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For: Commissioners C
From: Victor Stello, Jr.
Executive Director for Operations

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

Purpose: To inform the Commissioners of the staff's evaluation of the performance of Radiation Technology, Incorporated (RTI), during the probationary period from August 22, 1986, to February 28, 1987, as authorized by NRC Materials License No. 29-13613-02, Amendment No. 19, relative to the RTI facility in Rockaway, New Jersey; recent developments; and, the consequent recommendation by the staff to delay renewal of the license until specified issues are clarified and appropriate license conditions developed.

The Commissioners were previously advised of the staff's actions pertaining to RTI in SECY-86-93, dated March 21, 1986, and SECY-86-179, dated June 16, 1986. Further, since SECY-86-179, the NRC Office of Investigation (OI) issued two additional reports of their investigations conducted at RTI on October 21, 1986 (Case Nos. 1-86-006 and 1-86-009). Case No. 1-84-026 was previously issued by OI on June 9, 1986. A narrative summary of NRC actions relative to RTI from 1977 to August 1986 is included as Enclosure 1.

Discussion: On August 22, 1986, RTI's Materials License No.

29-13613-02 was renewed for a probationary period of six months; expiring February 28, 1987. In this matter, the Commission required the staff to take the following measures:

- a. During the six months probationary period, the staff was to schedule additional inspections to evaluate the licensee's performance, and to establish a frequent NRC presence.
- b. The staff was to conduct meetings, as necessary, with RTI employees to strongly convey the seriousness with which NRC views the company's actions, and the necessity to demonstrate improvement as a condition for any further renewal of the license.

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- c. The staff was to keep the Department of Justice informed of any actions that the Commission plans relative to RTI.

Relative to these directions, the following has been accomplished, respectively:

- a. During the six month probationary period, the staff has conducted thirteen separate inspections at RTI's irradiator facility in Rockaway, New Jersey. These inspections were performed in general accordance with the enclosed inspection plan (Enclosure 2). In order to evaluate the licensee's performance from these inspections, the staff elected to use the same NRC assessment technique typically reserved for power reactor licensees, i.e., the Systematic Assessment of Licensee Performance (SALP).

In the case of materials licenses, the SALP process is not usual because the frequency of inspection is much lower in comparison to the inspection frequency of power reactors. Consequently, a data base sufficient to support an analysis over a given time period is not usually available. However, the thirteen inspections performed at RTI in this six month period provided a sufficient data base to support SALP evaluation. The SALP report, included as Enclosure 3, describes the Staff's assessment of the licensee, and their qualitative judgment of the licensee's performance during this period.

While some areas were noted as requiring strengthening, such as preventative maintenance approaches, quality assurance program protocols, and the need to improve adherence to procedures, the SALP Board agreed that the licensee performance was generally satisfactory, and management attention and involvement were evident and directed toward radiological safety. At that time, the Board was of the opinion that the licensee had the potential and interest to continue to improve program performance.

However, since that time, changes have occurred in RTI's organization that are significantly different than previously evaluated, and could potentially alter the plan for program improvement that was expected to continue. For example, Dr. Robert Cockrell, the Vice President of Operations and Engineering and Radiation Safety Officer during this assessment period resigned the position March 31, 1987. As noted in the SALP, Dr. Cockrell was instrumental in bringing about the significant program

improvement observed, and consequently enhanced the credibility of the RTI organization in the view of the staff. While his replacement is believed to be competent and capable, and has so far demonstrated responsiveness and attention to radiological safety matters, his impact on the program has not been evaluated. In light of the incredibly poor performance prior to this probationary period, observe evaluation is necessary before warranting the program as being fully successful.

Compounding this significant staffing change, it has recently come to the NRC staff's attention that the company has endorsed a more conservative fiscal policy and does not plan any further expansion, but intends to maintain itself as a service company. While RTI maintains that licensed activities will not be adversely affected, the staff noted that on April 2, 1987, there was a significant reduction of the engineering support staff in the organization. Further, personnel hired in the probationary period for the purpose of enhancing the quality and implementation of personnel training and qualification were terminated. The staff also detected that the abruptness in which the licensee executed this personnel reduction may have adversely effected the morale of some of the remaining members of the organization.

While this matter does not directly effect regulatory matters, many of the observations noted in the SALP were predicted on the fact that there was sufficient technical depth in the organization to address the engineering and design problems that tended to surface; the licensee was committed to improve the quality of training personnel; and management was intending to continue to strengthen its oversight and control of matters involving licensed activities. The effect of the consequences of these recent changes on the continued implementation and maintenance of the safety program for licensed activities is now uncertain.

