

**Application and Review Checklist for (Acceptance, 1st, or 2nd) Review for SSD**

| SUMMARY DATA  |  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
|---|--|-------------------------------------|---------------------------------------|-------------------------------------|------------------------|-------------------------------------|--|--------------------------|-------------------------------|
| <p>Name and Complete Mailing Address of the Applicant: RAM Services<br/>510 County Highway V<br/>Two Rivers, WI 54241</p>   |  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <p>Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: Mr. Jordan 1-920-686-3889<br/>or Jerry Wiza (President) <a href="mailto:donjordan@ramservicesinc.com">donjordan@ramservicesinc.com</a></p>  |  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <p>The Applicant is (check one):</p> <table border="1"> <tr> <td><input type="checkbox"/></td> <td>Custom User</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Manufacturer</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Distributor</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Manufacturer and Distributor</td> </tr> </table>   |  | <input type="checkbox"/>            | Custom User                           | <input type="checkbox"/>            | Manufacturer           | <input checked="" type="checkbox"/> | Distributor  | <input type="checkbox"/> | Manufacturer and Distributor  |
| <input type="checkbox"/>  | Custom User  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <input type="checkbox"/>  | Manufacturer   |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <input checked="" type="checkbox"/>   | Distributor  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <input type="checkbox"/>  | Manufacturer and Distributor   |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <p>If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:</p> <p>Real Time Instruments Pty. Ltd.<br/>Lot 5 Mackay Marina Village<br/>Mackay, Queensland Australia. 4740</p>   |  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <p>If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:</p> <p>NA</p>   |  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <p>If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:</p> <p>NA</p>   |  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <p>Model Number:</p>  |  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <p>Principal Use Code (see Appendix C): H</p>   |  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <p>Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):</p> <p>RTI Allscan</p>  |  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <p>For Use by:</p> <table border="1"> <tr> <td><input checked="" type="checkbox"/></td> <td>Specific Licensees Only</td> </tr> <tr> <td><input type="checkbox"/></td> <td>General Licensees Only</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Both Specific and General Licensees</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Persons Exempt from Licensing</td> </tr> </table>  |  | <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 |
| <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  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <p>Leak-Test Frequency:</p> <table border="1"> <tr> <td><input type="checkbox"/></td> <td>Periodic Leak-Testing is Not Required</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>6 Months</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Attached is justification for a leak test frequency of greater than 6 months</td> </tr> </table>  |  | <input type="checkbox"/>            | Periodic Leak-Testing is Not Required | <input checked="" type="checkbox"/> | 6 Months               | <input type="checkbox"/>            | Attached is justification for a leak test frequency of greater than 6 months |                          |                               |
| <input type="checkbox"/>  | Periodic Leak-Testing is Not Required  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <input checked="" type="checkbox"/>   | 6 Months   |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <input type="checkbox"/>  | Attached is justification for a leak test frequency of greater than 6 months |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <p>Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):</p>  |  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <p>Radionuclides and Maximum Activities (including loading tolerance):</p> <p>cf-252 12.4 MBq [ 3 capsules total 12.4 MBq or 3 capsules each 12.4 MBq ]</p>   |  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <p><b>CERTIFICATION:</b></p> <p>THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.</p> <p>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.</p> <p>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.</p> |  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <p>Certifying Officer — Typed Name and Title</p>  |  |                                     |                                       |                                     |                        |                                     |  |                          |                               |
| <p>Signature: _____ Date: _____</p>   |  |                                     |                                       |                                     |                        |                                     |  |                          |                               |

