

## Application and Review Checklist for (Acceptance, 1st, or 2nd) Review for SSD 00-000

SUMMARY DATA	
Name and Complete Mailing Address of the Applicant: <i>Monaguel (Int'l)</i>	Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: <i>Rad Herrell, Health Physist</i>
The Applicant is (check one):	If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:
<input type="checkbox"/> Custom User	
<input checked="" type="checkbox"/> Manufacturer	
<input type="checkbox"/> Distributor	
<input type="checkbox"/> Manufacturer and Distributor	
If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:	Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:
Model Number: <i>4203</i>	Principal Use Code (see Appendix C):
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):	For Use by:
	<input type="checkbox"/> Specific Licensees Only
	<input type="checkbox"/> General Licensees Only
	<input checked="" type="checkbox"/> Both Specific and General Licensees
	<input type="checkbox"/> Persons Exempt from Licensing
Leak-Test Frequency:	Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):
<input type="checkbox"/> Periodic Leak-Testing is Not Required	Radionuclides and Maximum Activities (including loading tolerance):
<input checked="" type="checkbox"/> 6 Months	
<input type="checkbox"/> Attached is justification for a leak test frequency of greater than 6 months	
<b>CERTIFICATION:</b>  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	
Signature:	Date:

## APPENDIX A

CHECKLIST			
Registration Certificate Holder: <i>Honeywell International</i>			
Model: <i>4203</i>			
DESCRIPTION	OK/DEF		COMMENTS
	1 <sup>st</sup> Reviewer	2 <sup>nd</sup> Reviewer	
DESCRIPTION/CONSTRUCTION			<i>xfer from A2 to GA</i>
If registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so?			
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	<i>OK</i>		<i>Only change:</i>
Assembly methods (screw, welds, etc.); verify integrity			
Source mounting (size and integrity) and security			<i>material of construction</i>
Is source ANSI classification sufficient (from ANSI N43.6-1997 and ISO 2919):			<i>originally:</i>
Radiography - Unprotected ..... 43515			<i>only stainless steel</i>
Radiography - In Device ..... 43313			
Medical - Radiography ..... 32312			
Medical - $\gamma$ Teletherapy ..... 53524			<i>now:</i>
Medical - Brachytherapy ..... 53211			<i>add <del>W</del> Tungsten as option</i>
Medical - Source Applicators ..... 43312			
$\gamma$ Gauges - Unprotected ..... 43333			
$\gamma$ Gauges - In Device ..... 43232			
$\beta$ Gauges, Low Energy $\gamma$ Gauges, or X-ray fluorescence ..... 33222			
Oil Well Logging ..... 56522			
Portable Moist/Density ..... 43333			
Neutron Applications ..... 43323			
Calibration source activity > 30 $\mu$ Ci (1 MBq) ..... 22212			
$\gamma$ Irradiators (I) ..... 43323			
$\gamma$ Irradiators (II, III) ..... 43424			
$\gamma$ 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			
On-Off indicators (description, qty., location)			
Safety interlocks, guards, and so forth to prevent access to beam or high radiation levels			
Corrosion between unlike materials (e.g., aluminum and steel, depleted uranium & steel, and so forth)	<i>OK</i>		
Shielding efficiency and integrity			

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<p>For medical devices:</p> <p>Type of FDA approval:</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>Type of Medical Use:</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>List of FDA limitations of use provided</p>			N/A
Well logging (10 CFR 39.41) and irradiator (10 CFR 36.21) sources must be as nondispersible and nonsoluble as practical.			
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)			


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<b>LABELING</b>			<i>no changes to these sections x for from AZ to GA</i>
Complete and final copy of label attached			
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)			
Attachment and location(s) - visible to users?			
Method of attachment is durable and permanent under normal conditions of use			
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)			
Is label in compliance with regulatory requirements?			
<b>CONDITIONS OF USE</b>			
Estimated working life of the source/device (years, operational cycles)			
Actions to be taken when product reaches end of its working life.			
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)			
How the device will be used			
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing			
<b>PROTOTYPE TESTING/HISTORICAL USE</b>			
Tests methods and conditions (for source and device)			
Tests results			
Years of use (incidents, failures, etc.)			
Similarities to other sources/devices if they are used as basis.			
<b>RADIATION PROFILES</b>			
Survey instrument used (type, window thickness, sensitivity, <b>calibration dates</b> , etc.)			
Conditions: including environments, scatter (product in beam), and use of guards and shields			

## CHECKLIST

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Model:

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<b>RADIATION PROFILES (CONTINUED)</b>			<i>no changes to these sections:</i>
Distance from source/surface (per ANSI 538-1979, N43.8 - 2001)			
Shutter Open and Closed/Source Shielded			<i>x for from A2 to GA</i>
Verify radiation surveys for $\gamma$ radiation meet $inv^2$ law.			
Verify radiation surveys for non- $\gamma$ radiation have not been calculated using $inv^2$ law.			
<b>QUALITY ASSURANCE</b>			
Materials, subassemblies, services			
Assembly methods (screws, welding, etc.)			
Dimensions and tolerances			
Activity, radiation levels, leak tests			
Final inspection			
QA Manual and comparison of other (generally) accepted guidance (e.g., ANSI/ISO/ASQ 9001-2001)			
Additional measures for SSDs if ANSI/ISO/ASQ 9001-2001 is used			
<b>INSTALLATION</b>			
Fixed, portable, movable, fixed installation but portable source housing			
Inherent shielding, inaccessibility			
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers			
Mounting integrity			
<b>ACCOMPANYING DOCUMENTATION</b>			
Leak tests results and radiation surveys			
Operation safety instructions, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable			
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations			

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SERVICING									no changes to these sections: x for from GA to A2
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									
Relocation									
Maintenance									
Repair									
Source Exchange									
Calibration									
Leak Testing									
Radiation Survey									
Training									
FOREIGN VENDORS									
Drop ship									
Who and where is source installed									
Leak test and radiation surveys									
QA in the U.S.									

1<sup>st</sup> Reviewer Signature:*E. James*

Date:

8/21/2012

2<sup>nd</sup> Reviewer Signature:*Cynthia S. Long*

Date:

8/22/12