

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>Yokogawa Corp of America</i>	Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: <i>Todd Hess (Alshaz Bird)</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 type="checkbox"/> Manufacturer	
<input type="checkbox"/> Distributor	
<input checked="" 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>WG3101, WG4101</i>	Principal Use Code (see Appendix C): <i>E Beta, GL</i>
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.): <i>Beta Gauge</i>	For Use by:
	<input type="checkbox"/> Specific Licensees Only
	<input checked="" type="checkbox"/> General Licensees Only
	<input 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 checked="" type="checkbox"/> Periodic Leak-Testing is Not Required	<i>391-3-17-.62(G)(C)</i>
<input type="checkbox"/> 6 Months	Radionuclides and Maximum Activities (including loading tolerance):
<input type="checkbox"/> Attached is justification for a leak test frequency of greater than 6 months	<i>Kr-85, 1 Ci</i>
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:

APPENDIX A

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF		COMMENTS
	1 st Reviewer	2 nd Reviewer	
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?	✓	✓	only software/scan speed difference
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	✓	✓	
Assembly methods (screw, welds, etc.); verify integrity	✓	✓	
Source mounting (size and integrity) and security	✓	✓	keys, special tools
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	✓	✓	42341
Oil Well Logging 56522			
Portable Moist/Density 43333			
Neutron Applications 43323			
Calibration source activity > 30 μ Ci (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	✓	✓	"retire" position
On-Off indicators (description, qty., location)	✓	✓	
Safety interlocks, guards, and so forth to prevent access to beam or high radiation levels	✓	✓	small gap
Corrosion between unlike materials (e.g., aluminum and steel, depleted uranium & steel, and so forth)	✓	✓	
Shielding efficiency and integrity	✓	✓	

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For medical devices: Type of FDA approval: <ul style="list-style-type: none"> • Premarket notification (501(k)) • Premarket approval (PMA) • Investigational Device Exemption (IDE) • Humanitarian Device Exemption (HDE) Type of Medical Use: <ul style="list-style-type: none"> • 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.	N/A		
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)	N/A		

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LABELING			
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?	✓	✓	<i>mult. locations</i>
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?	✓	✓	<i>GL</i>
CONDITIONS OF USE			
Estimated working life of the source/device (years, operational cycles)	✓	✓	<i>20-30yrs</i>
Actions to be taken when product reaches end of its working life.	✓	✓	<i>return to man source exchange</i>
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	✓	✓	<i>EU lower than US</i>
PROTOTYPE TESTING/HISTORICAL USE			
Tests methods and conditions (for source and device)	✓	✓	<i>pg 7-9 of 200</i>
Tests results	✓	✓	
Years of use (incidents, failures, etc.)	✓	✓	<i>p. 58</i>
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	✓	✓	<i>with & without shield</i>

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RADIATION PROFILES (CONTINUED)			
Distance from source/surface (per ANSI 538-1979, N43.8 - 2001)	✓	✓	
Shutter Open and Closed/Source Shielded	✓	✓	
Verify radiation surveys for γ radiation meet inv^2 law.	N/A	N/A	
Verify radiation surveys for non- γ radiation have not been calculated using inv^2 law.	✓	✓	
QUALITY ASSURANCE			
Materials, subassemblies, services	✓	✓	Pg 65-66
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	✓	✓	fixed
Inherent shielding, inaccessibility	✓	✓	process line
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	✓	✓	

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implemented
in design


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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			* repair not include source housing; limited to non-rad or spec. activities on detector housing
Installation		✓	✓			
Relocation		✓	✓			
Maintenance	✓	✓	✓			
Repair	✗	✓	✓			
Source Exchange		✓	✓			
Calibration		✓	✓			
Leak Testing	N/A	N/A	N/A			
Radiation Survey		✓	✓			
Training		✓	✓			
FOREIGN VENDORS						
Drop ship				✓	✓	
Who and where is source installed				✓	✓	cust site
Leak test and radiation surveys				✓	✓	
QA in the U.S.				✓	✓	verify

1st Reviewer Signature: 

Date: 7/15/2012

2nd Reviewer Signature: 

Date: 8/14/12