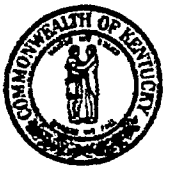
CABINET FOR HEALTH SERVICES
COMMONWEALTH OF KENTUCKY
FRANKFORT 40621-0001



DEPARTMENT FOR PUBLIC HEALTH

November 6, 1998

Craig A. Caris
Ronan Engineering Company
8050 Production Drive
Florence, KY 41042

Dear Mr. Caris:

This letter is in response to your application dated October 30, 1998, requesting registration of the Models RLL-1 and RLL-2 gauges. We are in the process of reviewing your application and have determined that the following additional information is needed in order to continue our review:

1. Your application requests registration and licensing of the Model RLL-1 and RLL-2 source holders. However, the application indicates that each holder will be installed into a housing that will provide the primary shielding for the sources. It appears that the housing will provide the primary shielding necessary for the device to meet the licensing requirements of 902 KAR 100:058. Therefore, it is requested that you either provide sufficient justification for how each source holder, without the primary shielding, meets the licensing requirements of 902 KAR 100:058, or resubmit the application to request registration and licensing of the source housings.

2. The first page of the application requests use of the Models PHI and HEG Series sources. However, the application only specified the source capsule for the PHI Series source. Please provide the capsule number, including dimensions of the capsule, for the HEG series source.

3. Please provide justification for why the devices should not be subjected to periodic leak testing during use.

4. Please provide complete details of the design of the source holders. Specifically, the details should include all dimensions, tolerances, and materials and methods of construction.

5. Please provide complete details of the design of the source housings. Specifically, the details should include all dimensions, tolerances, and materials and methods of construction. Please note that it is acceptable to provide ranges for dimensions and the specifications for materials of construction.

6. The application indicates that the dose rates at accessible surfaces will not exceed 2 mR/hr. Please indicate how this is verified since Ronan is requesting that general licensees install the device. Ronan may provide demonstration that the dose rates at accessible surfaces will not exceed 2mR/hr by: 1) registering the source housings, 2) verifying the dose rates on the source housings prior to distribution, and 3) providing specifications for the installation of the source housings (e.g., source housings will not be installed on piping less than "X" in diameter). If Ronan provides specifications for the installation of the source housing, Ronan must demonstrate that the dose rates at the accessible surface of the worst case installation do not exceed 2mR/hr.

7. Please indicate the type of detector that was used to determine the dose rates around the device and will be used to verify that newly manufactured devices meet the dose rate specified in the application.

8. Please provide additional justification for why the device labeling should be exempt from the coloring requirements of 10 CFR 20.1901.

9. Please indicate situations where it would be necessary to attach the device labeling using a stainless steel tether. In addition, please provide the details of the tether (size and method of attachment) and strength of the tether (force needed to break the attachment of the label to the device).

10. Please indicate how the labeling of the device will be clearly visible to all users of the device without subjecting them to the radiation beam.

11. Please indicate how Model RLL-2 devices labeled in accordance with figure D(1) of the application will include a radiation symbol. In addition, please provide the size of

the labeling in figure D(i) and verify that it will fit on the device.

12. Please indicate how devices distributed to specific licensees will be labeled. Please note that devices distributed to specific licensees should not indicate that use of the device is subject to a general license.

13. Please provide the ANSI N538 classification for each device.

14. Your application includes the typical environmental conditions for the device. Please note that the registration for the device will restrict use of the device to the maximum conditions specified in the application. For the devices to be used in environments with harsher conditions, Ronan needs to provide the extreme conditions and verification that the devices will maintain their integrity when subjected to these conditions.

15. Please demonstrate that the devices would maintain their integrity when subjected to bending forces likely to be encountered during installation of the devices.

16. The quality control section of the application indicates that each device will be wipe tested for the detection of 0.0005 uCi of removable activity. Please verify that this is correct or provide the correct value for the amount of removable activity.

17. Please provide justification for why users should be authorized to perform "unrestricted" activities for the devices. In doing so, please specifically list the activities that should be authorized for the users and include an estimate of the doses that persons performing the activities would be likely to receive.

18. Please provide a copy of the instructions, which will be provided to users, on how to perform the authorized activities.

19. The Radiation Safety Manual provided in your application references NRC regulations and requirements. Please indicate how Agreement State general licensees will know whom to contact in the Agreement State to verify compliance with Agreement State regulations or to provide the required reporting information. Specifically, will Ronan provide users with a listing of Agreement State contacts?

20. Please provide a complete safety analysis that demonstrates that the device meets the requirements of 902 KAR 100:058. Specifically, please provide estimates of the doses persons would receive during installation, servicing, storage, handling, and use of the device, and doses persons would receive under accident conditions. The analysis should include dose rates and times and distances from the device that are used to develop the estimated doses.

If you have any questions, please feel free to call me at 502/564-3700.

Sincerely,

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

c: John Volpe, Ph.D., Manager
Radiation Health & Toxic Agents Branch

John Lubinski
Nuclear Regulatory Commission