

From: John A. Grobe (JAG) RTII  
To: WLA, BAB1, FCC, JXD1, JRG1, OGJ, SHL, JRM4, WJS2, MHS  
Date: Thursday, December 22, 1994 4:43 pm  
Subject: Meeting with AMS

Waxelson, RTII B. Berson, RTII  
Flombs, NMSS J. DeCicco, NMSS  
Goldberg, OGC C. Jones, NMSS

Folks,

AMS counsel, Henry Billingsley, will prepare a list of issues that they would like to discuss with the NRC regarding the apparent violation of 10 CFR 20.2003. This list will be forwarded to my attention before 1/3/95. On that day, I will distribute it to all interested parties and determine whether there is need and we can support a meeting with the licensee. The licensee is holding open 1/11 on their schedules.

S Lewis, OGC

Madera, RTII

W. Sawinski, RTII

M. Stein, OGC

We need to keep in mind that we established a very unique set of circumstances with the 11/7 and 12/6 inspection reports. We issued the reports with no NOV and listing the violations as "apparent violations." Further we stated that we would meet with the licensee to discuss the apparent violations and determine the appropriate enforcement actions. This is very similar to the normal enforcement process. We will discuss next year the best way to proceed on these apparent violations.

Have a very happy and safe holiday season. See you next year!!

Jack

D/45

GROBE

DEC 22 1994

Advanced Medical Systems, Inc.  
ATTN: David Cesar, Treasurer  
121 North Eagle Street  
Geneva, OH 44041

RE: APPLICATION FOR RENEWAL OF NRC LICENSE 34-19089-01

Dear Mr. Cesar:

The renewal process enables NRC to reevaluate licensed programs which have been in operation for a five year period. During this five year period many licensees find that their programs have changed along with their business goals and operations and that NRC regulations and policy have also changed. Therefore, we require that licensees provide us with a complete license renewal application, describing all aspects of their licensed operations and radiation safety program and procedures as if they were applying for an NRC license for the first time, without reference to previously submitted documents. This renewal process was discussed with you by Roy Caniano and John Madera during a management visit to your facility in April 1994.

We have reviewed your application dated November 29, 1994, and are disappointed to find that you did not provide sufficient information to evaluate your program activities and procedures. Consequently, you will need to resubmit your application with the following subject areas appropriately addressed without any reference to previous correspondence:

1. Radioactive Material

Your application provided the appropriate elements, mass numbers, chemical and physical forms, and maximum amount of the material you will possess at any one time. However, you did not provide the necessary information concerning the disposition of the materials and activity which you have eliminated from previously licensed authorization. Therefore, in order for us to evaluate your request for a reduction in possession limits, please provide appropriate documentation which will account for the material you have transferred and/or disposed of.

Also, please indicate/approximate the type and quantity (activity) of radioactive material currently possessed at your facility. Specifically, provide information concerning your current inventory of radioactive material to include the quantities of material you possess in the form of sealed sources, bulk sources, facility contamination and both liquid and solid radwaste. This should be added to your radioactive material possession limits in items 6., 7., and 8. of your NRC license.

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2. Intended Use of Radioactive Material

Your application did not provide any information concerning intended use of the materials requested. Please provide information concerning the use of radioactive materials at your London Road facility, including possession incident to decommissioning and/or transfer to an authorized individual or entity. Specifically, you will need to provide detailed information concerning service operations (procedures, etc.).

3. Management Control and Responsibility

a. Senior Management

Resubmit a copy of your organizational chart illustrating the reporting path of the Radiation Safety Committee and/or Chairman of the Committee to Senior Management.

Submit a statement, signed by upper management, empowering the Radiation Safety Officer (RSO). The statement must describe the RSO's authority to oversee the licensed program, the responsibility for control and direction of the radiation safety program, and the authority to terminate licensed activities which pose a health and safety risk.

b. Radiation Safety Officer Staff (RSOS)

Provide an assessment regarding the adequacy of staff (including both numbers and qualifications) to support and maintain your radiation safety program. The assessment may be general, however, enough information should be provided to relate required services (e.g., audits, retraining, bioassay, response to emergencies, etc.), to facilities covered (e.g., number of laboratories, users, special uses, etc.).

c. Radiation Safety Officer

Submit a description of the duties and responsibilities of your RSO. The typical duties of a RSO would be:

- (1) To ensure that the use of radioactive materials is by or under the direct supervision of individuals specifically listed on your license.
- (2) To ensure that all users (where appropriate) wear personnel monitoring equipment when using radioactive materials.
- (3) To ensure that radioactive materials are properly secured against unauthorized removal at all times when not in use.

