



Northeast Ohio Regional Sewer District

3826 Euclid Avenue • Cleveland, Ohio 44115-2504

216 • 881 • 6600

FAX: 216 • 881 • 9709

March 18, 1996

Mr. James Taylor
Executive Director for Operations
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Request for Action on License #34-19089-01 Pursuant to 10 CFR 2.206

Dear Mr. Taylor:

On August 2, 1993, the Northeast Ohio Regional Sewer District (NEORSD) filed a petition (Prior Petition) with the Nuclear Regulatory Commission (NRC) requesting that the NRC take certain actions regarding NRC License # 34-19089-01 (License). The License is held by Advanced Medical Systems, Inc. (AMS). A copy of the Prior Petition is attached as Exhibit A. The Prior Petition related to operations at the AMS facility at 1020 London Road, Cleveland, Ohio (Facility).

One of the actions requested in the Prior Petition was the modification of the AMS License to include a requirement that AMS provide adequate financial assurance prospectively to cover public liability in the event of nuclear incidents at the Facility. Section 170 of the Atomic Energy Act of 1954 provides the NRC with explicit authority to take such action.

On June 16, 1994, Mr. Robert Bernero issued a Director's Decision (Decision) on behalf of the NRC rejecting the Prior Petition. A copy of the Decision is attached as Exhibit B. The Decision was based on a number of assumptions which have proven incorrect.

I.

One reason stated by Mr. Bernero for not requiring AMS to provide the requested financial insurance was the condition of the AMS Facility. However, in an eleven-page letter dated February 28, 1996 from Mr. John Madera, Chief, Nuclear Materials Licensing Branch, to AMS, a copy of which is attached as Exhibit C, many of the assumptions regarding the Facility relied upon by Mr. Bernero are called into serious question.

For example, on page 4 of this letter, it is made clear that there is no basis for the 40-curie source term that has been used in estimating potential releases from the Facility and that the proper number, although unknown at this time, is greater. This letter points out many additional deficiencies in the Emergency Plan for this facility, including inadequate assessments of the potential releases

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District is to enhance public health and welfare through the efficient, cost-effective conveyance and treatment of wastewater. This is accomplished by an organization dedicated to professionalism, fairness and consistency that anticipates and responds to the changing environmental needs of the community.

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as the result of earthquake or tornado damage. As stated on page 5 of the letter, "it is scientifically certain that a tornado passing over this facility would impose significant structural damage . . ."

Considering that over 60,000 curies of cobalt-60 are located at the Facility (page 3), Mr. Bernero's statement on page 7 of the Decision, "Accordingly, an accidental release of radioactive material from a material licensee's facility will be relatively confined compared to a reactor facility", appears to be unrealistic and inappropriate as it relates to the AMS Facility.

II.

On page 12 of the Decision, Mr. Bernero suggests a second reason for rejection of the Prior Petition, a Pacific Northwest Laboratory study on sanitary disposal of radioactive materials to be performed under NRC contract. The results of that study have been available for some time and do not support the Director's Decision.

In fact, this study concludes that existing records of discharges of radioactive waste to the sewers "grossly" underestimate the quantity of radioactive materials found at the receiving sewage treatment plants. The study also concludes that there is insufficient information to determine whether sanitary discharges made in compliance with the revised Part 20 requirements would concentrate at sewage treatment facilities in sufficient quantity to be a problem.

Contrary to Mr. Bernero's expectations, the study to which Mr. Bernero referred -- much of which was conducted at NEORSD facilities and with NEORSD cooperation and assistance -- is actually very persuasive evidence in favor of requiring the financial assurance requested in the Prior Petition. That is, since the study demonstrates that contamination of sewage treatment plants due to discharges of licensed materials cannot be ruled out, financial assurance to cover public liability in the event of such a nuclear incident is a reasonable precaution.

III.

As expressed by Mr. Bernero in both the Decision and his transmittal letter to NEORSD dated June 16, 1994 that accompanied the Decision, NRC's rejection of the Prior Petition was in part based on a revision to 10 CFR Part 20 that, according to Mr. Bernero's letter, "... no longer permits non-biological, dispersible material, such as the cobalt-60 used at AMS, to be disposed into the sanitary sewer."

Notwithstanding the revision, recent actions of the NRC have authorized AMS to release such material to the environment in a manner that allows insoluble material to reach the NEORSD sewer system.

