

CABINET FOR HEALTH SERVICES
COMMONWEALTH OF KENTUCKY
FRANKFORT 40621-0001



DEPARTMENT FOR PUBLIC HEALTH

December 22, 1998

CRAIG A CARIS
RONAN ENGINEERING COMPANY
8050 PRODUCTION DRIVE
FLORENCE KY 41042

Dear Mr. Caris;

A final review has been performed of the gauges, Models RLL-1 and RLL-2, requested to be approved for general licensing. The following additional information is needed prior to approval of the Model RLL-1 gauge. A second letter will follow for the RLL-2 gauge.

The following items are in reference to the Model RLL-1 device:

1. No confirmation is given that the label will have a yellow background and use the colors black, magenta or purple. In lieu of using these colors you may request an exemption from the color requirements by providing a justification as to why this exemption should be made.
2. The label does not include the statement that the label is to be maintained on the device in a legible condition.
3. Two figures of labels are included. One is designated as being a general license label. Is the second label to be used if the device is distributed as a specifically licensed device?
4. The listing of NRC Regional Offices includes a Region IV office at Walnut Creek, CA. This office has been closed.
5. The manual included as part of the application is still not up to date. Old references are given for NRC regulations. An indication is made that as the result of an employee's request, annual notification must be made of the radiation exposure. This is to be done on an annual



"An Equal Opportunity Employer M/F/H"

basis whether or not the employee requests the results. Also, the manual states notification must be made to the NRC if an employee exceeds 1.25 rem per quarter. This is no longer a requirement since exposure limits are based on an annual limit. The manual states personnel monitoring is required if persons are apt to receive a dose in excess of 23 mrem/week. Personnel monitoring is required if personnel have the potential to receive ten percent of the annual limit. The manual should also include a statement cautioning against tampering with the device.

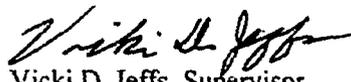
6. Provide the ANSI N538 classification for this device.
7. Justification provided for not performing leak tests was stated as based on 10 CFR 31.5(c)(2)(ii). This regulation is for gauges containing only 100 microcuries of radioactive material. The application states up to 900 microcuries may be used in the gauge, thus this justification is not appropriate. The justification for not performing leak tests should be based on the fact that no individual source contains more than a specified amount of material.
8. Page 2 indicates the spacers are steel balls; however, the type of steel is not described.
9. The wording on under the topic Installation should be changed to avoid any confusion. Currently it states "unrestricted activity". Since the word "unrestricted" is a radiation term, perhaps other wording should be used.
10. The previous submission stated Ronan reviewed each application to verify that dose rates at accessible surfaces did not exceed 2 mR/hr. The current submission states 5 mR/hr. Why was this maximum dose rate changed?
11. The formulas given on pages 7 and 8 of the application states a transmission factor for the cesium and cobalt capsules. Where was this factor obtained?
12. The radiation safety manual states that Ronan issues a report to the NRC of all transfers of devices. This should state that the NRC or the Agreement State in which the licensee is located is notified of these transfers and not just the NRC.
13. NRC recommends that dual units be included on the registration document. You are requested to include in parentheses the International System of Units value following the English units. This is to be done both for radiation levels and linear measurements. If a value is being restated, the restated measurement need not have the conversion following it since the conversion has already been included in the document.
14. The copy of NRC regulation 31.5 to be provided to the licensee is not the current version of that regulation.
15. Drawing 898 KS and others indicate the exposure rate at one foot is 0.30 mR/hr. The Radiation Safety Manual indicates in the text that the exposure rate is 0.25 mR/hr. The application states the exposure rate at one foot is less than 0.5 mR/hr. Please clarify.
16. The manual states that the licensee will be subject to inspection by the NRC or an Agreement State; however, the next line the licensee must afford the NRC, at all reasonable times, an opportunity to inspect. Please revise this sentence to include an Agreement State also.

Chris Caris
Page 3
December 22, 1998

17. All drawings and figures submitted with the application must be properly labeled. In some cases the test refers to a drawing or figure by an attachment number or letter but the drawing or figure is not labeled with that number or designation.

Due to the time constraint assigned by the NRC, it is requested, that all clarifications and additions required in the above items be forwarded to this office, in writing, at your earliest possible convenience. If you have any questions, please contact this office at (502) 564-3700.

Sincerely,



Vicki D. Jeffs, Supervisor
Radioactive Materials Section
Radiation Health and Toxic
Agents Branch

C: John Volpe, Manager