

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
Robert M. Bernero, Director

In the Matter of)	
)	
ADVANCED MEDICAL SYSTEMS, INC.)	Docket No. 030-16055
(Cleveland, Ohio))	
)	(10 C.F.R. § 2.206)

DIRECTOR'S DECISION UNDER 10 C.F.R. § 2.206

I. INTRODUCTION

By letter dated August 2, 1993, addressed to Mr. James M. Taylor, Executive Director for Operations, U. S. Nuclear Regulatory Commission ("NRC"), William B. Schatz, on behalf of Northeast Ohio Regional Sewer District ("District"), requested that the NRC take action with respect to Advanced Medical Systems, Inc. ("AMS"), of Cleveland, Ohio, an NRC licensee. The District requested, pursuant to 10 C.F.R. § 2.206, that the NRC institute a proceeding to modify the license of AMS to require AMS to provide adequate financial assurance, available in the form of insurance, to cover public liability pursuant to section 170 of the Atomic Energy Act of 1954, as amended. The District alleges the following bases for the request: (1) There is a large volume of evidence indicating prior discharge of cobalt-60 to the sanitary sewer, and (2) hundreds of curies of loose cobalt-60 remain in the London Road facility.

By letter dated November 24, 1993, I formally acknowledged receipt of the

Petition and informed the Petitioner that its request was being treated pursuant to 10 C.F.R. § 2.206 of the Commission's regulations. A notice of the receipt of the Petition was published in the Federal Register on Monday, December 6, 1993 (58 Fed.Reg. 64,341). The NRC staff sent a copy of the letter dated November 24, 1993, with the Petition, to AMS.

I have completed my evaluation of the matter raised by the Petitioner and have determined that, for the reasons stated below, the Petition should be denied.

II. BACKGROUND

The NRC issued License No. 34-19089-01 to AMS on November 2, 1979. The licensed operation, facilities and equipment had been previously owned and operated by Picker Corporation since 1959. From 1979 to mid-1991, the AMS License authorized the possession of 150,000 curies of cobalt-60 in solid metal form for the purpose of manufacturing of sealed sources for distribution to authorized recipients for use in teletherapy units (used at medical facilities for treatment of medical conditions). The License currently authorizes AMS to possess cobalt-60 in solid metal form in storage and to use this material in training of licensee personnel in the manufacture of NRC approved sealed sources; the current License does not authorize manufacture of sealed sources for distribution. In addition, the License continues to authorize possession of large quantities of cobalt-60 and cesium-137 in sealed sources, and plated depleted uranium shielding, incident to teletherapy and industrial radiography installation, maintenance, and service. The AMS License currently limits possession to 300,000 curies of cobalt-60 (150,000 curies as solid metal and 150,000 in sealed sources; although the solid metal

can be used to manufacture sealed sources, no manufacturing is authorized at present), 40,000 curies of cesium-137, and 4000 kilograms of depleted uranium. Based on NRC interviews and review of records, AMS stopped releases of processed radioactive liquids to the sewer system in 1989, and since then has generated little radioactive liquid waste, which it holds on site. See US NRC Report No. 030-16055/93002(DRSS) dated July 29, 1993. The facility that houses the licensed material is located on London Road in Cleveland, Ohio.

The Northeast Ohio Regional Sewer District is responsible for operating three wastewater treatment facilities in and around the Cleveland, Ohio, metropolitan area. Its Southerly Wastewater Treatment Center ("SWTC") has been operating since 1927 to remove grit and debris from wastewater generated in the District's service area. This process involves incineration of sludge, transport of the residual ash in a slurry to settlement and evaporation ponds, and eventual transfer of the dried ash to landfills.

In April 1991, the NRC identified cobalt-60 at the SWTC by chance during an aerial radiation survey of an unrelated site, namely, the Chemetron Corporation facility located in Newburgh Heights, Ohio. Surveys were subsequently performed at SWTC in September 1991 and March 1992, by Oak Ridge Institute for Science and Education ("ORISE") at the request of NRC, to determine the extent of the cobalt-60 contamination at the facility. The results of the ORISE surveys are reported in "Radiological Characterization Survey for Selected Outdoor Areas, Northeast Ohio Regional Sewer District, Southerly Wastewater Plant, Cleveland, Ohio," Final Report, August 1992 (hereafter referred to as "ORISE report"). The results of the ORISE surveys

indicated that there were elevated direct radiation readings that were caused by cobalt-60, with elevated soil and sediment sample concentrations. With background averaging 9 microrentgens per hour, exposure rates ranged from 6 to 580 microrentgens per hour. (ORISE report at 6.) The activity of background soil samples was less than 0.2 picocuries per gram; soil and sediment sample activity ranged from less than 0.1 to 9,990 picocuries per gram. (ORISE report at 6.)

