For the Nuclear Regulatory Commission.

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[FR Doc. 95–10726 Filed 5–1–95; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 030–31765, License No. 37–28540–01, EA 94–006]

Oncology Services Corp., Harrisburg, PA; Order Imposing Civil Monetary Penalties

I

Oncology Services Corporation (Licensee) was the holder of Byproduct Materials License No. 37–28540–01 (License) issued by the Nuclear Regulatory Commission (NRC or Commission) on August 3, 1990. The License authorized the Licensee to possess and use certain byproduct materials in accordance with the conditions specified therein at six facilities in Pennsylvania. The License was due to expire on August 31, 1995. However, on December 13, 1993, the Licensee requested termination of the License, with the License to be replaced by individual licenses issued to the facilities named as locations of use on the License. On August 24, 1994, License No. 37–28540–01 was terminated, and the NRC subsequently issued separate licenses for the following facilities previously named as locations of use under License No. 37–28540–01: Greater Pittsburgh Cancer Center (License No. 37–30163–01); Mahoning Valley Cancer Center (License No. 37–30086–01); Stoneboro Oncology Associates, P.C. (License No. 37–30092–01); Greater Harrisburg Cancer Center (License No. 37–30084–01); Indiana Regional Cancer Center (License No. 37–28179–02); and Exton Cancer Center (License No. 37–30087–01). In addition, a license was issued to Jefferson Radiation Oncology Center (License No. 37–30085–01).

II

An inspection of the Licensee's activities at its facilities located in Indiana, Pennsylvania and Pittsburgh, Pennsylvania was conducted on December 3–18, 1992, by an NRC Incident Investigation Team, following an event involving the Indiana, Pennsylvania facility in which there was a significant misadministration to a patient who died five days later, and significant radiological exposures to members of the public. In addition, NRC Region I performed an inspection on December 8, 1992, at the Licensee's Exton and Lehighton, Pennsylvania facilities. The results of these inspections indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was served upon the Licensee by letter dated May 31, 1994. The Notice states the nature of the violations, the provisions of the NRC requirements that the Licensee had violated, and the amount of the civil penalties proposed for the violations.

The Licensee responded to the Notice in letters dated August 31, 1994 and October 4, 1994. In its responses, the Licensee admits Violations III.C.2, III.D.5, III.E. III.F, and III.I; denies Violations I.A, I.B, II.A, II.B, III.A, III.B, III.C.1, III.D.1–4, III.D.6, III.G, III.H, and III.J.1–3 protests the amount of civil penalties proposed; and requests mitigation of the penalties, as appropriate.

III

After consideration of the Licensee's responses and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violations occurred as stated in the Notice, and that the penalties proposed for the violations designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, *it is hereby ordered* that:

The Licensee pay civil penalties in the cumulative amount of $280,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852–2738.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a ''Request for an Enforcement Hearing'' and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, PA 19406.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) Whether the Licensee was in violation of the Commission's requirements as set forth in Violations I.A, I.B, II.A, II.B, III.A, III.B, III.C.1, III.D.1–4, III.D.6, III.G, III.H, and III.J.1–3 of the Notice referenced in Seciton II above, and

(b) Whether, on the basis of such violations and the additional violations set forth in the Notice of Violation that the Licensee admitted, this Order should be sustained.

Dated at Rockville, Maryland this 24th day of April 1995.

For the Nuclear Regulatory Commission.

Hugh L. Thompson, Jr.,

Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support.

Appendix—Evaluations and Conclusion

On May 31, 1994, a Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was issued for violations identified during NRC inspections (including an Incident Investigation Team (IIT) inspection) at several Oncology Services Corporation (Licensee) facilities. The Licensee responded to the Notice on August 31, 1994 and October 4, 1994. The Licensee admitted Violations III.C.2, III.D.5, III.E, III.F, and III.I; denied Violations I.A, I.B, II.A, II.B, III.A, III.B, III.C.1, III.D.1–4, III.D.6, III.G, III.H, and III.J.1–3; and requested remission of the civil penalties. The NRC's evaluation and conclusion regarding the Licensee's requests are as follows:

Restatement of Violations in Section I of the Notice

I. A. 10 CFR 20.201(b) requires that each Licensee make such surveys as may be necessary to comply with the requirements of 10 CFR 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 sources of radiation under a specific set of conditions.

Contrary to the above, on November 16, 1992, the Licensee did not make a survey necessary to comply with the requirements of 10 CFR 20.101 which limits radiation exposure to individuals in restricted areas, and 10 CFR 20.105(b) which limits radiation levels in unrestricted areas. Specifically, although the room radiation monitor in the treatment room (restricted area) at the Indiana Regional Cancer Center (IRCC), flashed the red alarm signal even after the console of the High Dose Rate (HDR) afterloader unit showed that a 4.2 Curie iridium-192 source was safety retracted (because the source had broken off inside the patient), a radiation survey was not performed to confirm or discount the presence of a radiation hazard in the room or the patient as indicated by the alarming room monitor.

B. Condition 17 of License No. 37–28540–01, Amendment No. 3 dated August 19, 1992, requires, in part, that the Licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated June 1, 1990, and the letter dated August 2, 1990.

Item 9.C.3 of the application dated June 1, 1990, requires, in part, that a radiation monitor (PrimAlert or equivalent) be mounted on the wall [in the HDR afterloader treatment room] and will remain in place as a means of verifying a source ''safe'' or ''out'' condition.

Item 10.15.A.3 of the application dated June 1, 1990, requires, in part, that all attending personnel must remain in the control area during actual treatment and may not re-enter the treatment room until the room radiation detector (PrimAlert) indicates a safe condition prevails.

Item 6 of the letter dated August 2, 1990, states that failure of the radiation monitor will result in termination of the treatment until the monitor is replaced or repaired and, in the event of failure of the room monitor, no personnel will enter the room without a portable survey meter or audible dosimeter.

Contrary to the above, on November 16, 1992, during a patient treatment utilizing an iridium-192 source in a HDR afterloader, at the IRCC, when the wall-mounted radiation monitor flashed the red alarm signal to indicate a source ''out'' condition, a physician authorized user, who had been informed that the red alarm signal was flashing, entered the treatment room without a portable survey meter or audible dosimeter; and, at some point during the event, a Licensee technologist entered the treatment room and unplugged and replugged the power supply of the room radiation monitor to reset the alarm.

These violations represent a Severity Level I problem (Supplement IV and VI) Civil Penalty—$100,000.

