UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 7, 1997

Jeff Havenner
Department of the Army
Armament and Chemical Acquisition
and Logistics Activity
Rock Island, IL 61299-7630

Dear Mr. Havenner:

This letter is in response to your application dated October 3, 1996, requesting registration of the Model M22 Advanced Chemical Agent Detector/Alarm (ACADA), and our telephone conversations on April 2 and 3, 1997. We are in the process of evaluating your request. However, in order to continue our evaluation, the following information is necessary:

1. During our telephone conversations, we discussed the requirements related to evaluation of specifically licensed devices, devices possessed under a general license, and exempt devices as they relate to the model ACADA. Please clarify how you wish the device to be reviewed and registered and provide any additional information necessary to address the relevant regulatory requirements.

2. It is unclear from your application and additional information provided as to what will be the licensed/registered model designation of the device. Please provide the model designation of the device. This designation should also be included on the label.

3. The device must be properly labeled. As we discussed, depending upon how the device is licensed/registered (i.e., specific, general, or exempt), different requirements for labeling apply. Therefore, please provide the appropriate wording for the labels used for this device. These labels need to be permanently affixed to the device and made of a material that will retain its integrity during use. Please indicate the materials of construction of the labels, how they will be attached, and the location of the label on the gauge.

4. It was noted in the engineering drawings submitted that a statement was made on each that it is considered to be company confidential of Graseby Dynamics Ltd. The NRC can handle information submitted by licensees on a company proprietary manner (i.e., not to be disclosed to the public) when the materials are submitted in accordance with 10 CFR 2.790(b). In addition to the markings on the material to be considered proprietary, an affidavit is required to be submitted requesting that the materials be considered proprietary. Once this has been received, the NRC will consider the request on its merits.

5. Your quality assurance program should be adequate to ensure that the devices manufactured and distributed meet the criteria and commitments provided by you in your application and subsequent submissions and those in the registration certificate. Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," provides an example of an acceptable quality assurance program and is included with this letter for your reference.

6. Please provide a description of the maintenance, service, and leak testing that will be performed on the device and who will perform such tasks. Please address filter replacement in this discussion. For activities that will be performed by the user, please provide a copy of the procedures.
7. Prototype testing should simulate the conditions of normal use and likely accident conditions to which the gauge is likely to be subjected. Therefore, please provide the procedures followed, justifications for such tests, and the results of such tests, including leak test and integrity results.
8. As required in 10 CFR 32.51(b), leak test intervals of longer than six months require sufficient justification that the longer interval is warranted (i.e., performance characteristics of the device or similar devices and design features which have significant bearing on the probability or consequences of leakage of radioactive material from the device). Therefore, please provide sufficient information concerning the design features of your device and operating experience of similar devices that verifies the longer interval is warranted. You should include years of use of the devices, the number of leak tests performed, results of the leak tests, and information on any sources that were found to be leaking.
9. In our conversations, we discussed several typographical errors and needed clarifications that we had identified. Please address these in your response.
10. Drawing number 0614-2336, "Cell Assembly," indicates a tab (actually three) which holds the source in place within the IMS cell. Please address the process for installation of the source in these tabs and the potential for damage to the source during this process.

Please provide the requested information within thirty (30) days. Information that has previously been provided may be referenced in this response, if necessary. Enclosed with this letter are two additional documents that may be useful in preparing your response. If you have any questions, please contact me at (301) 415-5723 or Mr. Steven Baggett at (301) 415-7273.

Sincerely,

/S/

Brian W. Smith, Health Physicist
Sealed Source Safety Section
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
And Safeguards

Enclosures: Regulatory Guide 6.9
NUREG/CR-1156
NUREG-1550

Distribution:
SSSS r/f SSD-96-91 NE01

CUMENT NAME: C:\96FILES\SSSS\ARMY\ARMYDEF.LTR
ceive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

FFICE	SSSS		IMAB					
AME	Brian Smith		Doug Broaddus					
ATE	04/ /97		04/ /97					

OFFICIAL RECORD COPY