- b. On September 15, 1986, Mr. James M. Taylor, Director, Office of Inspection and Enforcement; Dr. Thomas Murley, Regional Administrator, Region I; and Mr. Thomas T. Martin, Director, Division of Radiation Safety and Safeguards, Region I, addressed the entire employee staff associated with RTI's Rockaway Facility, including several of RTI's executive corporate officers. At this meeting, the staff strongly conveyed the seriousness of the company's actions

with respect to previous willful disregard of NRC regulatory requirements, and the need to improve performance and regain the confidence of the NRC as a condition for license renewal.

The effectiveness of this meeting was apparent in subsequent inspections of the facility. NRC inspectors noted that the licensee's attitude and sensitivity to operating in accordance with regulatory requirements and maintaining safety systems operable had greatly improved. Conservatism with regard to facility operation was routinely exhibited. Further, licensee personnel were noted to be open and frank about problems that had been encountered, and kept the NRC regional office fully informed of anomalous occurrences and deficiencies.

Subsequently, the NRC regional staff met on December 18, 1986, and March 20, 1987, with the licensee's corporate executives including the newly appointed President, Mr. David Levitt. In these meetings, the licensee was appraised of the NRC's analyses of their performance and of the concerns relative to the managements intent and plan for the facility. These concerns were largely a result of recent information that had become available concerning the potential that radioactive material may have been previously buried on the site in nonconformance with existing regulations by the direction of the previous management of RTI.

On December 24, 1986, the licensee had notified that while performing some exploratory excavation on their own initiative, based on verbal information recently acquired by them, an anomalous indication of radiation had been found in a subsurface location. At that time, the licensee agreed not to pursue further excavation until the effort could be coordinated with both the NRC and State of New Jersey in order to assure adequate preparations proper safety precautions should buried radioactive material be encountered. No immediate action was taken due to the inclement weather and conditions that prevailed during the winter.

On March 9, 1987, the Office of Investigation, Philadelphia Field Office, revealed documents to the Region I staff that appeared to indicate the location of buried radioactive material. The same documents were provided by the licensee in the March 20, 1987 meeting with members of the regional staff. Subsequently, other documentation was uncovered that

supported that burials or re-burials (i.e. material that was reportedly buried between 1976-1977 that might have been unearthed and re-buried between 1981-1982) had occurred. Further, interviews conducted by members of the inspection staff, of personnel no longer associated with RTI, gave indication that radioactive material may have also been improperly stored or disposed of on RTI property without proper controls or restrictions.

In the light of Department of Justice's prosecutorial preparations involving RTI, and this new information, Region I accelerated actions to characterize the RTI property with respect to buried radioactive material and the possible storage or disposal of radioactive material on RTI property. Accordingly, a Confirmatory Action Letter (CAL) (Enclosure 4) was negotiated with the licensee and issued on March 24, 1987. The CAL documented the licensee's commitment to comprehensively survey and characterize suspected portions of the property relative to buried radioactive material.

Further, Region I requested technical assistance from Oak Ridge Associated Universities (ORAU) in surveying the unrestricted portions of the RTI property (about 250 acres), in an effort to identify the presence of any radioactive materials that may be stored or disposed of on the site. ORAU initiated this effort on April 13, 1987, and did identify the presence of some items containing low level radioactivity, but nothing of major consequence was discovered.

Following an analysis of both of these efforts, the region will make a determination relative to the need to extract any radioactive material that is suspected to be buried; and cause the consolidation and proper disposition of all other radioactive waste materials found.

- c. Throughout this probationary period, the staff kept the Department of Justice advised of any action or events that were pertinent, and provided OI with any new information that became available.

As part of their review, the Region I staff also has explored the financial interest in the company that is still maintained by Dr. Martin Welt. To this end it was determined that Dr. Welt owned as of February 6, 1987, about 1,000,000 shares of RTI, i.e., about 16% of the company. These shares are being maintained by RTI in

accordance with an irrevocable proxy which prevents Dr. Welt from having any influence over the Board of Directors or company policy. While two individuals on the Board of Directors are related to Dr. Welt, i.e., Dr. Arnold Orlander, Vice President of Sales (cousin), and Dr. Martin Sage (brother-in-law), the staff has found no evidence that these individuals have or intend to promote Dr. Welt's involvement in the company.

While these new developments, since Region I's assessment of the licensee's performance, do not clearly indicate that the licensee might be ineffective in continuing to improve program performance, such conditions are a significant challenge to a program that has just now become credible after years of willful neglect. This new challenge occurs at a time when the licensee needs to not only maintain, but continue to improve the control over licensed activities. In light of the fact that: (1) significant management change has recently occurred; (2) fiscal policy has been altered to be more conservative; (3) the technical staff has been abruptly reduced considerably; (4) the licensee is being stressed to provide technical resources to ameliorate concerns relative to buried radioactive material and effect disposition of other accumulated radioactive wastes; (5) several individuals previously restricted by the current license from performing in management functions (and as a result were not previously subject to evaluation in the probationary period) will likely assume management positions if the license is renewed; and (6) the observation by inspection personnel that recent personnel and administrative actions may have had detrimental effect on the morale of some of the remaining staff (e.g. further resignations may be expected), we suspect that the licensee's performance may level out and might even decline in time.

