



UNITED STATES
 NUCLEAR REGULATORY COMMISSION
 REGION I
 478 ALLENDALE ROAD
 KING OF PRUSSIA, PENNSYLVANIA 19108

Jim

Docket No. 030-07022

APR 17 1989

License No. 29-13613-02
 EA No. 89-080

MEMORANDUM FOR: William T. Russell, Regional Administrator
 THRU: Malcolm R. Knapp, Director *MR 4/17*
 Division of Radiation Safety and Safeguards
 FROM: Lee H. Bettenhausen, Chief
 Nuclear Materials Safety Branch
 SUBJECT: ENFORCEMENT CONFERENCE WITH RADIATION TECHNOLOGY, INC.
 (aka RTI, Incorporated)

Attached is background information for the Enforcement Conference to be held at Region I at 10:00 a.m. on April 26, 1989, with Radiation Technology, Incorporated. The meeting will include a discussion of violations identified during the inspection conducted on March 21 and 23, 1989.

Ten violations were identified during the course of the inspection. The principle areas of concern are the apparent programmatic breakdown of management controls, the licensee's failure to respond effectively to the failure of a personnel access control device that was important to safety, and the associated failure to discontinue operations until such safety device was fully functional.

A briefing is scheduled at 3:30 p.m. on April 24, 1989, in the DRSS Conference Room.

Lee H. Bettenhausen
 Lee H. Bettenhausen, Chief
 Nuclear Materials Safety Branch
 Division of Radiation Safety
 and Safeguards

Attachments:

1. Notice of Significant Licensee Meeting
2. Enforcement History
3. Inspection Report No. 030-07022/89-001
4. Draft Notice of Violation

Information in this record was deleted in accordance with the Freedom of Information Act, exemptions 5
 FOIA-90-334

E/B

William T. Russell

2

cc:

J. Allan, RI

~~██████████~~

L. Bettenhausen, RI

J. White, RI

D. Holody, RI

K. Christopher, RI

J. Gutierrez, RI

R. Cunningham, NMSS

J. Lieberman, OE

J. Goldberg, OGC

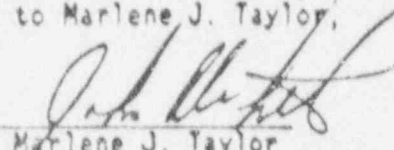
U.S. NUCLEAR REGULATORY COMMISSION
REGION I

NOTICE OF LICENSEE MEETING

Name of Licensee: Radiation Technology, Incorporated (RTI)
Name of Facility: Radiation Technology, Incorporated (RTI)
Docket No.: 030-07022
Time and Date of Meeting: 10:00 a.m., April 26, 1989
Location of Meeting: USNRC Region I, DRSS Conference Room
475 Allendale Road
King of Prussia, Pennsylvania 19406
Purpose of Meeting: Enforcement Conference to discuss the findings of
Inspection No. 030-07022/89-001, including failure to
discontinue irradiator operations with a personnel
access control device out-of-service
NRC Attendees: William T. Russell, Regional Administrator
Malcolm R. Knapp, Director, Division of Radiation
Safety and Safeguards
Lee H. Bettenhausen, Chief, Nuclear Materials Safety
Branch
Daniel J. Holody, Enforcement Officer
John R. White, Chief, Nuclear Materials Safety
Section C
Marlene J. Taylor, Health Physicist
Licensee Attendees: John Scandalios, President and CEO
Tass Varaklis, Vice President of Operations
and Engineering
John Russen, Radiation Safety Officer

Note: Attendance by NRC personnel at this meeting should be made known by
4:45 p.m., on April 25, 1989 via telephone call to Marlene J. Taylor,
Region I, at FTS 8-346-5311.

Prepared By:


Marlene J. Taylor

Distribution:

Victor Stello, Jr., Executive Director for Operations
Hugh L. Thompson, Jr., Deputy Executive Director for Regional Operations
James Lieberman, Director, Office of Enforcement
Robert M. Bernero, Director, Office of Nuclear Material Safety and Safeguards
Brent Clayton, Regional Coordinator, EDO
Richard Cunningham, Director, Division of Industrial and Medical Nuclear
Safety, NMSS
John H. Austin, Acting Chief, Medical, Academic, and Commercial Use Safety
Branch, NMSS
Lawrence J. Chandler, Office of the General Counsel
Jack R. Goldberg, Office of the General Counsel
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UNITED STATES
 NUCLEAR REGULATORY COMMISSION
 REGION I
 478 ALLENDALE ROAD
 KING OF PRUSSIA, PENNSYLVANIA 19408

APR 17 1989

Docket No. 030-07022
 EA 89-080

License No. 29-13613-02

Radiation Technology, Incorporated
 ATTN: Mr. John Scandalios
 President
 108 Lake Denmark Road
 Rockaway, New Jersey 07866

Gentlemen:

Subject: Inspection No. 030-07022/89-001

This letter refers to the inspection conducted by Mariene J. Taylor of this office on March 21 and 23, 1989, of activities authorized by NRC License No. 29-13613-02, and to the discussions of our findings held by Ms. Taylor with you and John J. Russen at the conclusion of the inspection.

Areas examined during this inspection are described in the NRC Region I Inspection Report which is enclosed with this letter. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations and measurements by the inspector.

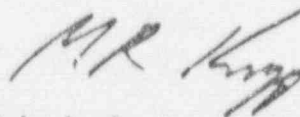
As discussed in a telephone conversation on April 13, 1989, between Mr. Varaklis and Mr. Lee Bettenhausen of this office, the apparent violations identified during this inspection will be the subject of an Enforcement Conference to be held at our office in King of Prussia, Pennsylvania at 10:00 a.m. on April 26, 1989. We understand that you, Tess Varaklis and John Russen of your staff will attend this meeting. You should be prepared to discuss the causes of these apparent violations and your proposed corrective actions. We are particularly concerned with your actions relative to the failure of the lock mechanism on the Maze Access Door in early February 1989, management's apparent failure to take effective corrective action, and their failure to discontinue operations as required by 10 CFR 20.203(c)(6). Enforcement action for these violations will be considered by the NRC following the Conference. A copy of the NRC Enforcement Policy as described in Appendix C of 10 CFR Part 2, is enclosed for your information. Directions to the NRC Region I office are also included.

In accordance with 10 CFR 2.790(a), a copy of this letter and the enclosures will be placed in the NRC Public Document Room.

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No reply to this letter is required. Your cooperation with us in this matter is appreciated.

Sincerely,



Malcolm R. Knapp, Director
Division of Radiation Safety
and Safeguards

Enclosures:

1. NRC Region I Inspection Report No. 030-07022/89-001
2. 10 CFR 2
3. Directions to the Region I Office

cc:

Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New Jersey

Roy P. Lessy, Jr.
Akin, Gump, Strauss, Hauer and Feld
1333 New Hampshire Avenue, N.W.
Suite 400
Washington, D.C. 20036

bcc:

Region I Docket Room (w/concurrences)
J. Lieberman, OE
L. Chandler, OGC
R. Cunningham, NMSS
J. Goldberg, OGC
D. Holody, RI
M. Knapp, RI
L. Bettenhausen, RI
J. White, RI
M. Taylor, RI

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-07022/89-001

Docket Nos. 030-07022

License No. 29-13613-02

Priority 1

Category E3

Licensee: Radiation Technology, Incorporated
108 Lake Denmark Road
Rockaway, New Jersey 07866

Inspection Conducted: March 21 and 23, 1989

Inspector:

John White
Marie J. Taylor, Health Physicist

4/14/89
date

Approved by:

John R. White
John R. White, Chief
Nuclear Materials Safety Section C

4/14/89
date

Inspection Summary: Routine Safety Inspection Conducted on March 21 and 23, 1989, (Report No. 030-07022/88-01) for the purpose of verifying and validating the licensee's performance with respect to matters that directly and indirectly affect radiological safety. The scope of this inspection includes determining conformance with regulatory requirements and assessing performance relative to management controls and quality operations.

Results: Within the scope of this inspection, ten violations were observed. 1) change of procedure without prior NRC consent as specified in License Condition 22 (Section 4); 2) failure to maintain high radiation area entry control device in accordance with 10 CFR 20.203 (Section 4); 3) failure to install the required water level gauge in accordance with the license application commitment (Section 4); 4) failure to establish the storage pool radiation monitor alarm in accordance with the license application commitment (Section 4); 5) failure of RSO to perform assigned duties as represented by License Condition 26 (Section 4); 6) failure to perform monthly confirmatory surveys of the Water Treatment System as represented by License Condition 26 (Section 4); 7) failure to respond to NRC required audits as specified in License Condition 20 A (Section 5); 8) failure to provide exposure history reports relative to terminated employees in accordance with 10 CFR 20.408 and 20.409 (Section 7); 9) failure to perform area radiation surveys in accordance with License Condition 15 (Section 8); 10) failure to adhere to procedures relative to the performance of preventative maintenance checks as represented in License Condition 26 (Section 9).

