

Appendix C: Application and Review Checklist

Application and Review Checklist SSD 01-37
 new device: NR-xxxx-D-1xx-S

"DISCONTINUE REVIEW"

| SUMMARY DATA | |
|--|--|
| Name and Complete Mailing Address of the Applicant: Scan Technologies, Inc. 303 Jacobsen Drive Rock Branch Industrial Park Poca, WV 25159 800-955-8321 | |
| Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: Carl Baldwin, RSO 800-955-8321 | |
| The Applicant is (check one): | |
| <input type="checkbox"/> | Custom User |
| <input type="checkbox"/> | Manufacturer |
| <input checked="" type="checkbox"/> | Distributor |
| <input type="checkbox"/> | Manufacturer and Distributor |
| If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer: Scantech International Party Ltd. 40 Maple Avenue Forestville, South Australia 5035 +61(8)82976144 | |
| If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor: NA | |
| Provide the Name, Complete Mailing Address, and Function of Other Companies Involved: Kanawha Scales & Systems, Inc. (shares same facilities with Scan Technologies) DEF-1.1 | |
| Model Number: CM-100 | |
| Principal Use Code (see Appendix F): D, H | |
| Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.): Conductive Materials Moisture Monitor | |
| For Use by: | |
| <input checked="" type="checkbox"/> | Specific Licensees Only |
| <input type="checkbox"/> | General Licensees Only |
| <input type="checkbox"/> | Both Specific and General Licensees |
| <input type="checkbox"/> | Persons Exempt from Licensing |
| Leak-Test Frequency: | |
| <input type="checkbox"/> | Periodic Leak-Testing is Not Required |
| <input checked="" type="checkbox"/> | 6 Months |
| Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5): 30.32 | |
| Radionuclides and Maximum Activities (including loading tolerance): FROM FORM Cf-252, 100 micrograms nominal FROM 1.5 75 micrograms max per capsule 1-4 capsules per device. loading tolerance +/- 2.0%, therefore max activity 102 micrograms. DEF-5 | |
| <input type="checkbox"/> | Attached is justification for a leak test frequency of greater than 6 months |
| CERTIFICATION: THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30 AND 32 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION. | |
| Certifying Officer — Typed Name and Title N/A | |
| Signature: N/A | |
| Date: | |

CHECKLIST

Registration Certificate Holder:

Model:

2nd review J.S.

| DESCRIPTION | OK/DEF | COMMENTS |
|---|--------------------|--|
| DESCRIPTION/CONSTRUCTION | | |
| If registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so? | NA | |
| Device/source design with complete engineering drawings (dimensions, tolerances, list of materials) | DEF-3 | <i>def</i> |
| Assembly methods (screw, welds, etc.); verify integrity | | <i>def</i> |
| Source mounting (size and integrity) and security | | <i>def</i> |
| Is source ANSI classification sufficient (from ANSI N542-1977): | 43323 | |
| Radiography - Unprotected | 43515 | both sources |
| Radiography - In Device | 43313 | already |
| Medical - Radiography | 32312 | registered |
| Medical - γ Teletherapy | 53524 | |
| γ Gauges - Unprotected | 43333 | DEF-5 |
| 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 | |
| Definition of shutter operation (locked in Off position OK , not locked in On position OK), Fail safe DEF , spacing and tolerances | DEF-13.6 | <i>def</i> |
| On-Off indicators (description, qty., location) both electric and mechanical - | OK | <input checked="" type="checkbox"/> |
| Safety interlocks, guards, etc. to prevent access to beam or high radiation levels | OK | <i>may need guards</i> |
| Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.) | OK | <i>clarify dose rate</i> |
| Shielding efficiency and integrity | | <i>Need more information</i> |
| For medical devices: Was a 510(k) provided? (provide written notification to FDA) | NA | <i>NA</i> |
| Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991) | NA | <i>NA</i> |
| See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.) ANSI N43.8-1979 (was ANSI N538-1979) | OK | <input checked="" type="checkbox"/> |
| LABELING | | |
| Copy of label | | |
| Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20) | N/A | <i>clarify dimensions text</i> |
| Permanent attachment and location(s) - visible to users? | DEF-11 | <i>def</i> Location /Rivetting |
| Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included) | DEF-11 | ANSI Classificatio Dimensions |
| CONDITIONS OF USE | | |
| Expected working life of the source/device (years, operations) | 10-15 Years | <input checked="" type="checkbox"/> |
| Actions to be taken when product reaches end of its working life. | OK | <input checked="" type="checkbox"/> Return to distributor |
| Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport) | OK | <i>data to -50C only</i> |
| How the device/source will be used | OK | <input checked="" type="checkbox"/> |

