



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

August 25, 2005

Docket No. 03030074
Control No. 137478

License No. 29-28056-01

David Stirling
Executive Vice-President, Research & Development
Celgene Corporation
7 Powder Horn Drive
Warren, NJ 07059

**SUBJECT: CELGENE CORPORATION, REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL
NO. 137478**

Dear Mr. Stirling:

This is in reference to your letter dated July 29, 2005 requesting to amend Nuclear Regulatory Commission License No. 29-28056-01. In order to continue our review, we need the following additional information:

1. Your application should have been signed by a management representative rather than the Radiation Safety Officer. Our most recent management contact was David Stirling, Executive Vice-President of Research and Development. Please submit a letter signed by a management representative indicating that management has reviewed the application and concurs in the statements and representations contained therein. Note also that a management representative should sign all future correspondence that requests a change in your license.
2. You requested that the RSO be authorized to provide annual refresher training, and/or to designate a qualified individual to provide initial or annual refresher training. Provide the following information:
 - a. the groups of workers to whom training will be provided and any variations in the minimum topics to be covered;
 - b. a description of the topics to be covered in (1) initial training and (2) refresher training for each group of workers; and
 - c. the minimum qualifications of individuals who will provide training.

Guidance for radiation safety training programs may be found in Section 8.8 and Appendix J of NUREG-1556, Volume 7, "Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope".

3. At the time of the renewal, your license was changed to authorize you to possess 100 millicuries of tritium and 99 millicuries of carbon-14. Authorization for tritium alone in quantities greater than 1000 millicuries requires provision of financial assurance. Authorization for carbon-14 alone in quantities greater than 100 millicuries requires provision of financial. Using the "unity rule", the fraction of tritium (100 millicuries/1000 millicuries = 0.1) plus the fraction of carbon-14 (99 millicuries/100 millicuries = 0.99) equals 1.09, which is greater than 1. Therefore the total amounts of these radionuclides authorized on the current license requires provision of \$225,000 financial assurance for decommissioning, in accordance with 10 CFR 30.35. You may either reduce the amounts of tritium and/or carbon-14 authorized on the license, or you must submit financial assurance for these materials.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material**; then **toolkit index page**. Or you may obtain these documents 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. 137478. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5040.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Elizabeth Ullrich

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

cc:
Michael T. Conroy, Radiation Safety Officer

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SISP Review Complete: (exu)

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