

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

ATOMIC SAFETY AND LICENSING BOARD PANEL

Before Administrative Judge  
Marshall E. Miller, Presiding Officer

Administrative Judge  
Dr. Harry Foreman, Special Assistant

In the Matter of

ADVANCED MEDICAL SYSTEMS, INC.  
Cleveland, Ohio

Docket No. 30-16055-ML-Ren

ASLBP No. 95-707-02-ML-Ren

(Source Material License  
No. 34-19089-01)

March 13, 1995

**MEMORANDUM AND ORDER**

**I. BACKGROUND**

In this proceeding, Advanced Medical Systems, Inc. seeks timely renewal of Material License No. 34-19089-01 for its facility located at 1020 London Road, Cleveland, Ohio. The Licensee seeks continued permission from the NRC to possess various quantities of radioactive materials for use in its manufacture of medically related devices.

As a result of the NRC's pending licensing action, four parties have petitioned for hearings on the renewal

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request.<sup>1</sup> On January 27, 1995, a single presiding officer was appointed to rule on the hearing petitions and to preside over a hearing if one is to be held. Under the Commission's regulations, any hearing would be conducted under 10 C.F.R. Part 2, Subpart L, informal hearing procedures.

## II. REGULATORY STANDARDS

Under the provisions of 10 C.F.R. § 2.1205(a), any person whose interest may be affected by a proceeding for the renewal of a license may file a request for a hearing. A request for a hearing filed by a person other than an applicant must describe in detail (1) the interest of the requestor in the proceeding; (2) how that interest may be affected by the results of the proceeding, including the reasons why the requestor should be permitted a hearing; (3) the requestor's areas of concern about the licensing activity that is the subject matter of the proceeding; and (4) the circumstances establishing that the request for a hearing is timely.

In ruling on a request for a hearing, the presiding officer must determine that the specified areas of concern are germane to the subject matter of the proceeding.<sup>2</sup> The

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<sup>1</sup>Under the provisions of 10 C.F.R. § 2.1205(f), the Staff has elected to participate as a party to this proceeding.

<sup>2</sup>10 C.F.R. § 2.1205(g).

issues the requestor wants to raise regarding the licensing action must fall within the range of matters properly subject to challenge in the proceeding,<sup>3</sup> and the statements of concern must be pleaded with enough specificity to allow a presiding officer the ability to ascertain whether what the requestor seeks to litigate is truly relevant to the subject matter of the proceeding.<sup>4</sup>

The presiding officer also must determine that the requestor meets the judicial standards for standing and consider, among other factors, the nature of the requestor's right to be made a party to the proceeding; the nature and extent of the requestor's property, financial or other interests in the proceeding; and the possible effect of any order that may be entered in the proceeding upon the requestor's interest.<sup>5</sup>

To be admitted as a party in an NRC proceeding, a petitioner must allege "a concrete and particularized injury that is fairly traceable to the challenged action."<sup>6</sup> A

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<sup>3</sup>Statement of Considerations, Informal Hearing Procedures for Materials Licensing Adjudications, 54 Fed. Reg. 8269, 8273 (February 28, 1989).

<sup>4</sup>*Sequoyah Fuels Corporation (Source Materials License No. Sub-1010), LBP-94-39, 40 NRC 314, 315-316 (1994).*

<sup>5</sup>10 C.F.R. § 2.1205(a).