**CHECKLIST**

**Registration Certificate Holder:**

**Model:**

| DESCRIPTION   | OK/DEF                   |                          | COMMENTS  |
|---|--------------------------|--------------------------|---|
|   | 1 <sup>st</sup> Reviewer | 2 <sup>nd</sup> Reviewer |   |
| <b>DESCRIPTION/CONSTRUCTION</b>   |                          |                          |   |
| If registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so? | ok                       | ✓                        |   |
| Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)   | def                      | def                      | need drawings of source holder identifying the parts, and an overall drawing of the device with overall dimensions in units |
| Assembly methods (screw, welds, etc.); verify integrity   | ok                       | ✓                        |   |
| Source mounting (size and integrity) and security   | ok                       | ✓                        |   |
| Is source ANSI classification sufficient (from ANSI N43.6-1997 and ISO 2919):   |                          |                          | Frontier Tech. Corp.  |
| Radiography - Unprotected ..... 43515   |                          |                          | FTC-100 series - OH-298-S-101-J   |
| Radiography - In Device ..... 43313   |                          |                          | Classification C6X644   |
| Medical - Radiography ..... 32312   |                          |                          |   |
| Medical - γ Teletherapy ..... 53524   |                          |                          |   |
| Medical - Brachytherapy ..... 53211   |                          |                          |   |
| Medical - Source Applicators ..... 43312  |                          |                          |   |
| γ Gauges - Unprotected ..... 43333  |                          |                          |   |
| γ Gauges - In Device ..... 43232  |                          |                          |   |
| β Gauges, Low Energy γ Gauges, or X-ray fluorescence ..... 33222  | ok                       |                          | QSA Global  |
| Oil Well Logging ..... 56522  |                          |                          | CVU.CY in - MA-1059-S-271-J   |
| Portable Moist/Density ..... 43333  |                          |                          | Classification C6V545   |
| Neutron Applications ..... 43323  |                          |                          |   |
| Calibration source activity > 30μCi (1 MBq) ..... 22212   |                          |                          |   |
| γ Irradiators (I) ..... 43323   |                          |                          |   |
| γ Irradiators (II, III) ..... 43424   |                          |                          |   |
| γ Irradiators (IV) ..... 53424  |                          |                          |   |
| Chromatography ..... 32211  |                          |                          |   |
| Static Eliminators ..... 22222  |                          |                          |   |
| Smoke Detectors ..... 32222   |                          |                          |   |
| 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)   | ok                       | ✓                        | Attachment 10 and 14  |
| Safety interlocks, guards, and so forth to prevent access to beam or high radiation levels  | ok                       | ✓                        |   |
| Corrosion between unlike materials (e.g., aluminum and steel, depleted uranium & steel, and so forth)   | ok                       | ✓                        |   |
| Shielding efficiency and integrity  | ok                       | ✓                        |   |

**CHECKLIST**

**Registration Certificate Holder:**

**Model:**

| DESCRIPTION  | OK/DEF                   |                          | COMMENTS |
|--|--------------------------|--------------------------|----------|
|  | 1 <sup>st</sup> Reviewer | 2 <sup>nd</sup> Reviewer |          |
| <p><b>For medical devices:</b></p> <p><b>Type of FDA approval:</b></p> <ul style="list-style-type: none"> <li>· Premarket notification (501(k))</li> <li>· Premarket approval (PMA)</li> <li>· Investigational Device Exemption (IDE)</li> <li>· Humanitarian Device Exemption (HDE)</li> </ul> <p><b>Type of Medical Use:</b></p> <ul style="list-style-type: none"> <li>· manual brachytherapy, 35.400</li> <li>· medical diagnosis, 35.500</li> <li>· photon-emitting remote afterloader, 35.600</li> <li>· photon-emitting teletherapy unit, 35.600</li> <li>· gamma stereotactic radiosurgery unit, 35.600</li> <li>· other medical, 35.1000 (intervascular brachytherapy, beta-emitting remote afterloaders, etc)</li> </ul> <p><b>List of FDA limitations of use provided</b></p> | w/A                      | NA                       |          |
| <p>Well logging (10 CFR 39.41) and irradiator (10 CFR 36.21) sources must be as nondispersible and nonsoluble as practical.</p>  | w/A                      | NA                       |          |
| <p>See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)</p>   | w/A                      | NA                       |          |

