

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION I
631 PARK AVENUE
KING OF PRUSSIA, PENNSYLVANIA 19406

1 6 MAR 1981

Docket Nos. 30-11643 30-12125

Micromedic Systems, Inc. ATTN: T. Frank Decker Director of Manufacturing 102 Witmer Road Horsham, Pennsylvania 19044

Gentlemen:

Subject: Inspection 81-01

This refers to the routine safety inspection conducted by Mr. c. Davis of this office on January 30, 1981 of activities authorized by NRC License Mos. 37-16707-01 and 37-16707-02G and to the discussions of our findings held by Mr. Davis with yourself and Dr. S. Mastin of your staff at the conclusion of the inspection.

The inspection was an examination of activities conducted under your licenses as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of your licenses. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, measurements made by the inspector, and observations by the inspector.

Our inspector also verified the steps you have taken to correct the item of noncompliance brought to your attention in the enclosure to our letter dated April 18, 1978. With regard to this item, the results of this inspection indicate it has not been fully corrected.

In addition, our inspector took smear samples in your preparation and storage areas which were analyzed in our Regional Office Laboratory in King of Prussia, Pennsylvania. The basic purpose of these independent measurements is to verify your capability for analyzing removable contamination in your preparation and storage areas. The results of our analyses were in agreement with your results and indicate levels were below minimum detectable activities.

Based on the results of this inspection, it appears that certain of your activities were not conducted in full compliance with NRC requirements as set forth in the Notice of Violation, enclosed herewith as Appendix A. These items of noncompliance have been categorized into the levels described in the Federal Register Notice (45 FR 66754) dated October 7, 1980. You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A. In addition to the need for corrective action

regarding these specific items of noncompliance, we are concerned about the implementation of your management control systems that permitted them to occur. Consequently, in your reply you should describe, in particular, those actions taken or planned to improve the effectiveness of your management control systems.

Item A in the Notice of Violation enclosed with this letter was identified during a previous inspection of your licensed activities on March 31, 1978 and described in the enclosure to our letter dated April 18, 1978. Your letter to this office dated May 4, 1978 stated that you had purchased the necessary monitoring equipment, had made appropriate measurements and that the evaluation of these measurement indicated that the average yearly concentration in effluent discharged from your facility was below the value specified in 10 CFR 20, Appendix B, Table II. From our January 30, 1981 inspection it appears that the stated corrective actions were not effective since this item has not been fully corrected.

Recurrent and incorrected items of noncompliance are given additional weight in the consideration and selection of appropriate enforcement action. Therefore, in your response to this letter, you should give particular attention to those actions taken or planned to ensure that identified items of noncompliance will be completely corrected and will not recur.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room.

Should you have an questions concerning this inspection, we will be pleased to discuss them with you.

Sincerely,

James H Lyner

James H. Joyner, Chief, Technical Inspection Branch, Division of

Engineering and Technical Inspection

Enclosure: Appendix A, Notice of Violation