<sup>6</sup>*Babcock and Wilcox Company (Pennsylvania Nuclear Services Operations, Parks Township, Pennsylvania), LBP-94-4, 39 NRC 47, 49 (1994), citing Transnuclear, Inc. (Export of 93.15% Enriched Uranium), CLI-94-01, 39 NRC 1, 5 (1994).*

prospective party must show that it could suffer an "injury in fact" because of the proposed licensing action and that its interest is within the "zone of interests" to be protected by statutes under which the requestor seeks to challenge the licensing action.<sup>7</sup> In this case, a requestor must allege an injury in fact within the zone of interests protected by the Atomic Energy Act of 1954, as amended ("AEA"),<sup>8</sup> or the National Environmental Policy Act of 1969, as amended ("NEPA").<sup>9</sup>

There are three components to the "injury in fact" requirement -- injury, cause and remedial benefit. The asserted injury must be "distinct and palpable" and "particular and concrete" as opposed to being "conjectural, hypothetical or abstract." The injury need not already have occurred, but when future harm is asserted, it must be "threatened or certainly impending" and "real and immediate." There must also be a causal nexus between the asserted injury and the challenged action. To establish injury in fact in

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<sup>7</sup>*Sacramento Municipal Utility District (Rancho Seco Nuclear Generating Station)*, CLI-92-2, 35 NRC 47, 56 (1992); *Babcock and Wilcox (Apollo, Pennsylvania Fuel Fabrication Facility - Decommissioning Plan)*, LBP-93-4, 37 NRC 72, 80, *appeal dismissed*, CLI-93-9, 37 NRC 190 (1993).

<sup>8</sup>42 U.S.C. 2011-2284.

<sup>9</sup>42 U.S.C. 4321-4347.

this case, the requestor bears the burden of establishing that the injuries it alleges will occur to its interests protected by the AEA or the NEPA.<sup>10</sup>

### III. ANALYSIS

Four requestors have petitioned for a hearing on the AMS license renewal application: the Earth Day Coalition, Cleveland, Ohio ("Coalition");<sup>11</sup> the Northeast Ohio Regional Sewer District, Cleveland, Ohio ("District");<sup>12</sup> the City of Cleveland, Ohio ("City");<sup>13</sup> and the Cuyahoga Emergency Management Assistance Center, County of Cuyahoga, Ohio ("CEMAC").<sup>14</sup> AMS has filed Answers to each petition.<sup>15</sup>

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<sup>10</sup>Apollo, LBP-93-4, 37 NRC at 81, citing *Cleveland Electric Illuminating Co.* (Perry Nuclear Power Plant, Unit 1), LBP-92-4, 35 NRC 114, 120 (1992).

<sup>11</sup>Earth Day Coalition, Request for Hearing (December 28, 1994).

<sup>12</sup>Northeast Ohio Regional Sewer District, Request for Hearing (December 29, 1994).

<sup>13</sup>City of Cleveland, Ohio, Request for Hearing (January 13, 1995).

<sup>14</sup>Cuyahoga County Local Emergency Planning Committee, Request for A Hearing; Petition to Intervene (January 27, 1995).

<sup>15</sup>Answer of Advanced Medical Systems, Inc. to Request of the Northeast Ohio Regional Sewer District (January 12, 1995); to Request of the City of Cleveland (January 12, 1995); to Request of the Earth Day Coalition (January 27, 1995); to Request of the Cuyahoga Emergency Management Assistance Center (February 27, 1995).

For reasons not fully explained, Counsel for AMS did not have a complete service list for this proceeding until

A. Northeast Ohio Regional Sewer District

Requestor District states that the AMS facility is within the service area of the District's waste water collection and treatment system. Citing past discharges of radioactive wastes from the facility into the District's sewer lines, the District states that it has significant financial interest in the future regulation and control of radioactive material at the AMS facility.<sup>16</sup> The District also cites a potential for its own facilities to discharge radioactive wastes into the general environment of Lake Erie if its facilities become contaminated from accidental releases from the AMS facility.

The District alleges that, because of the configuration of its sewer system, any radioactive releases from the AMS

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he was informed of this fact by the Senior Attorney for the Atomic Safety and Licensing Board Panel on February 22, 1995. Because of this shortcoming, the Presiding Officer was unable to determine if all entities involved with this proceeding had received the AMS filings. AMS re-served its four Answers and by motion asked the Presiding Officer to have its Answers considered timely. Motion of Advanced Medical Systems, Inc. as to Time for Service (February 27, 1995).

