

Advanced Medical Systems, Inc.

• 121 North Eagle Street • Geneva, Ohio 44041
(216) 466-4671 FAX (216) 466-0186

July 27, 1995

Mr. John Madera
U. S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-9820

Dear John:

Enclosed is the revised Trust Agreement for Advanced Medical Systems, Inc.'s financial assurance.

All the changes the USNRC requested have been made.

Sincerely,

David Cesar/cs

DAVID CESAR
Treasurer

DC/cs
Enclosure

E/S7

RECEIVED
JUL 28 1995
REGION III

STANDBY TRUST AGREEMENT
(AS MODIFIED AND RESTATED)

TRUST AGREEMENT, the Agreement entered into as of the 5th day of July, 1995, by and between ADVANCED MEDICAL SYSTEMS, INC., a Florida corporation herein referred to as "Grantor" and BANK ONE OHIO TRUST COMPANY, N.A., or other trustee acceptable to the Commission, the "Trustee").

WHEREAS, the U.S. Nuclear Regulatory Commission (NRC), agency of the U.S. Government, pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, has promulgated regulations in Title 10, Chapter I of the Code of Federal Regulations, Part [30, 40, 70, or 72]. These regulations, applicable to the Grantor, require that a holder of, or an applicant for, a Part 30, 40, 70 or 72 license provide assurance that funds will be available when needed for required decommissioning activities; and

WHEREAS, the Grantor has elected to use a letter of credit to provide such financial assurance for the facilities identified herein; and

WHEREAS, when payment is made under a letter of credit, this Standby Trust shall be used for the receipt of such payment; and

WHEREAS, AMS did enter into a Modified and Restated Standby Trust Agreement on the 30th day of March, 1995 with Bank One Ohio Trust Company, as Trustee; and

WHEREAS, Grantor desires to modify the Trust Agreement of March 30, 1995 and in the interests of clarity and convenience to restate in its entirety this Trust upon which the uses and purposes for which the property now held or hereafter acquired by the Trustee shall be held, managed and controlled; and

WHEREAS, the Grantor, acting through its duly authorized officers, has selected the Trustee to be the Trustee under this Agreement, and the Trustee is willing to act as trustee.

NOW, THEREFORE, the Grantor and the Trustee agree as follows:

SECTION 1. DEFINITIONS. As used in this Agreement:

(a) The term "Grantor" means the NRC licensee who enters into this Agreement and any successors or assigns of the Grantor.

(b) The term "Trustee" means the trustee who enters into this Agreement and any successor Trustee.

SECTION 2. COSTS OF DECOMMISSIONING. This Agreement pertains to the costs of decommissioning the materials and activities identified in License No. 34-19089-01 issued pursuant to 10 CFR Part [30, 40, 70, or 72] for the facility identified on Exhibits "A" and "A-1".

SECTION 3. ESTABLISHMENT OF FUND. The Grantor and the Trustee hereby establish a standby trust fund (the "Fund") for the benefit of the NRC. The Grantor and the Trustee intend that no third party have access to the Fund except as provided herein.

SECTION 4. PAYMENTS CONSTITUTING THE FUND. Payments made to the Trustee for the Fund shall consist of cash, securities, or other liquid assets acceptable to the Trustee. The Fund is established initially as consisting of the property, which is acceptable to the Trustee, described in Exhibit "B" attached hereto. Such property and any other property subsequently transferred to the Trustee are referred to as the "Fund", together with all earnings and profits thereon, less any payments or distributions made by the Trustee pursuant to this Agreement. The Fund shall be held by the Trustee, IN TRUST, as hereinafter provided. The Trustee shall not be responsible nor shall it undertake any responsibility for the amount of, or adequacy of the Fund, nor any duty to collect from the Grantor, any payments necessary to discharge any liabilities of the Grantor established by the NRC.

SECTION 5. PAYMENT FOR REQUIRED ACTIVITIES SPECIFIED IN THE PLAN. The Trustee shall make payments from the Fund to the Grantor upon presentation to the Trustee of the following:

- (a) A certificate duly executed by the Secretary of the Grantor attesting to the occurrence of the events, and in the form set forth in the attached Specimen Certificate; and

(b) A certificate attesting to the following conditions:

(1) that decommissioning is proceeding pursuant to an NRC-approved plan;

(2) that the funds withdrawn will be expended for activities undertaken pursuant to that Plan; and

(3) that the NRC has been given thirty (30) days prior notice of Advanced Medical System's intent to withdraw funds from the escrow fund.

No withdrawal from the Fund can exceed ten percent (10%) of the outstanding balance of the Fund unless NRC approval is attached.

In the event the Grantor breaches the requirements under 10 C.F.R. Part 30 or has the inability to direct decommissioning activities, the Trustee shall make payments from the Fund as the NRC shall direct, in writing, to provide for the payment of the costs of required activities covered by this Agreement. The Trustee shall reimburse the Grantor or other persons as specified by the NRC from the Fund for expenditures for required activities in such amounts as the NRC shall direct in writing. In addition, the Trustee shall refund to the Grantor such amounts as the NRC specifies in writing. Upon refund, such funds shall no longer constitute part of the Fund as defined herein.

SECTION 6. TRUST MANAGEMENT. The Trustee shall invest and reinvest the principal and income of the Fund and keep the Fund invested as a single fund, without distinction between principal and income, in accordance with general investment policies and guidelines which the Grantor may communicate in writing to the Trustee

from time to time, subject, however, to the provisions of this Section. In investing, reinvesting, exchanging, selling and managing the Fund, the Trustee shall discharge its duties with respect to the Fund solely in the interest of the NRC and with the care, skill, prudence, and diligence under the circumstances then prevailing which persons of prudence, acting in a like capacity and familiar with such matters, would use in the conduct of an enterprise of a like character and with like aims; except that:

(a) Securities or other obligations of the Grantor, or any other owner or operator of the facilities, or any of their affiliates as defined in the Investment Company Act of 1940, as amended (15 U.S.C. 80a-2(a)), shall not be acquired or held, unless they are securities or other obligations of the Federal or a State government;

(b) The Trustee is authorized to invest the Fund in time or demand deposits of the Trustee, to the extent insured by an agency of the Federal Government, and in obligations of the Federal Government such as GNMA, FNMA and FHLM bonds and certificates or State and Municipal bonds rated BBB or higher by Standard and Poors or Baa or higher by Moody's Investment Services; and

(c) For a reasonable time, not to exceed sixty (60) days, the Trustee is authorized to hold uninvested cash, awaiting investment or distribution, without liability for the payment of interest thereon.

SECTION 7. COMMINGLING AND INVESTMENT. The Trustee is expressly authorized in its discretion:

(a) To transfer from time to time any or all of the assets of the Fund to any common, commingled, or collective trust fund created by the Trustee in which the Fund is eligible to participate, subject to all of the provisions thereof, to be commingled with the assets of other trusts participating therein; and

(b) To purchase shares in any investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a-1 et seq.), including one that may be created, managed, underwritten, or to which investment advice is rendered, or the shares of which are sold by the Trustee. The Trustee may vote such shares in its discretion.

SECTION 8. EXPRESS POWERS OF TRUSTEE. Without in any way limiting the powers and discretion conferred upon the Trustee by the other provisions of this Agreement or by law, the Trustee is expressly authorized and empowered:

(a) To sell, exchange, convey, transfer, or otherwise dispose of any property held by it, by public or private sale, as necessary to allow duly authorized withdrawals at the joint request of the Grantor and the NRC or to reinvest in securities at the direction of the Grantor;

(b) To make, execute, acknowledge, and deliver any and all documents of transfer and conveyance and any and all other instruments that may be necessary or appropriate to carry out the powers herein granted;

(c) To register any securities held in the Fund in its own name, or in the name of a nominee, and to hold any security in bearer form or in book entry, or to combine certificates representing such securities with certificates of the same issue held by the

Trustee in other fiduciary capacities, to reinvestment interest payments and funds from matured and redeemed instruments, to file proper forms concerning securities held in the Fund in a timely fashion with appropriate government agencies, or to deposit or arrange for the deposit of such securities in a qualified central depository even though, when so deposited, such securities may be merged and held in bulk in the name of the nominee or such depository with other securities deposited therein by another person, or to deposit or arrange for the deposit of any securities issued by the U.S. Government, or any agency or instrumentality thereof, with a Federal Reserve bank, but the books and records of the Trustee shall at all times show that all such securities are part of the Fund;

(d) To deposit any cash in the Fund in interest-bearing accounts maintained or savings certificates issued by the Trustee, in its separate corporate capacity, or in any other banking institution affiliated with the Trustee, to the extent insured by an agency of the Federal government; and

(e) To compromise or otherwise adjust all claims in favor of or against the Fund.

