REPLY TO NOTICE OF VIOLATION DATED MARCH 3, 1993

Parkview Memorial Hospital
March 30, 1993

Violation: Radiation Safety Officer failed to sign dose calibrator and sealed source inventory records.

For more than 10 years The Radiation Safety Officer has consistently inspected the Nuclear Medicine records on a quarterly basis and initialled and dated these and other records as evidence that he saw and found them valid and complete. On January 28, 1993, the inspectors pointed out that his full signature is required, and at that time the RSO promised to put his full signature on these dose calibrator and inventory records in the future. On February 10, 1993, he put his full signature beside his previous initials on these records for the back 12 quarters. We are in full compliance with the the rule, then, as of February 10, 1993. Meeting the intent of the regulation has, in our view, always been carried out. The RSO's full signature will be used for his regular inspections of the Nuclear Medicine records in the future. The next such inspection is scheduled for April 7, 1993.

Violation: Failure to perform radiation safety surveys of High Dose-Rate Brachytherapy patients.

Parkview has consistently performed radiation safety surveys of Low Dose-Rate Brachytherapy patients, which are the ones hospitalized with temporary tube or seed sources. Parkview had not realized the regulation also applied to HDR patients, and had operated the room much like a cobalt teletherapy room. In the HDR Room, there is an **Area Radiation Monitor**, which has a battery backup power supply, and which is independent of and not connected to the HDR machine. The flashing light it gives is visible on TV from the control panel and alsc to a person who enters into the room. The Area Monitor has been relied upon for warning when the source is out and for assuring that it .s back in its shield. The Monitor has not been subject to giving erroneous warnings; it has functioned faithfully and good attention has been paid to it. A radiation safety survey meter is and has been available at the HDR control for use in any emergency. We do not believe we have caused any risk to patients for not using a survey meter, not only because of the Area Monitor, but also because every application has been with a **closed-end applicator**. The entire applicator has been removed from every patient before he/she leaves the HDR room. Upon receipt of NRC release 92-84, we realized the regulation requires surveys of HDR patients as well as LDR patients and immediatly began doing so. The first HDR patient to be surveyed with the survey meter was on January 12, 1993. Every HDR patient from January 12, 1993 onward, has been surveyed and the survey results have been recorded and initialled. Compliance with the regulation has been from January 12, 1993.

Unresolved Issue 1: The apparent lack of an independent check of the dose calculation associated with the HDR of December 9, 1992.

For gynecological cylinder HDR applications, the physics section had prepared an inventory of treatment plans, which are available to the Radiation Oncologists to choose from for use with a patient. Our independent check consists of having two persons separately make all the detailed calculations to implement the particular distribution specified by the Radiation Oncologist. In the case of the misadministration, the radiation distribution requested by the Oncologist was slightly different from any in the inventory, so that a standard distribution had to be modified. Thus it happened that the two persons who were to be doing independent computations were in fact collaborating on the plan. Also a third person was involved for part of the calculations. When a error in determining the location of the first position in the source-train was made by one of the two, the second person assented to it. During each step of the planning two and sometimes three persons were involved, so it is not quite the same as if one person had done all the planning alone. Changes in procedure have been made as of January 11, 1993, to enable each of the two physics persons to separately calculate where to reposition the first source location. This procedure was shown the inspectors on January 28. A copy of **all** the changes in procedure was given the inspectors, and a copy is attached. The procedure specifies that sufficient time will be taken to guarantee that every calculation check is fully independent.

Unresolved Issue 2: Absence of authorized user signatures and/or dates on certain written directives.

It has been common practice in this Radiation Oncology Department to consider the Oncologist's initials equivalent to his signature. Therefore the handwritten directives appeared on several HDR calculation forms followed only by the physician's initials. In every case, the form had previously been dated by a physics person (on the day of the procedure) who was preparing the form for calculation. Then the Oncologist signed (or initialed) the form with the date already on it. The form has been redesigned to provide the Oncologist space to write his written directive, his full signature, and the date. It is the physics person's responsibility to secure these three things before proceeding with the treatment. Full signatures and dates have been required and obtained as of February 1, 1993, which would be the date of our coming into full compliance.

Unresolved Issue 3: Timeliness of the review of patient charts for HDR patients.

The delay from December 9, 1992 to January 6, 1993, in reviewing this patient's dosage is entirely too long and did not conform to the understanding held in the physics section, namely that these would be reviewed within a week. This was not a written policy, however. The dosimetrist delayed reviewing this case because she thought it might take extra time or effort and she wanted to do it when there would be no interuptions. The changes in policy, previously referred to, puts down on paper that these charts will be reviewed within one week. This was made policy January 7, 1993.

Area of Concern: A cotton ball contaminated with radioactive material was found in the bathroom in the Nuclear Medicine Department.

The Nuclear Medicine Department immediately included the patient restroom in the existing departmental monitoring program (1/28/93). Area surveys are performed daily of the patient toilet area and lavatory. Additionally, the soiled trash is also monitored for radiation levels prior to disposal. No trash above background will be released into the normal trash.

PROCEDURE CHANGE - HDR GYN

At a meeting of the physics group [all 5 members] on 1/6/93, the following changes were adopted for implementation. These changes are intended to make calculations more simple and prevent errors.

The HDR calculation procedures and the data notebook were reviewed to identify areas of improvement, as follows:

1. The diagram showing the source and dummy seed positions will be re-done: The source position numbers will be eliminated, so that positions will be designated by seed locations and mm distances only. The diagram will be updated as necessary for each new source (e.g. 1st source position, currently 993mm, depends on source installation). The diagram for GYN use will be oriented so the tip is toward the top of the page. *(Done 1/8/93)*

2. A procedure will be written up showing how to reposition the starting point for GYN cylinders. *(Done 1/8/93)* The procedure will be explained to everyone in the physics department and a copy kept in the calculation data notebook. *(Done 1/11/93)*

3. When a Radiation Oncologist requests an HDR GYN procedure that is different from any of our inventory of distributions, the dosimetry should be pre-planned in advance of the actual procedure date, whenever possible. This would eliminate the need for decisions to be made in an adverse environment while the patient waits "on the table".

4. Otherwise, for a non-routine HDR application, the physics staff will take sufficient time to perform and review all dosimetry data before the treatment is given. This could well mean leaving the patient area and making the computations in the relative calm of an office. As always, two independent calculations/checks will be required. The patient could be waiting "on the table" easily one half hour, or longer, before treatment.

5. Upon receiving a request for an unusual or non-routine procedure or dosimetry problem from a Radiation Oncologist, every member of the physics staff will bring it to discussion among the entire physics staff. (This has wider meaning than just HDR's.)

6. Computer dosimetry for incidental bladder/rectal doses, etc. for HDR procedures will be completed within one week of the treatment date.

7. A system of transparency overlays for GYN cylinders will be developed. They will be of the standard magnification of our simulator radiographs. *(Done 1/8/93)*

Recorded by Janet Hodge, Senior Dosimetrist

Reviewed by John Agnew, Ph.D., Senior Physicist 1/7/93