Since this is only a suspicion and not an actuality, the NRC could continue to allow operation under timely renewal, since the licensee submitted a complete application for renewal on February 20, 1987, until it is evident that the licensee will be able to perform sufficiently. However, the current license is severely restrictive and may impede further performance improvement. Consequently, the staff proposes the following:

1. That the license be renewed for only a one year interval in order to monitor and reevaluate performance, and effect license modification as necessary if continued operation is permitted;

2. That conditions be incorporated into the license, that may be warranted as the result of the on-going characterization of RTI's property relative to the disposition of radioactive waste materials;
3. That the Commission authorize the staff to issue such license after all input is obtained, and the staff concludes that there is reasonable assurance that the activities proposed by the licensee are able to be conducted without undue risk to the health and safety of the public.

Following such action the staff intends to continue frequent inspection of the RTI Rockaway facility, and to increase inspection activities at RTI's facility in Salem, New Jersey, since the corporate changes identified affect both operations.

Enclosures 5 and 6 are the draft license and supporting safety evaluation report that we would expect to issue, without the additional input that is expected to be incorporated upon the completion of the field work relative to buried radioactive materials.

During this probationary period, RTI's past performance and their expected plan to construct another facility at the Port of Elizabeth was of major concern to the city of Elizabeth, New Jersey. At the city's request, the Region I staff met with certain city officials on January 29, 1987. At that meeting, the Regional staff explained the NRC's role in licensing and inspecting RTI's facilities. In that discussion the city voiced its objections to any construction of a facility in Elizabeth and the continued licensing of the facility in Rockaway. To this end, the Elizabeth City Council adopted a resolution on February 10, 1987, strongly urging the NRC to reject continued licensing of any of RTI's facilities, and request that this resolution be submitted to and considered by all of the Commissioners in connection with activities pertaining to continued licensing of RTI's Rockaway facility. In this regard the City of Elizabeth's resolution is included as Enclosure 7.

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Enclosures: As stated

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

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SUMMARY OF NRC ACTIONS RELATIVE TO
RADIATION TECHNOLOGY INCORPORATED
SINCE 1977

Radiation Technology, Incorporated has been licensed to operate a large irradiator near Rockaway, New Jersey since November 1970. The irradiator uses about 650,000 curies of cobalt-60 in sealed sources to produce high intensity gamma ray fields for the sterilization of various products, including medical equipment and supplies for industrial and scientific applications. The licensee is also involved in food irradiation research and has long been seeking FDA approval to irradiate food products for human consumption. RTI also owns and operates similar irradiator facilities in West Memphis, Arkansas; Haw River, North Carolina; and Salem, New Jersey through wholly owned subsidiaries.

RTI has been the subject of several escalated enforcement actions in the past relative to the Rockaway, New Jersey facility. The most serious incident occurred in 1977 when a plant worker was able to enter the irradiation room while the source was in the unshielded position. Such entry was possible because the safety interlock system designed to prevent such occurrence was purposely bypassed by the licensee. Consequently the worker received a radiation dose between 150 and 300 rem, an occupational exposure well in

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excess of regulatory limits. The license was temporarily suspended following this incident until the licensee took necessary corrective measures.

The events giving rise to the most recent Suspension Order were first noticed during a routine NRC inspection in September 1984. At that time, the inspector discovered the irradiator facility had been operating since April 1984 with an inoperable safety interlock on one of the two conveyor openings used to transfer product into the irradiation room. In response, Region I issued a Confirmatory Action Letter (CAL) to RTI on September 26, 1984, documenting the licensee's commitment to operate the facility only if all safety interlocks were operable and to cease operations if any safety interlock failed to function as required.

Subsequent review of this event revealed that the interlocks were bypassed by the operators as ordered by the Operations Manager. To determine if this represented intentional violations of NRC regulatory requirements, an OI investigation was requested on September 27, 1984. Since the immediate safety concern regarding the bypass on the conveyor opening interlocks was not as great as that associated with the bypass of the interlocks on the personnel access door, the staff delayed issuance of enforcement actions pending the results of the OI investigation (Case No. 1-84-026).

The investigative effort was initiated immediately but other priorities prevented completion until May 5, 1986. The investigation established that on numerous occasions between April 3, 1984, and September 20, 1984, employees of RTI intentionally violated license conditions by operating the irradiator

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after defeating the safety interlock system at the direction of the then President of RTI. Additionally, the investigation revealed that licensee employees continued to operate in violation of the license after the NRC inspection on September 1984, in spite of the RTI President's commitment, to the NRC inspector at the exit interview and in subsequent correspondence, to operate only with functioning interlocks. Consequently, the results of this investigation were provided to the Department of Justice for prosecutorial review.

