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UNITED STATES NUCLEAR REGULATORY COMMISSION

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In The Matter of:

ADVANCED MEDICAL SYSTEMS, INC.

* DOCKET NO. 30-16055-50
* LICENSE NO. 34-19089-01
* E.A. 87-139
* DATED: August 11, 1987
* ANSWER TO ORDER MODIFYING
* LICENSE, EFFECTIVE IMMEDIATELY,
* AND DEMAND FOR INFORMATION
* (REQUEST FOR HEARING CONTAINED
* HEREIN)

NOW COMES Advanced Medical Systems, Inc. (hereinafter referred to as "AMS"), pursuant to Section 10 CFR, Section 2.705 and states as follows:

1. Answering Section I of the Order Modifying License, Effective Immediately, and Demand for Information (hereinafter referred to as "the Order"), AMS admits that it is the holder of Byproduct Material License No. 34-19089-01 duly issued by the Nuclear Regulatory Commission (hereinafter referred to as "NRC") pursuant to 10 CFR Part 30. AMS further admits that that license, inter alia, authorizes possession and use of 150,000 curies of cobalt-60 as solid metal, 150,000 curies of cobalt-60 in sealed sources, and 40,000 curies of cesium-137 in the manufacturer installation and servicing of radiography and teletherapy devices. AMS further admits that the license further authorizes the installation, servicing, maintenance and dismantling of radiography and teletherapy units. AMS further admits the license, originally issued on November 2, 1979, was renewed on June 25, 1986,

LAW OFFICES
WICKENS, HERZER
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LORAIN, OHIO

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with an expiration date of October 31, 1986 and that a timely renewal application has been submitted.

2. Answering the first paragraph of Section II of the Order, AMS admits that its teletherapy source fabrication facility is located at 1020 London Road, Cleveland, Ohio (hereinafter referred to as "London Road Facility"). Except as so admitted, AMS denies each and every other allegation and/or inference contained in said paragraph.

3. Answering the second paragraph of Section II of the Order, AMS denies for want of knowledge or information sufficient to form a belief as to the truth thereof each and every allegation and/or inference contained therein.

4. Answering the third paragraph of Section II of the Order, AMS states that on February 20, 1986 representatives from NRC Region III met with representatives of AMS at the London Road facility, inter alia, and discussed for the first time the findings and recommendations in the ORAU's evaluation report, which report speaks for itself, and which had been completed in December of 1985 but not provided to AMS until January of 1986; except as so stated, AMS denies each and every allegation and/or inference contained in said paragraph.

5. Answering the fourth paragraph of Section II of the Order, AMS states the NRC issued correspondence dated March 7, 1986, which speaks for itself; that shortly thereafter AMS began the development and implementation of a clean up plan. Through correspondence dated April 16, 1986, AMS informed the NRC, inter alia: (1) of its progress on the development and implementation of its clean up plan; and (2) that it needed a time extension to respond to requests contained in the NRC's

March 7, 1986 correspondence because consultants indicated they could not meet the time requirements set forth by the NRC. Three weeks later the NRC issued correspondence dated May 6, 1986, which speaks for itself. Through correspondence dated May 29, 1986 AMS informed the NRC as to the status of its clean up activities and provided a decontamination plan developed by AMS consultants; except as so stated, AMS denies each and every allegation and/or inference contained in said paragraph.

6. Answering the fifth paragraph of Section II of the Order, AMS states that the NRC issued additional amendments and conditions to its license which speak for themselves and which, inter alia, prevented AMS from performing any further clean up; except as so stated, AMS denies each and every allegation and/or inference contained in said paragraph.

7. Answering the sixth paragraph of Section II of the Order, AMS states that through correspondence dated July 24, 1986 it issued to the NRC, inter alia, a copy of a contract by and between it and Rad Services, Inc. to, inter alia, perform decontamination of the London Road Facility, the full scope of which is set forth in said contract; except as so stated, AMS denies each and every allegation and/or inference contained in said paragraph.

8. Answering the seventh paragraph of Section II of the Order, AMS states that Amendment No. 9 was issued to its License, which speaks for itself, and that through correspondence dated September 10, 1986 AMS submitted a decontamination plan to the NRC, which correspondence and plan speak for themselves.

9. Answering the eighth paragraph of Section II of the Order, AMS states that on October 23, 1986 the NRC issued Amendment No. 10 to its license and that that license amendment and conditions 16 and 19.E, 15.A 19.C, 20 and Amendment 10 speak for themselves; except as so stated, AMS denies each and every allegation and/or inference contained in said paragraph.

