

August 11, 2003

Victor Hoang
Draeger Safety, Inc.
505 Julie Rivers, Suite 150
Sugar Land, TX 77478-2847

Dear Mr. Hoang:

This letter is in reference to your application dated May 20, 2003, requesting registration for Draeger Safety, Inc. Models 5000, 5100, 5600, and 5700 gas monitoring devices. In order to complete our review, please complete the additional information requested in the Enclosure.

We will continue our review upon receipt of this information. If we do not receive a response from you in 30 days, we will consider your request as having been abandoned and void the active control for your request. This action would be without prejudice to the resubmission of another request.

If you have any questions, please contact me at (301) 415-7904, or Nima Ashkeboussi at 301-415-7637.

Sincerely,
/RA/

John P. Jankovich, SSD Team Leader
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As Stated

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John P. Jankovich, SSD Team Leader
Ujagar S. Bhachu, C Eng., P Eng., FI Mech E
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
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Distribution: NMSS13
SSD 03-36

File Name: C:\ORPCheckout\FileNET\ML033300368.wpd

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ENCLOSURE

1. Additional Information Required

- 1.1 Please provide the dimensions (length, width, height) of detector unit in Figures 4a and 5a, but do not include the component numbers.
- 1.2 Please provide a summary, such as a table or a comparative text (including weight of each device) which delineates the differences between Models 5000, 5100, 5600, and 5700 (i.e. expand the information provided on pg C-3).
- 1.3 Page 17 refers to the use of explosion shielding. Please provide prototype test data with the use of the explosion shielding in explosive test conditions.
- 1.4 Please demonstrate that the product will meet the dose limit requirements as required by 10 CFR 32.27(a) and 32.28.
- 1.5 Please provide a copy of the point of sale label that is in compliance with the provisions of 10 CFR 32.29(b)(3)(iii).
- 1.6 Please describe the quality assurance functions that Draegar Safety, Inc. will perform in the U.S. on the units imported from the foreign manufacturer. Traditionally, cases involving foreign manufacturers, the QA/QC functions for fabrication are to be performed at the foreign facility and the U.S. distributor must audit the foreign facility periodically. Copies of records must be maintained in the U.S. Copies of documents certifying that the QA/QC commitments, made in the application, have been met and leak test results must be forwarded to the distributor from the foreign manufacturer with every lot of the product. The records must be reviewed and approved by the U.S. distributor before the release of the lot. Other QA/QC records must be forwarded to the U.S. location on a periodic basis and must be available upon request in a reasonable time. This policy does not exempt the U.S. distributor from ensuring that all QA/QC functions are performed and from being responsible for ensuring that the product is distributed with all statements and commitments made in the application and the registration certificate. Guidance may be obtained from NRC Regulation Guide 6.9.
- 1.7 Please show the location of the label affixed to the device corresponding to Figure 4a.
- 1.8 Page 15 of the application states that the device was tested at a free fall height of 10 cm. 10 CFR 32.26(b)(5) requires details of construction and design under normal and severe conditions of handling, storage, use, and disposal. Please demonstrate that this test represents likely accident conditions.
- 1.9 10 CFR 30.33 requires that a license for possession of byproduct material be obtained prior to the issuance of an exempt distribution license. Please provide a copy of your State of Texas possession license.
- 1.10 Please provide an estimate of the total quantity of byproduct material expected to be distributed annually as required by 10 CFR 32.26(b)(8).

2. Clarifications

- 2.1 Describe how the design of the device prevents access to the radioactive material is secured by transport methods as required by 10 CFR 32.26(b)(7).

- 2.2 Page 3 of the application states that the device temperature range for operation is between 0° and 50° C, while the temperature range for storage is -25° to 70° C. We intend to use the operation temperature range as a limiting condition for the operation of this device. If you disagree with this intention please provide your rationale for the device operating outside this temperature range.
- 2.3 Please confirm the number of sources to be used and their maximum activity.
- 2.4 Please provide information that demonstrates that the use of unlike materials (aluminum and steel) will not affect the safety of the sealed source.
- 2.5 10 CFR 32.26 requires that gas and aerosol detectors be designed to protect life or property from fires or airborne hazards. Page 3 of your application indicates that your product will be used in semiconductor plants and in analytical labs. Describe how this use will protect life or property from fires or airborne hazards. A product cannot be distributed pursuant to 10 CFR 32.26 if it is designed for purposes other than to protect life or property from fires or airborne hazards.
- 2.6 Your application indicates that the filter must be changed every six months by return to the manufacturer. If the filter is not changed, or contrary to the instructions, changed by the user, the effect of tritium build-up on the filter may cause radioactive material contamination problems on the product or user. Describe your evaluation of this potential problem and how it would be prevented. Keep in mind that products distributed to untrained persons, exempt from the regulations, must not have any flaws that would cause a contamination problem if not used according to instructions.