U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

Region I

Report No. 30-7022/78-01

Docket No. 30-7022

License No. 29-13613-02 Priority I Category E

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

Facility Name: Radiation Technology, Inc.

Inspection at: Radiation Technology, Inc.

Inspection conducted: April 6 and 26, 1978

Inspectors: Michael J. Slobodien — June 16, 1978
M. J. Slobodien, Radiation Specialist — date signed

Robert O McClintock — 6/16/78
for J. E. Glenn, Radiation Specialist — date signed

_____ — _____
date signed

Approved by: Robert O McClintock — 6/16/78
R. O. McClintock, Chief, Materials — date signed
Radiological Protection Section

Inspection Summary:

Inspection on April 6 and 26, 1978 (Report No. 30-7022/78-01)
Areas Inspected: Routine, unannounced inspection of licensed operations including tour of facilities, review of authorized operations, irradiator safety systems, leak tests, surveys, radiation in unrestricted areas, employee training, personnel radiation protection, inspector independent measurements, review of regulatory changes. The inspection involved 28 inspector hours onsite by two NRC inspectors.
Results: Of the ten areas inspected, eight items of noncompliance were identified in four areas (Infractions - unauthorized irradiator operator, failure to conduct service irradiator interlock tests at required frequency, failure to have operational door interlock at in-air irradiator upper conveyor, failure to perform conductivity and pH analyses of irradiator pool water at weekly intervals, failure to make water activity measurements at quarterly intervals, failure to make monthly radiation surveys at pool demineralizer, Deficiency - failure to document training of employees).

Region I Form 12
(Rev. April 77)

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DETAILS

1. Persons Contacted and Dates Contacted

Dr. Martin A. Welt, President (April 26, 1978)
Mr. Robert Buckley, Supervisor - Radiation Operations (April 6 and 26, 1978)
Dr. Seymour Preis, Laboratory Director (April 6, 1978)
Mr. Thomas Powell, Plant Superintendent (April 6, 1978)
Mr. S. Haram, Manager, Facilities Engineering and Production (April 6, 1978)

2. Entry to Facility

The inspectors arrived at the licensee's facility at 10:00 a.m. on April 6, 1978. The flashing light above the in-air irradiator cell was on indicating that the source rack was in the exposed position. The inspectors were met at the reception area by Mr. R. Buckley who, after being informed of the routine nature of the inspection, promptly escorted the inspectors to in-air and R&D irradiator areas. Buckley informed the inspectors that Dr. M. Welt, President and Radiation Safety Officer was away on business.

3. Review of Authorized Operations

Through questioning of R. Buckley and T. Powell, and a review of the operator's log book the inspectors determined that the service irradiator had been used in the batch mode only. Mr. R. Buckley stated that the continuous mode operation had been tested. R. Buckley stated that no continuous mode irradiations had been performed.

The shift supervisor's log book and irradiation log book indicated that medical devices, chemicals, and test samples had been irradiated in the period December 17, 1977 to April 4, 1978. R. Buckley stated that no corrosives or explosives had been irradiated. The inspectors noted that log book entries usually indicate the customer identification number, sample size, and irradiation conditions needed.

In response to inspector questions, R. Buckley stated that the following individuals operate the in-air irradiator: T. Powell, W. Anderson, D. Fosse, J. Stuz, F. O'Rourke, R. Buckley.

The inspectors confirmed that the control to operate the in-air irradiator was by key. The key was on a wire attached to an Eberline E-120 geiger counter equipped with a side window probe. The key is attached to the survey meter to ensure that the meter is carried to the personnel door which is operated by the control console key. Once the personnel door is open, the key is removed and the survey meter may be carried into the irradiator. This geiger counter is normally stored at the in-air irradiator control console. A copy of the instruction manual was available at the control console.

The finding that R. Buckley was operating the service irradiator constitutes noncompliance with condition 12.A of License 29-13613-02. However, the inspectors noted that the licensee had submitted a request, dated December 23, 1977, to the NRC's Radioisotope Licensing Branch to add R. Buckley to the list of authorized operators.

