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To	MR. B. BAGGETT	From	MR. G. BUENET
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Mr. Steven L. Baggett
Section Chief
U.S. Nuclear Regulatory Commission
Sealed Source Safety Section
Division of Industrial and Medical Nuclear Safety
Washington, D.C. 20555

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Request for Clarification

Dear Steve,

IMS has received contradictory interpretations of NRC regulations regarding distribution licenses, site licenses, and device registrations. The two scenarios described below are presented to illustrate the difference in the regulatory opinions we have received in the past months. We believe the interpretation illustrated in Scenario 2 is correct. It would be helpful if you could provide an authoritative opinion regarding these issues as they pertain to the startup of new IMS equipment in the United States.

Scenario 1:

It has been suggested in the past that IMS is not permitted to install new equipment containing radiation sources at a customer site until at least four conditions have been fulfilled, namely:

- the customer has a site license for the device to be installed
- IMS possesses an NRC device registration for the device to be installed
- IMS has a distribution/service license permitting us to perform the installation
- the site licensee and IMS concur that conditions stipulated in the IMS Radiation Safety Checklist are satisfied

Scenario 2:

It has also been suggested that IMS could begin installation and commissioning of a new device, provided that IMS has permission according to our license to possess the sources in question. According to this interpretation it is IMS, and not the site licensee, that possesses the sources during installation and commissioning. In this case, IMS retains exclusive control of and access to the radiation sources during installation and startup, and IMS would retain this exclusive control until:

- the system installation was complete
- the site license for the installation has been issued
- the device to be installed has been assigned an NRC device registration
- the site licensee and IMS concur that conditions stipulated in the IMS Radiation Safety Checklist are satisfied

Only after these conditions were fulfilled would IMS be allowed to relinquish control and possession of a device containing sealed radiation sources to a site licensee end-user. At this point IMS would literally "hand over the keys to the gauge" to the end-user.

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A significant difference between Scenario 1 and Scenario 2 is the timing of events. *Under Scenario 2, IMS could begin installation and commissioning of a device before the device is registered and before the end-user has obtained a site license.* A typical gauge installation and commissioning requires about three months to complete. During this period the radiation sources could be brought on site, provided that IMS has a license to possess the sources. In cases where regulatory approval is pending, Scenario 2 shortens the time required to bring new equipment into production.

We believe this interpretation of the regulations is correct because:

- IMS has not distributed the device until the keys are handed to the end user.
- The end-user does not yet possess the device during commissioning.
- During startup and commissioning the end-user is not yet necessarily equipped to assume responsibility for the radiation safety of the device. The device is not yet fully operational and the end-user personnel have not necessarily completed all their radiation safety training for the device.
- Under scenario 2 it is clear that IMS has the authority and responsibility to implement radiation safety measures on-site during commissioning. We submit that this unambiguous authority and responsibility are essential to site safety during system installation and commissioning.

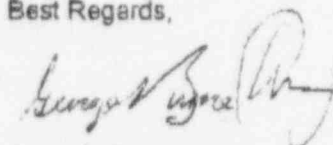
As a specific example for which clarification would be helpful we consider the pending startup of the **IMS Model 5321 Tube Gauge at Timken Steel in Canton, Ohio (Region III)**. We anticipate issuance of a device registration for this gauge in the first quarter of 1996. Timken has already applied for a site license for this installation. Region III has informed Timken that a site license should follow a few days after the device registration is issued.

IMS has the following questions pertaining to this installation. We hope these questions will serve to clarify the issues described above.

1. Could IMS legally have the sources shipped to the site *now* for the purpose of gauge commissioning, provided that:
 - IMS Inc. has a license to possess the sealed sources used in this gauge, and
 - IMS uses an approved lock-out device to maintain control of the device and to prevent access to the sources?
2. Does the NRC concur that IMS, and not Timken Steel, would possess these sources during gauge installation and startup?
3. Does the NRC concur that IMS, rather than Timken Steel, has the authority and responsibility to implement and maintain radiation safety measures at the installation site until the system can be turned-over to Timken Steel?

Please feel free to contact me to discuss this. Thank you for your help with this matter.

Best Regards,



George Burnet, VI
General Manager, IMS Inc.

cc: Sue Engelhardt, Engelhardt & Associates