

50.12(a)(1), the licensee stated that the requested action is authorized by law in that no prohibition of law exists which would preclude the activities which would be authorized by the exemption. In addition, the licensee stated that, for the reasons discussed above, the requested exemption does not present an undue risk to the public health and safety. Finally, the licensee stated that containment leak rate testing is not considered in the common defense and security of the nation.

With respect to the requirements of 10 CFR 50.12(a)(2)(iii), the licensee stated that special circumstances are present because compliance with the strict requirements of Appendix J would result in hardships significantly in excess of those contemplated when the regulation was adopted. The licensee stated that at the time the regulation was adopted, a presumption was made that a 2-year test interval would easily accommodate performance of the required tests during an operating cycle. However, development of new core designs have resulted in cycles of 24 months, or longer. Performance of the tests at the 24-month frequency would result in undue financial hardship resulting from extended reactor shutdown beyond that intended by the regulation with little or no compensatory increase in the level of safety or quality.

V

Based on the above, the staff finds there is reasonable assurance that the containment leakage-limiting function will be maintained and that a forced outage to perform Type B and C tests is not necessary. Therefore, the staff finds the requested exemption, to allow the Type B and C test intervals for the penetrations listed in the licensee's February 22, 1995 request to be extended for 60 days from their current expiration date, to be acceptable. The exemption request has been evaluated in a safety evaluation dated April 25, 1995.

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a), the requested exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. The Commission finds that the special circumstances as required by 10 CFR 50.12(a)(2) are present. The Commission's finding is based on the information provided by the licensee regarding 10 CFR 50.12(a)(2)(iii). In addition, as specified in 50.12(a)(2)(ii), special circumstances are present whenever the application of the

regulation in the particular circumstance would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule. The underlying purpose of the rule is to ensure that the components comprising the primary containment boundary are maintained and leak tested at periodic and appropriate intervals. The 24-month maximum interval was originally expected to bound the typical operating cycle, including a limited amount of mid-cycle outage time. The advent of advanced fuel types has made it possible to operate the facility for the 24 months with minimal, if any mid-cycle outage time. Strict adherence to the 24-month maximum interval is not necessary to meet the underlying purpose of the rule in that, taking into consideration the 60-day extension, the components that comprise the primary containment boundary will still be tested at a frequency that is appropriate to those components and their application. In addition, the 60-day extension represents a minimal increase in the existing 24-month interval required by the rule. Therefore, the staff finds the requested temporary exemption, to allow the Type B and C test intervals for penetrations described in the licensee's February 22, 1995 letter, to be extended for 60 days, to be acceptable.

An exemption is hereby granted from the requirements of Sections III.D.2(a) and III.D.3 of Appendix J to 10 CFR Part 50, which requires that Type B and C tests be performed during each reactor shutdown for refueling but in no case at intervals greater than 2 years, for a period of 60 days from the expiration of the current leak test for the affected penetrations.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will have no significant impact on the quality of the human environment (60 FR 19968).

This exemption is effective upon issuance.

Dated at Rockville, Maryland this 25th day of April 1995.

For the Nuclear Regulatory Commission.

Steven A. Varga,

*Director, Division of Reactor Projects—I/II,
Office of Nuclear Reactor Regulation.*

[FR Doc. 95-10733 Filed 5-1-95; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 030-32493; License No. 29-28685-01; EA 93-072]

Radiation Oncology Center at Marlton, Marlton, New Jersey; Order Imposing a Civil Monetary Penalty

I

Radiation Oncology Center at Marlton (Licensee) is the holder of Byproduct Materials License No. 29-28685-01 (License) issued by the Nuclear Regulatory Commission (NRC or Commission) on January 17, 1992. The License authorizes the Licensee to possess and use certain byproduct materials in accordance with the conditions specified therein. The License is due to expire on January 31, 1997. By a Confirmatory Action Letter dated February 5, 1993, the Licensee agreed to not obtain any sources of radioactive material authorized under the License until specifically authorized by NRC Region I. By a Confirmatory Order Modifying License (Effective Immediately) dated March 9, 1993, the Licensee was required to maintain any NRC-licensed material in a locked, stored, and shielded condition, and was prohibited from receiving any NRC-licensed material.