4. In-Air Irradiator Safety Systems

The inspectors reviewed the licensee's actions regarding testing of the in-air irradiator safety systems. The safety systems consist of interlock switches and associated electrical circuits, warning signs and visible lights, and audible signals and alarms. On April 6, 1978, in response to inspector questions, R. Buckley stated that the interlocks and safety systems on the in air irradiator were last tested and the test results recorded on December 17, 1977. R. Buckley stated that he had made tests of proper interlock function since December 17, 1977, on a few occasions, but that no records of such tests were made by him or the Radiation Safety Officer. R. Buckley stated that he did not conduct nor was he aware of any other individual conducting interlock tests each month since December 1977.

On April 26, 1978, Dr. Welt stated that interlocks are tested often, since, whenever the in-air irradiatior is inadvertantly shut down, due to power failure or failure of the "tote pushers" to move a product carrier into position within the required time, restarting of the in-air irradiator necessitates resetting of any interlocks which have been activated as well as reentry into the irradiator to reset the start up interlocks. The inspectors noted that at such times, the conveyor door interlocks, photoelectric cell in the irradiator labyrinth, and emergency shutdown cable may not be and usually are not tested.

In the inspectors presence on April 6, 1978, R. Buckley tested for proper functioning of the in-air irradiator interlock switches and electrical circuits and warning devices. Specifically, the function of the following was tested as described:

a. Lower and Upper Conveyor Door Safety Shutdown System

The cabaret-type doors for the upper and lower conveyor to the in-air irradiator each have a sliding dead bolt lock which contacts a switch inside a protective pipe cowling when the doors are closed and locked. When the switch is actuated by the dead bolt, it functions permissively to allow power to be applied to the source raise mechanism. When not actuated, the switch functions to interrupt power to the source raise mechanism which, if raised, will then lower the source rack to its shielded position in the irradiator pool while sounding a locally audible "source in motion" warning horn and actuating a "fault" light at the irradiator control console.

The switches and associated interlock circuitry were tested by raising the source in the routine manner and opening one of the conveyor doors. The test was then repeated for the other door. The lower conveyor door was opened first and the interlock worked properly by causing the source rack to lower into its shielding pool while sounding a clearly audible warning horn. A fault light was activated at the control console. The source was again raised to the in-air irradiate position after resetting the necessary circuitry. The upper conveyor door was then opened. The warning horn, console light and source lowering failed to occur. The inspectors waited for about 30-60 seconds, since there is a delay of about 6 seconds after opening the cabaret door, prior to activation of the safety shutdown system. When it became apparent that the safety circuit had failed to operate as intended, R. Buckley manually activated the shutdown system at the irradiator control console. The source lowered into the pool and warning horn sounded. R. Buckley then examined the upper conveyor door switch and determined that it was stuck in the actuated (depressed) position. The switch was repaired and the test repeated. Upon repeat testing the safety system operated as intended. In reply to inspector questions, R. Buckley stated that the switch had worked properly when tested about two weeks earlier. The inspectors stated that it was necessary to identify the cause of the switch failure so as to take remedial action to prevent its recurrence.

b. Personnel Door Solenoid Lock, In-Cell Radiation Monitor, and Control Console Key

There is a steel grate personnel door adjacent to the conveyors which provides access into the in-air irradiator maze. This door has a solenoid driven latch which is mounted on the door frame. A key switch is mounted on the opposite side of the door frame. This switch is operated by the irradiator console control key. When all interlock conditions are satisfied, turning the key in the switch allows power to be applied to the solenoid releasing the lock and allowing the door to be opened from outside the maze. The personnel door may be opened from inside the maze at any time with the interior door handle. Thus, under no circumstances is an individual inside the maze prevented from exiting.

The control console key must be used to operate all irradiator controls. If the key is removed at any time when the source is in the up position or when the source is being raised, operation is terminated and the source is lowered by the source raise mechanism into its shielding pool, and the locally audible "source in motion" warning horn is actuated until the source is indicated to be in its safe shielded position.

Inside the inner maze walkway mounted on the wall is a radiation monitor. There is a meter read out for this monitor at the irradiator control console. When the source is in its shielded position, a minimal background reading is present at the maze radiation monitor. As the source rises out of the pool, the maze monitor senses the increasing radiation and the console meter shows an up scale deflection; as the source continues to rise out of the shielding pool, the radiation level present at the maze radiation increases and causes a saturation of the instrument at which time the meter reading falls to zero.