Summary of Licensee's Response to Violation I.A

The Licensee in its responses, denies Violation I.A and states that the treatment room at the Indiana Regional Cancer Center was surveyed with what the Licensee terms ''a wall mounted survey instrument ('WMSI')'', the WMSI did not flash red in the presence of the authorized user, and the WMSI stopped flashing when the electrical connection was touched. The Licensee further asserts that the authorized user was not aware, prior to entering the treatment room, that the WMSI had flashed. The Licensee also asserts that all output on the Omnitron unit and console indicated that the source was parked and safe; no alarm went off on the Omnitron unit; and all personnel acted in accordance with what the Licensee terms its ''NRC approved Omnitron training.'' The Licensee states that the conduct of the authorized user and the Licensee was reasonable at all times and in conformity with NRC regulations.

The Licensee also states that the Omnitron machine failed; that failure was neither expected nor intended; and that the Licensee could not have prevented the failure. The Licensee also notes that it believes the NRC was in a much better position to understand the need for adequate surveys, yet the NRC license application reviewer did not find it necessary to require, or even request, the Licensee modify its license application or procedure to include a patient survey with a hand held survey meter after each treatment. The Licensee states that it believes that at all times it followed the applicable regulations, and that it was the victim of a machine failure and inadequate and/or outdated regulations. The Licensee further states that there was no intent to violate any regulations and that personnel were not reckless. The Licensee states that since the WMSI was not flashing when the authorized user was in the treatment room, to expect the authorized user to act other than as he did is not rational under the existing circumstances. The Licensee believes that, in any event, this violation would be classified at Severity Level IV.

NRC Evaluation of Licensee's Response to Violation I.A

The specific issue addressed in Violation I.A is whether the Licensee performed a survey as required by 10 CFR 20.101 to confirm or discount the presence of a radiation hazard in the room or the patient as indicated by the alarming room monitor. The fact that the wall mounted radiation monitor flashed the red alarm signal even though the Omnitron console showed that the source was safety retracted is the condition that triggered the requirement to conduct a survey pursuant to § 20.201. Thus, the Licensee cannot point to the same wall mounted radiation monitor as fulfilling the requirement to conduct the survey pursuant to § 20.201. Rather, the Licensee was required under those circumstances, pursuant to § 20.201, to perform an independent survey, such as by using a hand held radiation survey instrument, to determine which indicator was correct—the wall mounted radiation monitor, or the Omnitron console. The Licensee failed to do this and chose instead to discount the alarm from the wall mounted radiation monitor and to rely on the Omnitron console indicator.

As to the Licensee's statement that the regulations are inadequate or outdated, the Licensee does not identify any particular regulation. However, only 10 CFR 20.201 is cited in Violation I.A. An extensive revision of 10 CFR Part 20 became effective January 1, 1994, and the survey requirement of 10 CFR 20.201 is now codified at 10 CFR 20.1501. The language of the specific requirement has been changed only slightly. The survey requirement of 10 CFR 20.201 is not outdated or inadequate. It would have been a simple matter for the Licensee to comply with the requirement using the hand held survey instrument that the Licensee had on hand, which is a basic radiation protection practice.

Even before the authorized user (AU) arrived at the treatment room, Licensee technologists noticed that the wall mounted radiation monitor was flashing, knew that the Omnitron console indicated that the source was retracted safely, and yet they were present in the treatment room without having performed the survey required pursuant to § 20.201. At this point, such a survey was necessary to comply with the requirements of 10 CFR 20.101, which limits exposure to individuals in restricted areas. Thus, Violation I.A was occurring even before the AU entered the room.

Although knowledge on the part of the AU that the wall mounted radiation monitor had been flashing is not necessary to prove the violation, the fact that the AU was aware that the wall mounted radiation monitor was flashing as he entered the treatment room is corroborated by his testimony, as well as the testimony of others, in transcribed interviews. Additionally, the transcribed interviews of the AU consistently show that, while he was in the treatment room, he was aware that: (1) The wall mounted radiation monitor had been flashing; and (2) the Omnitron console showed that the source was safely retracted.

NRC agrees that the Omnitron source broke off and was not retracted, that this was neither expected nor intended by the Licensee, and that the Licensee could not have prevented the break. However, that does not change the fact that the survey required by 10 CFR 20.201 was not performed, which is a matter that was within the Licensee's control. Given the conflicting information from the flashing wall mounted radiation monitor and the Omnitron control panel, such a survey was reasonable under the circumstances to evaluate the extent of the radiation hazards that were present. Since such a survey was not performed, the NRC concludes that Violation I.A occurred as stated in the Notice. The issue of the severity level of the violation is addressed in the evaluation of the Licensee's Response to Violation I.B, below.

Summary of Licensee's Response to Violation I.B

The Licensee denies Violation I.B; incorporates its response to Violation I.A, summarized above; and asserts that Violation I.B would be a Severity Level IV violation. The Licensee states that the wall mounted radiation monitor should have continued to alarm, and that if the monitor had done so, the technologist and authorized user would have acted accordingly.

NRC Evaluation of Licensee's Response to Violation I.B

Licensee employees entered the treatment room while the wall mounted radiation monitor was alarming, indicating a non-safe condition, and they did so without a portable survey meter or audible dosimeter. If the employees believed that the wall mounted radiation monitor was functioning properly, they should not have entered the treatment room while it was alarming, which is a violation of License Condition 17. If the employees discounted the alarm because they believed that the wall mounted radiation monitor was not functioning properly (i.e., spuriously alarming), they should not have entered the treatment room without a portable survey meter or audible dosimeter, which is also a violation of License Condition 17.

Moreover, the requirements of License Condition 17 as cited in Violation I.B were being violated even before the authorized user entered the treatment room. The transcribed interviews clearly show that the monitor was alarming when the technologists entered the treatment room. The violation occurred upon entry. Thus, whether the monitor should have continued to alarm after the technologist entered the treatment room and manipulated its plug is not relevant to the existence of the violation. Accordingly, the NRC concludes that Violation I.B occurred as stated in the Notice.

Among other things, Violations I.A and I.B were classified in the aggregate as a Severity Level I problem in accordance with Supplements IV and VI of the NRC Enforcement Policy because: (1) Conducting the survey and complying with the requirements of License Condition 17 regarding the wall mounted radiation monitor, and the use of a portable survey meter or audible dosimeter in the event of a failure of the wall mounted radiation monitor, constitute a system designed to prevent or mitigate a serious safety event, and in this case, the system was not operable when actually required to perform; and (2) the violations resulted in acute radiation exposure and subsequent death of a patient. *See* Enforcement Policy (1993), Supplement IV, Example A.2; and Supplement VI, Examples A.2 and A.4.