SECTION 9. TAXES AND EXPENSES. All taxes of any kind that may be assessed or levied against or in respect of the Fund and all brokerage commissions incurred by the Fund shall be paid from the Fund. All other expenses incurred by the Trustee in connection with the administration of this Agreement and the Fund, including fees for legal services rendered to the Trustee, the compensation of the Trustee to the

extent not paid directly by the Grantor, and all other proper charges and disbursements of the Trustee shall be paid from the Fund.

SECTION 10. ANNUAL VALUATION. After payment has been made into this standby trust fund, the Trustee shall annually, at least thirty (30) days before the anniversary date of receipt of payment into the standby trust fund, furnish to the Grantor and to the NRC a statement confirming the value of the Trust. Any securities in the Fund shall be valued at market value as of no more than sixty (60) days before the anniversary date of the establishment of the Fund. The failure of the Grantor to object in writing to the Trustee within ninety (90) days after the statement has been furnished to the Grantor and the NRC shall constitute a conclusively binding assent by the Grantor, barring the Grantor from asserting any claim or liability against the Trustee with respect to the matters disclosed in the statement.

SECTION 11. ADVICE OF COUNSEL. The Trustee may from time to time consult with counsel with respect to any question arising as to the construction of this Agreement or any action to be taken hereunder. The Trustee shall be fully protected, to the extent permitted by law, in acting on the advice of counsel.

SECTION 12. TRUSTEE COMPENSATION. For its services as Trustee, Bank One Ohio Trust Company, N.A., or its successor, shall receive the compensation stipulated in its regularly published schedules of compensation in effect and applicable at the time such compensation shall become payable. A copy of the current fee schedule is attached hereto and marked Exhibit "F".

Once the Trust is funded, changes in the current fee schedule will be sent to the NRC Region III office.

SECTION 13. SUCCESSOR TRUSTEE. Upon ninety (90) days' notice to the NRC, the Trustee may resign; upon ninety (90) days' notice to NRC and the Trustee, the Grantor may replace the Trustee; but such resignation or replacement shall not be effective until the Grantor has appointed a successor Trustee and this successor accepts the appointment. The successor Trustee shall have the same powers and duties as those conferred upon the Trustee hereunder. Upon the successor Trustee's acceptance of the appointment, the Trustee shall assign, transfer, and pay over to the successor Trustee the funds and properties then constituting the Fund. If for any reason the Grantor cannot or does not act in the event of the resignation of the Trustee, the Trustee may apply to a court of competent jurisdiction for the appointment of a successor Trustee or for instructions. The successor Trustee shall specify the date on which it assumes administration of the trust in a writing sent to the Grantor, the NRC and the present Trustee by certified mail ten (10) days before such change becomes effective. Any expenses incurred by the Trustee as a result of any of the acts contemplated by this Section shall be paid as provided in Section 9 hereof.

SECTION 14. INSTRUCTIONS TO THE TRUSTEE. All orders, requests, and instructions by the Grantor to the Trustee shall be in writing, signed by such persons as are signatories to this Agreement or such other designees as the Grantor may designate in writing. The Trustee shall be fully protected in acting without inquiry in accordance

with the Grantor's orders, requests, and instructions. If the NRC is required to direct decommissioning as per Section 5 hereof, the NRC shall issue orders, requests, or instructions to the Trustee and these shall be in writing, signed by the NRC, or its designees, and the Trustee shall act and shall be fully protected in acting in accordance with such orders, requests, and instructions. The Trustee shall have the right to assume, in the absence of written notice to the contrary, that no event constituting a change or a termination of the authority of any person to act on behalf of the Grantor or the NRC hereunder has occurred. The Trustee shall have no duty to act in the absence of such orders, requests, and instruction from the Grantor and/or the NRC, except as provided for herein.

SECTION 15. AMENDMENT OF AGREEMENT. This Agreement may be amended by an instrument in writing executed by the Grantor, the Trustee and the NRC, or by the Trustee and the NRC, if the Grantor ceases to exist.

SECTION 16. IRREVOCABILITY AND TERMINATION. Subject to the right of the parties to amend this Agreement as provided in Section 15 hereof, this Trust shall be irrevocable and shall continue until terminated at the written agreement of the Grantor, the Trustee and the NRC, or by the Trustee and the NRC if the Grantor ceases to exist. Upon termination of the trust, all remaining trust property, less final trust administration expenses, shall be delivered to the Grantor or its successor.

SECTION 17. IMMUNITY AND INDEMNIFICATION. The Trustee shall not incur any personal liability of any nature in connection with any act or omission, made

in good faith, in the administration of this Trust, or in carrying out any directions by the Grantor or the NRC issued in accordance with this Agreement. The Trustee shall be indemnified and saved harmless by the Grantor or from the trust fund, or both, from and against any personal liability to which the Trustee may be subjected by reason of any act or conduct in its official capacity, including all expenses reasonably incurred in its defense in the event the Grantor fails to provide such defense.

In the event this Trust is or becomes subject to specific regulatory requirements of any governmental or quasi-governmental agency relating to hot cell operation or decommissioning, funding, administration, distribution of funds, or termination of this Trust, the Grantor accepts full responsibility for compliance with such rules, regulations or requirements.

SECTION 18. This Agreement shall be administered, construed and enforced according to the laws of the State of Ohio.

SECTION 19. INTERPRETATION AND SEVERABILITY. As used in this Agreement, words in the singular include the plural and words in the plural include the singular. The descriptive headings for each Section of this Agreement shall not affect the interpretation or the legal efficacy of this Agreement. If any part of this Agreement is

nvalid, it shall not affect the remaining provisions which will remain valid and enforceable.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their respective officers duly authorized.

WITNESSES:

"GRANTOR"
ADVANCED MEDICAL SYSTEMS, INC.

Janice M. Bred
Carmel A. Sinneretta

By: David Cesar
DAVID CESAR, Treasurer

"TRUSTEE"
BANK ONE OHIO TRUST
COMPANY, N.A.

David A. Faulstich
Charles S. T. [Signature]

By: [Signature]
Its: TRUST OFFICER

STATE OF OHIO)

) SS:

COUNTY OF Cuyahoga)

On this 30 day of JULY, 1995, before me a Notary Public in and for said County and State, personally appeared PHILIP ROSFLOCK, and he did depose and say that he is the TRUST OFFICER & V.P. of Bank One Ohio Trust Company, N.A., Trustee, which executed the above instrument and that the same is his free act and deed.

IN TESTIMONY WHEREOF, I have hereunto set my hand and official seal at CLEVELAND, Ohio, this 30 day of JULY, 1995.

[Signature]
NOTARY PUBLIC

JOYCE E. STALHEIM
Notary Public, State of Ohio
My Commission Expires 4-3-2000
(Recorded in Lake County)

EXHIBIT A

This Agreement demonstrates financial assurance for the following cost estimates for the following licensed activities:

U.S. NUCLEAR REGULATORY COMMISSION LICENSE NUMBER	NAME AND ADDRESS OF LICENSEE	ADDRESS OF LICENSED ACTIVITY	COST ESTIMATES FOR REGULATORY ASSURANCES DEMONSTRATED THIS AGREEMENT
34-19089-01	Advanced Medical Systems, Inc. 1020 London Road Cleveland, OH 44110	Same	\$1,800,000.00

EXHIBIT A-1

This facility shall be defined as the plant located at:

