

APPENDIX P-4

RECORDS OF DOSAGES AND USE OF BRACHYTHERAPY SOURCE

Radioactive Material Licensees who are authorized to use radioactive material for medical purposes must record the use of radioactive material to reflect proper use and accountability. Licensees are required to make and maintain records of each dosage and administration prior to medical use. Paragraphs RH-8403, RH-8707, RH-8713, and RH-8717 of the Rules and Regulation prescribe specific requirements. Records of use must be maintained for 3 years.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	
RH-8630	
RH-8670	Y

The records must include the following:

- Radiopharmaceutical;
- Patient's or human research subject's name or identification number (if one has been assigned) **Note: The Licensee Must Maintain Patient Confidentiality;**
- Prescribed dosage, determined dosage, or a notation that the total activity is less than 30 μCi (1.1 MBq);
- Date and time of dosage determination; and
- Name of the individual who determined the dosage.

Dosage determination for unit dosages for photon-emitting radionuclides shall be made by direct measurement. For other than photon-emitting radionuclides dose determination shall be made by either direct measurement or by a combination of decay correction based on the determination (e.g., measurement) made by the manufacturer or preparer licensed under NRC or equivalent Agreement State requirements.

If molybdenum concentration is measured under RH-8531, records of molybdenum concentration must be made under RH-8713 and must include, for each measured elution of technetium-99m:

- Ratio of the measurements expressed as μCi (kBq) of molybdenum-99 per MBq (mCi) of technetium-99m;
- Date and time of the measurement; and
- Name of the individual who made the measurement. If the licensee uses manual brachytherapy sources, the following records of use must be kept:

- When temporary implant brachytherapy sources are removed from storage, a record will include the number and activity of sources removed, the time and date they were removed from storage, the location of use, and the name of the individual who removed them from storage.
- When temporary implant brachytherapy sources are returned to storage, a record will include the number and activity of sources returned, the time and date they were returned to storage, and the name of the individual who returned them to storage.
- For permanent implants, a record will be made and will include the number and activity of sources removed from storage, the date they were removed from storage, the name of the individual who removed them from storage, the number and activity of sources not implanted, the date they were returned to storage, the name of the individual who returned them to storage, and the number and activity of sources permanently implanted in the patient or human research subject.