

ENFORCEMENT ACTION



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POLICY ISSUE

June 16, 1986

(NEGATIVE CONSENT)

SECY-86-179

For: The Commissioners

From: Victor Stello, Jr.
Executive Director for Operations

Subject: RADIATION TECHNOLOGY, INC., ROCKAWAY, NEW JERSEY

Purpose: To inform the Commission of the current status of enforcement actions against Radiation Technology, Inc. (RTI), Rockaway, New Jersey.

[REDACTED]

Discussion:

In SECY-86-93, the Commission was informed that on March 3, 1986, the Director, Office of Inspection and Enforcement (IE) issued an Order suspending a license of Radiation Technology, Inc., Rockaway, New Jersey based on findings that the licensee had operated its irradiator on numerous occasions with required safety interlocks on both conveyor and personnel access doors inoperable.¹ The Order suspended the license pending completion of a full investigation of these incidents. After the Order was issued, the licensee requested lifting of the suspension in several letters and meetings. The licensee's proposals for lifting the suspension included retaining independent consultants reporting directly to the RTI Board of Directors to conduct 24 hour surveillance of the licensee's operations to ensure that the facility was operated safely and in compliance with NRC requirements. In addition, the licensee proposed retaining an independent fourth party consultant to audit the activities on a weekly basis.

These licensee proposals provided reasonable assurance that temporary resumption of facility operations under these conditions would not endanger the health and safety of the public or plant workers. Based on these commitments,

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1 RTI owns and operates a large irradiator near Rockaway, New Jersey. A wholly owned subsidiary, South Jersey Process Technology, owns and operates an NRC-licensed irradiator near Salem, New Jersey. RTI also owns and operates irradiators through wholly owned subsidiaries in North Carolina and Arkansas. An up-to-date chronology of events is enclosed.



EX. 5

A/1

the Director, Office of Inspection and Enforcement issued a Conditional Recision of the Order Suspending License on March 13, 1986 again pending completion of the ongoing investigations. Since issuance of this Order the staff has conducted frequent unannounced inspections to verify that the operations are being conducted safely.

OI has conducted three full investigations of the events that led to issuance of the original suspension order. Although OI has only issued one of its three reports, all of the OI field work, which was ongoing at the time of the March 13 Order, is now essentially complete. On June 4, 1986, the Director, OI briefed the Director, IE, the Regional Administrator, Region I, and other staff on OI's findings. These findings indicate that Radiation Technology's Chief Executive Officer, three current managers, two former managers, four current irradiator operators and a contractor to RTI either (1) lied to the NRC during inspections and investigations conducted between September 1984 and May 1986, and/or (2) willfully directed the bypassing of required safety interlocks on the irradiator. OI will make a presentation of its findings to the Commission at the meeting scheduled for June 17, 1986.

On the basis of the recent OI findings, the staff had to determine whether immediate enforcement action was necessary to protect public health and safety even though all of the OI reports had not been issued.

 Ex. 4
However, the licensee had discussed plans to move some of those individuals to another licensed facility in Salem, New Jersey.
 Ex. 5

Since the suspension was conditionally lifted, the licensee's organization and management structure have changed significantly. The Chief Executive Officer has relinquished his position as President and, although he

remains the Chairman of the Board of Directors, has no responsibility for day-to-day direction of licensed activities. A new Vice-President of Operations and Engineering has been hired and given complete control of licensed activities. Further, a new Vice-President of Quality Assurance has also been hired. The position of President of RTI is temporarily held by three officers of the company while the search for a new President is pursued. Recently, the Manager of Operations was replaced following his resignation.

Under the direction of the new Vice-President of Operations and Engineering, operating procedures have been revised and upgraded, irradiator operators have been retrained and qualified, plant equipment has been repaired and replaced as necessary to enhance reliability, preventive maintenance procedures have been developed and implemented and the morale of the staff has apparently improved. Further, operators have been instructed by current RTI management to be completely truthful and open in all dealings with the NRC.

Ex 5

[REDACTED]

The previous President owns a significant part of the company, was active in facility operation to the point of directing the actions of the irradiator operators, and was.

Ex 6

[REDACTED]

The licensee continues to seek relief from the requirements of the Order under which it now operates. The licensee contends that the cost of the third party and fourth party consultants substantially exceeds the company's profit margin, is an unreasonable financial burden, and is punitive and no longer warranted, given the changes made in the organizational and management structure and the noted improvements in operations.