1020 London Road
Cleveland, Ohio

Parcel No. 1

Situated in the City of Cleveland, County of Cuyahoga and State of Ohio, and known as being part of Sub-lots Numbers 216, 217 and 251, and all of Sub-lots Numbers 254 to 258, both inclusive, in the Wolfe-Bill Realty Company's St. Clair London Road Subdivision on part of Original Euclid Township Lots Numbers 9 and 42, Tract Number 10, as shown by the recorded plat in Volume 54 of Maps, Page 24 of Cuyahoga County Records, and also a part of Original Euclid Township Lot Number 9, Tract Number 10, and together forming a parcel of land, bounded and described as follows: Beginning on the Southeastern side of Mandalay Avenue N.E., at the most Northernly corner of land conveyed to Great Lakes Warehouses, Inc., by deed dated February 15, 1971, and recorded in Volume 11181, Page 967 of Cuyahoga County Records; thence Northern 52 degrees 39' 40" East, 210 feet along the Southeastern side of Mandalay Avenue, N.E. to the Southwestern side of London Road N.E.; thence South 40 degrees 47' 10" East, 400.84 feet along the Southwestern side of London Road N.E., to the most Northernly corner of a parcel of land conveyed to the New York, Chicago and St. Louis Railroad Company, by deed dated April 11, 1948, and recorded in Volume 6477, Page 19 of Cuyahoga County Records; thence South 36 degrees 08' 00" West, 107.51 feet along the Northwestern line of land so conveyed to the Northwestern line of the 272nd parcel of land conveyed to the New York, Chicago and St. Louis Railway Company, by deed dated October 27, 1881, and recorded in Volume 361, Page 11 of Cuyahoga County Records; thence South 52 degrees 41' 20" West, 969.18 feet along the Northwestern line of the 272nd parcel so conveyed and along the Northwestern line of land conveyed to the New York, Chicago and St. Louis Railway Company, by deed dated November 10, 1910, and recorded in Volume 1108, Page 447 of Cuyahoga County Records and along the Northwestern line of land conveyed to the New York, Chicago and St. Louis Railroad Company, by deed of land conveyed to the New York, Chicago and St. Louis Railroad Company, by deed dated February 19, 1924, and recorded in Volume 1117, Page 124 of Cuyahoga County to the most Southernly corner of Parcel No. 1 of land conveyed to the City of Cleveland, by deed dated December 29, 1953, and recorded in Volume 8005, Page 465 of Cuyahoga County Records; thence North 17 degrees 16' 41" West, 40.00 feet along the Southwestern line of the first parcel of land so conveyed to the City of Cleveland to a point; thence North 52 degrees 41' 20" East, 189.63 feet parallel with the Southeastern line of land so conveyed to the City of Cleveland to the most Southernly corner of Parcel No. 1, 170 feet to the Southeastern side of Mandalay Avenue N.E.; thence North 51 degrees 19' 40" East along said Southeastern side, 17.25 feet to

the most southerly corner of land conveyed to Great Lakes
Fertilizers, Inc., as aforesaid; thence South 171° 20' 20" East
along the southeasterly line of said land, 225.80 feet to the
most southerly corner thereof; thence North 52 degrees 10' 40"
East along the southeasterly line of land so conveyed to Great
Lakes Fertilizers, Inc., 425.78 feet to the most easterly corner
thereof; thence North 17 degrees 20' 20" West along the
northeasterly line of said land, about 225 feet to the place of
beginning, be the same more or less, but subject to all legal
highways.

Parcel No. 2.

Situated in the City of Cleveland, County of Cuyahoga and State
of Ohio, and known as being part of Original Euclid Township Lot
No. 9, Tract No. 10, bounded and described as follows: Beginning
on the Southwesterly line of Parcel No. 1 of land conveyed to the
City of Cleveland, by deed dated December 29, 1953, and recorded
in Volume 8005, Page 469 of Cuyahoga County Records, at the most
easterly corner of Parcel No. 2 of land conveyed to the City of
Cleveland, by deed dated May 14, 1958, and recorded in Volume
9095, Page 335 of Cuyahoga County Records; thence South 37° 15'
43" East, along said Southwesterly line of Parcel No. 1 so
conveyed to the City of Cleveland and its Southeastern
prolongation to a point distant South 37° 15' 43" East, 25.80
feet from the Northwestern line of a parcel of land conveyed to
the New York, Chicago and St. Louis Railroad Company, by deed
dated February 28, 1924, and recorded in Volume 3112, Page 124 of
Cuyahoga County Records; thence S2 41° 20" East, 416.21 feet
parallel to said Northwestern line of land so conveyed to the
New York, Chicago and St. Louis Railroad Company to a point;
thence South 16° 09' 35" West, 200.56 feet to the most Southerly
corner of Parcel No. 2 of land conveyed to the City of Cleveland,
by deed dated May 14, 1958, and recorded in Volume 9095, Page 335
of Cuyahoga County Records; thence North 52° 41' 20" East, 37.78
feet to the place of beginning, be the same more or less, but
subject to all legal highways.

Parcel No. 115-33-001, 004

EXHIBIT B

Standby Letter of Credit number SB300980 dated January 27, 1995 in the amount of \$1,800,000.00.

EXHIBIT C

The designated representatives of the Grantor are:

Treasurer
Radiation Safety Officer

EXHIBIT D

CERTIFICATE OF EVENTS

Bank One Ohio Trust Company, N.A.
600 Superior Avenue
Cleveland, Ohio 44114

Attention: Trust Division

Gentlemen:

In accordance with the terms of the Agreement with you dated _____, I, _____, Secretary of Advanced Medical Systems, Inc. hereby certify that the following events have occurred:

1. Advanced Medical Systems, Inc. is required to commence the decommissioning of its facility located at Cleveland, Ohio (hereinafter called the decommissioning).
2. The plans and procedures for the commencement and conduct of the decommissioning have been approved by the United States Nuclear Regulatory Commission, or its successor, on _____ (copy of approval attached).
3. The Board of Directors of Advanced Medical Systems, Inc. has adopted the attached resolution authorizing the commencement of the decommissioning.

Secretary of Advanced Medical Systems, Inc.

Date

EXHIBIT E

CERTIFICATE OF RESOLUTION

I, _____, do hereby certify that I am Secretary of Advanced Medical Systems, Inc., a Florida corporation, and that the resolution listed below was duly adopted at a meeting of this Corporation's Board of Directors on _____, 19__.

IN WITNESS WHEREOF, I have hereunto signed my name and affixed the seal of this Corporation this _____ day of _____, 19__.

Secretary

RESOLVED, that this Board of Directors hereby authorizes the President, or such other employee of the Company as he may designate to commence decommissioning activities at Advanced Medical Systems, Inc. in accordance with the terms and conditions described to this Board of Directors at this meeting and with such other terms and conditions as the President shall approve with you upon the advice of counsel.

SCHEDULE F

TRUST DEPARTMENT FEE SCHEDULE

Annual fees are based on the market value of assets.

Administrative Fee

.6% of the first \$750,000 invested

.3% of the assets above \$750,000

Investment Management Fee

.6% of the first \$1,000,000 invested

.3% of assets above \$1,000,000

PLUS

Fees will be charged to income unless otherwise provided.

At the time of distribution of principal to anyone other than the Grantor, a deferred charge is made equal to 1% of the fair value of the trust assets distributed.

Appropriate additional compensation may be charged for services rendered which exceed the normal scope of account activities.

Minimum Fee: \$750.00 annually

Base Fee for Living Trusts: \$600.00 annually

Update on AMS Licensing Issues as of 8/1/95

1. Basement and ground water processing project

Amendment 32. was issued on March 17, 1995 to authorize AMS to process contaminated basement and ground water to 200 pCi/L and store it in special storage bladders in the facilities warehouse area. This process included water stored outside the facility in above ground tanks. Amendment 32. also authorized AMS to excavate around the outside underdrain system, remediate or replace it, reconnect the underdrain system to a sump pit, analyze the ground water until it consistently revealed no detectable non-soluble cobalt-60 and less than 200 Pci/L soluble cobalt-60, grout in the contaminated manhole and lateral on AMS property, develop a subsurface monitoring system to assess contamination migration from the facility, and to remediate the London Road interceptor in the vicinity of the abandoned lateral.

This amendment was important because it required AMS to maintain a positive hydrostatic pressure from outside to inside the facility's basement.

2. Renewal application

Deficiency letter mailed 4/17/95. Licensee given 45 days to respond. Response due June 1, 1995. Licensee FAXED a letter on 5/31 requesting an extension on their response to 6/16. Extension granted via letter dated June 7, 1995. Revised due date is June 16, 1995. Response received 6/16 and is currently being reviewed.

3. DFP/Cost Estimate

Deficiency letter mailed March 30, 1995. Licensee was given 30 days to respond. They requested an additional 30 days. Response due May 30, 1995 and received June 2, 1995. Licensee response inadequate; therefore, a TAR was submitted to HQ on 6/15/95 requesting contractor assistance. Per 6/26 telecall with Lou Bykoski, expect response to the Region NLT 7/18.