In order to open the personnel door the solenoid driven latch must be energized. This will not occur until the following are completed:

(1) The maze radiation monitor must be interrogated to assure the presence of a minimum radiation level by depressing a test button at the control console. During a previous inspection, Dr. M. Welt stated that a nonzero minimum meter deflection must be present to actuate a switch which acts permissively to allow power to be applied to the solenoid driven latch.

(2) A switch on the source raise mechanism must be activated. This occurs when the source raise mechanism is in the lowered position (indicating that the source rack is in its shielded position). The switch then acts permissively to allow power to be applied to the solenoid door latch. There are no switches which are actuated by the source rack itself to indicate that the source rack is in its shielded position.

(3) The key switch on the personnel door frame must be turned to the "on" position. This is done using the control console key. (Administrative control is used by the licensee to insure that a duplicate key is not available). The maze radiation monitor was tested passively after the source had been lowered into its shielded position by attempting to open the personnel door without first depressing the radiation monitor test button. The solenoid would not energize even though all other conditions were satisfied. After the test button was operated with a minimal maze radiation monitor meter reading present at the control console, the console control key was inserted into the key switch and it then did operate the solenoid driven latch.

A test of the console control key was made by raising the source then removing the key. The "source in motion" locally audible horn sounded and the source returned to its shielded position. The personnel door key switch did not operate the door solenoid until the testing of the maze radiation monitor as described above.

c. Personnel Door Roller Switch

A switch is attached to the steel grate personnel door lintel such that the switch is activated when the door is nearly or fully closed. When the switch is actuated it functions permissively to allow power to be applied to the source raise mechanism. When the door is not fully closed, the spring loaded switch is released and functions to interrupt power to the source raise mechanism. If the door is opened while the source is in a raised position, the safety circuit is designed to cause a fault light to activate at the control console and a warning horn to sound. This safety system does not have the provision for testing its function when the source is in the raised position.

However, this safety system was partially tested by attempting to raise the source in the normal fashion while leaving the personnel door open. Power could not be applied to the source raise mechanism indicating proper operation of the door switch. This safety system was tested with the source in its fully lowered position only.

d. Cell Maze Entry Photocell

An infrared photocell and detector is mounted in the personnel walkway about 6 feet beyond the entrance to the in-air irradiator maze. The purpose of this photocell is to detect the presence of an individual entering the maze. When the photocell detects its light beam it functions to permissively allow power to be applied to the source raise mechanism and the maze door solenoid lock. When the beam is blocked and the photocell does not detect the light beam, it functions to interrupt power to the source raise mechanism, causing the source raise mechanism to lower the source into its shielding pool if it is up or being raised and prevent raising of the source if it is in the shielding pool; if the source is lowered the locally audible "source in motion" horn is also actuated. This safety system was tested passively by blocking the photocell with a piece of cardboard and attempting to raise the source. The source raise mechanism did not operate with the photo cell blocked. An active test was not conducted.

e. Start-up Toggle Switch

The initial start-up procedure after any shutdown of the in-air irradiator, includes activiation of an in-cell toggle switch which sounds a warning buzzer and starts a timer. The operator must then exit the cell, close any open doors and place the control console control key in the "on" position before the 70 second timer runs out, or the start-up is terminated. This function was tested and worked properly.

f. Emergency Shutdown Cable

Along the perimeter of the interior of the in-air irradiator cell at about 48 inches above the floor is an emergency shutdown cable. The purpose of the cable is to allow an individual who might be in the irradiator proper inadvertently during start-up to terminate start-up. The cable operates a switch and the function of the cable and switch was tested by initiating the irradiator start-up sequence using the start-up toggle switch, then pulling the cable. Start-up ceased and a fault light lit at the control console. The irradiator could not be started until the fault light was reset.

g. Maze Door and Interior Warning Lights

During testing of interlocks, the inspectors observed that the above door and maze interior warning lights lit whenever the source was being raised, lowered, or in the full up position.

R. Buckley stated that the interlocks described above have not been tested on each day that the in-air has been started up. The inspectors noted that the licensee does not have a written procedure for routine or special interlock testing.

