



October 11, 1999

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**(64FR40295)**

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Secretary  
U.S. Nuclear Regulatory Commission  
Washington DC 20555-0001

AD...

RE: Proposed Changes to 10 CFR Parts 30, 31, 32, 170, and 171

Dear Secretary:

As a distributor of generally licensed devices, Metorex Inc. is deeply concerned about the proposed changes to the regulations within 10 CFR Parts 30, 31, 32, 170 and 171. These are as follows:

1. Metorex feels very strongly that all of the changes to Section 31.5 must have a classification of Category B for Agreement State Compatibility, as these changes will have distinct trans-boundry implications.

Section 31.5 establishes the General License for people purchasing, leasing, or otherwise possessing systems for the determination of quantitative or qualitative chemistry. Section 31.6 establishes the General License for Agreement State Specific Licensees to install and service Section 31.5 gauges within non-Agreement States.

**Category C for Agreement State compatibility is inappropriate because these General Licenses (and the restrictions they contain) have major and direct trans-boundary implications.**

To illustrate this with a real example, consider the State of New York. New York recently adopted regulations different from the existing or proposed NRC regulations in Section 31.5. (Note that affected firms based outside New York had no advance notice of this regulatory change and no opportunity to comment.)

Under the regulations that are New York's current version of 10 CFR 31.5, Industrial Code Rule 38.41(b), certain devices (gamma gauges, Sr-90, transuranics) may no longer be possessed under a General License within the State of New York.

This change affects some of our New York customers who have been required to apply for and obtain Specific Licenses for these gauges. Metorex and our competitors will be affected in terms of providing additional customer support for licensing, assuring shipments don't occur before we have Specific License verification, and added record keeping.

Acknowledged by card

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METOREX INC.



If, under Category C compatibility for 10 CFR 31.5, other Agreement States eliminate the General License for certain gauges, those states and the out-of-state service providers working within those states will be involved in the time-consuming process of negotiating new Specific Licenses (in duplication of existing licenses). This will not be a trivial undertaking, as the licenses that are generally quite complex.

Based on these trans-boundary licensing considerations, Metorex believes that it is inappropriate under current NRC guidelines to classify Sections 31.5 as Category C for Agreement State compatibility. We urge that Sections 31.5 and 31.6 be classified as Category B for Agreement State compatibility.

**Category C for Agreement State compatibility is counter-productive in terms of safety because** just as regulatory agencies do not have unlimited personnel and resources, firms that manufacture, distribute, and service 10 CFR 31.5 type gauges are also faced with real limits. The time radiation safety personnel spend attempting to comply with any Agreement States' unique versions of 10 CFR 31.5 (and 31.6) is directly at the expense of efforts that are meaningful to product safety, to training, to following up with customers who have not returned devices, etc.

Likewise, if Category C is designated for compatibility, regulators in Agreement State are likely to spend significant time and resources developing variations on NRC's 10 CFR 31.5 wording. Agreement State agencies are also likely to spend significant time and resources in processing licenses applications for activities and procedures that were already thoroughly reviewed by NRC or other Agreement States.

To use a concept popular in business today, the time radiation safety professionals (employed by licensees and by regulatory agencies) spend applying for, processing, and issuing Agreement State service licenses to duplicate existing NRC or Agreement State licenses is non-value-added in terms of safety.

Based on promoting the best use of resources in the interest of overall safety, Metorex urges that Sections 31.5 and 31.6 be classified as Category B for Agreement State compatibility.

2. Metorex recommends that the term "replacement device" in section 31.5(b)(8)(ii) be better defined. Does this term imply a replacement of one device with an identical device or is it simply replacement with a like device which is also generally licensed? Further, if the "replacement device" is identical, is it expected to have the same source serial number?
3. Metorex feels that it should be possible for a non-employee to be the responsible individual for a registered device, Section 31.5(c)(12). In many cases, a small company holds the device and the concepts of the regulations are not well enough understood by the management of the company. Hiring a consultant would greatly improve their awareness of the regulations and would better achieve the goals of this



regulation. Section 31.5 (c )(12) points out that appointment of this individual does not relieve the general licensee of the responsibility for enforcement of the conditions of the license.

4. Metorex is concerned about the requirement in the new paragraph 31.5(c )(13)(ii) that the user will be required to respond to the notification within 30 days. In the first round of notifications, this requirement could cause substantial burden for the manufacturers and distributors. As the NRC already recognizes, there are many general licensees who do not realize the requirement(s) imposed by a general license. These users will contact the manufacturers and/or distributor of the device and look for assistance in providing the required information. If all the notifications are mailed simultaneously, this may cause an undue burden on the supplier. We hope that this will be taken into account and that the NRC will provide the extra time required for the first round of registrations.
5. Metorex is concerned about the implication of the change to 32.51a(a) and (b). This change requires notification prior to the transfer of the generally licensed device and the comments suggest using the words "prior to purchase". Clarification is required regarding the method and extent of the notification. Is the proof of mailing such a notice prior to the shipment of a unit sufficient or is a document signed by a responsible individual required. Further, the phrase "prior to purchase" is ambiguous. In most cases, there are many steps in the purchase process, the quotation, the order the delivery and finally the invoice. In other cases, the devices are not purchased, but rather leased. In all of these cases, the point of "purchase" is ambiguous. Thus, Metorex feels that the proper point of notification is prior to the transfer.
6. Metorex strongly supports the concept of a National Database for all licensed devices instead of multiple databases created and maintained by the NRC and individual Agreement States. A National database will give the interested community one source of information regarding any licensed device. This will ultimately be much more efficient (and less costly) than maintaining multiple separate databases. Metorex currently supplies all of the requested information in the quarterly reports and in fact routinely supplies the serial number of the source installed in the device. Thus, we would have no objection to including this piece of information as it could help locate the licensee of a source that is discovered in an inappropriate location.

In addition, Metorex urges the NRC to move as quickly as possible to the electronic submission of all the information required on the quarterly reports. Most manufacturers and distributors of the generally licensed devices currently have the information in a computer database. The transcription of the information to printed reports and then entry into a central database can result in substantial errors. In addition, the use of electronic reporting will substantially reduce the amount of time (and thus the cost) required to report the information both on the part of the NRC and the reporting company.



7. Metorex is opposed to the concept of requiring a backup individual for the responsible individual. First, the requirement of a backup would make this class of registration more restrictive than the current specific license. Further, many generally licensed devices are possessed by very small companies and the inclusion of a backup individual would be impractical.

We welcome this opportunity to comment on the issues outlined above. If you have any comments or questions, please feel free to call me at (609) 406-9000 x122 or e-mail me at [John.Patterson@MetorexUSA.com](mailto:John.Patterson@MetorexUSA.com).

Sincerely,

A handwritten signature in black ink, appearing to read 'John I.H. Patterson'.

John I.H. Patterson, Ph.D.  
President