

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

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



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

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ORIGINAL SIGNED BY

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

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IMOB r/f IMNS r/f
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JLieberman HLThompson
JTaylor

*See previous concurrence

OFC	IMOB*	E	IMOB*		IMOB*		RIII*		OGC*	
NAME	JDeCicco:jed		CJones		FCombs		WAxelson		RWeisman	
DATE	5/4/94		5/4/94		5/4/94		5/13/94		5/31/94	

OFC	OGC*		IMNS/DD*		IMNS*		NMSS		NMSS	
NAME	JGoldberg		WBrach		CPaperiello		GArlotto		RBernero	
DATE	5/31/94		/ /94		6/3/94		/ /94		6/16/94	

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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) 504-1543.

Sincerely,

A handwritten signature in dark ink, appearing to read "M. Malsch", with a long horizontal line extending to the right.

Martin G. Malsch
Deputy General Counsel for
Licensing and Regulation

Enclosure: As stated

cc: W. Parler
R. Bernero

~~931209 2138~~ 7pp

Enclosure 3

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 161o. 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

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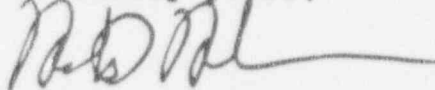
Pollution Control Act and the Resource Conservation and Recovery Act. Thus pretreatment to eliminate or reduce the regulated isotopes would not be required by these environmental statutes.

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

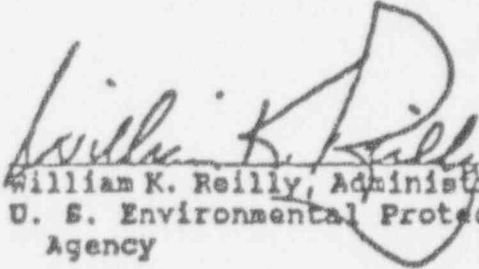
In carrying out this Memorandum of Understanding, the agencies will actively explore ways to harmonize risk goals and will cooperate in developing a mutually agreeable approach to risk assessment methodologies for radionuclides.

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



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



Northeast Ohio Regional Sewer District

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Mr. James Taylor
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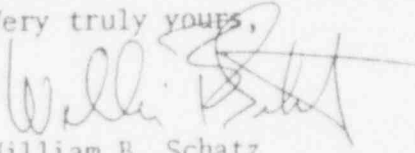
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William B. Schatz
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WBS/ydm

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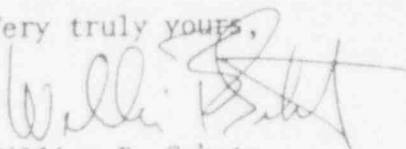
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