[REDACTED]

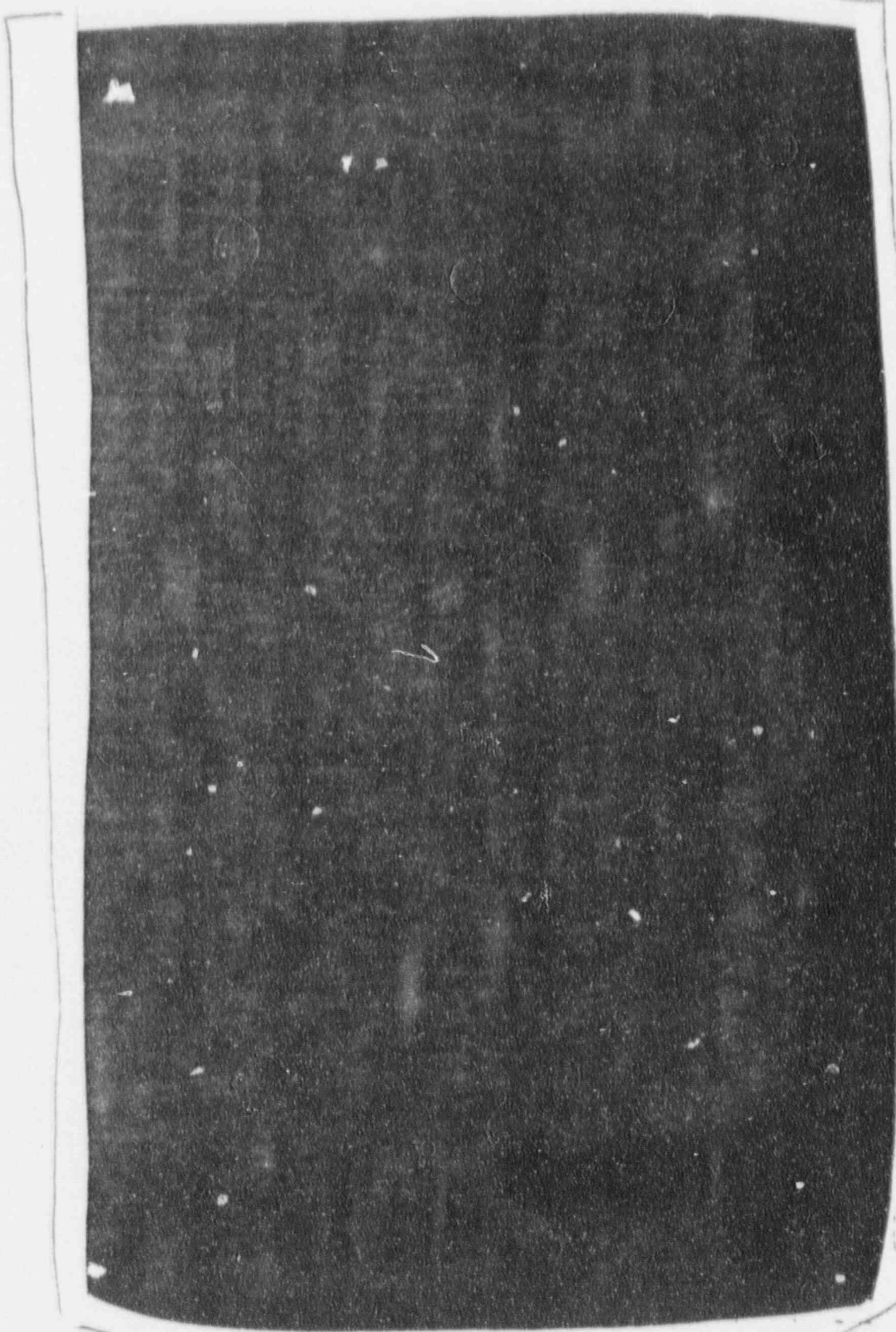
Ex 5

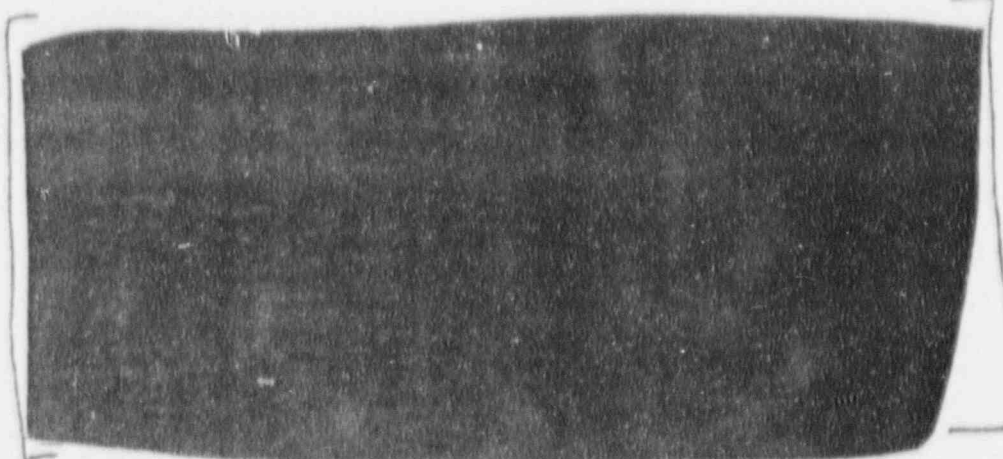


The Commissioners

- 5 -

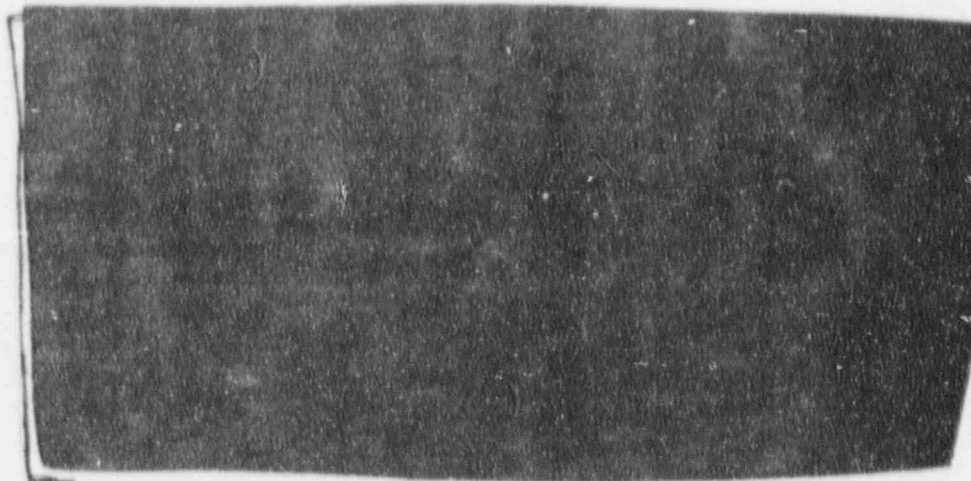
EX-5





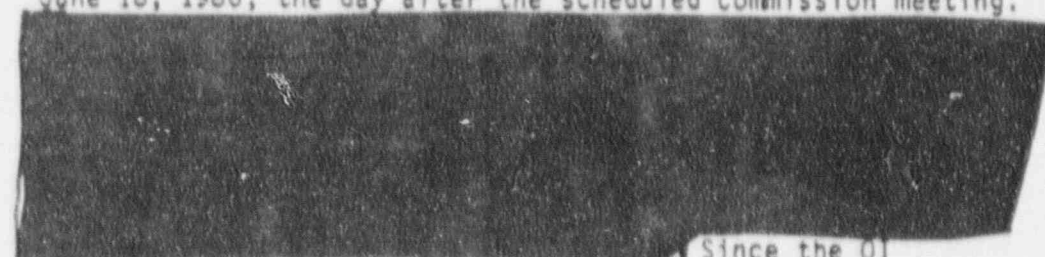
Ex 5

The staff will continue to monitor RTI's activities at the Rockaway facility, as well as the activities at RTI's other NRC licensed facility in Salem, New Jersey. Further, the staff will maintain contact with the States of North Carolina and Arkansas regarding the RTI facilities in those states.



Ex 5

As a result of repeated requests from the licensee to discuss lifting of the conditions under which it is currently operating, an enforcement conference has been scheduled for June 18, 1986, the day after the scheduled Commission meeting.



Ex 5

Since the OI investigation is now completed and the agency has the information it needs to make a decision, this decision should be made as quickly as possible.

The Commissioners

- 7 -



Ex 5

Victor Stello, Jr.
Victor Stello, Jr.
Executive Director for Operations

Enclosure: as stated

This paper is tentatively scheduled for consideration at a Closed Meeting on Tuesday, June 17, 1986. If the Commission does not provide direction to the staff on June 17, 1986, SECY will notify the staff on Wednesday, June 18, 1986 that the Commission by negative consent, assents to the action proposed in this paper.

DISTRIBUTION:

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ENCLOSURE

RADIATION TECHNOLOGY: SUMMARY OF EVENTS


Type of Licensee: Radiation Technology Inc. (RTI) operates a large irradiator facility which uses sealed cobalt-60 sources to produce high intensity gamma ray fields for sterilization of medical equipment and for other industrial applications.

