

UNITED STATES NUCLEAR REGULATORY COMMISSION REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

APR 1 1993

Docket No. 55-4559 License No. SOP-2888-6 EA 93-045

12:04

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. William F. Olsen [HOME ADDRESS DELETED UNDER 10 CFR 2.790]

Dear Mr. Olsen:

## SUBJECT: NOTICE OF VIOLATION AND EXPIRATION OF LICENSE

The Nuclear Regulatory Commission (NRC) has received a letter dated December 4, 1991, from Boston Edison Company, informing us that Boston Edison Company no longer has a need to maintain your operating license for the Pilgrim Nuclear Power Station. We also received a letter dated December 5, 1991, from Boston Edison Company (BECo) containing information about your confirmed positive test for alcohol (copies of each letter are enclosed). We plan to place both of the letters from Boston Edison Company in your 10 CFR Part 55 docket file. Further, the NRC's Office of Investigations investigated the situation; a synopsis of the investigation is enclosed and will also be placed in your docket file.

In accordance with 10 CFR 55.55(a), the determination by your facility licensee that you no longer need to maintain a license has caused your license SOP-2888-6 to expire as of December 4, 1991. In addition, the following violation is being issued on your docket:

10 CFR 55.53(j) prohibits the licensee from performing activities authorized by a license issued under 10 CFR Part 55 while under the influence of alcohol. "Under the influence" is defined in 10 CFR 55.53(j) to mean that the "licensee exceeded, as evidenced by a confirmed positive test, the lower of the cutoff levels for drugs or alcohol contained in 10 CFR Part 26, Appendix A, of this chapter, or as established by the facility licensee."

Contrary to the above, on December 3, 1991, the licensee violated 10 CFR 55.53(j) as evidenced by the following: the licensee performed licensed duties on December 3, 1991, immediately before the submission to a breathalizer test allowed by a second breathalizer test and a blood confirmatory test which indicated that the licensee was under the influence of alcohol in that the cutoff level of 0.04 percent blood alcohol concentration was exceeded.

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## Mr. William F. Olsen

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## This is a Severity Level III violation (Supplement I).

The purpose of the Commission's Fitness-for-Duty requirements is to provide reasonable assurance that nuclear power plant personnel work in an environment that is free of drugs and alcohol and the effects of the use of these substances. The abuse of alcohol is a serious matter which undermines the special trust and confidence placed in you as a licensed operator. This violation is categorized as a Severity Level III violation in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, because the abuse of alcohol by licensed operators is a significant regulatory concern. Because your license has expired, you are not required to respond to the Notice of Violation, a response is required within 30 days of the date of this letter addressing the specific basis for disputing the violation. This response should be sent to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406-1415 and marked, "Open by Addressee Only."

The purpose of this letter is to make clear to you the consequences of your violation of NRC requirements governing fitness-for-duty as a licensed operator, in accordance with 10 CFR Part 55. If you reapply for an operating license, you will need to satisfy not only the requirements of 10 CFR 55.31, but also those of 10 CFR 2.201, by addressing the reasons for the violation and the actions you have taken to prevent recurrence in order to ensure your ability and willingness to carry out the special trust and confidence placed in you as a licensed operator and to abide by all fitness-for-duty and other license requirements and conditions.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, enforcement actions are placed in the NRC Public Document Room (PDR). A copy of this letter without its enclosures and with your address removed will be placed in the PDR unless you provide a sufficient basis to withdraw this violation within the 30 days specified above for a response to this Notice of Violation.

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USNRC REGION 1 - OFFICE REG. ADM.

Mr. William F. Olsen

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Should you have any questions concerning this action, please contact Mr. Lee Bettenhausen, of my staff. Mr. Bettenhausen can be reached at either the address listed above or telephone number (215) 337-5291.