It was originally deduced (memorandum for Carl J. Paperiello, Deputy Regional Director from Loren J. Hueter, Radiation Specialist on the subject of Report on Trip to General Chemical Corporation (Non-licensee) 5000 Warner Road, Cleveland, Ohio and to Northeast Ohio Regional Sewer District, 6000 Canal Road, Cleveland, Ohio (Docket No. 030-18276; License No. 34-17726-02) dated June 13, 1991), based on the history and analysis of layers of incinerator ash in the fill areas, that the cobalt-60 began entering the treatment facility in the late 1970's or early 1980's. The history of SWTC revealed that, after renovation of the incinerators between 1975 and 1978, the current ponds were put into use for the first time. The ponds were then cleaned for the first time from December 1982 to March 1983, and all the excavations placed in the north fill area. The ash from the evaporation ponds was removed in vertical sections, and spread horizontally in the fill areas. The only timing sequence that can be determined is that cobalt-60 contamination entered SWTC prior to the 1982 cleaning. The contamination apparently originated from discharges to the sewer system in the Cleveland area that is serviced by the District.

The District removes ash from the ponds every few years so that the facility

can continue to use the ponds and continue its water treatment process. The District has transferred the dried ash from the evaporation ponds to an onsite fill area at SWTC. The NRC approved the site characterization strategy for the ash removal and has conducted confirmatory surveys along with ORISE following the transfer of ash from the evaporation ponds. Radiological characterization of the facility is ongoing to better determine the amount of cobalt-60 that is actually present on the SWTC site.

III. DISCUSSION

The District's petition requests the NRC to require AMS to provide adequate financial assurance, available in the form of insurance, to cover public liability pursuant to section 170 of the Atomic Energy Act of 1954, as amended, to cover any contamination that might be caused by loss of control of radioactive material by AMS. While applying to any contamination resulting from a future release from the AMS operation, the request in the Petition also appears to apply to the contamination already present at the District's SWTC. The NRC has treated the request in broad terms, i.e., as applying to possible future events resulting in offsite contamination as well as the currently existing contamination on the AMS site. (The District had filed a petition (dated March 3, 1993) pursuant to 10 C.F.R. § 2.206, requesting that the NRC require AMS to assume all costs resulting from the off-site release of cobalt-60 that has been deposited at the SWTC. That Petition is currently pending before the NRC.) The concerns which form the bases for the Petitioner's request and the evaluation of the staff are provided below.

A. Regulatory Framework.

1. Summary of Price-Anderson provisions

The Petitioner requests that the NRC apply the provisions of section 170 of the Atomic Energy Act of 1954, as amended ("Act"), 42 U.S.C. § 2210 ("Price-Anderson provisions"), to require AMS to obtain insurance for public liability. Section 170a. in part provides that:

Each license issued under section 103 and 104 and each construction permit issued under section 185 shall, and each license issued under section 53, 63, or 81 may, for the public purposes cited in section 2i., have as a condition of the license a requirement that the licensee have and maintain financial protection of such type and in such amount as the [Commission] in the exercise of its licensing and regulatory authority and responsibility shall require in accordance with subsection [170]b. to cover public liability claims.

Thus, section 170a. provides that the Commission must require all of its power reactor licensees to have and to maintain financial protection (e.g., liability insurance) to cover public liability claims. Nuclear reactors are licensed pursuant to either section 103 or 104 of the Act. Reactors at nonprofit educational institutions are exempt from the provisions of section 170a., but are subject to the provisions of 170k. Section 170a., however, also authorizes the Commission to exercise its discretion to determine whether materials licensees should be required to have and maintain financial protection.

2. Commission Application of Price-Anderson to Material Licensees

Because the Commission issued the AMS License under section 81 of the Act, the Commission may exercise its discretion under the Price-Anderson provisions, as discussed above, in determining whether to require AMS to have and to maintain

financial protection (i.e., liability insurance). As a matter of policy, the Commission generally has chosen not to require financial protection of a licensee whose license has been issued pursuant to sections 53, 63, or 81 of the Act. The rationale for this policy rests on the NRC's determination that the magnitude of compensation for potential personal injury or property damage associated with activities conducted under materials licenses is significantly less than that associated with the operation of facilities licensed pursuant to sections 103 or 104 of the 1954 Act (i.e., nuclear reactors). Not only is the quantity of radioactive material much less for material licensees than that contained in the inventories at reactor sites, but there are other significant differences. For example, the material licensee's radioactive material is in a non-pressurized, ambient-temperature state compared to a reactor's inventory, which is maintained in a highly energized condition or environment, characterized by high temperature and pressure. Accordingly, an accidental release of radioactive material from a material licensee's facility will be relatively confined compared to a reactor facility. This, in turn, leads to much lower potential for the need for involvement of offsite support for a material licensee's accidental release, as compared to an accidental release from a reactor.

