



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

November 19, 1998

Ellicott Machine Corporation International
ATTN: Charles H. Johnson
Radiation Safety Officer and
International Sales Manager

Dear Mr. Johnson:

I am responding to your facsimile dated October 13, 1998. In your facsimile you ask if the information sent to you by Ronan Engineering Company (Ronan) on one of their gauging devices was accurate. The device described was distributed under an incorrect interpretation of exempt distribution regulations pursuant to 10 CFR 32 and must now be licensed under a specific or general license. However, if the device was received before October 21, 1998, the person receiving the device would be exempt from all regulation.

Ronan was advised in a letter dated June 30, 1998 (enclosed), to discontinue advising their customers to combine exempt quantity sources in their gauge designed for this purpose. A 60 day grace period was authorized for Ronan to continue distributing this gauge until a device review and a general distribution license could be issued by the State of Kentucky authorizing this gauge as a generally licensed device. Ronan requested and received an extension in a letter dated August 21, 1998 (enclosed), so that they would be able to continue distributing the gauge until the State finished its review. This extension expired on October 21, 1998. They have applied to the Nuclear Regulatory Commission (NRC) for another extension and this is now under consideration. Any gauges designed for use with multiple exempt quantity sources and distributed by Ronan prior to October 21, 1998, are therefore exempt from regulatory requirements. Recipients of this device prior to October 21, 1998, must maintain a dated record of purchase indicating distribution from Ronan prior to October 21, 1998. Gauges distributed after this date must be distributed under a specific license and if distributed to general licensees, Ronan must have been issued a general distribution license.

If a customer receives a generally licensed gauge from Ronan they must abide by the conditions of use described in the applicable general license regulations, device registry certificate, and general distribution license. Such items as installation and leak tests are reviewed during the device registry process and would be incorporated in the Ronan general distribution license and conveyed to customers by product labels.

As indicated before, NRC does not plan to take any action at this time regarding devices already in use having multiple exempt quantities of byproduct material unless a radiological safety hazard is identified. A limited staff analysis indicated that the 10 exempt quantities combined in the Ronan device did not pose a risk to health and safety. However, NRC plans to conduct a formal risk assessment to determine if: 1) the bundling of exempt quantities in gauging devices, and the distribution of these devices to persons exempt from licensing, is acceptable without the imposition of regulatory controls, 2) if there are any other public safety concerns with these devices, and 3) whether any further action is warranted.

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November 19, 1998

C. Johnson

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If the risk assessment demonstrates a low risk to the public, NRC would initiate rulemaking to authorize the distribution of these devices to persons exempt from licensing. It is anticipated that the risk assessment and rulemaking process will take 2 to 3 years.

If we can be of any further assistance, please call Anthony Kirkwood of my staff on (301) 415-6140 or Internet: ask@nrc.gov.

Sincerely,

original signed by LWC

Larry W. Camper, Chief
Materials Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Materials Safety
and Safeguards

Enclosures: As stated

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DATE	11/18/98		11/18/98		11/18/98			

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C. Johnson

- 2 -

low risk to the public, NRC would initiate rulemaking to authorize the distribution of these devices to persons exempt from licensing. It is anticipated that the risk assessment and rulemaking process will take 2 to 3 years.

If I can be of any further assistance, please call me on (301) 415-6140 or Internet: ask@nrc.gov.

Sincerely,

Original Signed By:
Anthony S. Kirkwood

Anthony S. Kirkwood
Materials Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Materials Safety
and Safeguards

Enclosures: As stated

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NAME	ASKirkwood:ask <i>ask</i>		CTRaddatz <i>CR</i>		LWCamper			
DATE	11/06/98		11/ /98		11/ /98			

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June 30, 1998

Ronan Engineering Company
Measurements Division
ATTN: Bon Cahill
General Manager
8050 Production Drive
Florence, Kentucky 41042

Dear Mr. Cahill:

In a facsimile dated May 7, 1994, Ronan Engineering Company (Ronan) requested verification that the advice it had planned to give its customers to put multiple exempt quantity sources in a tube inside a mold housing a radiation detector, would not put Ronan, its customers, or the persons supplying sources under a Nuclear Regulatory Commission (NRC) license issued pursuant to 10 CFR 32.18, in violation of NRC regulations. In a letter dated June 3, 1994, NRC responded that the situation described did not violate any NRC regulations.