HQ Response received 7/1/95. Deficiency letter has been drafted. *at*

4. Financial Instrument and Standby Trust Agreement (STA)

Technical Assistance Request submitted to HQ for contractor review on 4/14/95. A telephone call was made to HQ re: status. Was informed the package is in hands of contractor. HQ will do what they can to push through. Following HQ review it must go through OGC for concurrence. This typically takes 10 to 14 days. *to 1/95*
choice (suit)
with design

Called Lou Bykoski on 6/1 to check on status of contractor's review. Lou stated that their review is complete and he expects to receive their comments on 6/2. He will then forward to OGC for concurrence. As noted above, this typically takes 10 - 14 days.

EJ58

Contractor comments received 6/19. A deficiency letter is in typing as of 6/22.

Deficiency letter mailed 6/28. Modified and restated STA very poor and deficient. Contractor suggested AMS resubmit new STA in accordance with R.G. 3.66, or go back to original 11/92 STA and make modifications per our March 1995 letter. Licensee given 30 days to respond.

AMS response received 7/28.

1/10 - TAR being drafted & HQ for review of new T. Agreement

5. Amendment request to: 1) evaporate water in bladders, 2) install sampling device, 3) reconnect underdrain, and 4) discharge water to sewer with Co-60 < 200 pCi/liter.

This action was submitted to HQ for technical assistance on 4/7/95. NMSS response received 6/6/95 and supplemented with information from Bob Shewmaker on 6/7/95. Deficiency letter regarding 3 of the 4 above requests (excluding the evaporator request) sent to AMS on 6/14/95. The licensee's response to the deficiency letter is due 7/14/95. A second TAR was sent to NMSS on 6/14/95, regarding the evaporator request.

Regarding no. 1, see number 11. and 13. below.

Regarding no. 2, NRC informed AMS that installation of the device is O.K. as long as it is not used to show compliance with Part 20 limits for sanitary sewerage disposal. Regarding no. 4, AMS informed by NRC that they are O.K. as long as concentrations are within Part 20 limits.

Regarding no. 3, AMS has been allowed to reconnect the underdrain to a new manhole.

6. Emergency Plan

Deficiency letter issued 6/7/95. Response due 7/7/95. Comments on AMS's emergency plan received in early June from two offsite response organizations. Comments from other response organizations expected within next few weeks. The Region will wait until AMS forwards all the comments it receives from offsite response organizations, before the region will review them for appropriateness. An additional 30 days was granted for the licensee to respond.

- Response to letter received 6/8, Dir. reviewed*
7. Amendment to change analytical labs

Was issued on May 18, 1995 via Amendment No. 33.

8. Amendment to increase the release criterion for treated water into the storage bladders from 200 to 1,000 pCi/L of water

Was issued on June 9, 1995 via Amendment No. 34

9. Amendment to extend due date of June 17 For Water Processing Project Completion as required by License Condition 19. of license

Amendment # 35 issued 6/16/95, tying-in interim milestone completion dates for various phases of the project. Amendment #35 requires that the activities required by License Condition # 19 be completed by 7/7/95, with the exception of remediation of the London Road interceptor.

10. Amendment Request to Allow the RSO to Make Minor Changes as the Water Processing Project Continues

Amendment # 36 was issued on June 21, 1995, authorizing the RSO to make minor changes to operations that are not considered to be safety significant. AMS's request for this amendment received via letter dated 6/6/95, and supplemented by letter dated 6/14/95. Also issued in this amendment was authorization to re-connect a new manhole and lateral to the underdrain system. This does not allow connection to the sewer system, nor does it preclude them from requirement to continue to take water samples for cobalt-60 concentration.

11. Amendment no. 37 issued 6/27/95

Amendment 37 authorizes installation of water evaporator eqpt. per licensee's 3/22/95 and 6/18/95 letters. The amendment does not authorize operation of the device. This is specified in L/C no. 21. Cover letter described 5 additional areas the licensee must submit for our review and approval prior to receiving authorization to operate the evaporator. Also, cover letter states that we are currently reviewing AMS proposal to install a water sampling device in lateral, and soil sampling program as described in their 6/16 letter to us. This has been controlled in under C/N 98777 as additional info. to C/N 98334.

12. FAXED AMS response to our 6/14 letter to R. Shewmaker for assistance in review on 7/3.

Asked Bob to look at AMS response to his questions which were incorporated in our 6/14 deficiency letter (C/N 98777). We are reviewing Bob's response.

13. Amendment no. 38 issued

This amendment authorizes the licensee to operate the evaporator.

14. AMS request for amendment to L/C 19.D., E. and F.

The action is in typing. We have granted AMS flexibility to change specific project deadlines (milestone dates) without requesting an amendment. Written notification will be required, along with a justification for the change. This action will be amendment no. 39 to the license.

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Amendment 32. was issued on March 17, 1995 to authorize AMS to process contaminated basement and ground water to 200 pCi/L and store it in special storage bladders in the facilities warehouse area. This process included water stored outside the facility in above ground tanks.

Amendment 32. also authorized AMS to excavate around the outside underdrain system, remediate or replace it, reconnect the underdrain system to a sump pit, analyze the ground water until it consistently revealed no detectable non-soluble cobalt-60 and less than 200 Pci/L soluble cobalt-60, grout in the contaminated manhole and lateral on AMS property, develop a subsurface monitoring system to assess contamination migration from the facility, and to remediate the London Road interceptor in the vicinity of the abandoned lateral.

This amendment was important because it required AMS to maintain a positive hydrostatic pressure from outside to inside the facility's basement.

2. Renewal application

Deficiency letter mailed 4/17/95. Licensee given 45 days to respond. Response due June 1, 1995. Licensee FAXED a letter on 5/31 requesting an extension on their response to 6/16. Extension granted via letter dated June 7, 1995. Revised due date is June 16, 1995. Response received 6/16 and is currently being reviewed.

3. DFP/Cost Estimate

Deficiency letter mailed March 30, 1995. Licensee was given 30 days to respond. They requested an additional 30 days. Response due May 30, 1995 and received June 2, 1995. Licensee response inadequate; therefore, a TAR was submitted to HQ on 6/15/95 requesting contractor assistance. Per 6/26 telecall with Lou Bykoski, expect response to the Region NLT 7/18.

Response received 7/8/95. Deficiency letter has been drafted.

4. Financial Instrument and Standby Trust Agreement (STA)

Technical Assistance Request submitted to HQ for contractor review on 4/14/95. A telephone call was made to HQ re: status. Was informed the package is in hands of contractor. HQ will do what they can to push through. Following HQ review it must go through OGC for concurrence. This typically takes 10 to 14 days.

Called Lou Bykoski on 6/1 to check on status of contractor's review. Lou stated that their review is complete and he expects to receive their comments on 6/2. He will then forward to OGC for concurrence. As noted above, this typically takes 10 - 14 days.

E159

Contractor comments received 6/19. A deficiency letter is in typing as of 6/22.

Deficiency letter mailed 6/28. Modified and restated STA very poor and deficient. Contractor suggested AMS resubmit new STA in accordance with R.G. 3.66, or go back to original 11/92 STA and make modifications per our March 1995 letter. Licensee given 30 days to respond.

AMS response received 7/28.

5. Amendment request to: 1) evaporate water in bladders, 2) install sampling device, 3) reconnect underdrain, and 4) discharge water to sewer with Co-60 < 200 pCi/liter.

This action was submitted to HQ for technical assistance on 4/7/95. NMSS response received 6/6/95 and supplemented with information from Bob Shewmaker on 6/7/95. Deficiency letter regarding 3 of the 4 above requests (excluding the evaporator request) sent to AMS on 6/14/95. The licensee's response to the deficiency letter is due 7/14/95. A second TAR was sent to NMSS on 6/14/95, regarding the evaporator request.

Regarding no. 1, see number 11. and 13. below.

Regarding no. 2, NRC informed AMS that installation of the device is O.K. as long as it is not used to show compliance with Part 20 limits for sanitary sewerage disposal. Regarding no. 4, AMS informed by NRC that they are O.K. as long as concentrations are within Part 20 limits.

Regarding no. 3, AMS has been allowed to reconnect the underdrain to a new manhole.

6. Emergency Plan

Deficiency letter issued 6/7/95. Response due 7/7/95. Comments on AMS's emergency plan received in early June from two offsite response organizations. Comments from other response organizations expected within next few weeks. The Region will wait until AMS forwards all the comments it receives from offsite response organizations, before the region will review them for appropriateness. An additional 30 days was granted for the licensee to respond.

7. Amendment to change analytical labs

Was issued on May 18, 1995 via Amendment No. 33.

