

From: Seung Lee
To: TSK
Date: Wed, Feb 2, 2000 7:23 AM
Subject: Acceptance Review of SSD 00-02 (NR-702-101-B)

Good morning, Traci!

I performed acceptance review for the amendment request of SSD 00-02 and found it looks OK. If you have any questions, please let me know.

Thank you very much and have a nice day.

Seung

Acceptance Review

2/2/52

SUMMARY DATA

Name and Complete Mailing Address of the Applicant: Metorex, Inc. Princeton Crossroads Corp. Center 250 Phillips Blvd EWing, NJ 08618		Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: John I. H. Patterson, Ph.D., pres. dent 1-609-406-9000, ext 122	
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	Metorex International Oy Niittisillankuja 5 PO Box 85 FIN-02631 ESPOO Finland	
<input type="checkbox"/>	Manufacturer		
<input checked="" 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: N/A		Provide the Name, Complete Mailing Address, and Function of Other Companies Involved: N/A	
Model Number: sups 0494 & 2476		Principal Use Code (see Appendix F): U	
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 checked="" 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	10 CFR 31.5 Radionuclides and Maximum Activities (including loading tolerance): Am-241 30 mCi Cm-244 80 mCi	
<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

John I. H. Patterson P.S.O. / President

Signature: _____ Date: _____

CHECKLIST

Registration Certificate Holder: *DeFonco, Inc.*

Model: *Supr 04842 2076*

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)	✓	
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)	✓	
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>WJA</i>
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	✓	
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)	5-10	
Actions to be taken when product reaches end of its working life.	✓	<i>return to Manufacturer</i>
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	✓	See instruction
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		
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.		
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		
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		
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		
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					
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.				√	

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52

FedEx USA Airbill

FedEx Tracking Number **8131 5881 7501**

RECIPIENT: PEEL HERE

1 From This portion can be removed for Recipient's records.
Date **1/17/00** FedEx Tracking Number **813158817501**

Sender's Name **John I.H. Patterson** Phone **609 406-9000**

Company **METOREX INC**

Address **250 PHILLIPS BLVD**

City **EWING** State **NJ** ZIP **08618**

2 Your Internal Billing Reference **SUPS Registry Amendment Paperwork**

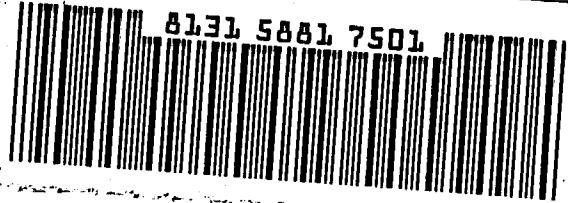
3 To Recipient's Name **USNRC** Phone **800 368-5642**

Company **Materials Safety Branch**

Address **Division of Industrial & Medical Nuclear Safety**

Two White Flint North
11545 Rockville Pike

City **North Bethesda** State **MD** ZIP **20852**



Form I.D. No. **0215** **SFA33** **Recipients Copy**

4a Express Package Service
 FedEx Priority Overnight
 FedEx Standard Overnight
 FedEx 2Day
 FedEx Express Saver

4b Express Freight Service
 FedEx 1Day Freight
 FedEx 2Day Freight
 FedEx 3Day Freight

5 Packaging
 FedEx Letter
 FedEx Pak
 Other Pkg.

6 Special Handling
 Saturday Delivery
 Sunday Delivery
 HOLD Weekday at FedEx Location
 HOLD Saturday at FedEx Location
Does this shipment contain dangerous goods?
 No
 Yes
Dry Ice
Cargo Aircraft Only

7 Payment **B/E**
 Sender
 Recipient
 Third Party
 Credit Card
 Cash/Check

Total Packages **1**
Total Weight **3**
Total Charges

8 Release Signature Sign to authorize delivery without obtaining signature.

0099303826

359

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.
Questions? Call 1-800-Go-FedEx (800-463-3339)
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SFS 499 Rev. Date 11/98 Part #1548135 ©1994-98 FedEx PRINTED IN U.S.A.

CONVERSATION RECORD

TYPE:

Outgoing Telephone X
Incoming Telephone
Meeting

NAME OF PERSON CONTACTED:
John Patterson, President

ORGANIZATION:
METOREX Inc.

TIME:
2:30PM

DATE:
12/10/99

SUBJECT: The licensee stated his assumption that NRC apparently dropped SUPS Probe from the Registration Certificate NR-701-D-104-B. (This certificate was originally issued as TX227D101G, on August 12, 1988 and subsequently amended a number of times to accommodate transfers and product changes additions.)