Recently, AMS sought to discharge the contents of a 3000-gallon water storage tank, tank number 880, onto the ground at the Facility. It is highly probable that a portion of these contents

would flow overland across the neighboring facility and enter the street catch basin, which leads to the NEORSD system. Testing of the water in this tank 880 by NRC, NEORSD, and even AMS had shown detectable amounts of insoluble cobalt-60.

In a letter dated February 26, 1996, a copy of which is attached as Exhibit D, Mr. Geoffrey Wright, NRC Region III, stated that AMS had been informed that due to the presence of insoluble cobalt-60, dumping such water in a manner that was likely to reach the sanitary sewer would be an apparent violation of 10 CFR 20.2003. Subsequent to this letter, according to Mr. John Madera, AMS claimed to have circulated the contents of tank 880 through a 1 micron filter.

This treatment of the cobalt-60 contaminated water was apparently conducted without prior notice to the NRC, and certainly without prior notice to the Ohio Environmental Protection Agency (OEPA), or the NEORSD. This pretreatment was also conducted without the opportunity for any of these agencies to inspect or observe the treatment equipment.

As stated in the letter dated March 6, 1996 from the OEPA to AMS, a copy of which is attached as Exhibit E, this pretreatment system was in fact installed without required OEPA authorization and any discharge from tank 880 will be deemed a violation. Mr. Madera confirmed by telephone that AMS had detected insoluble cobalt-60 in samples taken from tank 880 following pretreatment.

On March 7, 1996, however, the NEORSD was informed by telephone by Mr. John Madera, NRC Region III, that the NRC was authorizing AMS to discharge the contents of storage tank number 880 onto the ground. Mr. Madera explained the justification for this action by the NRC by telephone to the NEORSD: Because not all of AMS' samples showed insoluble cobalt-60, and there was not a standard sampling protocol in place, NRC could not call the proposed discharge a violation of 10 CFR 20.2003 and successfully uphold that violation in court if AMS sued. So the NRC would do nothing.

The provisions of 10 CFR 20.2003 can be read no other way than to mean zero discharge of insoluble radioactive material, and to place an affirmative duty upon the licensee proposing to discharge to demonstrate that the radioactive material proposed to be discharged is readily soluble. In testing for the presence of insoluble radionuclides at relatively low levels, it is not surprising that not all samples would show positive detects.

Insolubility, practically by definition, indicates the presence of a second material phase that cannot be realistically expected to be precisely uniformly distributed. The very fact that some samples show detects while others do not confirms the insoluble, inhomogeneous character of the radionuclide detected. Mr. Madera nevertheless authorized discharge of this tank, without any confirmatory testing by the NRC.

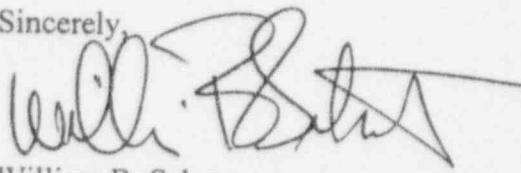
Mr. Taylor
March 18, 1996
Page Four

These NRC actions raise serious questions as to the validity of Mr. Bernero's revised Part 20 justification for denying the Prior Petition. Obviously, if the NRC will not enforce its revised regulation unless all samples show positive detects, the revision is an empty gesture.

As set forth above, substantial additional factual information has become available regarding the justification for requiring financial assurance for public liability from AMS subsequent to the date of the Decision. The new information also refutes the assumptions underlying Mr. Bernero's rejection of the Prior Petition.

Therefore, based on the new information presented in this petition, the NEORSD requests that this petition be treated as a new request for action on a license pursuant to 10 CFR 2.206. Please direct any questions regarding this petition to either Thomas Lenhart or Lawrence English of my legal staff. They may be reached at 216-881-6600.

Sincerely,



William B. Schatz
General Counsel

encl.

cc: Ramona Travota, USEPA
Robert Bastian, USEPA
Michael Cook, USEPA
Michael Kalstrom, Cuyahoga County LEPC
Donna Kniss, Ohio EPA
William Gruber, City of Cleveland
Erwin Odeal, NEORSD
Thomas Lenhart, NEORSD
Lawrence English, NEORSD

EXHIBIT "A"



Northeast Ohio Regional Sewer District

3826 Euclid Avenue • Cleveland, Ohio 44115-2504

216 • 881 • 6600

FAX: 216 • 881 • 9709

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 2, 1993

Mr. James Taylor
Executive Director for Operations
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Request for action pursuant to 10 CFR 2.206

Dear Mr. Taylor:

The Northeast Ohio Regional Sewer District ("District") Southerly Wastewater Treatment Center has been contaminated by disposal of Cobalt-60 into the sanitary sewer system. The characterization and remediation of this contamination is ongoing and will cost the District, at a minimum, in excess of one million dollars. The remediation costs could rise into the billions of dollars if off-site disposal is required.