8. Amendment to increase the release criterion for treated water into the storage bladders from 200 to 1,000 pCi/L of water

Was issued on June 9, 1995 via Amendment No. 34

9. Amendment to extend due date of June 17 For Water Processing Project Completion as required by License Condition 19. of license

Amendment # 35 issued 6/16/95, tying-in interim milestone completion dates for various phases of the project. Amendment #35 requires that the activities required by License Condition # 19 be completed by 7/7/95, with the exception of remediation of the London Road interceptor.

10. Amendment Request to Allow the RSO to Make Minor Changes as the Water Processing Project Continues

Amendment # 36 was issued on June 21, 1995, authorizing the RSO to make minor changes to operations that are not considered to be safety significant. AMS's request for this amendment received via letter dated 6/6/95, and supplemented by letter dated 6/14/95. Also issued in this amendment was authorization to re-connect a new manhole and lateral to the underdrain system. This does not allow connection to the sewer system, nor does it preclude them from requirement to continue to take water samples for cobalt-60 concentration.

11. Amendment no. 37 issued 6/27/95

Amendment 37 authorizes installation of water evaporator eqpt. per licensee's 3/22/95 and 6/18/95 letters. The amendment does not authorize operation of the device. This is specified in L/C no. 21. Cover letter described 5 additional areas the licensee must submit for our review and approval prior to receiving authorization to operate the evaporator. Also, cover letter states that we are currently reviewing AMS proposal to install a water sampling device in lateral, and soil sampling program as described in their 6/16 letter to us. This has been controlled in under C/N 98777 as additional info. to C/N 98334.

12. FAXED AMS response to our 6/14 letter to R. Shewmaker for assistance in review on 7/3.

Asked Bob to look at AMS response to his questions which were incorporated in our 6/14 deficiency letter (C/N 98777). We are reviewing Bob's response.

13. Amendment no. 38 issued

This amendment authorizes the licensee to operate the evaporator.

14. AMS request for amendment to L/C 19.D., E. and F.

The action is in typing. We have granted AMS flexibility to change specific project deadlines (milestone dates) without requesting an amendment. Written notification will be required, along with a justification for the change. This action will be amendment no. 39 to the license.

ARTER & HADDEN

1100 Huntington Building
925 Euclid Avenue
Cleveland, Ohio 44115-1475
216/696-1100
Facsimile 216/696-2645

Writer's Direct Dial Number:
(216) 696-2537

August 2, 1995

RECEIVED
95 AUG -7, AM 9:42
OHIO STATE
EMERGENCY RESPONSE
COMMISSION

Mr. Kenneth A. Schultz
State Emergency Response Committee
c/o Ohio EPA/DERR
1800 Watermark Drive
Columbus, Ohio 43215-1099

Re: Advanced Medical System
Our File: 62931/49779

Dear Mr. Schultz:

In response to the invitation set forth in your July 5, 1995 letter, Advanced Medical Systems, Inc. ("AMS") herewith responds to SERC Resolution No. 95-74 proposing the designation of AMS as an additional facility subject to the chemical emergency planning process pursuant to R.C. 3750.04 and 3750.05.

The presentations of Mr. Miller on behalf of AMS, and Jack Grobe of NRC at the April 12, 1995 meeting demonstrated that there was no need for SERC to take any action with regard to the AMS facility. Further, NRC emergency planning requirements were shown to be more than adequate to meet any reasonable contingency to be expected at the AMS facility. Although SERC also was advised at this meeting that it lacked the legal authority to regulate the activities of AMS, our principal focus was on demonstrating that any legitimate concerns that SERC may have were being addressed by AMS and the NRC. The decision of SERC to ignore these presentations and to issue the resolution is unfortunate. It also is beyond SERC's legal authority, as we will demonstrate.

E/60

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ARTER & HADDEN

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Neither Ohio's "Community Right to Know Act", Chapter 3750 of the Ohio Revised Code, nor the federal statute upon which Ohio's legislation and SERC's authority is grounded, 42 U.S.C. 11001 et seq. (hereinafter "EPCRA") authorize the imposition of emergency plans on facilities licensed by the Nuclear Regulatory Commission (hereinafter "NRC") where such facilities already have emergency plans that are imposed and controlled by the NRC.

Federal law preempts Ohio Revised Code Chapter 3750 and SERC's emergency planning requirements.

State regulation of the radiation hazards of NRC licensed facilities via a state imposed emergency plan is preempted by the Atomic Energy Act of 1954, 42 U.S.C. 2011 et seq., (hereinafter "AEA") and amendments and regulations thereto. See 10 C.F.R. Part 30; State of Ohio, ex rel. Celebrezze v. Nuclear Regulatory Commission (6th Cir. 1989), 868 F.2d 810.

As the United States Supreme Court has held, the AEA and the amendments thereto create a "comprehensive regulatory scheme" that embrace the production, possession, and use of three types of radioactive material, source, special nuclear, and byproduct material. Train v. Colorado Public Interest Research Group (1976), 426 U.S. 1, 5-6. See also 42 U.S.C. 5841. The AEA's "pervasive scheme for regulating radioactive materials preempts any state regulation of radiation hazards." Brown v. Kerr-McGee Chemical Group (7th Cir. 1985), 767 F.2d 1234, 1241, cert. denied, (1986), 475 U.S. 1066. See also Train, supra.

In a case directly addressing Ohio's attempt to modify an NRC approved emergency plan, State of Ohio, ex rel. Celebrezze v. Nuclear Regulatory Commission the Sixth Circuit expressly stated that "the responsibility for making final determinations on the adequacy of off-site emergency preparedness plans rests with the NRC." 868 F.2d 810, 816. Further, state disapproval of a plan "does not automatically invalidate an existing plan or mandate a public hearing on whatever issues the state considers important. Such a possibility would substantially impair NRC's statutorily defined role as the ultimate adjudicator of the adequacy of

ARTER & HADDEN

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emergency plans." Id. Cf. Hanni v. Cleveland Electric Illuminating Co. (Cuyahoga Cty., 1983), 87 Ohio App.3d 295, 303, 304 citing, English v. General Electric Co. (1989), 496 U.S. 72, 85.

Pursuant to the AEA, the NRC is authorized to and charged with regulating AMS's emergency planning with regard to Cobalt 60. No other party, including SERC, has this authority. The NRC imposes emergency plan requirements upon AMS pursuant to the NRC's licensing regulations. 10 C.F.R. Part 30. AMS is not subject to the SERC emergency planning process because it would impede "NRC regulations that are expressly aimed at promoting safety in nuclear facilities." Competing regulation of AMS's emergency planning by SERC would constitute "a direct and substantial interference" with NRC licensing regulations that have specific emergency planning requirements. See Hanni, 87 Ohio App.3d 295, 304. Indeed, the courts have uniformly struck down state and local attempts to impose different obligations on NRC licensees. See e.g., State of Ohio, ex rel. Celebrezze, supra; Jersey Central Power and Light Co. v. Township of Lacey (3rd Cir. 1985), 772 F.2d 1103, 1112 cert. denied (1986), 475 U.S. 1013 (local ordinance prohibiting storage of radioactive waste preempted by AEA); County of Will v. Chem-Nuclear Systems, Inc. (Oct. 7, 1987), U.S. Dist. N.D. Ill. No. 87 C 1478, 1987 WL 18362 (county ordinance requiring special use permit preempted and could not be applied to facility that compacted low level nuclear waste); United States v. City of New York (S.D. N.Y. 1978), 463 F.Supp. 604 (City ordinance requiring permit and emergency plan preempted by AEA); Brown v. Kerr-McGee, supra.

The chemical emergency planning process set forth in R.C. 3750.04 conflicts with NRC emergency planning requirements and cannot apply to AMS. The NRC has established detailed emergency plan requirements which a licensee must meet in order to obtain an NRC license. See 10 C.F.R. 30.32. Although these NRC regulations acknowledge the existence of the federal Emergency Planning and Community Right-to-Know Act ("EPCRA"), only state and federal reporting requirements remain applicable to NRC licensees. 10 C.F.R. 30.32(i)(3)(viii) n.1. NRC regulations expressly provide that NRC licensees "shall follow the emergency plan approved by the

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[Nuclear Regulatory] Commission" and may change the plan only with the approval of the NRC. 10 C.F.R. 30.34(f).

AMS already has formulated and submitted its plan pursuant to NRC requirements. AMS is not required and cannot be compelled to satisfy conflicting state planning requirements.