II

An NRC inspection of the Licensee's activities was conducted on February 2 and 4, 1993. The results of this inspection indicated that the Licensee has not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated May 31, 1994. The Notice states the nature of the violation, the provisions of the NRC requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violation.

The Licensee responded to the Notice in letters dated August 31, 1994, October 4, 1994, and December 1, 1994. In its responses the Licensee denies Examples A.3, A.4, B.1, B.2, D., and G. of the violations, denies in part and admits in part Examples A.1, A.2, and C. of the violation, and admits Examples A.5, E., and F. of the violation. The Licensee also protests the amount of the civil penalty proposed and requests mitigation of the penalty as appropriate.

III

After consideration of the Licensee's response 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, with the

exceptions of Examples A.3 and G of the violation, the violation occurred as stated in the Notice; the Examples A.3 and G of the violation will be withdrawn; and the penalty proposed for the violation 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 a civil penalty in the amount of \$80,000 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, Pennsylvania 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 the violation in the Notice referenced in Section II above, and the following specific examples given with the violation: Examples A.1, A.2, A.4, B.1, B.2, C., and D.; and

(b) whether, on the basis of the violation set forth in the Notice of Violation, 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 Penalty (Notice) was issued for a violation identified during an NRC inspection of Radiation Oncology Center at Marlton (ROCM) (Licensee). The licensee responded to the Notice on August 31, 1994, October 4, 1994, and December 1, 1994. The Licensee denies Examples A.3, A.4, B.1, B.2, D., and G. of the violation, denies in part and admits in part Examples A.1, A.2, and C. of the violation, and admits Examples A.5, E., and F. of the violation. In addition, the Licensee protests the amount of the civil penalty proposed and requests mitigation of the civil penalty as appropriate. The NRC's evaluation and conclusion regarding the Licensee's requests are as follows:

Restatement of Violation

10 CFR 35.21(a) requires, in part, that the licensee, through the Radiation Safety Officer (RSO), shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.

Contrary to the above, the Licensee, through the RSO, did not ensure that radiation safety activities were performed in accordance with approved procedures and regulatory requirements in the daily operation of the Licensee's byproduct material program. Specifically, the RSO named on the Radiation Oncology Center at Marlton (ROCM) license stated at the enforcement conference that, although she had signed the license submittal, she believed that her responsibilities and authorities were primarily a medical function and not a regulatory function. She said that she was aware that she was named as the RSO on the license and added, "I was told that being—I was the fixed fixture there, that was the easiest thing to do, and that is all I was told. I had no concept of what that entailed." The following are specific examples of the failure of the Licensee, through the RSO, to ensure that radiation safety activities were performed in accordance with approved procedures and regulatory requirements in the daily operation of the Licensee's byproduct material program:

A. Condition 14 of License No. 29-28685-01 requires that the Licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 11, 1991, letter received December 18, 1991, and letter dated January 15, 1992.

1. Item 8.B of the Licensee's application, dated July 11, 1991, requires that all source exchanges be carried out by Omnitron Factory Personnel under the observation of the RSO.

Contrary to this requirement, source exchanges carried out by Omnitron Factory Personnel were not always under the observation of the RSO. Specifically, the RSO stated that although she observed the first source exchange at the facility on March 5, 1992, she did not observe the three subsequent source exchanges on June 4, September 16, and December 9, 1992.

2. Item 10.12 of the Licensee's application, dated July 11, 1991, requires that surveys of radiation levels in all adjacent areas and controlled areas be performed at initial installation and then quarterly thereafter at source exchanges and that results of the surveys be maintained.

Contrary to this requirement, surveys of radiation levels in all adjacent areas and controlled areas were not performed during the source exchanges which occurred on March 5, June 4, and September 16, 1992. In addition, the Licensee was unable to supply the inspectors with documentation demonstrating that surveys were performed in any adjacent areas following the December 9, 1992 source change.

3. Item 10.15.A.4 of the Licensee's application, dated July 11, 1991, requires, in part, that a daily check of all interlocks, safety systems and alarms be performed and documented in log books, that daily operational system checks be recorded, and that source position indicators (visual and radiation detection) be checked before each use and recorded.