<sup>16</sup>By way of background, the District has filed three petitions for enforcement actions against AMS pursuant to 10 C.F.R. § 2.206, two of which are still pending. See 59 Fed. Reg. 47959 (September 19, 1994) and 58 Fed. Reg. 19282 (April 13, 1993). Even though these two petitions are pending and raise some of the same issues raised in its hearing petition, the District is not precluded from requesting a hearing with respect to the AMS renewal application. See Georgia Power Co. (Vogtle Electric Generating Plant, Units 1 and 2), LBP-93-5, 37 NRC 96, 98 n.2, aff'd CLI-93-26, 38 NRC 25 (1993).

facility would affect a great portion of its system and its waste water treatment plants. The District states that its financial interest in this proceeding is as least as great as its property interests. It alleges that it has incurred costs well over one million dollars as a result of prior AMS discharges and that a sudden large release could be devastating to its operations. Moreover, the District is concerned for the health and safety of the employees who maintain its system.

The District states that its primary concern is the ability of AMS to maintain proper control over its radioactive material in light of the record of past problems at the AMS facility. A second concern involves the lack of an emergency plan for the AMS facility. The District alleges that since radioactive material that may be released in a fire or other disaster would ultimately be washed into the sewer system, there should be a realistic assessment of the potential for releases under various accident scenarios. A third concern involves the adequacy of the amount of financial assurance AMS has posted for decommissioning of the facility. A fourth concern involves the ability of AMS to provide for remediation of offsite releases if such releases occur.

The District's petition for hearing was filed within 30 days of the submission of the AMS license renewal

application and is therefore timely under the provisions of 10 C.F.R. § 2.1205. All of the four concerns enumerated by the District appear germane to the subject matter of this proceeding -- the renewal of the AMS license to possess radioactive materials at its Geneva, Ohio facility. The District has properly alleged that its sewer system, which services the AMS facility, could be directly impacted by accidental radioactive discharges or during efforts to control accidents at the site. It has also properly alleged that its interests would be threatened by deficiencies in emergency planning and the lack of financial assurance for the site if the license were renewed with deficiencies in those areas. It has standing to become a party to this proceeding. The Northeast Ohio Regional Sewer District's request for a hearing is therefore granted.<sup>17</sup>

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<sup>17</sup>The AMS Answer to the District's Petition, as with its Answers to the other three Petitions, generally presents arguments which address the merits of the areas of concern raised by the Requestors. However, the areas of concern are not contentions, as contentions are understood in a construction or operating license proceeding, and need not be argued on the merits by an opposing party at the inception of the proceeding, but rather, at the time of its written presentation. See 10 C.F.R. § 2.1233(c) and (d). Subpart L practice requires a petitioner to allege areas of concern merely to demonstrate to the Presiding Officer that the issues it seeks to raise are somehow linked to the licensing action. The threshold for pleading an area of concern is very low -- whether it is germane to the subject matter of the proceeding. See Statement of Considerations, Informal Hearing Procedures for Materials Licensing Adjudications, 54 Fed. Reg. 8269 (February 28, 1989); *Sequoyah Fuels Corporation* (Source Materials License No. Sub-1010), 40 NRC 314, 315-316 (1994). None of the AMS Answers address whether the areas of concern raised by the

B. The City of Cleveland

Requestor City states that the AMS facility is located within the jurisdiction of the City, and is located adjacent to both residential housing and commercial businesses. The City's primary interest in the proceeding is to ensure the health and safety of the citizens within its jurisdiction. An accidental release of radioactive material could pose a major threat to the health and well-being of those citizens. The City also states that it has an interest in protecting the health and safety of fire, police, emergency medical and other city personnel who would be called upon to act if there were an accident at the AMS facility. The City is also interested in the economic well-being of the areas surrounding the AMS facility due to alleged past releases of radioactive materials and the condition of the AMS facility itself.