SERC is barred by federal law from imposing its emergency planning process upon AMS, an NRC licensee. It is a fundamental principle of administrative law that the powers of an agency or commission, such as LEPC and SERC, are legislatively granted and that SERC has only the regulatory authority granted. Johnson's Markets, Inc. v. New Carlisle Dept. of Health (1991), 58 Ohio St.3d 28. SERC's issuance of an order designating AMS as an "additional facility" subject to SERC's emergency planning process exceeds SERC's authority as granted by Revised Code Chapter 3750 and 42 U.S.C. 11001 et seq. as neither statute authorizes an agency to impose an emergency plan on an NRC licensed facility. NRC emergency plan requirements have preempted state regulation in this area.

SERC is not authorized to designate AMS as an additional facility because such an order is inconsistent with EPCRA and violates R.C. 3750.02.

Ohio Revised Code Chapter 3750 demonstrates a second reason that AMS cannot be compelled to submit an emergency plan required by SERC. In its July 5, 1995 letter, SERC concedes that only certain facilities are subject to the emergency planning requirements of Ohio Revised Code Chapter 3750. Ohio Admin. Code 3750-20-01 provides that where an extremely hazardous substance is not present in an amount equal to or exceeding the threshold planning quantity as stated in Ohio Admin. Code 3750-20-10, then a facility may only be designated as an additional facility if the requirements of R.C. 3750.05 are met.

R.C. 3750.05 requires that an order designating an additional facility must be in accordance with R.C. 3750.18. R.C. 3750.18 requires SERC to act in conformity with R.C. 3750.02(B)(2)(g).

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Significantly, R.C. 3750.02(B)(2)(g) provides in pertinent part that SERC's adoption of rules "shall not be inconsistent with 42 U.S.C. 11001 (EPCRA, or the regulations adopted under it)."

The purpose of the EPCRA, upon which Chapter 3750 is founded, is to provide the public with information regarding hazardous chemicals where a facility produces, uses or stores such hazardous chemical. See H. Rep. No. 99-253(I), 99th Cong., 2d Sess. 4 (1986), reported in 1986 U.S.C.C.A.N. at 2841. In its July 5, 1995 notice SERC concedes that Cobalt 60 is neither a hazardous nor an extremely hazardous substance within the terms of Chapter 3750 or SARA Title III. Indeed, the Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. 6901 et seq., expressly excludes from the definition of hazardous waste "byproduct material as defined by the Atomic Energy Act." 42 U.S.C. 6903(27). Ohio's definition of hazardous waste tracks the federal statute. Ohio Admin. Code 3745-51-03. Obviously, where there is no hazardous chemical at a facility within the meaning of the statute, the facility is not subject to EPCRA or Chapter 3750 -- the statutes are simply not intended to address that facility.

Further, 42 U.S.C. 11001 and the regulations promulgated thereunder, particularly 40 C.F.R. 355.40(a)(2)(ii) and (v) (1995) expressly provide that emergency release notification requirements do not apply to: (ii) Any release which is a "federally permitted release" as defined in section 101(10) of CERCLA; or (v) Any release not meeting the definition of release under Section 101(22) of CERCLA, and therefore exempt from Section 103(a) reporting. See also Ohio Admin. Code 3750-25-01(B), which provides that release notification reporting requirements of R.C. 3750.06 are not required for a federally permitted release as defined in §101(10) of CERCLA, nor for any release of source, byproduct, or special nuclear material from a nuclear incident as defined by the AEA. Although SERC may not be attempting to impose R.C. 3750.06 requirements upon AMS at this time, the entirety of EPCRA and 3750 demonstrate it was not the legislature's intent to impose conflicting state obligations upon NRC licensees. Indeed, there is no reason to do so since the NRC already imposes emergency planning and notification requirements upon all licensees, including AMS, as a condition of the NRC license. Applying R.C. 3750.05 and 3750.04

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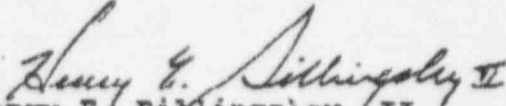
Mr. Kenneth A. Schultz
August 2, 1995
Page 6

to AMS would be inconsistent with EPCRA and therefore SERC cannot designate AMS as an additional facility.

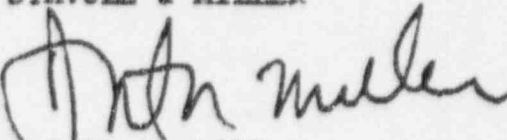
SERC has no legal authority to designate AMS as an additional facility subject to the emergency planning requirements of R.C. 3750.04 and 3750.05.

Very truly yours,

ARTER & HADDEN


Henry E. Billingsley, II

STAVOLE & MILLER


Dwight A. Miller

Advanced Medical Systems, Inc.

121 North Eagle Street • Geneva, Ohio 44041
(216) 466-4671 FAX (216) 466-0186

August 2, 1995

Mr. Michael S. Kalstrom, Secretary
Cuyahoga County Local Emergency Planning Committee
1255 Euclid Avenue
Room #102
Cleveland, Ohio 44115-1807

Dear Mr. Kalstrom:

Thank you for your response to Advanced Medical Systems, Inc.'s Emergency Plan. Your comments have been addressed on the following attachment. The revised Emergency Plan, incorporating the commitments made on the attachment, is being submitted to you under separate cover. You may expect receipt by September 30, 1995.

If you have any questions, please contact me.

Sincerely,



DAVID CESAR
Treasurer

DC/cs
Attachment

cc: John Madera - USNRC
Robert Meschter - AMS-RSO

E/61

RESPONSE TO COMMENTS FROM CUYAHOGA EMERGENCY MANAGEMENT ASSISTANCE CENTER

Agency Comment #1: the Waste Hold-up Tank Room or WHUT room is not included in the Emergency Plan for this facility, save for a map with no supporting text or documentation. Emergency responders must be made aware of the response risks involved with the WHUT room and its current contents. The LEPC believes that the WHUT room must be included in the Emergency Plan for this facility.

AMS Response: Concur.

Action Taken: The floor plans are being re-drawn to more accurately depict the location and type of hazards present throughout the building. The WHUT Room will be specifically addressed within the Plan.

Agency Comment #2: The "Consultant's Report" following Section 3.4 makes no assessment of the contents of the WHUT room. The only materials discussed in the "Dose Assessment from a "Worst Case" Release of Cobalt-60" are an undocumented 29 curies of materials (based upon the consultant's "understanding"), whose location is neither mapped nor specifically discussed. It is presumed that the assessment was meant to include "unsealed sources" of radioactive materials and that it excludes the WHUT room, though the only exclusion mentioned in the Hot Cell. The NRC presented a somewhat different inventory at recent public meetings in Columbus and offered a modeling approach using all materials (both sealed and unsealed). The LEPC believes that both of these approaches leave room for further inquiry, that the WHUT room must be included in the "Dose Assessment" and that the assessment should examine possible exposures starting at the property line.

AMS Response: Partially concur.

Action Taken: Attachment 1 will be revised to reflect current conditions.

Agency Comment #2A: The LEPC also believes that the hazards for Cuyahoga County are not adequately represented. The risk of tornadic storms is virtually dismissed without documentation. Other hazards for this facility are not even discussed. For example, the facility's location adjacent to a railroad, and the planned installation of an evaporation unit inside the building suggest additional accident scenarios that should be reexamined. The LEPC believes that more work is necessary to complete and document a representative hazards analysis for this facility.

AMS Response: The reviewer does not appear to understand the type and form of radioactive materials present at AMS and the potential for their negative impact on emergency workers and the surrounding population. The evaporation system that AMS may install will be used to rid the facility of 100,000 gallons of water contains less radioactivity than is permitted under the Drinking Water Standards of 40 CFR 171.

Action Taken: Attachment 1 will be revised to reflect current conditions. The building floor plans are being re-drawn to more accurately depict the location and type of hazards present throughout the building.

Agency Comment #3: The Emergency Plan includes not detailed inventory of the radioactive materials stored at this facility. The LEPC believes that the specific locations and amounts of all radioactive materials on site should be included in the Emergency Plan. The inventory should also provide information to emergency responders regarding the physical condition of these materials. For example, emergency responders should know that the unsealed radioactive waste materials in the WHUT Room may offer a higher respiratory risk that sealed sources stored elsewhere

AMS Response: The radioactive material inventory is subject to change with regard to locations in the facility depending on the work activities involved. The physical condition of the radioactive material is subject to change depending on work activities. Source material of significance is stored in inaccessible locations (i.e., in the source garden, hot cell, WHUT room etc.) These areas cannot be entered by responders.