Contrary to this requirement, as of February 4, 1993, daily checks of all interlocks, safety systems and alarms were not performed and documented in log books. Specifically, Licensee personnel believed that the performance of these checks was the responsibility of the physics consultant even though the physics consultant was only present for approximately one half of the total patient treatments, and the ROCM staff did not perform these daily checks when the physics consultant was not present. In addition, the Licensee was unable to provide any documentation indicating that daily checks of all the inter-locks, safety systems and alarms; daily operational system checks; and daily checks of source position indicators (visual and radiation detection) were performed on the occasions when the physicist was present.

4. Item 8.E.5 of the Licensee's application, dated July 11, 1991, requires, in part, that each operator/user of the HDR individually demonstrate competence in the emergency procedures during "dry run" emergencies using several failure modes for each operator.

Contrary to this requirement, as of February 4, 1993, each operator/user of the HDR did not individually demonstrate competence in the emergency procedures during "dry run" emergencies using several failure modes for each operator.

5. Item 9.1.C.4 of the Licensee's application, dated July 11, 1991, requires, in part, that the radiation monitor (PrimAlert) have a battery backup.

Contrary to this requirement, as of February 4, 1993, the Licensee did not have a battery back-up to operate the radiation monitor (PrimAlert).

B. 10 CFR 19.12 requires, in part, that all individuals working in or frequenting any

portion of a restricted area be instructed in the purposes and functions of protective devices employed, and in the appropriate response to warning made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material.

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.

Contrary to these requirements,

1. As of February 4, 1993, individuals working in or frequenting portions of a restricted area were not instructed in the purposes and functions of protective devices employed. Specifically, the Licensee failed to instruct the dosimetrist in the proper use of the radiation survey meter. The dosimetrist, when questioned by the inspector on the operation and use of the survey meter, stated that the X1000 setting was the instrument's "lowest strength" scale. The X1000 setting is actually the highest scale setting on the instrument.

2. As of February 4, 1993, individuals working in or frequenting portions of a restricted area were not instructed in the appropriate response to a warning made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material. Specifically, the Licensee failed to adequately train the dosimetrist to identify and respond to HDR error messages.

When questioned by the inspector on February 4, 1993, the dosimetrist did not know the meaning of the error messages from a random printout of a treatment execution record, dated May 7, 1992, which contained several error messages.

C. 10 CFR 35.31(b) requires that a licensee that makes minor changes in radiation safety procedures, as permitted under 10 CFR 35.31(a), retain a record of each change until the license has been renewed or terminated. The record shall include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the RSO, and the signatures of the affected authorized users, and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

Contrary to this requirement, prior to February 2, 1993:

1. The Licensee made a minor change in its radiation safety procedures, as permitted under 10 CFR 35.31(a), by posting emergency procedures that differed from those procedures submitted to the NRC in support of the license application, and the Licensee did not retain a record of the change that included the effective date of the change, the reasons for the change, a summary of the radiation matters that were considered before making the change, the signature of the RSO, and the signatures of the affected authorized users, and of management.

2. The Licensee made a minor change in its radiation safety procedures, as permitted

under 10 CFR 35.31(a), by using HDR calibration procedures that differed from those procedures submitted to the NRC in support of the license application, and the Licensee did not retain a record of the change that included the effective date of the change, the reason for the change, a summary of the radiation matters that were considered before making the change, the signature of the RSO, and the signatures of the affected authorized users, and of management.

D. 10 CFR 35.32 requires, in part, that each licensee, as applicable, establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

Contrary to this requirement, from March through December 1992, the Licensee engaged in licensed activities (namely, the administration of brachytherapy radiation doses using an iridium-192 source in an HDR unit) which required the establishment of a quality management program, and as of February 5, 1993, the Licensee had not established a written quality management program.

E. 10 CFR 35.51(a)(3) requires that the apparent exposure rate from a dedicated check source as determined at the time of calibration, be conspicuously noted on the instrument with the date of calibration.

