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November 22, 1989

Director, Office of Enforcement
U.S. NUCLEAR REGULATORY COMMISSION
Washington, D.C. 20555

Attention: Document Control Desk

Docket No. 03-20402
License No.04-23240-01
EA 89-148
Re: 10CFR 2.201
10CFR 2.205

Subject: United States Testing Company, Inc.
Answer to Notice of Violation and Proposed
Imposition of Civil Penalties: EA 89-148

Gentlemen:

By letter dated September 26, 1989, the Nuclear Regulatory Commission (NRC) transmitted to Unitech Services Group, United States Testing Company, Inc. (UST) its Notice of Violation and Proposed Imposition of Civil Penalties relating to NRC Inspection Report No's. 89-02 and 89-03. In this letter the NRC identified two groups of alleged violations: (1) violations representing a breakdown in UST's compliance with a system of NRC requirements intended to protect against exposure in excess of 10 CFR Part 20 limits and 10 CFR Part 34 security requirements; and (2) violations involving failure to properly label the radiographic exposure device and its transportation overpack. Pursuant to 10 CFR 2.201 and 2.205 and the terms of the NOV, attached is UST's Answer to each of the alleged violations.

As discussed more fully in UST's Answer to the NOV, UST admits Violation I-E and Violation II, but has chosen to contest the other violations as inaccurate and incomplete representations of UST's activities in the specified areas. Proper application of NRC Enforcement Policy would result in a determination that both the Severity Level and proposed civil penalty are not appropriate.

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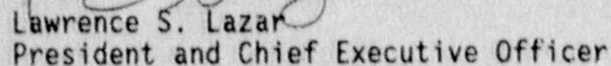
Should there be any question concerning our response to this Notice of Violation, please contact either myself, or Mr. Joseph Mohrbacher of my staff at 201-792-2400.

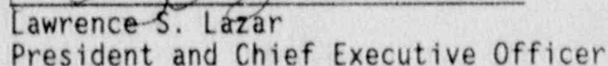
Sincerely,
UNITED STATES TESTING COMPANY, INC.



Lawrence S. Lazar
President and Chief Executive Officer

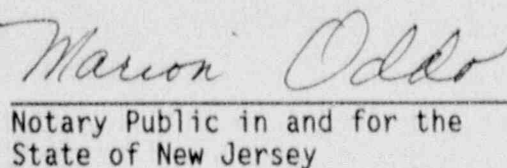
cc: Regional Administrator
USNRC Region V

I, Lawrence S. Lazar, being sworn, subscribe to and say that I am President and Chief Executive Officer for United States Testing Company; that I have full authority to sign and file with the Nuclear Regulatory Commission the attached Answer to NRC Notice of Violation and Proposed Imposition of Civil Penalties -- EA 89-148 and am familiar with the contents thereof; and that the matters set forth therein are true and correct to the best of my knowledge and belief.



Lawrence S. Lazar
President and Chief Executive Officer

Subscribed and sworn to before me a Notary Public in and for the State of New Jersey this 21st day of November, 1989.



Notary Public in and for the
State of New Jersey

MARION ODDO
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires May 8, 1994

Docket No. 030-20402
EA 89-148
Re: 10CFR 2.201
Re: 10CFR 2.205

ATTACHMENT 1

UNITED STATES TESTING COMPANY, INC.

ANSWER TO NOTICE OF VIOLATION

AND

PROPOSED IMPOSITION OF CIVIL PENALTIES

NOVEMBER, 1989

UNITED STATES TESTING COMPANY, INC.
ANSWER TO VIOLATIONS I AND II

Restatement of Violation I.A.

"10 CFR 20.201(b) requires each licensee to make such surveys as may be necessary to comply with the requirements in part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other source of radiation under a specific set of conditions.

10 CFR 20.105(b)(1) provides, in part, that except as authorized by the Commission, no licensee shall use licensed material in such a manner as to create, in any unrestricted area from radioactive material, radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of two millirems in any one hour.

Contrary to the above requirements, at the time of the inspection, the expected radiation exposure in Room 3029 during planned radiographic operations had not been evaluated as necessary to assure compliance with 10 CFR 20.105(b)(1). If the inspector and the Radiation Safety Officer of the VA Medical Center had not intervened, individuals in Room 3029 would have received approximately 5 mrem in one hour."

Response

Denied.

