

RTI Inc

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

030-07022

Information in this record was deleted
in accordance with the Freedom of Information

August 1, 1989

Con Agt. exemptions *b and 7c*
FOIA: ~~7-23-90-334~~

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

License No. 29-13613-02

8/6/89
Aug-6-I
Merrill
8/8/89

Dear Mr. Kinneman:

As agreed to at our meeting of July 27, 1989, we are resubmitting the qualifications of Paul O. Shapiro and John Schlecht for the positions of radiation safety officers for the Process Technology of North Jersey facility.

Mr. John Schlecht has, in addition to his formal training at Rensselaer Polytechnical Institute, over one years practical experience in Engineering at a Nuclear Power Station, an additional year experience as a Health Physicist at the National Institute of Health, and over a years experience as Physicist at RTI, including more than one months actual time operating the irradiator.

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, and has taken and evaluated radiation surveys. He has over three months involvement with the design and installation of the safety and operational controls for the new irradiator source rack.

Mr Schlecht has successfully completed several courses in Radiation Science from Georgetown Graduate School and Rensselaer as well as Radiation Safety Training Courses at the National Institute of Health. Copies of Mr. Schlechts' resume and details of his training are attached.

To comply with NRC guidelines requiring 3 months (12 weeks) actual OJT, Mr. Schlecht currently has completed 5 weeks OJT. In addition he has spent more than three months involved in the evaluation, development and installation of the safety interlock and operational control system of the RTI 2102 -B irradiator. This equivalent OJT should meet the guidelines as specified in the Reg Guide. In his new position as Plant Manager he will continue to receive OJT and should have completed 12 weeks of OJT about the end of September 1989.

9102050195 901106
PDR FOIA
JONES90-334 PDR

OFFICIAL RECORD COPY

D/5 111101
Rec'd via AUG 02 1989

August 1, 1989

Page 2

Mr. John D. Kinneman, Chief

Mr. Paul O. Shapiro, in addition to his formal training at Lycoming College and New York University Graduate School, 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 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 and inspections (reviewed by the NRC), developed RTI's configuration controlled procedure manual, developed with the Corporate RSO 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 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, seminars on Toxicology, Handling of Toxic Materials, completed 40 hours of Radiation Safety Officer Training at the Central Connecticut State University and a 3 day course given by Stan. A. Huber Consultants, Inc. on Radiation Training and Management, Radiation Safety Programs, Emergency Response and Record Keeping Requirements. Copies of Mr. Shapiro's resume and details of his training are attached.

To comply with NRC guidelines requiring 3 months (12 weeks) actual OJT, Mr. Shapiro currently has 2 weeks completed. He will continue to receive OJT at the rate of about 2 weeks per month and should have completed 3 months of OJT by the end of 1989.

We appreciate your review of this information. Please advise us if your review finds that either or both Mr. Schlecht or Shapiro have met the requirements as specified in the Reg Guide.

Sincerely yours,

J. Scandalios
Mr. John N. Scandalios
President

cc: M. Knapp (NRC)
Bettenhausen (NRC)

John D. Schlecht



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
 Corporate Radiation Physicist
 January 1988 - Present

- * Assisted in design and construction of RTI 2102-B Irradiator.
- * 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
- * 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
 1987

- * 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
1985 - 1986

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

Applicable Courses

Undergraduate - Rensselaer Polytechnic Institute

Radiological Engineering, Nuclear Reactor Analysis, Reactor Engineering, Nuclear Energy Conversion, Heat Transfer, Plasma Engineering, Quantum Physics I II III, Physics I II III, Experimental Physics, Chemistry I II, Fundamental Particles, Intermediate Mechanics, Physical Thermodynamics, Holography, Astronomy I II, 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, PC's
PARDES, GRACE1, QADGP, HECTIC, FCOST, RADSTRS computer codes

Honors

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

RSO Training - John D. Schlecht

page 1 of 2

<u>Date(s)</u>	<u>Training</u>
1/4/88 - 7/15/88	Assisted in design of Safety Interlocks and control system of RTI 2102-B irradiator. Design Co-60 configuration for Irradiator.
1/11/88 - 1/12/88	Loaded 200,000 curies of Co-60 sources into North Carolina's source rack.
7/16/88 - 8/1/88	Assisted in construction of RTI 2102-B irradiator.
5/9/88	Loaded two GE model 1500 casks with 120,000 curies of Co-60.
5/12/88	Loaded two GE model 1500 casks with 43,000 curies of Co-60.
5/16/88	Loaded two GE model 1500 casks with 56,000 curies of Co-60.
6/15/88	Loaded 90,000 curies of Co-60 into North Carolina's source rack.
7/15/88	Unloaded 197,710 curies of Co-60 from AECL F-168 shipping cask at North Jersey.
7/30/88 - 8/1/88	Loaded 838,737 curies of Co-60 into North Jersey's source rack.
8/14-30/88	OJT on RTI 2102-B irradiator. Equivalent to 2 weeks full time.
10/12/88	Passed RTI Irradiator Operator Qualification Exam with 94% score.
11/20/88	Unloaded 486,591 curies of Co-60 from South Jersey source rack.
11/21/88	Loaded 363,442 curies of Co-60 into two GE model 1500 shipping casks.
11/22/88	Unloaded 363,311 curies of Co-60 from two GE model 1500 shipping casks at North Jersey.
11/23/88	Loaded 123,149 curies of Co-60 from GE model 1500 shipping cask.