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Sincerely,

Marin W. Hooges

Marvin W. Hodges, Director Division of Reactor Safety

Enclosures (w/original letter only)

- 1. BECo letter, December 4, 1991
- 2. BECo letter, December 5, 1991
- Synopsis, NRC Office of Investigation Report 1-92-002

cc w/o enclosures: Boston Edison Company



UNITED STATES NUCLEAR REGULATORY COM MISSION REGION 1 475 ALLENDALE ROAD

KING OF PRUSSIA, PENNSYLVAL IA 19406 1415

APR 1 6 1993

Docket No. 030-29567 License No. 20-27908-01 EA 93-005

Mr. Paul Rosenbaum, President Cameo Diagnostic Centre, Inc. 155 Maple Street Springfield, Massachusetts 01105

# RETURN TO DE FILES

Dear Mr. Rosenbaum:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$1,750 (NRC Inspection Report No. 030-29567/92-001)

This letter refers to the NRC inspection conducted on December 29, 1992, at Cameo Diagnostic Centre, Springfield, Massachusetts, of activities authorized by NRC License No. 20-27908-01. The inspection report was sent to you on January 28, 1993. During the inspection, apparent violations of NRC requirements were identified. On February 18, 1993, a transcribed enforcement conference was conducted with you and other members of your staff to discuss the apparent violations, their causes and your corrective actions. The Enforcement Conference Report was sent to you under separate cover on March 10, 1993.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The first two violations, which are set forth in Section I of the enclosed Notice, involved (1) the willful use of NRC licensed material at a new location for approximately one month between November and December 1992, even though you were not authorized by your license to use licensed material at that location; and (2) the willful failure to inform the NRC of such use, even though you repeatedly were informed, in telephone conversations with the NRC on November 12, 19, and 25, 1992, as well as in an NRC letter dated November 13, 1992, that such use at the new location was prohibited without a license amendment or license renewal authorizing work at the new location.

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Notwithstanding this prior notice, you continued using NRC regulated material at the unauthorized location and did not inform the NRC of such use, either during those telephone conversations, or afterwards, until the NRC independently learned, on December 11, 1992, that such use had been occurring at your new location since early November 1992. Your NRC license allowing use of radioactive material is a privilege granted to you under the provisions of the Atomic Energy Act, and the NRC expects and requires your continued compliance with all applicable regulatory requirements. Your actions in this case undermined the trust bestowed upon you in the NRC licensing process to protect public health and safety. In this case, you violated that privilege and trust. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, these violations are classified in the aggregate as a Severity Level III problem.

To emphasize the significance of willful violations of NRC requirements and the need for providing complete and accurate information to the NRC, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,750 for the violations set forth in Section I of the enclosed Notice.

The base civil penalty amount for a Severity Level III problem is \$500. The escalation and mitigation factors set forth in the enforcement policy were considered and the base civil penalty was increased by 250% to \$1,750. The penalty was escalated 50% based on the NRC identification of the violations; escalated 100% based on the existence of prior notice, as described above; and escalated 100% based on the duration of the violations. Your corrective action was not judged to be timely or self-initiated, and therefore, mitigation based on this factor is not appropriate. Mitigation based on licensee performance is not appropriate because the violations were willful.

The remaining violations are described in Section II of the enclosed Notice. The violations include: (1) the failure to ensure, through the Radiation Safety Officer (RSO), that radiation safety activities are performed in accordance with the approved procedures and regulatory requirements; (2) failure to develop and implement a written program to keep doses as low as reasonably achievable (ALARA); (3) failure to properly calibrate the survey meters; (4) failure to maintain proper dose calibrator calibration records; (5) failures related to required survey procedures; and (6) failure to include the range down to 10 microcuries in the dose calibrator linearity test.

Collectively, the remaining violations (Section II of the Notice) represent a lack of management attention toward licensed responsibilities. It is particularly troublesome to NRC that the RSO did not clearly understand or implement his responsibilities under the terms of your license, in that he failed to ensure that radiation safety activities were performed in accordance with approved procedures and regulatory requirements. These violations indicate a need for increased management oversight of the radiation safety program, attention to detail by individuals using licensed material, and surveillance through comprehensive audits. Any similar problem in the future may result in escalated enforcement action.

