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# THE CLEVELAND CLINIC FOUNDATION

One Clinic Center 9500 Euclid Avenue Cleveland, Ohio 44195-5108

A National Referral Center An International Health Resource

Office of Quality Management / H18  
216/444-2100

September 28, 1990

Ms. Evelyn R. Matson  
Radiation Specialist  
U.S. Nuclear Regulatory Commission  
Region III  
799 Roosevelt Road  
Glen Ellen, IL. 60137

Dear Ms. Matson:

Apparently there is some confusion about our written action plan that we agreed to deliver to the Region III Nuclear Regulatory Commission after our visit last spring. I sent a letter with the details of our written action plan to Dr. Mallett on June 25, 1990. I trust he received that letter, but I am enclosing a second copy to document our response. I hope this is sufficient with respect to your request.

Sincerely,

*Thomas Keys*

Thomas F. Keys, M.D.  
Director, Office of Quality Management

TFK:jrh  
encl.

cc: Steven J. Aron, Jr., Ph.D.  
Radiation Safety

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# THE CLEVELAND CLINIC FOUNDATION

One Clinic Center 9500 Euclid Avenue Cleveland, Ohio 44195-5108

A National Referral Center An International Health Resource

Office of Quality Management / H18  
216/444-2160

June 25, 1990

Bruce S. Mallett, Ph.D.  
Chief Nuclear Material Safety Branch  
Nuclear Regulatory Commission  
Region 3  
799 Roosevelt Road  
Glen Allen, IL. 60137

Dear Dr. Mallett:

As I promised during our recent visit to the Nuclear Regulatory Commission on May 2, 1990, here is an action plan for the quality assurance program of the Department of Radiation Therapy, that has been approved by the Office of Quality Management.

1. All reporting requirements of the Nuclear Regulatory Commission will be initially submitted to the Radiation Safety Officer for review and action prior to being forwarded to the Department of Radiation Therapy.
2. Calibration certificates for radiation therapy survey meters will be maintained and updated by the Radiation Safety Officer.
3. Regular meetings will occur with the Chairman and the Administrator of the Department of Radiation Therapy and the Radiation Safety Officer.
4. When an emergency or urgent condition arises, direct communication will occur between the Chairman of the Department of Radiation Therapy and the Radiation Safety Officer. If the department chairman is not available, communication will occur with the administrator, the chief physicist, or the floor supervisor.

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If the Radiation Safety Officer is not available, communication will occur both to the Radiation Safety Office and to the Chairman or Vice-Chairman of the Radioisotope and Radiation Safety Committee.

5. In order to prevent "misadministration" the following procedure has been instituted:
  - a. All charts which have a change in prescription are "flagged".
  - b. No chart will leave dosimetry unless released personally by the dosimetrist assigned to the case.
  - c. Records of all patients treated on the cobalt machine will be countersigned by either a physician, physicist, administrator or floor supervisor on a day-to-day basis before the patient can be treated.
  - d. Prior to each treatment, the technologist staff will review the prescription page to make sure that a prescription has not been changed without being flagged.
6. To assure that timely reporting of "misadministration" occurs, the following actions will take place:
  - a. Any suspected or potential incident of misadministration, will be reported immediately by radiation therapy personnel to the Chairman of the Department of Radiation Therapy. If the Chairman is unavailable, it will be reported to the administrator, chief physicist or floor supervisor. Any of these four people has the authority to report a possible misadministration to the Radiation Safety Officer.
  - b. The Radiation Safety Officer will contact the NRC within 24 hours of the incident. If the Radiation Safety Officer is not available, a message will be sent to the Radiation Safety Office and the Chairman or Vice-Chairman of the Radioisotope and Radiation Safety Committee will be immediately contacted, who will report to the NRC within the 24 hour requirement. If this is not possible, the Radiation Therapy Department Chairman or his designee will directly communicate information to the NRC within the 24 hour requirement.

- c. The Radiation Safety Officer will conduct an annual in-service program reviewing the reporting requirements and other appropriate concerns regarding radiation safety for the Radiation Safety Department.
7. Finally, the entire quality assurance program of the Department of Radiation Therapy will be reviewed semiannually by the Office of Quality Management.

Sincerely yours,

*Thomas Keys*

Thomas F. Keys, M.D.  
Director, Office of Quality Management

TK:jrh

cc: Steven Aren, Jr., Ph.D.  
Raymundo T. Go, M.D.  
Patrick Higgins, Ph.D.  
Floyd D. Loop, M.D.  
Michael Modic, M.D.  
Melvin Tefft, M.D.