Reason

The NRC is basing this violation on one independent measurement made with an instrument that was not under the Quality Control/Quality Assurance Program of the NRC. In other proceedings, the NRC has alleged violations of regulations for the use of instruments not belonging to and under the continual control of the licensee. The same standard should be applied to NRC activities.

It also appears that the NRC disregarded all other radiation survey results and misinterpreted the shielding effect of added lead. The instrument readings cited in the Notice of Violation do not appear to be consistent with either another reading from the same instrument or other survey readings and dose rate calculations. Additional lead-shielding which was applied between shots would not in and of itself explain the different readings on the instrument in Room 3029. The alleged exposure rates simply cannot be independently verified. We question such reliance on one selective, but questionable instrument reading while ignoring other conflicting radiation survey results. Therefore, the alleged potential exposure rates should not form the basis for a violation.

The Inspector recognized such inherent questions and uncertainties, since an apparent violation based on the instrument reading in Room 3029 was not identified in the original inspection report dated July 14, 1989. The calculations methodology available to and used by the radiographer were reviewed and accepted by the Region V staff following our July 20, 1989 enforcement meeting of July 20, 1989, at Region V Offices. Those calculations showed Room 3029 to be outside the Restricted Area.

Because the alleged possible exposure to patients in Room 3029 cannot be verified and are in conflict with other calculations, this alleged violation cannot be sustained.

Restatement of Violation I.B.

"10 CFR 34.41 requires, in part, that the radiographer or radiographer's assistant maintain direct surveillance of each radiographic operation to protect against unauthorized entry into a high radiation area.

10 CFR 20.202(b)(3) defines "High Radiation Area" as any area, accessible to personnel, in which there exists radiation originating in whole or in part within licensed material at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirem.

Contrary to the above, at the time of the inspection while the source was exposed, neither the radiographer nor the radiographer's assistant maintained continuous direct surveillance of the operation to protect against unauthorized entry into the high radiation area surrounding the source. Specifically, neither the radiographer nor his assistant was assigned to monitor the door from the stairway on the 4th and 5th floors to prevent a person from entering the high radiation area."

Response

Denied.

Reason

The requirement is for a licensee to provide surveillance of the operation to prevent unauthorized entry into the High Radiation Area. The NRC interpreted, as stated in the July 20, 1989 Enforcement Hearing, this to mean that each of the eight doorways mentioned in the report required a separate monitor and that any unauthorized entry into the Restricted Area be prevented.

Reason

Whereas, UST interprets this requirement to provide surveillance of the Restricted Area such that remedial action could be taken to prevent unauthorized entry into the High Radiation area if the Restricted Area is penetrated. Such remedial action would include retraction of the source, shouting out to the person, etc.

The inspection report indicates that the UST method was effective. UST personnel identified a nurse who intentionally penetrated the Restricted Area. The report does not mention that the nurse had been pre-warned by both UST personnel and the Hospital Coordinator. The Hospital had warning signs, in addition to those of UST, posted on each entrance of the evacuated areas. The evacuation of patients had been coordinated with the Hospital staff by the Hospital coordinator. Therefore, it is difficult to understand the nurse's claim of being unaware of the potential hazard and that she thought the UST person was a hospital patient; nor can we understand the apparent willingness of the NRC to accept the nurse's statement as fact.

The High Radiation Area had a radius of only eighteen (18) inches. The UST radiographer believed that a penetration of the Restricted Area could have been detected and remedial action taken to prevent entry to the High Radiation Area. That is, in fact, what happened. Therefore, UST maintains that its implementation of this requirement was appropriate, correct and effective.

Restatement of Violation I.C.

"Condition 15 of License No. 04-23240-01, Amendment No. 6, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in a letter dated November 22, 1988, which incorporated Radiation Safety Manual, UST-RP-1188.

Section 710, page 7.7 of the Radiation Safety Manual, referenced in License Condition 15, states, in part, that the radiographer and radiograph's assistant(s), if present, shall act as guards, and that they must be alert at all times to prevent anyone from entering the restricted area.

Restatement of Violation I.C.- (Con'td.)

10 CFR 20.3(a)(14) defines "Restricted Area" as any area access to which is controlled by the licensee to protect individuals from exposure to radiation and radioactive materials.

Contrary to the above, at the time of the inspection while the source was exposed, neither the radiographer nor his assistant acted as guards to prevent entry into portions of the restricted area in that portions of the restricted area boundary were obstructed from the view of the radiographer and his assistant by walls. For example, individuals could cross unobserved into portions of the restricted area that existed in a stairway or adjacent to a west door on the fourth and fifth floors of the job site building."