10. Answering the ninth paragraph of Section II of the Order, AMS states that it issued a letter dated December 23, 1986 to the NRC, which letter speaks for itself, and that the NRC issued a letter dated February 11, 1987 which also speaks for itself; except as so stated, AMS denies each and every allegation and/or inference contained in said paragraph.

11. Answering the tenth paragraph of Section II of the Order, AMS states that it issued a letter dated March 20, 1987, which letter speaks for itself, that on April 2, 1987, Region III staff and AMS representatives met, and that AMS issued a letter dated April 10, 1987 to the NRC, which speaks for itself; except as so stated, AMS denies each and every allegation and/or inference contained in said paragraph.

12. Answering Section III of the Order, AMS denies each and every allegation and/or inference contained therein.

13. Answering Section IV of the Order, AMS denies each and every allegation and/or inference contained therein.

14. Answering Section V of the Order, AMS states that the same is not an allegation, but is an order which, inter alia, requires the commencement of decontamination of the London Road facility by August 31, 1987, and the commencement of the redesign, reconstruction and

upgrading of the London Road facility by August 31, 1987; AMS denies or contests each and every allegation and/or order contained in Section V of the Order.

15. Answering the first paragraph of Section VI of the Order, AMS acknowledges that pursuant to 10 CFR Section 2.202(b) it may, in its answer, request a hearing and that any other person adversely affected by this Order may request a hearing within twenty (20) days of its issuance. Further answering the first paragraph Section VI, AMS acknowledges that an answer to this Order or any requests for hearing shall be submitted to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and a copy shall also be sent to the Assistant General Counsel for Enforcement at the same address and the Regional Administrator, NRC Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137. Further answering the first paragraph of Section VI of the Order, AMS acknowledges that if a person other than the licensee requests a hearing, that person shall set forth with particularity the manner in which the petitioner's interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d). Further answering the first paragraph of Section VI of the Order, AMS acknowledges that upon the failure of licensee to answer or request a hearing within the specified time, the Order shall be final without further proceedings and that an answer to the Order or a request for hearing shall not stay the immediate effectiveness of this Order.

16. Answering the second paragraph of Section VI of the Order, AMS acknowledges that if a hearing is requested by licensee or a person whose interest is adversely affected, the Commission will issue an Order

designating the time and place of any hearing and if a hearing is held, the issue to be considered at such hearing shall be whether this Order shall be sustained. Further answering the second paragraph of Section VI, AMS hereby requests a hearing on all issues placed in controversy by its Answer to Order Modifying License, Effective Immediately and Demand for Information, whereat it will be granted the opportunity to, inter alia, appear and present evidence. Accordingly, AMS demands that the commission issue an order designating the time and place of the hearing whereat the issue to be considered will be, inter alia, whether the Order should be sustained.

17. Answering Section VII of the Order, AMS states that the same is not an allegation, but is, inter alia, an order requiring the production of information; as such, AMS denies and contests each and every allegation and/or inference contained in said section, and responds to the individual requests for information as follows:

- A. Responding to Section VII A,1, AMS states it will provide its financial statements and balance sheets for the previous three years, but objects to the request on the basis the same does not reasonably identify or otherwise limit what is being requested;
- B. Responding to Section VII, A,2, AMS states it will provide its quarterly financial statements and balance sheets for the four previous quarters, but objects to the request on the basis the same does not reasonably identify or otherwise limit what is being requested;
- C. Responding to Section VII, A,3, of the Order, AMS states it will provide the requested information;
- D. Responding to Section VII, A,4, of the Order AMS states it will provide the requested information;

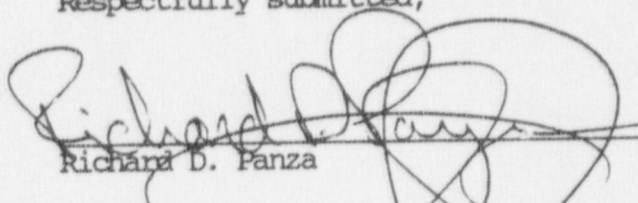
E. Responding to Section VII A,5, of the Order, AMS states it will provide the requested information;

F. Responding to Section VII B,1-3, of the Order, AMS states that it intends to comply with the requests contained therein, but specifically objects to the general nature i.e. lack of specificity, of the requests contained therein.

