.
3) Appendix Q - Model Leak Test Program
4) Appendix N - Model Emergency Procedures
5) Appendix O - Model Procedures for Ordering and Receiving Packages
6) Appendix P - Model Procedures for Safely Opening Packages Containing Radioactive Materials
7) Appendix S - Model Procedures for Developing, Maintaining, and Implementing Written Directives
8) Appendix M (R.G. 10.8) - Model procedures for Unit Dosage and Multi Dose Vial Record Systems

7. Please confirm that you reserve the right to upgrade your survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

8. The application stated that you will implement the following NUREG 1556 Volume 9 model procedure appendices:

1) Appendix K - Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program
2) Appendix M - Model Procedures for an Occupational Dose Program
3) Appendix T - Model Procedures for Safe Use of Unsealed Licensed Material
4) Appendix R - Model Procedures for Area Surveys
5) Appendix W - Model Procedures for Waste Disposal by Decay-In-Storage

These model procedures are an acceptable way to meet NRC regulations. Please note that you may make changes to these radiation protection program procedures as provided for in 10 CFR 35.26. Please also note these procedures may be overly prescriptive for your activities. For this reason, many applicants choose instead to submit the suggested responses listed in NUREG 1556 Volume 9 Appendix C for these five items. We strongly recommend this approach. If you decide to submit the suggested

responses, we will disregard the submission of these procedures in your application.

As stated previously, please provide this information within 30 days. You may fax your response to 610-337-5269, referencing mail control 136820. Please notify me when the fax is sent so I will know to look for it. You may e-mail or call me with any questions.

Thank you,

Chris Hott
Health Physicist
Medical Branch
Division of Nuclear Materials Safety
NRC Region 1
610-337-5142

CC: Swest4444@aol.com

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