Although the NRC has been cooperative in this remediation effort, the Agency has consistently stated that the costs must be absorbed by the District and its ratepayers, despite the District's innocence in this matter. Chairman Ivan Selin recently stated that the NRC is completely powerless to seek cost recovery from the source of this material regardless of the degree of culpability of the licensee. Mr. Selin further stated that the victim in an off-site contamination case such as the Southerly Treatment Center must rely on state tort law to recover costs from the Licensee. Unfortunately for the victim, tort law will only provide an adequate remedy if a judgment can be obtained against a licensee with the financial resources to pay the judgment. In many situations, the judgment in contamination cases may force the licensee into bankruptcy leaving the victim to cover the remediation costs plus the additional cost of the legal action. The NRC may in such cases be left with an abandoned, contaminated facility.

In addition to requiring financial assurance for site decommissioning, the Atomic Energy Act, in 42 U.S.C. Section 2210,

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Mr. James Taylor
August 2, 1993
Page 2


permits the NRC to require financial protection to cover public liability claims as a license condition of most licensees. The District has been informed by the NRC, however, that such financial protection has never been required of a licensee other than in the nuclear power industry, where it is mandatory. As a result of this NRC policy, publicly owned treatment works across the nation, as well as other potential victims, may find themselves in a position similar to that of the District and its ratepayers. In the event of an abandoned, contaminated facility, the impact on a municipality could be devastating.

The District therefore requests, pursuant to 10 CFR 2.206, that the NRC require financial protection, available in the form of insurance, of certain of its materials licensees. The amount of such financial protection could vary based upon the risk to the public posed by the licensee. The District specifically requests that adequate financial assurance to cover public liability be required of Advanced Medical Systems, Inc. due to the large volume of evidence indicating prior discharge of Cobalt-60 to the sanitary sewer, and due to the hundreds of curies of loose Cobalt-60 that remain in the London Road facility.

In addition to requiring adequate financial protection, the District also requests that the NRC license of all generators of radiological waste located within Cuyahoga County and Summit County, Ohio, be amended to require that licensees provide not less than 24 hours advance notice to the appropriate sewage treatment plant prior to releasing radioactive material to the sanitary sewer. In a separate petition for rulemaking pursuant to 10 CFR 2.802, the District is requesting that 10 CFR 20.303 (and 10 CFR 20.2003) be revised to require the same notification provision in all licenses issued by the NRC.

Your prompt response to this petition would be appreciated as this is a matter of great concern to the District.

Very truly yours,



William B. Schatz
General Counsel

WBS/ydm

cc: Richard Bangart
Philip Olson
John Martin
Ken Kirk
Senator Glenn
Senator Metzenbaum
Representative Hoke
Representative Stokes
Erwin Odeal
Thomas Lenhart
Barry Koh
Law Director City of Cleveland

EXHIBIT "B"

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

JUN 16 1994

Docket No. 030-16055
(10 CFR § 2.206)

William B. Schatz
General Counsel
Northeast Ohio Regional Sewer District
3826 Euclid Avenue
Cleveland, Ohio 44115-2504

RECEIVED

JUN 22 1994

Legal Department
N. E. O.

Dear Mr. Schatz:

This letter is in response to your Petition, dated August 2, 1993, on behalf of the Northeast Ohio Regional Sewer District. The Petition requested that the U.S. Nuclear Regulatory Commission take action with respect to Advanced Medical Systems, Inc., (AMS) to modify the AMS license to require, *inter alia*, that AMS provide adequate financial assurance to cover public liability pursuant to section 170 of the Atomic Energy Act of 1954, as amended.

Your request was referred to the staff for consideration pursuant to 10 CFR § 2.206 of the Commission's regulations. For the reasons stated in the enclosed "Director's Decision Under 10 CFR § 2.206," the Petition has been denied.

