A. Training -

Physicians - must be authorized for brachytherapy on a current New York State Department of Health radioactive materials license; must have specific training in this therapy modality including at a minimum: 40 hours of clinical experience under the supervision of an authorized physician - user; and a course (e.g., one given by the manufacturer's representative) in use of the treatment planning system for the device.

Technicians - must be licensed therapy technicians with specific training in this therapy modality, including a course (e.g., one given by the manufacturer's representative) in use of the treatment planning system for the device if the technician will use the system.

Physicist - should be certified in therapeutic radiological physics by a recognized board; have experience in the uses and dosimetry of this modality; and have attended a course (e.g., one given by the manufacturer's representative) in the use of the treatment planning system for the device.

Submit

1. Documentation of required training and experience for each physician who will be an authorized user for this therapy modality.

2. Documentation of required training and experience for the physicist who will be named on the license for this device

3. A statement that any therapy technician who will use the treatment planning system for the device will have attended a course in its use, such as one given by the manufacturer's representative.

4. Outline of training provided to device operators (all operators other than authorized users must be New York State licensed radiation therapy technologists) along with name and affiliation of instructor conducting the training.

This must include training in emergency source retraction in the event of power or mechanical failure of the apparatus, and participation in "dry-runs" of emergency procedures.
5. State the frequency of training and outline the topics covered, including "dry-runs" of emergency procedures.

B. Describe continuous viewing system for each treatment room

1. Primary
2. Backup if primary system fails, or commit to halting treatments.

C. Describe area security for each treatment room

1. Interlocks on entry, etc.
2. Restricted area(s) controls (e.g., signs, locks, alarms, lights, etc.)
3. If other radiation-producing devices are in the room, means of assuring only one device in operation at a time
4. Means of verifying source "safe" condition (e.g., permanently installed radiation monitor)
5. Confirm that, once tripped, the entry interlock must be reset before activation of device.

D. Operating Procedures - you need not provide a copy of procedures, but you need to supply the following minimum commitments:

1. Have implemented written operating procedures which include a requirement that the patient be under continual observation during each procedure
2. Copies given to appropriate staff
3. Procedures:
   a. Require securing unit, console, room when unattended
   b. Require that only the patient be in room with device activated
   c. Require that only an authorized physician - user or a licensed therapy technologist use the device for treating patients.
4. Daily (or on each day of use) checks will be performed and will include checks of:
   a. Interlocks
4. b. Reproducibility of source positioning within catheter within $\pm 1$ mm (may be done by autoradiography)

c. Verification of source position indicators (e.g., lights, alarms, room monitor)

d. Inspection of guide tubes for kinks and other imperfections

5. Treatment time calculations will be independently verified before treatment is begun.

6. At the time of each treatment for a particular patient the applicator position will be confirmed by radiography or fluoroscopy.

7. The device will be serviced and maintained by qualified personnel in accordance with the manufacturer's schedule.

E. Tests and Calibrations

1. Timer accuracy must be verified monthly and must not result in an error greater than 1% of the prescribed dose. Describe your procedure for determining timer accuracy.

2. The error in dose due to source travel time must be determined initially and semi-annually, and a correction must be used in all instances where an error of more than 1% of the prescribed dose might be introduced. Describe your procedure for determining travel time error.

3. Sources must be calibrated before they are used for treatment. Describe your procedures for calibrating sources that will ensure dose accuracy to within $\pm 5\%$.

F. Emergency Procedures - Submit a copy of emergency procedures, including plans for emergency source retraction in the event of power or mechanical failure of the apparatus, and specify that these procedures will be posted near each place of use. As a minimum, your procedures should include:

1. When the procedures are to be followed;

2. Step-by-step actions and by whom these actions are to be taken;

3. Giving first consideration to minimizing exposure to patient;

4. Requiring securing area, posting warning notice, and;

5. Providing names and on-duty/off-duty telephone numbers of at least two people to be notified.