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2-12-89

DETAILS

1.0 Persons Contacted

*John Scandalios, President & Chief Executive Officer
Tass Varaklis, Vice President-Operations and Engineering
*John Russen, Radiation Safety Officer
John Singleton, Plant Supervisor
Andy Fredrich, Irradiator Operator
Mike Ayers, Irradiator Operator
Ann Bishop, Clerical Staff
John Schlecht, Physicist

*Present at Exit Interview

2.0 Purpose and Scope

2.1 Scope of Activities

Radiation Technology Incorporated (RTI) is authorized by License No. 29-13613-02 to use, receive, acquire, possess, and transfer the listed by-product material subject to specified conditions:

<u>Material</u>	<u>Max. Amount (Form)</u>	<u>Use</u>
A. Cobalt 60	12,000 Curies per source; 3,000,000 Curies, total (Sealed Sources)	RTI Model 2101, Irradiator for service irradiation; storage in pool irradiator
B. Cobalt 60	320 Curies (Sealed Source)	Storage in AMERAY Irradiator
C. Strontium 90	30 Microcuries (Sealed Source)	Instrument Calibration
D. Strontium 90	120 Millicuries (Sealed Source)	Storage
E. Hydrogen 3	15 Curies	Storage
F. Scandium 46 (with trace activation products)	10 Millicuries (Gemstones)	Storage
G. Cobalt 60	10 Millicuries (Contamination any form)	Storage
H. Cesium 134	0.1 Millicurie (Rocks)	Storage

2.2 Purpose of Inspection

On March 17, 1988, License No. 29-13613-02 was amended in its entirety for a probationary period of two years, to expire March 31, 1990. The current amendment, Amendment No. 25, was issued January 7, 1989. The purpose of the inspection was to verify and validate that the licensee was performing in accordance with applicable regulatory requirements, was maintaining adequate management control over licensed activities, and that the health and safety of workers and the general public is not compromised by continued operations.

3.0 Organizational Structure

This inspection verified that licensed activities were being performed under the supervision and in the physical presence of only those persons specifically identified in Condition 11.A of License No. 29-13613-02. Pursuant to Condition 11.E of the license, it was verified that persons specifically excluded were not involved in any licensed activity.

The licensee has recently moved their corporate operations to the Rockaway facility. Mr. John Booth has resigned as President of Radiation Technology, Inc. but remains a member of the Board of Directors. Mr. John Scandalios has since replaced Mr. Booth as President and CEO.

License Condition 1 names the licensee as Radiation Technology, Incorporated. Correspondence from the licensee since October 1988, indicates the licensee's name as Process Technology of North Jersey, a wholly owned subsidiary of RTI, Incorporated. The proposed name change and the associated requirement for a license amendment was discussed with the Vice President of Operations and Engineering on January 19, 1988. A license amendment request relative to this matter was sent to the NRC in a letter dated March 23, 1989, and is currently under review.

4.0 Control of Facility, Design and Equipment

In August 1988, the licensee refurbished the facility and installed a batch irradiation processing system. The area in the pool from which pool water was previously leaking was repaired during the refurbishing of the facility. No further leakage problems have been identified.

On February 1, 1989, one of the operators experienced a problem with the console key switch. In an effort to resolve the problem, the RSO removed the key switch from the console and exchanged it with the start-up key switch located in the cell. On February 9, 1989, the first shift operator noted a malfunction with the cell start-up key switch, i.e., the switch remained in the "on" position allowing the operator to initiate start-up of the irradiator without activating the cell start-up key switch, contrary to the design of this safety feature.

At that time, the RSO met with the Vice President of Operations and the Vice President of Quality to review the license to determine if it would be possible to remove the cell start-up key switch and install a toggle switch in its place, temporarily. The licensee decided that to do so would not violate the license. Subsequently, a toggle switch was installed to allow operation of the irradiator until a replacement key switch was received. A new key switch was installed on the first shift February 10, 1989.

License Condition 22 states that the licensee shall follow the written procedures contained in the following: Procedure 9.100 "Irradiator Start-up", Procedure 9.102 "Irradiator Interlock Testing", and Procedure 9.500 "Preventative Maintenance". All changes to these procedures must be approved, prior to implementation, by the Commission.

Procedure 9.100 submitted with letter dated May 25, 1988, requires the 90 second start-up time delay (cell start-up key switch) to be activated with the machine key. The licensee's removal of the 90 second start-up time delay key switch (cell start-up key switch) and the installation of a toggle switch for the purpose of continuing irradiator operations without the prior approval from the NRC is an apparent violation of License Condition 22.

In late January 1989, an operator experienced trouble with the personnel access door lock mechanism, a component of the Maze Access Control system. The mechanism was loose which caused the interlock malfunction. The RSO was notified. Subsequently, the RSO and the operator tightened the door lock mechanism which resolved the malfunctioning of the interlock. This problem continued to recur requiring the operator to repeatedly tighten the lock mechanism.

During the week of February 5, 1989, the operator again experienced problems with the personnel access door lock mechanism which affected the interlock. In this case, the lock mechanism malfunctioned such that it no longer provided a positive lock to prevent inadvertent personnel access to the irradiator cell. This condition was such that an individual could have opened the access door without the irradiator key. The operator notified the RSO and the Plant Superintendent of the problem. While there was an attempt to once again tighten the lock mechanism, no effective corrective action was taken to resolve this matter and processing was allowed to continue.

On February 14, 1989, during an audit, the Vice President of Quality was able to open the personnel access door without having to use the irradiator key. The source immediately dropped to the shielded position as a result of the operation of the backup access control system. Operations were immediately suspended until the lock mechanism was replaced later that day.

10 CFR 20.203(c)(6)(1) requires that each entrance or access point to a high radiation area be equipped with entry control devices which shall function automatically to prevent individuals from inadvertently entering the area when such radiation levels exist.

The licensee's failure to equip the access to the irradiator cell, a high radiation area, with a fully functional personnel access door lock mechanism for approximately nine days is an apparent violation of 10 CFR 20.203(c)(6)(1).

Section D of Item 10.1 contained in letter dated April 8, 1988, states that the Radiation Safety Officer is responsible for ensuring full compliance with all elements of the Radiation Protection Program for the Plant. The correct operation of the Maze Access Control, specifically the electric latch that locks the cell door shut while the irradiator is in the exposed position is a required safety feature and an element of the plant's Radiation Protection Program.

The failure of the Radiation Safety Officer to assure all elements of the Radiation Protection Program, including Maze Access Control, were adequately established, implemented and maintained is an apparent violation of License Condition 26.

Section 9.1.H of the letter dated April 8, 1988, describes the irradiator control alarms available at this facility. Item 5 of this section states that there will be a needle gauge in the control room to monitor the irradiator pool water level. As of March 23, 1989, the licensee had not installed such a gauge; nor was such installation planned. This discrepancy was addressed in an internal quality assurance audit, dated September 23, 1988. However, no corrective action was taken. Currently, the licensee has the high and low water alarms monitored only by the systems computer.

The licensee's failure to have a needle gauge to monitor the irradiator pool water level is an apparent violation of License Condition 26.

Item 4 of Section 9.1.H. contained in the letter dated April 8, 1988, requires that a radiation monitor be mounted over the storage pool that would alarm if high radiation levels existed. This alarm is to be audible in both the control room and the storage pool room.

A check of the monitor performed by the inspector and an operator revealed that the alarm was audible in the storage pool area and the area outside the control room, but not in the control room. This deficiency was previously identified during a licensee's safety audit on February 14, 1989, however, no corrective action was taken.

The licensee's failure to have the storage pool's radiation monitor alarm audible in the control room is an apparent violation of License Condition 26.

The survey meters utilized by the operators to enter the cell were operable and had been calibrated within the last six months. The survey meters had been calibrated by Radiation Management Consultants (RMC).

The monitors used to detect elevated radiation levels in the Water Treatment System and in the storage pool are checked by the licensee for proper operation every six months. Procedure 10.2.E.3 submitted in letter dated June 7, 1988, requires that the monitor on the Water Treatment System be verified for proper operation monthly by using a portable survey instrument.

An irradiator operator stated that the monitor on the Water Treatment System is checked every six months for proper operation with a check source, but a monthly verification of proper functioning with a portable instrument is not performed. The inspector noted that though weekly surveys of the Water Treatment System were performed, such surveys were not sufficient to verify the proper functioning of the installed radiation monitor.

The licensee's failure to perform monthly confirmatory surveys of the Water Treatment System to assure proper operation of its radiation monitor is an apparent violation of License condition 26.

pH and conductivity checks of the pool water are conducted weekly. Results were within specifications. Prior to release, water is checked for cobalt 60 content to be less than 5×10^{-6} microcuries per milliliter, and proper pH (7.0 ± 0.5). All results were within specifications.

5.0 Audits

Quarterly audits are conducted by Michael Slobodian as required by License Condition 20.A., and were last performed on September 24, 1988 and December 21, 1988. A written report of the findings was furnished to both the licensee and to the NRC. License Condition 20.A. also requires that the licensee, within ten working days of the receipt of each report, provide to the Commission and to the Board of Directors of Radiation Technology, Incorporated, a written description of any corrective actions taken in response to the audit findings.

A review of Commission records indicate that no response was received from the licensee regarding their corrective actions to the items identified in the December 21, 1988, audit conducted by Mr. Slobodian. The RSO stated that he had not written a response to the audit because he was not aware that it contained any deficiencies. The inspector informed the RSO that the audit contained several deficiencies which required corrective action responses.

The licensee's failure to respond to a quarterly audits conducted under License Condition 20.A. is an apparent violation of this condition.

The licensee also conducts their own safety audits. These are conducted by the Vice President of Quality. The last audits were performed on September 23, 1988 and February 14, 1989. The licensee is required by internal procedures to respond to the deficiencies identified.

The audits conducted by Mr. Slobodien and the Vice President of Quality identified several deficiencies regarding the operation of the facility. However, the licensee has failed in several instances to provide the corrective actions needed to rectify these deficiencies. For example, as of the date of the inspection, the licensee had not provided corrective action responses for the following deficiencies: failure to have a needle gauge to monitor the irradiator pool water level was identified September 23, 1988; failure to have the storage pool radiation monitor's alarm audible in the control room was identified February 14, 1989; failure to use approved procedures was identified September 23, 1988; failure to provide exposure reports to terminated employees was identified December 21, 1988; and failure to perform area radiation surveys as required by License Condition 15 was identified September 24, 1988 and December 21, 1988.

6.0 Training and Instruction to Employees

The inspector reviewed the training files for the two operators who were most recently qualified. Both individuals had successfully completed written examinations. The graded examinations were maintained in their respective files. The operators interviewed were knowledgeable of the licensee's operating and emergency procedures.