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- (4) To perform routine inspections of all areas using or storing radioactive materials.
- (5) To ensure that the terms and conditions of your license are met, and that all required records are maintained.
- (6) To immediately halt any activity judged to be a threat to health, safety, the environment or a violation of the conditions of your license or the regulations.

d. Audit Program

Radiation Safety Officer and Staff Audits

Describe the audit mechanism implemented by the RSO and his staff to determine compliance with the terms and conditions of the NRC license. Your audit program should include: (1) routine unannounced inspections of each area where material is used and stored; (2) evaluation of worker/technician training through discussion and observation of work practices, and; (3) performance of independent surveys of work and storage area.

4. Training Program:

Confirm that training provided pursuant to 10 CFR 19.12 will include all occupational workers and ancillary personnel whose duties may require them to work in the vicinity of radioactive material. In addition, please commit to providing this training before new personnel assume their duties with, or in the vicinity of radioactive material, during annual refresher training, and whenever there is a significant change in duties, regulations, or the terms of the license. Also, confirm that you will maintain records of this training. Records should include the names of the attendees, topics, and date of training.

Your formal training program for authorized users (sealed source handlers) and service personnel must be provided. This program can be as previously submitted, however, it should be re-submitted to reflect all pertinent changes, e.g. management structure, administration, technical aspects, etc.

5. Facilities and Equipment

Submit a detailed diagram of the facilities for each location where radioactive material will be used. Include a description of area(s) assigned for receipt and storage (including waste). Your diagram(s) should show:

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- a. Adjacent areas across the walls from use and storage areas.
- b. Descriptions of the ventilation system with pertinent airflow rates for locations where radioactive material may become airborne.
- c. A specified scale with indicated dimensions.
- d. Appropriate postings/labels to identify laboratories, work areas, and equipment e.g., fume hoods, special sinks, preparation areas, protective clothing change areas, etc.

6. Radiation Safety Program:

Your radiation safety program must outline the formal requirements necessary to maintain control of your licensed activities. These controls and provisions are related to organization and management, procedures, recordkeeping, material control and accounting, and management review to ensure safe operations under the license. Your radiation safety program description should be in narrative form, and should follow the subject matter presented in Section 10 of the enclosed Regulatory Guide 10.5 Revision 3, as it relates to your program. Specifically, please respond to the following items:

- a. 10.2: Administrative Procedures;
- b. 10.2.1: Control of Procurement and Use;
- c. 10.2.3: Emergency Procedures;
- d. 10.2.4: Operating and Handling Procedures;
- e. 10.2.5: Other Procedures (i.e., Standard Operating Procedures);
- f. 10.3: Inventory and Accountability;
- g. 10.4: Audits and Appraisals;
- h. 10.4.1: Management and Radiation Safety Committee Audits;
- i. 10.4.2: Radiation Safety Officer and Staff Audits
- j. 10.6: Exposure Control and Monitoring;
- k. 10.6.1: External
- l. 10.6.2: Internal
- m. Facility Survey Program (ISP procedures);
- n. Survey Instrument Calibration Program (ISP procedure);
- o. Leak Test Program (ISP procedure); and
- p. 11: Waste Management

The areas addressed in Regulatory Guide 10.5, as outlined above, can also be addressed by referencing specific AMS ISP procedures (your SOP) and/or other procedures that you have instituted to manage your radiation safety program. However, these manuals/procedures must be submitted in their entirety for our review. This was discussed with you and Mr. Meschter on December 6, 1994, during a telephone conference.



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7. Emergency Plan:

10 CFR 30.32(i)(3) requires that you provide an Emergency Plan in accordance with the guidance provided in Regulatory Guide 3.67, which has been previously provided to you. This is a requirement for new licensees as well as those who are up for renewal. Your application failed to provide an updated copy of your Emergency Plan. The updated version must reflect changes in management control, administration, technical aspects, etc. that have occurred since initial acceptance of your Emergency Plan by the NRC. Please follow the guidance in Regulatory Guide 3.67, and submit your plan for our review.

8. Decommissioning Funding Plan and Financial Assurance Mechanism:

In order for us to complete our review of your renewal application and issue a renewed license, we need to review and accept your Decommissioning Funding Plan (DFP) and financial assurance mechanism. Pursuant to 10 CFR 30.35(c)(2), you were required to submit your DFP with your license renewal application which was required to be submitted by December 1, 1994 (10 CFR 30.36). While you failed to comply with these requirements, you indicated in your renewal application dated November 29, 1994 that your DFP will be submitted by December 31, 1994. Should your DFP not be submitted by December 31, 1994, this matter will be reviewed for appropriate enforcement action.