RSO Training - John D. Schlecht

page 2 of 2

<u>Date(s)</u>	<u>Training</u>
11/23/88	Unloaded 123,149 curies of Co-60 from GE model 1500 shipping cask.
11/24/88	Loaded 1,290,489 curies of Co-60 into North Jersey source rack.
7/13/89 - 7/28/89	OJT on RTI 2102-B irradiator. Equivalent to three weeks full time. Total to 7/28/89 equals five (5) weeks of OJT training.

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. Developed operational training programs and assisted in training of Operators.

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...Revlon 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.

Paul O. Shapiro...page 4

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

EDUCATION: B.A., Biochemistry, Locoming 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 ANMI meeting on Process Guidelines for Gamma Irradiation of Medical Devices.
Aug. 6-7, 1986	Conducted Radiation Safety Audit and Inspection at PTI NC.
Aug. 13-14 1986	Conducted Radiation Safety Audit and Inspection at Salem.
Sept. 5, 1986	Reviewed and evaluated Jim Nicolosi's radiation safety audit.
Sept 11, 1986	Conducted a Radiation Safety Audit and Inspection 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 and Inspection 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 and Inspection at PTI Ark.
Jan. 5, 1987	Review of renewal application for NRC license #29-13613-02
Jan 6-7, 1987	Conducted Radiation Safety Audit and Inspection at PTI Ark.
Jan. 28-29, 1987	Conducted Radiation Safety Audit and Inspection at No. J.
Feb. 4, 1987	Prepared RTI Radiation Safety Program.

Training Record

page 2 of 4

Paul O. Shapiro

April 20, 1987.	Conducted Radiation Safety Audit and Inspection at No.J.
April 29, 1987	Conducted Radiation Safety Audit and Inspection at Salem.
May 6-7, 1987	Conducted Radiation Safety Audit and Inspection at PTI NC.
May 19-20, 1987	Conducted Radiation Safety Audit and Inspection 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 and Inspection 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 and Inspection 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 Niccolosi radiation safety audit.

111104

Training Record

page 3 of 4

Paul O. Shapiro

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 and Inspection at No.J.

Sept. 25-26, 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.

Training Record

page 4 of 4

Paul O. Shapiro

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 through July 27, 1989	On the Job Operator training (part time). Equivalent to 2 weeks full time.

29-1361302

CONVERSATION RECORD

TIME 2:00 P

DATE 8/7/89

TYPE

VISIT

CONFERENCE

TELEPHONE

INCOMING
 OUTGOING

Location of Visit/Conference: Returned Mr. Stern: 1:30 pm call.

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

David Stern

ORGANIZATION (Office, dept., business, etc.)

Didn't identify

TELEPHONE NO.

Rm. 710	
NAME/SYMBOL	INT
Mr. Linnell, RF	
C. A. H... ..	
J. Miller, RF	
J. L... ..	
J. H... ..	
J. M... ..	
W/ 29-1361302	

SUBJECT

Employment at RTI

SUMMARY

Mr. Stern previously worked at RTI (during the period when DeWalt was president). He has talked to Paul Shapiro, currently QA Mgr @ RTI, about employment as a Radiation Physicist. He asked if we (the NRC) would have a problem with him returning to RTI in that position? I told him the current license conditions prohibit only Walt, Louis & Powell from being involved with licensed activities at RTI. He said that he had been one of those previously prohibited from certain activities. I noted that that prohibition was lifted. I asked if he knew if the section requires him to be named on the license. He said he didn't, but would that be a problem if it did, or should we "cross that bridge when we come to it." I said "the latter." I stressed the need for strict compliance with NRC requirements, and noted that the NRC had taken into condition (in our previous dealings with Walt et al) the fact of Dr. Walt's personality and ^{organizational} the level of those who might have done something about the wrongdoing. I told him I heard that

ACTION REQUIRED

None

NAME OF PERSON DOCUMENTING CONVERSATION

J. Jagne

SIGNATURE

DATE

8/7/89

ACTION TAKEN

Information in this record was deleted in accordance with the Freedom of Information Act, exemptions 6 and 7C.

SIGNATURE

FOIA: 90-334

TITLE

DATE

D/6

CONVERSATION RECORD

TIME

DATE

TYPE

 VISIT CONFERENCE TELEPHONE INCOMING OUTGOING

ROUTING

NAME/SYMBOL	EXT

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

ORGANIZATION (Office, dept., bureau, etc.)

TELEPHONE NO.

SUBJECT

SUMMARY

if reemployed by RTI, that he'd recognize his obligation to perform in accordance with the license. He said he'd learned his lesson. He doesn't make the same mistake twice.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

ACTION TAKEN

SIGNATURE

TITLE

DATE

50271-101

U.S. GPO: 1989-241-175/80261

CONVERSATION RECORD

OPTIONAL FORM 271 (12-79)
DEPARTMENT OF DEFENSE