

REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

INSTRUCTIONS: Send this request AND a copy of all related letters/applications and drawings to the Chief, Sealed Source Safety Section, OWFN Mail Stop O-6 H3. Change the License Tracking System milestone to 19 and assign to reviewer code 1-5.

NOTE: Retain a copy of this request with the application and background files.

REQUESTER Web Research Company		REGION/LOCATION: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> HQ <input type="checkbox"/> LFARB	
TELEPHONE NUMBER 612-328-3714	DATE	TYPE OF ACTION REQUESTED (Check as appropriate) <input type="checkbox"/> SOURCE REVIEW <input type="checkbox"/> AMENDMENT OF REGISTRATION SHEET NUMBER(S) <input type="checkbox"/> DEVICE REVIEW <input type="checkbox"/> CUSTOM REVIEW	
NAME OF APPLICANT Thomas A. Kent			
MAIL CONTROL NUMBER(S)			
LETTER/APPLICATION DATE 10/07/1999	LICENSE NUMBER(S)		

COMMENTS:
7317 Cahill Road #251
Minneapolis, MN 55439-2080

FOR SSSS USE ONLY

REVIEWER Michele Burgess	MODEL NUMBERS MS 9 Series	NUMBER ASSIGNED 99-58
DATE RECEIVED 10/18/1999	DATE ASSIGNED 10/18/1999	DATE TO FEES 10/18/1999

TYPE OF ACTION (Indicate the number of each type)

<input checked="" type="checkbox"/> COMMERCIAL DISTRIBUTION (FORMAL)		<input type="checkbox"/> USE BY A SINGLE APPLICANT (CUSTOM)	
SOURCE (9C)	DEVICE (9A)	SOURCE (9D)	DEVICE (9B)
<input checked="" type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT	<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT	<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT	<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT
<input type="checkbox"/> NO SAFETY EVALUATION REQUIRED NO FEES REQUIRED		<input type="checkbox"/> LICENSING ACTION REQUIRED (IF KNOWN) <input type="checkbox"/> YES <input type="checkbox"/> NO	

OTHER (Specify)
Fee paid in the amount of \$1,580.00. Check #3438

TOTAL NUMBER OF REVIEW HOURS	NUMBER OF DEFICIENCY LETTERS	NOTES New application for Mossbauer sources containing Tin-119m to be distributed only to specific licensees in accordance with 10 CFR 32.210.
NUMBER OF DEFICIENCY CALLS		

FOR FEE USE ONLY

TYPE OF FEE APP		FEE CATEGORY <input type="checkbox"/> 9A <input type="checkbox"/> 9B <input type="checkbox"/> 9C <input type="checkbox"/> 9D	
AMOUNT RECEIVED \$1,580	CHECK NUMBER 3438	DATE OF CHECK 10/13/99	LOG Oct. 1 99 SSD
APPROVED BY Sh		DATE OF RETURN 10/22/99	
COMMENTS			

WEB RESEARCH COMPANY
7317 CAHILL RD. #251
MINNEAPOLIS, MN 55439-2080
(612) 328-3714

**NORWEST BANK
MINNESOTA, N.A.**
EDEN PRAIRIE, MN 55344
17-1/910 - 215

3438

PAY TO
THE ORDER
OF

US Nuclear Regulatory Commission

Date 10/13/1999
\$ **1,580.00

One Thousand Five Hundred Eighty and 00/100*****

DOLLARS
 Security features included. Details on back.

US Nuclear Regulatory Commission
Sealed Source Safety Section
Div. of Industrial & Medical Nuclear Safe
Washington, DC 20555-0001

Thomas G. Hunt MP

Memo SS DR evaluation fee for Category 9C

⑆09⑆0000⑆9⑆ 35⑆7302765⑆

3438

SUMMARY DATA

Name and Complete Mailing Address of the Applicant:

**WEB Research, Co., Inc.
7317 Cahill Road, #251
Minneapolis, MN 55439**

Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:

**Thomas A. Kent, Ph.D., President
(612)328-3714, or
Chris Pirie (Health Physicist consultant)
(800)525-8339**

The Applicant is (check one):

<input type="checkbox"/>	Custom User
<input type="checkbox"/>	Manufacturer
<input checked="" type="checkbox"/>	Distributor
<input type="checkbox"/>	Manufacturer and Distributor

If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:

**RITVERC GmbH
19402
St. Petersburg
2nd Murinsky Avenue, 28
Russia**

note - foreign

If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:

N/A

Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:

**Radiation Safety & Control Services, Inc.
91 Portsmouth Avenue
Stratham, NH 03885**

Health Physics Consultant

Model Number:

MSn-9 Series

Principal Use Code (see Appendix D):

Foil Source (S) (or Gamma Gauge (G)?)

Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):

Mössbauer Effect Source

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:		Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5): 10 CFR 30 specific licensees
	Periodic Leak-Testing is Not Required	
XX	6 Months	Radionuclides and Maximum Activities (including loading tolerance): Sn-119m, 30 millicuries \pm 10 %
	Attached is justification for a leak test frequency of greater than 6 months	
<p>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 ANYMATTER WITHIN ITS JURISDICTION.</p>		
Certifying Officer -- Typed Name and Title <p style="text-align: center;">Thomas A. Kent, Ph.D., President</p>		
Signature: <i>Thomas A. Kent</i>		Date: <i>10/11/99</i>

APPENDIX C

SUMMARY DATA

Name and Complete Mailing Address of the Applicant:		Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:	
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 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:		Principal Use Code (see Appendix F):	
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 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 type="checkbox"/>	6 Months		
<input type="checkbox"/>	Attached is justification for a leak test frequency of greater than 6 months		

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: Also see attached deficiency letter dtd 4/11/00

Model:

DESCRIPTION	OK/DEF	COMMENTS
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?	OK	yes - relative size diff only
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	N/A	
Is source ANSI classification sufficient (from ANSI N542-1977):	✓	<p> 97C 51243 23233 > for the TP Imp VP 23333 Amerkes ↑ 2, 3, 3 Mossbauer \$4344 sources 1L-1365-213 </p> <p> 502919-1980 Chromatography 32211 Static elec 22222 meter Smoke Det 32222 → misc AUS </p> <p> OK But what about the tolerances on the test criteria, anywhere from 2-20%. The tests are minimums, must meet or exceed to claim the class numbers. </p> <p>GOST a ISO? need GOST</p>
Radiography - Unprotected	✓	
Radiography - In Device	✓	
Medical - Radiography	✓	
Medical - γ Teletherapy	✓	
γ Gauges - Unprotected	✓	
γ Gauges - In Device	✓	
β Gauges, Low Energy γ Gauges, or X-ray fluorescence	✓	
Oil Well Logging	✓	
Portable Moist/Density	✓	
Neutron Applications	✓	
γ Irradiators (II, III, IV)	✓	
γ Irradiators (I)	✓	
Static Eliminators	✓	
Smoke Detectors	✓	
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, 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		
Copy of label	✓	<i>descriptive</i>
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	✓	<i>OK</i>
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)		<i>Model name confusion</i>
CONDITIONS OF USE		
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		
Tests methods and conditions (for source and device)	✓	<i>GOST - 150 - need to check against ANSI</i>
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, etc.)		
Conditions: including environments, scatter (product in beam), and use of guards and shields	//	<i>used as unshielded source</i>
Distance from source/surface (per ANSI 538-1979)	//	
Shutter Open and Closed/Source Shielded	//	
Verify radiation surveys for γ radiation meet inv^2 law.	✓	<i>from table in draft very correct</i>
Verify radiation surveys for non- γ radiation have not been calculated using inv^2 law.	//	

phant $\$$ 47.2
 30 1.3
 100 0.1

** check Sr-119m
 type of rad
 thought γ
 * scatter, etc due to
 product in beam?*

C-4

$$I_1 d_1^2 = I_2 d_2^2$$

$$I_1 = I_2 \left(\frac{d_2^2}{d_1^2} \right)$$

$1.3 \frac{30^2}{100} = 46.8 \checkmark$
 $0.1 \frac{100}{30} = 1.11 \checkmark$

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
QUALITY ASSURANCE		
Materials, subassemblies, services		<i>mem of w Russia - lic needs to audit Russia</i>
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		
Fixed, portable, movable, fixed installation but portable source housing		<i>used as unshielded source in a lab-type set-up</i>
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		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	OK ✓	
ACCOMPANYING DOCUMENTATION		
Leak tests results and radiation surveys	✓	<i>need to provide rad prog file info w/ the distribution</i>
Transportation documents		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable	✓	<i>need to provide leak test info to user</i>
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					
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	X		/		
Relocation			/		
Maintenance			/		
Repair			/		
Source Exchange			✓	/	
Calibration				/	
Leak Testing				/	
Radiation Survey				/	
Training				/	
FOREIGN VENDORS					
Drop ship					<i>Russian source material</i>
Who and where is source installed					
Leak test and radiation surveys					
QA in the U.S.					