As discussed during the June 19, 1998, telephone conversation between you and Mr. Lubinski, NRC, the NRC Office of General Counsel (OGC) has determined that the NRC position that was transmitted in the June 3, 1994, letter was in error. Specifically, that decision finds that combining of exempt sources is inconsistent with the regulations pursuant to 10 CFR 30.18, 32.18, 32.19 and 32.20. Because the exemption provided in 10 CFR 30.18, as set out in the regulation itself, is applicable only as long as no individual or discrete quantity of the byproduct materials exceeds the quantity limit specified in 10 CFR 30.71, Schedule B, and as long as the quantities set out in that schedule are originally received and remain separate and distinct from other quantities of exempt byproduct materials, Ronan's instructions and the jig that it provides to its customers is in direct conflict with the NRC's requirements for labeling of exempt sources which instruct persons not to combine exempt quantities. The labeling requirements in section 32.19, which address shipments to persons exempt, instruct 32.18 licensees to label the "immediate container" with information identifying the radioisotope and the quantity of radioactivity, and in addition to that information, "shall also bear the words ... 'Exempt Quantities Should Not Be Combined.'" Therefore, while the exemption in section 30.18 provides for persons without a license to possess and use a wide variety of byproduct materials, and to possess and use specific byproduct materials without restriction as to the total quantity which may be possessed and used at any one time, the regulations do not authorize, but rather prohibit, grouping exempt quantities of byproduct material. Please be advised that Ronan must discontinue its program of advising its customers to combine exempt quantity sources.

Ronan may distribute these devices to specific or general licensees. However, in order to do so, Ronan must have the device design evaluated and registered with Kentucky, an Agreement State, and if distributed to general licensees, Ronan must have its general distribution license amended.

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B Cahill

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At this time, devices already in use having multiple exempt quantities of byproduct material may continue to be used. NRC does not plan to take any action with respect to these devices or users unless a radiological safety hazard is identified. As discussed on June 24, 1998, with Mr. Steven Baggett of my staff, NRC will allow Ronan to continue to distribute devices having multiple exempt quantities of byproduct material for a period of 60 days from the date of this letter.

NRC plans to perform a risk assessment to determine if there are any public safety concerns with these devices and whether any further action is warranted. If the risk assessment demonstrates a low risk to the public, NRC would initiate rulemaking to authorize the distribution of these devices to persons exempt from licensing. It is anticipated that the risk assessment and rulemaking process will take 2 to 3 years.

Sincerely

(orig. signed by J. Piccone, for)
Frederick C. Combs, Acting Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Materials Safety
and Safeguards

cc: Vickie Jeffs,
State of Kentucky

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DATE	06/25/98		06/26/98		06/26/98		06/25/98

OFC	IMNS NMSS						
NAME	for F.C. Combs						
DATE	06/29/98						

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Ronan Engineering Company
Measurements Division
ATTN: Bon Cahill
General Manager
8050 Production Drive
Florence, Kentucky 41042

August 21, 1998

Dear Mr. Cahill:

In a letter dated June 30, 1998, Ronan Engineering Company (Ronan) was informed that the Nuclear Regulatory Commission (NRC) position that was transmitted to Ronan in a June 3, 1994, letter was in error. Ronan was advised that it must discontinue its program of advising its customers to combine exempt quantity sources. Rather, Ronan was further advised that it may distribute these devices to specific or general licensees. However, in order to do so, Ronan must have the device design evaluated and registered with Kentucky, an Agreement State, and if distributed to general licensees, Ronan must have its general distribution license amended. NRC has allowed Ronan to continue to distribute devices requiring multiple exempt quantities of byproduct material for a period of 60 days from the date of the June 30, 1998, letter. This period expires on August 29, 1998.

In a letter dated July 17, 1998, you requested an extension of the August 29, 1998, date. You stated that you have an urgent need to distribute these devices because a substantial portion of Ronan's business has been invested in this product. In addition, we are aware that you have submitted a request to the State of Kentucky to review this device for general license distribution. Ms. Vicki Jeffs, with the State of Kentucky, has indicated that they have received your application for a device review and will likely complete the review within 60 days. For these reasons, NRC will extend the period allowed Ronan to continue to distribute devices requiring multiple exempt quantities of byproduct material for an additional period of 60 days from the date of this letter or upon authorization from the State of Kentucky to distribute your devices requiring multiple exempt quantities of byproduct material as generally licensed devices, whichever occurs first.

Sincerely, original signed by J. Lubinski for

Steven L. Baggett, Deputy Chief
Materials Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Materials Safety
and Safeguards

cc: Vicki Jeffs, State of Kentucky

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