Restatement of Violations in Section II of the Notice

II.A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the Licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the Licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, from November 16, 1992 to December 1, 1992, licensed material consisting of Curie quantities of iridium-192 was located at a nursing home, a waste disposal facility, and several vehicles, which are unrestricted areas, and the licensed material was not secured against unauthorized removal nor was it under the constant surveillance and immediate control of the Licensee.

B. 10 CFR 20.105(b) requires that, except as authorized by the Commission in 10 CFR 20.105(a), no Licensee shall possess, use, or transfer licensed material in such a manner as to create radiation levels in unrestricted areas which, if an individual were continuously present in the area, could result in his receiving a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days.

Contrary to the above, from November 16, 1992 to December 1, 1992, the Licensee allowed the creation of radiation levels in unrestricted areas, such that if an individual were continuously present in the area, he could have received a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days. Specifically, the Licensee allowed the creation of radiation levels of approximately 2000 millirem per hour at a distance of one meter in unrestricted areas, specifically a nursing home, a waste disposal facility, and several vehicles.

These violations represent a Severity Level I problem (Supplement IV) Civil Penalty—$100,000.

Summary of Licensee Response to Violations II.A and II.B

The Licensee denies Violations II.A and II.B and incorporates by reference its response to the violations in Section I. The Licensee contends that the source was lost, not possessed, used, transferred or stored. According to the Licensee, loss is an accidental act, while, as used in NRC regulations, possession, use, transfer and storage are deliberate acts. The Licensee asserts that the cited violations would have required knowledge of attending personnel that the source was still in the patient, but since they did not know the source was still inside the patient, the Licensee did not possess, use, transfer or store material in violation of any regulations.

NRC Evaluation of Licensee's Response to Violations II.A and II.B

The Notice does not assert, expressly or otherwise, that the violations were knowing or deliberate. Neither 10 CFR § 20.207 nor § 20.105 require a knowing failure to maintain control of licensed material, or knowing exposure of individuals to radiation, in order to establish a violation. Under the regulations in 10 CFR part 20, licensees are strictly held accountable for loss of

radioactive material and for radiation levels in unrestricted areas caused by such loss. As a result of the Licensee's use of the source on November 16, 1992, the source escaped the Licensee's control and was transferred to the nursing home and, subsequently, to other unrestricted areas, where it created radiation levels far in excess of the allowable limits. Therefore, the NRC concludes that Violations II.A and II.B occurred as stated in the Notice.

Restatement of Violations in Section III of the Notice

III.A. 10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

10 CFR 35.25(a)(1) requires, in part, that a Licensee that permits the use of byproduct material under the supervision of an authorized user shall instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material.

Condition 17 of License No. 37–28540–01, Amendment No. 3 dated August 19, 1992, requires, in part, that the Licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated June 1, 1990.

Item 8 of the application dated June 1, 1990, requires, in part, that training for HDR device operators will include emergency training where the device operator will demonstrate emergency routine competence during a ''dry run'' emergency of the source not retracting.

Contrary to the above, individuals who were working in the HDR afterloader treatment room, a restricted area, at three of the Licensee's six facilities in Pennsylvania, had not been adequately instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and the conditions of the license, as evidenced by the following examples:

1. As of December 18, 1992, technologists working in a restricted area at the Indiana facility were not adequately instructed in how to use a survey meter, the meaning of a high radiation area, the methods of performing HDR afterloader door interlock checks, the significance of the alarm setpoint (the preset value) of the wall-mounted radiation monitor, the meaning of HDR afterloader error messages, the activity of the sources contained in the HDR unit and their potential radioactive hazard, or the corporate policy that requires the staff to survey each patient treated with the HDR afterloader unit with a portable survey meter before the patient's release, and in addition, individuals who operated the HDR device had not performed a ''dry run'' emergency; and

2. As of December 8, 1992, Licensee personnel working in restricted areas at the Exton and Lehighton facilities had not been instructed in the applicable provisions of the Commission's regulations and the NRC license, and individuals who operated the HDR device had not performed a ''dry run'' emergency of the source not retracting.

B. 10 CFR 35.25(a)(1) requires, in part, that a Licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall instruct the supervised individual in the Licensee's written quality management program.

Contrary to the above, as of December 8, 1992, the Licensee did not instruct personnel who used iridium-192 under the supervision of an authorized user at the Exton facility in the Licensee's written quality management program.

C. 10 CFR 20.202(a) (1) and (3) requires, in part, that: Each Licensee supply appropriate personnel monitoring equipment to, and require the use of such equipment by, each individual who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable value specified in 10 CFR 20.101(a); and each Licensee supply appropriate personnel monitoring equipment to, and require the use of, such equipment by each individual who enters a high radiation area.

Contrary to the above,

1. On November 16, 1992, during a treatment of a patient with iridium-192 in a HDR afterloader unit, the physician authorized user at the Indiana facility entered the treatment room, a restricted area, and, although the wall-mounted radiation monitor had flashed the red alarm signal to indicate the presence of a radiation field, the authorized user did not wear his personal monitoring equipment; and,

2. On December 1, 1992, the authorized user at the Indiana facility, in efforts to retrieve the iridium-192 radioactive source, entered a high radiation area at the Browning-Ferris Industries waste facility in Carnegie, Pennsylvania, and did not wear his personnel monitoring equipment.

D. Condition 17 of License No. 37–28540–01 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated June 1, 1990, and a letter dated August 16, 1991.

1. Item 10.2 of the application dated June 1, 1990, states that the Licensee will establish and implement the ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2.

Appendix G to Regulatory Guide 10.8, Revision 2, requires, in part, that the RSO [Radiation Safety Officer] be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

Contrary to the above, as of December 3, 1992, the RSO did not maintain close contact with all users and workers. For example, Medical Director/Authorized Users at the Indiana and Lehighton facilities were not aware of who the RSO was. Additionally, the RSO had not visited the Lehighton facility in the past 6–9 months.

2. Item No. 10.15.A.1 of the June 1, 1990, application requires that emergency procedures be conspicuously posted near the control console.

Contrary to the above, on December 8, 1992, the emergency procedures were not posted at the Exton facility.

3. Item No. 10.15.B.1 of the June 1, 1990, application requires that the calibration of the HDR afterloader source and device include a check of source travel time error and accuracy of the timing device.

Contrary to the above, as of December 8, 1992, the calibration of the HDR afterloader source and device at the Exton facility did not include a check of source travel time error and accuracy of the timing device.

4. Item No. 10.12 of the June 1, 1990, application requires that surveys of radiation levels in adjacent and control areas be performed at each source exchange and logged.

Contrary to the above, as of December 8, 1992, surveys of radiation levels in adjacent and control areas were not performed at each source exchange at the Exton facility.