In 1976, however, the Commission determined that there was a significant radiological hazard associated with the operation of some "plutonium processing and fuel fabrication plants." (Compare the definition of "plutonium processing and fuel fabrication plant" in 10 C.F.R. § 70.4 with that in 10 C.F.R. § 140.3(h). Not all such plants licensed pursuant to 10 C.F.R. Part 70 are required to have financial protection pursuant to

10 C.F.R. § 140.13a.) The Commission exercised its discretionary authority under the Price-Anderson provisions to require licensees of "plutonium processing and fuel fabrication plants" (as defined in 10 C.F.R. 140.3(h)), licensed under section 53 of the 1954 Act, to have financial protection in an amount equal to the maximum amount of liability insurance available from private sources. (See 10 C.F.R. §§ 70.4, 140.3(h), and 140.108.) Currently, no person holds a license to operate such a facility.

Finally, in order to assure that all licensees within a particular class are treated uniformly, it has been the policy of the Commission, in implementing the Price-Anderson provisions, to impose requirements upon a defined class of licensees by promulgating regulations of general applicability, rather than issuing orders to individual licensees. Notwithstanding the above, the Commission requires that licensees, and not the public, bear the burden of prompt cleanup of accidental contamination from releases in violation of Commission requirements.

B. Application of Price-Anderson to Existing Conditions

That discharge of cobalt-60 to the sanitary sewer has occurred is well established. Records of licensees in the District service area that were licensed for cobalt-60 indicate that licensees were authorized to discharge cobalt-60 to the sanitary sewerage under controlled conditions.

Insurance coverage in general, and under Price-Anderson in particular, however, is *prospective*, and does not cover pre-existing conditions such as

property damage that has already occurred. Any insurance required now could not be used to satisfy a claim by the District to pay for cleanup of the cobalt-60 contamination now on the District's site. Accordingly, the imposition of financial protection requirements (e.g., liability insurance) pursuant to section 170 on AMS would not provide the District with a remedy for the bases it asserts. Likewise, any contamination on the AMS site is also a pre-existing condition and would not be covered by any insurance required pursuant to section 170. Accordingly, the District's bases for its request do not warrant the NRC granting the request.

Moreover, with respect to AMS' onsite contamination, the scope of the Price-Anderson coverage is limited to claims for public liability, i.e., legal liability arising out of or resulting from a nuclear incident or precautionary evacuation except, *inter alia*, claims for loss of, or damage to, or loss of use of property which is located at the site and used in connection with the licensed activity (See section 11.w of the Act, 42 U.S.C. § 2014(w)); it does not provide funds for cleanup *per se*. (In general, a "nuclear incident" means any occurrence causing bodily injury, sickness, disease, or death, or loss of or damage to property, or loss of use of property, arising out of or resulting from the radioactive, toxic, explosive, or other hazardous properties of source, special nuclear, or byproduct material. See section 11.q of the Act, 42 U.S.C. § 2014(q).) With regard to the onsite contamination alleged by the District, therefore, requiring insurance pursuant to section 170 would be to no avail. In view of the foregoing, even if it were not a pre-existing condition, the contamination on the AMS site in and of itself does not provide a basis for requiring insurance pursuant to Price-Anderson.

In exercising its authority to protect the public health and safety pursuant to section 161 of the Act, 42 U.S.C. § 2201, the Commission has imposed requirements on its licensees to provide financial assurance for decommissioning which require the licensees to set aside funds to pay for remediation of any onsite contamination prior to license termination. See 10 C.F.R. § 30.35. With regard to the contamination on the AMS site and AMS' continued possession of byproduct material, funding of onsite cleanup is covered by the Commission's decommissioning funding plan requirements, which provide adequate protection for the public health and safety. On July 7, 1992, AMS provided decommissioning financial assurance by certification as permitted by 10 C.F.R. 30.35(c)(2), and will be required to include a decommissioning funding plan in its next application for license renewal; the current AMS license expires in December 1994. In view of the above, the District has not provided a basis for imposing additional requirements under Price-Anderson on AMS with regard to existing contamination on the AMS site or at the District's SWTC.

C. Possible Future Public Liability Claims

The possibility remains, nevertheless, that the contamination existing on the site might be spread to areas offsite or that future operations could result in offsite contamination. As set forth below, however, the District has not provided a basis for granting its request.

