


## CONVERSATION RECORD

<b>TYPE:</b> Outgoing Telephone Incoming Telephone x Meeting			
<b>NAME OF PERSON CONTACTED:</b> Dr. John Patterson	<b>ORGANIZATION:</b> Metorex	<b>TIME:</b> 8:45 am	<b>DATE:</b> 12/15/99
<b>SUBJECT:</b> Extension of due date			
<b>SUMMARY:</b> 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.			
<b>ACTION REQUIRED:</b> None.			
<b>PLACE THIS RECORD IN:</b> Registration File NR-0701-D-104-B QA File Incident File General File			
<b>PERSON DOCUMENTING THE CONVERSATION:</b> John Jankovich	<b>SIGNATURE:</b> 	<b>DATE:</b> 12/15/99	

*NMSS #2 Public*

Safety Review  
8/26/99 JPF

**SUMMARY DATA**

<b>Name and Complete Mailing Address of the Applicant:</b> Metorex SSD-99-47		<b>Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:</b> J. Patterson 609-406-9000	
<b>The Applicant is (check one):</b>		<b>If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:</b>  no change	
<input type="checkbox"/>	Custom User		
<input type="checkbox"/>	Manufacturer		
<input type="checkbox"/>	Distributor		
<input checked="" type="checkbox"/>	Manufacturer and Distributor	<b>If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:</b> NA	
<b>Model Number:</b> SPS Probe, NR-0701-D-104-B		<b>Principal Use Code (see Appendix F):</b>	
<b>Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):</b> X-ray fluorescence analyzer		<b>For Use by:</b>	
		<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
<b>Leak-Test Frequency:</b>		<b>Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):</b>	
<input type="checkbox"/>	Periodic Leak-Testing is Not Required	<b>Radionuclides and Maximum Activities (including loading tolerance):</b> 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**

<b>Signature:</b>	<b>Date:</b>
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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
<b>LABELING</b>		
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)		
<b>CONDITIONS OF USE</b>		
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		
<b>PROTOTYPE TESTING/HISTORICAL USE</b>		
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
<b>RADIATION PROFILES</b>		
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 $\gamma$ radiation meet $inv^2$ law.	✓	
Verify radiation surveys for non- $\gamma$ radiation have not been calculated using $inv^2$ law.	✓	

**CHECKLIST**

**Registration Certificate Holder:**

**Model:**

DESCRIPTION	OK/DEF	COMMENTS
<b>QUALITY ASSURANCE</b>		
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		
<b>INSTALLATION</b>		
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		
<b>SAFETY INSTRUCTIONS</b>		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys		} no change
<b>ACCOMPANYING DOCUMENTATION</b>		
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

APPENDIX C

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<b>The Applicant is (check one):</b> <input type="checkbox"/> Custom User <input type="checkbox"/> Manufacturer <input type="checkbox"/> Distributor <input checked="" type="checkbox"/> Manufacturer and Distributor		<b>If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:</b> no change	
<b>If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:</b> NA SIPS Probe		<b>Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:</b> no change	
<b>Model Number:</b> NR-79-D-104-B		<b>Principal Use Code (see Appendix F):</b> no change	
<b>Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):</b> X-ray fluorescence analyzer		<b>For Use by:</b> <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	
<b>Leak-Test Frequency:</b> <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		<b>Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):</b> no change	
<b>Radionuclides and Maximum Activities (including loading tolerance):</b> no change			

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**Certifying Officer — Typed Name and Title**

**Signature:**

**Date:**

**CHECKLIST**

**Registration Certificate Holder:**

**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		
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		
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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)		
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.)		



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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)		
<b>CONDITIONS OF USE</b>		
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		
<b>PROTOTYPE TESTING/HISTORICAL USE</b>		
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.		
<b>RADIATION PROFILES</b>		
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 $\gamma$ radiation meet $inv^2$ law.		
Verify radiation surveys for non- $\gamma$ radiation have not been calculated using $inv^2$ law.		

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**CHECKLIST**


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

DESCRIPTION	OK/DEF	COMMENTS
<b>QUALITY ASSURANCE</b>		
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		
<b>INSTALLATION</b>		
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		
<b>SAFETY INSTRUCTIONS</b>		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys		
<b>ACCOMPANYING DOCUMENTATION</b>		
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		

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**Model:**

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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		
Installation					
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.					