Contrary to this requirement, as of February 4, 1993, the apparent exposure rate from a dedicated check source as determined at the time of calibration, was not conspicuously noted on the instrument with the date of calibration.

F. 10 CFR 19.11 (a) and (b) require, in part, that the Licensee post current copies of Part 19 and 20, and the license, or post a notice describing these documents and where they may be examined. 10 CFR 19.11(c) also requires that the licensee post a Form NRC-3, "Notice to Employees."

Contrary to this requirement, as of February 4, 1993, the Licensee did not post current copies of Parts 19 and 20, and the license, or a notice describing the documents and where they could be examined, and did not post a Form NRC-3.

G. 10 CFR 30.51(a) requires each licensee to keep records showing the receipt, transfer, and disposal of byproduct material.

Contrary to this requirement, as of February 4, 1993, the Licensee did not keep records showing the receipt, transfer, and disposal of byproduct material. Specifically, the Licensee did not maintain records of the source receipt and transfer for disposal.

This is a Severity Level II violation (Supplement VI).

Summary of Licensee's Response to Example A.1 of the Violation

The Licensee admits this example in part and denies it in part, but does not state specifically what it admits or denies. The Licensee states that, although the RSO was not present in the room during the source exchange, the RSO or the physicist was physically present at the facility during the source exchanges, or readily available in case of an emergency, and thus the RSO was overseeing the source exchanges. The

Licensee believes that this was all that was intended by its license application, that the RSO may delegate duties, and that the physical presence of the RSO during a source exchange would violate ALARA principles. The Licensee believes that, in any event, this example would constitute a Severity Level IV violation.

NRC Evaluation of Licensee's Response to Example A.1 of the Violation

The Licensee's application is clear in requiring that all source exchanges be carried out by Omnitron Factory Personnel under the observation of the RSO. With proper planning and the application of common radiation protection methods, the RSO could observe source exchanges without violating ALARA principles. At the transcribed enforcement conference, the RSO confirmed that she observed the first source exchange but did not observe the three subsequent source exchanges. Since source exchanges occurred that were not under the observation of the RSO, the NRC concludes that this example of the violation occurred as stated in the Notice. The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

Summary of Licensee Response to Example A.2 of the Violation

The Licensee admits this example in part and denies it in part, but does not state specifically what it admits or denies. The Licensee states its belief that surveys of radiation levels in adjacent areas and/or controlled areas were performed during the source exchanges which occurred on March 5, June 4, and September 16, 1992, by Omnitron for the Licensee's benefit. The Licensee, in its letter dated December 1, 1994, provided Omnitron's record of surveys conducted during the source exchange on December 9, 1992, as well as other records of surveys conducted on March 5, June 4, and September 16, 1992. The Licensee believes that, in any event, this would constitute a Severity Level IV violation.

NRC Evaluation of Licensee's Response to Example A.2 of the Violation

Omnitron's record of surveys conducted on December 9, 1992 does not show that all adjacent areas were surveyed as required by License Condition 14. Regarding the records of other surveys that the Licensee submitted, the NRC inspection report indicates that the inspectors did see documentation of partial surveys for March 5, 1992, June 4, 1992, and September 16, 1992. With the exception of the survey record for December 17, 1992, the survey records that the Licensee submitted show that the surveys did not include all adjacent areas as required by the license condition. As noted in the inspection report, examples of adjacent areas that were not surveyed include a staff restroom, a utility room, the patient examination room, and the patient dressing room. Therefore, the NRC concludes that this example of the violation occurred as stated in the Notice. The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

Summary of Licensee Response to Example A.3 of the Violation

The Licensee states that it denies this example. The Licensee states that, contrary to the NRC findings, checks were performed and an entire log indicating that certain checks were performed does exist. In its letter dated December 1, 1994, the Licensee provided numerous log entries to show that checks were performed.

NRC Evaluation of Licensee's Response to Example A.3 of the Violation

The NRC staff has reviewed the log entries provided by the Licensee on December 1, 1994. Based on those records, which were not provided during the inspection or the transcribed enforcement conference, the NRC staff is withdrawing this example of the violation. The withdrawal of this example of the violation does not change the fact that the violation occurred, nor does it affect the appropriateness of the amount of the civil penalty assessed for the violation in this case, given the nature of the violation and the numerous other examples of the violation that are not being retracted.