5. The Licensee's letter dated August 16, 1991, requires, in part, that the key for the linear accelerator and the key for the HDR afterloader unit be on the same ring to prohibit the simultaneous activation of these units.

Contrary to the above, on December 8, 1992, the key for the linear accelerator and the key for the HDR afterloader unit

were not on the same ring at the Exton facility and the Lehighton facility. At each facility, the inspector noted that the linear accelerator key was in the linear accelerator console and the HDR key was in the HDR console.

6. Item 4 of the letter dated August 2, 1990, requires, in part, that ancillary personnel will receive an orientation program and an annual review of the basic principles related to identifying, and proper procedures in working in, areas controlled under this license. Instructions for individuals will include the subjects listed on page A–1 of NRC Regulatory Guide 10.8, Rev. 2.

Regulatory Guide 10.8, Rev. 2, page A–1, requires instruction in potential hazards associated with radioactive material in each area where the employee will work.

Contrary to the above, as of December 4, 1992, ancillary personnel at the IRCC facility were not informed about radiation hazards associated with a 3.7 Curie iridium-192 source in a source container located in the HDR afterloader treatment room. Specifically, housekeeping personnel had access to the keys to the treatment room and offered to move the source container which measured approximately 80 millirem per hour at the surface.

E. 10 CFR 20.203(c)(1) requires that each high radiation area be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words: ''Caution High Radiation Area.''

Contrary to the above, on December 8, 1992, the high radiation area in the HDR afterloader treatment room at the Exton facility was not posted as required with the required sign bearing the radiation caution symbol and the words: ''Caution High Radiation Area.''

F. 10 CFR 35.51(c) requires, in part, that a Licensee check each survey instrument for proper operation with the dedicated check source each day of use.

Contrary to the above, as of December 8, 1992, the Licensee at the Exton facility routinely did not check its survey meter with a dedicated check source on days when the instrument was used.

G. 10 CFR 35.25(a)(3) requires, in part, that a Licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall periodically review the supervised individual's use of byproduct material and the records kept to reflect this use.

Condition 17 of License No. 37–28540–01 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated June 1, 1990, and a letter dated August 16, 1991.

Item 10.15.A.4 of the application dated June 1, 1990, requires, in part, that daily checks of interlocks, safety systems, and alarms be performed and logged.

Contrary to the above, as of December 3, 1992, supervised individuals at the IRCC facility routinely did not perform daily interlock checks as required in conjunction with operating the HDR afterloader containing iridium-192, and the Licensee did not review their performance of this procedure.

H. 10 CFR 35.21(b)(2) requires, in part, that the RSO establish, collect in one binder or file, and implement written policy and procedures for:

(v) Using byproduct material safely,

(vi) Taking emergency action if control of byproduct material is lost,

(viii) Performing checks of survey instruments and other safety equipment, and

(x) Training personnel who work in or frequent areas where byproduct material is used or stored.

Contrary to the above, as of November 16, 1992:

1. The RSO did not establish and implement written policy and procedures for using byproduct material safely. Specifically, although iridium-192 was in use in HDR afterloader units at the Indiana, Exton, and Lehighton facilities, written procedures entitled, ''Oncology Services Corporation, Department of Physics, HDR Treatment Manual'', existed only in draft form and the RSO had not distributed them to the staff.

2. The RSO did not establish and implement procedures for taking emergency action if control of byproduct material was lost. Specifically, the RSO had not established or implemented such procedures as of December 1, 1992, when the Licensee retrieved a 3.7 Curie iridium-192 source from a waste disposal facility and transported it back to the Licensee's facility.

3. The RSO did not implement procedures at the IRCC for performing checks of survey instruments and other safety equipment. Specifically, the RSO did not implement procedures for checking survey instruments for proper operation with a dedicated check source on days when the instrument was used, as required by 10 CFR 35.51(c); and for checking the treatment room door interlock in conjunction with operating the HDR afterloader, as required by License Condition 17, application dated June 1, 1990, Item 10.15.A.4.

4. The RSO did not establish and implement written policy and procedures for training personnel who work in or frequent areas where byproduct material is used or stored. For example, the RSO believed that it was the responsibility of the physicist at the Indiana, PA, facility to provide such training to the individuals there; however, the medical physicist stated that his contract did not indicate that he should provide training.

I. 10 CFR 35.13(e) requires that a Licensee apply for and must receive a license amendment before it adds to or changes the areas of use or address or addresses of use identified in the application or on the license.

Contrary to the above, on or about April 23, 1991, the Licensee's RSO changed the area of use of iridium-192 in a HDR afterloader for a shielding experiment from the shielded therapy room at the Greater Harrisburg Cancer Center, the area of use identified in the application, to an area outside of the building and, as of that date, the Licensee had not applied for or received a license amendment authorizing the change.

J. 10 CFR 71.5(a) requires that a Licensee who transports licensed material outside the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

1. 49 CFR 173.24(f)(ii) requires, in part, that closures on packagings shall be so designed and closed that under conditions normally incident to transportation, the closure is secure.

49 CFR 173.475(c) requires, in part, that before each shipment of any radioactive materials package, the shipper shall ensure by examination or appropriate tests that each closure device of the packaging is properly installed, secured, and free of defects.

Contrary to the above, on December 1, 1992, the Licensee transported a radioactive materials package containing 3.7 Curies of iridium-192 and there was no closure device on the packaging.

2. 49 CFR 177.817(a) requires that a carrier not transport a hazardous material unless it is accompanied by a shipping paper prepared in accordance with 49 CFR 172.200–203. Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

Contrary to the above, on December 1, 1992, the Licensee transported 3.7

Curies of iridium-192, a radioactive material, without a shipping paper.

3. 49 CFR 172.504 prescribes requirements for placarding vehicles used to transport hazardous materials. Specifically, Table 1 requires that the transport vehicle be placarded on each side and each end with a ''RADIOACTIVE'' placard when transporting packages bearing a ''RADIOACTIVE YELLOW–III'' label (footnote 4).

Contrary to the above, on December 1, 1992, the Licensee transported 3.7 Curies of iridium-192 outside the confines of its plant in a package with the required YELLOW–III label, and the transport vehicle was not placarded with a ''RADIOACTIVE'' placard.

These violations represent a Security Level II problem (Supplement IV, V and VI) Civil Penalty—$80,000.

Summary of Licensee's Response to Violations III.A and III.B

The Licensee denies Violations III.A and III.B and states that at all times it adequately instructed all personnel in relevant areas consistent with 10 CFR 19.12, 10 CFR 35.25(a)(1), and the license, and that it would be incorrect for NRC to take the position that each and every individual must be knowledgeable about each and every regulation and/or license condition. The Licensee believes that, in any event, these violations would be classified at Severity Level III.

