20885

October 8, 1999

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE PRESIDING OFFICER

In the Matter of	)	
	)	
DEPARTMENT OF ARMY	)	Docket No. 30-34610-ML
Aberdeen Proving Ground, Maryland	)	
	)	
(Denial of Materials License for M22/GID-3	)	
Automatic Chemical Agent Detector Alarm)	)	
	)	

NRC STAFF RESPONSE TO
QUESTIONS POSED BY PRESIDING OFFICER

I. INTRODUCTION

By order of September 13, 1999, the Presiding Officer denied the intervention request filed by Graseby Dynamics, Ltd. (Graseby) and directed the parties to provide an outline of the issues to be considered in this proceeding and to address the form of Graseby's participation, if any. Memorandum and Order (Intervention Request; Schedules; Prehearing Conference), dated September 13, 1999 (Order) (unpublished). The Presiding Officer later directed the parties to also address two questions regarding the issues in the proceeding. Memorandum, dated September 23, 1999 (Memorandum) (unpublished).

By letter dated October 6, 1999, Graseby informed the NRC that it does not want to intervene in the above-captioned proceeding, but would like to participate in the upcoming prehearing conference as a technical resource for the U.S. Department of the Army (Army). *See* Letter from R.J. Dann, Graseby Dynamics, Ltd., to Office of the Secretary, dated October 6, 1999 (Letter). On October 7, 1999, the U.S. Department of the Army (Army)

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filed its response to the Presiding Officer. Response to Charles Bechhoefer, Presiding Officer (PO), Memorandum Dated September 23, 1999, dated October 7, 1999 (Army Reply). The Staff provides its response below.

I. DISCUSSION

A. Relevant Issues

The issue in the proceeding is whether the Staff properly denied the Army's application for registration and licensing of the model M22/GID-3 Automotic Chemical Agent Detector/Alarm for distribution pursuant to 10 C.F.R. § 32.26, "Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer." That provision sets forth requirements that need to be met if, *inter alia*, a product is to be initially transfered for use pursuant to 10 C.F.R. § 30.20. Under § 30.20(a), a person other than those "who manufacture, process, produce or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material," is exempt from the requirements for a license under the Atomic Energy Act and the regulations "to the extent that such person receives possesses, uses, transfers, owns, or acquires byproduct material, in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to § 32.26." 10 C.F.R. § 30.20(b) further provides that any person who desires to initially transfer such product for use as a detector, should apply for a license pursuant to 32.26, which states that the product may be initially

transferred by the licensee to persons exempt from the regulations pursuant 10 C.F.R. § 30.20(a).

At issue in the proceeding is whether the ACADA device, which the Army has designed to allow users (*i.e.*, exempt persons) to remove the source module from the outer housing to perform maintenance on electrical components in the outer housing, is a detector or product as contemplated by 10 C.F.R. § 32.26. The Staff believes that the regulation applies to gas or aerosol detectors designed to protect life or property, which can be used or discarded by exempt persons without the need to satisfy any license requirements.

This interpretation is based on the express terms of 10 C.F.R. § 32.26, which states that the regulation pertains to detectors (or products) and requires information to be submitted regarding "the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions for handling, storage, use, and disposal of the gas and aerosol *detector* to demonstrate that the *product* will meet the safety criteria set forth in §32.27," 32.26(b) (emphasis added). In addition, the regulation contains repeated references to the licensing of a "product" that is a *detector*. The Statement of Considerations for 10 C.F.R § 32.26 also indicates that "the manufacturer or importer is responsible for providing a *product* which meets specified safety requirements so that regulation of the user is not necessary.[1] In promulgating 10 C.F.R. § 32.26, the Commission concluded that its

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[1] "Part 30-- Rules of General Applicability to Licensing of Byproduct Material; Part 32 -- Specific Licenses to Manufacture, Distribute or Import Exempted and Generally Licensed items Containing Byproduct Material: Exemption of Byproduct Material in Gas and Aerosol Detectors [Final Rule]," 34 Fed. Reg. 6653 (April 18, 1969) (emphasis added).

(continued...)

revised regulations would not constitute an unreasonable risk to the common defense and security and to the health and safety of the public. 34 Fed. Reg. 6653.

