PROCESS TECHNOLOGY
QUALITY STATUS
AND
IMPROVEMENT PLAN

August 6, 1990

PROCESS TECHNOLOGY QUALITY STATUS AND IMPROVEMENT PLAN

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PROCESS TECHNOLOGY QUALITY STATUS AND IMPROVEMENT PLAN

A. SUMMARY

On June 27, 1990, the NRC placed Process Technology's facility on its "Priority Facilities" list. As a result of that action, it is considered necessary and appropriate to formally document actions, either already implemented or planned, to improve Process Technology's performance. This document, the details of which follow, has been given the title, "Process Technology Quality Status and Improvement Plan" (henceforth, "The Improvement Plan").

The Improvement Plan had its origins in a policy statement issued by Mr. Scandalios on March 9, 1989, a few weeks after his arrival at Process Technology. This Policy is to:

1. Receive only those products clearly permitted by appropriate regulatory authorities; and

2. To handle, irradiate, and ship all products so that they:
   - consistently conform to the requirements established;

- are in full compliance with all applicable legal regulations;
- meet specifications established by the products owner; and
- comply with Process Technology's internal standards to assure the quality of irradiation service, product handling, and employee safety.

B. INTRODUCTION

The Improvement Plan is divided into several basic sections. Section "C" covers actions Process Technology had taken prior to placement on the "Priority Facilities" list. This section is vital to Process Technology in that it is not clear that the NRC was fully aware of these actions prior to this submittal. Section "D" covers the formal commitments being made by Process Technology to take additional actions because of being added to the "Priority Facilities" list. It is to be noted that it has been our intention to do most section "D" items on a more informal basis prior to our placement on the "Priority Facilities" list. Section "E" is a statement by Management. Section "F" is a tabulation of our actions.

C. ACTIONS TAKEN TO IMPROVE PERFORMANCE

1. Establishing a New Management Team

Following the resumption of operations in 1986, there was a series of temporary Presidents at Process Technology. When Mr. Scandalios arrived in late February, 1989, he began a process of evaluating operations at the facility and the other facilities owned by Process Technology's parent corporation. His first priority was to develop an effective management team. This new management team was needed to assure compliance with company procedures, to run our facilities safely, and in accordance with government requirements. The lessons learned from the U.S. Nuclear Regulatory Commission, Region I inspection in March, 1989, and the enforcement conference in April, 1989, helped to confirm Mr. Scandalios' belief that tough, hands-on management would be necessary to bring about the type of operations appropriate for Process Technology's activities.

As will be explained in detail below, a number of efforts were commenced to change the attitude of Process Technology personnel. In fact, these efforts included not only that facility, but also the other facilities run by Process Technology's parent corporation. It was made clear to management and employees that the company was to operate in strict compliance with all

procedures. One result of these efforts was that managers who did not demonstrate the ability or willingness to operate under this policy resigned or were asked to resign. Other technically competent people who believe in and are committed to the new safety attitudes and policies at Process Technology, were assigned to the responsibilities of those individuals who had left. This included management changes at every one of the facilities operated by Process Technology's parent corporation.

In addition to the above, a Radiation Safety Committee was created to make sure all levels of management were informed of and made responsible for, correcting deficiencies identified through internal or external audits or inspections. The Vice-President for Quality, who had been identifying problems in the past, but who had lacked the authority to assure corrective actions were taken, assumed an enhanced Vice Presidential position which included a role as the Corporate RSO. In this new position, he has the authority and the responsibility to follow up on problems he identifies, to be certain that adequate corrective actions are taken. Further, an experienced and degreed RSO, with a background in administering a government radiological safety program and in operating the irradiator at Process Technology, assumed the RSO position at the facility during 1989. Our RSO's resume is provided for information as an attachment to our improvement plan.

We believe the above changes, as well as the actions described below, have served to create a management team that has brought about a substantial improvement in safety and effectiveness to Process Technology's operations.

We will continue to monitor the effectiveness of our organization and our managers to ensure that the new team will achieve our safety goals.

2. Corrective Actions

An issue that was of special concern to Mr. Scandalios when he first joined Process Technology, as exemplified in some of the undisputed findings in the March, 1989, inspection, was the question of assuring corrective actions were taken when issues were clearly identified during either internal or external audits and inspections. To assure that expedient corrective action is taken regarding radiological concerns, Procedure 10.0 "Radiation Protection Program" was implemented in the second quarter of 1989. This procedure set up the Radiation Safety Committee. The committee is composed of the Corporate Officers, the RSO, and the Plant Manager. The committee has met monthly since May 1989.

