UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 28, 1995

Mr. Stanislaw Piorek, Ph.D.
Vice President
Research and Technology Development
Metorex, Inc.
860 Town Center Drive
Langhorne, PA 19047

Dear Mr. Piorek:

This letter is a follow-up to our meeting on March 14, 1995, in which we discussed several issues pertaining to your registered devices, and reporting requirements for transfers of devices to persons generally licensed. The following is our understanding of the issues discussed and the commitments made to ensure compliance with the regulations:

1. In April of 1993, registration certificate NR-0701-D-101-G was issued for the Models HEPS, LEPS, DOPS, SAPS, SSPS, and SLPS X-Ray fluorescence (XRF) probes. A result of the issuance of this certificate was to re-focus the safety review on the actual probes (as compared to the previously registered 820, 840, and 880 XRF systems) as they contain the licensable material and are wholly separable from the electronics package of the analysis system. In the previous configuration, the accountability of the licensable material was limited as each probe was labeled with the system model number (820, 840, or 880) and each system could contain more than one probe. A result of labeling each probe as a separate device is that the accountability of the licensed material is greatly increased. However, review of your quarterly transfer reports submitted in accordance with 10 CFR 32.52 since April 1993 indicates that model numbers for the probes have not been included in the reports.

   Starting with your next quarterly transfer report, you committed to revising the report to include the specific probe model numbers as indicated on the device label.

2. You indicated during the meeting that probes that had undergone source change with no change in isotope or increase in initial activity had been reported as initial transfers in your quarterly transfer reports. You also indicated that the general licensees in those cases did not report the devices as being returned in accordance with 10 CFR 31.5. Please note that persons specifically licensed under 10 CFR 32.51 to distribute devices to persons generally licensed under 10 CFR 31.5, who receive devices from general licensees for source exchange, with no change in isotope or increase from initial activity, are not required to report the redistribution of the device as an initial transfer in accordance with 10 CFR 32.52. Likewise, the general licensee would not be required to report the transfer in accordance with 10 CFR 31.5. However, in cases where there is a change in isotope or an increase from the initial activity of the source, or in which the device is redistributed to another general licensee, the distributor would be

NE01

required to report the redistribution as an initial transfer in accordance with 10 CFR 32.52, and the general licensee would be required to report the transfer in accordance with 10 CFR 31.5.

Starting with your next quarterly transfer report, you committed to no longer reporting transfers of devices, received for source exchange with no change in isotope or increase from the initial activity, returned to the same general licensee, and not reported as a transfer by the general licensee in accordance with 10 CFR 31.5, as initial transfers. You also committed to providing additional guidance to general licensees on when a transfer must be reported under 10 CFR 31.5, and to provide a copy of the guidance to this office for incorporation into your registration file.

Although not required of Metorex, in cases where a general licensee is required to report a transfer in accordance with 10 CFR 31.5, you may wish to consider indicating on your quarterly transfer report that the device has been transferred to Metorex by the general licensee. This additional information would not be entered into the NRC general license tracking database (the database), but would only be used as a cross reference to the report required to be submitted by the general licensee.

3. A question was raised as to how Metorex should re-label and report devices returned by a general licensee for source exchange that were originally labeled as a Model 820, 840, or 880. The following procedures may be used by Metorex in these situations:

   a. Devices for which there is no change in isotope or increase from initial source activity, and returned to the general licensee as a replacement device in accordance with 10 CFR 31.5 (not relabeled):

      - Metorex would not be required to report the exchange as an initial transfer under 10 CFR 32.52.

      - The general licensee would not be required to report the exchange as a transfer under 10 CFR 31.5.

   b. Devices for which there is no change in isotope or increase from initial source activity, and that are relabeled and returned to the general licensee:

      - Would be required to be relabeled according to the current convention approved in the device registration certificate.

      - Metorex would be required to treat the exchange as an initial transfer and report the transfer in accordance with 10 CFR 32.52. In addition to the information required in 10 CFR 32.52, the report should contain a statement that the [old model number] has been replaced with the [new model number], and should include the date of initial transfer of the old model number.

