

DCS

CAMEO DIAGNOSTIC CENTRE, INC.

SPECIALIZED MEDICAL IMAGING AND MEASUREMENTS

155 MAPLE STREET / SPRINGFIELD, MA 01105

(413) 788-7000

July 23, 1993

Director, Office of Enforcement  
U.S. Nuclear Regulatory Commission  
Washington, D. C. 20555

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

Subject: Answer to a "Notice of Violation and  
Proposed Imposition of Civil Penalty  
\$1750" dated April 16, 1993

Dear Sir,

Nearly three months ago a request was made for ten documents dealing with herein matter. To date none has been provided. Thus it is with one hand tied behind his back that licensee responds to the phone call by J. DelMedico and your letter of June 25, 1993 and the April 16, 1993 "Notice of Violation And Proposed Imposition Of Civil Penalty". In the event that there appears to be a discrepancy between statements to be made hereunder and those made at the Feb. 18, 1993 Enforcement Conference it is because NRC has refused to furnish at least a copy of the transcribed testimony, an absolute fundamental defense document.

In its Notice of Violation and Proposed Imposition of Civil Penalty, NRC sets forth as "Violations Assesed a Civil Penalty" Items I, A and B, and claims these violations represent Severity Level III problems in appendix C of 10 CFR Part 2, supplements VI and VII. Such claims are incorrect. The fine and penalty should never have been imposed and most certainly ought to be declared nullified; as should the statement that "the violations were willful". Such statement and other similar allegations reek with personal animus.

According to NRC's 10 CFR Part 2 appendix C, Supplement VI provides examples of violations in each of five severity levels as guidance in determining the appropriate severity level for violations. Under C, Severity Level III, paragraph 10 states "A failure to receive required NRC approval prior to the implementation of a change in licensed activities THAT HAS RADIOLOGICAL OR PROGRAMMATIC SIGNIFICANCE ---- and a CHANGE IN THE LOCATION WHERE LICENSED ACTIVITIES ARE BEING CONDUCTED ----" (emphasis added).

From the very beginning of this action, this licensee has always maintained that public health and safety was never an issue. NRC has never challenged this assertion. Indeed had public health and safety been an issue to the slightest possible degree, then NRC should have immediately issued an immediate cease and desist order. That NRC did not do so confirms the assessment that the change in location where licensed activities were conducted did not have radiological sig-

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nificance, and therefore the change in location from 110 to 155 Maple Street is not a Severity Level III violation. Accordingly, Violation I. A. as Severity Level III violation is denied for reasons as stated.

Also denied is Violation I.B. as Severity Level III violation. The basis for denial is that it does not comport with the facts as presented at the Feb. 18, 1993 Enforcement Conference. Testimony and documentary evidence were presented to prove that licensee was forthright and candid with NRC. Consider the following: How did NRC become aware that Cameo Diagnostic Centre (CDC) was newly located? Answer is because NRC was informed on Oct. 21, 1992 that CDC was going to move and again on Nov. 10, 1992 that CDC did move. NRC states that its staff had the understanding that NRC licensed materials were not being used at the new location; that a close-out survey at the old location had to be submitted; that CDC was deliberately flaunting NRC possession regulations. It is not unreasonable to believe that the refusal of NRC to release the ten documents requested almost three months ago is intended to deny CDC's president the opportunity to refute these and other pejorative statements about his actions during the period Nov. 10, 1992 through Jan. 21, 1993.

Under "II Other Violations of NRC Requirements", the following responses are submitted:

A. In admitting this violation, licensee proposes that it is NRC itself that is at fault for creating this problem. In its procedures for licensing physicians to use by-product material in humans, NRC makes the assumption that any physician with certain specified training is thereby qualified to become an authorized user as well as a radiation safety officer. NRC is negligent in not requiring its own competency examinations. For a physician to become competent in diagnosing coal miners pneumoconiosis (black lung disease) he or she must pass a competency exam. In the case against CDC, NRC was negligent in not requiring proof of competency when it approved the credentials of CDC's former RSO. Nevertheless NRC is already aware a new RSO has accepted total responsibility to assure compliance with all NRC requirements. Further, diligence by CDC management is being exercised to assure compliance.

B. Violation is admitted. A written radiation protection program, including provisions for keeping doses ALARA has been developed, implemented and is now in full compliance.

C. Violation is denied. The inspection team made the assumption that radioactive waste discarded on days other than a Monday, ipso facto, had to contain waste that was less than 60 hours old and therefore in violation. That is pure bunk - a fiction and not supported by any facts or evidence.

D. Violation is denied. The inspection team made the assumption that the lowest scale on the survey meter, which had admittedly not been calibrated, was the scale most commonly used at CDC. This was also not true, a fiction not supported by facts or evidence. After all, there were four meters present at the inspection. Who was to say which of the meters were used most commonly on which scale? On the subject of meters, in the meeting with P. Henderson and S. Shankman on Oct. 21, 1992, the statement was made that the NRC requirement for a 1000 mr/hr survey meter would be waived but that Headquarters approval would be needed to allow 50 mr/hr meters if 100 mr/hr meters were not available. This example of flexibility in administering the rules of NRC was in fact the basis of licensee's belief that NRC was flexible in requiring a fee for filing an amendment for address change. Regrettably, the entire EA 93-005 episode, sad and costly as it has been and will be, is due to an NRC representative bending 10 CFR 35.51 and the assumption that flowed from that example of regulatory flexibility.

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E. Violation is admitted. Full compliance has been achieved and is in effect.

F. Violation is admitted. Full compliance has been achieved and is in effect.

G. Violation is denied. The inspection team made the statement "the licensee did not perform an area survey of dispensing, preparation and imaging areas after each procedure". What did "each procedure" mean? An imaging procedure? The statement is too vague and without substantive meaning.

Based on all the above information presented under oath, under pains and penalties of perjury, the licensee hereby protests the civil penalty in whole; and requests remission of the penalty.

July 23, 1993  
Date

Paul J. Rosenbaum  
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