



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

September 19, 1996

George Burnet, VI
General Manager
Isotope Measuring Systems, Inc.
108 Blue Ridge Drive
Cranberry Twp., PA 16606

Dear Mr. Burnet:

This responds to your facsimile dated December 20, 1995, and subsequent telephone conversations, requesting clarification of several issues concerning the requirements for the transfer of devices containing sealed sources from IMS (transferor) to a site licensee (receiver), and the installation of those devices.

Your letter posed two scenarios regarding the interpretation of when a transfer is considered to have been made and when a licensee is considered to be in possession of a device containing a sealed source, and asked which of these scenarios is, pursuant to NRC regulations, the correct interpretation. It is important to first note that the point at which licensed material is legally transferred from one licensee to another is based on the specific circumstances of the physical transfer in light of the applicable regulations governing this activity (i.e., 10 CFR Parts 30, 32-36, and 39, or Agreement State equivalents), as well as the specific conditions of both parties' licenses (please keep in mind that this discussion pertains to specific licensees, although some of it may also pertain to general licensees). Section 30.34 of 10 CFR specifies the terms and conditions of licenses issued by the NRC. In particular, paragraph (c) of this section specifies, in part, that "Each person licensed by the Commission ... shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license." Therefore, the activities listed in your example -- installation of a gauge at Timken's facility prior to issuance of a registration certificate to IMS and licensure by Timken -- would be allowed only if specifically authorized by regulation and by IMS's license, where "transfer" has not taken place since Timken is not yet licensed. If the installation occurs in an Agreement State, this activity would also need to be in accordance with the Agreement State's regulations.

Your analysis that scenario 2 is the correct interpretation of NRC regulation is basically correct. The following would apply to the specific activities listed in your scenario 2 and the activities described in your example, and are numbered to correspond to your specific questions:

1. IMS may deliver licensed material (sealed source) to a facility, prior to that facility being licensed to receive and possess the material or to issuance of a registration certificate for the device into which the sealed source is to be installed, when:
 - a) IMS has a specific license authorizing receipt and possession of the sealed source at the facility, and
 - b) IMS possesses, and maintains control over, the material at the facility until:
 - (1) the facility is authorized by license to receive and possess the material; and
 - (2) IMS transfers possession and control of the material to the licensee.

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The same objective could be accomplished if the facility was authorized by license or exemption to receive and possess the sealed source.

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In either case, prior to installing a device containing a sealed source at a facility, IMS must be specifically authorized by license to perform this activity. In addition, a lock-out device, as mentioned in your letter, can only be used by IMS to maintain control over licensed material at a facility if the lock-out device and associated procedures are specifically approved and authorized on IMS's license. Specifications of the lock-out device and the lock-out procedures must be reviewed by the regional licensing staff and found to be adequate to maintain control over the material, restrict access for the purposes of protecting persons from undue risks from exposure to the material, and be in accordance with the requirements in 10 CFR part 20. IMS would, at all times, be fully responsible for the safe control and use of the licensed material until it was transferred to the licensee.

2. In the event that the requirements of (1.) above are met, IMS would be considered the possessor of the sealed source at the facility until such time as:
 - a) The facility is authorized by license to receive and possess the material, and
 - b) IMS relinquishes control of the material and transfers possession of it to the licensee, and
 - c) IMS notifies the licensee that the material has been transferred to it, and
 - d) The licensee accepts the material and its possession and control, and
 - e) The transfer and receipt of the material are in accordance with the conditions and requirements of IMS's and the facility's licenses and any applicable registration certificates, and in accordance with the regulations of the NRC and/or Agreement State, as applicable.

The amount of time IMS could be authorized to possess the sealed source at the facility prior to its transfer would be limited by IMS's approved installation and lock-out procedures, any specific limitations on the facility's license, and by any Agreement State reciprocity time limitations (typically 180 days).

3. As indicated in 1. and 2. above, IMS could only be authorized to maintain radiation safety measures at the installation site if these activities are specifically approved on IMS's license and the governing authority's regulations. However, IMS would be, at all times, fully responsible for ensuring radiation safety and control over licensed material it possesses and uses.

If you would like to have the specific activities listed in your letter approved as authorized activities for IMS, you should submit an application for amendment to your specific license to the NRC Region I office for review. This application must contain all specific activities you wish to have approved, applicable procedures that will be followed, and descriptions of any lock-out devices to be used.