Events Preceding Issuance of the Order Suspending License dated March 3, 1986


1. September 1984 - NRC unannounced inspection
 - Inspector found that licensee had been periodically operating the irradiator with the interlock system on conveyor openings to the service irradiator disabled, contrary to license. Apparently done under direction of Management.
 - A Confirmatory Action Letter (CAL) was issued by Region I to assure licensee would operate with required interlock systems operable and cease operation if any safety interlocks became inoperable.
 - An OI investigation of circumstances was requested.
2. December 1985 - OI investigators found that:
- January 1986
 - President and Operations Manager directed disabling of interlocks in April, 1984 memorandum, and the licensee continued to operate at times with conveyor interlock systems disabled after the CAL was issued.
 - In November 1985, the licensee replaced its interlock system without seeking required NRC approval.
3. Feb. 26, 1986 - NRC unannounced inspection
 - Inspectors found that licensee was operating its facility while the interlock on the personnel access door to the irradiator was inoperable contrary to license requirements.
4. March 3, 1986 - Order Suspending License Effective Immediately issued, pending results of further OI investigation.




Enclosure 1

Events Following the March 3 Suspension and Preceding Conditional
Rescission of Suspension, dated March 13, 1986

5. March 4-10, 1986 - Licensee submitted several proposals and met with NRC staff seeking reinstatement of its license to operate. Proposals which addressed various staff concerns included:
- repairing failed systems and doing other maintenance
 - complete check of interlock system by qualified engineer
 - retraining of personnel
 - 
 - establishment of management structure that acknowledged preeminence of safety by introduction of a "Third Party" to provide oversight of daily operations of the facility
 - The "Third Party" was given authority to halt operations if unsafe conditions and noncompliance with NRC requirements were found
 - An additional consultant ("Fourth Party") was also proposed to provide audits of operations and corrective actions with reports directly to the NRC and RTI Board of Directors.
6. March 13, 1986 - Conditional Rescission of the Suspension was issued subject to the licensee's consent to additional conditions for operation. These included:
- full-time supervision of daily operations by the licensee-proposed independent "Third Party" consultant (Hydro Nuclear Services)
 - training of employees in requirements of the Order
 - audits by the additional "Fourth Party" consultant.

Events Following Conditional Rescission of Suspension, dated March 13, 1986

7. March 13, 1986 - Third Party Consultant identifies violation of Rescission Order.
 - Violation involved operation of irradiator on March 13, 1986 after issuance of the Rescission Order, but prior to the NRC receiving a copy of the contract between the licensee and its "Third Party" consultant, as required by the Order. "Third Party," Hydro Nuclear Services, orders shutdown of the irradiator until the NRC has received a copy of the contract.
 - No major safety problems identified
8. March 14, 1986 - NRC unannounced inspection
 - Reviews violation identified by Consultant on March 13, 1986.
 - No major safety problems identified.
9. March 15, 1986 - "Fourth Party" consultant,  performs audit EX. 6
 - Discusses March 13, 1986 shutdown - licensee "believed it was following the order faithfully".
 - All other applicable provision of the Order were being followed.
 - "No unacceptable conditions were identified".
10. March 16, 1986 - Licensee requests hearing on suspension Order.
11. March 17, 1986 - Licensee continues to seek changes to the Conditional Rescission.
 - The "Third Party" consultant has shut down facility operations several times when it felt conditions warranted it. Each time, licensee takes action to satisfy "Third Party" and resumes operations.
 - Staff remains convinced terms of conditional rescission are necessary to provide reasonable assurance for safe operation.
12. March 20, 1986 - NRC unannounced inspection
 - No violations or safety problems identified

13. March 21, 1986 - Hydro Nuclear Services report covering period March 13 - March 20, 1986
- "Irradiator . . . has operated in a safe condition and met the requirements specified by the NRC"
 - Discusses shutdown of licensee on March 13, 1986
14. March 22, 1986 -  performs "Fourth Party" audit Ex. 6
- Includes list of recommendations to improve licensee's program
 - No major safety problems are identified
15. March 26, 1986 - Hydro Nuclear Services report covering period March 20-26, 1986
- Discusses repeated equipment failures
 - "Irradiator . . . has operated in a safe condition and met the requirements specified by the NRC"
16. March 28, 1986 -  performs "Fourth Party" audit Ex. 6
- Identifies open and closed items from previous audit
 - No major safety problems are identified
17. April 2, 1986 - Hydro Nuclear Services report covering the period March 27 - April 2, 1986
- Identifies problem areas in shift turnover and training in shipment of radioactive materials
 - "Irradiator . . . has operated in a safe condition and met the requirements specified by the NRC"
18. April 8, 1986 -  performs "Fourth Party" audit Ex. 6
- Identifies findings requiring corrective action
 - Inadequate survey records
 - Inadequate training in DOT regulations
 - Improvement needed in analytical procedures
 - Improper functioning of demineralizer (air in-leakage)
 - RTI internal audit revealed 50 commitments, many of which are not being met