- If the serial number of the probe is changed, both the old and new serial numbers would need to be provided.

- The general licensee would not be required to report the exchange as a transfer under 10 CFR 31.5.

c. Devices for which there is a change in isotope or an increase from initial activity, or that are not returned to the same general licensee as a replacement device according to 10 CFR 31.5:

- Would be required to be relabeled according to the current convention approved in the device registration certificate, but would not be required to be assigned a new serial number.

- The general licensee returning the device to Metorex would be required to report the transfer in accordance with 10 CFR 31.5.

- Upon redistribution, Metorex would be required to report the transfer of the device in accordance with 10 CFR 32.52.

4. As discussed in the meeting, the issues described in points 1 and 2 above indicate that information provided in your quarterly transfer reports between April 1993 and the date of your last quarterly transfer report is incorrect in some cases. Therefore, you committed to submitting a "correction report" coincident with your next quarterly transfer report. This report will contain corrected information as indicated above for these dates. In addition, if redistributions or initial transfers, as discussed in item 3 above, occurred and were not reported by Metorex in accordance with 10 CFR 32.52, corrected information for these transfers should also be submitted in your "correction report."

5. You requested a clarification as to who would be considered as an appropriate point of contact for the general licensee for inclusion in the quarterly transfer reports. This person should be an individual who has the responsibility for maintaining control over the device and for the maintenance and servicing of the device. As discussed in our meeting, it is considered sufficient to provide either an individual's position or the specific name of the person currently in that position as the point of contact. In addition to providing this information, you committed to providing the point of contact's phone number, whenever possible.

6. The following information was requested in order to update our files, and you committed to supplying the information, as available:

a. Updated drawings of the source holder and associated mountings for the Courier 10 and 20 models.

b. Updated user's manuals for all devices.

7. You committed to addressing the issue of restricting access to the sealed source for general licensees and to providing additional information for review, as necessary.

8. You committed to providing complete information for review as to the differences between the labeling of devices intended for distribution to persons specifically and generally licensed.

9. Several issues associated with the quality assurance and control (QA/QC) programs of both the manufacturers of the devices and Metorex were discussed. You committed to providing complete information on each program, as applicable. In addition, you committed to providing a schedule for submission of this information for review and the proposed time frame for implementation of each program. Upon receipt of acceptable programs, this information will be incorporated into your registration file. To assist you in this process, I have enclosed Policy and Guidance Directive 6.9, "ESTABLISHING QUALITY ASSURANCE PROGRAMS FOR THE MANUFACTURE AND DISTRIBUTION OF SEALED SOURCES AND DEVICES CONTAINING BYPRODUCT MATERIAL," for your review and use.

In addition to the above, you indicated that you will be contacting the NRC Region I office to amend your license to specifically call out the X-MET probe model numbers and approved isotopes, as indicated on your registration certificate. As suggested in the meeting, you may wish to include a reference on your license to the previous model numbers (820, 840, and 880) and a statement that the probes were previously distributed as these model numbers, for clarity purposes. The regional staff would also be able to advise you if any of the commitments discussed in this letter require licensing action.

If you have any questions or feel our understanding of the commitments made during the meeting differ from your understanding, please contact me at (301) 415-5847 or Mr. David Tang at (301) 415-5799.

Sincerely,

Original Signed by

Douglas A. Broaddus, Mechanical Engineer
Sealed Source Safety Section
Source Containment and
Devices Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosure: As stated

Distribution:

SSSS Staff SCDB r/f SSD-94-40 NE01

SSD File # NR-0701-D-101-G

DOCUMENT NAME: C:\WPDOCS\SSDS\INACTIVE\METOREX.MTG

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	SCDB	C	SCDB	C					
NAME	DABroaddus		DTTang						
DATE	03/29/95		03/29/95						

OFFICIAL RECORD COPY