An NRC inspection on February 26, 1986, noted that the licensee had been operating the irradiator facility for several days prior to the inspection while the radiation monitor, which actuates the personnel access door interlock when the radiation source is exposed, was malfunctioning. The malfunction caused the access door to be kept locked even when the source was in the shielded position and prevented normal access to the radiation cell. Instead of repairing the monitor, the licensee continued to operate the facility. In this condition, licensee personnel routinely effected entry by tripping the door lock when the radiation source appeared to have returned to the shielded position. In response, the NRC, (1) requested the licensee to cease all operations until the monitor was repaired, (2) conducted daily inspections to assure that the facility was being operated safely and that all interlocks were functioning, and (3) requested an OI investigation of the operation of the facility with the inoperable radiation monitor to determine if the licensee intentionally violated a licensed condition by bypassing a safety interlock system on the irradiator. An Order Suspending the License was issued on March 3, 1986.

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On March 13, 1986, the NRC issued a Conditional Rescinding of the Order Suspending License after the licensee agreed to third and fourth party oversight of facility operations, with uncensored performance reporting directly to the NRC. On March 16, 1986, the licensee requested a hearing on the original Suspension Order, but withdrew the request on April 11, 1986.

The OI investigation (Case No. 1-86-006), completed in April 1986, concluded that RTI's operators intentionally bypassed safety interlocks on the personnel access door to the irradiator cell when the radiation monitoring unit was inoperable. On May 6, 1986, a third OI investigation (Case No. 1-86-009) was initiated at the request of Region I's Regional Administrator. This request was based on concerns that had been expressed to the regional staff by the third party oversight organization and other parties associated with RTI. In this case OI was asked to determine: (1) whether the then President of RTI improperly aided one of the third party representatives on the required familiarization examinations; (2) if the then President directed RTI employees to withhold information from the third party organization in violation of the March 13, 1986, Conditional Rescinding of the Order Suspending the License; (3) whether the then President directed third party organization employees to refrain from submitting their audit reports to the RTI Board of Directors; (4) whether the then President backdated a September 21, 1984, RTI memorandum directing employees not to bypass safety interlocks to deceive the NRC; and (5) whether certain RTI employees made false statements to investigators and inspectors when previously interrogated relative to activities at RTI.

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While items (1) and (3) could not be substantiated, OI did conclude that the third party organization was not informed of all equipment malfunctions. Further, OI reported that seven employees, including operators and managers, conspired to lie to investigators relative to resolution of problems affecting the personnel access door safety interlock, and made false statements to investigators relative to being "coached" prior to OI interviews. In fact, it was learned that the President intimidated employees and provided them with the company's position on events on which they might be questioned by NRC investigators. Additionally, OI learned that some documentation was backdated at the direction of the then President but it was not concluded that the memorandum in question was one of those documents.

However, based on the evidence of willful violation of NRC regulatory requirements and conspiracy to deceive the NRC relative to activities affecting personnel safety that these three investigations revealed, an Order Suspending Licenses was issued June 23, 1986.

This Order suspended all licensed activities at RTI's Rockaway, New Jersey facility pending NRC review of the licensee's renewal applications, and prohibited the transference of any employee or officer of the licensee involved with this facility between April 3, 1984, and February 26, 1986, to any of RTI's other irradiator facilities without the approval of Region I's Regional Administrator. In response to this Order, the licensee made several submittals to the NRC, including the, "Licensee's Answer to Immediately Effective Order Suspending License," dated July 18, 1986, which was provided via sworn affidavit from the newly designated Chairman of the Board, RTI. In

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this submittal the licensee detailed a corrective action program which identified among other items that the then President (also identified as the Chief Executive Officer, previous Chairman of the Board, and Director of RTI) had resigned; and, the then President's stock was placed in a voting trust with an independent trustee, to be voted in accordance with the direction of the majority of the Board of Directors. This submittal further identified the appointment of the new Chairman of the Board and a new Vice President of Operations and Engineering. Subsequent submittals by RTI further identified admission that the then President, did willfully violate NRC regulatory requirements and was responsible for conspiring to subvert NRC investigatory efforts. Personnel most responsible for directing activities contrary to NRC regulatory requirements and attempting to deceive the NRC were identified as having been removed from the company.

These submittals and the licensee's application for license renewal were evaluated by the staff. The staff's Safety Evaluation Report concluded that there was now reasonable assurance that the activities proposed by the licensee could be conducted without undue risk to the health and safety of the public; and recommended renewal of the license for a probationary period of six months. Consequently, on August 22, 1986, the suspension of the license was lifted, and License No. 29-13613-02 was renewed with an expiration date of February 28, 1986.

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