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October 11, 1999

Secretary  
United States Nuclear Regulatory Commission  
ATTN: Rulemakings and Adjudications Staff  
Washington D.C. 20555-0001

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OCT 13 1999  
30,31,32 170+171  
(64FR40295)

Re: Proposed Changes to 10 CFR Parts 30, 31, 32, 170, and 171  
Requirements for Certain Generally Licensed Industrial Devices  
RIN 3150-AG03

Dear Sir or Madam:

As a manufacturer of devices that are distributed under the general license in 10CFR31.5 Ohmart/VEGA offers the following comments.

**Accountability** – The need for these regulations as specified in the background information is due to the number of devices that have been lost or unaccounted for which resulted in costly clean up due to capsules being melted or ruptured. Exposure or risk to the general public has been minimal; therefore, I suggest that any rulemaking that does not directly affect the accountability issue be deleted. Additional requirements on labeling, length of storage, or the information supplied to the customer will have little or no effect on the accountability of the radioactive material.

**National Database** – The most important part of trying to maintain accountability is the formation of a national database. Multiple State run databases would only lead to high cost and difficulty in maintaining the integrity of the database. A database of all general licensed devices requiring registration would not be that large considering that it would be smaller than most States' automobile licensing databases. The cost cannot be that high. Given your estimate of 5000 affected licensees, a portion of the proposed fee of \$50 each would result in \$250,000 of annual income to construct and maintain this database. The States could be required to submit the data and pay for part of the funding or they could defer and let their licensee file directly with the NRC.

**Compatibility** – These rules need to have the highest level of compatibility to ensure consistency of notification and traceability through the initial shipment and original installation of the device. This should guarantee that at least the first movement of the device is recorded with consistency and accuracy.

We routinely deal with all of the Agreement States and find it very difficult to keep abreast of most rule changes. There is no mechanism in place for someone who is

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not a licensee in a particular state to be made aware of any changes of staff and rules. We send letters annually to all of the Agreement States asking for changes in the rules. Many times we only hear if they want a fee paid.

I am keenly aware of State's rights issues and the home rule debate but the lost or non-accountability of radioactive material is a serious matter that is contrary to the basic principles of radiation safety, which would require type A compatibility. At the least it has significant transboundary implications and should be considered type B compatibility.

**Responsible Individual** - We agree that there needs to be a clearly defined person responsible for all devices that contain radioactive material. Some of the discussion on this issue mentions the need for a named backup individual. We feel that this is unnecessary. What would help accountability is a clear understanding that the management at each licensee site is aware of these requirements much in the way OSHA and EPA requirements are the ultimate responsibility of the owner or plant manager.

**Labeling** – Additional rulemaking on labeling is unnecessary and should be considered as part of the device registration. All containers or devices are required to be labeled now by 10CFR 20.1904(a). The wording that refers to *permanent, embossed or engraved* will result in confusion. Many components that would be shipped as part of the manufacturing process would be labeled and contain no radioactive material. Any label must be removable to meet the requirements of 10CFR20.1904(b).

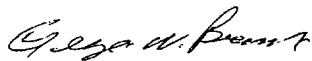
**Information supplied to customers** – I agree with the intent of this portion of the proposed rule to try and make sure a person purchasing a device with radioactive material and their management understands all of the implications and requirements of owning a device containing radioactive material. Too many times I meet individuals who think that a device is possessed under the manufacturer's general license. The rule as worded is too vague as to the timeframe and as to what level of documentation is required to ensure that the information has been given to the customer. As a distributor we can only make a good faith effort to get the information to the end user.

**Devices containing radioactive material below the defined limit** – Since the purpose of these regulation changes is to increase the accountability of devices, the limit for Cs-137 that requires registration should be lowered. Currently some manufacturers are attempting to circumvent the rules and the interest of public health and safety by packaging or directing other people to repackage exempt quantities of radioactive material. If the proposed rule were to state that any quantity of Cs-137, Co-60, Sr-90, Am-241 or any other transuranic distributed under 31.5 would require registration, the loophole that allows significant quantities to be unaccounted for and improperly disposed of could be closed. This would still allow for the use of individual exempt quantities of material to be used as calibration or check sources.

**Storage of devices** – These rules place an arbitrary limit on the storage of devices not in service. Clarification needs to be made for devices that may be out of service but are planned to be reused at a future date that could be several years. In addition, for some critical applications a spare device might be kept in storage for years. It is also possible for a general licensee to possess a device that is kept in secure storage because there is no path for disposal or transfer. Am-241 is an example of what would be orphaned waste. The portions of this rule that require a responsible individual and reporting will be sufficient to ensure accountability of sources in storage.

Thank you for the opportunity to comment on these proposed rules. If you require addition information or have any question please contact me at 513-272-0131 or e-mail at [gbrown@ohmartvega.com](mailto:gbrown@ohmartvega.com).

Sincerely,



George W. Brown  
Radiation Safety Officer  
Training Manager