Three items of interest should be noted. First, the revision of 10 CFR Part 20 no longer permits non-biological, dispersible material, such as the cobalt-60 used at AMS, to be disposed into the sanitary sewer. In connection with this revision, the NRC has published an advance notice of proposed rulemaking requesting comment and/or information as to whether an amendment to the new regulations in effect is needed. Second, the Commission has expressed its view that the Atomic Energy Act of 1954 does not prohibit actions by state or local authority on bases other than protection of public health and safety from radiological hazards. This is explained in a letter dated 11/9/93 from M. G. Malsch, NRC, to M. J. Fitzgerald, GAO, and a letter dated 11/9/93 from M. G. Malsch, NRC, to H. B. McFadden, Laramie, Wyoming, City Attorney, both of which are enclosed with this letter and referenced in the enclosed Director's Decision. Third, in a Staff Requirement Memorandum dated June 28, 1993, the Commission has requested the NRC staff to address the issue of rulemaking on the subject of financial assurance for cleanup of an accident for material licensees with a potential for significant contamination.

With regards to the petition dated March 3, 1993, you filed pursuant to 10 CFR § 2.206, we intend to consider your consultant's report on the cobalt-60 characterization at the Southerly Treatment Center, which is currently expected to be completed in June, 1994, before issuing our decision on that Petition. Please forward a copy to me within two weeks after your

consultant submits it to you. Accordingly, we will make a decision on your March 3, 1993, Petition within a reasonable time after receiving your consultant's report.

A copy of the Decision will be filed with the Secretary of the Commission for its review in accordance with 10 CFR § 2.206 of the Commission's regulations. As provided by this regulation, the Decision will constitute the final action of the Commission 25 days after the date of issuance of the Decision unless the Commission, on its own motion, institutes a review of the Decision within that time.

A copy of the Notice which is being filed with the Office of the Federal Register for publication is enclosed.

Sincerely,



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

Enclosures:

1. Director's Decision DD-94-06
2. Federal Register Notice
3. Ltr dtd 11/9/93 from
M. Malsch, NRC, to
M. Fitzgerald, GAO
4. Ltr dtd 11/9/93 from
M. Malsch, NRC, to
H. McFadden, Laramie, WY

cc: Advanced Medical Systems, Inc.
ATTN: Ms. Sherry Stein, Dir.
of Regulatory Affairs
1020 London Road
Cleveland, Ohio 44110

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSIONOFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
Robert M. Bernero, Director

In the Matter of

ADVANCED MEDICAL SYSTEMS, INC.
(Cleveland, Ohio))
)
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)
)Docket No. 030-16055
(10 C.F.R. § 2.206)DIRECTOR'S DECISION UNDER 10 C.F.R. § 2.206I. 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

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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.

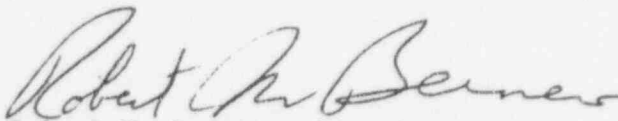
IV. CONCLUSION

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

U.S. NUCLEAR REGULATORY COMMISSIONDOCKET NO. 030-16055ADVANCED MEDICAL SYSTEMS, INC.ISSUANCE OF DIRECTOR'S DECISION UNDER 10 C.F.R. § 2.206

Notice is hereby given that the Director, Office of Nuclear Material Safety and Safeguards, has issued a decision concerning a Petition dated August 2, 1993, submitted by the Northeast Ohio Regional Sewer District regarding Advanced Medical Systems, Inc. (AMS).

By letter dated November 24, 1993, the NRC staff formally acknowledged receipt of the Petition and informed the Petitioner that their Petition would be treated as a request under 10 CFR § 2.206. The Petition requested the U.S. Nuclear Regulatory Commission to 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 Director of the Office of Nuclear Material Safety and Safeguards has determined to deny the Petition. The reasons for this Decision are explained in a "Director's Decision Under 10 CFR § 2.206" (DD-94-06), which is available for public inspection in the Commission's Public Document Room located at 2120 L Street, NW, DC 20555, and at the Local Public Document Room, Perry Public Library, 3735 Main Street, Perry, Ohio 44081.

A copy of this Decision will be filed with the Secretary for the Commission's review in accordance with 10 CFR § 2.206. As provided by this regulation, the

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Decision will constitute the final action of the Commission 25 days after the date of issuance of the Decision unless the Commission on its own motion institutes a review of the Decision within that time.

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

FOR THE NUCLEAR REGULATORY COMMISSION

A handwritten signature in dark ink, appearing to read "Robert M. Bernero", is written over the typed name.

