APPENDIX I

Records of Radiopharmaceutical Use

RECORDS OF UNIT DOSAGE USE

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Lot number or control number, if assigned;
5. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
6. Molybdenum-99 concentration (if applicable);
7. Date of administration or disposal;
8. If administered,
    - Prescribed dosage;
    - Measured activity in millicuries or microcuries and date and time of measurement;
    - Patient name and identification number if one has been assigned; and
    - Initials of the individual who assayed and administered the dose.
9. If discarded, the date and method of disposal; and
10. Initials of the individual who made the record.

RECORDS OF MULTIDOSE VIAL USE

For each multidose vial received from a supplier or prepared in-house, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt or preparation;
4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml);
5. Molybdenum-99 concentration (if applicable);

6. If administered,

    - Prescribed dosage;
    - Date and time dosage was drawn and measured;
    - Calculated volume that is needed for the prescribed dosage;
    - Measured activity in millicuries or microcuries; and
    - Patient name and identification number if one has been assigned.
    - Initials of the individual who assayed and administered the dose.

7. If discarded, the method of disposal and date; and

8. Initials of the individual who made the record.

RECORDS OF MOLYBDENUM-99 GENERATOR USE

The regulations require that each licensee who uses a technetium generator to prepare radiopharmaceuticals must test each elution or extraction for its molybdenum concentration. This measurement is usually made with a dose calibrator. Licensees may not administer radiopharmaceuticals that contain more than 0.15 microcurie of Mo-99 per millicurie of Tc-99m at the time of administration. If an elution or extraction has a higher concentration, there may be a manufacturing defect that should be reported.

The procedure for measuring molybdenum concentration is based on the use of a "molybdenum breakthrough pig." The dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons, but only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert from measured Mo-99 to total Mo-99.

Each time a generator is eluted, make a record of the:

1. Date and time of elution;

2. Measured Mo-99 activity in microcuries;

3. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer;

4. Measured Tc-99m activity in millicuries;

5. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and checkmark that the ratio is less than 0.07 microcurie of Mo-99 per millicurie of Tc-99m. If it isn't, stop and notify the Radiation Safety Officer (RSO). The 0.07 action level allows for the quicker decay of the Tc-99m through the day of use. It is assumed that the material will be used within 6 hours, at which time the concentration of Mo-99 to Tc-99m would have doubled.

6. Initials of the person who made the record.