NRC Evaluation of Licensee Response to Violations III.A and III.B

The Licensee was not cited for failure to instruct each and every individual in every NRC requirement. 10 CFR 19.12 requires that training for workers be commensurate with potential radiological health protection problems in restricted areas. Additionally, training must fulfill specific regulations such as 10 CFR 35.25(a)(1), as well as specific commitments made by the Licensee and incorporated into the license by condition. Violations III.A and III.B were identified as a result of discussions between OSC personnel and NRC inspectors or investigators. NRC does not dispute that some training did occur. However, as documented in the inspection report, the Incident Investigation Team (IIT) report, and the investigation by NRC's Office of Investigations (OI), the training that was given was not adequate to meet the requirements. The Licensee's general assertion that it complied with all requirements does not refute the fact that the specific subjects described in Violations III.A and III.B were not covered adequately in the training that the Licensee gave to the personnel described in Violations III.A and III.B. Thus, the NRC concludes that the violations occurred as stated in the Notice.

The NRC did not categorize the individual violations and examples of violations in Section III of the Notice by severity level. Rather, the NRC considered the violations in the aggregate as a single problem categorized at Severity Level II. The Enforcement Policy defines a Severity Level II violation or problem as one of very significant concern. Clearly, this severity level is appropriate here because the number and nature of the violations represent a very significant corporate management breakdown in the control of licensed activities; and the lack of attention to, and understanding of, regulatory requirements on the part of Licensee management and its RSO contributed to the November 1992 event. The purpose of aggregating violations is to focus the Licensee's attention on the fundamental underlying causes for which enforcement action is warranted, and to reflect the fact that several violations with a common cause are more significant collectively than individually, and therefore, warrant a more substantial enforcement action. See Enforcement Policy, Section IV.A. In this case it was necessary to focus the Licensee's attention on the importance of meticulous oversight of the corporate radiation safety program, the lack of which was a common causative factor in the violations.

Summary of Licensee's Response to Violation III.C

The Licensee denies Example III.C.1 and states that it supplied and required the use of personnel monitoring equipment; however, the authorized user had no reason to believe that it was necessary to wear a film badge. The Licensee further incorporates by reference its response to Violations A and B in Section I of the Notice. The Licensee believes that, in any event, Example III.C.1 would constitute a Severity Level V violation. The Licensee admits Example III.C.2 but believes that it constitutes a Severity Level V violation.

NRC Evaluation of Licensee Response to Violation III.C

10 CFR 20.202(a)(1) requires that the Licensee require the use of appropriate personnel monitoring equipment by each individual who enters a restricted area (the HDR treatment room) under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 25 percent of the occupations dose limits specified in 10 CFR 20.101(a). The treatment room constituted a restricted area because access to this area was controlled by the Licensee for purposes of protection of individuals from exposure to radiation and radioactive materials. *See* 10 CFR 20.3(a)(14). With a 4.2 Curie iridium–192 source in the unshielded configuration, an individual entering the treatment room would be likely to receive a dose in excess of 25% of the occupational dose limits specified in 10 CFR 20.101(a).

Moreover, 10 CFR 20.202(a)(3) requires that the Licensee require the use of personnel monitoring equipment by each individual who enters a high radiation area. The treatment room constituted a high radiation area because, when the source is in an unshielded configuration, radiation levels in the treatment room are such that a major portion of the body could receive in any one hour a dose in excess of 100 millirem. *See* 10 CFR 20.202(b)(3). The Licensee was well aware of this fact, because it had posted the room as a high radiation area at the time of the November 16, 1992 event.

The requirement that the Licensee supply and require the use of appropriate personnel monitoring equipment does not depend on the individual's perception of a radiation hazard, but rather on the fact of a radiation hazard that may result in an exposure in excess of the limit in § 20.202(a)(1), or that requires posting as a high radiation area as per § 20.202(a)(3). Any time that the authorized user (AU) supervised the use of the HDR unit, he could be called upon to make an emergency entry into the treatment room with the source in an unshielded configuration. The Licensee should have been well aware of this fact, because the license application specifies training for its employees in emergency procedures involving entry into the treatment room with the source in an unshielded configuration. *See* License Condition 17, Application dated June 1, 1990, Item 10.15.C. Thus, the Licensee should have assured that the AU wore his personnel monitoring equipment whenever he supervised the use of the HDR unit. The AU did enter the treatment room with the source in an unshielded configuration and he was not wearing his personnel monitoring equipment. Therefore, the NRC concludes that Example III.C.1 occurred as stated in the Notice. Moreover, even if the Licensee had provided an adequate reason to withdraw Example III.C.1, Violation III.C still occurred as evidenced by the

Licensee's admission of Example III.C.2. The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Response to Violation III.D.1

The Licensee denies Violation III.D.1, states that *the RSO* did not fail to discharge his duties, states that the RSO did not violate any regulation relating thereto, and notes that the NRC has not cited any such specific regulation and that the RSO had an ALARA program in place. The Licensee states that there is no requirement that the Licensee have any physical presence at any facility. In addition, the Licensee states that the RSO and a physicist were in communication with the Lehighton facility by telephone and fax.

NRC Evaluation of the Licensee Response to Violation III.D.1

The Licensee was required, pursuant to License Condition 17, to follow the commitments it made in the June 1, 1990, application to the NRC. Item 10.2 of the application required that Appendix G of Regulatory Guide 10.8 be followed which in turn required the RSO to be in ''close contact'' with all users and workers in order to develop ALARA procedures for working with radioactive materials. The Licensee specifically committed in its license application that *the RSO* would do this. The development of ALARA procedures is a continuing and evolving process and requires firsthand observations and audits of employee knowledge, work, and work conditions. The fact that some ALARA procedures may have been in place does not relieve the Licensee of full compliance with this requirement.

The mere fact that the RSO may have been in communication by telephone or facsimile does not disprove the violation. In order for that fact to be relevant at all, the Licensee would have to show that such communications were with all users and workers and were for the purpose of developing ALARA procedures, which the Licensee has not done. Clearly, communications concerning, for example, patient treatment parameters, would have no bearing at all.

The NRC determined, via interviews, that the Medical Director and authorized user at the Indiana, Pennsylvania and Lehighton, Pennsylvania facilities were not aware, at the time of the IIT and the NRC inspection in December 1992, who the RSO was. Additionally, the RSO had not visited the Lehighton facility in the past 6–9 months. Also, as determined during the inspection of the Exton facility, the technologist and the medical physicist at the Exton facility both believed that the medical physicist was the RSO. Accordingly, it is appropriate to conclude that the RSO did not maintain close contact with all users and workers as required by License Condition 17. Therefore, the NRC concludes that Violation III.D.1 occurred as stated in the Notice.