Summary of Licensee Response to Example A.4 of the Violation

The Licensee denies the example and asserts that relevant personnel attended Omnitron training where dry runs were performed and emergency situations and procedures were taught and discussed. The Licensee believes that, in any event, this could constitute a Severity Level IV violation.

NRC Evaluation of Licensee's Response to Example A.4 of the Violation

While Omnitron training may have covered emergency situations, License Condition 14 specifically requires that each operator/user of the HDR individually demonstrate emergency routine competence during "dry run" emergencies using several failure modes for each operator. At the transcribed enforcement conference, the Medical Director, recalling the portion of the Omnitron training that pertained to emergency situations, stated, "[t]o the best of my recollection, I believe they went through some of the descriptive terms on how to re crank the machine manually, and I believe they showed us the knob. But I cannot say with any degree of recollection that we actually went through it." As noted in the inspection report, the dosimetrist stated to inspectors that she had not performed "dry run" emergencies using several failure modes. Therefore, the NRC concludes that this example of the violation occurred as stated in the Notice. The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

Summary of Licensee Response to Example A.5 of the Violation

The Licensee admits this example of the violation, but states its belief that this would constitute a Severity Level IV violation.

NRC Evaluation of Licensee's Response to Example A.5 of the Violation

The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

Summary of Licensee Response to Example B of the Violation

The Licensee denies this example. The Licensee states that failure to answer all questions posed by the inspector does not necessarily constitute evidence that employees were not adequately trained in accordance with the commitments in the application or in the regulations. The Licensee believes that at all times personnel were trained as required under the license and under the applicable regulations. The Licensee states that 10 CFR 19.12 only requires that personnel be trained "commensurate with potential radiological health protection problems in the restricted area." The Licensee also states that "the NRC did not allege that the dosimetrist did not know how to operate a hand held survey meter or that she was not trained in its operation." The Licensee asserts that the dosimetrist was trained pursuant to license requirements. The Licensee believes that, in any event, this would constitute a Severity Level IV violation.

NRC Evaluation of Licensee's Response to Example B of the Violation

As documented in the inspection report, the dosimetrist was asked to demonstrate the operation and use of the radiation survey meter. The dosimetrist incorrectly set the instrument response dial to the X1000 scale, stating that this was the instrument's lowest strength scale. The inspectors asked the dosimetrist to repeat this demonstration and explanation a second time and the dosimetrist produced the same result. The dosimetrist is the individual who operated the HDR unit at Marlton. When the inspectors asked the dosimetrist to explain the meaning of the "error code" and "error class" messages on a printout of a treatment record, the dosimetrist stated that she did not know the meaning of the error messages.

The NRC staff finds that the dosimetrist's lack of understanding of the differences between the highest setting on the meter and the lowest setting on the meter, as well as the lack of understanding concerning response to HDR error messages are clear evidence that adequate training was not provided.

10 CFR 19.12 also requires that all individuals working in or frequenting any portion of a restricted area shall be instructed in precautions or procedures to minimize exposure, and in the purposes and function of protective devices employed. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area. The dosimetrist operated the HDR. In an emergency situation, the dosimetrist's duties could involve use of a survey meter to determine the status and location of the source in the restricted area as a means of protecting herself as well as other employees and patients. The Licensee clearly recognized that emergency situations could arise because it discussed "dry run" emergency procedures

in its license application. In addition, since the dosimetrist's duties included operation of the HDR, this individual should have been knowledgeable on the meaning of error messages and how to respond to error messages generated by the HDR unit. Error messages could indicate hazardous conditions in the restricted area. Therefore, this individual was required by 10 CFR 19.12 to be trained by the Licensee on the meaning of the error messages, how to respond to error messages, and the use of a hand-held survey meter. Based on the above, the NRC concludes that this example of the violation occurred as stated in the Notice. The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

Summary of Licensee Response to Example C of the Violation

The Licensee states in its response that it admits in part and denies in part this example. The Licensee asserts that it did record certain changes and may not have recorded others. The Licensee further asserts that, in this case, there was no potential or actual impact on health and safety. The Licensee believes that, in any event, this would constitute a Severity Level V violation.