To summarize:

- (i) A person who receives, possesses, or uses a sealed source or device containing a sealed source must be authorized by license for these activities prior to performing these activities.
- (ii) A person who wishes to install a device containing a sealed source must have a specific license authorizing such activities at the installation site, prior to the installation.

Summary point (i) above would be met by the person wishing to receive the sealed source or device applying for and receiving a license in accordance with the requirements in 10 CFR Part 30, or equivalent Agreement State regulation, authorizing the desired activities. In particular section 30.3 of this Part specifies "... no person shall ... transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued pursuant to the regulations in [10 CFR]." It should be noted that possession and use are separate activities and, therefore, the receiver may (if authorized) possess the device and sealed source prior to receiving specific authorization for their use. However, the receiver could not use the device and sealed source until this specific authorization has been granted. This authorization could be granted only after the receiver has met the requirements contained in 10 CFR 30.32(g), or equivalent Agreement State regulation, which describes the requirements to obtain a license for the use of byproduct material in the form of a device containing a sealed source.

Summary point (ii) above would be met by the installer applying for, and receiving, a specific license authorizing these activities in accordance with 10 CFR Parts 30 [as described in the above paragraph] and 32, or equivalent Agreement State regulations. In particular, 10 CFR 32.1, specifies, in pertinent part that "... this part prescribes requirements for the issuance of specific licenses to persons who introduce byproduct material into a product or material owned by or in the possession of the licensee or another and regulations governing holders of such licenses." This section further specifies that "... this part describes procedures and prescribes requirements for the issuance of certificates of registration ... to manufacturers or initial transferors of ... devices containing sealed sources which are to be used by persons specifically licensed under part 30 of this chapter or equivalent regulations of an Agreement State." Therefore, a person wishing to introduce byproduct material into a product in the possession of another licensee, or wishing to manufacture or initially transfer a device containing a sealed source, must have these activities specifically approved in accordance with the regulations in 10 CFR Parts 30 and 32, or equivalent Agreement State regulations.

Only after the conditions in (i) and (ii) above, and any additional limiting conditions listed on the installer's and the receiver's licenses, have been met could the installation and transfer be made and the installer relinquish control and possession of the device/sealed source to the receiver.

Please note that the installation, acquisition, receipt, possession, transfer, and use of a device not containing licensed material are not subject to the regulations contained in Chapter 10 of the Code of Federal Regulations (CFR) and, therefore, do not require authorization by license. However, once licensed material (i.e., a sealed source) is incorporated into a device for use by a licensee, the device (including its manufacture and installation) is subject to the regulations contained in Chapter 10 and must be transferred in accordance with 10 CFR 30.41, or equivalent Agreement State regulation. In addition, the installation, transfer, and receipt of the device and sealed source must be in accordance with the requirements and conditions listed on the transferor's specific license, the receiver's specific license, and any applicable registration certificates issued for the device.

In addition, we would like to call to your attention that:

- A certificate of registration is not required in all situations prior to the installation, transfer, and receipt of a device containing a source. However, a safety evaluation and, typically, a registration certificate are required prior to the receiver's possession and use of the device.

- As indicated above, the construction and installation of a device not containing licensed material may be performed regardless of whether the installer or receiver has a license, or if a registration certificate has been issued for the device. However, if a sealed source is incorporated into a device for which a registration certificate has been issued, the device's construction, installation, and transfer (including activities performed prior to the issuance of the registration certificate or installation of the sealed source) must be (or have been) in conformance with the commitments and representations made in support of the application for the registration certificate, and with the conditions of the registration certificate.

The requirements for a safety evaluation and registration certificate are contained in sections 30.32(g), 10 CFR Part 30 and 32.210, 10 CFR Part 32, or the equivalent regulations of an Agreement State. Please refer to these sections for more information on these requirements.

I hope that this adequately responds to your request. Please be aware that, except as noted, the above response has been written in general terms in order to apply to a number of situations. Specific conditions at a particular site may allow additional flexibility or require additional approvals. If you are unsure if your license allows activities you wish to be performed, you should contact a Region I, license reviewer to obtain additional clarification. For questions concerning activities allowed under the receiver's license, you should contact the receiver directly, or contact the appropriate NRC regional office or Agreement State office.

If you have questions concerning this response, do not hesitate to call me at (301) 415-5847 or Mr. Steven Baggett at (301) 415-7273.

Sincerely,

/s/

Douglas A. Broadus, Mechanical Engineer
Sealed Source Safety Section
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

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