The finding that the upper conveyor door interlock on the in-air irradiator was inoperable on the day of the inspection and that the various interlocks for the in-air irradiator were not tested upon start-up on any given day constitutes noncompliance with condition 16 of the license.

5. In-Air and R&D Irradiator Leak Tests, Water Quality Test, Radiation Contamination Surveys

The inspectors reviewed the results of leak tests for the cobalt-60 sources in the service and R&D pools and the AECL-C-160 self contained irradiator. These tests were last performed on December 17, 1977, by R. Buckley using the licensee's sodium iodide detector and scaler; the results were recorded in R. Buckley's notebook. At that time, the licensee reported no detectable activity in either irradiator pool or on the leak test wipe of the AECL C-160 contained irradiator. Mr. Buckley stated that no additional leak tests or tests for pool water activity had been made since December 17, 1977. Mr. Buckley explained that the method for pool water activity testing is to take a 40 milliliter sample of pool water and count it for ten minutes on a 3 inch sodium iodide crystal coupled to a scaler. He estimated that the sensitivity of this test was about 10^{-7} uCi/ml. The inspectors noted from R. Buckley's notebook that on December 17, 1977, the sodium iodide detector background was 347 counts per minute and a gross counting rate for a pool water sample was 365 counts per minute.

Based on the licensee's data, the inspectors calculated an estimated minimum detectable activity (MDA) for cobalt-60 in pool water. Dr. M. Welt estimated a total efficiency for the 3 X 3 inch sodium iodide detector used with a wide open single channel as 20%.

MDA 1σ (68% confidence level)

$$\frac{\sqrt{\frac{347 \text{ c/min}}{10 \text{ min}}}}{(40 \text{ ml})\ (0.2)\ (2.22 \times 10^6 \frac{\text{dpm}}{\text{uCi}})} = 3.3 \times 10^{-7} \text{ uCi/ml}$$

MDA 2σ (95% confidence level)

$$\frac{2 \times \sqrt{\frac{347 \text{ c/min}}{10 \text{ min}}}}{(40 \text{ ml})\ (0.2)\ (2.22 \times 10^6 \frac{\text{dpm}}{\text{uCi}})} = 6.6 \times 10^{-7} \text{ uCi/ml}$$

The calculations indicate that the licensee's counting system is capable of detecting cobalt-60 concentrations below those listed in Table II of Appendix B, 10 CFR 20. The inspectors provided two water samples to the licensee for evaluation of cobalt-60. Each sample was supplied in a 40 milliliter bottle provided and normally used by the licensee for counting leak test samples. The 40 milliliter samples supplied contained a total of 0.050 and 0.074 microcuries of cobalt-60. These samples were counted by R. Buckley on the licensee's 3 X 3 inch sodium iodide detector coupled to a scaler. R. Buckley reported the result of sample counting to be 0.044 and 0.054 microcurie, respectively. Dr. Welt and R. Buckley indicated that no cobalt-60 calibration sources were available but one had been ordered.

The inspectors discussed the leak test method with R. Buckley and pointed out to him that the procedures incorporated into the license require quarterly water samples of 100 ml from in-air and R&D pools to be analyzed on the sodium iodide detector coupled to a multichannel analyzer.

From a review of licensee records and discussions with R. Buckley it was determined that the contamination and radiation surveys of the irradiator areas and demineralizer room required to be performed on a quarterly frequency had last been performed on December 17, 1977. R. Buckley stated that contamination and pool water surveys had not been made in recent weeks because the counting equipment was not operating.

The inspectors determined by questioning R. Buckley during the inspection that pH and conductivity measurements required by the license to be made on a weekly frequency had not been performed since December 17, 1977. Mr. Buckley also noted that to his knowledge surveys in the demineralizer room had not been conducted at the required monthly frequency. He stated that to his knowledge surveys were last made on December 17, 1977, and included surveys of the pool water demineralizer filter.

