

(3150-0011), NEOB-10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395-3084.

The NRC Clearance Officer is Brenda Jo. Shelton, (301) 415-7233.

Dated at Rockville, Maryland, this 8th day of May, 1996.

For the Nuclear Regulatory Commission.  
Gerald F. Cranford,  
*Designated Senior Official for Information Resources Management.*

[FR Doc. 96-13514 Filed 5-29-96; 8:45 am]

BILLING CODE 7590-01-P

[Docket Nos. 50-325 and 50-324]

**Carolina Power & Light Company;  
Notice of Withdrawal of Application for  
Amendment to Facility Operating  
License**

The U.S. Nuclear Regulatory Commission (the Commission) has granted the request of Carolina Power & Light Company (the licensee) to withdraw its December 29, 1992, application for proposed amendment to Facility Operating License Nos. DPR-71 and DPR-62 for the Brunswick Steam Electric Plant, Units 1 and 2, located in Brunswick County, North Carolina.

The proposed amendment would have revised the Type A test acceptance criterion for the as found containment integration leakage rate from 0.75 La to 1.0 La (and 0.75 Lt to 1.0 Lt) that represents the maximum allowable containment leakage rate.

The Commission had previously issued a Notice of Consideration of Issuance of Amendment published in the Federal Register on June 23, 1993, (58 FR 34070). However, by letter dated January 30, 1995, the licensee withdrew the proposed change.

For further details with respect to this action, see the application for amendment dated December 29, 1992, and the licensee's letter dated January 30, 1995, which withdrew the application for license amendment. The above documents are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the University of North Carolina at Wilmington, William Madison Randall Library, 601 S. College Road, Wilmington, North Carolina 28403-3297.

Dated at Rockville, Maryland, this 16th day of May 1996.

For the Nuclear Regulatory Commission.

Brenda L. Mozafari,

*Project Manager, Project Directorate II-1,  
Division of Reactor Projects—I/II, Office of  
Nuclear Reactor Regulation.*

[FR Doc. 96-13516 Filed 5-29-96; 8:45 am]

BILLING CODE 7590-01-P

[Docket No. 030-03368; License No. 46-02645-03; EA 96-004]

**Department of the Army, Madigan  
Army Medical Center, Tacoma,  
Washington; Order Imposing Civil  
Monetary Penalty**

I

Madigan Army Medical Center (MAMC, Licensee) is the holder of NRC Materials License No. 46-02645-03, first issued by the Atomic Energy Commission on May 12, 1960. The Nuclear Regulatory Commission (NRC or Commission) issued its first license amendment to MAMC on May 26, 1977. The license authorizes the Licensee to possess byproduct material of various types and to use such material in implementing a nuclear medicine program in accordance with the conditions specified therein.

II

An inspection and investigation of the Licensee's activities were conducted June 6 through December 21, 1995, following the Licensee's report of medical misadministrations that were discovered in June 1995. The results of the inspection and investigation, documented in a report issued on January 5, 1996, NRC Inspection Report No. 030-03368/95-01 and Investigation Report 4-95-027, indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A predecisional enforcement conference was conducted on January 18, 1996, at the Licensee's facility. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$8,000 was served upon the Licensee by letter dated February 22, 1996. The Notice described the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations.

The Licensee responded to the Notice in two letters both dated March 21, 1996 (Reply to a Notice of Violation and Answer to a Notice of Violation). In its responses, the Licensee admitted the violations but requested mitigation of the proposed civil penalty based on actions taken by the Madigan Army

Medical Center (MAMC) to identify and correct the violations.

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 the violations occurred as described in the Notice, and that the penalty proposed for the violations 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 \$8,000 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, MD 20852-2738.

V

The Licensee may request a hearing within 30 days of the date of this Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and include a statement of good cause for the extension. 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 IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

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 (or if written approval of an extension of time in which to request a hearing has not been granted), 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 issue to be considered at such hearing shall be: whether, on the basis of the violations admitted by the Licensee, this Order should be sustained.

Dated at Rockville, Maryland, this 20th day of May 1996.

For the Nuclear Regulatory Commission.  
James Lieberman,  
*Director, Office of Enforcement.*

## Appendix—Evaluation and Conclusions

On February 22, 1996, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$8,000 was issued to Madigan Army Medical Center (MAMC or Licensee) for violations identified during an NRC inspection and investigation. The Licensee responded to the Notice in two letters both dated March 21, 1996. The Licensee admitted the violations but requested mitigation of the proposed civil penalty based on actions taken by MAMC to identify and correct the violations.

### *Restatement of Violations Assessed a Civil Penalty*

#### I. Violations Assessed a Civil Penalty

A. 10 CFR 35.25(a) (1) and (2) require, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user shall: (1) instruct the supervised individual in the licensee's written quality management program (QMP); and (2) require the supervised individual to follow the written QMP procedures established by the licensee.

Item 4 of the licensee's QMP specified, in part, that when computer calculations are performed, an individual who did not make the original calculations will check the dose calculation parameters.

