

APPENDIX P
RADIATION SAFETY PROGRAM
AND
OPERATING PROCEDURES

I. Radiation Safety Program

According to the Rules and Regulations, RH-1004, Radioactive Material Licensees are required to “develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities...to insure compliance with the provisions of this Part” (Section 3). According to RH-8300, medical use licensees shall implement and maintain a program that will help insure the protection of the public and licensee personnel who are occupationally exposed to ionizing radiation. As a minimum, the Radiation Safety Program shall include the following elements:

- Description of the organizational structure and the management commitment for ensuring implementation of the Radiation Safety Program (See Item 25)
- Policy statement and requirement to maintain radiation dose ALARA (Appendix A)
- Description of equipment and facilities adequate to protect personnel, the public, and the environment (See Item 16)
- Conduct of licensed medical activities by individuals qualified by training and experience (See Item 10)
- Written operating and emergency procedures (See Items 22 and 23)
- Program to annually review the Radiation Safety program (See Item 25)
- Records management (See Item 24)

II. Operating Procedures

Operating procedures must be developed, implemented, and maintained current. The purpose of operating procedures is to provide Authorized Users and licensee personnel with specific instructions and guidance on how to safely perform all required operations, including radioactive material storage and transportation. **A complete copy of all Radiation Safety Operating Procedures must be submitted to the Department as part of the application.**

This section summarizes operating procedures. Many of these procedures are covered in greater detail in other sections of this document.

- The Licensee must develop, implement, and maintain specific operating procedures which contain the following elements:
 - Steps to take to maintain radiation dose ALARA (see Appendix A)
 - Institutional Radiation Safety Committee operation (as required by RH-8300)
 - Instructions for the appropriate handling and use of radioactive material so that no person is likely to be exposed to a radiation dose in excess of the limits prescribed in the Rules and Regulations
 - Instructions for opening packages containing licensed material (see Appendix L);
 - Using radioactive material, operating therapy treatment devices, and performing routine maintenance on devices containing sealed sources, according to the manufacturer's written recommendations and instructions and in accordance with regulatory requirements (see Sub-Appendices P-2 and P-7).
 - Instructions and methods for conducting area radiation and contamination surveys; instructions for performing operability checks of radiation survey instruments (see Appendix K);
 - Instructions for administering licensed material in accordance with the Written Directives (see Sub-Appendix P-2);
 - Steps to ensure that patient release is in accordance with RH-8420 (see Sub-Appendix P-3);
 - Instructions for calibration of survey and dosage measuring instruments (see Appendix G);
 - Instructions for maintaining accountability of radioactive material during use, transport and storage (see Sub-Appendix P-6).
 - Instructions for maintaining security of radioactive material during use and while in transport and storage (see Appendix N).
 - Periodic spot checks of therapy device units, sources, and treatment facilities (see Item 14.C.);

- Instructions for radioactive waste management (see Appendix M);
- Personnel monitoring and the use of personnel monitoring equipment (see Appendix H).

AND

The licensee must insure the following:

- Make Operating Procedures available to all users (e.g., post the procedures or the location of procedure storage);
- Maintain a current copy of the procedures at each location of use (or, if this is not practicable, post a notice describing the procedures and stating where they may be examined).
- When developing the procedures described above, the licensee is reminded that RH-1004 requires that the licensee use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA.
- When receiving and using radioactive material, the licensee is reminded that they must be licensed to possess the radioactive material and that the radioactive material must be secured (or controlled) and accounted for at all times.
- Sealed sources and unsealed radioactive material used for therapy can deliver significant doses in a short time period. The Rules and Regulation, Paragraphs RH-1303.c, RH-1303.d, RH-1306.a, and RH-1308 describe access control to high and very high radiation areas and the security of radioactive material. Unauthorized access to radioactive material by untrained individuals could lead to a significant radiological hazard. Many licensees achieve access control by permitting only trained individuals to have access to radioactive material (e.g., keys, lock combinations, security badges). Accountability of radioactive material may be ensured by conducting physical inventories, controlling receipt and disposal, and maintaining use records.

III. Additional Procedural Guidance (not covered elsewhere in the Licensing Guide)

The following Table lists additional topics that must be included/incorporated in the Operating Procedures. These topics are not addressed elsewhere in the Licensing Guide. Additional discussion and procedural guidance is provided on each topic, as noted in the Table P-1, Sub-Appendix. The Licensee may incorporate the guidance provided in the Sub-Appendix or may develop and submit equivalent procedures.

Table P-1. Additional Guidance for Topics to be Included in Operating Procedures

Topic	Sub-Appendix
Safe Use of Unsealed Radioactive Material	P-1
Procedures for Administrations When a Written Directive is Required	P-2
Release of Patients or Human Research Subjects	P-3
Records of Dosages and Use of Brachytherapy Source	P-4
Safety Procedures for Treatments when Patients Are Hospitalized	P-5
Sealed Source Inventory	P-6
Installation, Maintenance, Repair, and Inspection Of Therapy Devices containing Sealed Sources	P-7
Minimization of Contamination	P-8
Mobile Medical Service	P-9

The following technical references are provided to assist the Applicant.

- NCRP Report No. 37, “Precautions In The Management of Patients Who Have Received Therapeutic Amounts of Radionuclides”
- NCRP Report No. 105, “Radiation Protection for Medical and Allied Health Personnel”, 1989,
- NCRP Report No. 107, “Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel” 1990,

These references may be obtained from the
National Council on Radiation Protection and Measurements,
7910 Woodmont Avenue,
Suite 800,
Bethesda, MD 20814-3095,

or ordered electronically at <http://www.ncrp.com>.