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Thomas W. Ortiger
Director

December 18, 1996

Paul H. Lohaus
Deputy Director
Office of State Programs
U.S. Nuclear Regulatory Commission
Document Control Desk
P1-37
Washington, DC 20555

Dear Mr. Lohaus:

Thank you for your letter of September 11, 1996 regarding the recognition of international standards for sealed source and device (SS&D) evaluations. We appreciate the information as it clarified several issues that we have encountered in our sealed source and device reviews regarding ISO Standards and Regulatory Guide 6.9. However, a few points of clarification are necessary.

Regarding special form testing in Item 1, our question was not whether special form testing could replace ANSI testing but rather could this document be accepted as a stand alone document for special form testing. The international documents appear to compare fairly well with the requirements of 49 CFR 173.469

In Item 2 of your letter, you appear to have contradicted a previous precedent set by NRC. At one point, I believe France was advised by NRC to accept a source evaluation performed by California. Should this policy be reciprocal and extended to evaluations performed by our European counterparts as well? Certainly, once certain foreign authorities are considered to be competent by NRC or an Agreement State, we should recognize their standards/certificates. We are apparently prepared to do this for Certain ISO standards. Illinois would be very interested to know if your staff has seen any other documents from foreign entities that may be considered acceptable.

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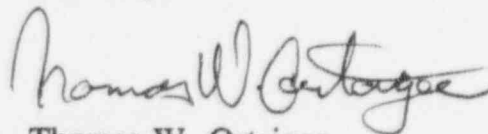
In Item 3, we interpreted the leak test document from the Physical Technical Federal Institution, Berlin, to be a document establishing leak test frequencies for sources based on the prototype testing rather than a leak test record as you suggest. The document appears to indicate that no further leak testing is required after the initial leak test if the source is to be contained in a device that protects it from environmental hazards. Certainly, no information regarding the details of testing was included as you noted. This was included in a separate document in the submittal.

The information submitted in Items 4 and 5 of your letter is reassuring in that it suggests other standards can be substituted for currently recognized standards if justified, particularly in regard to quality assurance. We have been making an extensive effort to ensure that our licensees' programs meet Regulatory Guide 6.9 even to the point of requiring licensees to re-submit their QA plans in their entirety to include these additional components. Your statements indicate that only minor modifications may be necessary if they are currently operating within an ISO 9000 framework.

The Department is comparing each submittal to recognized standards and guidance documents (i.e., Reg. Guide 10.10, ANSI N542, Reg. Guide 6.9, etc.) as suggested. However, since many of our distributors are based in Europe, one would hope in the future that we could establish an agreement with competent foreign authorities recognizing these reviews in their entirety much as we do with the Agreement States and NRC. Obviously, much work remains toward that end, but it seems that we are already moving in that direction with the acceptance of many of the ISO standards.

The Department appreciates your comments on these issues. They will certainly facilitate future SS&D reviews. If we may be of any further assistance, please contact our Division of Radioactive Materials at (217) 785-9947.

Sincerely,

A handwritten signature in dark ink, appearing to read "Thomas W. Ortiger", is written over a horizontal line.

Thomas W. Ortiger
Director

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