Summary of Licensee's Response to Violation III.D.2

The Licensee denies Violation III.D.2 and states that emergency procedures were available but not vertically posted because they kept falling down, and that it immediately posted the procedures following the inspection. The Licensee believes that, in any event, this constitutes a Severity Level V violation.

NRC Evaluation of Licensee Response to Violation III.D.2

The Licensee stated that the emergency procedures kept falling down. The inspection report states that the procedures were available but not posted at the time of the inspection, and that this was corrected before the inspectors left the facility. During the inspection, the medical physicist obtained a copy of a set of emergency procedures which was incomplete (contained blanks), and the Licensee had to fill in the blanks with Licensee specific information, and post the procedures conspicuously near the control console so that appropriate staff would have access to the procedures. The Licensee specific information had not been entered on the emergency procedures prior to the inspection. Therefore, even the emergency procedures that were available, but not posted, were incomplete.

At the time that the Licensee established its HDR brachytherapy program, the blanks in the emergency procedures should have been filled in with Licensee specific information and the procedures should have been conspicuously and durably posted near the control console so that appropriate staff would have immediate access to it. This was not done. There, the NRC concludes that Violation III.D.2 occurred as stated in the Notice. The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Response to Violation III.D.3

The Licensee denies Violation III.D.3 and states that Exton personnel always did hand calculations and always checked the source travel time error and accuracy of the timing device by using the clock on the wall and their wrist watches. The Licensee believes that, in any event, Violation III.D.3 would constitute a Severity Level V violation.

NRC Evaluation of Licensee Response to Violation III.D.3

The Licensee's unsupported general assertion that the calculations and checks for timing device accuracy and travel time error were in fact performed does not demonstrate that the violation did not occur. During the inspection, the NRC found evidence that the checks of the source travel time error and accuracy of the timing device were not done. Specifically, as noted in Section 7 of NRC Inspection Report 30–31765/92–001, issued on December 23, 1992, the record of the HDR calibration performed at Exton indicated that the source output was checked but that the source travel time error and accuracy of the timing device were not checked. Therefore, the NRC concludes that the violation occurred as stated in the Notice. The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Response to Violation III.D.4

The Licensee denies Violation III.D.4 and states its belief that Omnitron personnel performed surveys for the benefit of the Licensee. The Licensee believes that, in any event, Violation III.D.4 would constitute a Severity Level IV violation.

NRC Evaluation of Licensee Response to Violation III.D.4

The Licensee's response provides no facts or records to support the Licensee's assertion that the surveys in question were ever performed by Omnitron. While Omnitron personnel may have performed some surveys in connection with their work during source exchanges, the Licensee provides no evidence that any such surveys included all adjacent areas as well as control areas. Therefore, the NRC concludes that Violation III.D.4 occurred as stated in the Notice. The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Response to Violation III.D.5

The Licensee admits the violation but believes that it would constitute a Severity Level IV violation.

NRC Evaluation of Licensee Response to Violation III.D.5

The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B above.

Summary of Licensee's Response to Violation III.D.6

The Licensee states that since it does not have sufficient knowledge as to the specific truth regarding whether ancillary personnel (specifically, housekeeping personnel) were informed about radiation hazards associated with a 3.7 curie iridium-192 source in a source container located in the High Dose Rate (HDR) afterloader treatment room, it must deny this violation. The Licensee believes that, in any event, Violation III.D.6 would constitute a Severity Level IV violation.

NRC Evaluation of Licensee Response to Violation III.D.6

Housekeeping personnel interviewed by the NRC staff were not aware of the radiation hazards associated with a 3.7 curie iridium-192 source. Specifically, on December 4, 1992, OSC housekeeping personnel unlocked the area where the iridium source was being stored following the source retrieval operation and accompanied NRC inspectors into the area, and the housekeeping personnel had not been informed about the radiation hazards associated with the source. Therefore, the NRC concludes that Violation III.D.6 occurred as stated in the Notice. The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Responses to Violations III.E–F

The Licensee admits the violations but believes that Violation III.E would constitute a Severity Level V violation and that Violation III.F would constitute a Severity Level IV violation.

NRC Evaluation of Licensee Response to Violation III.E–F

The issue of the Severity Level of the violations is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Response to Violation III.G

The Licensee states that daily interlock checks were consistently done by individuals at IRCC, and that there was no requirement for the Licensee to review such completed checks as of December 1992. In addition, the Licensee notes that such checks would have been reviewed at an annual audit. The Licensee believes that, in any event, Violation III.G would constitute a Severity Level IV violation.

NRC Evaluation of Licensee's Response to Violation III.G

Licensee technologists interviewed by the Incident Investigation Team (IIT) indicated that daily HDR interlock checks routinely were not performed as required. This is corroborated by the fact that there is not a log record for every check required. The Statements of Consideration for 10 CFR 35.25, ''Supervision'', state: ''The purpose of supervision is to provide *assurance* that technologists and physicians do not use byproduct materials in a manner that is contrary to the requirements of the license, the regulations, or that is hazardous to the public health and safety [emphasis added].'' See 51 Fed. Reg. 36940. While the Licensee was not required to review each and every check on a daily basis, it was required, pursuant to 10 CFR §§ 35.11, 35.25(a)(2), and 35.25(a)(3), to perform periodic reviews at a frequency sufficient to provide reasonable assurance that individuals working under the supervision of an authorized user were complying with, among other things, License Condition 17 with respect to the performance of daily interlock checks. It is clear from the fact that the noncompliance was occurring, undetected to the Licensee, that a single audit at the end of the year would not suffice. The NRC concludes that Violation III.G occurred as stated in the Notice. The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Response to Violation III.H

The Licensee denies the violation and states that at all times the RSO fully complied with relevant regulatory requirements, including implementing and distributing policies and procedures, and gathering materials. The Licensee also states that the RSO was immediately notified about the November 16, 1992 incident and instructed personnel how to respond appropriately.

NRC Evaluation of Licensee Response to Violation III.H

The Licensee provides no information to support its general assertion that it complied with all regulatory requirements or to refute the facts documented in the Incident Investigation Team (IIT) report, and the investigation by NRC's Office of Investigations (OI), upon which the violations are based. Accordingly, the NRC concludes that the violation occurred as stated in the Notice.

