Application and Review Checklist SSD 01-16 and SSD 01-51 (IPI)
NR-0348-D-106-B NR-0348-D-109-B NR-0348-D-111-B and NR-0348-805
The Application and Review Checklist are shown on the following pages.

<table>
<tr><th colspan="3">SUMMARY DATA</th></tr>
<tr><td colspan="2">Name and Complete Mailing Address of the Applicant:

NAME/ADDRESS CORRECTION TO: OK

Agilent Technologies
2850 Centerville Road
Wilmington, DE 19808</td><td>Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:
response letters to:
Tom Zunino, Work Place Service Manager, 302-633-8071
technical contact:
David Bennett, RSO, 302-633-8262</td></tr>
<tr><td colspan="2">The Applicant is (check one):</td><td rowspan="5">If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:</td></tr>
<tr><td></td><td>Custom User</td></tr>
<tr><td></td><td>Manufacturer</td></tr>
<tr><td></td><td>Distributor</td></tr>
<tr><td>x</td><td>Manufacturer and Distributor</td></tr>
<tr><td colspan="2">If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:</td><td>Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:
custom source manufacturers: Amersham, IPL</td></tr>
<tr><td colspan="2">Model Number: various</td><td>Principal Use Code (see Appendix F): various</td></tr>
<tr><td colspan="2" rowspan="5">Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):

ECD</td><td>For Use by:</td></tr>
<tr><td></td><td>Specific Licensees Only</td></tr>
<tr><td></td><td>General Licensees Only</td></tr>
<tr><td>x</td><td>Both Specific and General Licensees</td></tr>
<tr><td></td><td>Persons Exempt from Licensing</td></tr>
<tr><td colspan="2">Leak-Test Frequency:</td><td rowspan="2">Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):</td></tr>
<tr><td></td><td>Periodic Leak-Testing is Not Required</td></tr>
<tr><td>x</td><td>6 Months</td><td rowspan="2">Radionuclides and Maximum Activities (including loading tolerance):

Ni-63, 5-15 millicuries</td></tr>
<tr><td></td><td>Attached is justification for a leak test frequency of greater than 6 months</td></tr>
</table>

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:

Model:

DESCRIPTION	OK/DEF	COMMENTS
DESCRIPTION/CONSTRUCTION	N/A	
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)		
Assembly methods (screw, welds, etc.); verify integrity		
Source mounting (size and integrity) and security		
Is source ANSI classification sufficient (from ANSI N542-1977): Radiography - Unprotected ..... 43515 Radiography - In Device ..... 43313 Medical - Radiography..... 32312 Medical - γ Teletherapy .... 53524 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 γ Irradiators (II, III, IV) ..... 43424 γ Irradiators (I) .... 43323 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)		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels		
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)		
Shielding efficiency and integrity		
For medical devices: Was a 510(k) provided? (provide written notification to FDA)		
Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991)		
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
LABELING	OK	request only added additional info to the existing label, no info removed
Copy of label		
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)		
Permanent attachment and location(s) - visible to users?		
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)		
CONDITIONS OF USE	N/A	
Expected working life of the source/device (years, operations)		
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	N/A	
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	N/A	
Survey instrument used (type, window thickness, sensitivity, etc.)		
Conditions: including environments, scatter (product in beam), and use of guards and shields		
Distance from source/surface (per ANSI 538-1979)		
Shutter Open and Closed/Source Shielded		
Verify radiation surveys for γ radiation meet inv^2 law.		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
Verify radiation surveys for non-γ radiation have not been calculated using inv^2 law.		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
QUALITY ASSURANCE	DEF	see 8/28/01 def letter
Materials, subassemblies, services		
Assembly methods (screws, welding, etc.)		
Dimensions and tolerances		
Activity, radiation levels, leak tests		
QA Manual and comparison of manual to Regulatory Guide 6.9		
INSTALLATION	N/A	
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		
SAFETY INSTRUCTIONS	N/A	
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys		
ACCOMPANYING DOCUMENTATION	N/A	
Leak tests results and radiation surveys		
Transportation documents		
Operation, 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
SERVICING				N/A	
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				DEF - QA performed by foreign source supplier (see QA section) OK - updated company names of source suppliers	
Drop ship					
Who and where is source installed					
Leak test and radiation surveys					
QA in the U.S.					

OTHER:
see 8/28/01 def letter

Reviewers:
Michele Burgess MTB
John Jankovich

disposition of def questions:

OK 1. Your March 5 letter informs us that Agilent has not been conducting two tests during fabrication as specified in the registration certificate commitments. Please indicate when this practice started, and report the total number of ECDs involved

OK for the pesticide test since not needed
NA for the ionization current test b/c it is part of QA - review with Q#6, NA - b/c #10 says ISO 9001

OK 2. Please provide full corporate name and address for all source manufacturers.

OK 3. Verify that the changes, described in item 3 of your letter dated March 5, to the metal label attached to the ECD constitute only an addition to the information currently on the label, and that you are not removing any information from the label that was previously specified

OK 4 In reviewing the background information for your products, we discovered that we can not locate a copy of Hewlett-Packard's September 9, 1980, letter referenced in registration certificate NR-0348-D-106-B Please provide a full copy, including any attachments.

OK 5 What is the purpose of the "analysis of a standard pesticide sample"? We need this information to determine whether this test is necessary. **not nec**

OK 6 As a certificate holder for a custom source, via the NR-0348-D-106-S and NR-0348-D-109-S certificates, you are responsible for ensuring that all commitments made regarding the design of the source are carried out. You requested that the "measurement of the ionization current" test be transferred to the source manufacturer. It is our understanding that the "measurement of the ionization current" is used to verify the activity of the cells Please confirm or provide corrected information regarding the purpose of the test. In addition, if the test is used to confirm activity, please provide details regarding how this will be incorporated into your QA program's oversight of the manufacturer in order to ensure that no device exceeds the allowable activity. Regarding the NR-0348-D-111-S certificate, explain how Agilent ensures that all ECDs are distributed with the correct activity if this test is not performed by Agilent

NA - b/c #10 says ISO 9001

OK 7 Your March 9 letter requests a change to "A careful visual inspection of new cells per documented sampling scheme " Please specify the scheme, and describe the visual inspection, or provide the test procedure.

NA - b/c #10 says ISO 9001

OK 8 Your March 9 letter requested a reduction in the visual inspection of the plated surface of the ECDs, from 100% of the units to a sampling plan. Please confirm that the wipe and leak tests will still be performed on every cell

OK 9 Your March 5 letter informed us that Agilent is now ISO 9001 registered. Please indicate whether this is to the American or British standard. If you are indicating that you have begun manufacturing and distributing under this registration, please provide a copy of the ISO registration, and provide a listing of the sealed source and device registration certificates for which the ISO 9001 registered QA program applies. Please note that this would mean that you must continue to manufacture and distribute under the an ISO 9001 registration, and change to that commitment would require an amendment to all registration certificates listed.

OK per policy - do not have to review QA plan, can accept this instead. have them commit that all units will be produced under a current active ISO9001 certificate

OK10 During our review, we noted that the QA plan in the file is dated October 3, 1990. Please indicate whether this is still a current version. If there is a more recent version, please provide a copy along with a list of items that have changed.

NA b/c #10 says ISO 9001 certified

OK11. Although your March 5 letter also lists your four inactive certificates, we do not see any requested changes to these certificates. Please verify that there are no changes requested, or identify the changes requested for your inactive certificates so that we may continue our review.