



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

April 14, 2009

Docket No. 03038020  
Control No. 143628

License No. 31-31364-01

Mitchell Silverstein  
Director of Facilities  
PsychoGenics Inc.  
765 Old Saw Mill River Road  
Tarrytown, NY 10591

SUBJECT: PSYCHOGENICS INC., REQUEST FOR ADDITIONAL INFORMATION  
CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 143628

Dear Mr. Silverstein:

This is in reference to your application dated April 6, 2009 applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. You have requested for materials in the quantity of millicuries per year. Your license will be listed for a total amount of material at any one time, which includes the amount of material on hand in waste and storage. Please state the maximum possession limit for each isotope.
2. 10 CFR 30.32(g) requires that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State; **or** contain the information identified in 10 CFR 32.210(c). Please provide this information for the sealed source(s) requested in your application.
3. If you intend to use more than one millicurie of phosphorus-32 in a procedure, submit special safety instructions to be provided to individuals. Your procedures should include:
  - a. the use of low density shielding (e.g., plexiglass) in order to keep Bremsstrahlung radiation at a minimum,
  - b. a mandatory radiation survey and wipe test for radioactive contamination after each use,
  - c. the use of finger extremity monitors for procedures that involve one millicurie or more,

- d. a dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the radiation protection officer be present during new procedures, and
  - e. the use of eye protection for procedures that involve 10 millicuries or more.
4. If you intend to use more than one millicurie of radioiodine in a procedure, submit special safety instructions to be provided to individuals. Your procedures should include:
- a. A mandatory radiation survey and wipe test for radioactive contamination after each use.
  - b. Bioassay procedures for individuals working with millicurie quantities of radioiodine.
  - c. The use of vented hoods for iodination and for the storage of millicurie quantities of radioiodine.
  - d. A dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the radiation protection officer be present during new procedures.
  - e. Procedures for measuring the concentration of radioiodine from the hoods where material is stored and where iodinations are performed.
5. If licensed materials are to be used in animals, please submit:
- a. a description of the animal housing facilities,
  - b. a description of the training that will be provided to individuals caring for animals containing licensed materials, and
  - c. a copy of the instructions provided to animal caretakers for handling of animals, animal waste carcasses, and cleaning and decontamination of animal cages.

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

6. It is unclear if you plan to calibrate your portable survey instruments or just provide a source check. If you plan to calibrate survey instruments then provide procedures for the calibration of your survey meters, including:
- a. The training of the individual who will do the calibrating of the survey meters.
  - b. Where the calibration will take place.
  - c. Calculations to determine source to detector distance.

- d. Step-by-step procedures to perform the calibration.

If you do not plan to calibrate your portable survey instruments please make it clear that you will have persons licensed to provide calibration services of your instrumentation.

- 7. In accordance with NUREG-1556, Volume 7, Section 8.10.3., provide either of the following: A statement that:

“Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.” or

A description of the procedures for ensuring that no sealed sources have been lost, stolen or misplaced with more detail than given in the application.

- 8. In accordance with NUREG-1556, Volume 7, Section 8.10.6, please state that you have developed procedures for security of materials and emergencies.
- 9. Please provide a telephone number and electronic mail address for your proposed Radiation Safety Officer, Daguang Wang, Ph.D.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 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. 143628. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

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 Dennis R. Lawyer***

Dennis R. Lawyer  
Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

cc:  
Daguang Wang, Ph.D., Radiation Safety Officer

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**SUNSI Review Complete: DLawyer**

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