

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
Carl J. Paperiello, Director

In the Matter of)	
)	
ADVANCED MEDICAL SYSTEMS, INC.)	Docket No. 030-16055
(Cleveland, OH))	
)	License No. 34-19089-01

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

I. INTRODUCTION

By letter dated August 19, 1994, addressed to Mr. James M. Taylor, former Executive Director for Operations, U. S. Nuclear Regulatory Commission (NRC), William B. Schatz, Esq., on behalf of the Northeast Ohio Regional Sewer District (District), requested that the NRC take action with respect to Advanced Medical Systems, Inc. (AMS), of Cleveland, OH, an NRC licensee.¹ The District requested, pursuant to 10 C.F.R. § 2.206, that the NRC amend License

¹ Northeast Ohio Regional Sewer District submitted two previous Petitions for action against AMS under 10 C.F.R. § 2.206. In a Petition dated March 3, 1993, and supplemented by letters dated September 13, 1994, October 13, 1994, and April 29, 1996, the Petitioner requested that NRC: (1) modify AMS' License No. 34-19089-01 to require that AMS assume all costs resulting from the off-site release of cobalt-60 that has been deposited at the Petitioner's Southerly Wastewater Treatment Center; (2) order AMS to decontaminate the sewer connecting its facility with the public sewer at London Road, and continue down stream with such decontamination to the extent that sampling indicates is necessary; (3) commence enforcement action against AMS for violation of 10 C.F.R. §§ 303(a), 401(c)(3) and 20.2003; and (4) take action on the AMS license to safely, immediately, and reasonably decontaminate the London Road interceptor (the sewer). The second request had been partially granted when the NRC amended the AMS license to require remediation of the sewer line connecting AMS Facility with the public sewer, and the Petition was denied in all other respects. *Advanced Medical Systems, Inc.* (DD-97-13), 45 NRC 460 (1997). In a second Petition dated August 3, 1993, the Petitioner requested that the NRC take action to require AMS to provide adequate financial assurance to cover public liability pursuant to section 170 of the Atomic Energy Act of 1954, as amended. The second petition was denied. *Advanced Medical Systems, Inc.* (DD-94-6), 39 NRC 373 (1994).

No. 34-19089-01, to require AMS to install, maintain, and operate a radiation alarm system on all drains at 1020 London Road, Cleveland, OH (AMS Facility), that lead to either sanitary or storm sewers.

The District asserts two major reasons as the bases for the request. First, it views the quantity of cobalt-60 waste in the AMS Facility's basement as a major threat based on the following: (a) the NRC has admitted that the existing contamination at the AMS Facility continues to pose a risk; (b) the contamination that exists at the AMS Facility is estimated to include 393 curies, as of 1988, of loose, "talcum-like" cobalt-60 scattered on the floor of the basement waste hold-up room; (c) cobalt-60 contamination was found in the sewer line connecting the AMS Facility to the public sewer, and was found directly under the AMS discharge; (d) the District has already incurred costs of nearly \$2 million to address loose cobalt-60 contamination at the Easterly and Southerly Wastewater Treatment Plants; (e) the NRC has been unable or unwilling to explain the source of the cobalt-60 on the District's property, and unable to identify any likely sources for the cobalt-60 other than the AMS Facility; and (f) the quantity of cobalt-60 at the Southerly Plant exceeds that which the AMS records show was released by AMS into the sewer system. Secondly, the original license for this site, issued to Picker in 1959, contained a requirement for an alarm system to detect unmonitored discharges. The District states that such an alarm system was not a condition of the subsequent AMS license, despite a recommendation from Oak Ridge Associated Universities that such an alarm system be installed, along with control valves, to shut off flow to the sewer if the alarm sounds.