As discussed above, the Commission has adopted a policy of exercising its discretionary authority to apply the Price-Anderson provisions with respect to

classes of licensees rather than to individual licensees. The circumstances presented by the possibility of offsite contamination by AMS do not provide sufficient justification to deviate from that policy. The likelihood of accidental release of cobalt-60 from the AMS facility has diminished and continues to do so for several reasons, including the following: First, AMS is no longer authorized to manufacture sealed sources, and the use of raw material for this process has ceased. Second, efforts are being made by AMS to contain and dispose of loose radioactive material presently at the facility, decreasing their inventory substantially. Third, AMS is listed on the Site Decommissioning Management Plan, which provides for heightened NRC attention toward an objective of timely decontamination of the site to unrestricted use criteria and the eventual removal of the site from the list. Fourth, present disposal regulations allow disposal of only soluble radioactive material into the sanitary sewer, as discussed further below. In addition, the bases the District alleges in support of the Petition do not distinguish AMS from other materials licensees for the purposes of application of the Price-Anderson provisions. The District has not provided sufficient information, nor are we aware of information at this time, which would warrant extension of Price-Anderson to all materials licensees similar to AMS. In view of the above, the District's request concerning Price-Anderson coverage is denied. Moreover, because the Commission requires each licensee to be responsible for any remediation of offsite contamination resulting from a release of byproduct material in violation of regulations or license conditions, no action is required to modify the AMS License as requested by the District. In view of the foregoing, the District has presented no basis warranting the granting of its request.

The NRC notes that the 1991 revision to 10 C.F.R. Part 20, which became mandatory January 1, 1994, included several revised criteria for permissible release of radioactive material into the sanitary sewer. Since insoluble material was involved in a number of sewage treatment facility cases, the new rule eliminates the options to release either insoluble, or readily dispersible material, unless it is biological material, into a sanitary sewer system. Revised Part 20 also lowers allowable concentrations of radionuclides released into the sanitary sewer. Because a 1992 NRC study demonstrated that, under certain conditions, the potential to exceed the Part 20 public dose limit exists, NRC has contracted with Pacific Northwest Laboratory to perform additional studies on possible mechanisms at sewage treatment facilities that could lead to reconcentration of radionuclides. This multi-task contract began in October 1993; a report is due later this year. In connection with this study, the Commission has issued an advanced notice of proposed rulemaking in which the Commission has requested comments on whether an amendment to the current regulations governing the release of radionuclides from licensed nuclear facilities to sanitary sewer systems is needed. (59 Fed. Reg. 9146 (Feb. 25, 1994)). The facts regarding the District's SWTC were one set of circumstances prompting the Commission to issue the notice.¹

¹ The Commission recently expressed its views that although the Atomic Energy Act of 1954 preempts dual Federal-State regulation of radiation hazards, it does not prohibit actions by state or local authority on bases other than protection of public health and safety from radiological hazards. See letter dated 11/9/93 from M. Malsch, NRC to M. Fitzgerald, GAO; and letter dated 11/9/93 from M. Malsch, NRC, to H. McFadden, Laramie, Wyoming, City Attorney. The above matters do not provide a basis for granting the District's request, nor change the results of the analysis in this Decision.

Finally, it should be noted that the Commission has requested the NRC staff, in a Staff Requirement Memorandum dated June 28, 1993, to address the issue whether financial assurance for materials licensees for cleanup of an accident with the potential for significant contamination should be required. The staff will recommend that rulemaking be initiated if it appears that the benefit of such requirements outweighs the costs.


IV. CONCLUSION

The staff has carefully considered the request of the Petitioner. In addition, the staff has evaluated the bases for the Petitioner's request. For the reasons discussed above, I conclude that no substantial public health and safety concerns warrant NRC action concerning the request.

As provided by 10 C.F.R. § 2.206(c), a copy of this Decision will be filed with the Secretary of the Commission for the Commission's review. The Decision will become final action of the Commission twenty-five (25) days after issuance unless the Commission on its own motion institutes review of the Decision within that time.

Dated at Rockville, Maryland, this 16th day of June 1994.

FOR THE NUCLEAR REGULATORY COMMISSION


Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards

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FOR THE NUCLEAR REGULATORY COMMISSION

ORIGINAL SIGNED BY

Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards

*See previous concurrence

OFC	IMOB*	E	IMOB*	IMOB*	RIII*	<i>Reviewed</i> OGC	E
NAME	JDeCicco:jed		CJones	FCombs	WAxelsson	<i>No legal objection</i> RWeisman	
DATE	5/4/94		5/4/94	5/4/94	5/13/94	5/31/94	

OFC	<i>M</i> OGC	<i>N</i>	<i>IMNS/D</i>	<i>IMNS</i>	NMSS	NMSS
NAME	JGoldberg		WBrach	CPaperiello	GArlotto	RBernero
DATE	5/13/94		5/13/94	5/13/94	1/94	6/16/94

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