

February 15, 2000

Dr. John I. H. Patterson, President
Metorex, Inc.
Princeton Crossroads Corporate Center
250 Phillips Boulevard
Ewing, NJ 08618

Dear Dr. Patterson:

This letter is in response to your request dated January 14, 2000, requesting an amendment to registration certificate NR-0701-D-101-B to include SUPS 0484 and SUPS 2476 probes. In reviewing the application, we find that it is lacking significant amounts of the required information. In an Enclosure to this letter, we have summarized the major issues not addressed in your application.

With incomplete documents and unavailability of adequate information the NRC Staff is unable to complete a safety evaluation of your devices. Therefore, we have discontinued the review of your application. This is without prejudice to re-submission of your application. If you decide to re-submit your application for registration, please ensure that you have included sufficient information to allow NRC to evaluate your device and similar instruments.

If you have any questions, please call me on (301) 415-7273 or Seung J. Lee of my staff on (301) 415-5787.

Sincerely,

original signed by: John Jankovich for:

Frederick C. Sturz, Section Leader
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

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ENCLOSURE

The issues below have not been adequately addressed in the application dated January 14, 2000.

1. Your letter dated November 12, 1999, Attachment 1 of your application makes a reference to Enclosures 1 through 4. These enclosures are missing from your submission. Please provide a copy of the enclosures.
2. The manufacturer's address in p1 of Attachment 3 is different from the registration certificate NR-701-D-101-B. Please clarify this apparent discrepancy.
3. Your Attachment 1 suggests that Columbia Scientific Instruments requested registration and safety evaluation for general license only. However, the registration certificate NR-701-D-101-B is for both specific and general licensees. Please clearly state the type of license you are seeking for SUPS Models 0484 and 2476.
4. What does SUPS stand for?
5. The section entitled, "Practical Safety Aspects in the Use of the SUPS Probe," p5 of Attachment 3 stated that "The probe must be used by only a person who have been trained to operate the probe so that they do not cause radiation danger to themselves or to the nearby people." As a generally licensed device, the SUPS should be redesigned so that the device can be safely operated by persons not having training in radiological protection according to 10 CFR 32.51(a)(2)(i).
6. The section entitled, "Practical Safety Aspects in the Use of the SUPS Probe," p5 of Attachment 3 stated that "[i]f the shutter has not fully covered the source the measuring window must be covered by at least 1 mm thick lead plate and the probe must be sent for repair." Please provide packing, transportation, receipt inspection for return of sources to the manufacturer and/or disposal of damaged instruments.
7. From your application it is not clear as to which SUPS model the attached photograph applies.
8. Provide the radiation profiles with shutter open and closed in the SUPS Probe at 5, 10, and 30 cm.
9. The Measurements of the radiation profiles section on p44 of Attachment 3 stated that "[r]eadings were taken both shutter closed and having 2.5 m thick stainless steel sample as an ordinary sample." Was a 2.5 m thick stainless steel sample actually used?
10. Provide an external radiation dose or dose commitment under accident conditions (such as fire and explosion) as specified in 10 CFR 32.51(a)(2)(iii).
11. Add the words "CAUTION - RADIOACTIVE MATERIAL" on Label 1 shown on p11 of Attachment 3 as specified in 10 CFR 32.51(a)(3)(iii).

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12. Please state how your serial numbering system will differentiate the new devices from the old ones.
13. As a generally licensed device, the SUPS should have tamper-resistance hardware or assembly method. Provide the locations and methods of tamper-proof in Construction of the Probe section on p6 of Attachment 3.
14. Please provide for SUPS Models shutter: manufacturer's name, reliability, historical data, and specifications, as provided for the other Models.
15. Please provide results of prototype testing that demonstrates the effectiveness of the containment, shielding, and the safety features under both normal and likely accidental conditions of handling, storage, use, and disposal of this product. Please provide the tests and procedure used. Also, provide details on the drop, impact, and temperature testing associated with transportation of the product.
16. The distributor should ascertain and document annually that the manufacturer maintains the ISO 9001 qualifications. Provide a copy of the ISO 9001 certificate of the manufacturer in your application.
17. Provide an inspection procedure to ensure, prior to distribution, that:
 1. Correct labeling on the device and inclusion of correct user manual/materials
 2. Tamper-resistance hardware is in place as described in the application
 3. Overall device appearance
 4. Device safety features function properly
 5. Review the paper work documenting QA/QC and leak testing from the manufacturer to ensure that all required was completed properly and that leak test was done within 6 months.
18. Only the following part drawings are provided:
 1. in Figure 1, parts 1, 3, 4, 5, 6, 7, and 9;
 2. in Figure 5, parts 1, 4, 6, 7, 13, and 14;
 3. In Figure 12, part 12.

Please provide the missing part descriptions and drawings in Figures 1, 5, and 12. Please indicate on the drawings the units of measures and weights.
19. Please provide the English translation of the text for Figures 2, 4, 6, 7, 8, 11, 12, 16, 17, 18, and 19.
20. Revise the SECTION ON RADIATION SAFETY AND REGULATIONS (GENERAL LICENSE) and X-MET 880 OPERATING INSTRUCTION MANUAL to include SUPS Models 0484 and 2476. In addition, the document contains a large number of erroneous statements and outdated information throughout its text. You may contact us directly to discuss some of these issues.
21. SAFETY INSTRUCTIONS FOR SUPS PROBE states that "[t]he probe may be operated only by a person who is trained to use the probe, or under the supervision of a trained

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person." For generally licensed devices, there is no such requirement in the provisions of 10 CFR 32.51(a)(2)(i). Revise this statement.

NRC FORM 567
(8-93)

U. S. NUCLEAR REGULATORY COMMISSION

*Rejected
2-15-2000*

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>Motorex, 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>SURS 0484, SURS 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"/> YES <input type="checkbox"/> NO
<input type="checkbox"/> OTHER (Specify)			

TOTAL NUMBER OF REVIEW HOURS	NOTES <i>Amendment to restore the SURS 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 <i>Fee not required</i>	FEE CATEGORY <input type="checkbox"/> 9A <input type="checkbox"/> 9B <input type="checkbox"/> 9C <input type="checkbox"/> 9D		
AMOUNT RECEIVED <i>Per 8/2 (99) rule.</i>	CHECK NUMBER	<input type="checkbox"/> MATANN UPDATED AS REQUIRED	
DATE OF CHECK	LOG <i>Feb. 20 15:00</i>	<input type="checkbox"/> MATSYS UPDATED AS REQUIRED	
APPROVED BY <i>SL</i>	DATE RETURN <i>2/14/00</i>	DATE	

COMMENTS

NRC FORM 567
(8-83)

U. S. NUCLEAR REGULATORY COMMISSION

*Rejected
2-15-2000*

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

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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)		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		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 <i>Fee not required</i>	FEE CATEGORY <input type="checkbox"/> 9A <input type="checkbox"/> 9B <input type="checkbox"/> 9C <input type="checkbox"/> 9D	
AMOUNT RECEIVED <i>Rec 8/9/99 Rec'd</i>	CHECK NUMBER	<input type="checkbox"/> MATANN UPDATED AS REQUIRED
DATE OF CHECK	LOG <i>26.001 SC+D</i>	<input type="checkbox"/> MATSYS UPDATED AS REQUIRED
APPROVED BY <i>SH</i>	DATE RETURN <i>2/14/00</i>	DATE

COMMENTS