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(RDS)

July 26, 1990

Docket No. 030-16055
License No. 34-19089-01
EA 90-051

Advanced Medical Systems, Inc.
ATTN: Seymour S. Stein, Ph.D.
1020 London Road
Cleveland, OH 44110

Gentlemen:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 030-16055/90001)

This refers to an NRC inspection conducted on January 23 - 26, 1990, at Advanced Medical Systems, Inc. (AMS) in Cleveland, Ohio. An inspection report documenting the findings of this inspection was sent to you on March 13, 1990. An Enforcement Conference between me and members of the Region III and Headquarters staffs and you and members of your staff was conducted in Cleveland, Ohio on March 27, 1990.

This inspection identified several violations: (1) the emergency electrical generator for your air handling and radiological monitoring equipment was inoperable; (2) bioassays of workers were not performed as required; (3) high radiation area access controls were not adequate; (4) an alarming dosimeter used during a hot cell entry had not been calibrated within 6 months prior to its use; (5) physical inventories of sealed sources and devices had not been conducted; (6) the evaluation of exposure to an individual in excess of 40 MPC hours was not documented; (7) an external semiannual audit of facilities and procedures was not conducted as required; (8) the master alarm panel did not properly indicate opening of the basement door, nor was there any warning light over the basement door as required; and (9) the roof area was not conspicuously posted as a radiation area.

With regard to the specific violation for failure to conduct physical inventories of radioactive material, we understand that you have such an inventory underway which will be completed by the end of the year. We also understand that you will propose, in a request for a license amendment, an alternative means of assuring that the location and amount of licensed material in your possession is accurately known. During the Enforcement Conference, you discussed the difficulties inherent in performing a physical inventory at six month intervals. While we appreciate those difficulties, you should be aware that you are required to comply with NRC license conditions and

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regulations unless you request and receive specific relief in the form of a license amendment.

In addition to the violations that were identified, the NRC staff identified the following concerns regarding your operations: (1) your corrective actions regarding problems with the automatic start of the emergency generator, including two previous failed tests, were not initially effective; (2) there was no battery powered emergency lighting in your hot cell or other radiological areas to provide illumination during the loss of offsite power and inoperability of the emergency generator that occurred on January 24, 1990; (3) the hot cell HEPA filtration system was supported by rope which could fail in the event of a fire in that area; and (4) the accumulation of radwaste located in various areas of the facility appeared to be excessive. Collectively, these violations and concerns demonstrate inadequate attention to detail and inadequate management oversight regarding the radiation safety requirements of your license.

On March 27, 1990, we conducted an Enforcement Conference to review the apparent violations and to determine the corrective actions you have taken regarding these items. We note that you have initiated or completed corrective actions for the individual problems identified during the January inspection. However, you did not completely address the underlying causes of these violations, and therefore also failed to address the steps you plan to take to preclude repetition of these violations. Some underlying causes that we identified included: (1) AMS management was not fully aware of the regulatory requirements, including the procedures contained in its license; (2) aggressive action was not taken by AMS management to self-identify and correct problems; and (3) AMS erroneously believed it could change practices required by license conditions prior to the receipt of written NRC approval in the form of a license amendment. In addition, we were concerned that during the enforcement conference, you failed to demonstrate an awareness of the significance of the failure to maintain the emergency generator in operable condition.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" 10 CFR Part 2, Appendix C (1990) (Enforcement Policy), the violations described in the enclosed Notice of Violation (Notice) represent a breakdown in control over your licensed activities and have been classified as a Severity Level III problem. In accordance with the Enforcement Policy, a civil penalty normally is proposed for a Severity Level III problem. However, in this case, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support, I have decided not to propose a civil penalty. This decision is based on the positive steps you have taken to improve your facility over the past several years, especially with regard to decontamination of the facility and ongoing improvements to the hot cell ventilation system, and the positive safety attitude expressed by your Radiation Safety Officer during the



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tour prior to the Enforcement Conference and at the Enforcement Conference. We expect you to fully resolve the management issues identified above without the need for a civil penalty.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The response is required within 30 days of the date of this letter transmitting the Notice. In addition to your response to the specific violations, we also request that you address the apparent underlying causes of the violations discussed above. Specifically, we request that you describe:

- A. Plans for ensuring that the management team of AMS fully understands the applicable regulatory requirements, including 10 CFR Parts 19, 20, and 30, and the requirements of License No. 34-19089-01, including the licensee's own procedures which formed the basis for the license and which are currently referenced in License Condition 17, Amendment No. 17.
- B. Plans for self-identification of safety issues and violations through internal and/or independent audits. These audits should include direct observation of worker activities as well as oversight of programmatic activities required by the license. These plans should include specific dates or frequencies at which adherence to requirements will be reviewed.
- C. Corrective action plans, including root cause evaluations, that will address how, by whom, and in what time frame the items noted as a result of the self-identification of problems in Item B will be addressed.

You should be fully aware that we are using enforcement discretion as permitted in the NRC Enforcement Policy, anticipating that you will correct the underlying causes of the violations.

We note that your communications with NRC representatives during the tour of your facility prior to the Enforcement Conference and during the Enforcement Conference were professional. We appreciate that professionalism and hope that future technical and regulatory differences will be discussed and resolved in a similar professional manner.

After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements. It is anticipated that an on-site review will be conducted within the next six months to examine your corrective actions.

In accordance with 2.790 of the NRC's "Rules of Practice, Part 2, Title 10, Code of Federal Regulations, a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

Advanced Medical Systems, Inc.

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The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the paperwork reduction act of 1980, Pub. L. 96-511.

Sincerely,

A. Bert Davis
Regional Administrator

Enclosures:

1. Notice of Violation
2. Inspection Report
No. 030-16055/90001

cc w/enclosures:
DCD/DCB (RIDS)

RIII
WHS
Schultz/db
07/25/90

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Grobe
07/25/90

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Nofelius
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Paperniello
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Davis
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