This process assures that top management is aware of and involved with radiological safety matters. We believe this program has had a positive effect in preventing problems being identified but not corrected. Copies of the minutes of the committee meetings are available. As part of this program, the Plant Manager is required to report to the committee, on a weekly basis, concerning corrective actions for the items cited on internal or external audit reports, until the corrective action is completed.

This committee will continue to operate to improve the safety of operations.

3. Attention to "Doing Things Right"

Following the April, 1989, enforcement conference, it was made clear to employees that they were expected to follow the strict guidelines set out by the new president. As described above several significant management changes were necessary, and were made, in the process of creating a team that has nuclear excellence as their goal. These changes were not limited to the corporation's New Jersey facility. They included management changes at both the North Carolina and Arkansas facilities.

Process Technology's new team is dedicated to our policy of:

- assuring all areas of operations are in strict compliance with government regulations;

- assuring ALARA principles are considered;

- placing an emphasis on prevention;

- ensuring corrective actions are taken promptly;

- maintaining safety as the paramount concern in everyone's mind; and

- working to assure things are done right 100% of the time.

Positive results of this policy were evident in changes in employee attitudes and improved attention to detail. Several examples serve to illustrate these changes.

After the new management team was in place and after efforts to communicate the philosophy of strict compliance to all Process Technology personnel were commenced in the second and third quarters of 1989, Process Technology's internal audits showed an overall improvement in attitudes and performance in Process Technology's operations. We believe this improvement shown in these audits is evidence that the corporate philosophy was beginning to reach all levels of our operations. Copies of the audit reports are available.

One example of what we believe is an improvement in both attitudes and performance was the handling of an exposed film badge which, we believe, was well managed by the new team. The NRC was notified immediately, with good communications and cooperation on both sides, and the event was satisfactorily resolved. (NRC Region I Report No. 030-07022/90-002, March 20, 1990).

Low level radioactive contamination is, we believe, another example of an issue handled well by the new team. Studies were undertaken to determine the extent of the contamination that apparently occurred years ago at the facility. Four specific areas were identified and marked. Progress reports and a clean up plan were sent to Region I. After receiving feedback from Region I, a reevaluation was performed and a final clean-up plan was submitted to the NRC. Under the final plan the drummed contaminated material and the ground contamination will be appropriately handled by February 1991.

Continuing management attention, and resources, will be placed on assuring that things are done correctly.

4. Preventive Maintenance and Equipment Performance

Process Technology has increased its emphasis on equipment performance and preventive maintenance. Discussions are held by the plant RSO, the Corporate RSO, and the Operators to locate possible problem areas and to take appropriate corrective or preventive action. One example of this is the procurement and installation of a back-up computer terminal for the irradiator.

One of the major efforts by the new team was a review of irradiator operations. In the review, safety features and operations were validated. Some were identified as requiring improvements, and those improvements were made. The Preventive Maintenance (PM) procedure was improved. Replacement parts are being documented and tracked. Management reviews the PM records to determine items of concern appropriate for preventive actions. For example, documentation showed that the 90 second time delay start-up switch in the cell was requiring frequent replacement or repair due to its presence in a high radiation area. Upon evaluation, additional shielding was installed to reduce the rate of deterioration. As a result of concerns expressed by NRC, Process Technology is also paying closer attention to the performance of approximately 21 limit switches in the irradiator. We are tracking the performance of these switches to determine if and when corrective or preventive actions are required.

These important areas are receiving, and will continue to receive, the necessary attention to assure proper performance of nuclear and personnel safety functions.

5. Staffing

The company has focused attention on concerns expressed by the NRC in the past regarding staffing and supervision of the shifts. It appeared to the NRC that back shifts were staffed by the newest, least trained personnel. As a result of those concerns, Radiation Safety Audits are conducted to periodically review all shifts and operators. Additionally, operators assigned to the night shift must first qualify with a seasoned operator and are assigned only after the RSO is satisfied that they should be placed on that shift. Management, including the Plant Manager, the Vice President of Quality, and the President make unannounced visits to the operational areas on all shifts.

The responsibility of management to determine the adequacy of its operations is fully recognized by Process Technology. Actions of the type stated above will continue to be conducted.