CHECKLIST

Registration Certificate Holder:

Model:

2nd reviewer T. Janakovich

| DESCRIPTION | OK/DEF | COMMENTS |
|--|--------------|---|
| Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing | N/A | <i>NA</i> |
| PROTOTYPE TESTING/HISTORICAL USE | | |
| Tests methods and conditions (for source and device) <i>fire test - OK</i> <i>corrosion - OK</i> | DEF | ✓ DROP, FIRE and Vibration |
| Tests results | DEF | ✓ Incorrect calibration of survey meters |
| Years of use (incidents, failures, etc.) <i>not sufficient b/c does not provide leak test results, only lack of shutter failure</i> | | ✓ Need clarification of data |
| Similarities to other sources/devices if they are used as basis. | N/A | |
| RADIATION PROFILES | | |
| Survey instrument used (type, window thickness, sensitivity, etc.) | DEF-13 | <i>needs calibration</i> 6 month calibration required on S. meters |
| Conditions: including environments, scatter (product in beam), and use of guards and shields | | — Clarification required |
| Distance from source/surface (per ANSI 538-1979) | OK | ✓ |
| Shutter Open and Closed/Source Shielded | OK | ✓ |
| Verify radiation surveys for γ radiation meet inv^2 law. | N/A | — |
| Verify radiation surveys for non- γ radiation have not been calculated using inv^2 law. | OK | ✓ |
| QUALITY ASSURANCE | | |
| Materials, subassemblies, services | OK | ✓ |
| Assembly methods (screws, welding, etc.) | DEF-4 | ✓ |
| Dimensions and tolerances | DEF-4 | ✓ |
| Activity, radiation levels, leak tests | OK | ✓ |
| QA Manual and comparison of manual to Regulatory Guide 6.9 | OK | ✓ |
| INSTALLATION | | |
| Fixed, portable, movable, fixed installation but portable source housing | X | <i>fixed</i> |
| Inherent shielding, inaccessibility | | <i>may need guards</i> |
| Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers | DEF | <i>def</i> Needs clarification |
| Mounting integrity | DEF | ✓ Needs more specific direction |
| SAFETY INSTRUCTIONS | | |
| Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys | OK | ✓ |
| ACCOMPANYING DOCUMENTATION | | |
| Leak tests results and radiation surveys section 4 says copy of profile as in N538 (Fig 5) given | DEF | ✓ Needs clarification |
| Transportation documents | Not provided | <i>NA</i> |

CHECKLIST

Registration Certificate Holder:

Model:

2nd reviewer

| DESCRIPTION | OK/DEF | COMMENTS |
|--|--------|----------|
| Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable | DEF-13 | |
| For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations | N/A | — |

SERVICING

The following activities may be performed by the persons indicated:

| Activity | by a General Licensee | Only by a Specific Licensee | Will be Offered by the Applicant |
|------------------|-----------------------|-----------------------------|----------------------------------|
| Installation | | X | x |
| Relocation | | X | x |
| Maintenance | | X | X |
| Repair | | x | ? |
| Source Exchange | | x | x |
| Calibration | | x | ? |
| Leak Testing | | x | X |
| Radiation Survey | | x | X |
| Training | | | ? |

✓

FOREIGN VENDORS

| | | | |
|-----------------------------------|----|---|---------------------------------------|
| Drop ship | | | Sources supplied by USA manufacturers |
| Who and where is source installed | | | <i>clarify company role IN USA</i> |
| Leak test and radiation surveys | OK | ✓ | |
| QA in the U.S. | | | Needs clarification. |

OTHER:

Reviewers:

Ujagar S. Bahchu.....(R/A)

Ujagar S. Bahchu

John Jankovich

JPJ 2/21/02