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



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

NOV 09 1993

Martin J. Fitzgerald, Esq.
Associate General Counsel
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Fitzgerald:

In your letter of October 6, 1993, addressed to the General Counsel of the Nuclear Regulatory Commission, you requested our response to a number of questions regarding the concentration of radioactive materials in publicly owned treatment works. Your questions and our responses are contained in the enclosure to this letter. If you have further questions, please call me at (301) 504-1740, or Robert L. Fonner at (301) 504-1643.

Sincerely,

A handwritten signature in dark ink, appearing to read "M. Malsch", is written over a horizontal line.

Martin G. Malsch
Deputy General Counsel for
Licensing and Regulation

Enclosure: As stated

cc: W. Parler
R. Bernero

Enclosure 3

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QUESTION 1. Does the NRC have the authority to require publicly-owned treatment works (POTWs) to test for concentrations of radioactive materials subject to the jurisdiction of the Atomic Energy Act? If so, under what authority? Would the POTWs be responsible for the payment for such tests?

ANSWER

Sections 161b. and 161i. of the Atomic Energy Act of 1954, as amended, authorize the NRC to promulgate rules and issue such orders as the Commission may deem necessary to protect health and safety with regard to regulated radioactive materials. This authority may be applied to unlicensed persons if necessary (see 10 CFR 2.202). The POTWs would be responsible for the payment for such tests if ordered. The NRC has no appropriated funds to pay for licensee or nonlicensee testing.

QUESTION 2. Under what authority and on what conditions does the NRC test for concentrations of radioactive materials subject to regulation under the Atomic Energy Act at POTWs? Who is responsible for the payment for such tests? Please explain.

ANSWER

The NRC may itself conduct sampling and testing under the authority of 161c. of the Atomic Energy Act of 1954, as amended. Such

sampling and testing may be done as the consequence of an inspection where the NRC inspectors take samples in order to ascertain regulatory compliance or need for regulatory action. The NRC inspectors use standard sampling techniques and normally split samples with the affected person. The stimuli for such inspections or investigations are varied. They may be routine, stem from allegations, or result from survey overflights based upon other evidence of contamination in the area being surveyed. The NRC bears the cost of its own testing, unless, in the case of licensees, the underlying inspection is subject to a fee pursuant to 10 CFR Part 170.

QUESTION 3. Does the NRC have the authority to require that the POTWs periodically report to the NRC any buildup of radioactive materials at their facilities? If so, under what authority?

ANSWER

The NRC has authority under section 161c. of the Atomic Energy Act of 1954, as amended, to obtain such information as the Commission may deem necessary to assist it in exercising any authority under the Act, enforcement or administration of the act, or any regulation or order issued thereunder. Pursuant to 10 CFR 2.204 a Demand For Information may be issued to a licensee or an unlicensed

person. If the POTW is a licensee, section 1610. also provides authority to require reports.

QUESTION 4. Does the NRC have any authority to regulate the concentration of radioactive materials subject to the Atomic Energy Act at a POTW if the concentration of such materials is not of a licensable amount? Please explain.

ANSWER

The NRC has no general regulations establishing de minimis quantities or concentrations of material not subject to regulation. However, certain kinds and quantities of radioactive materials have been exempted by rule from regulation when possessed by unlicensed persons. For example, 10 CFR 40.13 establishes exemptions for source material when it does not exceed .05% by weight of the compound or mixture in which it is found, in bulk untreated ore, in gas lamp mantles, and certain metallurgical alloys and counterweights. Exempt quantities and concentrations of byproduct material are limited to specific items, such as smoke detectors, which are manufactured or distributed under license. In these cases, the safety of the product in the hands of unlicensed persons has been carefully evaluated. Thus, the concept of "licensable amount" is inappropriate. The circumstances of each situation have to be reviewed against the codified regulations to determine if the regulatory requirements for exemption have been met. If those

requirements have not been met, the material remains subject to regulation.

QUESTION 5. Does the NRC have the authority to require that its licensees notify the POTWs prior to the disposal of any radioactive materials? If so, under what authority? What are the pros and cons of such a requirement?