6. Training

Historically, training was not consistent, regular, or well documented in that lesson plans and attendance sheets were not utilized. With an emphasis on improving training, lesson plans have been prepared, continue to be added to, updated, and utilized. Training schedules are prepared in advance and all operators receive regular documented training. Some type of training is given on approximately a monthly basis.

During training it is stressed that if there is any doubt about how to proceed, or doubt about whether a specific action is permitted, clarification from management is to be received even if it means operations must be stopped until the issue is resolved.

These actions reflect the corporate philosophy that the most important asset of our company is a well trained staff. Manager's evaluations or appraisals are based, in part, on the training they have given their staff.

Our efforts, fully supported by management, will continue.

7. Improvements and Adherence to Procedures

After the April, 1989 enforcement conference, procedures relating to irradiation safety were reviewed by Operations, Corporate Quality, and an outside Radiation Health Physics Consultant. As a result, a number of procedures were rewritten and improved. Also, the procedure control system has been given new emphasis. Procedures are numbered, dated and approved by management. Operational and radiation safety procedures have been submitted to the NRC for review.

The corporate message has been emphasized that procedures must be correct and followed. This approach to safety has been emphasized by written warnings to some people who have not complied with our policy. In one instance an employee was dismissed who did not heed formal warnings. Managers' evaluations or appraisals are based, in part, on the level of compliance achieved by them and their staffs.

Procedure review is an on going task. Plant managers have programs for reviewing procedures and procedures will be reviewed at intervals of approximately two years or as necessary.

The emphasis by management on procedures will continue.

8. Documentation

Documentation was considered inadequate by executive management. It was made clear to managers that they would be held responsible, to the president, for improving documentation performance. All managers were instructed on the importance of complete and accurate documentation, especially regarding any item relating to irradiation operations or radiation safety.

We believe that these actions have resulted in a much higher quality of record keeping for Process Technology operations. Managements emphasis on complete and accurate documentation and records will continue.

9. Reporting to NRC

Process Technology understands its duty and is committed to providing, accurate and complete information to the NRC in all communications. We will continue to be sensitive in our communications and responsibilities and will promptly take action when necessary to assure ourselves tha. the NRC has received or is receiving accurate information. We believe the handling of the film badge incident displays the type of prompt and effective communications that Process Technology wants to have with the NRC.

With regard to .he computer signal problem discussed in more detail below, although the NRC agreed there was no safety concern or violations, there was concern whether it would have been appropriate to inform the NRC. Although, to our knowledge, the incident was not reportable, we intend to be more sensitive to issues which, although not reportable or of safety concern to the NRC, may be of interest to the NRC. We will attempt in such situations to establish, through telephone contacts with the NRC, whether additional information, including written follow-up, may be desired.

Management will continue to emphasize the importance of reporting events to the NRC.

10. Safety Evaluations

All personnel have been made aware that the irradiator must operate in accordance with specifications. No on the spot solutions are acceptable. Recently, corrective action was necessary on a faulty computer signal from a limit switch. All aspects, including radiological safety, were discussed and evaluated by the RSO and the Corporate RSO. Other than routine maintenance or preventive maintenance, we will continue to have all problems reviewed by the RSO.

The RSO will review any unusual irradiator problems with the Corporate RSO or President, prior to restart.

11. Independent Audits

From February 26, 1986 to March 21, 1989 the NRC Region I inspectors visited Process Technology's facility approximately 38 times. On only 3 of those occasions were violations noted. These were relatively minor. Two of the violations were Severity Level 4 and one was a Severity Level 5. From August 16, 1989 to July 31, 1990, about five inspections were conducted which noted two relatively minor Severity Level 4 violations. Only the one inspection conducted in March, 1989 has resulted in special NRC attention.

As required by NRC, nine quarterly, Independent Audits were conducted by Mr. Michael Slobodien, our health physics consultant and former NRC employee, between February 1988 and March 1990. Eleven internal audits were conducted by the Vice-President of Quality between January 1988 and June 1990.

These audits and the NRC inspections provided valuable information that was used by Process Technology, particularly after the creation of the Radiation Safety Committee, to improve operations.

The above discussions have highlighted the actions already taken since 1986. Most of these actions have been implemented since

John Scandalios assumed the Presidency of Process Technology. While we fully intend to continue the above efforts, the placement of Process Technology's facility on the "Priority Facilities" list indicates that more must be done. The second part of this improvement plan describes additional actions Process Technology intends to take to reach our goal of excellence.