The NRC recognizes that corrective actions, as mandated by the amended license conditions, and as described at the enforcement conference, have been taken to ensure that appropriate attention is provided to the radiation safety program to preclude the recurrence of such violations in the future. These actions included: (1) replacing the RSO; (2) implementing initial and subsequent periodic audits of the radiation safety program; and (3) providing training to the users of radioactive materials. The NRC also recognizes that you were issued a License Amendment on January 12, 1993, which allowed resumption of licensed activities at the new location, subject to certain conditions, including retraining of the users, and conduct of audits.

During the transcribed enforcement conference, you emphasized that Tc-99m is the only NRClicensed material involved in your program, that it is obtained in unit doses from a local nuclear pharmacy, and that the radiation dose accumulated by your employees is very low. Based on your explanations, Violations II.B., II.C., II.E., and II.F. have been categorized at Severity Level V; however, if these violations recur, they will be considered to be more significant and may be subject to escalated enforcement action. Based in part on your explanations at the enforcement conference, and as further explained below, some apparent violations discussed at the enforcement conference are not being cited.

The failure to post a storage area with the appropriate caution sign is not being cited because it would normally be categorized at Severity Level V and was corrected during the inspection. Upon review of the guidance in Information Notice 93-10, the NRC staff has reconsidered the apparent violation involving failure to retest the dose calibrator upon reinstallation at your new address. Upon review of the guidance in Information Notice 89-74, we have also reconsidered the apparent violation involving failure to wipe test packages of empty, used radiopharmaceutical containers that you returned to the nuclear pharmacy. You should be aware; however, that a contamination survey of such packages is strongly recommended, and that a violation will be issued if contamination levels are found to exceed regulatory limits.

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Although they are not being cited as violations, deficiencies in personnel training, and the knowledge of some authorized users regarding the patient dosage schedule, all of which are documented in the inspection report, should be addressed in the response to this letter, as required below. The NRC staff believes that inadequate training is a root cause of the violations in Section II of the Notice. Also, while the use of a standard patient dosage schedule is allowed under the NRC licensing scheme, all authorized users should clearly be familiar with it.

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You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken with regard to the violations in the enclosed Notice, as well as the deficiencies noted above, and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

the 1/m

Thomas T. Martin Regional Administrator

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalty

cc w/encl: Public Document Room (PDR) Nuclear Safety Information Center (NSIC) Commonwealth of Massachusetts (2)

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#### ENCLOSURE

## NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY

Cameo Diagnostic Centre, Inc. Springfield, Massachusetts 01105 Docket No. 030-29567 License No. 20-27908-01

During an NRC inspection conducted on December 29, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

- I. Violations Assessed a Civil Penalty
  - A. 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, as of November 3, 1992, the licensee changed the address and location at which byproduct material was used from 110 Maple Street, Springfield, Massachusetts to 155 Maple Street, Springfield, Massachusetts, and the licensee did not receive an amendment to authorize the change of location until January 12, 1993.

B. 10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee be complete and accurate in all material respects.

Contrary to the above, the licensee did not provide to the Commission, information that was complete and accurate in all material respects. Specifically, the licensee did not inform the Commission that it had begun using licensed material at its new location (155 Maple Street, Springfield, Massachusetts), even though the licensee was reminded, in telephone conversations with the NRC on November 12, 19, and 25, 1992, and in a letter dated November 13, 1992, that licensed materials could not be used at the new location until a license amendment was obtained. This information was material because, had the correct information been known, it would have resulted in action by the NRC to prohibit licensed activity at the new address until a license amendment had been granted.

These violations represent a Severity Level III problem (Supplements VI and VII).

Civil Penalty - \$1,750.