Smoke detectors, for example, are used by the general public (*i.e.*, exempt persons) under this regulation. The source module is secure in the product casing and users merely change the battery without separating the source module from the device. Thus, there are no safety concerns raised associated with such usage. The ACADA, however, has been designed to allow removal of the inner source module to allow exempt users to perform maintenance on the device. The source module cannot be licensed under 10 C.F.R. § 32.26 since it is only a part of the product and is not a detector designed to protect life or property. *See* 10 C.F.R. § 32.26; 34 Fed. Reg. 6653. Therefore, the denial of the application was proper.

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[1](...continued)
In noticing the proposed rule the Commission stated:

> The proposed amendments are expected to simplify in a manner consistent with the Commission's published criteria for the approval of products intended for use by the general public (30 F.R. 3462), the Commission's regulatory process applicable to byproduct material contained in gas and aerosol detectors. . . . The proposed exemption would apply to "gas and aerosol detectors" designed to protect life or property from fires and airborne hazards. The term "gas and aerosol detectors" includes detectors indicators, testers, and analyzers for gases, vapors, dusts, fumes, mists, and other airborne contaminants, products of combustion . . . and oxygen deficient atmospheres.

"Byproduct Material in Gas and Aerosol Detectors: Exemption from Licensing [Proposed Rule]," 33 Fed. Reg. 16089 (November 1, 1968).

B. The Participation of Graseby

The Presiding Officer has noted that Graseby may support the Army's case or that Graseby could be granted party status as a matter of discretion if it provides additional detailed information. Order at 6, *citing, Virginia Electric & Power Co.* (North Anna Power Station, Units 1 and 2), ALAB-363, 4 NRC 631 (1976).[2] Graseby has since indicated that it does not wish to intervene in this proceeding. *See* Letter at 1. The Army has also indicated that it intends to rely on Graseby only as an expert. Army Reply at 3. The Staff has no objection to Graseby serving as a resource to the Army in this proceeding.

C. Response to Questions

> 1. Please address specifically and succinctly the factors, circumstances or regulations, if any, that changed between July 2, 1998, when NRC Staff discussed with the Army "an alternative approach of registering an internal cell module as the exempt use product," and May 17, 1999, when NRC Staff informed the Army that such an approach was not acceptable. [Memorandum at 1]

Earlier this year, the Staff determined that the licensing the internal cell module was not legally permissible under 10 C.F.R. § 32.26 based on a reading of the regulation and the Statements of Consideration that accompanied the promulgation of that regulation. Hence it was concluded that the inner source module, once separated from its housing, would not

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[2] A petitioner has the burden to demonstrate that it can make a valuable contribution to the development of a sound record, including by showing a significant ability to contribute on substantial issues of law or fact which will not be otherwise properly raised or presented. *See Portland General Electric Co.* (Pebble Springs Nuclear Plant, Units 1 and 2), CLI-76-27, 4 NRC 610, 616-17 (1976). Graseby has no unique contribution or expertise on the legal issue to be raised in this proceeding, *i.e*, whether the ACADA may be licensed under 10 C.F.R. § 32.26 for distribution to persons exempt from license requirements.

be a detector or life-saving product as contemplated by NRC regulations. 10 C.F.R. § 30.20 exempts persons possessing or using gas or aerosol detectors from licensing if such products have been manufactured or initially transferred in accordance with a specific license issued pursuant to 10 C.F.R. § 32.26. The inner source module separated from the outer device housing of the ACADA does not function as a detector and cannot be licensed as an exempt product pursuant to 10 C.F.R. § 32.26.[3]

> 2. [Are there] other approaches by which the Army could achieve the result it appears to desires -- e g., by granting a suer license collectively to all soldiers (no specifically identified by name) who may be called upon to use the ACADA device, subject to a requirement that all soldiers authorized to use the ACADA would be adequately trained before doing so. [Memorandum at 1]

The Army has a specific license that authorizes U.S. Army and National Guard civilian and/or military personnel, trained in accordance with the application, dated October 29, 1997, to use the ACADA device at U.S. Army and National Guard Installations and temporary job sites of the licensee throughout the United States and any other locations where the Commission maintains jurisdiction. *See* Amendment 34 to License