By letter dated September 7, 1994, the NRC formally acknowledged receipt of the District's letter, and informed the District 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 September 19, 1994 (59 Fed. Reg. 47,959). The NRC Staff sent a copy of its acknowledgment letter, with a copy of the Petition, to AMS. By letter dated November 9, 1995, the NRC informed the District that further action on its request was being deferred until completion of an ongoing proceeding on AMS' November 29, 1994, application to renew its license. While that proceeding has not been terminated, the NRC staff has decided to deny the renewal application. See letter from C. Paperiello, NRC to S. Stein, AMS, dated September 28, 1998. Accordingly, it is now appropriate for the staff to consider the action requested by the District.

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

II. BACKGROUND

In 1959, the Atomic Energy Commission (AEC) (predecessor to the NRC) issued License No. 34-07225-09 to Picker X-Ray Corporation (Picker), for operation of a sealed-source manufacturing facility located at 1020 London Road. The license authorized Picker to receive, store, and encapsulate cobalt-60 for the purpose of installing these encapsulated sources in approved devices and distributing the sources to customers having valid licenses. The facility at 1020 London Road had been built specifically for the intended purpose of handling and encapsulating large quantities of cobalt-60 (in the kilocurie range); the building included a hot cell for encapsulating the cobalt-60, and various support areas, including a heavily shielded room that contained two stainless steel tanks to collect liquid radioactive waste [waste hold-up tanks (WHUT)]. During the manufacturing of encapsulated sources, it was not uncommon that

the hot cell would become contaminated with oxidized cobalt-60. To maintain control of contamination and radiation levels, the cell would be cleaned periodically, with the liquid waste generated by the cleanup diverted to the WHUT room, which had a combined holding capacity of 600 gallons. The stored liquid radioactive waste was then discharged to the sanitary sewer at irregular intervals, depending on the volume of liquid waste generated during normal operations. In a manual entitled "Radiation Safety Procedures for the Picker X-Ray Corporation, Waite Manufacturing Division, Inc.," dated December 1959, a procedure outlined the equipment and steps followed to discharge the liquid waste to the sewer. The liquid radioactive waste was pumped directly from the WHUT into the sanitary sewer system through a drain in the basement floor. The hose from the WHUT to the sewer drain was continuously monitored during discharge, with the liquid passing through a solenoid valve, an in-line monitor consisting of a G-M tube with a rate meter and a strip chart recorder, and a water meter. The solenoid valve opened only during intentional discharge from the WHUT, and only when the monitoring system detected count rates below a preset level, ensuring that only authorized concentration levels were being discharged. A record of the total discharge would be indicated by the total volume of liquid discharged and the count rate information from the monitor, calculating the average concentration and the total activity. The description of the monitoring process did not have the detection system operating continuously, but only while discharging from the hold-up tanks to the sanitary sewer drain.

In a letter submitted to the AEC dated January 25, 1974, Picker submitted a manual entitled "Radiation Safety Procedures for the Picker Corporation, Isotope Operations," requesting it supersede the then effective manual, "Radiation Safety Procedures for the Picker X-Ray Corporation, Waite Manufacturing Division, Inc.," mentioned above. This new manual modified the facility's liquid waste disposal method and system, and was later revised in September

1976. See Inspection Report No. 030-16055/93003(DRSS) at 13. The AEC, and later the NRC, did not incorporate the January 1974 letter, the manual, and the subsequent September 1976 revision, into Picker's license. In February 1974 (OR Inspection Report No. 74-01 for License No. 34-07225-09 at 6), Picker modified its liquid radioactive waste discharge procedure from the in-line continuous monitor, to a batch disposal method. This batch disposal system consisted of a 55-gallon drum located outside the room housing the WHUT, atop a stand pipe connected to a floor drain leading to the sanitary sewer line. Waste water was pumped from the WHUT to the 55-gallon drum, the drum liquid was then agitated by an electrically driven trolling motor, and, after agitation, the liquid was sampled to determine its radioactive concentration. After determining radioactivity concentration and the volume in the 55-gallon drum, for recording concentration and total quantity of radioactive material, the plug at the bottom of the drum was removed to discharge the contents to the sanitary sewer. This batch method of disposal was continued until Picker terminated this license in November 1979.