Summary of Licensee's Response to Violation III.I

The Licensee admits that the RSO conducted the experiment, but states that the RSO took all measures to assure that such experiment was done safely and without risk, and this was not a willful violation but was done for the purpose, in part, of radiation safety. The Licensee believes that, in any event, Violation III.I would constitute a Severity Level IV violation.

NRC Evaluation of Licensee Response to Violation III.I

The Licensee admits that the RSO conducted the experiment and does not deny that the RSO changed the area of use of iridium-192 from the shielded therapy room to an area outside the building without first applying for or receiving a license amendment authorizing the change. The Licensee and its RSO may not pick and choose which regulatory requirements they will follow, even if they believe that noncompliance would somehow further radiation safety. 10 CFR 35.13(e) requires that the Licensee apply for and receive a license amendment before changing the area of use specified in the license. Moreover, willfulness is not a necessary element of a violation of 10 CFR 35.13(e). Accordingly, the NRC concludes that Violation III.I occurred as stated in the Notice. The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Response to Violations III/J.1–3

The Licensee states that its intent was not to become a shipper or a carrier of licensed material but under the extenuating circumstances, the Licensee contacted the NRC and was told what to do to retrieve the source. In addition, the Licensee states that at no time did the NRC attempt to alert the Licensee about the regulations cited in the Notice. The Licensee states that at the time of the incident, it did not transport sources, and as such was not generally knowledgeable about such. The Licensee further states that the Licensee took extreme precautions and brought the source back in a safe, secured container. Finally, the Licensee states that since it quickly retrieved the source after the NRC specifically told the Licensee to get the source, it would be unfair to cite the Licensee for these

violations. The Licensee believes that, in any event, Violations III.J.1–3 would constitute Severity Level V violations.

NRC Evaluation of Licensee Response to Violations III.J.1–3

Prior to the incident, the Licensee requested a license amendment to permit it to transport licensed material as part of its licensed activities. License Condition No. 15 of Amendment No. 03, dated August 19, 1992, authorized the Licensee to transport licensed material in accordance with the provisions of 10 CFR Part 71, ''Packaging and Transportation of Radioactive Material''. Therefore, the Licensee should have been familiar with the provisions of 10 CFR Part 71. In any case, the Licensee transported the radioactive source on December 1, 1992, and therefore was bound by the requirements in 10 CFR 71.5(a). The fact that the NRC advised the Licensee to retrieve the Licensee's source does not excuse the Licensee from the requirements of Part 71, nor does it excuse the Licensee from its ignorance of the requirements of Part 71. At no time did NRC suggest that applicable regulations should not be followed. Since these requirements were not met, the NRC concludes that Violations III.J.1–3 occurred as stated in the Notice. The issue of the Severity Level of the violations is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Request for Mitigation

The Licensee states that subsequent to the Indiana event, Licensee management took corrective action by: immediately and voluntarily suspending HDR treatments at the Licensee's facilities that did not have full-time physicists for HDR treatments in order to review its entire HDR program; fully and timely complying with any and all Confirmatory Action Letters (CALs); replacing its RSO with a brachytherapy specialist; replacing multiple contract physicists; and hiring additional, qualified full-time physicists. The Licensee states that its proposed replacement of the RSO constitutes corrective action regarding all issues raised by the NRC, and notes that its new RSO has regularly been physically present at the Greater Pittsburgh and Greater Harrisburg facilities to review the entire HDR program.

The Licensee also notes that it has completely modified its HDR program, that the revised program has been approved by the NRC, and that Licensee management has been highly involved with the HDR program and has met on a regular basis with the new RSO. In addition, the Licensee notes that it has restructured its physics program, which has resulted in at least quarterly training/refresher courses in radiation safety and regulatory compliance at all facilities for all staff. Further, the Licensee notes that is authorized users have attended an intensive training session with the new RSO regarding HDR usage, safety and emergency responses. The Licensee also notes that it hired a Certified Health Physicist (CHP) as Vice President of Regulatory Affairs and gave the CHP broad management authority, and that the CHP is responsible for the day-to-day radiation safety program company-wide.

The Licensee also states that it believes that the fines imposed are inappropriate and unsupported by the facts and applicable law. The Licensee states that to apply the $100,000 per violation discretionary fine on the Licensee is now warranted and is unfair. In addition, the Licensee states that the NRC has attempted to impose the $100,000 fine twice for one alleged failure, that being the alleged failure by the authorized user to do a survey with a hand held survey meter; and asserts that the loss of the source was not a separate action and cannot be separated from the alleged survey failure. With respect to the $80,000 fine for the violations in Section III, the Licensee submits that the alleged violations, even if true, do not constitute a Severity Level II problem. The Licensee claims that it appears that NRC has not taken the past exemplary conduct of the Licensee into consideration and the Licensee requests that this conduct be reviewed again.

The Licensee cites a number of enforcement sanctions taken by the NRC against other licensees, which the Licensee believes supports its claim that the sanction imposed on the Licensee is not only unfair and inappropriate, but unlawful. The Licensee requests that the fines be reduced to $14,000.

NRC Evaluation of Licensee's Request for Mitigation

Pursuant to Section 234 of the Atomic Energy Act, as amended, the NRC is authorized to impose civil penalties of up to $100,000 per violation per day for each day that a violation continues. Normally, proposed civil penalties are determined after application to the base civil penalty of the mitigating and escalating factors in Section VI of the Enforcement Policy, including corrective action and licensee performance. Section VII.A of the Enforcement Policy provides, however, that notwithstanding the outcome of the normal civil penalty adjustment process, the NRC may exercise its full enforcement authority to ensure that the resulting enforcement action appropriately reflects the level of NRC concern regarding the violations at issue and conveys the appropriate message to the licensee, in order to provide an appropriate sanction when particularly serious violations or serious breakdowns in management controls have occurred. In view of the particularly serious violations, which resulted in the death of a patient and exposure of numerous members of the public to radiation in excess of regulatory limits, and in view of the necessity of emphasizing to the Licensee the importance of meticulous management oversight of the radiation safety program, a very significant civil penalty was warranted. The NRC appropriately exercised its statutory authority when it proposed a $100,000 civil penalty each for the violations in Section I and II of the NOV, and an $80,000 civil penalty for the violations in Section III. The NRC also expects that these penalties will give all other similar licensees, including the successor licensees to OSC, an incentive to closely scrutinize their operations to avoid similar violations.