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[3] Army contends that it was misled by the NRC and that the denial of the application was done without a reasonable basis or any advance warning, relying on qualified statements from a Staff member in April 1998, *see* Hearing File Document 7(E-mail from Anthony Kirkwood, NRC, to J. Manfre, dated April 8, 1998). The cited correspondence does not indicate NRC approval of the application and neglects to mention that the Army was aware that the Staff, as of March 1999, was seeking legal advice and that the Army also wanted to be informed about whether a licensing option was permissible under the regulations. *See* Hearing File Document 27 (Letter from Col. Stephen Reeves, Army, to Larry Camper, NRC, dated April 9, 1999). Moreover, the basis for the denial was set forth in the May 17, 1999, denial letter. *See* Hearing File Document 28. Thus, the Army's insistence that the denial came without any basis or advance warning is unfounded.

No. 12-00722-06, dated August 20, 1998 (attached). The license includes requirements to conduct leak testing and physical inventories, and to submit reports to the NRC. In addition, pursuant to 10 C.F.R. § 20.2201(a)(ii), licensees are to report any lost, stolen or missing licensed material that becomes known to the licensee (depending on the quantity of the material).

By obtaining a 10 C.F.R. § 32.26 license, the Army apparently seeks to reduce the resource burden associated with the specific license, *e.g.*, leak test requirements, and requirements to inventory and report lost devices or leaking radioactive sources while retaining the ability to have the device maintained by exempt users wherever the ACADA is stored or used. Such maintenance necessarily involves removal of the source module from the outer housing would result in the device losing its exempt status and could pose a danger to public health and safety if the inner source module is mishandled.

Alternative approaches, include: (1) modifying the design of the ACADA to preclude maintenance being performed at other than the distribution point; (2) applying for a general license under 10 C.F.R. Part 31, which would reduce some regulatory requirements, but the uses of general license devices have been limited to particular locations; (3) applying for amendments that would to reduce or eliminate certain requirements in Army's specific license; (4) issuing 10 C.F.R. § 32.26 licenses and registrations to multiple Army distribution points where all maintenance activities would be

conducted; and (5) a petition for rulemaking to allow the distribution of the ACADA to exempt persons.[4]

The viability of alternative approaches depends on the Army's ability to submit information that demonstrates that elimination or relaxation of the certain requirements (*e.g.*, leak testing, accountability, and reporting requirements) are consistent with public health and safety.

As for the example posed by the Presiding Officer in Question 2, *see* Memorandum at 1, the Army's specific license allows soldiers (not identified by name) to use the device at various locations so long as the various license requirements are met.

D. Army "Motions"

The Army asked that the Presiding Officer direct the Staff produce to the Army "all documents, records, files, notes, etc., in its files, records, systems of records, etc., which relate to the licensing and processing of the ACADA's exemption application and subsequent denial, no previously provided and not part of the Hearing File" and states that its request is made "pursuant to 10 CFR § 2.744 and the Freedom of Information Act (FOIA)." *See* Army

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[4] Contrary to the Army position, see Army Reply at 2-3, the Staff does not believe that an exemption from 10 C.F.R §32.26 is a viable option since the exemption would have to show that the ACADA, with its inner source module removed, constitutes a "product" that functions as a life saving detector.

Reply at 5.[5] The Army further seeks a summary judgment order, pursuant to 10 C.F.R.§ 2.749, arguing that there are no material facts at issue. *Id.* [6]

The 10 C.F.R. § 2.744 discovery request, the FOIA Request and the motion for summary disposition must be rejected as such relief is not permitted in a 10 C.F.R. Part 2, Subpart L, proceeding. *See* 10 C.F.R. § 2.1231(d) (no party may seek discovery from any other party, the NRC or its personnel whether by document production, deposition, interrogatory, or otherwise); "Informal Hearing Procedures for Materials Licensing Adjudications," 54 Fed. Reg. 8269-8270 (February 28, 1989) (discovery and other procedures used in formal NRC adjudications are not available in informal proceedings). By providing copies of the hearing file, the Staff has fulfilled its obligation to provide the Army with documents sufficient to afford it a full and fair hearing in this informal proceeding. *See* Letter from Mitzi Young to Charles Bechhoefer, dated September 13, 1999. The Army's motion for summary disposition should be denied because it is based on conclusory and mistaken assertions, and, hence, does not demonstrate that there are no genuine issues as to a material fact in this proceeding. Thus, assuming that summary disposition (a formal adjudication tool from 10 C.F.R. Part 2, Subpart G) is appropriate at this stage of an informal

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[5] In NRC practice, motions should be reflected in the captions of filings in which they are raised. *E.g., Duke Power Co.* (Cherokee Nuclear Station, Units 1, 2 and 3), ALAB-457, 7 NRC 70, 71 (1978).