Action Taken: The building floor plans are being re-drawn to more accurately depict the location and type of hazards present throughout the building.

Agency Comment #4: The "Emergency Pre-Plan Operating Procedures" included as Appendix A appear to be generic procedures. Have any of the officials referred to in various sections of Appendix A agreed to the procedures outlined? If so, they should be listed at least by title and agency. [Examples given.]

AMS Response: Partially concur.

Action Taken: Appendix A will be replaced with a site-specific document.

Agency Comment #5: The Emergency Plan makes a reference to the authority of the Radiation Safety Officer in its "Statement of Policy". No similar reference is made to his alternates, listed as Secondary Contacts on the "Emergency Contact Personnel" summary. Are they authorized to make decisions in the event the Radiation Safety Officer is not available?

AMS Response: Yes, Secondary Contacts understand their responsibilities.

Action Taken: None.

Agency Comment #6: The LEPC believes that the following telephone numbers should be added to the list of "Emergency Civil Response Agencies". [Numbers given].

AMS Response: Partially concur.

Action Taken: The company will add The Cuyahoga County Emergency Management Division to the emergency call list.

Agency Comment #7: The AMS Plan does not include procedures for reporting an emergency release of more than 10 curies of Cobalt-60. Such a release report must follow the attached guidelines by federal and state law. Agencies to be notified and the reportable amount should be made clear to the responsible officials and be included in the Plan.

AMS Response: The AMS reporting requirements in regard to licensed activities are clearly specified in license requirements and USNRC regulations. AMS has incorporated these requirements in ISP-37, "Emergency Response and Notifications".

Action Taken: None required.

Referenced Comment #1: Is the plan available to employees for review?

AMS Response: Yes.

Action Taken: None required.

Referenced Comment #2: We are not convinced that the "absolute worst-case incident" referred to in paragraph one has been identified.

AMS Response: None required.

Action Taken: None required.

Referenced Comment #3: Section 2, in #1 WHUT Room is excluded.

AMS Response: The WHUT Room is in the basement and the basement is a restricted area. Therefore, the WHUT Room is included by default. The WHUT Room is also sealed and not accessible to humans.

Action Taken: None required.

Referenced Comment #4: Section 2, In #2 where is the "emergency area"?

AMS Response: "Emergency area" should be interpreted as "the area in the building in which an emergency (i.e., fire) is taking place".

Action Taken: None required.

Referenced Comment #5: Page iv, Who is in charge if RSO is not available?

AMS Response: On radiological issues, there is a "chain of command" that is as shown in Appendix A. In the absence of the RSO, the alternate RSOs assume command on radiological issues. In the absence of the alternate RSOs, a company representative assumes command.

Action Taken: None required.

Referenced Comment #6: Page 1-2, 1.1., WHUT Room is excluded from the general inventory discussion at the top of this page.

AMS Response: Concur. The radioactivity that currently exists in the WHUT Room should be included in the possession limit.

Action Taken: The section on Licensed Activity Description is being modified to include the quantity of cobalt-60 that currently exists in the WHUT Room, based upon an analysis of the data provided in the SEG "Waste Holdup Tank Room Survey", May, 1995:

Item	Form	Material Description	Estimated Activity (Ci)
Licensed Material	Solid	Bulk Metal	23,000
Licensed Material	Solid	Sealed Sources	75,000
Packaged Waste	Solid	Materials contained in high-level waste storage, LSA boxes and drums in the basement of the facility.	29
Packaged Waste	Solid	Solid waste generated during treatment project.	0.4
Unpackaged Waste	Solid/ Sludge	Materials contained in WHUT Room.	53
Surface Contamination	Solid	Uncharacterized surface activity in the restricted areas of the facility.	11
Total			93.4

Referenced Comment #7: Page 1-2, Section 1.2., An effort to list schools, hospitals, extended care care [sic] facilities and fire stations by name and address would have added to the plan by illustrating a community evaluation in the context of this facility.

AMS Response: AMS does not understand the meaning nor the intent of this comment.

Action Taken: Figure 1-11 is being replaced with one that clearly designates the position of AMS with respect to nearby schools, hospitals, police and fire stations and other major facilities.

Referenced Comment #8: Population estimates would have added to the plan for the reasons listed above.

AMS Response: AMS does not understand the meaning nor the intent of this comment.

Action Taken: None.

Referenced Comment #9: Page 1-1, Section 1.2., The basement is listed as "restricted" without explanation.

AMS Response: It appears that the reviewer does not have sufficient knowledge of radiological issues to comment on this portion of the Emergency Plan.

Action Taken: None.

Referenced Comment #10: Page 1-3, Section 1.2.1., Had trouble locating "heavy dashed line" listed in paragraph.

AMS Response: The entire facility is considered to be controlled for purposes of radiological protection.

Action Taken: The reference to dashed lines will be deleted.

Referenced Comment #11: Page 1-3, Section 1.2.1., WHUT Room excluded from list of "restricted areas" in paragraph 4.

AMS Response: The WHUT Room is not an "activity center". It is sealed and inaccessible by humans.

Action Taken: None required.

Referenced Comment #12: Page 1-4, Section 1.2.3., Discussion about Hot Cell "window" does not mention lead bricks for shielding in the event of an accident.

AMS Response: Since this section provides a general description of the facility, specific uses of items, materials, and resources in particular areas is not required.

Action Taken: None required.

Referenced Comment #13: Page 1-4, Section 1.2.3., The service life of the hot cell door is listed as "long". When was it installed and how much of its estimated life expectancy remains?

AMS Response: The phrase "long service life" refers to the bearings and not the door itself. The bearings were installed in 1959. There is a 40-ton concrete block serving as the door to the Hot Cell.

Action Taken: None required.

Referenced Comment #14: Page 1-6, Section 1.2.4., Where is the emergency Generator listed in paragraph 2? Is there a manual activating procedure?

AMS Response: The emergency generator is in the "clean equipment room". The manual activating procedure is to position the ON-OFF switch to the ON position.

Action Taken: None required.

Referenced Comment #15: Pages 2-5, Section A.9., Where is the "clean side of the basement?"

AMS Response: The "clean side" is on the east side of the building at the foot of the steps.

Action Taken: None required.

Referenced Comment #16: Page 2-5, Sections 2.1., 2.2., Where is the "portable HEPA system?"

AMS Response: Since the device is portable, at any point in time it may be anywhere within the controlled area.

Action Taken: None required.

Referenced Comment #17: Page 3-1, Section 3.2.1., What are releases "permitted by 10 CFR Part 20?"

AMS Response: It appears that the reviewer does not have sufficient knowledge of radiological issues to comment on this portion of the Emergency Plan.

Action Taken: None.

Referenced Comment #18: Page 3-2, Section 3.3., There are other accidents that could occur. For example there could be an accident involving the evaporation unit that is to be installed inside the building, or there could be a rail accident.

AMS Response: The evaporation system that AMS is attempting to install will be used to rid the facility of 100,000 gallons of water that contains less radioactivity than is permitted under the Drinking Water Standards of 40 CFR 171. It is not clear how this device nor its purpose could contribute to a radiological emergency. While a rail accident is a possibility, it is not considered to present a limiting scenario.

Action Taken: None.

Referenced Comment #19: Page 3-3, Section 3.3., "The risk of a tornado should not be dismissed without documentation. There is a tornado risk for this area. We also have a risk of flooding, thunderstorms, and winter storms. Earthquakes are possible. We have had Presidential declarations for federal disaster assistance twice in the last five years and required state assistance for a wind storm that caused widespread debris damage and loss of electricity in 1993.

AMS Response: The disasters that occurred in the last five years did not impact the London Road facility. It appears that the reviewer is not knowledgeable of the numerical risk factors regarding tornados in the vicinity of the facility and the low probability of their occurrence. Furthermore, if a tornado were able to cause a structural collapse, the loose radioactive materials would be quickly dispersed and thus contribute negligible radiation dose to any impacted individuals. A tornado event is not considered to present a limiting scenario.

Action Taken: None.

Referenced Comment #20: IEM Letter, The consultant's report needs further analysis (see cover letter). Some effort to review the possibility of soil and other types of collateral contamination should also be evaluated.

AMS Response: It appears that the reviewer does not have sufficient knowledge of radiological issues to comment on this portion of the Emergency Plan.

Action Taken: Attachment 1 will be revised to reflect current conditions.