The Licensee's assertion that Problems I and II constitute a single violation is mistaken. Problems I and II involve violations of separate and distinct NRC requirements, with separate and distinct facts and consequences. Problem I involves a failure to perform surveys and to use radiation safety devices in violation of 10 CFR 20.201(b) and License Condition 17, which led to a misadministration resulting in acute radiation exposure and subsequent death of the patient. Problem II involves a loss of control of a radioactive source and the creation of radiation levels in unrestricted areas in violation of 10 CFR 20.206 and 10 CFR 20.105, which led to exposures of numerous members of the public to radiation in excess of regulatory limits. Therefore, separate violations are clearly justified. *Atlantic Research Corporation*, ALJ–78–2, 7 NRC 701 (1978).

The issue of the severity level of the violations in Section III of the NOV was addressed under ''NRC Evaluation of Licensee's Response to Violations III.A and III.B.''

The NRC acknowledges that the Licensee has taken corrective actions and is aware of the Licensee's past performance. However, in this case, the NRC exercised discretion to escalate the civil penalties, which supersedes the normal application of the adjustment factors, as explained above. In addition,

civil penalties are imposed, in part, to deter future violations by not only the involved licensee, but other licensees conducting similar activities. *See* Enforcement Policy, Section VI.B.

Contrary to the Licensee's statements, the civil penalties proposed in this case are within the authority of the NRC. The Licensee's comparison of the civil penalties in this case with civil penalties in other cases does not bring the NRC's exercise of its lawful authority into question. Of decisive importance is the NRC's clear authority to exercise discretion in the choice of enforcement sanctions and the ordering of enforcement priorities. *Advanced Medical Systems, Inc.*, (CLI–94–6), 39 NRC 285, 320 (1994). A sanction is not rendered invalid because it is more severe than that issued in other cases. *Id.* As explained above, the NRC acted within its statutory authority and the bounds of the Enforcement Policy when NRC exercised its discretion to escalate the civil penalties in this case. A rigid uniformity is not required in enforcement decisions, which inherently involve the exercise of informed judgment on a case-by-case basis. *Id. See also, Radiation Technology, Inc.*, (ALAB–567), 10 NRC 533, 541 (1979).

NRC Conclusion

The NRC has concluded that the violations occurred as stated in the Notice and an adequate basis for mitigation of the civil penalties was not provided by the Licensee. Consequently, the proposed civil penalties in the amount of $280,000 should be imposed.

[FR Doc. 95–10731 Filed 5–1–95; 8:45 am]
BILLING CODE 7590–01–M

[Docket No. 50–278]

PECO Energy Company; Public Service Electric and Gas Company; Delmarva Power and Light Company; Atlantic City Electric Company (Peach Bottom Atomic Power Station, Unit 3); Exemption

I

PECO Energy Company, et al. (PECo., the licensee), is the holder of Operating License No. DPR–56, which authorizes operation of the Peach Bottom Atomic Power Station, Unit 3, at steady state reactor core power levels not in excess of 3293 megawatts thermal. The license provides, among other things, that the licensee is subject to the rules, regulations and order of the Commission now or hereafter in effect.

The plant is a boiling water reactor located at the licensee's site in York County, Pennsylvania.

II

Section 50.54(o) of 10 CFR Part 50 requires that primary reactor containments for water cooled power reactors be subject to the requirements of Appendix J to 10 CFR Part 50. Appendix J contains the leakage test requirements, schedules, and acceptance criteria for tests of the leak tight integrity of the primary reactor containment and systems and components which penetrate the containment.

Section III.D.2(a) of Appendix J to 10 CFR Part 50 requires that Type B leak rate tests, except for air locks, be performed during reactor shutdown for refueling, or other convenient intervals, but in no case at intervals greater than 2 years. Type B tests are intended to detect local leaks and to measure leakage across each pressure-containing or leakage-limiting boundary for certain reactor containment penetrations.

Section III.D.3 of Appendix J to 10 CFR Part 50 requires that Type C leak rate tests be performed during each reactor shutdown for refueling but in no case at intervals greater than 2 years. Type C tests are intended to measure containment isolation valve leakage rates for certain containment isolation valves.

III

By letter dated February 22, 1995, the licensee requested a one-time exemption from the requirements of Appendix J, Sections III.D.2(a) and III.D.3 for a period of 60 days for the isolation valves or leakage boundaries for 80 penetrations. In its request, the licensee provided a list of the affected penetrations and associated plant-specific leak test procedures, the date when the leak tests had last been performed and the date when the current leak test will expire.

The licensee has implemented a 24-month operating cycle schedule at the Peach Bottom facility. The last refueling outage for Unit 3, 3R09, commenced in September 1993 and ended in November 1993 and the next refueling outage, 3R10 is scheduled to commence no later than September 30, 1995. The leak tests for which the licensee has requested schedular exemption were last conducted during the refueling outage 3R09, based on the information provided in the licensee's application. The licensee has stated that the affected leak test require either that safety systems be isolated or require access to the drywell, either of which would require the reactor to be shutdown.

The licensee has divided the affected leak tests into two categories: (1) Those that require shutdown reactor conditions but come due prior to the latest scheduled commencement of 3R10 on September 30, 1995, and (2) those that require reactor shutdown conditions and come due after the scheduled commencement of 3R10. There are 52 leak test surveillance procedures affecting 47 penetrations or penetration groups in the first category. These tests and penetrations are listed in Table 1 of the licensee's February 22, 1995 request. The earliest of these tests falls due on August 12, 1995, up to 49 days prior to the scheduled shutdown. The licensee has requested an exemption for 60 days which will allow the unit to operate until the beginning of the planned outage without shutting down to perform leak tests and which will allow for flexibility in planning the leak tests during the outage.

There are 28 leak test surveillance procedures affecting 29 penetrations in the second category described previously. These tests are listed in Table 2 of the licensee's February 22, 1995 submittal. The licensee has requested an exemption of 60 days to allow for flexibility in planning these leak tests during the outage. The licensee stated that all of the affected penetrations will be leak tested prior to restart from 3R10.

IV

The licensee presented information in support of its request for a 60-day extension of the Type B and C test intervals. The maximum allowable leakage rate for maintaining primary containment (L_a—minimum pathway leakage) is 125,417 cc/min. The as-found total Type B and C minimum pathway leakage rate observed during Unit 3 refueling outage 3R09 during the fall of 1993 was 33,434 cc/min. The as-left leak rate for that same outage was 27,188 cc/min.

PECo stated that an extension of the leak test interval to allow for 49 days of operation in not likely to significantly decrease the margin between as-found leak rates and L_a.

PECo also stated that the remainder of the total 60-day extension, requested for outage planning flexibility, will have minimal safety significance since the unit will be in cold shutdown. Primary containment integrity is not required during cold shutdown.

The licensee provided information regarding the requirements of 10 CFR 50.12, ''Specific Exemptions.'' With respect to the requirements of 10 CFR