In 1979, Picker sold the facility and operation at 1020 London Road to AMS. The provisions of the AMS license application were similar to the previous Picker license, with many of the procedures carried forward to the AMS license, including the batch method for liquid radioactive waste release described above. AMS used the same batch method for disposal of liquid radioactive waste as Picker, from the time that AMS' initial license (License No. 34-19089-01) was issued on November 2, 1979, until April 1986. In 1986, AMS installed a 200-gallon plastic tank to collect waste from the drain leading from decontamination showers, the laundry, and sinks, and discontinued use of the 55-gallon drum for discharge. One of the two tanks in the WHUT room, a 500-gallon tank, was no longer receiving liquid waste when the 200-gallon tank was installed in 1986, and the use of the other tank in the WHUT room (100-gallon capacity) was discontinued in 1988, when the WHUT room was isolated. The batch method of

determining concentration and total volume of the liquid discharge from the 200-gallon tank, to show compliance, continued until May 1989, when discharge to the sanitary sewer (via floor drains) was discontinued completely.

III. DISCUSSION

The District's petition requests the NRC to require AMS to install, maintain, and operate a radiation alarm system on all drains at the AMS Facility that lead to either sanitary or storm sewers. The request to modify the license by having alarms installed appears to be an effort to put in place a mechanism that would indicate when cobalt-60 is entering the District's sanitary sewer system, and, in turn, to stop the entry of the cobalt-60 into the sanitary sewer system on positive indication of material.

Most of the bases for the Petition are restatements of facts, or existing information in previously published documents, that are associated with the facility at 1020 London Road. Since 1989, when AMS changed its decontamination process to a dry method, AMS' records indicate that AMS has not disposed of any radioactive waste into the sanitary sewer drain.

The District has incurred costs of nearly \$2 million addressing the cobalt-60 contamination at its Easterly and Southerly wastewater treatment plants. The District's apparent concern in this Petition is the threat that the London Road facility poses to the District's treatment facilities, primarily pertaining to the imposition of additional costs through release of cobalt-60 from the AMS facility into the District's system. As described below, however, neither the nature or

activity of the contamination in the WHUT room, in light of the condition of the WHUT room, nor the requirements formally applicable to Picker, establish any basis to take the requested action. This cobalt-60 contamination is in a dry state, and the WHUT room is completely isolated from the sewer system and from accidental access. There are no floor drains in the WHUT room, and there is no water supply into or out of the room. Accordingly, the existence of contamination of 393 curies (14.5 terabecquerels) of loose, "talcum-like" cobalt-60 in the WHUT room in the basement does not warrant granting of the District's request.

The District indicated there had been an alarm and control system that had once been in place when Picker operated the facility, up to November of 1979. In connection with this type of system, the District states that the system had not been a required condition of the license after Picker terminated work at the facility, and operations continued under the AMS license. In its original license application to show compliance with the regulations at that time, Picker included conditions requiring a water-monitoring system that detected concentration levels in a drainpipe. The system that Picker described in the Informational Memorandum No. 6, "Calibration and Evaluation of Water Monitor System," submitted by Picker to the NRC on December 2, 1959, was used as both a control system, to prevent discharge above a preset limiting concentration, and as a method of showing compliance with then-applicable regulations. However, this documentation does not indicate that there had been any alarm as part of the system -- nor is it documented, from that time, why the in-line system was discontinued, and a batch method used in its stead, in 1974. See OR Inspection Report 74-01, License No. 34-07225-09, transmittal dated May 3, 1974. Two interviewees questioned during a 1993 inspection indicated that the in-line system was discontinued because the in-line G-M detector needed to be replaced, but was no longer manufactured or available. See Report No. 030-16055/93003 (DRSS) at 11. Both procedures, the in-line monitoring method and the

batch method, at the time they were being used, satisfied the requirement to show compliance independently, and, therefore, either procedure was considered acceptable at the time of the request.