A review of the training files for the other operators showed that they had received and passed the required refresher training.

Several new Materials Handlers were given their required Radiation Worker training and test on March 19, 1989, but did not pass. These individuals are to receive additional training and be retested. A new test for these individuals was being developed at the time of the inspection.

General radiation safety training had been given to the other office staff on January 18, 1989. A video tape on Radiation Safety was also given to these employees to review.

No violations identified.

7.0 Personnel Protection - External

The inspector reviewed personnel dosimetry records that were maintained by the licensee. Records were maintained in accordance with 10 CFR 20.401 and there were no exposures in excess of the regulatory limits.

A review of dosimetry reports to terminated employees showed that numerous employees had not received their dosimetry reports even though they had left the company several months ago; and that a copy of these reports had not been furnished to the Commission. This deficiency was identified in the December 21, 1988, audit conducted by Mr. Slobodien, but was not corrected until March 22, 1989, when identified by the inspector as a possible violation.

10 CFR 20.408(b) and 20.409(b) requires the licensee to report to the Commission, and to the individual involved, the radiation exposure of each individual who has terminated employment. Such report shall be furnished within 30 days after the exposure of the individual has been determined by the licensee or 90 days after the date of termination of employment or work assignment, whichever is earlier.

The licensee's failure to send terminated individuals their exposure reports and to furnish a copy of these reports to the Commission within the allotted time is an apparent violation of 10 CFR 20.408(b) and 20.409(b).

Area surveys are conducted in the restricted area and its adjacent areas by the licensee on a quarterly basis. No areas of concern have been identified.

8.0 Receipt and Transfer of Material

The licensee shipped cobalt 60 from their South Jersey facility to their Rockaway facility on August 15, 1988, and November 22 and 23, 1988. In both cases RTI was the shipper and maintained the documents needed for the transfers.

Audits conducted by both Mr. Slobodien and the Vice President of Quality indicate that records of the surveys conducted on the shipments were not always complete and in one instance records of surveys were not maintained.

An audit conducted on September 24, 1988, by Mr. Slobodien indicated that after receiving and installing several cobalt 60 sources in the irradiator, on or about August 15, 1988, area radiation surveys were not conducted until September 12, 1988. In that period, processing occurred. A copy of the survey results was not sent to the Commission until October 11, 1988.

The December 21, 1988, audit conducted by Mr. Slobodien again identified that area radiation surveys were not conducted after receiving and installing additional cobalt 60 sources in the irradiator on November 22 and 23, 1988, and prior to the initiation of processing. A survey was conducted by the licensee on December 8, 1988. A copy of the survey was forwarded to the Commission on December 12, 1988.

License Condition 15 requires that after installation of cobalt 60 source(s) greater than the quantity for which a previous radiation survey has been conducted, and prior to initiation of the irradiation program, a radiation survey shall be conducted to determine the maximum radiation levels in each area adjoining the irradiation room. A detailed report of the results of the survey is to be sent to the Commission no later than 30 days following the installation of the source(s).

The licensee's failure to perform area radiation surveys after installation of additional cobalt 60 source(s) and prior to initiation of the irradiation program is an apparent violation of License Condition 15.

9.0 Maintenance and Inspection

The inspector reviewed logs of safety interlock tests and noted that these were being performed as required on a daily basis. The inspector requested the licensee to perform a safety interlock test during the inspection. All interlocks were verified to be operational and functioning.

The inspector reviewed the weekly, monthly and quarterly preventative maintenance records. The records indicate that maintenance checks were not initiated until January 20, 1989, even though the irradiator renewed operations in August 1988 following a two week shut down for refurbishing. In addition, the records indicate that from January 20, 1989, to March 23, 1989, no quarterly or semiannual preventative maintenance checks had been performed. Additionally, the records indicate that not all of the monthly checks had been performed.

A licensee employee stated that the operators do not always have enough time to perform these procedures. The Plant Superintendent stated that the delay, from August 1988 following the start-up of operations to January 1989, in performing these procedures was due to the fact that the procedures had not been written by the Vice President of Operations and Engineering or approved by the Radiation Safety Officer. However, he indicated that he believed that the preventative maintenance checks had been performed. From inspection of the Operator's Log, the inspector noted that the only preventative maintenance performed appeared to be cleaning and housekeeping activities.

Failure of the licensee to perform the required preventative maintenance procedures at the required frequency is an apparent violation of License Condition 26.

The sources in the cell and storage pools were inventoried on August 1, 1988, and December 1, 1988. The licensee had identified records deficiencies regarding inventories of other sources such as check sources. Corrective action was taken and licensee records indicate that an inventory of the other material possessed under this license was conducted on March 14, 1989. While no other records were available to show that previous inventories had been conducted, the licensee is aware that a

physical inventory of all material possessed under this license must be conducted on a semiannual basis. This is considered a licensee-identified violation in accordance with 10 CFR 2, Appendix C.

A review of the licensee's preventative maintenance procedures revealed that the licensee has been using procedures that have not had Commission approval. Such procedures were not submitted for Commission approval until December 12, 1988, and are currently under review.

The use of draft procedures prior to Commission approval for irradiator start-up (Procedure 9.100) and interlock checking (Procedure 9.102) was also identified in the Vice President of Quality's September 23, 1988 audit.

10. Exit Interview

The inspector met with the individuals identified in Section 1 at the conclusion of the inspection and discusses the scope and findings of this inspection.

MISCELLANEOUS INFORMATION OF RTI, INCORPORATED

CORPORATE OFFICE: 108 LAKE DENMARK ROAD, ROCKAWAY, NJ 07866

SUBSIDIARIES:

PROCESS TECHNOLOGY NORTH JERSEY
SAME ADDRESS AS ABOVE

PROCESS TECHNOLOGY NORTH CAROLINA
HAW RIVER, ALAMANCE COUNTY, NC

PROCESS TECHNOLOGY SOUTH JERSEY
CURRENTLY NOT OPERATING (NO SOURCES INSTALLED);
COMPANY IS SEEKING DISPOSITION OF THE FACILITY
SALEM COUNTY, NJ

OFFICERS:

JOHN N. SCANDALIOS, PRESIDENT AND DIRECTOR
PAUL O. SHAPIRO, VICE PRESIDENT-QUALITY ASSURANCE
R. STEPHEN MAICO, CONTROLLER AND SECRETARY

DIRECTORS:

KENNETH COOK, 1/85, DIRECTOR OF SIMON CARVES, STOCKPORT, GB (SIMON
ENGINEERING (MULTINATIONAL FOOD AND ENGINEERING COMPANY)

SANDERS DAVIES, 11/86, MANAGING PARTNER DAVIES AND DAVIES (CERTIFIED
PUBLIC ACCOUNTANTS) AND ASSOCIATED WITH SIMON ENGINEERING.

C. W. MCMILLAN, 5/85, PRESIDENT, MCMILLAN AND FARRELL ASSOCIATES, INC.
(WASHINGTON LOBBYING AND CONSULTING FIRM) FORMALLY ASST SECY
AGRICULTURE, UNITED STATES

GEORGE M. WHITMORE, 5/88, MANAGING DIRECTOR OF AYERS, WHITMORE AND
COMPANY (MANAGEMENT CONSULTING FIRM) A DIVISION OF A. T. KERNEY, INC.;
AND CHAIRMAN OF CLASSIFIED FINANCIAL CORPORATION

JOHN N. SCANDALIOS, 7/89, PRESIDENT OF RTI SINCE 2/89; FORMALLY
PRESIDENT AND CEO CADILLAC CABLE CORPORATION (CABLE AND WIRE
MANUFACTURING FIRM)

THEO MULLER, 4/90, UNKNOWN

Information in this record was deleted
in accordance with the Freedom of Information
Act, exemptions 5
FOIA- 90-334

E/4

RTI CURRENTLY EMPLOYS THREE EXECUTIVES AND ABOUT 40 OTHER EMPLOYEES BETWEEN THE TWO OPERATING FACILITIES AND THEIR CORPORATE OFFICE.

AT ROCKAWAY:

JOHN SCHLECT, PLANT MANAGER AND RSO
ANDREW FRIEDRICH, OPERATIONS MANAGER
A. BEETLE, Q.C. TECHNICIAN, PRODUCT DOSIMETRY

OPERATORS: M AYRES, R. KIEM, M. ROSA, J. FARMER
TRAINEES: M. HOLMIER

MATERIAL HANDLERS: 8 TO 11 EMPLOYED

ONE MAINTENANCE ENGINEER

1.2 MILLION CURIES OF CO-60 ARE CURRENTLY INSTALLED AT ROCKAWAY

PROPERTY:

AT ROCKAWAY THE COMPANY OWNS A 15 ACRE PARCEL ON WHICH THE IRRADIATOR FACILITY AND CORPORATE OFFICE IS LOCATED, AND AN ADDITION 248 ACRE PARCEL (FORMALLY OWNED BY THIOKOL CORPORATION AS A ROCKET MOTOR TEST FACILITY)



Release

FINANCIAL AND STOCK INFORMATION:

AS OF 3/90, AGGREGATE VALUE OF VOTING STOCK: \$1,650,265 BASED ON AVERAGE CLOSING BID OF \$ 0.28 ON 3/1/90

COMMON STOCK \$.01 PAR VALUE, 15,000,000 SHARES AUTHORIZED, 6,599,519 ISSUED, 6,598,719 OUTSTANDING

OWNERS:

CEDE AND CO., BOWLING GREEN STATION, NY., 3,535,865 SHARES, 53.6%
(A NOMINEE FOR BROKER-DEALERS WHO HOLD ALL THE SHARES FOR THEIR RESPECTIVE CUSTOMERS; CEDE HOLDS SHARES OF RECORD ONLY)