NRC Evaluation of Licensee's Response to Example C of the Violation

10 CFR 35.31 authorizes medical use licensees to make minor changes in radiation safety procedures that are not potentially important to safety. 10 CFR 35.31(b) requires that if these changes (ministerial changes) are made, the licensee must maintain a record as specified in the regulation. There is no exception granted to the Licensee to only record certain changes. Since the Licensee did not maintain a record of some changes, the NRC concludes that this example of the violation occurred as stated in the Notice. The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

Summary of Licensee Response to Example D of the Violation

The Licensee states in its response that it denies this example. The Licensee asserts that it had a written quality management program (QMP) which was in effect at the relevant times. In addition, the Licensee states that it has modified its quality management plan pursuant to completion of a review of its HDR program, and that the modified plan has been submitted to the NRC.

NRC Evaluation of Licensee's Response to Example D of the Violation

The requirement is that the Licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The inspection report indicates that inspectors did find a copy of "Quality Management of Brachytherapy Patients High Dose Rate Techniques" authorized by David Cunningham of Oncology Services Corporation and dated January 16, 1992. This

document was in a notebook containing other HDR records. According to the inspection report, the facility Medical Director/RSO had no knowledge of the document. In addition, the Medical Director/RSO stated at the time of the inspection that no one at the facility had received training on the document. Further, at the time of the inspection, the Licensee had not submitted its quality management program (QMP) to NRC as required by 10 CFR 35.32(f)(2). Since the Medical Director/RSO had no knowledge of the QMP, had not trained the staff on the QMP, and had not submitted the QMP to NRC, it is clear that the QMP was neither established nor maintained so as to provide high confidence that radiation from byproduct material would be administered as directed by the authorized user. Therefore, the NRC concludes that this example of the violation did occur.

Summary of Licensee Response to Example E of the Violation

The Licensee admits this example, but states its belief that this would constitute a Severity Level V violation.

NRC Evaluation of Licensee's Response to Example E of the Violation

The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

Summary of Licensee Response to Example G of the Violation

The Licensee states in its response that it denies this violation. The Licensee states that it believes that certain records were maintained and that Omnitron also kept records for the benefit of the Licensee. The Licensee, in its letter dated December 1, 1994, provided copies of shipping papers showing the transfer of sources back to Omnitron, and copies of leak test results performed on sources by Omnitron. The Licensee believes that, in any event, this would constitute a Severity Level V violation.

NRC Evaluation of Licensee's Response to Example G of the Violation

The NRC staff has reviewed the records submitted by the Licensee on December 1, 1994. The particular shipping records that the Licensee submitted, which include the transferee, isotope, activity, and date, meet the requirement for records of the transfer of byproduct material. The leak test records that the Licensee submitted meet in part the requirement for records of receipt of licensed material. The leak test records did identify the transferor, isotope, and activity; but not the date of receipt. However, because the Licensee has other records, such as source exchange records, that identify the date of receipt, the NRC is withdrawing this example of the violation. The withdrawal of this example of the violation does not change the fact that the violation occurred, nor does it affect the appropriateness of the amount of the civil penalty assessed for the violation in this case, given the nature of the violation and the numerous other examples of the violation that are not being retracted.

Summary of Licensee's Request for Mitigation

The Licensee states in its response that it has taken numerous corrective actions to strengthen and improve all aspects of its radiation safety program. The licensee also states that over the past eighteen months, it has attempted to continually review and update its HDR program and staff, and emphasize the importance of radiation safety and applicable regulations. In addition, the Licensee indicates that management has attended courses regarding RSO duties and responsibilities. The Licensee also notes that five patients were treated with the HDR unit between March 1992 and December 1992 and there were no misadministrations or incidents.