The Oak Ridge Associated Universities report that recommended monitoring the discharge to the sanitary sewer and placing a servo-valve mechanism on the drains was part of a larger report. See "Evaluation of the Operational Radiation Safety and Fire Protection Programs of the Advanced Medical Systems, Inc., London Road Facility, Cleveland, Ohio," December 1985. This method was given as an alternative for developing a contingency plan for controlling release to the sanitary sewer system in case of a major spill into the basement. The other alternative offered in this report was to seal the drains in the basement floor, so that any release could be monitored before releasing to the sewer system. AMS chose this latter alternative as a means of preventing an unmonitored release. The method of sealing the drains was determined to be appropriate to ensure compliance with 10 C.F.R. § 20.303 (1985). A continuous monitor could be used for the purpose of detecting a major unintended release, but might be relatively insensitive for normal operations.

In October 1994, the District issued an Executive Director's Order to AMS terminating all sewer service effective October 24, 1994. In November 1994, the District placed a compression plug in the AMS lateral sewer line that connects the AMS Facility to the District's sewer system under London Road. Thus, in effect, the District isolated the AMS Facility's sanitary and storm drain lines from the sanitary sewerage treatment system. In mid-1995, AMS grouted shut the entire lateral line, to immobilize any residual cobalt-60 that remained in the lateral. AMS' grouting of the lateral line blocked release, through the lateral, from the AMS Facility to the District's sewer system. At some point following the grouting operation, the District removed

the compression plug on AMS' lateral sewer line. Currently, there are drains at the AMS Facility that lead from the rooftop (for rainwater) to the main sewer system in London Road, but there are no other drains from the facility that are connected to the sewer system. The lateral connector, which connects all drains originating from within the AMS Facility to the District's sewer line, remains grouted. Also, in a settlement agreement between the District and AMS, executed on December 20, 1996, the District indicated that it would allow re-connection of the AMS Facility to its London Road Interceptor pursuant to procedures set forth in the agreement, provided that several conditions were first satisfied. As of the date of this Director's Decision, AMS has not executed all the conditions in the agreement. The December 1996 settlement agreement states that re-connection shall be in full accordance with several criteria and requirements, with one of the requirements being that AMS must agree not to discharge any cobalt-60 into the sanitary sewer system, directly or indirectly. See Settlement Agreement dated December 20, 1996, at 10, forwarded by a letter from Dwight Miller, Stavole & Miller, Attorneys and Counsellors at Law, to John Madera, Chief, Materials Inspection Branch 1, Region III, dated January 6, 1997. With this agreement for re-connection in place, and with the only connection between the interior of the AMS Facility and the District's sewer system grouted, until AMS satisfies the condition of the settlement agreement, the requested requirement for an alarm system is not necessary at this time.

The existence of unsealed cobalt-60 at the AMS Facility does represent a potential risk. As the NRC staff has previously stated, the possibility remains that the contamination existing on site might be spread to areas offsite or that future operations could result in offsite contamination. Such offsite contamination would not necessarily spread to the District's system, however. In addition, the likelihood of accidental release of cobalt-60 from the licensee's facility has diminished and continues to do so. *Advanced Medical Systems* (DD-94-6) 39 NRC 373, 379

(1994). Since 1994, the amount of cobalt-60 that could be released in an accident at the licensee's facility has been greatly diminished because of disposals to a licensed disposal site. See NRC Inspection Report No. 030-16055/97001(DNMS) (March 7, 1997). Moreover, NRC inspection and review of records have not revealed any documentation at AMS or other evidence that would indicate discharges into the sanitary sewer system have been in excess of authorized limits. *Advanced Medical Systems, Inc.* (DD-97-13) 45 NRC 460, 465 (1997). As the situation exists today, the NRC staff concludes that neither the contamination at the facility nor the licensee's drainage system present an immediate health and safety hazard to the public, and that the requested action is not warranted.

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, the District's request for action pursuant to section 2.206 is denied, and no action pursuant to section 2.206 is being taken in this matter.

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

Dated at Rockville, Maryland, this __4th__ of __November__, 1998.

FOR THE NUCLEAR REGULATORY COMMISSION

(original signed by)

Carl J. Paperiello, Director
Office of Nuclear Material Safety
and Safeguards

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* See previous concurrence

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