* THE WELT GROUP, INC, MORRIS PLAINS, NJ, 604,618 SHARES, 9.2%

* RUTH S. WELT, MORRIS PLAINS, NJ, 686,896 SHARES, 10.4%

* MARTIN A. WELT, MORRIS PLAINS, NJ, 1,015,781 SHARES, 15.4%

ALL DIRECTORS AS A GROUP, 1,469,903 SHARES, 21.2%

ALL DIRECTORS AND EXECUTIVE OFFICERS AS A GROUP, 1,512,725 SHARES, 21.7%

* BY A VOTING AGREEMENT DATED 8/6/86, VOTING CONTROL OF 1,012,060 SHARES OWNED BY MARTIN WELT, 27,500 SHARES OWNED BY HIS WIFE, AND 150,748 SHARES HELD BY HIS WIFE AS CUSTODIAN WAS GRANTED TO THE BOARD OF DIRECTORS FOR A FIVE YEAR PERIOD OR UNTIL THE SHARES WERE SOLD TO A NON-AFFILIATED THIRD PARTY. SIMULTANEOUSLY, MARTIN WELT DELIVERED HIS IRREVOCABLE PROXY TO THE COMPANY COVERING ALL SHARES OWNED OR ACQUIRED BY HIM TO BE VOTED BY THE BOARD OF DIRECTORS. THE AGREEMENT ALSO COVERED 328,825 SHARES THAT WELT SOLD TO ALVIN ABRAMS SINCE ABRAMS IS NOT A NON-AFFILIATED THIRD PARTY. THE 604,618 SHARES HELD BY THE WELT GROUP, 100 SHARES OWNED BY C.W. MCMILLAN, 3750 SHARES OWNED BY A FORMER DIRECTOR OF THE COMPANY (MARTIN ORLANDER) ARE COVERED BY THE VOTING AGREEMENT. AS A RESULT THE VOTING AGREEMENT COVERS AN AGGREGATE OF 1,033,603 SHARES. IN A DOCUMENT DATED 2/23/90 DELIVERED TO THE COMPANY BY MRS. WELT, SHE CLAIMED THAT THE WELT GROUP, INCLUDING ANDREW WELT, BRUCE WELT, AND SYD WELT, MAINTAIN THEIR RIGHT TO VOTE THEIR SHARES ON ALL ISSUES AS A RESULT OF AN ALLEGED BREACH OF CONTRACT BY THE COMPANY RELATIVE TO THE AGREEMENT WITH MARTIN WELT. LITIGATION IS PENDING.

AS OF 12/89:

WORKING CAPITAL \$430,649
TOTAL ASSETS \$7,854,034

CURRENT LIABILITIES \$1,608,317
LONG-TERM DEBT \$3,071,712
TOTAL LIABILITIES \$4,680,029

STOCKHOLDERS EQUITY \$3,174,005

ASSETS/LIABILITIES (WORKING CAPITAL RATIO) IS 1.27
RATIO OF SALES TO TOTAL ASSETS WAS .41

COMPARED TO 1988, REVENUES INCREASED BY 11% DUE TO INCREASED MARKETING ACTIVITIES. AT THE SAME TIME, RTI SUSPENDED OPERATION AT THE SALEM FACILITY, AND SOLD THE ARKANSAS FACILITY TO REDUCE OVERHEAD AND OPERATING LOSSES. REPORTEDLY, SUCH ACTION RESULTED IN A 60% INCREASE IN PROFITS, AND A DECREASE OF 78% IN OPERATIONAL LOSSES.

OTHER ITEMS OF INTEREST:

- 1 AS A RESULT OF NRC'S PREVIOUS ENFORCEMENT ACTION AND DEPARTMENT OF JUSTICE CONVICTIONS OF RTI AND CERTAIN FORMER OFFICERS, THE US DEFENSE LOGISTIC AGENCY SUSPENDED THE COMPANY AND ITS SUBSIDIARIES FROM ELIGIBILITY FOR US GOVERNMENT CONTRACTS IN 1988. IN 1989 DLA ENTERED INTO A NEGOTIATED SETTLEMENT AGREEMENT WITH THE COMPANY WHICH REMOVED THE SUSPENSION. PURSUANT TO THE AGREEMENT, THE COMPANY INSTITUTED A CODE OF BUSINESS ETHICS AND STANDARDS OF BUSINESS CONDUCT. THE COMPANY IS REQUIRED TO PROVIDE SEMI-ANNUAL STATUS REPORTS TO DLA RELATIVE TO COMPLIANCE WITH THAT CODE. THE AGREEMENT PROHIBITS THE COMPANY FROM HAVING ANY DEALINGS WITH MARTIN WELT AND SEVERAL FORMER EMPLOYEES, INCLUDING ENTERING THE PREMISES, AND PROHIBITS THE DIRECTORS AND OFFICERS FROM HAVING CONTACT WITH THEM. BREACH OF THE AGREEMENT WILL BE CAUSE FOR THE SUSPENSION OF ALL US GOVERNMENT CONTRACTS. AS OF 12/89, U S GOVERNMENT CONTRACTS AMOUNTED TO LESS THAN 5% OF THE COMPANY'S BUSINESS.

RTI, INCORPORATED: NORTH JERSEY PROCESS TECHNOLOGY
ASSESSMENT OF LICENSE OPERATIONS BASED ON INSPECTION
- CONDUCTED FEBRUARY 12-13, 1990

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GENERAL FINDINGS:

1. The Plant Manager (John Schlecht) is also designated as plant RSO. He is qualified as operator, has experience as a health physicist at NIH, degreed in physics, knowledgeable of the system, and
2. All operators have been subjected to a formal Radiation Safety Training (40 hours), OJT Irradiator Operator Training (3 months), and continuous (at least monthly) refresher training in procedures. Based on several interviews, and review of records, the primary operators (Rosa, Kiem, Ayres))

3. =

The majority of the reactive maintenance performed occurs on back shifts.

Since the licensee has not been logging replacement parts in accordance with Procedure 12.100,

The inspectors observed that the device is in fact replaced about once every two weeks. The source movement micro-switches appear to be replaced every two to three weeks.

Information in this record was deleted
in accordance with the Freedom of Information
Act, exemptions 5
FOIA- 90-334

E/5

start at 2134. However, the source remained down and the system alarmed "Carrier Missing at C1A" and C1A Travel Timed Out". After repeated attempts to re-start, the PM finally aborted the run at 2211. After repeated attempts to clear the alarm and re-start, the PM shut-down the system at 0044 on 8/13/89 and cancelled the third shift.

On 8/13/89, the PM and the Plant Radiation Safety Officer (PRSO) resumed activities to correct the problem. All carriers were removed and the transfer cylinders were manually returned to the correct positions. Again re-start was attempted at 0851, but the source remained down with the alarm "Carrier Missing at C1A". When an attempt was made to re-start in the Static condition, the source remained down and alarmed "Carrier Missing at C1B". All micro-switches tested satisfactory at C1A and C1B using a voltmeter.

At about 1021, following repeated attempts to clear the alarm "Carrier Missing at C1A", the PM entered the irradiator control program and forced out the alarm through output C143 in the program logic, reportedly in an attempt to diagnose the problem. Such action allowed the source to be raised in the Static Mode. Subsequently, the PM and PRSO conducted further systems tests, including Safety Interlock Tests, in an attempt to resolve the problem.

Without resolving the cause of the alarm condition, the PM and PRSO elected to continue the original product run. The carriers from the original product run were replaced in the cell and production was continued at 1329 using 3 minute static dwells. Following each static irradiation, the PM and PRSO entered the cell and manually moved the carriers to the next dwell position. The product run was completed at 1412 after nine 3-minute cycles.

Upon completion of that product run, the PM and PRSO loaded the cell with another product that was intended for static irradiation and turned over the shift at 1600 to the second shift operator, with instructions to perform static dwell only. The second shift operator commenced irradiation at 1636; and continued the activity through twenty-four 2-minute static irradiation cycles. The product run was completed at 2114. No irradiation was performed on the third shift.

On 8/14/89, the PM and PRSO resumed activities to resolved the problem. All limit switches for cylinders C1A and C1B were replaced. The forced output to the system logic was removed from C143, "Carrier Missing at C1A". The problem was resolved. Following, a SIT was performed, and the irradiator returned to normal operation.

From discussion with the PM and Corporate RSO, neither considered the action to by-pass the "Carrier Missing at CIA" alarm as a change to the Start-Up procedure, and consequently license condition.

6.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
476 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19408

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for
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note

MAY 11 1990

Docket No. 030-07022

License No. 29-13613-02

Process Technology of North Jersey
Subsidiary of RTI Incorporated
ATTN: Mr. John Scandalios
President
108 Lake Denmark Road
Rockaway, New Jersey 07866

Gentlemen:

Subject: Reactive Inspection No. 030-07022/90-002

This letter refers to the special safety inspection conducted by Richard H. Ladun and James P. Dwyer of this office on March 20, 1990, of activities authorized by NRC License No. 29-13613-02, and to the discussions of our findings held by Mr. Ladun with Paul Shapiro and John Schlecht at the conclusion of the inspection.

W/D

Areas examined during this inspection are described in the NRC Region I Inspection Report which is enclosed with this letter. Within these areas, the inspection consisted of the examination of activities related to a reported film badge exposure in excess of 10 CFR 20.101 standards, irradiator cell safety interlock systems, and selected record review.

Within the scope of this inspection, no violations were identified.

In accordance with Section 2.790 of the NRC's "Rules of Practice", Part 2, Title 10, Code of Federal Regulations, a copy of this letter, and the enclosures will be placed in the Public Document Room. No reply to this letter is required.

Your cooperation with us is appreciated.