| LABELING   |       |     |  |
|--|-------|-----|--|
| Complete and final copy of label attached  | ok    | ✓   |  |
| Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)                                 | ok    | ✓   |  |
| Attachment and location(s) - visible to users?   |       | def | location is not specified                                      |
| Method of attachment is durable and permanent under normal conditions of use   | ok    | ✓   |  |
| Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included) | def   | def | Activity 6 mCi white Request ask for 12.4 nCi mcr?             |
| Is label in compliance with regulatory requirements?   | def   | def |  |
| CONDITIONS OF USE  |       |     |  |
| Estimated working life of the source/device (years, operational cycles)  | ok    | ✓   | working life 30 years  |
| Actions to be taken when product reaches end of its working life.  | ok    | ✓   | Device will be refurbished                                     |
| Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)  |       | ✓   | - 30 to 50°C<br>see Attachment 17, 18                          |
| How the device will be used  | ok    | ✓   |  |
| Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing   |       | NA  |  |
| PROTOTYPE TESTING/HISTORICAL USE   |       |     |  |
| Tests methods and conditions (for source and device)   |       | def | Attachment 16<br>drop test + vib. test<br>results not provided |
| Tests results  | def   | def | prototype system currently<br>in operation for 6 months        |
| Years of use (incidents, failures, etc.)   | def   | NA  |  |
| Similarities to other sources/devices if they are used as basis.   |       | NA  |  |
| RADIATION PROFILES   |       |     |  |
| Survey instrument used (type, window thickness, sensitivity, calibration dates, etc.)  | ✓     | ✓   | Attachment 8   |
| Conditions: including environments, scatter (product in beam), and use of guards and shields   | ✓     | ✓   |  |
| RADIATION PROFILES (CONTINUED)   |       |     |  |
| Distance from source/surface (per ANSI 538-1979, N43.8 - 2001)   | b/c ✓ | ✓   |  |
| Shutter Open and Closed/Source Shielded  | b/c ✓ | def | profile w/shutter,<br>open is not<br>provided                  |
| Verify radiation surveys for $\gamma$ radiation meet $inv^2$ law.  |       | NA  |  |

|  |     |       |   |
|--|-----|-------|---|
| Verify radiation surveys for non- $\gamma$ radiation have not been calculated using $inv^2$ law.   |     | ✓     |   |
| QUALITY ASSURANCE  |     |       |   |
| Materials, subassemblies, services   | OK  | ✓     | } QA checklist  |
| Assembly methods (screws, welding, etc.)   | OK  | ✓     |   |
| Dimensions and tolerances  | OK  | ✓     |   |
| Activity, radiation levels, leak tests   | OK  | ✓     |   |
| Final inspection   | OK  | ✓     |   |
| QA Manual and comparison of other (generally) accepted guidance (e.g., ANSI/ISO/ASQ 9001-2001)   |     | } def | No QA program for manufacturer<br>US audit; independence of auditor is needed |
| Additional measures for SSDs if ANSI/ISO/ASQ 9001-2001 is used   |     |       |   |
| INSTALLATION   |     |       |   |
| Fixed, portable, movable, fixed installation but portable source housing   | OK  | ✓     | 20% above rad. profile was stated as OK                                       |
| Inherent shielding, inaccessibility  | OK  | def   |   |
| Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers  | OK  | ✓     |   |
| Mounting integrity   | OK  | ✓     |   |
| ACCOMPANYING DOCUMENTATION   |     |       |   |
| Leak tests results and radiation surveys   |     | ✓     |   |
| Operation safety instructions, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable |     | def   | Op. Manual is not provided  |
| For Distribution to General Licensees:<br>Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations         | N/A | NA    |   |

| 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                           |                                  | OK  | ✓ |  |
| Relocation  |                       | X                           |                                  |     |   |  |
| Maintenance   |                       |                             | X                                |     |   |  |
| Repair  |                       |                             | X                                |     |   |  |
| Source Exchange   |                       | X                           | X                                |     |   |  |
| Calibration   |                       |                             | X                                |     |   |  |
| Leak Testing  |                       |                             | X                                |     |   |  |
| Radiation Survey  |                       |                             | X                                |     |   |  |
| Training  |                       |                             | X                                |     |   |  |
| FOREIGN VENDORS   |                       |                             |                                  |     |   |  |
| Drop ship   |                       |                             |                                  | N/A | ✓ |  |
| Who and where is source installed                                   |                       |                             |                                  | N/A | ✓ |  |
| Leak test and radiation surveys                                     |                       |                             |                                  | N/A | ✓ |  |
| QA in the U.S.  |                       |                             |                                  | N/A | ✓ |  |

1<sup>st</sup> Reviewer Signature: *[Signature]* Date: July 3, 2012

2<sup>nd</sup> Reviewer Signature: *[Signature]* Date: 8/22/12