

(7) The applicant identifies and lists the qualifications of the individual(s) designated as the RSO (Sec. E.42) and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

(8) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the

- (i) Instruments to be used;
- (ii) Methods of performing the analysis; and
- (iii) Pertinent experience of the person who will analyze the wipe samples.

(9) If the applicant intends to perform "in-house" calibrations of survey instruments the applicant must describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in Sec. E.25.

(10) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

(11) The applicant identifies the locations where all records required by this part and other parts of this chapter will be maintained.

(f) Specific Licenses for Irradiators.

(1) The applicant shall satisfy the general requirements specified in Section C.25 and the requirements contained in this part.

(2) The application must describe the training provided to irradiator operators including:

- (i) Classroom training;
- (ii) On-the-job or simulator training;
- (iii) Safety reviews;
- (iv) Means employed by the applicant to test each operator's understanding of these regulations and licensing requirements and the irradiator operating and emergency procedures; and
- (v) Minimum training and experience of personnel who may provide training.

(3) The application must include an outline of the written operating and emergency procedures listed in Section X.53 that describes the radiation safety aspects of the procedures.

(4) The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

(5) The application must include a description of the access control systems required by Section X.23, the radiation monitors required by Section X.29, the method of detecting leaking sources required by Section X.59 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

(6) If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Agency. The description must include the:

- (i) Instruments to be used;
- (ii) Methods of performing the analysis; and
- (iii) Pertinent experience of the individual who analyzes the samples.

(7) If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by an organization specifically authorized by the Agency, an Agreement State or the NRC to load or unload irradiator sources.

(8) The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by Section X.61.

(g) Specific License for a PET License. An application from a medical facility or educational institution to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Part C, equivalent Agreement State requirements, or 10 CFR Part 35 shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under Part C, another Agreement State, or an NRC license with requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in Section C.28(j)(1)(ii).