- Failure to follow commitments "can be viewed as a breakdown in management controls"
- 19. April 11, 1986 - RTI withdraws March 16, 1986 request for a hearing on the suspension order
- 20. April 16, 1986 - NRC unannounced inspection:
 - o Identifies one violation - the maze monitor was wired into the interlock system such that, contrary to licensee conditions, the personnel door could be opened before the radiation levels in the maze were at a safe level. This was corrected by the licensee prior to the conclusion of the inspection.
- 21. April 16, 1986 - Hydro Nuclear Services report covering the period April 10-April 16, 1986.
 - o Discusses improved morale and "smoother operating facility".
- 22. April 18, 1986 - [REDACTED] performs "Fourth Party" audit EX. 6
 - o Significant progress has been made in developing radiation protection training program
 - o Demineralizer has been repaired
 - o Two outstanding items
 - survey records
 - internal audit findings
- 23. April 23, 1986 - Hydro Nuclear Services report covering the period April 17 - April 23, 1986
 - o Describes training to be provided by licensee to its irradiator operators on April 24-25, 1986.
 - o Discusses correction of violation identified during April 16, 1986 NRC inspection
 - o "Irradiator . . . has operated in a safe condition and met the requirements specified by the NRC"
- 24. April 27, 1986 - [REDACTED] performs "Fourth Party" audit EX. 6
 - o "Evidence of the last three independent audits points to a strong effort to meet commitments"

- "It is appropriate to seek a reduction in the level of independent oversight"

25. April 30, 1986 - Hydro Nuclear Services report covering the period April 24 - April 30, 1986

- Discusses problem with perimeter fence
- "Irradiator . . . has operated in a safe condition and met the requirements specified by the NRC"

26. May 6, 1986 - Hydro Nuclear Services report covering the period April 30 - May 6, 1986

- Discusses continuing problem with perimeter fence
- "RTI is presently meeting 45 of 61 NRC commitments . . ." and schedules have been prepared to ensure that responsible personnel know when each commitment is to be performed"

27. May 20, 1986 - NRC unannounced inspection

- No violations or safety problems identified

28. May 21, 1986 - Hydro Nuclear Services report covering the period May 14 - May 20, 1986

- "On May 14, 1986, a cease and desist order of irradiator operations was issued by the Third Party due to malfunctions that resulted in totes being turned over and creating hazardous working conditions . . . and operation of the irradiator was allowed to resume two hours after the shutdown"

29. June 5, 1986 - Hydro Nuclear Services report covering the period May 28 - June 3, 1986

- Reports the installation of an "Emergency Conveyor Stop Button" on the irradiator console to improve the health and safety of RTI employees
- "Irradiator . . . has operated in a safe condition and met the requirements specified by the NRC"

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RECEIVED-REGISTRATION

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February 11, 1991

Mr. Richard Lavins
FOI Staff
1717 H Street NW
Nuclear Regulatory Commission
Washington, DC 20555

APPEAL OF INITIAL FOIA DECISION

91-A-5CE(90-553)

Rec'd 2-19-91

Re: FOIA 90-553

Dear Mr. Lavins,

I would like to take this opportunity to formally appeal the decision of the NRC to withhold documents recently requested by me. It is my belief that the intent of Congress was to require the dissemination of the information being requested, unless it involves national security, confidential business matters or material that is directly involved with an ongoing investigation and which would compromise a fair and unbiased result. I can understand that there may be one or two documents that will fit this category, but it is hard to conceive that all of the many documents cited in Appendix A to E as being withheld for just that reason.

Further, I would like to request in addition to the material currently being sought, Transcripts of NRC Enforcement materials involving Radiation Technology, Inc. (RTI) which took place in May, June and July 1986. Enclosed with the official transcripts should be all handwritten notes of participants if available and internal memos associated with those enforcement matters.

Your prompt attention to this request would be appreciated.

FREEDOM OF INFORMATION
ACT REQUEST

FOIA-91-70
Rec'd 2-19-91

Sincerely,



Martin A. Welt, Ph.D.

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