

JUN 29 1995

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

Dear Mr. Cesar:

The NRC and its contractor have completed the review of your "modified and restated" standby trust agreement which you submitted to replace one that was previously submitted to the NRC.

Your March 1995 standby trust agreement differs substantially from that recommended in Regulatory Guide 3.66. The modifications necessary to make the submitted agreement suitable for use under the decommissioning financial assurance requirements would entail almost a complete redrafting of the agreement. Therefore, to ensure adequate protection for NRC, we recommend that you replace the submitted standby trust agreement with one that closely matches the recommended wording of Regulatory Guide 3.66 (enclosed). The NRC believes that this can be easily accomplished if you return to your November 16, 1992, standby trust agreement and revise it as requested in our letter of March 13, 1995 (enclosed).

- I. The submitted agreement contains many fundamental flaws that make it inappropriate for use as a financial assurance mechanism for NRC. For example, the agreement does not satisfy a number of conditions specified on pages 3-12 and 3-13 of Regulatory Guide 3.66 that must be met if the agreement is to be acceptable to NRC:
    - A. The trust must be a three-party agreement whereby the licensee transfers assets to a trustee "to hold on behalf of the beneficiary, the Commission or State agency." The submitted agreement does not establish that NRC is the beneficiary, nor does it reference NRC in all appropriate places.
    - B. The agreement "should state that the fund will be disbursed to the licensee only upon presentation to the trustee of {certain certifications}." Although Section 4 of the agreement seems to require presentation of the necessary certifications, additional language in the same section and in other sections seems to require only that the grantor provide the trustee with written instruction of payment.
    - C. The trustee should be replaced "only by mutual agreement of the Commission or State agency, the licensee, and the trustee." Under the submitted agreement, however, AMS may replace the trustee unilaterally.
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- II. In addition, AMS has added a considerable amount of text to the wording recommended in Regulatory Guide 3.66. Many of these additions may not serve NRC's best interests, such as the following examples:
- A. The agreement contains several added paragraphs at the beginning of the agreement referencing other trust agreements and amendments. The agreement states it is being used to "restate in its entirety the trusts upon which and the uses and purposes for which the property now held or hereafter acquired by the Trustee shall be held, managed, and controlled." The purposes and language of the previous trusts may not be compatible with NRC's interests. In addition, the paragraphs do not mention the most recent agreement (dated November 16, 1992), and they erroneously date the July 1992 standby agreement as July 1994.
  - B. The agreement contains an added paragraph (paragraph 3 on page 2) which states that "the property now held in said Trust shall be disbursed to the Grantor." Although this paragraph may apply only to property in the trust being replaced (this is unclear due to the uncertain status of the earlier trust), it could be interpreted to direct the trustee to disburse any property in the fund to the grantor, including funds needed for decommissioning.
  - C. The agreement adds an unacceptable condition in its delineation of the trustee's investment responsibilities (Section 5a). The agreement directs the trustee to invest and reinvest money "without being limited by any statute or rule of law of the State of Ohio regarding investments by trustees now or hereafter in effect." State laws and statutes may provide important protections for beneficiaries and may also establish minimal acceptable standards for trustees.
  - D. The agreement specifically allows the trustee "to borrow money and mortgage or pledge any property, at any time constituting a portion of said trust upon such terms and conditions as said Trustee shall deem wise." Such activity, however, could preclude funds in the trust from being available when needed for decommissioning.
- III. Finally, in numerous instances the agreement revises or omits wording recommended in Regulatory Guide 3.66. Problematic examples of such revisions include the following:
- A. The agreement does not adequately cite NRC's authority for requiring decommissioning financial assurance. For example, in paragraph 3 on page 1, the agreement fails to cite the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974. In addition, the paragraph cites only "certain regulations applicable to the Grantor, requiring that an owner or operator of a hot-cell facility shall provide assurance when

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needed for decommissioning the facility." This reference does not specifically identify NRC's regulations in Title 10, Chapter 1 of the Code of Federal Regulations, Part 30, 40, 70, and 72" as called for by the recommended wording. These references are necessary to ensure that the mechanism was executed to assure only decommissioning costs. The paragraph also ensures that NRC regulations will be considered as applicable to interpreting any ambiguities in the terms of the mechanism.

- B. The agreement modifies the recommended wording regarding the trustee's use of counsel (in Section 8) to state that such counsel "shall be counsel to the Grantor." Although the section goes on to say that the trustee "may" consult with independent counsel in the event of a conflict of interest on the part of grantor's counsel, the effect of the section is to require the trustee to consult at least with grantor's counsel, even in the event of a conflict of interest.
- C. The agreement omits numerous references to NRC. For example, in Section 11 the agreement omits the sentence "If the NRC issues orders, requests, or instructions to the Trustee 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." Such omissions may diminish NRC's powers and protections. In this example, the omission precludes NRC from directing the Trustee regarding the trust.
- D. The trust agreement does not state a "due diligence" standard, as recommended in Regulatory Guide 3.66 that "the Trustee shall discharge its duties . . . solely in the interest of the beneficiary and with the care, skill, prudence, and diligence . . . 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."
- E. The agreement does not require 90 days notice, or any notice, to NRC prior to the resignation of trustee.
- F. The agreement does not include the recommended severability provision "If any parts of this agreement are invalid, it shall not affect the remaining provisions which will remain valid and enforceable." Consequently, there is increased risk that the entire agreement could be invalidated due to errors in some sections.