On April 26, 1978, R. Buckley tested the resistivity of the R&D Pool water in the presence of the inspectors. He used a Beckman resistivity meter which he stated had been purchased recently. The resistivity measured 5000 ohm-cm. The inspector noted that the licensee's letter dated November 18, 1970 and referenced in condition 16A of license number 29-13613-02 specifies that the lower

limit for operations for pool water conductivity is 50,000 ohms. Dr. Welt stated that the high water conductivity* was caused by an improperly installed strainer in the pool demineralizer. This had been repaired and according to Dr. Welt pool water quality was expected to improve.

*The inspectors note that this licensee normally refers to pool water quality measured by resistivity in ohms-cm as conductivity in ohms. The inspectors further note that such terminology is in common usage at similar facilities. High conductivity is indicated by low values of resistivity (i.e. 5000 ohm-cm), low conductivity is indicated by high values of resistivity (i.e. 200,000 - 1,000,000 ohm-cm).

a. The finding that pool water samples were not taken and analyzed for cobalt-60 at quarterly intervals constitutes noncompliance with condition 16 of the license. The inspectors noted that a pool water sample had been taken on April 22, 1978, and analyzed for cobalt-60 activity and that the activity was reported as "no detectable." The previous water sample was taken for cobalt-60 analysis on December 17, 1977.

b. The finding that weekly pH and conductivity measurements of the service and R&D pools had not been made as required constitutes noncompliance with condition 16 of the license.

c. The finding that weekly radiation surveys of the demineralizer filter were not made as required constitutes noncompliance with condition 16 of the license.

6. R&D Irradiator Safety Systems and Surveys

The inspectors reviewed operations of the R&D facility separately with R. Buckley and T. Powell on April 6, 1978. All operations appeared to be in accordance with the license with the exceptions of surveys and leak tests identified in section 4 of this report.

The inspectors asked R. Buckley to demonstrate the operability of the wall mounted radiation monitor/alarm in the R&D area. R. Buckley depressed the test button which causes an internal check source to move in front of the detector portion of the monitor. The radiation detected caused the monitor meter movement to move up

scale but the meter failed to reach the preset alarm set point. Buckley then manually lowered the alarm set point and again depressed the test button. The meter again moved up scale and contacted and passed the set point but the audible alarm bell failed to sound when the set point was reached or exceeded. Buckley made adjustments to the alarm bell. Upon a third test, both the monitor and alarm operated properly.

The inspectors noted that cigarette butts were littering the floor of the R&D pool area. The room is prominently posted as a no smoking area, since work is done with flamable methyl methacrylate in the area.

7. Receiving Pool Area

The inspectors toured the receiving pool room with R. Buckley. Two 55 gallon drums containing contaminated materials were observed. Radiation levels on the top of the drums were 0.3 mR/hr as measured by an E-120 geiger survey meter equipped with an end window (1.2 mg/cm^2) probe last calibrated on March 15, 1978. The survey was performed by M. Slobodien. Several water treatment cartridges, containing small quantities of radioactive material were stored in the receiving pool room, according to statements by R. Buckley. All items were properly labelled with a Caution Radioactive Materials sticker.

8. Unrestricted Areas

The inspectors toured the unrestricted areas outside of the licensee's irradiator areas with R. Buckley. No radiation levels were identified, in excess of limits specified in 10 CFR 20.105. A water, soil and vegetation sample was taken at a run off area on the licensee's property. This was analyzed at the Region I Laboratory on April 7 and 10, 1978, using a 3 x 3 inch sodium iodide detector and Tracor Northern 1026 channel multichannel analyzer. The analysis indicated cobalt-60 present at 1.3×10^{-5} uCi/ml $\pm$ 2×10^{-7} uCi/ml. This is below the levels allowed for water in unrestricted areas according to Table II, Appendix B, 10 CFR 20.

9. Training

The inspectors reviewed the status of the training of personnel with R. Buckley and T. Powell. From the discussions with R. Buckley on April 6, 1978, it was learned that since December 17, 1977, no training as outlined in the licensee's October 12, 1977 letter has been conducted. Mr. Buckley stated that he had been given some responsibility for training and had given a quiz to production employees in December 1977. Dr. Welt stated on April 26, 1978, that he has held training discussions with employees regarding radiation safety. None of the sessions have been documented as required in the licensee's letter dated October 12, 1977.

The finding that the training of licensee employees has not been documented as required constitutes noncompliance with condition 16 of the license.