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## II. Other Violations of NRC Requirements

A. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements. 10 CFR 35.21(b) requires that the Radiation Safety Officer shall establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; the Radiation Safety Officer shall investigate spills; the Radiation Safety Officer shall brief management once each year on the byproduct material program; and the Radiation Safety Officer shall approved to safety with the advice and consent of management.

Contrary to the above, as of December 29, 1992, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with approved procedures and regulatory requirements. Specifically, the Radiation Safety Officer did not establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; the Radiation Safety Officer did not investigate spills that occurred; the Radiation Safety Officer did not brief management once each year on the byproduct material program; and the Radiation Safety Officer did not approve or disapprove minor changes made to the radiation safety program.

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

B. 10 CFR 35.20(a) requires that each licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses ALARA.

Contrary to the above, as of December 29, 1992, the licensee had not developed and implemented a written radiation protection program that includes provisions for keeping doses ALARA.

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

C. 10 CFR 35.92(a) permits a licensee to dispose of byproduct material with a physical half-life of less than 65 days in ordinary trash, provided, in part, that the licensee first holds such byproduct material for decay a minimum of ten half-lives.

Contrary to the above, on May 31, 1988, July 5, 1988, August 29, 1988, December 20, 1990, June 28, 1991, December 6, 1991, and May 29, 1992, the licensee disposed of technetium-99m in ordinary trash without first holding some of this material for decay a minimum of ten half-lives. Specifically, licensee personnel informed the inspectors during the inspection that for all of these dates when the waste material was disposed, some of the waste material had been generated during scans performed during the 60 hours prior to the disposal, and therefore that material was not held for a minimum of 10 half-lives (60 hours for technetium-99m) prior to disposal.

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

D. 10 CFR 35.51(a)(1) and (3) require, in part, that a licensee calibrate the survey instruments used to show compliance with 10 CFR Part 35 on all scales with readings up to 1000 millirem per hour with a radiation source, and that the licensee conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration.

Contrary to the above, as of December 29, 1992, four CDV-700 Geiger-Mueller survey instruments used by the licensee to show compliance with 10 CFR Part 35, had not been calibrated on the lowest scale, which has a maximum reading of 0.5 millirem per hour, and which is the scale most commonly used at the licensee's facility. Furthermore, the apparent exposure rate from a dedicated check source as determined at the time of calibration was not conspicuously noted on the instrument from April 1, 1987 through December 29, 1992.

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

E. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity upon installation and at least quarterly thereafter over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

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Contrary to the above, the licensee's dose calibrator linearity test performed December 1992 did not include the range from 200 microcuries down to 10 microcuries.

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

F. 10 CFR 35.50(e), 35.50(e)(2), 35.50(e)(3) and 35.50(e)(4) require, in part, that a licensee retain records of tests for dose calibrator constancy, accuracy, linearity, and geometrical dependence, and that the records of tests for accuracy, linearity, and geometrical dependence include the signature of the Radiation Safety Officer.

Contrary to the above, as of December 29, 1992: (1) the licensee maintained records of only one check of dose calibrator constancy for each week of use, even though this test is required to be performed on a daily basis; and (2) the licensee's records of the accuracy, linearity, and geometrical dependence tests of its dose calibrator did not include the signature of the Radiation Safety Officer (RSO) nor did the RSO review these records.

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

G. Condition 14 of Amendment 3 of License No. 20-27908-01 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated October 8, 1986, and a letter dated November 20, 1986. Item 7 of the letter dated November 20, 1986, requires that area surveys be performed after each procedure. Item 17 of the application dated October 8, 1986, requires that area surveys include dispensing, preparation, injection, and imaging areas.

Contrary to the above, as of December 29, 1992, the licensee did not perform an area survey of dispensing, preparation, and imaging areas after each procedure. Specifically, the licensee performed surveys of only the injection area after each procedure.

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

Pursuant to the provisions of 10 CFR 2.201, Cameo Diagnostics Centre, Inc. (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice

hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (...) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licence may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuckar Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

Dated at King of Prussia, Pennsylvania this // day of April 1993.