Sincerely,

John R. White, Chief
Nuclear Materials Safety Section C
Division of Radiation Safety
and Safeguards

Information in this record was deleted
in accordance with the Freedom of Information
Act, exemptions 5
FOIA-90-334

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UNITED STATES
 NUCLEAR REGULATORY COMMISSION
 REGION 1
 476 ALLENDALE ROAD
 KING OF PRUSSIA, PENNSYLVANIA 19406

MAY 24 1990

MEMORANDUM FOR: Richard E. Cunningham, Director
 Division of Industrial
 and Medical Nuclear Safety, NMSS

FROM: Malcolm R. Knapp, Director
 Division of Radiation Safety and Safeguards, RI

SUBJECT: BACKGROUND INFORMATION FOR SENIOR MANAGEMENT
 MEETING, JUNE 12-13, 1990

In accordance with your memorandum transmitted May 14, 1990, background material relative to Process Technology North Jersey is attached. Technical contact for this matter is John R. White, Chief, Nuclear Materials Safety Section C, FTS 346-5102.

MR Knapp
 Malcolm R. Knapp, Director
 Division of Radiation Safety
 and Safeguards

Attachment As Stated

- cc:
 T. Martin, RI
 R. Cooper, RI
 J. White, RI
 NRC Center File
 DINS Central File
 NMSS r/f
 MOB r/f
 PGoldberg, NMSS
 RWilde, NMSS
 JHickey, NMSS
 GSjoblom, NMSS
 JStohr, RI
 CNorelius, RIII
 ABeach, RIV
 RScarano, RV
 JGlenn, NMSS
 CHaughney, NMSS

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PBS

NRC RI DRSS

JUN 22 1990 09:03

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PREDECISIONAL
BACKGROUND INFORMATION
ON
PROCESS TECHNOLOGY NEW JERSEY,
A SUBSIDIARY OF RTI, INCORPORATED

Facility: Process Technology New Jersey (PTNJ), formally Radiation Technology, Incorporated, now a subsidiary of RTI, Incorporated (RTI)

Location: 108 Denmark Road, Rockaway, New Jersey

Docket No.: 030-07022

License No.: 29-13613-02

Type of Facility: Large Service Irradiator, Wet Storage,
1.2 Million Curies, Cobalt-60

Operational Date: November 1970

NRC Responsible Region: Region I, King of Prussia, Pennsylvania
Thomas T. Martin, Regional Administrator

Malcolm R. Knapp, Director
Division of Radiation Safety
and Safeguards (FTS 346-5283)

Lee H. Bettenhausen, Chief
Nuclear Materials Safety Branch
(FTS 346-5251)

John R. White, Chief
Nuclear Materials Safety Section C
(FTS 346-5102)

Management Personnel (RTI and PTNJ)

John Scandalios, Chief Executive Officer and President, RTI; President, PTNJ

Paul Shapiro, Vice-President, Quality; Corporate Radiation Safety Officer (RSO), RTI

John Schlecht, Plant Manager and Plant RSO, PTNJ



UNITED STATES
 NUCLEAR REGULATORY COMMISSION
 REGION I
 478 ALLENDALE ROAD
 KING OF PRUSSIA, PENNSYLVANIA 19406

Wheeler
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MAY 31 1990

Docket No. 030-07022
 EA No. 89-080

License No. 29-13613-02

Process Technology North Jersey
 ATTN: Mr. John Scandalios, President
 108 Lake Denmark Road
 Rockaway, New Jersey 07866

Information in this record was deleted
 in accordance with the Freedom of Information
 Act, exemptions 5
 FOIA-90-334

Gentlemen:

Subject: Enforcement Conference on June 14, 1990

On April 17, 1989, you were informed of the results of an inspection conducted by Ms. Marlene Taylor of this office on March 23, 1989. Subsequently, an Enforcement Conference was held on April 26, 1989 to discuss the findings of that inspection. A report of that conference was provided to you on August 22, 1989. Following that conference, the NRC Office of Investigations (OI) initiated an investigation to determine: (1) the veracity and accuracy of certain statements and information that were presented to the NRC at that Enforcement Conference; (2) whether any operators had ever gained access to the irradiator cell without use of the required access key, and if so, was management aware of such activities; and (3) if licensee management, including the Radiation Safety Officer (RSO), had prior knowledge that the irradiator cell door lock mechanism was not properly functioning before it was discovered as defective in an audit conducted on February 13, 1989.

During this investigation, OI found that: (1) the licensee, acting with careless disregard for the regulations, violated the requirements when operators gained keyless access to the irradiator by either climbing over the gate or by forcing the "locked" door open; and (2) the RSO and Plant Superintendent acted with careless disregard for the regulations in allowing irradiator operations to continue with a less than fully functional door lock mechanism.

OI also found that (1) the CEO/President, two Vice Presidents, and the Radiation Safety Officer (RSO) acted in careless disregard of the regulations in the Enforcement Conference when: (1) they denied or failed to acknowledge that they had any knowledge of keyless entries of the irradiator cell; (2) the RSO stated that the system computer records all entries into the cell (an assertion used to support that there were no keyless entries made into the cell), when he did not know that statement to be true at the time, and was later disproved; (3) the RSO willfully misrepresented his prior knowledge of damage to the cell door lock mechanism; and (4) an operator intentionally misinformed the NRC of the manner in which the cell door was breached by two other operators. Synopses of OI's main and supplemental investigative efforts are provided as Enclosures 1.a and 1.b, respectively.

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These findings, which involve the completeness, accuracy, and veracity of information provided to the NRC, raise questions regarding the ability and willingness of Process Technology North Jersey to comply with NRC requirements for complete and accurate information. Therefore, as discussed in a telephone conversation between you and Mr. John R. White of this office on May 24, 1990, these findings will be reviewed at a second Enforcement Conference at our office in King of Prussia, Pennsylvania at 10:00 a.m. on June 14, 1990.

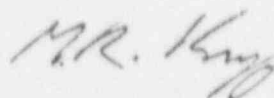
The purpose of this second Enforcement Conference is (1) to assure that we have an accurate understanding of the facts associated with OI's findings, and (2) to determine if there are mitigating or extenuating circumstances that should be considered by the NRC in determining the appropriate enforcement action. Consequently, you should be prepared to discuss the findings set forth in the OI synopses, your assessment of causes, and the details of any corrective measures taken or planned. This Enforcement Conference will be transcribed.

We acknowledge the fact that the former RSO and the former Vice President of Engineering are no longer employees of Process Technology North Jersey. However, we understand that you and other members of your staff will attend this meeting.

Enforcement action for these findings will be considered by the NRC following this conference. The NRC Enforcement Policy is described in Appendix C of 10 CFR 2, and is provided in Enclosure 2. Directions to the NRC office are provided in Enclosure 3.

In accordance with 10 CFR 2.790, a copy of this letter and Enclosures 1.a and 1.b will be placed in the NRC Public Document Room. No reply to this letter is required. We appreciate your cooperation in this matter.

Sincerely,



Malcolm R. Knapp, Director
Division of Radiation Safety and Safeguards

Enclosures:

- 1.a Synopsis of Office of Investigations Report No. 1-89-006
- 1.b. Synopsis of Office of Investigations Report No. 1-89-006S
2. 10 CFR 2 Appendix C, NRC Enforcement Policy
3. Directions to the NRC Region I Office

cc:

Public Document Room
Nuclear Safety Information Center
State of New Jersey

June 26, 1990

Mike,
Karen
Annette
Margaret
Steve

Chairman Carr:

6/26/90

SUBJECT: PERIODIC BRIEFING ON OPERATING REACTORS AND FUEL FACILITIES (Wednesday, 6/27/90 - 9:00 a.m.)

This is an information briefing by the staff, discussing the results of the Senior Management Meeting held in Region I June 12-13, 1990.

6/26/90 - not responsible to report

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FOIA: 90-334

meeting.

In addition to the power plants, the staff will brief on three priority material licensees; Combustion Engineering (Windsor, CT), Process Technology (Rockaway, NJ), and American Radiolabeled Chemicals (MO). Note that Combustion Engineering was on this list at the last Commission briefings.

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attached 6/26/90

03C-07022

Process Technology North Jersey

Subsidiary of RTI Inc.

108 LAKE DENMARK ROAD, ROCKAWAY, NJ 07866
(201) 625-8400 • FAX: (201) 625-7820

May 1, 1989

Mr. John White, Chief
Nuclear Materials Safety Section C
United States Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, Pennsylvania 19406

License No. 29-13613-0

Log	May 15
Remitter	Process Technology North Jersey
Check No.	239
Amount	\$230
Fee Category	302 3P
Type of Fee	AMND
Date Check Rec'd.	6/17/89
Date Completed	
By	[Signature]

Dear Mr. White:

Process Technology of North Jersey in its continuing efforts to improve Radiation Safety and strengthen its Radiation Protection Program is designating Mr. John Schlecht and Mr. Paul O. Shapiro as RSO's for the Rockaway N.J. facility, in addition to Mr. Russen. Copies of their resumes and an organizational chart are attached. Please amend our license by adding these two names as RSO,s in addition to Mr. Russen.

Enclosed is our check for \$230.00 to cover the cost of this amendment.

The addition of Mr. Schlecht and Shapiro will add a level of expertise to the facilities Radiation Protection Program. Each in his own is qualified to be an RSO but in combination bring expertise in Engineering, Physics, Chemistry, Biochemistry, Quality, and Training to assure the safest possible in-house program.

In support of Mr Schlecht and Mr. Shapiro we would like to bring the following information to your attention.

In re Mr. John Schlecht, in addition to his formal training at Rensselear Polytechnical Institute, he has over one year practical experience in Engineering at a Nuclear Power Station, an additional year experience as a Health Physicist at NIH, and over a year experience as Physicist at RTI, including over one month actual Operations experience. While at RTI he has, under the supervision of the Corporate RSO, been involved in the movement of cobalt pencils, loading and unloading cobalt from shipping flasks, calibrating radiation detection equipment, taking and evaluating radiation surveys, designing and installation of the new irradiator source rack and controls. Mr Schlecht has successfully completed several courses in Radiation Science from Georgetown Graduate School and Rensselear as well as Radiation Safety Training Courses at the National Institute of Health.