The City asserts that its interests will be affected by the license renewal because, it alleges, the AMS facility is already contaminated and its decontamination or decommissioning will potentially affect Cleveland residents, businesses and city employees. Any potential releases of radioactivity would affect these groups more than others

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Requestors are germane in the context of the license renewal application. Moreover, the AMS Answers fail to address whether each Requestor has established the requisite standing to request a hearing.

since they live and work in proximity to the AMS facility. The City also claims both present and future financial interests in the licensing of AMS because the financial burden of planning for an emergency at the facility and providing training for emergency personnel has fallen on the City. It states that it has been forced to form a Task Force of governmental agencies to come up with an adequate emergency response plan for the AMS site. In summation, the City claims that the effect of granting a renewal license without including sufficient terms and conditions to safeguard the City's citizens would leave the City with the "lion's share" of the responsibility for dealing with existing and future problems at AMS.

The City adopts as its areas of concern the nine issues outlined by the NRC Staff's letter to AMS, dated December 22, 1994, which details deficiencies the Staff found in the AMS renewal application. The City, however, fails to enumerate what these concerns are, with the exception of two.<sup>18</sup> It states that these two -- Item Number Seven in the Staff's letter regarding the emergency plan for the AMS facility, and

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<sup>18</sup>The NRC Staff has elected to be a party to this proceeding under the provisions of 10 C.F.R. § 2.1205(f). While the Staff did not expressly list its areas of concern in its Notice of Participation, it implicitly stated its concerns by attaching the December 22, 1994 letter from John A. Grobe, Chief, Nuclear Materials Inspection, Section 2, to Advanced Medical Systems which detailed nine specific deficiencies in the AMS license renewal application.

Item Number Eight in the same letter regarding decommissioning funding and financial assurance -- are of the most immediate concern. The concerns allege inadequacies involving onsite emergency preparedness and insufficiencies in funding for accidental contamination both on and offsite.

The City has included with its petition for hearing the affidavits of two City Attorneys attesting to the dates upon which the City received actual notice of the AMS renewal application. The City's request was filed within 30 days of its having received actual notice of the application. Under the provisions of 10 C.F.R. § 2.1205(c), the request is timely. The two concerns enumerated by the City, regarding the inadequacy of the AMS emergency response plan and the insufficiencies in decommissioning funding and financial assurance, are germane to the proceeding. The City has standing to request a hearing because its interest could be directly affected if the license were renewed and there were deficiencies in those areas. The City of Cleveland's request for a hearing is granted.

C. Cuyahoga Emergency Management Assistance Center

The third of the requestors, Cuyahoga County Local Emergency Planning Committee, presents an unusual question.

The timely<sup>19</sup> petition was forwarded to the NRC on "Cuyahoga Emergency Management Assistance Center" letterhead, but the text of the petition describes the concerns of the Cuyahoga County Local Emergency Planning Committee ("LEPC"). While the letter states that LEPC is the agency with primary responsibility for emergency planning within Cuyahoga county, it goes on to state that LEPC will be seeking a variance from the Ohio State Emergency Planning Commission to formally add the AMS facility to the list of facilities subject to LEPC jurisdiction. Moreover, the letter states that it is not certain that LEPC can obtain jurisdiction over the AMS facility. Without some link to the AMS facility which serves as a basis for a potential concrete or particularized injury to LEPC, LEPC has failed to establish that it has standing to request a hearing.

However, even if LEPC has failed to demonstrate that it has met the judicial concepts of standing, it can participate in the hearing under the provisions of 10 C.F.R. § 2.1211(b). That provision permits a representative of an interested state, county, municipality or an agency thereof to

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<sup>19</sup>The petition states that it was filed within 30 days of LEPC's receiving actual notice of the AMS license renewal request.

participate in a Subpart L proceeding and to make written and oral presentations in accordance with 10 C.F.R. §§ 2.1233 and 2.1235. Therefore, LEPC will be allowed to participate as a representative of an interested county under and to the extent allowed by the provisions of 10 C.F.R. § 2.1211(b) upon submission to the Presiding Officer (and service upon the parties) of an affidavit of a Cuyahoga County official attesting that LEPC is representing the County's interests in this matter. Such affidavit shall be served on the Presiding Officer within 30 days of the date of this Order.