ANSWER

The NRC has authority under section 1610. of the Atomic Energy Act of 1954, as amended, to require licensees to submit such reports as may be necessary to effectuate the purposes of the Act. It is not possible without considerable study of the implications of such a reporting requirement to identify meaningful pros and cons. However, the agency must comply with the requirements of the Paperwork Reduction Act in establishing the need for such reporting. One example may illustrate the complexity of the issue. Currently excreta from patients undergoing diagnostic or therapeutic treatment with isotopes (e. g. iodine 131 for certain thyroid conditions) may be flushed to sanitary sewers without restriction. Implementation of a reporting requirement for such occurrences may be difficult to achieve.

QUESTION 6. What authority, if any, do the POTWs have to refuse to allow NRC licensees to make disposals of radioactive materials into their systems? Please explain.

ANSWER

A recent letter to the city attorney for Laramie, Wyoming, discusses the issue raised in this question. A copy of the letter is attached. As the letter explains, a POTW may under certain circumstances refuse to allow disposals of radioactive materials into the treatment system.

QUESTION 7. To address the problem of excessive concentrations of radioactive materials at POTWs, how should the NRC and the Environmental Protection Agency coordinate their efforts?

ANSWER

The NRC and the EPA have established a coordinating committee of senior officials to discuss matters of mutual concern on an ongoing basis. A Memorandum of Understanding between the agencies, dated March 16, 1992, establishes the basic charter for cooperation between the agencies. A copy of the MOU is attached. This matter has not been the subject of discussions by the coordinating committee and there is no reason to believe that lack of coordination has contributed to the type of problem suggested.

Nonetheless, both NRC and EPA have a regulatory interest in waste water treatment sludges and incinerator ash and this matter will be placed on the committee's agenda.



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

NOV 09 1993

Hugh B. McFadden, Esq.
Laramie City Attorney
Corthell and King
221 South Second Street
P. O. Box 1147
Laramie, Wyoming 82070

Dear Mr. McFadden:

In your letter to the NRC of September 9, 1993 you requested an expression of views on the following question: "Can a municipality lawfully regulate or prohibit the discharge of radioactive materials into its wastewater treatment system, with or without an industrial pretreatment program mandated by EPA?" We understand the context of your question to be a city plan to begin producing sludge in 1996, and the related facts that Laramie has a hospital with a nuclear medicine department and that the University of Wyoming does some research with radioisotopes.

By necessity our response has to be general, limited to the principles of law that govern this agency and its relationships with states and municipalities. The primary legal principle is that the Atomic Energy Act of 1954, as amended, occupies the field with respect to issues of radiation protection in the use of source, byproduct, and special nuclear material, as these terms are defined in the Act. If, however, the basis for the state or local governmental action is something other than the protection of workers and public from the health and safety hazards of regulated materials, the action is not preempted. See, e.g. Pacific Gas and Electric Co. v. State Energy Resources Conservation and Development Commission, 461 U. S. 190 (1983). As a consequence of the Atomic Energy Act occupying the field dual Federal-State regulation of the radiation hazards associated with use of these materials is not allowed. See 10 C.F.R. 8.4 and 10 C.F.R. Part 150.

However the extension of these general Federal preemption principles to actions of State or Local government entities in their proprietary capacity (say as owners of POTWs) raises additional issues which have not been resolved definitely. More important here, however, is that if the city of Laramie were to have sound reasons, other than radiation protection, to require pretreatment of wastes from the hospital or university to eliminate or reduce radioactivity, such pretreatment would not fall afoul of the Atomic Energy Act. Thus, NRC regulations that allow users of regulated materials to discharge to sanitary sewers do not compel a waste water treatment operator to accept those radioactive materials. We note, however, that the materials regulated by this agency are exempted from regulation under the Federal Water

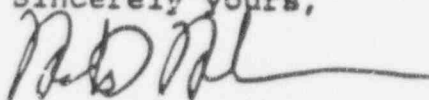
Pollution Control Act and the Resource Conservation and Recovery Act. Thus pretreatment to eliminate or reduce the regulated isotopes would not be required by these environmental statutes.

In January of 1994 new rules take effect in 10 C.F.R. Part 20 that will limit the discharge to sanitary sewer systems to only those licensed materials which are soluble in water or which are readily dispersible biological material (such as may be found in a university research laboratory), see 10 C.F.R. 20.2003. Finally, there is no limit on radioactivity that may be discharged to a sanitary sewer in excreta from patients undergoing medical diagnosis or therapy. You may wish to consult with the radiation safety officers of the hospital and university to gain an understanding of the technical characteristics of the isotopes used in these institutions and their fate in waste water treatment.