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in accordance with the Freedom of Information
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MAY 08 1989

In re Mr. Paul O. Shapiro, in addition to his formal training at Lycoming College and New York University Graduate School, he has over 25 years of experience in the development and management of sophisticated management and quality techniques. He has several years experience in the development and implementation of sophisticated technical training programs, is an expert in the development of control systems, knowledgeable in government regulatory affairs, and a seasoned professional manager. He has been employed by RTI as Director and then Vice President Quality for over 3 years. During that time he has developed RTI's radiation safety audit program (accepted by the NRC), has conducted numerous radiation safety audits (reviewed by the NRC), developed RTI's configuration controlled procedure manual, developed with Dr. Cockrell and then T. Varaklis operational procedures including those related to radiation safety, been involved with the radiation safety review of all facility changes related to radiation safety, assisted the RSO, T. Varaklis, in movement of cobalt and the start of the clean up of the R & D pool, monitored the receipt and shipment of cobalt at several RTI facilities, reviewed radiation survey data, participated in radiation surveys and water testing, assisted in the development and review of radioactive material licenses, as well as experience in actual irradiator operations. Mr. Shapiro has successfully completed the RTI Radiological Health and Safety course given by Mr. Les Ross, seminars on Toxicology, Handling of Toxic Materials, completed 40 hours of Radiation Safety Officer Training at the Central Connecticut State University and a second 3 day course given by Stan. A. Huber Consultants, Inc. on Radiation Training and Management, Radiation Safety Programs, Emergency Response and Record Keeping Requirements.

Your expedient approval is requested.

Respectfully submitted



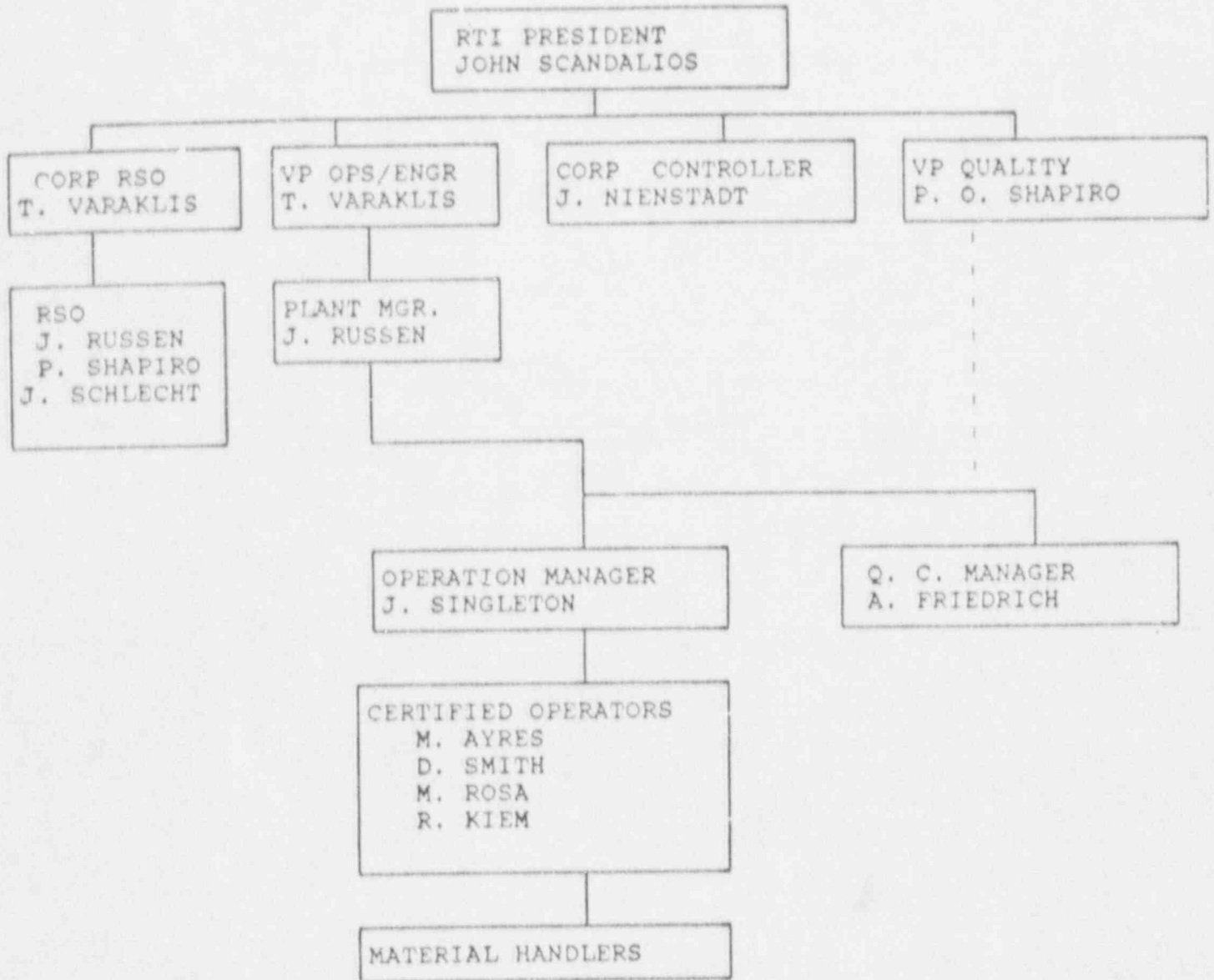
John Russen, RSO

Enc/

cc:
RTI Corporate file
RSO File
J. Scandalios

PROCESS TECHNOLOGY OF NORTH JERSEY

ORGANIZATIONAL CHART



May 1, 1989

PAUL O. SHAPIRO

QUALITY ASSURANCE...PRODUCT/PROCESS DEVELOPMENT
CORPORATE MANAGEMENT

SUMMARY: More than 25 year's experience in the development and management of sophisticated management and quality control techniques and processes in the irradiation, pharmaceutical, and health care fields... developed dosimetry and operational systems for control of contract gamma sterilization of medical devices, pharmaceuticals, cosmetics and food products ...expertise in government licensing and regulations, domestic and international...development of new products and processes for increased market penetration...proven talent for innovative approaches and problem solving.

EXPERIENCE/ 1986-Present...RTI Inc.,
ACHIEVEMENTS: Rockaway, New Jersey

As Vice President of Quality am responsible for the development, implementation and maintenance of a total Quality Program including the monitoring, auditing, and inspection of Radiological Health requirements.

Developed and implemented Corporate procedures with a configuration controlled manual to include all company functions. Implemented a Corporate Quality Policy, audit function, and systematic approach to operations. Validated quality procedures and implemented new analytical techniques resulted in substantial cost savings. Developed, implemented, and monitored state of the art dosimetry systems.

Organized and produced Corporate policy statements relating to all phases of employee activity.

Updated preventive maintenance and material processing systems to reduce cost and comply with regulations. Developed new systems to assure compliance with government regulations.

1980-1986...Revlon Research Center, Edison, New Jersey

As Associate Director-Quality GMP Compliance-World Wide was responsible for the development, management, and administration of a corporate quality assurance and good manufacturing practice compliance program. Involved providing professional quality and GMP guidance to all company facilities in the cosmetic division, worldwide.

As Dean of the Revlon Research Center Institute for Quality had the responsibility of developing, administrating, conducting, and implementing training for Revlon management worldwide.

Paul O. Shapiro...page 2

1980-1986...Peylon Research Center, Edison, New Jersey (cont)

Accomplishments:

- ... Developed and wrote a good manufacturing practice manual used by all facilities.
- ... Developed training programs and instructed quality managers, GMP managers, general managers, and other plant personnel worldwide on QA/GMP requirements.
- ... Developed and utilized a GMP audit checklist and reported to top management each plants compliance.
- ... Provided assistance to manufacturing plants worldwide for the preparation of procedure manuals, training programs, internal auditing and test methods.
- .. Developed and implemented a GMP program in one of the largest plants which reduced contamination problems to almost zero.
- ... Assisted manufacturing plants trouble shoot systems and develop corrective action plans. In one area developed a computerized system resulting in savings over \$120,000/year.

1972-1980...Whatman, Inc., Clifton, New Jersey

Director of Quality Assurance for the Chemical Separations Division of this international company, my responsibilities covered establishing new company-wide GMP procedures and written manufacturing, and test procedures. Represented the company in dealings with FDA, OSHA, and EPA; prepared written manuals and trained line personnel at all levels to comply with Medical Device laws. Created a complete product recall system in line with FDA guidelines.

Accomplishments:

- ... Improved QC procedures resulting in a 50% reduction in testing time.
- ... Planned an automated computer-controlled test evaluation procedure to reduce evaluation time by 75%.
- ... To satisfy FDA on compliance matters, prepared Device Master Records, initiated Device History Records, developed and wrote Quality Control manual and company GMP manual.
- ... Improved inventory control to save \$80,000 the first year.

1970-1972...Warner-Lambert Pharmaceutical Company, Morris Plains,
New Jersey

Senior Scientist with General Diagnostics Division, responsible for pilot plant development of diagnostic test kits and reagents. Perfected necessary analytical quality control test procedures; wrote and tested manufacturing procedures.

1968-1970...Wyeth Laboratories, Radnor, Pennsylvania

As supervisor, reporting to the V.P. Product Coordination, maintained health registration of Wyeth drugs throughout the world. Coordinated all phases of registration including clinical trials, pharmacology, toxicology, analytical studies, labeling, packaging, patents, licensing, and government regulations. Utilized knowledge of FDA rules dealing with IND's and NDA's as well as health registration laws worldwide; had contact with key government officials worldwide. Accomplishments:

- ... Developed system to maintain health registration status for over 50 products in more than 70 countries.
- ... Developed and wrote testing specifications for over 30 products used for health registration purposes.

