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Secretary
U.S. Nuclear Regulatory Commission
Washington DC
20555-0001
Attn: Rulemakings and Adjudications Staff

Subject: Comments re. Proposed Changes to 10 CFR Parts 30, 31, 32, 170, and 171

Dear Secretary:

AEA Technology QSA Inc is a manufacturer and distributor of generally licensed devices, and also a supplier of sealed sources to Original Equipment Manufacturers (OEMs) that then incorporate the sources into generally licensed devices. Due to the significant impact of the proposed modifications to the regulations in to 10 CFR Parts 30, 31, 32, 170, and 171, we would like to offer the following comments. The comments are presented in the order proposed.

1) There does not appear to be a strong technical justification for the types and quantities of devices that require the annual registration and fee. Many of the sources that we provide for the devices meet special form requirements and have achieved the appropriate ANSI/ISO classification for use. They are designed and constructed to withstand hypothetical accident conditions and extreme environments of use. They are normally a double or triple encapsulation making it impossible to inadvertently open up a capsule. All of these characteristics significantly minimize any safety implications even if the device were abandoned or lost. These physical considerations do not appear to have been considered in establishing registration requirements.

2) With the proposal to identify a responsible individual, it should be made clear that it is not the vendor's responsibility to assess the competency or reporting structure of the organization. We will provide whatever name is supplied to us by the user.

3) We do not support the requirement for a backup responsible individual. This would make the requirements for a generally licensed device more restrictive than the requirements for a specific device. In addition the majority of our end users are very small companies and having a second designated individual is impractical.

4) Although the intent of NRC is to educate the end user of the requirements for a generally licensed device, we do not believe the proposal is necessary. It is difficult to implement, will not increase safety and it will be unenforceable.

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The requirement for certain information to be provided to the end user "prior to transfer" is vague on when the information is to be given to the prospective user. In addition providing the information to the personnel making the decision to use the device still allows that the information may not get to the individual that will be ultimately responsible for compliance. It will be difficult to demonstrate compliance that the information was given by the vendor and then reviewed by the end user. Does a record need to be kept showing the information was sent which is then auditable?

We agree that the potential user should be made aware that there are regulatory requirements inherent in the use of the device, however this is normally covered in the sales brochures. The specific requirements and copies of regulations should be given at time of sale with the product. We do not support providing estimated disposal costs as it will be difficult to determine those as they vary significantly over time and contracts/vendors. In addition the requirement to provide disposal costs to general licensees would be more restrictive than what is currently required for a specific licensee. Disposal costs are not required to be given to a specific licensee.

We believe the current requirement to provide information with the device is adequate. The additional information proposed to be given to the end user will not significantly increase compliance. However enforcement of the existing requirements will meet the intent of the proposed requirement.

5) We recommend that NRC clearly define "replacement devices" in Section 31.5(b)(8)(ii)) and the word "replaced" in Section 32.52(a)(3). We routinely ship out replacement devices and/or sources to load into a device. If the device is undergoing a standard reload with a new source, is this a "replacement" since it is a different source? In addition it would be difficult to track what specific source is replacing another source. This should be a user responsibility and not a vendor responsibility.

The timing of a replacement is not clear in the proposed regulation. We do not routinely receive back the old source until the new source has been installed in the device. When would this be required to be reported?

6) We do not feel the civil penalties proposed for the loss or unauthorized disposal reflect real safety implications. In the case of Po-210, the safety hazard involved is minimal.

7) We support the establishment of one national database instead of separate databases maintained by each Agreement state A national database allows for one organization to enter the data resulting in less errors and more consistency. With one database for all devices, any discrepancies can be quickly found and followed up on. This would result in quicker response times when a device appears to be lost or unaccounted for. In addition it would be a

waste of resources and a significant duplication of effort to have 30 plus separate databases created.

AEA Technology has experience in establishing similar databases and could provide assistance if NRC would like support.

8) NRC states it is planning to classify Section 31.5 as Category C for Agreement State compatibility. We believe this is inappropriate as there are significant trans-boundry considerations

There are some recent inconsistencies in how certain gauges/devices are handled by individual agreement states. Some states are requiring that some generally licensed devices now be specifically licensed. This is basically ignoring the SSDR information and review performed by another agreement state and/or NRC and the resulting conclusion and approval that the device meets all the requirements to be generally distributed. This results in states not accepting the SSDR for an already assessed device and spending time and resources to perform another review. This is inefficient and counter productive to safety.

It is very difficult and sometimes impossible to stay current with all the various amendments and differences betweeen state regulations. As a result it is very possible that a generally licensed device could be shipped to a user in an agreement state that now requires a specific license for the end user. This would result in both the distributor and user being out of compliance.

Consistency in the regulations important to safety should be a fundamental practise. Consistency in the regulations significantly improves the chance of compliance by both the end user and the distributor thereby increasing safety. If the states and NRC have inconsistent levels of concern over the same device, ie it could be generally licensed in one state and specifically licensed in another then the public and users get conflicting views on whether or not it is safe.

We strongly urge that Sections 31.5 and 31.6 be classified as Category B for Agreement State compatibility.

Although the current NRC regulations allow the use and distribution of generally licensed devices (ie they were assessed as having no significant safety risk when used by personnel without specialized training) it appears as though we are creating a new class of license. Although a license is not required, there are still several requirements the user has to meet prior to getting the device, in essence there are additional prerequisites that must be accomplished by the vendor and end user prior to receiving the device. Many of these prerequisites are going to be difficult to demonstrate compliance.

We appreciate the chance to comment on these proposals. If you would like to discuss further, please contact me.

Sincerely,

Cathleen Roughan
Regulatory Affairs and Safety Manager

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