D. Earth Day Coalition

Requestor Earth Day Coalition submitted a one-page letter as its request for hearing listing several concerns related to the pending renewal application. Among those concerns are the present contamination of the AMS facility, the possible contamination of the sewer system servicing the AMS facility, the lack of emergency planning and the potential for a major accident at the AMS facility. While the concerns listed by the Coalition appear germane to the subject matter of this proceeding, it has failed to set forth the necessary facts to establish that it has standing to intervene as required by the Commission's regulations. The Coalition merely states that it is a "non-profit

environmental education and advocacy organization located in Cleveland . . . [whose] interest in this hearing is not commercial or financial . . . [but] strictly in public education and information and environmental issues."

The Coalition fails to allege any injury, concrete, particularized or otherwise, that may accrue to it as an organization as a result of the license renewal. The Commission has long held that a mere institutional interest in providing information to the public is insufficient to establish standing in its proceedings.<sup>20</sup> The Coalition could have alleged injury to at least one of its members in order to derive standing in its own right. However, the Coalition failed to describe any injury accruing to one of its members, and further failed to provide an affidavit from a member authorizing the organization to represent him or her in the proceeding, which are the two elements necessary for organizational standing on behalf of a member.<sup>21</sup>

The Earth Day Coalition has not established standing to participate as a party to this proceeding. Its hearing request is therefore denied.

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<sup>20</sup>Transnuclear, Inc. (Export of 93.15% Enriched Uranium), CLI-94-01, 39 NRC 1, 5 (1994).

<sup>21</sup>See Northern States Power Co. (Pathfinder Atomic Plant), LBP-89-30, 30 NRC 311, 314 (1989).

IV. ORDER

For all the foregoing reasons and upon consideration of the entire record in this proceeding, it is, this tenth day of March, 1995

ORDERED

1. The petition for hearing of the Northeast Ohio Regional Sewer District is **granted**;
2. The petition for hearing of the City of Cleveland is **granted**;
3. The petition for hearing of the Cuyahoga County Local Emergency Planning Committee is **denied** in part. Upon submission to the Presiding Officer (and service upon the parties) of an affidavit of a Cuyahoga County official attesting that LEPC is representing the County's interests in this matter, LEPC will be allowed to participate in the hearing as the representative of an interested county under and to the extent allowed by the provisions of 10 C.F.R. § 2.1211(b). The affidavit must be served on the Presiding Officer within 30 days of the date of this Order;
4. The petition for hearing of Earth Day Coalition is **denied**.

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In accordance with the provisions of 10 C.F.R. § 2.1205(n), the denial of the hearing request of Earth Day Coalition and the partial denial of the hearing request of

the Cuyahoga County Local Emergency Planning Committee may be appealed to the Commission within ten days after this Order is served.

  
Marshall E. Miller  
Marshall E. Miller, Presiding Officer  
ADMINISTRATIVE JUDGE

Daytona Beach, Florida

March 13, 1995

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

In the Matter of

ADVANCED MEDICAL SYSTEMS, INC.  
Cleveland, Ohio  
(Renewal of Material License No.  
34-19089-01)

Docket No.(s) 30-16055-ML-REN

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing LB M&O (LBP-95-03)  
have been served upon the following persons by U.S. mail, first class, except  
as otherwise noted and in accordance with the requirements of 10 CFR Sec. 2.712.

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Docket No.(s)30-16055-ML-REN  
LB M&O (LBP-95-03)

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Dated at Rockville, Md. this  
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Office of the Secretary of the Commission