Maine Radiation Control Program
Policy 95-01 Guidance on Required Elements of a Written Directive

MEMORANDUM

TO: All Medical Licensees

FROM: Maine Radiation Control Program

SUBJECT: Quality Management Program

In accordance with Maine regulations, adopted January 1, 1994, a Quality Management Program, QMP, is required by all medical licensees that are licensed for teletherapy, gamma stereotactic radiosurgery, brachytherapy, or administration of greater than 30 microcuries of I-125 or I-131 or any therapeutic administration of a radiopharmaceutical.

This program ***must*** be in place and a copy of it sent to the Division of Health Engineering, Radiation Control Program by ***January 27, 1995***. The QMP must be approved by this Program. You may alternatively make reference to the QMP submitted to the NRC in January of 1992 if there are no changes, and the program is presently implemented as submitted.

The QMP, as outlined by G.9 of the State of Maine Rules Relating to Radiation Protection, must include written policies and procedures to meet specific objectives as defined by the Rules.

The following information notice is being issued to assist licensees and does not constitute new regulations.

If you have any questions or comments regarding this information notice, please contact Robert J. Schell, Acting Manager, Radiation Control Program, at (207) 287-5676.

INFORMATION NOTICE 95-01

TO: All Medical Licensees

FROM: Robert J. Schell, Acting Manager, Maine Radiation Control Program

SUBJECT: Guidance on Required Elements of a Written Directive as Defined in ***Part G.2***

This information notice provides guidance on a number of issues regarding the required elements of written directives defined in Part G.2. The following questions are addressed: (1) Is there a specific format the authorized user must follow when preparing a written directive for brachytherapy other than HDR (“all other brachytherapy”)? (2) What are the

Maine Radiation Control Program's expectations for "total source strength," as it is used in the definition of written directive, G.2.R (6) for all other brachytherapy? (3) May the authorized user specify, in the written directive, a range of doses or dosages for a specific patient? (4) May the authorized user specify a range of dates for the overall treatment period? (5) When an authorized user initials a written directive, is the requirement to sign a written directive satisfied? and (6) Must the authorized user date the written directive at the time of the signing, or may a predated written directive be signed?

1. **Format of a Brachytherapy Written Directive:**
A written directive for all brachytherapy, other than HDR, as described in Part G.2.R and subparagraph (6) of that definition, "written directive," is "an order, in writing for a specific patient, dated and signed by an authorized user containing the following information:
(a) Prior to implantation: the radioisotope, number of sources, and source strengths; and
(b) After implantation, but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose)."

Some authorized users do not prepare written directives for manual brachytherapy strictly as described in Part G.2. Such licensees prepare a "treatment plan" (which contains the information described in Part G.2.R.(6)(a)) and serves as part (a), and, subsequently, prepare another document containing the information specified in part (b) of the definition of written directive in G.2. In these cases, part (b) is signed and dated by the authorized user either prior to implantation or after implantation, but prior to completion of the treatment. Part (a) is usually not signed. The two documents may, or may not, be on the same form.

Licensees may use a "treatment plan" as part (a) provided it contains the required elements. Such a written directive would be prepared in two steps, once prior to implantation and the second after implantation, therefore, parts (a) and (b) must each be signed and dated by an authorized user. There is no requirement that parts (a) and (b) be contained on the same or separate forms.

2. **Total Source of Strength:**
The definition of written directive, specified in Part G.2.R.(6)(b), "for all other brachytherapy" requires, in part, that, after implantation, but before completion of the procedure, "the total source strength and exposure time (or equivalently, the total dose)" be specified. It is common practice to use nominal source strength when describing the activity of the sources when planning a therapy procedure. However, since the actual source strength is required to accurately determine the total dose, licensees must use the actual source strength and exposure time if the total dose is not specified.

3. **Use of Range of Doses:**
Some licensees prescribe a range of doses or dosages when preparing written directives, especially for therapeutic use of I-131 sodium iodide or for manual brachytherapy.

Historically, Radiation Control Program (RCP) inspectors have not cited licensees for the use of prescribed ranges because prescribing a range of doses or dosages was not a violation of any RCP requirement, and was the standard of practice. However, the "Quality Management Program and Misadministrations" rule (QM rule), which becomes effective on January 27, 1995, requires that byproduct material be administered as directed by an authorized user. If a range is used on a written directive, the responsibility for determining the exact dose or dosage for the administration falls on the individual administering the treatment, who is frequently not the authorized user. Therefore, although a range of doses or dosages may be clinically acceptable for a given treatment, a single value must be specified on the written directive. If the authorized user makes a decision to revise that dose or dosage, the written directive must be modified in accordance with Part G.9, footnote 1.

4. **Overall Treatment Period:**
A question has been raised as to whether a range is acceptable for the "overall treatment period" (e.g., eight to 10 weeks) on a written directive for teletherapy administrations. In the Statement of Consideration for this provision, the Nuclear Regulatory Commission stated that: "the phrase 'overall treatment period' was added to emphasize that the treatments will end after the specified number of weeks, unless the treatment period is revised by the authorized user prior to continuing."

The overall treatment period may have to be adjusted due to a patient's adverse reactions, a missed appointment by the patient, or other reasons. However, it is necessary to include the overall treatment period on the written directive to ensure that treatments are not administered more or less often, discontinued, or extended over a longer period of time than intended, without the involvement of the authorized user. Therefore, a range is not acceptable for the overall treatment period.

5. **Signature:**
Section G.2.R and G.9 requires that a written directive, signed and dated by an authorized user, be prepared prior to administration of certain specific applications of byproduct material. The staff believes the common practice of physician authorized users to initial, rather than sign, the written directive meets this requirement.

6. **Dating:**
The authorized user must date the written directive at the time of signature. This date attests to when the written directive was signed, and not to when the treatment is to be administered.