The Licensee states that it: (1) Immediately and voluntarily suspended all HDR treatments in order to review the entire HDR program; (2) fully and timely complied with any and all CALs; and (3) replaced its contract physicist with a full-time physicist who, as RSO under the license, would provide necessary onsite RSO continuity needed to assure Licensee management and the NRC that the HDR program could run safely and in accordance with all regulations at all times. The Licensee also states its belief that the replacement of the RSO constitutes required and necessary corrective action regarding the identified issues, noting that the new physicist has held quarterly meetings where radiation safety, and regulatory issues have been reviewed with the staff. According to the Licensee, staff members have attended additional outside training and the authorized users have attended a six hour Radiation Safety Officers Review Course. In addition, the Licensee states that it has hired a Certified Health Physicist to assist in the coordination and oversight of all aspects of the Licensee's radiation safety program.

The Licensee states its belief that by hiring a full-time physicist to serve as RSO and obtaining the assistance of the Certified Health Physicist, it has clearly demonstrated that it has committed the resources necessary to develop and implement an appropriate, comprehensive and long lasting commitment to address the root cause of the violations. The Licensee believes that its new program, which permits only the physicist and physician to be involved with actual HDR patient treatments, will assure the NRC that none of the examples of the violation will be repeated.

The Licensee contends that a fine of \$80,000 for what the Licensee terms "a number of Level IV and V violations" is arbitrary, capricious and unsupported by any of the NRC rules, regulations and/or legislative history. In support of this argument, the Licensee claims that similar enforcement actions involving similar violations by Part 35 licensees resulted in substantially smaller penalties. The Licensee further states that these citations collectively do not constitute a Severity Level II program and, in any case, the maximum penalty should be \$8,000 before any mitigation. The Licensee asserts that it has an exemplary record having had no previous violations or misadministration. The Licensee cites a number of NRC Enforcement sanctions which

the Licensee believes supports its claim that the sanction imposed on the Licensee is inappropriate.

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 past 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. Given the seriousness of the violation in that the RSO failed to devote time or attention to the radiation safety program and that corporate management created the environment in which this was allowed to occur, a large civil penalty is warranted to emphasize the unacceptable performance of the Licensee, its RSO, and its corporate owner; and to emphasize the need for the Licensee and its corporate owner, as well as other licensees engaged in similar activities, to assure that controls are in place to avoid similar violations. The NRC appropriately exercised its statutory authority when it proposed an \$80,000 civil penalty for the violation.

As the Licensee's arguments that some of the examples are appropriately classified at Severity Level IV or V, the NRC did not categorize the individual examples of the violation in the Notice by severity level. Rather, the NRC categorized the single violation, including all of the listed examples, at Severity Level II. The violation is appropriately categorized at Severity Level II because it is of very significant regulatory concern and involved high potential impact on the public. Enforcement Policy Section IV. The guidance given by the examples in Supplements I-VII of the Enforcement Policy is neither exhaustive nor controlling in classifying the severity level of violations. The NRC reviews each enforcement action on its own merits to ensure that the severity level of a violation is characterized at the level best suited to the significance of the violation, which may warrant an adjustment to the severity level categorization. Enforcement Policy, Section IV. In this case, the violation represents a near total failure of the RSO to address her regulatory responsibilities and an equally serious failure of licensee management to exercise oversight over the radiation safety program in order to ensure that regulatory requirements were met, all of which created a high potential impact on the public for an incident similar to the November 1992 misadministration and

radiological event at the owner's facility in Indiana, Pennsylvania.

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.

The civil penalties proposed in this case are within the authority of the NRC. The Licensee's comparison of the civil penalty in this case with civil penalties in other cases does not bring 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 neither required nor possible in enforcement decisions, which inherently involve the exercise of informed judgement 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: (1) With the exceptions of Examples A.3 and G., the violation occurred as stated in the Notice; (2) Examples A.3 and G are being withdrawn; (3) the withdrawal of these two examples of the violation does not change the fact that the violation occurred nor does it affect the appropriateness of the amount of the civil penalty assessed for the violation; and (4) an adequate basis for mitigation of the civil penalty was not provided by the Licensee. Consequently, the proposed civil penalty in the amount of \$80,000 is being imposed.

