

CONVERSATION RECORD

TYPE: Outgoing Telephone Incoming Telephone x Meeting			
NAME OF PERSON CONTACTED: Dr. John Patterson	ORGANIZATION: Metorex	TIME: 8:45 am	DATE: 12/15/99
SUBJECT: Extension of due date			
SUMMARY: Dr. Patterson asked on the telephone, in addition to his latter dated December 14, 1999, to extend the due date of Metorex's response to NRC,s deficiency letter. He indicated that Metorex will respond by the end of December 1999, or by January 7, 2000, the latest. I gave him verbal approval on the telephone.			
ACTION REQUIRED: None.			
PLACE THIS RECORD IN: Registration File NR-0701-D-104-B QA File Incident File General File			
PERSON DOCUMENTING THE CONVERSATION: John Jankovich	SIGNATURE: 	DATE: 12/15/99	

NMSS #2 Public

Safety Review
8/26/99 JPF

SUMMARY DATA

Name and Complete Mailing Address of the Applicant: Metorex SSD-99-47		Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: J. Patterson 609-406-9000	
The Applicant is (check one):		If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer: no change	
<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: NA	
Model Number: SPS Probe, NR-0701-D-104-B		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.): X-ray fluorescence analyzer		For Use by:	
		<input type="checkbox"/>	Specific Licensees Only
		<input type="checkbox"/>	General Licensees Only
		<input checked="" type="checkbox"/>	Both Specific and General Licensees
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): no change	
<input checked="" 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:
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CHECKLIST

Registration Certificate Holder:

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?		
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)		<i>def. question</i>
Assembly methods (screw, welds, etc.); verify integrity	✓	
Source mounting (size and integrity) and security		<i>def. question</i>
Is source ANSI classification sufficient (from ANSI N542-1977):		
Radiography - Unprotected 43515	✓	<i>no change</i>
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		<i>no change</i>
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.)		<i>def. question</i>
Shielding efficiency and integrity		
For medical devices: Was a 510(k) provided? (provide written notification to FDA)	<i>NA</i>	
Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991)	<i>NA</i>	
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)		<i>no change</i>

APPENDIX C

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
LABELING		
Copy of label		} no change
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		
Expected working life of the source/device (years, operations)		} no change
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)		} def. question
Tests results		
Years of use (incidents, failures, etc.)		
Similarities to other sources/devices if they are used as basis.	N/A	no change
RADIATION PROFILES		
Survey instrument used (type, window thickness, sensitivity, etc.)	✓	
Conditions: including environments, scatter (product in beam), and use of guards and shields		def. question
Distance from source/surface (per ANSI 538-1979)	✓	
Shutter Open and Closed/Source Shielded		def. question
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.	✓	

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
QUALITY ASSURANCE		
Materials, subassemblies, services		} no change def. question to update
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		} no change
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		} no change
ACCOMPANYING DOCUMENTATION		
Leak tests results and radiation surveys		} no change
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		

APPENDIX C

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				} no change	
Relocation					
Maintenance					
Repair					
Source Exchange					
Calibration					
Leak Testing					
Radiation Survey					
Training					
FOREIGN VENDORS					
Drop ship					} no change
Who and where is source installed					
Leak test and radiation surveys					
QA in the U.S.					

Acceptance Review
7/26/99 JPF

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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: no change	
If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor: NA SIPS Probe		Provide the Name, Complete Mailing Address, and Function of Other Companies Involved: no change	
Model Number: NR-79-D-104-B		Principal Use Code (see Appendix F): no change	
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.): X-ray fluorescence analyzer		For Use by: <input type="checkbox"/> Specific Licensees Only <input type="checkbox"/> General Licensees Only <input checked="" 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): no change	
Radionuclides and Maximum Activities (including loading tolerance): no change			

CERTIFICATION:

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Certifying Officer — Typed Name and Title

Signature:

Date:

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Model:

Amendment, the items with ✓ were reviewed

DESCRIPTION	OK/DEF	COMMENTS
DESCRIPTION/CONSTRUCTION	<i>one</i>	
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):	<i>same</i>	
Radiography - Unprotected 43515		
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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)		
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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)		
Tests results		
Years of use (incidents, failures, etc.)		
Similarities to other sources/devices if they are used as basis.		
RADIATION PROFILES		
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Conditions: including environments, scatter (product in beam), and use of guards and shields		
Distance from source/surface (per ANSI 538-1979)	✓	
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Verify radiation surveys for γ radiation meet inv^2 law.		
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Dimensions and tolerances		
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QA Manual and comparison of manual to Regulatory Guide 6.9		
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		
SAFETY INSTRUCTIONS		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys		
ACCOMPANYING DOCUMENTATION		
Leak tests results and radiation surveys		
Transportation documents		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable		
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Activity	by a General Licensee	Only by a Specific Licensee	Will be Offered by the Applicant		
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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.					