D ACTIONS BEING TAKEN TO FURTHER IMPROVE PERFORMANCE

1. Communications

There is an obvious and important need to further improve communications and trust between the NRC and Process Technology. Accordingly, the management of Process Technology has launched an effort to improve communications at all levels of the NRC and Process Technology. Because of the difficult schedules of the Commissioners during July and August, we began our efforts by having visits from the President of Process Technology to each of the Commissioners in accordance with their busy schedules. While at NRC headquarters the President also met with senior management of the headquarters staff to improve communications with those individuals. In addition a meeting was held between the Regional Administrator and the President of Process Technology. We hope that the visit with the Regional Administrator, or the Deputy Regional Administrator, becomes an annual event to provide additional assurance of good communication.

We believe that it would be advantageous to have an NRC representative, familiar with operations at a variety of materials licensees, come to our facility and talk to Process Technology management and operators once a year to discuss

current regulatory issues and lessons learned from other material licensees. We have already implemented actions to keep abreast of the latest developments in radiological safety. Managers attend and participate in seminars and meetings, such as those held by nuclear organizations. Both the RSO and Corporate RSO are members of ASTM Committee E 10 "Nuclear Technology and Applications" and have participated in related seminars and meetings. U.S. NRC Regulatory Guides and Draft Regulatory Guides are received and reviewed. The new U.S. NRC Bulletins, such as NRC information Notice No. 89-82 relating to material licensee concerns, are reviewed and discussed with all operators.

We are committed to improving communications with the NRC and taking advantage of the lessons learned.

2. Maintaining and Improving Employee Performance

Process Technology plans to continue its practice of holding meetings with operators to discuss audit and inspection results (internal, consultant, and NRC) to assure that concerns related to proper operations are reaching appropriate individuals. In addition, the President and/or Vice President will hold a meeting with employees on at least a semi-annual basis to review the status of audit findings, corrective actions, the results of any actions proposed as a result of "lessons learned information" received from NRC, and to reenforce the corporate safety policy.

We will reemphasize to all employees that they have the responsibility to question actions that they believe to be wrong and/or questionable with respect to either NRC regulations or company procedures. We will reemphasize to all employees that if they do not get a satisfactory answer to their questions, they are to escalate the question through the management chain and to the NRC if they are not satisfied with the answer they are receiving. The need to assure completeness and accuracy of all communications with the NRC will be reconveyed to all employees.

We will continue to stress good communications with our employees to assure open communication channels exist.

3. The Integrity Program

The current training program taken by all employees will continue to stress that, if there is any doubt about how to proceed, or doubt about whether a specific action is permitted, clarification from management is to be received even if it means operations must be stopped until the issue is resolved. A key element of this continuing training program is the "Standards of Business Conduct" or ethics training program. The ethics training program consists of formal regularly scheduled training regarding Good Manufacturing Procedures and ethics. It emphasizes honest and trustworthy practices and law abiding business activities.

L. Management Statement

Mr. Scandalios has made it clear to management and other employees that any employee not adhering to the rules may be dismissed. Those who did not believe or could not accept his message are no longer with the company. Our company will continue to commit the management attention and resources necessary to satisfy NRC concerns and to continue to improve operations. If concerns remain with the NRC about our operations, we believe that the above actions will lead quickly to a resolution of those concerns. Process Technology wants to acknowledge that many of the above elements of our Improvement Plan were either suggested or made more effective because of suggestions and information provided through NRC inspections or independent audits mandated by NRC. These efforts have amply demonstrated that more can be accomplished when NRC and Process Technology cooperate to improve operations. We are committed to achieving excellence in our operations. We are determined to see Process Technology's facility removed from the NRC's "Priority Facilities" list.

F. Tabulation Of Actions

Attached to this Improvement Plan is a table which summarizes the information contained above and which gives the status of each action.

Attachments:

A- Table of Improvement Plan's Actions and Status

B- Resume of RSO

TABLE OF

IMPROVEMENT PLAN'S ACTIONS AND STATUS

ACTION ITEM	STATUS OF ACTION ITEM
C.1 Establishing a New Management Team.	C.1 A new Management team is in place that is dedicated to improving Process Technology's safety performance
C.2 Corrective Actions	C.2 The Radiation Safety Committee is fully functional and will continue to receive management attention.
C.3 Attention to "Doing Things Right"	C.3 Management has taken and will continue to take any actions necessary to assure this philosophy is understood and implemented.

