

## TABLE 64-23 V

### QUALITY MANAGEMENT PROGRAM

a. In addition to the definitions in Subdivision 7.12.b., the following definitions are applicable to a quality management program:

1. Misadministration - the administration of an external beam radiation therapy dose:

A. Involving the wrong patient, wrong treatment modality, or wrong treatment site; or,

B. When the treatment consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten (10) percent of the total prescribed dose; or

C. When the calculated weekly administered dose differs from the weekly prescribed dose by more than thirty (30) percent; or

D. When the calculated total administered dose differs from the total prescribed dose by more than twenty (20) percent of the total prescribed dose;

2. Prescribed dose - the total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic radiation machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique;

3. Recordable event - the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by fifteen (15) percent or more from the weekly prescribed dose;

4. Written directive - an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site and overall treatment period.

b. Scope and Applicability. Each applicant or registrant subject to Subdivision 7.12.f. or 7.12.g. shall establish and maintain a written quality management program to provide high confidence that radiation will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

1. Prior to administration, a written directive is prepared for any external beam radiation therapy dose;

A. Notwithstanding Subparagraph b.i., a written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose;

B. Notwithstanding Subparagraph b.i, if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by an authorized user within forty eight (48) hours of the oral revision;

C. Notwithstanding Subparagraph b.i., if, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive shall be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared and signed by an authorized user within twenty four (24) hours of the oral directive.

2. Prior to the administration of each course of radiation treatments, the patient's identity is verified, by more than one method, as the individual named in the written directive;
3. External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives;
4. Each administration is in accordance with the written directive; and
5. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

**c. Development of Quality Management Program.**

**1. Each application for registration subject to Subdivisions 7.12.f. or 7.12.g. shall include a quality management program that specifies staff, duties and responsibilities, and equipment and procedures as part of the application required by Section 5. of this rule. The registrant shall implement the program upon issuance of a registration by the agency;**

**2. Each existing registrant subject to Subdivisions 7.12.g. or 7.12.h. shall, within thirty (30) days of July 1, 2001, submit to the agency a written certification that a quality management program has been implemented.**

d. As a part of the quality management program, the registrant shall:

1. Develop procedures for, and conduct a review of, the quality management program including, since the last review, an evaluation of a representative sample of patient administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program;
2. Conduct these reviews at intervals not to exceed twelve (12) months;
3. Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the requirements of Subsection b.; and
4. Maintain records of each review, including the evaluations and findings of the review, in an auditable form, for three (3) years.

e. The registrant shall evaluate and respond, within thirty (30) days after discovery of the recordable event, to each recordable event by:

1. Assembling the relevant facts including the cause;
2. Identifying what, if any, corrective action is required to prevent recurrence; and
3. Retaining a record, in an auditable form, for three (3) years, of the relevant facts and what corrective action, if any, was taken.

f. The registrant shall retain:

1. Each written directive; and
2. A record of each administered radiation dose, in an auditable form, for three (3) years after the date of administration.

g. The registrant may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

h. The registrant shall evaluate each misadministration and shall take the following actions in response to a misadministration:

1. Notify the agency by telephone no later than the next calendar day after discovery of the misadministration;
  2. Submit a written report to the agency within fifteen (15) days after discovery of the misadministration. The written report shall include: the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian (this person will subsequently be referred to as "the patient"), and if not, why not, and if the patient was notified, what information was provided to the patient. The report shall not include the patient's name or other information that could lead to identification of the patient;
  3. Notify the referring physician and also notify the patient of the misadministration no later than twenty four (24) hours after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the patient or that, based on medical judgment, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting with the referring physician. If the referring physician or patient cannot be reached within twenty four (24) hours, the registrant shall notify the patient as soon as possible. The registrant shall not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification;
  4. Retain a record of each misadministration for five (5) years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence; and
  5. If the patient was notified, furnish, within fifteen (15) days after discovery of the misadministration, a written report to the patient by sending either a copy of the report that was submitted to the agency, or a brief description of both the event and the consequences as they may effect the patient, provided a statement is included that the report submitted to the agency can be obtained from the registrant;
- j. Aside from the notification requirement, nothing in Paragraph 7.12.e.8. affects any rights or duties of registrants and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

## **TABLE 64-23 W**

### **ALTERNATIVE QUALITY MANAGEMENT PROGRAM**

a. In addition to the definitions in Subdivision 7.12.b., the following definitions are applicable to a quality management program:

1. Misadministration - the administration of an external beam radiation therapy dose:
  - A. Involving the wrong patient, wrong treatment modality, or wrong treatment site; or,
  - B. When the treatment consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten (10) percent of the total prescribed dose; or
  - C. When the calculated weekly administered dose differs from the weekly prescribed dose by more than thirty (30) percent; or
  - D. When the calculated total administered dose differs from the total prescribed dose by more than twenty (20) percent of the total prescribed dose;

2. Recordable event - the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by fifteen (15) percent or more from the weekly prescribed dose;
  3. Written directive - an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site and overall treatment period.
- b. Each registrant shall establish and maintain a written program to provide assurance that radiation is administered to humans as directed by the authorized user. The program shall include the following elements:
1. Procedure for preparing written directives for the administration of radiation, however, a written directive is not required when an authorized user personally administers a dosage provided the pertinent facts are documented as otherwise required;
  2. Procedure for verifying by more than one method the identity of the individual to be administered radiation;
  3. Procedure for updating the therapy operating and emergency procedures manual;
  4. Procedure for verifying that final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;
  5. Procedures assuring that administration of radiation is carried out as specified in the written directive or the therapy operating and emergency procedures manual;
  6. Procedures for identifying and evaluating unintended deviations from the written directive or the therapy operating and emergency procedures manual including taking appropriate action for recordable events and misadministrations;
- c. Each registrant shall evaluate and respond to misadministrations.
- d. Each registrant shall evaluate and respond to recordable events within thirty (30) days after discovery by assembling the relevant facts, identifying the cause of the recordable event, and taking appropriate action, if any is required, to prevent recurrence.
- e. Each registrant shall conduct an annual evaluation of the human administration program including any recommendations for changes to be made as well as any modifications made since the last evaluation and, if required, revise procedures to assure that the radiation is administered as directed by the authorized user. Modifications made to the program shall not decrease the effectiveness of the program.
- f. Each registrant shall retain, in auditable form, for three (3) years:
1. Each written directive;
  2. A record of each administered radiation dose where a written directive is required;
  3. A record of each annual review of the program including the evaluations and findings of the review;
  4. A record of each recordable event, the relevant facts, and any corrective actions taken