The problem of certain radioactive materials ending up in the sludges from waste water treatment, or in ash from the incineration of sludges, is well known to the staff of the NRC. A generic study is underway to understand the dimensions of the issue and whether it poses a particular health and safety matter that needs to be dealt with by more specific regulation. The Atomic Energy Act encourages the useful and beneficial uses of radioisotopes in medicine and research, at the same time the NRC is highly cognizant of the health risks to third parties that may result from such uses. We believe that our regulation is appropriately balanced between the need to protect the public from the undue hazards of the regulated materials and also to allow their beneficial use in a controlled manner.

I hope that this response will be helpful to you. If you have any further questions you may call either me at area code 301-504-1740, or Robert L. Fonner at area code 301-504-1643.

Sincerely yours,



Martin G. Malsch
Deputy General Counsel for
Licensing and Regulation

GUIDING PRINCIPLES FOR EPA/NRC COOPERATION AND DECISIONMAKING

Introduction

The Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC), in recognition of a mutual commitment to the effective and efficient protection of public health and safety and the environment, have developed this Memorandum of Understanding in order to establish a basic framework within which EPA and NRC will endeavor to resolve issues of concern to both agencies that relate to the regulation of radionuclides in the environment.

Goal

The goal of this Memorandum of Understanding is to foster cooperation in fulfilling the responsibilities of each agency to ensure protection of the public health and safety and the environment in accordance with existing agency responsibilities and authorities.

Principles

EPA and NRC, in carrying out the respective responsibilities of the two agencies in the regulation of radionuclides, will strive to:

1. Base regulatory decisions on a determination that such actions will result in a substantial reduction of significant risk to the public health and safety and the environment, and in making such decisions consider, to the extent permitted by law, the importance of the risk reductions to be achieved when compared to other radiological risks already subject to existing regulations, the overall economic impact on NRC licensees of additional regulatory requirements to achieve such reductions, and pursue the most efficient, cost-effective course in the regulation of those licensees.
2. Focus agency priorities on those significant safety and environmental problems subject to the authority of both agencies that offer the greatest potential for substantial risk reduction;
3. Avoid unnecessary duplicative or piecemeal regulatory requirements for NRC licensees, consistent with the legal responsibilities of the two agencies, and ensure that standards and regulations, when issued, can be effectively implemented; and

4. Effectively and responsibly carry out the provisions of Reorganization Plan No. 3 of 1970. Under the Plan, EPA issues generally applicable environmental limits on radiation exposure or levels, or concentrations or quantities of radioactive materials, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive materials, and NRC implements these standards by the use of its licensing and regulatory authority.

Implementation Guidance

A. Scope

For certain facilities or materials licensed or regulated by the NRC, EPA is required by statute to develop environmental standards for radionuclides which are applicable directly to NRC-regulated facilities or materials. For example, EPA is required to develop generally applicable environmental standards for offsite releases from radioactive material in high-level waste repositories under the Nuclear Waste Policy Act. For other program activities, such standards are authorized but, depending sometimes on the circumstances, are not legally required. With the exception of Section C, below, this Memorandum of Understanding is intended to address issues associated with both types of standards. Section C applies according to its terms where EPA standards are not legally mandated. This MOU does not apply to matters arising under RCRA or CERCLA.

B. General

Each agency will keep the other generally informed of its relevant plans and schedules regarding such activities, will respond to the other agency's requests for information to the extent reasonable and practicable, and will strive to recognize and ameliorate to the extent practicable anticipated problems with regard to implementation and consistency with other program activities.

Each agency will deal with the other in a spirit of cooperation to achieve the goals of this Memorandum of Understanding. Agency management will endeavor, to the maximum possible extent, to resolve informally and in a timely manner those differences identified as a result of the procedures contained in this Memorandum of Understanding. If differences cannot be resolved, the respective General Counsels of each agency will arrange for the matter to be presented by the necessary parties to the heads of both agencies for resolution.

Each agency will keep the other fully informed of its priorities for the development of regulations and will endeavor to develop a common understanding of the priorities and schedules for resolution, with the highest priorities accorded to initiatives which offer the greatest potential for significant risk reduction.

If both agencies agree, in accordance with these principles and guidance, that duplicative regulation in a particular area is undesirable, but nevertheless is required by law, then the agencies will cooperate in considering and, if appropriate, supporting legislative changes.