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[Docket No. 50-244]

Rochester Gas and Electric Company (R. E. Ginna Nuclear Power Plant); Exemption

I

Rochester Gas and Electric Corporation (RG&E) is the holder of Facility Operating License No. DPR-18, which authorizes operation of R. E. Ginna Nuclear Power Plant at steady-state power levels up to a maximum of 1520 megawatts thermal. The facility is a pressurized water reactor located at the licensee's site in Wayne County, State of New York. The license provides

among other things, that the facility is subject to all rules, regulations, and Orders of the Commission.

II

Appendix J of Part 50 of Title 10 of the Code of Federal Regulations, "Primary Reactor Containment Leakage Testing for Water-Cooled Reactors," Section III.D.3, requires that Type C leakage rate testing be performed each reactor shutdown for refueling, but in no case at intervals greater than 2 years.

By letter dated March 15, 1995, RG&E requested a one-time Exemption from two parts of 10 CFR Part 50, Appendix J, Section III.D.3. First, RG&E requests an Exemption from performing Type C tests during the 1995 refueling outage except for isolation valves which have maintenance performed on them or valves which have not demonstrated acceptable leakage during the previous two leakage rate tests. Second, RG&E requests an Exemption from performing Type C tests within a 2-year interval, as required by the regulation. RG&E requests up to a 1-month extension of the 2-year interval for 129 containment isolation valves.

The last Type C tests were performed during the 1994 refueling outage after March 10, 1994. RG&E stated in the March 15, 1995, letter that the 1996 refueling outage will commence on March 31, 1996, with Cold Shutdown reached on April 1, 1996. RG&E requested an Exemption from the 2 year test interval until April 10, 1996, an interval 1 month greater than the required 2 year test interval.

The R. E. Ginna Nuclear Power Plant has a total of 151 containment isolation valves. RG&E has proposed to exempt 129 of these valves from Type C testing during the 1995 refueling outage. The other valves would be tested during the 1995 refueling outage either because maintenance has been done on them or they have not passed the RG&E's criterion for exemption of two successful consecutive tests.

The NRC staff finds RG&E's proposal to be acceptable for several reasons. As discussed in RG&E's March 15, 1995 letter, the performance of the containment isolation valves and the R. E. Ginna Nuclear Power Plant overall containment integrity have been good. The as-left Type A test leakage rate is 35% of L_a . The current Type B and C as-left maximum path leakage rate is 61% of the 0.6 L_a Appendix J limit. Therefore, there is reasonable assurance that the 1-month extension of the 2-year interval will not result in exceeding the Appendix J limits.

In addition, RG&E has proposed to limit the Exemption only to those valves

on which no maintenance has been done and which have passed the last two consecutive Type C leakage rate tests. The NRC staff has granted similar requests in the past. On February 2, 1994, the NRC staff granted a similar Exemption to the River Bend Station licensee, and by letter dated April 29, 1987, the NRC staff granted a similar request to the Washington Public Power Supply System, Unit 2 licensee.

The NRC staff, therefore, grants the requested one-time Exemption to the R. E. Ginna Nuclear Power Plant licensee subject to the condition that the Exemption apply only to those valves on which no maintenance has been done and which have passed the last two consecutive Type C leakage rate tests. The Exemption is granted until plant shutdown for the 1996 refueling outage, not to extend beyond April 10, 1996.

III

Section 50.12 of the Commission's regulations permit granting an Exemption from the regulations when special circumstances are present. According to 50.12(a)(2)(ii), special circumstances are present whenever application of the regulation in question is not necessary to achieve the underlying purpose of the rule.

The underlying purpose of Appendix J, Section III.D.3, is to assure a leak tight containment to mitigate the consequences of an accident. The past leakage rate data and available margin to the allowed technical specifications, as discussed above, are sufficient to assure that the underlying purpose of Appendix J, Section III.D.3, is achieved.

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, this Exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security.

Accordingly, the Commission hereby grants an Exemption from 10 CFR Part 50, Appendix J, Section III.D.3.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of the Exemption will have no significant impact on the environment (60 FR 20513).

Dated at Rockville, Maryland, this 26th day of April 1995.

This Exemption is effective upon issuance. For the Nuclear Regulatory Commission.

Steven A. Varga,

*Director, Division of Reactor Projects—I/II,
Office of Nuclear Reactor Regulation.*

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