

## APPENDIX Q

### **Quality Management Program (QMP)**

A written directive will be provided prior to administration of the procedures indicated below except where a delay would jeopardize the patient's health.

This facility will perform the following types of procedures:

- Diagnostic nuclear medicine procedures using greater than 30  $\mu\text{Ci}$  (1.11 megabecquerels) of iodine 131 as sodium iodide;
- Therapeutic radiopharmaceutical procedures;
- Brachytherapy procedures;
- High dose rate remote afterloader procedures;
- Gamma stereotactic radiosurgery procedures; and/or
- Teletherapy procedures.

An oral directive will be acceptable if a delay to write a directive would jeopardize the patient's health because of the emergent nature of the patient's condition. The information contained in the oral directive will be immediately documented in the patient's record and a written directive will be prepared and signed by the authorized user within 48 hours.

An oral revision to an existing written directive will be acceptable when a delay to provide a written revision to an existing directive would jeopardize the patient's health. The oral revision will be immediately documented in the patient's record and a revised written directive will be signed by the authorized user within 48 hours of the oral revision.

A written directive that changes an existing written directive can be made for any procedure if the revision is dated and signed by an authorized user prior to the administration of radioactive materials or radiation.

Patients will be identified by more than one method. Prior to the treatment, staff will determine the patient name, the patient date of birth or verify from the hospital identification bracelet the patient's identity.

Final plans of treatment and related calculations, manually or computer generated for brachytherapy, teletherapy, high dose rate remote afterloader and gamma stereotactic radiosurgery will be compared and verified that they agree with the written directive. Verify that any computer-generated calculations are correctly transferred into the consoles of therapeutic medical units. Verifications will be conducted by the therapist on the first day of treatment. The medical physicist will further verify the treatment plans and calculations within three patient treatment days.

If the treatment plan and calculations do not agree with the written directive, the patient will not be treated until the authorized user has been consulted for clarification. If required the written directive will be revised or the treatment plan and calculations will be modified.

Each administration agrees with the written directive.

Any unintended deviation from the written directive is identified, evaluated and appropriate action will be taken at time of discovery.

A review of the QMP will be conducted at intervals not to exceed 12 months. This review and evaluation will include a representative sample of all patient administrations within the review period, all recordable events during the review period and all medical events.

The number of patient cases to be sampled will be based on the principles of statistically accepted sampling and represent each treatment modality performed in the institutions. An error rate or lot tolerance percentage defective of 2%, 5% or 10% per modality will be used. The number of patient cases to be reviewed would follow this table:

Lot Tolerance Percent Defective (Percent Error)		
Lot Size	Sample Size	Acceptance Number
1 to 30	All	0
31 to 50	30	0
51 to 100	37	0
101 to 200	40	0
201 to 300	43	0
301 to 400	44	0
401 to 2,000	45	0
2001 to 100,000	75	1

The review of the quality management program will be maintained for three years for department review.

Copies of the quality management program will be maintained for the duration of the license.