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

SUMMARY DATA	
Name and Complete Mailing Address of the Applicant: Honeywell (Int'l)	**Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:** Rod Harrell, Health Physicist
The Applicant is (check one): [ ] Custom User [X] Manufacturer [ ] Distributor [ ] Manufacturer and Distributor	**If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:**
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: 4203	**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:** [ ] Specific Licensees Only [ ] General Licensees Only [X] Both Specific and General Licensees [ ] Persons Exempt from Licensing
Leak-Test Frequency: [ ] Periodic Leak-Testing is Not Required [X] 6 Months [ ] Attached is justification for a leak test frequency of greater than 6 months	**Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):** **Radionuclides and Maximum Activities (including loading tolerance):**

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	
Signature:	**Date:**

CHECKLIST

Registration Certificate Holder: Honeywell International

Model: 4203

DESCRIPTION	OK/DEF		COMMENTS
	1st Reviewer	2nd Reviewer	
DESCRIPTION/CONSTRUCTION			xfer from AZ to GA
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)	OK		Only change: material of construction
Assembly methods (screw, welds, etc.); verify integrity			
Source mounting (size and integrity) and security			
Is source ANSI classification sufficient (**from ANSI N43.6-1997 and ISO 2919):** Radiography - Unprotected ..... 43515 Radiography - In Device ..... 43313 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 Oil Well Logging ..... 56522 Portable Moist/Density ..... 43333 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			originally: only Stainless steel now: add [redacted] Tungsten as option
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)	OK		
Shielding efficiency and integrity			

CHECKLIST			
Registration Certificate Holder:			
Model:			
DESCRIPTION	**OK/DEF**		**COMMENTS**
	1st Reviewer	**2nd Reviewer**	
For medical devices: **Type of FDA approval:** • **Premarket notification (501(k))** • **Premarket approval (PMA)** • **Investigational Device Exemption (IDE)** • **Humanitarian Device Exemption (HDE)** **Type of Medical Use:** • **manual brachytherapy, 35.400** • **medical diagnosis, 35.500** • **photon-emitting remote afterloader, 35.600** • **photon-emitting teletherapy unit, 35.600** • **gamma stereotactic radiosurgery unit, 35.600** • **other medical, 35.1000 (intervascular brachytherapy, beta-emitting remote afterloaders, etc)** **List of FDA limitations of use provided**			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.)			

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF		COMMENTS
	1st Reviewer	2nd Reviewer	
LABELING			no changes to these sections x-fer from AZ to GA
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?			
CONDITIONS OF USE			
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			
PROTOTYPE TESTING/HISTORICAL USE			
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.			
RADIATION PROFILES			
Survey instrument used (type, window thickness, sensitivity, **calibration dates**, etc.)			
Conditions: including environments, scatter (product in beam), and use of guards and shields			

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF		COMMENTS
	1st Reviewer	2nd Reviewer	
RADIATION PROFILES (CONTINUED)			no changes to these sections:
Distance from source/surface (per ANSI 538-1979, N43.8 - 2001)			
Shutter Open and Closed/Source Shielded			✗ fee from AZ to GA
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			
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			
INSTALLATION			
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			
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			
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations			✓

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION				OK/DEF		COMMENTS
				1st Reviewer	2nd Reviewer	
SERVICING						no changes to these sections: x fer from QA to AZ
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.						

1st Reviewer Signature: Eric Janssen **Date:** 8/21/2012

2nd Reviewer Signature: Cynthia S. Long **Date:** 8/22/12