Referenced Comment #21: Page 4-1, Section 4.2.1., Who would report emergency release of more than 10 curies of ⁶⁰Co to the Cleveland Fire Department, LEPC, SERC, and the National Response Center? See attached guidelines.

AMS Response: AMS does not understand the meaning nor the intent of this comment.

Action Taken: None.

Referenced Comment #22: Page 5-2, Section 5.1.2., Who is authorized to act in the absence of the RSO?

AMS Response: On radiological issues, there is a "chain of command" that is as shown in Appendix A. In the absence of the RSO, the alternate RSOs assume command on radiological issues. In the absence of the alternate RSOs, a company representative assumes command.

Action Taken: None required.

Referenced Comment #23: Page 4, Section 2.B., Should there be any precautions, i.e., evacuation or shelter-in-place announcement for residents and business?

AMS Response: No.

Action Taken: None

Referenced Comment #24: Page 8, Section 12.1., An accurate inventory would assist with the theft investigations.

AMS Response: AMS has accurate inventory of material that is currently accessible.

Action Taken: None.

Referenced Comment #25: Appendix C. Distribution list needs to be revised to reflect additional agencies.

AMS Response: Concur.

Action Taken: See comments on #6.



Advanced Medical Systems, Inc.

1020 London Rd.
Cleveland, Ohio 44110
216-692-3270

August 2, 1995

Mr. James Caldwell
Nuclear Materials Inspection, Section 2
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523 4351

Re: Application to Amend USNRC License No. 34-19089-01

Dear Mr. Caldwell:

On June 21, 1995, Advanced Medical Systems, Inc. (AMS) was issued Amendment No. 36 to the referenced license number to permit treatment of contaminated water that currently exists in the basement of the London Road facility. In Item 19 of that amendment, AMS was directed to complete subitems "D" and "E" by July 7, 1995, and to begin item "F" by July 8, 1995. Because of delays in receiving the necessary permits and authorizations, and because the scope of excavation activities was not as expected, AMS was unable to meet this deadline.

On July 21, 1995, AMS submitted an application to amend the referenced license to permit greater flexibility in meeting the milestones without requiring submittal of continuous amendment applications in response to delays that are beyond our control. To date, no action has been taken on that request. However, in our application we agreed to communicate revised milestone dates to the USNRC, along with the reason for any change that may be necessary. The following is the current status of the milestones that were reflected in our July 19, 1995 status report:

Item	Scheduled Start Date	Scheduled Completion Date	Current Status
Treat basement water	May 17, 1995	--	Complete
Install new manhole	July 3, 1995	--	Complete
Excavate in vicinity of 4" line, disconnect foundation drainage system, and remediate 4" line, 15" line and foundation drainage system.	July 3, 1995	July 28, 1995	Complete
Grow in existing lateral connection and existing manhole	July 3, 1995	August 11, 1995**	Anticipated start date is August 4, 1995.

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Item	Scheduled Start Date	Scheduled Completion Date	Current Status
Re-connect foundation drainage system to new manhole	July 3, 1995	August 11, 1995	Complete.
Remediate ⁶⁰ Co activity that exists at the outfall of the existing lateral system in the NEORSD Interceptor	August 11, 1995**	Revised start date is August 30, 1995**	Awaiting NEORSD authorization to access manhole. Requests for entry are being made daily.

** Actual start date subject to timely NEORSD approval to access the London Road Interceptor at the location of the outfall.

Again, these dates are subject to change based upon a variety of external factors. In the event that additional changes are necessary, I will immediately communicate the revised dates to the USNRC, along with the reason for the change.

I would also like to take this opportunity to correct a statement that appeared in my letter to you of July 19, 1995. In that letter, it was erroneously stated that the excavated area under the high-level waste storage area on the west side of the building would be grouted in. First, the mislabeled area in question is actually the area under the ISA air lock. Second, since this area had minimal residual contamination and was located where water intrusion would be negligible, it was backfilled with clean soil rather than injected with grout. AMS regrets any confusion this erroneous statement may have caused.

If I can answer any questions or provide you with additional information, please call me at (216) 692-3270. I will continue to keep you informed of the status of this project.

Sincerely,



Robert Meschter, RSO

cc: D. Cesar
D. A. Miller, Esq., Stavole & Miller

Advanced Medical Systems, Inc.

121 North Eagle Street • Geneva, Ohio 44041
(216) 466-4671 FAX (216) 466-0186

August 2, 1995

Mr. James R. Williams, Chief of Staff
State of Ohio Adjutant General's Department
Emergency Management Agency
2855 West Dublin Granville Road
Columbus, Ohio 43235

Dear Mr. Williams:

Thank you for your response to Advanced Medical Systems, Inc.'s Emergency Plan. Your comments have been addressed on the following attachment. The revised Emergency Plan, incorporating the commitments made on the attachment, is being submitted to you under separate cover. You may expect receipt by September 30, 1995.

If you have any questions, please contact me.

Sincerely,



DAVID CESAR
Treasurer

DC/cs
Attachment

cc: John Madera - USNRC
Robert Meschter - AMS-RSO

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**RESPONSE TO COMMENTS FROM
STATE OF OHIO, ADJUTANT GENERAL'S DEPARTMENT
EMERGENCY MANAGEMENT AGENCY**

Agency Comment: Page 5-4, Section 5.5., second line. "In the event of an emergency, however, it may be necessary for members of the emergency response team to receive exposures up to the EPA guidelines; i.e., less than 75 Rem for either a lifesaving action or less than 25 Rem for entry into hazardous areas to protect the facility or control fire." EPA guidelines (table 202 on page 2-10 of EPA 400-R-92-001, Manual of Protective Action Guidelines and Protective Actions for Nuclear Incidents) states 25 Rem for lifesaving or protection of large populations and 10 Rem for protecting valuable property.

AMS Response: Concur

Action Taken: Page 5-4, Section 5.5., second line is being modified to reflect the appropriate dose limits.

Agency Comment: Page 5-4, Section 5.5.1., 75 Rem is again used for lifesaving activities. EPA-400 guidelines state 25 Rem.

AMS Response: Concur.

Action Taken: Page 5-4, Section 5.5.1. is being modified to reflect the appropriate dose limit.

Agency Comment: Page 9-1, Section 9.1. The second paragraph refers to EPA-520. EPA-400 is the applicable document.

AMS Response: Concur.

Action Taken: Page 9-1, Section 9.1. is being modified to reflect the appropriate document.

Agency Comment: Appendix A, Page 4, Section 2.g. "The maximum dose allowable to save equipment is 25 Rem". The EPA-400 limit for protective valuable property is 10 Rem. The limit for all other activities is 5 Rem.

AMS Response: Concur.

Action Taken: Appendix A will be replaced with a site-specific document that will reflect the appropriate dose limits.

Agency Comment: Appendix A, Page 9, Section 13.1.3. "The maximum dose allowable for lifesaving actions is 75 Rem". EPA-400 limit for lifesaving is 25 Rem. 25 Rem may be exceeded only on a voluntary basis to persons fully aware of the risks involved.

AMS Response: Concur.

Action Taken: Appendix A will be replaced with a site-specific document that will reflect the appropriate dose limits.

Agency Comment: Appendix C. There are three agencies that play a primary role in radiological response and planning on the state level. They are Ohio Emergency Management Agency, Ohio Department of Health and Ohio Environmental Protection Agency. We recommend that you add ODH and OEPA to your distribution list. [Addresses provided]

AMS Response: Concur.

Action Taken: Appendix C is being modified to incorporate the additional agencies.

Advanced Medical Systems, Inc.

121 North Eagle Street • Geneva, Ohio 44041
(440) 466-4671 FAX (216) 466-0186

August 3, 1995

Mr. Richard Connelly, Manager
Northeast Ohio Regional Sewer District
Water Quality Industrial Surveillance
3826 Euclid Avenue
Cleveland, Ohio 44115-2504

Dear Richard:

Thank you for your comments dated June 23, 1995, regarding Advanced Medical Systems, Inc.'s Emergency Plan.

We have reviewed your submittal, and those comments which are relevant will be incorporated into the Emergency Plan. Those which are not incorporated are deemed to be irrelevant and will not add to the effectiveness of the AMS Emergency Plan.

The comments of the USNRC and other responders are currently being incorporated into our Emergency Plan. This revised plan will be distributed by September 30, 1995.

If you should have any questions, please contact me.

Sincerely,



DAVID CESAR
Treasurer

DC/cs

cc: Robert Meschter - AMS-RSO
John Madera - USNRC

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