C. Governing Criteria and Procedures

This Section applies to the issuance of regulations for releases applicable to NRC regulated facilities or activities for releases into the environment of source, byproduct or special nuclear materials under the Clean Air Act. It also applies to the issuance of such regulations under the Atomic Energy Act and other provisions of law which may give rise to duplication of effort and overlapping regulation of NRC regulated facilities or activities, but only to the extent issuance of such standards is authorized but not legally mandated. Subject to the above, EPA and NRC agree as follows:

1. Criteria

- EPA's decisions not to impose emission standards for hazardous air pollutants under the Clean Air Act for NRC licensed materials or facilities will, in accordance with 112(d)(9) of the Clean Air Act, be based upon a determination that NRC's regulatory program provides an ample margin of safety to protect the public health. Similarly, EPA's decisions to impose or not impose other regulations regarding NRC licensed materials or facilities will be based upon a determination as to whether NRC's regulatory program achieves a sufficient level of protection of the public health and environment. /This determination may be influenced by particular risk reduction or risk prevention goals being pursued and this Memorandum of Understanding does not reflect agreement on such goals at this time. Ideally, agreement on risk reduction or prevention goals for radionuclides will be reached pursuant to paragraph D. below but in a particular case where EPA and NRC cannot agree on such goals, this Memorandum of

Understanding is without prejudice to EPA deciding to proceed with regulation, without NRC concurrence, based upon an EPA inability to find that NRC's program provides a sufficient level of protection.

- EPA and NRC will jointly seek to minimize unnecessary duplication of effort and overlapping regulation of NRC-licensed materials and facilities.

2. Procedures: In developing regulations in accordance with its authorities, if EPA, after finding that NRC's regulatory program fails to provide a sufficient level of protection of the public health and safety or the environment, identifies an area where it believes that EPA regulation applicable to NRC licensees regarding radionuclides may be necessary, EPA will, before developing and proposing rules in the Federal Register, informally and promptly inform the NRC of the basis for its position. If NRC believes that such direct regulation of its licensees by EPA is unnecessary, the two agencies will endeavor to resolve any issues, including consideration of information from NRC regarding the level of protection achieved by NRC regulatory programs and any necessary modifications to NRC's regulatory program, so that duplicative regulation and implementation are avoided. Decisions rendered pursuant to this paragraph will fully consider the implementation of existing regulatory programs in assessing the level of protection being achieved by regulated facilities. Final EPA conclusions on whether EPA will impose regulations applicable to NRC-licensed materials or facilities, and final NRC conclusions on whether NRC will develop modifications to its program, will be accomplished in a public process based upon a full and public record. Any decision made pursuant to this memorandum is subject to review and modification based upon actual experience with its implementation.

Similarly, if NRC undertakes the development of new regulations that would affect the level of protection of public health and safety and the environment related to an area where EPA has authority to issue regulations applicable to NRC licensees, or if NRC undertakes any rulemaking or other regulatory activity to fulfill its agreements made pursuant to this Memorandum of Understanding, NRC will promptly and informally notify and consult with EPA before developing and proposing rules in the Federal Register, and before any final decision by the Commission on the proposal.


Where either agency is developing new regulations for radionuclides in an area not covered by an existing regulatory program, the agencies will, before proposing new regulations, consult concerning what the proper division of responsibility should be.

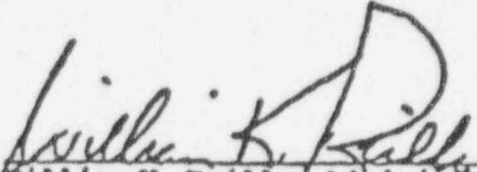
D. Risk Assessment

In carrying out this Memorandum of Understanding, the agencies will actively explore ways to harmonize risk goals and will cooperate in developing a mutually agreeable approach to risk assessment methodologies for radionuclides.

E. Other Provisions

1. Nothing in this Memorandum of Understanding limits the authority of either agency to exercise independently its authorities with regard to matters that are the subject of this Memorandum of Understanding.
2. Nothing in this Memorandum of Understanding shall be deemed to establish any right nor provide a basis for any action, either legal or equitable, by any person or class of persons challenging a government action or a failure to act.
3. This Memorandum of Understanding will remain in effect until terminated by the written notice of either party submitted six months in advance of termination.


Ivan Selin, Chairman
U. S. Nuclear Regulatory
Commission


William K. Reilly, Administrator
U. S. Environmental Protection
Agency

March 16, 1992

EXHIBIT "C"