EARLIER EXPERIENCE: Other earlier positions as Senior Biochemist, Scientist, and Laboratory Supervisor provided a solid foundation for later accomplishments. These positions were with Carter Wallace, Warner-Lambert, St. Joseph's Hospital, and Bellevue Hospital.

Some of my contributions in functional areas are profiled below:

PRODUCTION/PROCESS DEVELOPMENT: As Manager of Quality Control/Production with Whatman, Inc., I developed the entire manufacturing process for a new product line with full budget responsibility and a support staff of 12 technical personnel. I designed the equipment to handle ultra-high pressure production procedures, developed organic solvent systems, selected and tested all new equipment and processes. I coordinated all activities of this state-of-the-art operation.

QUALITY ASSURANCE: Involved with new products from a quality viewpoint from inception through packaging, labeling, and shipping. had final approval on all advertising and promotional literature from a technical aspect to ensure that accuracy and compliance standards were adhered to.

RESEARCH AND DEVELOPMENT: At Warner-Lambert my success in R&D led to development of 3 new marketed products.

EDUCATION: B.A., Biochemistry, Lycoming College, 1956
Graduate courses in Biochemistry, Bacteriology, Enzymology and Patent Law, New York University. Additional seminars in Management of Quality Control, Toxicology, and Handling of Toxic Materials. Completed in house training programs on Radiological Health and Safety. Successfully completed 40 hours of Radiation Safety Officer Training at Central Connecticut State University.

MEMBERSHIPS: American Society of Quality Control
Regulatory Affairs Professional Society
Past Chairman Education Committee
Voting member-AAMI Radiation Sterilization Subcommittee
ASTM Committee E 10 and Food Dosimetry Subcommittee

Active in numerous civic associations: Randolph Soccer Club, founder and past chairman; North Jersey Junior Soccer Club, founder and past chairman; Indian Guides Area Chief; Eagle Scout Scoutmaster, BSA; Dover Jaycees, past President. Soccer coach and referee, enjoy stamp and coin collecting, and camping.

Training Record

Paul O. Shapiro

June 16, 1986	Attendance at AAMI meeting on Process Guidelines for Gamma Irradiation of Medical Devices.
Aug. 6-7, 1986	Conducted Radiation Safety Audit at PTI NC.
Aug. 13-14 1986	Conducted Radiation Safety Audit at Salem.
Sept. 5, 1986	Reviewed and evaluated Jim Nicolosi's radiation safety audit.
Sept 11, 1986	Conducted a Radiation Safety audit at No.J.
Oct. 7, 1986	Participated in Design Review of No. J. plant modification.
Oct. 27-29, 1986	Review and approval of No. J. radiological operations and safety procedures.
Oct. 30, 1986	Conducted a Radiation Safety Audit at No. J.
Nov. 15, 1986	Reviewed with RSO possible radiological safety problems.
Nov. 20, 1986	40 hours of RTI Operator Training given by L. Ross. Final exam score 93%.
Dec. 18, 1986	Reviewed Radiation Safety program with Mr. John White, Region I, NRC.
Dec. 19, 1986	Conducted Radiation Safety Audit at PTI Ark.
Jan. 5, 1987	Review of renewal application for NRC license #29-13613-02
Jan 6-7, 1987	Conducted Radiation Safety Audit at PTI Ark.
Jan. 28-29, 1987	Conducted Radiation Safety Audit at No.J.
Feb. 4, 1987	Prepared RTI Radiation Safety Program.
April 20, 1987	Conducted Radiation Safety Audit at No.J.

April 29, 1987	Conducted Radiation Safety Audit at Salem.
May 6-7, 1987	Conducted Radiation Safety Audit at PTI NC.
May 19-20, 1987	Conducted Radiation Safety Audit at PTI Ark.
May 26--30, 1987	Attendance at ASTM meeting on Radiation Dosimetry, Jackson Hole, Wyoming.
June 11-15, 1987	Conducted Radiation Safety Audit at No.J.
July 17, 1987	Review and response of M. Slobodien Radiation Safety Audit Report.
August 11, 1987	Review of license conditions with NRC, King of Prussia, Pa.
August 27-28, 1987	Conducted Radiation Safety Audit of No.J.
Sept. 14-18, 1987	Radiation Safety Officer Course - Central Connecticut State University (Radiation Safety Associates) New Britain, Conn.
Sept. 21-22, 1987	Attendance at AAMI meeting on Process Control for Gamma Irradiation of Medical Devices.
Dec. 14, 1987	Seminar "Irradiator Safety and Licensing" by Robert D. Jarrett USDA.
Dec.15-17, 1987	Attendance at Engineering Conference on Radiation. Santa Barbara, Calif.
Jan. 5, 1988	Review and evaluation of Process Control system for NC irradiator.
March 11, 1988	Review and evaluation of proposed No.J. operational procedures.
March 11, 1988	Review and evaluation of Nicolosi radiation safety audit.
March 21, 1988	Review and evaluation of license #29-13613-02 conditions and evaluation of facilities compliance to same.
April 11, 1988	Review of No.J. radiation license in respect to action dates.
April 26, 1988	Review and evaluation of NRC Report 30-07033/87-99
May 25, 1988	Review of 10 CFR parts 19 and 20 with Plant Managers and RSO's.

May 9-11, 1988	Seminar - Relationship between Quality Improvement and Nuclear Regulations by Stan A. Marash at ASQC 42nd Annual Quality Congress.
June 6-7, 1988	Attendance at AAMI meeting on Process Control for Gamma Irradiation of Medical Devices.
July 12, 1988	Reviewed M. Slobodien radiation safety audit.
July 21, 1988	Reviewed North Carolina Regulations for Protection Against Radiation.
July 27-30, 1988	Attendance at ASTM Conference on Radiation Dosimetry.
Aug. 26, 1988	Reviewed No. J. NRC license and evaluated compliance to requirements.
Sept. 16, 1988	Review and evaluation of license #29-13613-02 conditions and evaluation of facilities compliance to same.
Sept. 17, 1988	Reviewed and evaluated computer control system for No.J.
Sept. 22, 1988	Conducted Radiation Safety Audit at No.J.
Sept. 25-28, 1988	Attendance at AAMI meeting on Process Control Guidelines for Gamma Irradiation of Medical Devices.
Oct. 13, 1988	Participated in No.J. Operator Training Course.
October 18, 1988	Conducted ALARA evaluation with RSO.
Oct. 20-21, 1988	Radiation Safety and Management Course - Stan A. Huber Consultants, New Lenox, IL.
Sept. 20, 1988	Reviewed Reg Guides on application for Radiation Safety Evaluation .
Nov. 11, 1988	Reviewed and evaluated validation of No.J. process control system.
Nov. 30, 1988	Conducted audit at No. J. of Quality Assurance program for unloading and movement of cobalt.
Dec 5-9, 1988	Review and preparation of amendment to NRC license #29-13613-02
Dec. 8, 1988	Review of No. J. current license compliance.

Feb 2-3, 1989 Review and evaluation of proposed changes to
9 CFR part 20.

Feb. 22-27, 1989 Attendance at ASTM Conference on Radiation
Dosimetry.

Feb. 31, 1989 Attendance at AAMI meeting on Process Control
Guidelines for Gamma Irradiation of Medical
Devices.

April 13-22.1989 On the Job Operator training (part time).

John D. Schlecht

10/1/88

Education

Rensselaer Polytechnic Institute - Troy, NY
B.S. Physics, Nuclear Engineering minor, 1986

Columbia University - New York, NY
M.S Nuclear Engineering, expected 1990

Experience

RTI, Inc. - Rockaway, NJ
Radiation Physicist
January, 1988 - Present

- * Managed dosimetry program for gamma sterilization service utilizing Cobalt-60.
- * In charge of management and shipment of megacurie amounts of Cobalt-60.
- * Drafted corporate procedures to comply with NRC and FDA regulations. (10CFR, 21CFR, 49CFR).
- * Drafted NRC license amendments for all corporate facilities.
- * Instructed employees on radiation safety.
- * Designed source loading methods to maximize throughput
- * Assisted in design and construction of RTI model 2102-B commercial gamma irradiator.
- * Over 30 days experience in operation of commercial gamma irradiator.
- * Designed method to characterize field utilizing ORNL/RSIC QADGP computer code.

National Institutes of Health - Bethesda, MD
Health Physics Associate
February 1987 - January 1988

- * Managed radiological safety program for area containing over 300 laboratories in large biomedical research facility. Program covered a broad range of Health Physics responsibilities including: contamination surveys and control, exposure control, personnel training and consultation.
- * Instructed classes on radioactive waste management for NIH course "Radiation Safety in the Laboratory".
- * Performed shielding and dosimetric calculations.
- * Drafted technical paper detailing calculations of Beta exposures to the lens of the eye.
- * Administered radiotherapy doses to patients.
- * Decommissioned radioactive waste handling facility.

Virginia Power - Surry Nuclear Power Station
Plant Performance Engineer - CoOp
June 1985 - December 1985 and May 1986 - Sept 1986

- * Reviewed and updated technical documents to conform to NRC requirements.
- * Assisted senior staff in flux maps, snubber inspections and other plant engineering tasks.

Courses

Undergraduate - Rensselaer Polytechnic Institute

Radiological Engineering, Nuclear Reactor Analysis,
Reactor Engineering, Heat Transfer, Plasma Engineering,
Quantum Physics I II III, Physics I II III
Fundamental Particles, Intermediate Mechanics, Physical
Thermodynamics, Holography, 6 Advanced Math courses.