10. Personnel Protection - External

Personnel in the licensee's restricted area were observed to be wearing film badge dosimeters to measure external exposure to radiation. The film badges were worn at waist level at the front of the body. The film badges had been supplied by the RS Landauer Corporation and were worn in the designated film badge holder.

Film badge records for the period October 1977, through March 1978, reviewed by the inspectors showed that the licensee had changed film badge vendors in November of 1977. Since that time, two persons have had positive badge readings of 20 mrem and 30 mrem, respectively. All other measurements were reported as being below the minimum detectable dose.

Records of personnel exposure prior to November showed that the dose received by the individual exposed in September 1977 has been recorded as the film badge reading of 125.755 rem. Dr. Welt was advised by the inspectors that an evaluation of a dose received under those circumstances must be made and include all other data available to the licensee. This would include time-distance studies, medical evaluation, and partial shielding of the film badge by the exposed individual. The inspectors noted that medical data placed the dose at 175-220 rem.

11. Inspector Measurements

The inspectors made radiation and contamination measurements in restricted and unrestricted areas with a Ludlum Model 16 analyzer coupled to a 1 x 1 inch sodium iodide detector and smears counted on the Region I low background gas-flow proportional counter. Water samples were taken from both the service irradiator pool and the R&D pool. A water sample of run-off from the licensee's property was taken from an unrestricted area as discussed in Section 8 of this report.

Radiation levels in the restricted and unrestricted areas were acceptable. Contamination levels were in the range of 0-40 dpm/100 cm^2. Water concentrations from the various areas sampled are summarized below.

Area	Status	Cobalt-60 [5] Concentration	Unrestricted Area MPC_W [1]
In air irradiator shielding pool	Restricted Area	$3 \times 10^{-7} \pm .4 \times 10^{-7}$ $\frac{uCi}{ml}$ [2, 3]	5×10^{-5} $\frac{uCi}{ml}$
R&D irradiator shielding pool	Restricted Area	$1.7 \times 10^{-6} \pm .6 \times 10^{-7}$ $\frac{uCi}{ml}$ [3]	5×10^{-5} $\frac{uCi}{ml}$
		$2.2 \times 10^{-6} \pm .8 \times 10^{-7}$ $\frac{uCi}{ml}$ [4]	5×10^{-5} $\frac{uCi}{ml}$
Drainage run off to Lake Denmark north of receiving building in an unrestricted area on licensee's property within fence boundary	Unrestricted Area for purposes of radiation protection		
-- Clarified solution		$2.9 \times 10^{-7} \pm 1.4 \times 10^{-7}$ $\frac{uCi}{ml}$ [3]	5×10^{-5} $\frac{uCi}{ml}$
-- Water and solids		$1.3 \times 10^{-5} \pm 2 \times 10^{-7}$ $\frac{uCi}{ml}$ [3]	5×10^{-5} $\frac{uCi}{ml}$

NOTES:

1. MPC_W: Maximum Permissible Concentration in Water from Appendix B, Table II, 10 CFR 20.
2. Minimum detectable activity at 95% (2σ) confidence level is 6.7×10^{-8} uCi/ml.
3. Sample collected April 6, 1978
4. Sample collected April 26, 1978
5. Error shown are 95% (2σ) confidence limits

12. Review of Regulatory Changes

The inspectors reviewed the licensee's actions in implementing the requirements of 10 CFR 20.203(c)(6). As of April 26, 1978, the licensee was in compliance with all sections except as follows:

-- 10 CFR 20.203(c)(6)(vii)

-- 10 CFR 20.203(c)(6)(viii)

Specifically, tests were not being carried out to insure that the service irradiator interlocks are checked for proper operation prior to initial operation on any day that operations were not uninterrruptedly continued from the previous day. The entry/exit portal of the service irradiator is not equipped with the instrumentation required by 10 CFR 20.203(c)(6)(viii).

The licensee's president was advised of the requirement to report to the NRC before June 14, 1978, actions taken or planned to bring the licensed program into compliance by December 14, 1978, as provided in the regulation.

13. Exit Interview

The results of the inspection were reviewed with Dr. M. Welt at the conclusion of the inspection on April 26, 1978, and during a telephone conversation on April 27, 1978.