Contrary to the above, the licensee did not meet the above requirements as specified in the following examples:

1. As of June 6, 1995, the licensee had not assured that individuals working under the supervision of an authorized user, i.e., the medical physicist and dosimetrist, were adequately instructed in the licensee's written QMP. Specifically, although the medical physicist and dosimetrist had signed a record indicating that they had reviewed department procedures, including the QMP, they had neither received specific instruction in the procedures incorporated in the QMP nor read each of the procedures.

2. Between February 1994 and May 1995, the licensee took no action to require or assure that individuals working under the supervision of an authorized user, i.e., the medical physicist and dosimetrist, were aware of, or were following, the licensee written QMP procedures established by the licensee. Specifically, computer calculations performed were not checked by an individual who did not make the original calculations. (01012)

B. 10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written

QMP to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

10 CFR 35.32(a) (3) and (4) require, in part, that the QMP include written policies and procedures to meet the objectives that: (1) final plans of treatment and related calculations for brachytherapy are in accordance with the applicable written directives and (2) that each administration of radiation from brachytherapy is in accordance with the applicable written directive.

Contrary to the above, between February 1994 and May 1995, the licensee's QMP did not include written procedures that met the above stated objectives. Consequently, in five cases involving patients undergoing brachytherapy treatment during this time period, incorrect data values were entered in a computerized treatment planning system used to develop final treatment plans. The entry of incorrect data resulted in errors in the calculated dose rates identified in final treatment plans, thus causing the administered doses to deviate substantially from the prescribed doses specified in the authorized users' written directives. (01022)

These violations represent a Severity Level II problem (Supplement VI). Civil Penalty—\$8,000

### *Summary of the Licensee's Request for Mitigation*

MAMC responded to the Notice on March 21, 1996, admitting the violations but requesting mitigation of the proposed \$8,000 civil penalty based on its actions to identify and correct the violations. MAMC noted in its response that "NRC enforcement actions are intended to act as a deterrent against future violations and to encourage prompt identification and comprehensive correction of violations." MAMC then noted that it had identified the violations and made immediate extensive modifications to the radiation safety program and Quality Management Program (QMP) to ensure that the violations would not recur. MAMC described each of the corrective actions and stated that "processes have been implemented to ensure compliance with the QMP as well as a broad range of internal controls developed to prevent reoccurrence." MAMC stated that a standard civil penalty for a Severity Level II violation (\$4,000) should be sufficient, noting that this would more appropriately match the intent of NRC's Enforcement Policy and more accurately reflect MAMC's efforts in identifying and correcting the program deficiencies.

### *NRC Evaluation of Licensee's Request for Mitigation*

The Licensee is correct that among the stated purposes of the NRC Enforcement Policy (NUREG-1600) is to encourage prompt identification and comprehensive correction of violations. In this case, normal application of the enforcement policy guidance in Sections VI.B.2.b and c did in fact result in credit for MAMC's identification of the violations and corrective actions. However, Section VII.A. of the Enforcement Policy provides that civil penalties may be escalated

to ensure that the proposed civil penalty reflects the significance of the circumstances and conveys the appropriate regulatory message to the licensee. The violations which led to the misadministrations are of very significant regulatory concern to the NRC.

There were at least five cases involving patients undergoing brachytherapy treatment where MAMC administered radiation in excess of what was intended before MAMC discovered an error in its computerized treatment planning program. At least one of these patient misadministrations was later determined by medical consultants of the Licensee and the NRC to have had potential adverse health effects for the patient involved.

It was determined by NRC inspection and investigation that the misadministrations were caused, at least in part, by the Licensee's failure to assure that the MAMC staff was implementing the facility's Quality Management Program (QMP) as required and failure to adequately oversee the QMP. Additional training of the Licensee's personnel and increased management oversight could have prevented the misadministrations. These misadministrations were preventable.

The violations in this case were classified as a Severity Level II problem in recognition of this fundamental breakdown in the very program that is intended to prevent such misadministrations from occurring. The Enforcement Policy provides at Section VII.A.1(a) that discretion should be considered to escalate civil penalties in cases where problems are categorized at Severity Level I or II. As noted in Section I of the Enforcement Policy, enforcement action should be used not only to encourage identification and prompt, comprehensive correction of violations, but also as a deterrent to emphasize the importance of compliance with NRC requirements. While no violation is acceptable, the fact that these violations were preventable cannot be tolerated. In this case, discretion was clearly warranted to assess a civil penalty to MAMC, notwithstanding application of the identification and corrective action factors, to emphasize the importance of preventing significant misadministrations through supervision, training and management oversight. Considering the significance of the actual effects of the violations and their root causes, it was appropriate and wholly consistent with the Enforcement Policy guidance to deny mitigation, exercise discretion and assess a civil penalty of \$8,000.

### *NRC Conclusion*

The NRC concludes that an adequate basis for mitigation of the civil penalty is not provided by the Licensee. The NRC also concludes that the proposed civil penalty of \$8,000 is appropriate and should be imposed by order.

[FR Doc. 96-13515 Filed 5-29-96; 8:45 am]

BILLING CODE 7590-01-P