[6] Instead of identifying issues for litigation, the Army erroneously contends that it was mistreated by the Staff, but also that NRC's regulations do not apply to the ACADA, a "military unique item." *See* Army Reply at 3-4. Assuming, arguendo, that the Army is correct that NRC regulations do not apply, then the Army should withdraw its hearing request because no NRC license is needed. The Staff maintains, however, that the denial was appropriate and based on a reasonable reading of the applicable regulation.

proceeding, the motion should be denied. *Accord, Curators of University of Missouri*, LBP-90-45, 32 NRC 449, 454-55 (1990).

As for the FOIA Request, the request is misdirected as the Presiding Officer is not the responsible official to act on such requests. *See* 10 C.F.R § 9.23(b). Therefore, each of the Army's requests should be rejected.

III. CONCLUSION

As discussed above, the issue in this proceeding is whether the ACADA, device that which is designed to allow disassembly for maintenance by any user, can be licensed under 10 C.F.R. § 32.26. The options to the requested license would require the Army to submit separate applications and demonstrate that its request should be granted.

The Staff does not object to Graseby serving as a resource to the Army's case in this proceeding, but the "motions" filed by the Army should be rejected.

Respectfully submitted,

Mitzi A. Young
Counsel for NRC Staff

Dated in Rockville, Maryland
this 8th day of October, 1999

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 34

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

030-13027

Licensee	In accordance with application dated March 20, 1995
1. Department of the Army U.S. Army Armament and Chemical 2. Acquisition and Logistics Activity ATTN: AMSTA-AC-SF Rock Island, IL 61299-7630	3. License number 12-00722-06 is renewed in its entirety to read as follows:
	4. Expiration date August 31, 2008
	5. Docket No. 030-13027 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Hydrogen-3	A. Gas in sealed glass ampoules	A. Not to exceed 10 curies (370 GBq) per device (See Condition No. 10)
B. Hydrogen-3	B. [illegible]	B. Not to exceed 10.2 curies (377 GBq) per device (See Condition No. 10)
C. Hydrogen-3	C. [illegible]	C. Not to exceed 5.79 curies (214 GBq) per unit (See Condition No. 10)
D. Promethium-147	D. 3M Model IE2X Sealed [illegible] encapsulated ceramic bound sources in rifle sights	D. One millicurie per sight, total not to exceed one curie
E. Hydrogen-3	E. Tritium gas sealed in glass in rifle sights	E. Nine millicuries per sight, total not to exceed nine curies
F. Hydrogen-3	F. Sealed glass ampoules in sights (Mb Microtec AG Model Nos. 400/1, 400/2, 400/3, 400/4, 400/5 or 400/6)	F. No single sight to exceed 210 millicuries, 42 curies total
G. Americium-241	G. Plated Foils (Amersham Corp. Model No. AMM5 or N.R.D. Model A001)	G. No single cell to exceed 300 microcuries, 25 curies total

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 12-00722-06
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6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
H. Nickel-63	H. Plated Sources (Du Pont Merck Model No. NER-004R, or Amersham Model Nos. N5C or NBCD)	H. Not to exceed 15 millicuries per source and 1500 curies total

9. Authorized Use:

A. To be used in fire control devices containing self-luminous tritium sources and for possession incident to maintenance and repair of these devices and installation into artillery systems.

B. For use in Muzzle Reference Sensors (MRS) on the family of main battle tanks used by the United States military services.