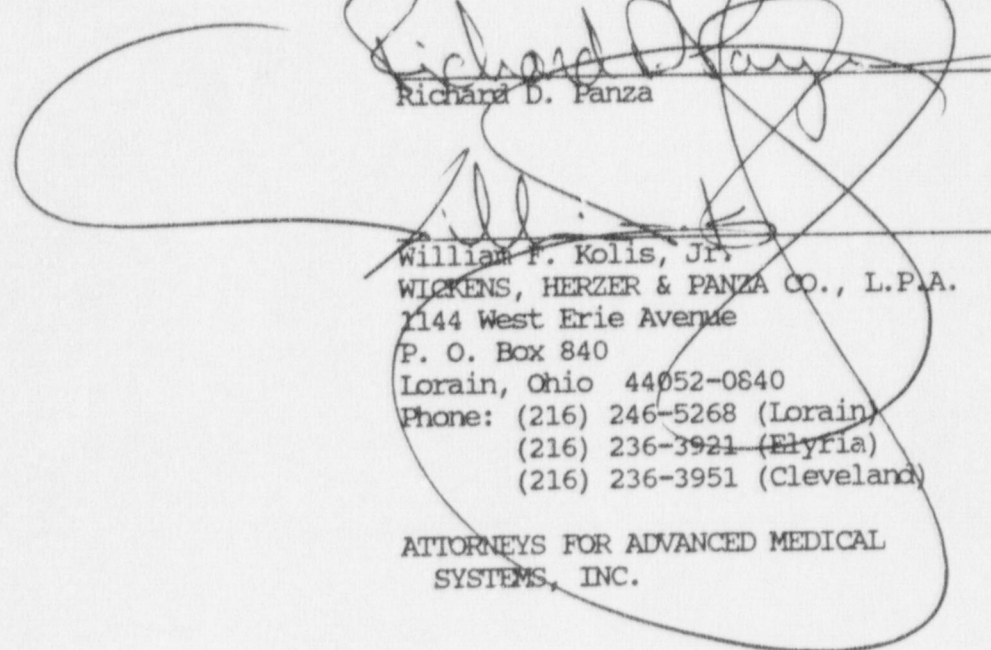
18. In answer to the allegations of improper conduct which the Deputy Executive Director for Regional Operations, claims led him to conclude that "the NRC lacks reasonable assurance that decontamination, redesign, reconstruction and upgrading of the licensee's London Road facility will be initiated and completed in an orderly and timely fashion to assure the health and safety of the public, including licensee's employees will be protected . . ." and further that "the public health, safety and interest require that those efforts commence forthwith . . ." [See Order Section IV, p. 7.] AMS specifically and affirmatively states that it has attempted in a reasonable and timely fashion to, inter alia, affect the decontamination, redesign, and reconstruction of its London Road facility, but has been blocked in its efforts to do so by, inter alia, (1) the NRC's delay in responding to proposed decontamination plans, (2) the NRC's imposition of financially and temporally unreasonable requests, and (3) the NRC's unjustified partial suspension of its license on October 10, 1986. Further, AMS specifically and affirmatively states that the present status of the contamination complained of by the NRC does not warrant the invocation of "effective immediately" status under 10 CFR Section 2.201(c), and that unless the Order is rescinded or modified, the same may adversely

impact upon AMS' ability to operate and effect reasonable decontamination. Further, specifically and affirmatively answering the Order, AMS states that the NRC has failed to join a party necessary to this litigation.

Respectfully submitted,



Richard D. Panza



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ATTORNEYS FOR ADVANCED MEDICAL
SYSTEMS, INC.

STATE OF OHIO)

COUNTY OF ASHTABULA)

VERIFICATION

I, Theodore Hebert, General Manager of Advanced Medical Systems, Inc., and its authorized representative, One Factory Row, Geneva, OH 44041, with full authority state that I have read the foregoing Answer to Order Modifying License, Effective Immediately, and Demand for Information and hereby depose and state that I know the contents thereof, and to the best of my knowledge, information and believe the denials, admissions and statements contained therein are true and that the same are not interposed for delay.

Theodore Hebert
Theodore Hebert

Sworn to and subscribed in my presence this 10th day of August, 1987.

Marilyn D. Block (Zubal)
NOTARY PUBLIC

MARILYN D. BLOCK, Notary Public
State of Ohio
My Commission Expires May 19, 1988

PROOF OF SERVICE

The undersigned hereby certifies that a true, accurate and complete copy of the foregoing Answer to Order Modifying License, Effective Immediately, and Demand for Information (Request for Hearing Contained Herein) was sent via ordinary U.S. mail, on this 11 day of August, 1987, to:

Director,
Office of Inspection and Enforcement
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Regional Administrator
NRC Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Assistant General Counsel
for Enforcement
Office of Inspection and Enforcement
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555


William F. Kolis, Jr.

PERSONS UPON WHOM FUTURE DOCUMENTS MAY BE SERVED

Service of all future documents in this matter upon Advanced Medical Systems, Inc. can be accomplished by forwarding the same to:

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