Graduate - Columbia and Georgetown Universities

Radiation Science/Radiological Physics, Nuclear Technology

Special - National Institutes of Health

Radiation Safety in the Laboratory, Radiation Safety for
Authorized Users of radioactive material

Skills

Operation of nuclear instrumentation.
BASIC, FORTRAN, PASCAL, IBM 360/370, IBM PC
PARDES, GRACE1, QADGP, HECTIC, FCOST computer codes

Honors

Rensselaer Dean's List of Distinguished Students.
National Institutes of Health Merit Award.

M²

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1. *I*

1. APPLICATION: STUDENT
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REF: 10001
DATE: 10/10/87
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TORONTO, ONTARIO M5S 1A5

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Stemberly
7/7/87

Martin A. Welt, Ph.D.
4 Rocky Heights Road
Morris Plains, New Jersey 07950

EX. 6

201-334-4321 (D)

June 12, 1990

Mr. John R. White
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

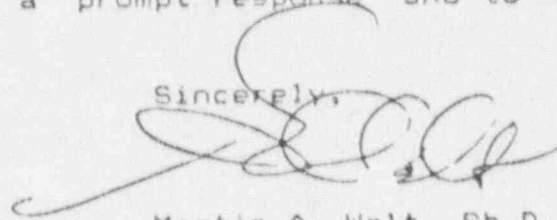
Dear Mr. White:

As discussed with you this morning, I would like to request a meeting to discuss my situation, as pertains to my future in the field of radiation processing in the United States, and to my future relationship with RTI, Inc.

I am in receipt of the faxed letter from Tim Martin, dated June 11, 1990, and believe that this material can serve as the starting point for the meeting.

I will look forward to a prompt response and to our first meeting.

Sincerely,



Martin A. Welt, Ph.D.

Information in this record was deleted
in accordance with the Freedom of Information
Act, exemptions b + 7C
FOIA- 90-334

D/12

~~7007030244~~
2PP

10

RADIATION TECHNOLOGY INCORPORATED
108 Lake Denmark Road
Rockaway, New Jersey 07866

License No. 29-13613-02

Docket No. 030-07022

Enforcement Conference Attendees:

Licensee:

John Scandalios, President & CEO
Tass Varaklis, Vice President of Operations & Engineering
John Russen, Radiation Safety Officer
Roy P. Lessy, Jr., Legal Counsel
Robert Riley, Legal Counsel

NRC:

W. Russell, Regional Administrator
M. Knapp, Director DRSS
J. Joyner, Division Project Manager
L. Bettenhausen, Chief NMSB
J. White, Chief NMSS C
D. Holody, Enforcement Specialist
K. Christopher, Enforcement Specialist
J. Gutierrez, Regional Counsel
M. Taylor, Health Physicist

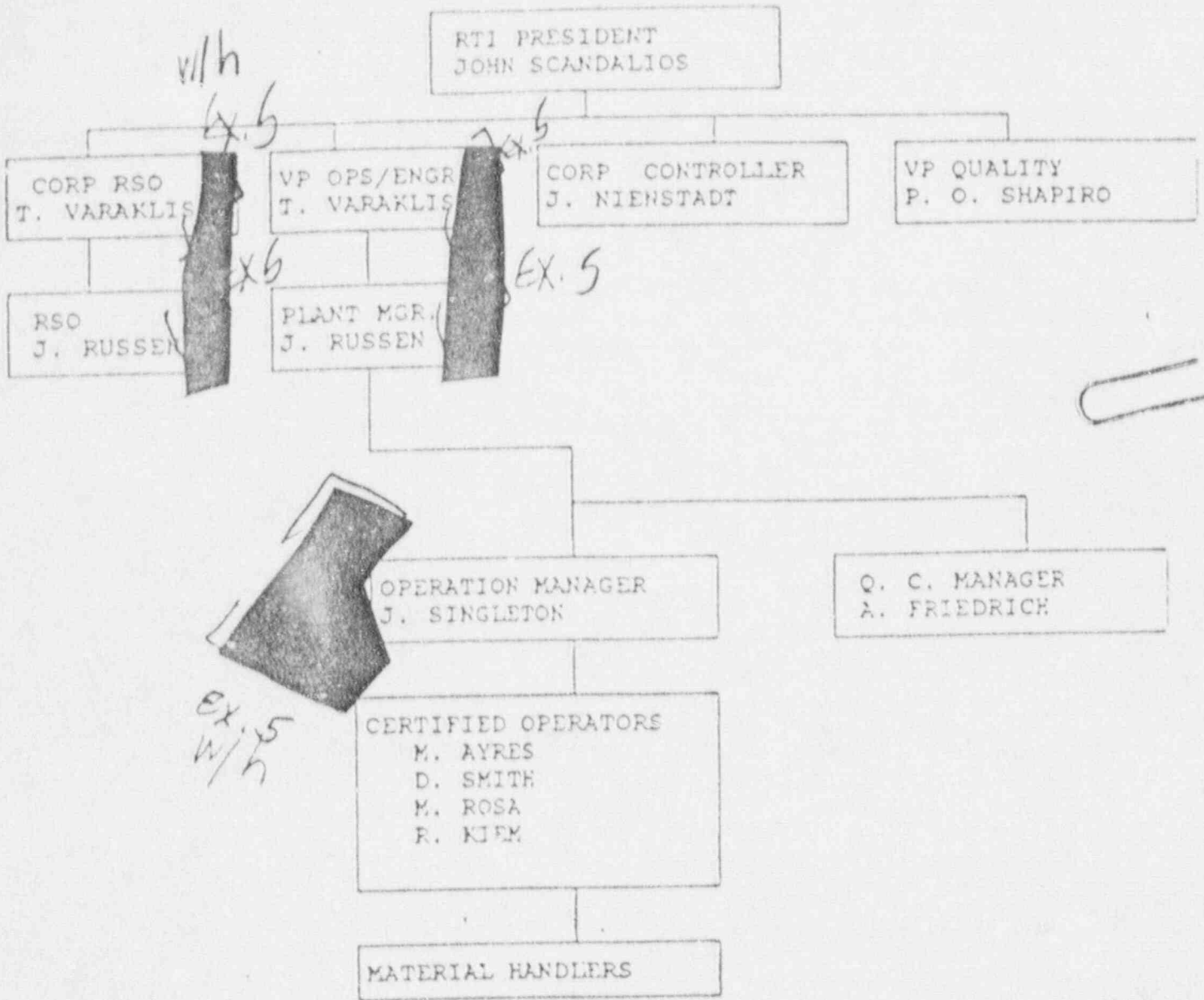
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Act, exemptions 5
FOIA- 90-334

E.S.

E11

PROCESS TECHNOLOGY OF NORTH JERSEY

ORGANIZATIONAL CHART



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in accordance with the Freedom of Information
Act, exemptions 5
FOIA- 90-334

April 28, 1986

E/2

As requested by FOIA
Transmitted by [unclear]
7/7/87
EOL
[unclear]

AKIN, GUMP, STRAUSS, HAUER & FELD

ATTORNEYS AT LAW

A PARTNERSHIP INCLUDING PROFESSIONAL CORPORATIONS

1333 NEW HAMPSHIRE AVENUE, N.W.

SUITE 400

WASHINGTON, D.C. 20036

(202) 887-4000

FAX (202) 887-4288

2100 ONE CONGRESS PLAZA

111 CONGRESS AVENUE

AUSTIN, TEXAS 78701

(512) 499-6200

3200 REPUBLICBANK CENTER

700 LOUISIANA STREET

HOUSTON, TEXAS 77002

(713) 221-0101

1100 FIRST CITY CENTER
1700 PACIFIC AVENUE
DALLAS, TEXAS 75201-4618
(214) 969-2800

1500 INTERFIRST PLAZA
300 CONVENT STREET
SAN ANTONIO, TEXAS 78205
(512) 270-0800

WRITERS DIRECT DIAL NUMBER (202) 887-4558

July 17, 1990

By Hand Delivery

Mr. Donnie H. Grimsley, Director
Division of Freedom of Information and
Publications Services
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

FREEDOM OF INFORMATION
ACT REQUEST

FOIA-90-334
Rec'd 7-17-90

Re: Freedom of Information Act Request

Dear Mr. Grimsley:

The following is filed under the Freedom of Information Act,
5 U.S.C. Sec. 552. Please provide complete copies of the
following documents.

All documents discussing, referencing, reporting on,
analyzing or otherwise addressing Process Technology,
and/or Process Technology North Jersey, and/or its
parent corporation, RTI, Inc. created or dated after
February, 1989. This request includes SECY papers,
Commission vote sheets, telephone logs, and any other
documents in the NRC's possession in whatever form,
with the exception of enforcement reports, audit
reports or items from previous FOIA requests already
provided to this law firm. You may also exclude
documents provided in response to a separate FOIA
request, also hand delivered today, for which we have
requested expedited response.

Pursuant to 5 U.S.C. Sec. 552(a)(6)(A)(i), please provide a
response to this request within 10 days. We are willing to pay
all fees associated with this request, you do not need to contact
me again for permission to proceed once you have established the
applicable fee. I will have a courier pick up the response as

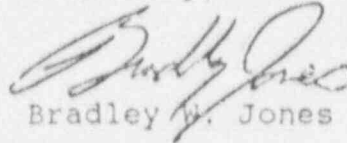
~~9161225203~~
JRP

AKIN, GUMP, STRAUSS, HAUER & FELD

Donnie H. Grimsley
July 17, 1990
Page 2

soon as it is available. If any portion of this request is denied, please provide an explanation of the reasons for the denial, including the specific statutory exemption relied on, as required by 5 U.S.C. Sec. 552(a)(6)(A)(i) and NRC regulations in 10 CFR Sec. 9.27(b)(2).

Sincerely,



Bradley W. Jones

cc: SECY