9. Waste Management:

You should describe your methods for disposal of radioactive waste. Your application should include, where appropriate for the types of waste involved, provisions for monitoring and segregating waste (radioactive from nonradioactive, short half-life from long, liquid from solid waste). The following items should be considered and addressed in your application:

- a. Transfers to a recipient (usually a waste disposal service company or the original supplier) properly licensed to receive such waste in accordance with paragraph 20.2001(a)(1) of 10 CFR Part 20. State the name and license number of the receiving company.
- b. Storage of radioactive material with half-lives greater than 65 days should be characterized regarding volume and anticipated time in residence at your facility prior to disposal. The NRC does not consider storage as a substitute for final disposal of radioactive waste. Other than storage for radioactive decay, low level radioactive waste (LLW) should be stored only when disposal capacity is unavailable and for no longer than is necessary, e.g., no longer than 2 years. NRC Information Notice No. 90-09, "Extended Interim Storage of Low-Level Radioactive Waste For Fuel

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Cycle and Material Licensees", outlines the provisions and requirements for interim storage. If you find that the interim storage provision applies to your program, it will be necessary for you to address in your application the information outlined in the Information Notice.

- c. Release into air or water pursuant to 20.2003(a)(1) of 10 CFR Part 20. You should discuss the monitoring and control mechanisms in place to ensure compliance with the appropriate requirements.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 397891.

If you have any questions or require clarification on any of the information stated above, you may contact me at (708) 829-9834.

Sincerely,

Original Signed By  
John A. Grobe, Chief  
Nuclear Materials Inspection  
Section 2

Enclosures:

1. Regulatory Guide 10.5, Rev.3
2. Regulatory Guide 3.67
3. IN 90-09

cc/w enclosures: Robert Meschter, RSO  
1020 London Rd.  
Cleveland, OH 44110

Mayor Michael White, Cleveland  
Lisa Mehringer, Cleveland  
Irv Ball, Cuyahoga County  
Robert Owen, Ohio  
Erwin Odeal, NEORS

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Jennifer Horan, Volunteer Services

Organizations listed in parentheses are not members.

The mission of The Earth Day Coalition is to build a healthy, safe and sustainable earth, by developing and promoting a common environmental agenda with the people of Northeast Ohio. - Est. 1990

December 28, 1994

US Nuclear Regulatory Commission  
Office of the Secretary  
One White Flint North  
11555 Rockville Pike  
Rockville, MD 20852

re: Request for Hearing: Operating License  
Advanced Medical Systems, Inc.  
Cleveland, Ohio

To Whom It May Concern,

In accordance with 10 CFR 2.1205, The Earth Day Coalition requests a hearing regarding the operating license for the Advanced Medical Systems, Inc. (AMS) regarding their possession of radioactive materials. We would prefer this hearing to be held in Cleveland so neighbors of this facility and interested members of the public in northeast Ohio can fully participate.

We believe that AMS has repeatedly failed to adequately account for and contain their licensed radioactive materials. AMS has demonstrated a lack of will and ability to abide by their license to safely possess and not contaminate their own facility and the environment in northeast Ohio.

The Earth Day Coalition is most concerned about the extensive cobalt 60 contamination on-site at this facility as it is in a residential neighborhood of the city of Cleveland. It is our understanding that there is little or no, and certainly inadequate, emergency planning for the AMS facility in Collinwood if there would be a natural disaster, fire, flooding, intrusion, or continued mishaps from AMS employees. We are also concerned about the extensive cobalt 60 on-site where it has been and has the ability to continue to be inadvertently released into the surrounding neighborhood (and ultimately residents), either by air or water (rain).

We are also very concerned about the past and continuing contamination of our public wastewater treatment plants, the Southerly and the Easterly plants of the northeast Ohio Regional Sewer District in Cleveland, Ohio. Ultimately, the releases of cobalt 60 from the AMS sewer to the wastewater plants end up in the Cuyahoga River and Lake Erie, the source of drinking water for millions of people. As you know, a 3 million Pci/g particle of cobalt 60 was found at the Southerly. Extensive contamination still exists on-site at the Southerly.

The Earth Day Coalition is a non-profit environmental education and advocacy organization located in Cleveland, Ohio. Our interest in this hearing is not commercial or financial. We are interested strictly in public education and information and environmental issues.

Thank you for your attention to our concerns.

Sincerely,

Chris Trepal

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