Response

Admitted as to the placement of the rope adjacent to the west door, denied as to the stairway.

Reason

In setting up the Restricted Area boundaries, UST personnel were conservative in the placement of barrier ropes. The boundaries could have been moved closer to the source and still have maintained radiation dose rates within regulatory requirements. The conservative posting was for convenience and an additional margin of safety. The UST radiographer would have been able to spot an intruder and could have taken remedial action to prevent penetration of the small (18" radius) High Radiation Area.

Further, the inspector's reference to Section 710 of the Radiation Safety Manual is taken out of context. The reference actually reads: "The Radiographer and Radiographer's Assistant(s), if present, shall act as guards. They must be alert at all times to prevent anyone from entering the area. If unauthorized personnel cannot be prevented from entering the area, the source shall be immediately returned to its shielded position. No personnel shall enter these areas until they are given permission from the Radiographer in charge or except as required under declared emergency conditions."

Further, UST contends its interpretation and control are in compliance with NUREG/BR-0024 "Working Safely in Gamma Radiography". Therefore, UST maintains that it is being penalized for being overly cautious in setting up and controlling the restricted areas.

Restatement of Violation I.D.

"10 CFR 34.43(b) requires, in part, that a survey be made around the entire circumference of the radiographic exposure device after each radiographic exposure.

Contrary to the above, at the time of the inspection, the radiographer did not survey the entire circumference of the radiographic exposure device after each radiographic exposure."

Response

Denied.

Reason

The radiographer had been trained in the correct survey process, and conducted the survey per NUREG/BR-0094 page 68. The licensee compliance to the NUREG meets 10 CFR 34.43(b).

Restatement of Violation I.E.

"10 CFR 20.203(c) provides, in part, that each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words "Caution High Radiation Area".

Contrary to the above, at the time of the inspection while the source was exposed, the high radiation area surrounding the source was not posted with "Caution High Radiation Area" signs."

Response

Admitted.

Reason

While the radiographer had been properly trained and had the signs on-site with him, he did not post the signs as required. However, boundary ropes and signs defining the Restricted Area were in place and the radiographer maintained complete surveillance of the 18" radius High Radiation Area, while the source was exposed.

Restatement of Violation II.A.1.

"10 CFR 71.5(a) requires each licensee who transports licensed material outside of the confines of its plant or other place of use to comply with the applicable requirements of 49 CFR Parts 170 through 189.

Restatement of Violation II.A.1. - (Con'td.)

49 CFR 172.403(a) requires in part that each package of radioactive material must be labeled as provided in that Section. Paragraph (c) of Section 172.403 requires a D.O.T. White I label for radioactive materials packages with surface radiation levels of less than 0.5 mrem/hour.

Contrary to the above, at the time of the inspection, neither the radiographic exposure device (Model IR-100, Serial Number 2926) nor the overpack storage box which contained the device in the radiography vehicle was labeled with D.O.T. White I labels, even though there were surface radiation levels up to 0.4 mrem/hr at the exterior surface of the storage box."

Response

Admitted.

Reason

The exposure device was transported in an IR-100 overpack box which was also serving as a blocking and bracing device. The IR-100 is an approved shipping container for the purposes of transportation. The radiographer failed to affix the DOT White I label to the overpack.

Restatement of Violation II.A.2.

"49 CFR 173.25 requires, in part, that persons transporting radioactive material in overpacks must mark the overpack with a statement indicating that the inner package complies with prescribed specifications, unless specification markings on the inside packages are visible."

Contrary to the above, the overpack storage box was not marked with any statement indicating that the inner package complied with prescribed specifications, and specification markings on the inside package were not visible.

Response

Admitted.

Reason

The container, as stated above, is UST's method of compliance with DOT blocking and bracing requirements. The radiographer failed to assure the proper labeling was affixed to the overpack.

Corrective Actions

UST has temporarily suspended radioisotope radiographic operations at our San Diego facility for reasons not related to these NRC allegations. Until our Corporate Radiation Safety Director is satisfied that radiographic operations can be carried out in compliance with regulations and license conditions, licensed operations will remain suspended. Prior to resumption of operations, a readiness review will be conducted to ensure the effectiveness of corrective actions.

Request for Mitigation

For the reasons previously stated in this response, UST believes that all of the violations as alleged violations did not occur and full mitigation of the proposed fine is appropriate. UST requests that the denied alleged violations be either withdrawn entirely or recategorized as Severity Level IV or Severity Level V, and that all fines be eliminated.