TABLE OF

IMPROVEMENT PLAN'S ACTIONS AND STATUS (cont)

ACTION ITEM	STATUS OF ACTION ITEM
C.4 Preventive Maintenance & Equipment Performance	C.4 The improved Preventive Maintenance Procedure has been implemented and will continue to receive management attention.
C.5 Staffing	C.5 Process Technology has completed upgrading both training and experience for operators, including unannounced visits to the back shift. These actions will continue.
C.6 Training	C.6 Process Technology has, and will continue to implement its improved training procedures.

TABLE OF

IMPROVEMENT PLAN'S ACTIONS AND STATUS (cont)

ACTION ITEM	STATUS OF ACTION ITEM
C.7 Improvements and Adherence to Procedures	C.7 Process Technology's procedure upgrade program has been completed. This is an ongoing task which will continue to receive management attention.
C.8 Documentation	C.8 Maintenance of complete and accurate information is Process Technology's policy and management has so informed all employees.
C.9 Reporting to NRC	C.9 Process Technology has sensitized employees to, and will continue to stress the importance of, reporting events to the NRC.

TABLE OF

IMPROVEMENT PLAN'S ACTIONS AND STATUS (cont)

ACTION ITEM	STATUS OF ACTION ITEM
C.10 Safety Evaluations	C.10 All employees have been instructed that procedures are to be followed and any unusual circumstances shall be addressed by management before operations continue.
C.11 Independent Audits	C.11 The Radiation Safety Committee has and will continue to assure that the results of ongoing audits and NRC Inspections are promptly and appropriately addressed by Process Technology.

TABLE OF

IMPROVEMENT PLAN'S ACTIONS AND STATUS (cont)

ACTION ITEM	STATUS OF ACTION ITEM
D. Communications	D.1 Meetings with each Commissioner, the Deputy EDO, the Director of NMSS, and the Regional Administrator have been held. Management will continue to place emphasis on good communications.
D.2 Maintaining and Improving	D.2 Process Technology has and will continue to hold periodic meetings with our employees to discuss lessons learned with our audits or inspections.
D.3 The "Integrity" training Program.	D.3 All employees have taken this program as of June 1990. Future employees will also be required to take this program.

John D. Schlecht
P.O. Box 1561
Greenwood Lake, NY 10925
(914) 477-8263

Education

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

Experience

Process Technology Inc.
Plant Manager and Radiation Safety Officer
July 1989 - Present

- Managed all aspects of gamma sterilization facility including Quality Control, plant maintenance, personnel, employee training, shipping and receiving, and regulatory affairs (NRC, FDA, USDA).
- Trained all personnel on radiation safety and ALARA program.
- Ensured strict adherence to GMP's (Good Manufacturing Practice).
- Certified Operator RTI 2102-B Irradiator.
- Responsible for ensuring strict regulatory compliance for all shipments of radioactive material.

RTI Inc. - Rockaway, NJ
Corporate Radiation Physicist
January 1988 - July 1989

- 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.
- 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, snubber 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/Associations

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

Martin A. Welt, Ph.D.
4 Rocky Heights Road
Morris Plains, New Jersey 07950
201-[illegible]-0043 (H)
201-334-9321 (O)

December 4, 1990

NUCLEAR REGULATORY AGENCY
Region 1
Freedom of Information Office
475 Allendale Road
King of Prussia, PA 19406

FREEDOM OF INFORMATION
ACT REQUEST

FOIA-90-553
Rec'd 12-11-90

Dear Sir:

Under the Freedom Of Information Act, I hereby request the following information within the time constraints of the Act.

LICENSEE
: RTI, INC.

108 Lake Denmark Road
Rockaway, NJ 07866

INFORMATION REQUEST:

1. Copies of all Inspection Reports for 1989 & 1990.
2. Copies of all correspondence by the licensee to the NRC concerning areas of non-compliance, licensing, inspections and Notices of Violation.
3. All correspondence from the NRC to the licensee concerning the topics mentioned in (2) above.

Your prompt attention to this request would be appreciated.

Very truly yours,

Martin A. Welt, Ph.D.

cc: RTI File

[illegible]

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