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Due to the many substantive differences in protection provided by the submission relative to the recommended standby trust agreement in Regulatory Guide 3.66, please submit a new standby trust agreement along with all related documents (such as evidence that the party signing the agreement is authorized to represent the company) that closely follows the terms and conditions recommended in Regulatory Guide 3.66, or return to your November 16, 1992, standby trust agreement and revise it as requested in our March 13, 1995 letter.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 00209.

If you have any questions or require clarification on any of the information stated above, you may contact us at (708) 829-9887.

Sincerely,

Original Signed By  
John R. Madera, Chief  
Nuclear Materials Licensing Section

License No. 34-17089-01  
Docket No. 030-16055

Enclosures:

1. Ltr dated 3/13/95
2. Regulatory Guide 3.66

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March 13, 1995

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

Dear Mr. Cesar:

We have completed our review of your Decommissioning Funding Plan submitted with your application for renewal of NRC License No. 34-19089-01, and find that we will need additional information as noted below:

1. Revise Exhibit A to the Standby Trust Agreement to Reflect All Costs Assured (*Regulatory Guide 3.66*, page 4-26)

Exhibit A to your standby trust agreement has not been revised to reflect the increase in the amount of financial assurance from \$750,000 to \$1,800,000. As a result, the standby trust allows the trustee to make payments of only \$750,000, rather than \$1,800,000, towards the decommissioning of the facility. *Regulatory Guide 3.66* "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72" (June 1990), page 4-26, recommends that Schedule A (which corresponds to the submitted Exhibit A) list the amount of financial assurance demonstrated by the standby trust agreement. To ensure that the standby trust provides adequate financial assurance to NRC, revise Exhibit A to reflect the full amount of the current cost estimate.

2. Revise the Standby Trust Agreement as Needed to Correctly Identify the Address of the Licensed Facility

Section 2 of the revised standby trust agreement states that the agreement pertains to the costs "... for the facility identified on Exhibits 'A' and 'A-1.'" The two exhibits appear to reference different facilities, however. Exhibit A identifies the address of the licensee as 1020 London Road, whereas Exhibit A-1 defines the facility as the plant located at 1120 London Road. To ensure that the trustee has the information needed to administer the standby trust, revise the standby trust agreement as needed to correctly identify the address of the licensed facility.



- (3) Submit Evidence Indicating that the Party Signing the Standby Trust Agreement for the Licensee is Authorized to Represent the Company  
(Regulatory Guide 3.66, page 3-14)

The submission does not provide any evidence indicating that the party signing the mechanism is authorized to enter into a standby trust agreement for the licensee, as recommended in *Regulatory Guide 3.66*, page 3-14. Evidence of authority to represent the licensee is necessary to ensure the validity and enforceability of the mechanism. Submit a copy of the corporate by-laws or other evidence indicating that the party signing the standby trust agreement is authorized to do so.

We also have some concerns regarding your cost estimate for decommissioning your facility. However, these issues will be discussed in another deficiency letter which will address the technical issues of your application for renewal.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 15 days, and refer to Control Number 00209.

If you have any questions or require clarification on any of the information stated above, you may contact us at (708) 829-9887.

Sincerely,

Original Signed by John A. Grobe

John A. Grobe, Chief  
Nuclear Materials Inspection Section 2

Enclosure: Regulatory Guide 3.66

See Attached Distribution

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## PUBLIC NOTICE

## DESIGNATION OF ADDITIONAL PLANNING FACILITY

## CUYAHOGA COUNTY

The State Emergency Response Commission (SERC) is hereby announcing its intention to issue an order to require Advanced Medical Systems, Incorporated (AMS) of 1020 London Rd., Cleveland, Ohio to be subject to the emergency planning requirements of Sections 3750.04 and 3750.05 of the Ohio Revised Code. In response to the Cuyahoga County Local Emergency Planning Committee's (LEPC) request, the Commission evaluated the facility's size, nature of operations, and its proximity to the community. It is believed that designation as an additional planning facility will enable the LEPC to conduct a risk analysis and develop a site specific emergency response plan for AMS. The LEPC has developed site specific emergency response plans for 305 facilities possessing "extremely hazardous substances" within Cuyahoga County as required by Sections 3750.04 and 3750.05 of the Revised Code. AMS was found to possess cobalt 60 in non-sealed sources. Cobalt 60 is not one of the 360 listed chemicals designated as "extremely hazardous substances." Therefore, to bring this facility under the emergency planning requirements of the Emergency Planning and Community Right-to-Know Act, Chapter 3750 of the Revised Code, the SERC must issue an order designating AMS as an additional planning facility.

Section 3750.05 requires the SERC to seek written public comment on its intent to issue such an order. Comments are to be submitted to:

State Emergency Response Commission  
c/o Ohio EPA/DERR  
1800 WaterMark Dr.  
Columbus, Ohio 43215-1099

Written comments must be received within 45 days of the date of this notice. The SERC will vote on whether to issue an order designating AMS as an additional planning facility after the end of the comment period.

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