C. For use in the M67 sight unit on the M120 and M121, 120-mm mortar.

D. and E. For possession incidental to collection and disposal as radioactive waste only.

F. To be used in Ranger Antiarmor Support Weapon System for enhanced night firing capability.

G. To be used in Model M43A1 Chemical Agent Detectors for detection of aerosols and gases.

H. To be used in Models CAM, RAM or GID-3 Chemical Agent Monitor for aerosol/vapor detectors.

CONDITIONS

10. The total possession limit for Hydrogen-3 shall not exceed 1.5×10^6 curies (55 PBq).

11. A. Licensed material listed in Item 6.A. through 6.C. and 6.F. may be stored at Rock Island Arsenal, Rock Island, Illinois and at Blue Grass Army Depot, Richmond, Kentucky and may be used at U.S. Army, National Guard and Marine Corps installations and temporary job sites throughout the United States and any other location where the Commission maintains jurisdiction for regulating the possession and/or use of licensed material. Ampoules containing hydrogen-3 shall not be opened or removed from fire control devices except as necessary for device repair and maintenance only at facilities that meet criteria for depot level maintenance as described in application dated October 29, 1997.

COPY

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SUPPLEMENTARY SHEET

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B. Licensed material listed in Items 6.D. and 6.E. may be possessed incident to collection and disposal as radioactive waste only, throughout the United States and any other location where the Commission maintains jurisdiction for regulating the possession of licensed material.

C. Licensed material listed in Items 6.G. and 6.H. may be stored at Rock Island Arsenal, Rock Island, Illinois and at Blue Grass Army Depot, Richmond, Kentucky and may be used at U.S. Army and National Guard installations and temporary job sites of the licensee throughout the United States and any other location where the Commission maintains jurisdiction for regulating the possession and/or use of licensed material.

12. A. Licensed material in Items 6.A. through 6.F. shall be used by, or under the supervision of, Jeffrey Havenner or U.S. Army, National Guard and Marine Corps. civilian and/or military personnel trained in accordance with application dated October 29, 1997.

B. Licensed material in Items 6.G. and 6.H. shall be used by or under the supervision of, Jeffrey Havenner or U.S. Army, and National Guard civilian and/or military personnel trained in accordance with application dated October 29, 1997.

C. Radiation Safety Officer: Jeffrey Havenner

D. Alternate Radiation Safety Officer: [illegible]

13. Sealed sources containing licensed material [illegible]

14. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

15. The licensee shall conduct a physical inventory every twelve (12) months to account for all sealed sources and plated foils and sources received and possessed under the license. The records of the inventories shall be maintained for inspection by the Commission, and shall include the quantities and kinds of byproduct material, location of sealed sources and plated foils and sources and the date of the inventory.

16. A. The sources specified in Items 7.G. and 7.H. shall be tested for leakage and/or contamination at intervals not to exceed 12 months.

B. In the absence of a certificate from a transferor indicating that a leak test has been made within 12 months prior to the transfer, a sealed source or plated foil or source received from another person shall not be put into use until tested.

C. Sealed sources or plated foil or sources need not be leak tested if:

(I) they contain only hydrogen-3; or

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(II) they contain only a radioactive gas; or

(III) the half-life of the isotope is 30 days or less; or

(IV) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

(V) they are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or plated foil or source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

D. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, ATTN: [illegible] Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.

E. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

17. Notwithstanding the color requirements in 10 CFR 20.1901 (a), the licensee is authorized to label fielded items of equipment with colors as described in letter dated October 29, 1997.

18. Maintenance operations on the Chemical Agent Monitor or Chemical Agent Detector will not include or involve any repair or contact with the nickel-63 plated source or americium-241 plated foil.

19. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated October 29, 1997 (with enclosures) excluding Item 10, Subitem 11, addressing decommissioning; and

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B. Letters dated October 29, 1997, May 13, 1998, May 26, 1998 (requesting deletion of Item 11, "Decommissioning" from application dated October 29, 1997) and August 14, 1998.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date AUG 20 1998

By Loren J. Hueter
Loren J. Hueter
Materials Licensing Branch
Region III

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE PRESIDING OFFICER

In the Matter of	)	
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U.S. DEPARTMENT OF ARMY	)	Docket No. 30-34610-ML
Aberdeen Proving Ground, Maryland	)	
	)	
(Denial of Materials License for M22/GID-3	)	
Automatic Chemical Agent Detector Alarm)	)	
	)	

CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF RESPONSE TO QUESTIONS POSED BY PRESIDING OFFICER" in the above-captioned proceeding have been served on the following by U.S. Mail, first class, and/or, as indicated by a single asterisk, through deposit in the Nuclear Regulatory Commission's internal mail system, or as indicated by double asterisk, by e-mail or facsimile transmission, this 8th day of October, 1999:

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