SUMMARY: Metorex believes that SUPS Probe, which was registered as a part of Model 880 Analyzer in the past by Metorex's predecessors but appears to have been dropped as the registration certificate was revised and reissued to the succeeding distributors, is not included in Metorex's current registration and distribution license. Consequently, some previous distributions of the SUPS Probe appear inconsistent with Metorex's license.

After reviewing the amendments of the registration and discussions with Brian Smith and Susan Green I called Mr. John Patterson. I told John that the connection between the language of the registration certificate associated with the issues in question and subsequent cross reference to probe models could not be established with a certainty. John agreed with this assessment. I suggested to John and he agreed that more constructive action would be as indicated under the action required title.

ACTION REQUIRED:

1. Metorex will submit the names and addresses of the licensees who currently have SUPS Probe.
2. Metorex will submit an application and required information to include SUPS Probe in their registration certificate. John stated it will take him a couple of weeks to submit the application and licensee related information.
3. NRC SSD Registration Assistant to close out case 93-63.

PLACE THIS RECORD IN: Registration File NR-701-D-101-B
QA File
Incident File
General File NE01
cc. Traci Kime

PERSON DOCUMENTING THE CONVERSATION:
Ujagar S. Bhachu

SIGNATURE: 

DATE:
12/16/99

REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

INSTRUCTIONS: Send this request AND a copy of all related letters/applications and drawings to: The Sealed Source Safety Section, ATTN: Chief, OWFN Mail Stop 6 H3. Change the License Tracking System milestone to 19 and assign to reviewer code I-5.
NOTE: Retain a copy of this request with the application and background files.

REQUESTER <i>Metorex Inc.</i>		REGION/LOCATION: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> HQ <input type="checkbox"/> LFDCB	
TELEPHONE NUMBER	DATE	TYPE OF ACTION REQUESTED (Check as appropriate)	
APPLICANT'S NAME <i>John Patterson</i>		<input type="checkbox"/> SOURCE REVIEW	<input checked="" type="checkbox"/> AMENDMENT OF REGISTRATION SHEET NUMBER(S)
MAIL CONTROL NUMBER(S)		<input type="checkbox"/> DEVICE REVIEW	
LETTER/APPLICATION DATE <i>1-14-2000</i>	LICENSE NUMBER(S)	<input type="checkbox"/> CUSTOM REVIEW	<i>NR-701-D-101-B</i>

COMMENTS:
*Princeton Crossroads Corporate Center
250 Phillips Boulevard
Living, New Jersey 08618*

FOR SSSS USE ONLY

REVIEWER <i>Seung Lee</i>	MODEL NUMBERS <i>SUPS 0484, SUPS 2476</i>	NUMBER ASSIGNED <i>00-02</i>
DATE RECEIVED <i>1-18-00</i>	DATE ASSIGNED <i>1-24-00</i>	DATE TO FEES <i>1-24-00</i>

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 type="checkbox"/> NEW AMENDMENT	<input checked="" type="checkbox"/> NEW AMENDMENT	<input type="checkbox"/> NEW AMENDMENT	<input type="checkbox"/> NEW AMENDMENT
<input checked="" type="checkbox"/> NO SAFETY EVALUATION REQUIRED NO FEES REQUIRED		<input type="checkbox"/> LICENSING ACTION REQUIRED IF KNOWN	
<input type="checkbox"/> OTHER (Specify)		YES NO	

TOTAL NUMBER OF REVIEW HOURS	NOTES <i>Amendment to restore the SUPS Probe in above noted registry.</i>
NUMBER OF DEFICIENCY LETTERS	
NUMBER OF DEFICIENCY CALLS	

FOR BILLING PURPOSES ONLY

<input type="checkbox"/> NAME CHANGE	<input type="checkbox"/> ADDRESS CHANGE	<input type="checkbox"/> NEW REGISTRATION -- ADD TO BILLING	<input type="checkbox"/> PRODUCT INACTIVE -- REMOVE FROM BILLING
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FOR FEE USE ONLY

TYPE OF FEE	FEE CATEGORY <input type="checkbox"/> 9A <input type="checkbox"/> 9B <input type="checkbox"/> 9C <input type="checkbox"/> 9D			
AMOUNT RECEIVED	CHECK NUMBER	<input type="checkbox"/> MATANN UPDATED AS REQUIRED		
DATE OF CHECK	LOG	<input type="checkbox"/> MATSYS UPDATED AS REQUIRED		
APPROVED BY	DATE RETURN	DATE		

COMMENTS