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Appendix C: Review Checklist

MANUFACTURER/DISTRIBUTOR: Scan Technology REGISTRATION #:

MODEL #: Analyzer-5

REFERENCES: Kit Rondeau, Eric Jameson

DESCRIPTION FIRST PAGE	OK/DEF	COMMENTS
Registrant's name and address	OK	
Manufacturer's and distributor's name and address	OK	
Custom user's name and address	NA	
Model number		
Type (from Reg. Guide 10.10 or 10.11)	OK	
User's authority to possess(specific, general, both, exempt)		
Radionuclides, activity (Max w/% error), form, manufacturer, model, NRC registered (note on registration certificate if source is registered as part of the device)	OK	
Leak test frequency no periodic leak test for: krypton-85, tritium, radioactive gas, isotopes with half-lives of 30 days or less, beta- or gamma-emitting material of no more than 3.7 MBq (100 microcuries), or alpha-emitting material of no more than 370 kBq (10 microcuries). Greater than 6 month frequency: use criteria in 10 CFR 32.51(b) or 32.74(b)(1)	OK	supplied
DESCRIPTION/CONSTRUCTION		
If registrant is requesting to register more than one source/device on a certificate, are designs similar enough to do so?	NO	
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	YES	
Assembly methods (screw, welds, etc.); verify integrity		
Source mounting (size and integrity) and security Is source ANSI classification sufficient: Radiography - Unprotected - 43515 Radiography - In Device - 43313 Medical - Radiography - 32312 Medical - γ Teletherapy - 53524	OK	supplied

DESCRIPTION	OK/DEF	COMMENTS
γ Gauges - Unprotected - 43333 γ Gauges - In Device - 43232 β Gauges, Low Energy γ Gauges, or X-ray fluorescence - 33222 Oil Well Logging - 56522 Portable Moist/Density - 43333 Neutron Applications - 43323 γ Irradiators (II, III, IV) - 43424 γ Irradiators (I) - 43323 Static Eliminators - 22222 Smoke Detectors - 32222 (from ANSI N542-1977) Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances	OK	
On-Off indicators (description, qty., location) Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	OK	
Corrosion between unlike materials (aluminum & steel, depleted uranium & steel, etc.) see "Corrosion" information		
Shielding efficiency and integrity	OK	
For medical devices - was a FDA 510k provide? (provide written notification to FDA)	NA	
Well logging sources must be nondispersible and nonsoluble. (see Appendix H for a list of approved well logging sources)	NA	
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)		
LABELING		
Copy of label	YES	
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	YES	
Permanent attachment and location(s) - visible to users? Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	YES.	
CONDITIONS OF USE		
Expected working life of the source/device (years, operations)		

DESCRIPTION	OK/DEF	COMMENTS
Actions to be taken when product reaches end of its working life.	[illegible]	~~Scantech~~ no estimated life time
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	OK	
How the device will be used	OK	
Meets dose limits of Part 32 for G and E distribution	OK	
PROTOTYPE TESTING/HISTORICAL USE		
Tests methods and conditions (for source and device)	OK	
Tests results	OK	
Years of use (incidents, failures, etc.)		
Similarities to other sources/devices if they are used as basis.	YES	
RADIATION PROFILES		
Survey instrument used (type, window, sensitivity, etc.)	OK	
Conditions	OK.	
Distance from source/surface (per ANSI 538-1979)	OK	
Shutter On and Off/source shielded	OK	
Scatter (product in beam)	OK	
Guards and shields in place	—	optional
Verify radiation surveys for γ radiation meet inv^2 law.		
Verify radiation surveys for non-γ radiation have not been calculated using inv^2 law.	✓	
QUALITY ASSURANCE		
Materials, subassemblies, services	OK	
Assembly methods (screws, welding, etc.)	OK	
Dimensions and tolerances	OK.	
Activity, radiation levels, leak tests	OK	
QA Manual	OK.	
INSTALLATION		

DESCRIPTION	OK/DEF	COMMENTS
Fixed, portable, movable, fixed installation but portable source housing		
Inherent shielding, inaccessibility	OK	
Interlocks, locks, barriers	OK	
Beam access: size of air gap/opening to beam (verify size with new GL rule)		
Mounting integrity	OK	
SAFETY INSTRUCTIONS		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	OK	
ACCOMPANYING DOCUMENTATION		
Leak tests results and radiation surveys	OK	
Transportation documents	no	
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable	OK	
For GL dist. Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations	N/A	
SERVICING		
Manufacturer provides or user performs: ✓ Installation ___ Calibration ___ Relocation ___ Leak Test ✓ Maintenance ___ Radiation Survey ___ Repair ✓ Training ✓ Source Change/Installation		
FOREIGN MANUFACTURERS		
Drop ship		
Who and where is source installed	Scantek at commissioning.	
Leak test and radiation surveys	NRL/AS cert.	
QA in the U.S.	no	