8.5 ITEM 5: RADIOACTIVE MATERIAL

8.5.1 SEALED SOURCES AND DEVICES

Regulation: 10 CFR 30.32(g), 10 CFR 30.33(a)(2), 10 CFR 32.210, 10 CFR 34.20.

Criteria: Applicants must provide the manufacturer's (or distributor's) name and model number for each requested source assembly (the sealed source and a connector that attaches the source to the control cable), exposure device, and source changer. Licensees will only be authorized for radiographic exposure devices, source assemblies or sealed sources containing byproduct material meeting NRC performance requirements and specifically approved or registered by NRC or an Agreement State. Also, identify any depleted uranium that is used as shielding material (radiographic exposure devices, source changers and some collimators contain depleted uranium).

Discussion: NRC or an Agreement State performs safety evaluations of radiography source assemblies, exposure devices and source changers prior to distribution of these sources/devices to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate issued to the manufacturer (or distributor). Therefore, if the source assemblies, exposure devices, or source changers are approved for use by NRC or an Agreement State agency, the applicant need only note the manufacturer's (or distributor's) name and model number of the sources/devices in its license application to demonstrate that the requirements are met. Manufacturers and distributors of industrial radiography equipment may voluntarily include the items of associated equipment that were used in the industrial radiography system with their sealed sources and devices that are registered. To include associated equipment in the certificate of registration, the manufacturer's or distributor's application must include information that demonstrates the associated equipment meets the minimum criteria in 10 CFR 34.20.

Consult with the proposed supplier to ensure that sources and devices conform to the sealed source and device designations registered with NRC or an Agreement State. For licensees to ensure that they use radiographic equipment in accordance with registration certificates, licensees may want to review the certificate, discuss with the manufacturer, or obtain a copy of the certificate. Licensees may not make modifications to exposure devices, source changers, source assemblies and associated equipment unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

Consult with the manufacturer of the associated equipment (i.e., equipment that is used in conjunction with the exposure device that drives, guides, or comes in contact with the source) to be sure that the associated equipment is compatible with the sources and devices. Licensees must demonstrate that associated equipment meets the performance requirements in 10 CFR 34.20. NRC Regulatory Issue Summary 2005-10, "Performance-Based Approach for Associated Equipment in 10 CFR 34.20," (Appendix F) alerts licensees to distinguish between items of equipment that are considered to be associated equipment and items of equipment that

are not. For example, the portion of the connector that is attached to the end of the control cable is actually a component of the source assembly and is subject to the safety evaluation that must be completed by NRC or an Agreement State before the source assembly may be specifically authorized for use by a licensee. RIS 2005-10 also contains a number of ways that licensees can demonstrate that their associated equipment meets the performance requirements stated in 10 CFR 34.20.