

**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>EADS Southern North America</i>	
Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: <i>Richard Kohn, President 858-457-2000</i>	
The Applicant is (check one):	
<input type="checkbox"/>	Custom User
<input type="checkbox"/>	Manufacturer
<input type="checkbox"/>	Distributor
<input checked="" type="checkbox"/>	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: <i>N/A</i>	
Provide the Name, Complete Mailing Address, and Function of Other Companies Involved: <i>Hazen Research, Inc. distributor of source used in device</i>	
Model Number: <i>CNA series</i>	
Principal Use Code (see Appendix C): <i>H: Gen Neutron Source</i>	
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.): <i>Neutron Analyzer</i>	
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 checked="" type="checkbox"/>	Periodic Leak-Testing is Not Required
<input type="checkbox"/>	6 Months
<input type="checkbox"/>	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): <i>H-3 3.3 Ci nom / 3.63 mCi</i>	
<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: *EADS SODERN*

Model: *CNA 5009*

DESCRIPTION	OK/DEF		COMMENTS
	1 <sup>st</sup> Reviewer	2 <sup>nd</sup> 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?	<i>ED</i>	<i>LP</i>	<i>change shielding material, overall size</i>
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	<i>ED</i>	<i>LP</i>	
Assembly methods (screw, welds, etc.); verify integrity	<i>ED</i>	<i>LP</i>	<i>interlocking shield pieces</i>
Source mounting (size and integrity) and security	<i>ED</i>	<i>LP</i>	<i>unchanged</i>
Is source ANSI classification sufficient (from ANSI N43.6-1997 and ISO 2919):			
Radiography - Unprotected ..... 43515			
Radiography - In Device ..... 43313			
Medical - Radiography ..... 32312			
Medical - $\gamma$ Teletherapy ..... 53524			
Medical - Brachytherapy ..... 53211			
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 ..... <u>43323</u>	<i>ED</i>	<i>LP</i>	<i>okay - from previous evaluation also, equipped w/ interlocks to shut power, thus, can turn beam OFF</i>
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	<i>ED</i>	<i>LP</i>	<i>electrical power supply</i>
On-Off indicators (description, qty., location)	<i>ED</i>	<i>LP</i>	
Safety interlocks, guards, and so forth to prevent access to beam or high radiation levels	<i>ED</i>	<i>LP</i>	<i>external perimeter fence</i>
Corrosion between unlike materials (e.g., aluminum and steel, depleted uranium & steel, and so forth)	<i>ED</i>	<i>LP</i>	<i>N/A steel &amp; HDPE</i>
Shielding efficiency and integrity	<i>ED</i>	<i>LP</i>	

**CHECKLIST**

Registration Certificate Holder: *BADS Sweden*

Model: *CNA series*

DESCRIPTION	OK/DEF		COMMENTS
	1 <sup>st</sup> Reviewer	2 <sup>nd</sup> Reviewer	
<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>			<p><i>N/A</i></p>
Well logging (10 CFR 39.41) and irradiator (10 CFR 36.21) sources must be as nondispersible and nonsoluble as practical.	<i>N/A</i>		
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)	<i>N/A</i>		

CHECKLIST			
Registration Certificate Holder: <i>EADS Southern</i>			
Model: <i>CNA series</i>			
DESCRIPTION	OK/DEF		COMMENTS
	1 <sup>st</sup> Reviewer	2 <sup>nd</sup> Reviewer	
LABELING			
Complete and final copy of label attached			<i>not changed</i>
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)			<i>not changed</i>
Attachment and location(s) - visible to users?	<i>ED</i>	<i>LP</i>	<i>perimeter fence</i>
Method of attachment is durable and permanent under normal conditions of use			<i>not changed</i>
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)			<i>not changed</i>
Is label in compliance with regulatory requirements?			<i>not changed</i>
CONDITIONS OF USE			
Estimated working life of the source/device (years, operational cycles)			<i>not changed</i>
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)	<i>ED</i>	<i>LP</i>	<i>shielding effective</i>
Tests results			<i>no other tests needed</i>
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.)	<i>ED</i>	<i>LP</i>	<i>viz perimeter restrictions</i>
Conditions: including environments, scatter (product in beam), and use of guards and shields			<i>not changed</i>

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**CHECKLIST**


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**Registration Certificate Holder:****Model:**

DESCRIPTION	OK/DEF		COMMENTS
	1 <sup>st</sup> Reviewer	2 <sup>nd</sup> Reviewer	
<b>RADIATION PROFILES (CONTINUED)</b>			
Distance from source/surface (per ANSI 538-1979, N43.8 - 2001)			not changed
Shutter Open and Closed/Source Shielded			↓
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			not changed
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	ED	LP	fixed
Inherent shielding, inaccessibility	ED	LP	
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers	ED	LP	barriers
Mounting integrity			
<b>ACCOMPANYING DOCUMENTATION</b>			
Leak tests results and radiation surveys	ED	LP	
Operation safety instructions, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable	ED	LP	
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations			N/A

**CHECKLIST**

**Registration Certificate Holder:**

**Model:**

DESCRIPTION				OK/DEF		COMMENTS
				1 <sup>st</sup> Reviewer	2 <sup>nd</sup> Reviewer	
<b>SERVICING</b>						
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	EJ	LP	
Installation	N/A	✓	✓			
Relocation	↓		✓			
Maintenance	↓		✓			
Repair	↓		✓			
Source Exchange	↓	ⓧ	✓			
Calibration	↓					
Leak Testing	↓	N/A	N/A			
Radiation Survey	↓		✓			
Training	↓		✓			
<b>FOREIGN VENDORS</b>						
Drop ship				EJ	LP	
Who and where is source installed				EJ	LP	cust site
Leak test and radiation surveys				EJ	LP	survey only
QA in the U.S.				EJ	LP	start-up commissioning

**1<sup>st</sup> Reviewer Signature:** *Eric James*

**Date:** 3/14/2007

**2<sup>nd</sup> Reviewer Signature:** *Paul [unclear]*

**Date:** 4/3/07