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(64 FR 40295)

October 12, 1999

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

Re: Proposed Revisions to 10 CFR 31.5, 32.51, and 32.52 for Generally-Licensed Devices

Gentlemen:

Troxler Electronic Laboratories, Inc manufactures and distributes gauging devices for measuring the physical properties of materials (soil, asphalt, concrete) under a specific license issued by the State of North Carolina. Some of the devices are distributed to NRC or Agreement State general licensees and would be subject to the proposed revisions to 10 CFR 31.5, 32.51, and 32.52

We understand that the intent of the revisions is to achieve better compliance with general license requirements by making licensees more aware of their regulatory responsibilities. We support that objective; however, we are not convinced that the proposed registration program is necessary. The background to the proposed rule states "The NRC has not contacted or inspected general licensees on a regular basis because of the relatively small radiation risk posed by these devices." This may explain the relative lack of regulatory awareness on the part of general licensees. The NRC expresses concern about improper handling and disposal of devices that "In some cases, ...has resulted in radiation exposure to the public and contamination of property". However, the NRC also states that "known exposures have generally not exceeded the public dose limits." These statements offer scant justification for burdening manufacturers, distributors, and general licensees with more reporting and record keeping requirements and costly registration fees. The NRC states that "these problems could be resolved with more frequent and timely contact between general licensees and the NRC." We agree with that conclusion, however, we do not agree that any new regulatory requirements are necessary in order to do so. Instead, the NRC should utilize the information already being provided by manufacturers/distributors in quarterly reports of devices transferred, or by general licensees in response to written requests from the NRC under 10 CFR 31.5 (c)(11), to contact and inspect general licensees. The existing rules and requirements are adequate, if utilized and enforced.

Although we do not support the creation of a registration program for general licensees at this time, we have reviewed the proposed rule and evaluated its impact on manufacturers and licensees. Specific comments are provided below about several aspects of the proposed rule that seem particularly unnecessary and inappropriate.

1. The proposed revision to 32.51(a) would require distributors to provide general licensees with certain additional information before the device is transferred (i.e., prior to purchase). We recommend revising the rule to state that the information must be provided with the device. As discussed in NRC Information Notice 99-26, manufacturers/distributor should communicate with the customer about applicable regulatory requirements prior to purchase. However, the Commission's proposal to regulate communications prior to purchase is fraught with complications and is not

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likely to lead to improved compliance. Many inquiries about products do not result in a purchase. Multiple contacts may occur between different representatives of both the distributor and customer over a period of time leading up to a purchase, making it difficult to know who has been informed of what and by whom. Most importantly, information transmitted prior to purchase (perhaps months before actual deliver of the device) may be lost or forgotten by the time the device arrives or may never reach the hands of the responsible person. On the other hand, information transmitted with the device has a high probability of reaching the responsible person, making them aware of applicable requirements, and improving the likelihood of regulatory compliance. Finally, compliance with a "prior to purchase" requirement would be difficult to demonstrate and to enforce as well.

2. Requiring distributors to maintain records for 3 years beyond the useful life or disposal of device (potentially several decades) as proposed under 32.52(c) is unnecessary, since the same information would be submitted to the Commission in quarterly reports. The premise of this record retention requirement seems to be that the Commission and State Agencies are unable to keep track of the information that is reported to them. We do not think that serving as "backup" to the Commission is a reasonable basis for a record retention requirement. The presumption that this requirement would have no impact on distributors because they already keep such records indefinitely also is incorrect. Long term retention of records to meet a regulatory requirement requires more rigorous systems, procedures, and training than are necessary to meet normal business needs and involves commensurately greater time and costs.

3. The new reporting requirements proposed in 32.52 (a) and (b) would place an additional burden on distributors to obtain and report information that should be provided directly to the Commission by the general licensee during device registration. The new reporting requirements amount to having the distributor register on behalf of the licensee. To ensure the accuracy of the information obtained and increase general licensee awareness of their responsibilities, the Commission should obtain this information directly from the licensee. Further specific comments are provided below.

   (a) The distributor should not have to report whether the device is a replacement, and if so, the type, model, and serial number of the one returned. The Commission already receives quarterly reports from the distributor on all devices transferred to general licensees and, under the proposed rule, would also receive annual registration information from the general licensees for all devices possessed. Licensees are also required by 30.51 to maintain records of all receipts, transfers, and disposals. Contrary to the Commission's supposition that distributors could include this information in quarterly reports without a significant burden, we do not currently keep information about which device replaces another and it would not be easy to do so. Changes would have to be made to database systems and procedures at significant costs. We also disagree with the assumption that information provided by the distributor would be more accurate than that provided by the licensee. If the Commission needs to know about replacements, they should obtain this information directly from the licensee. This could be accomplished by deleting the exception in 31.5(c)(8)(ii) for reporting about replacement devices.

   (b) The distributor should not have to provide the mailing address of the location of use of the device. We already provide the address to which the device is

delivered (shipping address). In most cases, this will be the location of use, but if not, the general licensee should report the actual location of use during device registration. We do not currently have the capability to maintain a "location of use" address that is different from the shipping address in our database for each device. This requirement would necessitate modifying our systems and procedures at significant cost. We believe the device shipping address that is currently reported to the Commission should be adequate for initially contacting the general licensee concerning registration.

(c) The distributor should not have to report "the name and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations." We currently report a contact name and address, which should be sufficient for making initial contact with the licensee. The name of the responsible person, if different from the contact person reported, should be provided by the licensee during registration. Implementing this requirement would again require modifying systems and procedures at significant costs.

4. The proposed rule on registration in 31.5(c)(13)(ii) only requires the licensee to respond to the requests from the Commission. It appears that a licensee who is not contacted by the Commission is under no obligation to register. The proposed rule should be changed to require the general licensee to register within a specific time period after receipt of the device, regardless of whether contacted by the Commission. The Commission may choose to prompt the licensee to register based on the information provided by the distributor, but the statement "Registration must be done by verifying, correcting, and/or adding to the information provided in a request from the Commission" should be deleted from the proposed rule.

Troxler currently sells very few generally licensed devices. Therefore, the cost of changing systems and procedures and of training personnel to implement the proposed requirements would be very significant relative to the income derived from sales of these devices. Further, the registration program fees would adversely affect existing customers and discourage potential new customers from buying these products. We strongly urge the NRC to reconsider the need for the registration program and to focus on utilizing the information that is already provided by manufacturers/distributors in quarterly reports, or that would be provided by licensees in response to requests from the NRC in accordance with the recent revision to 10 CFR 31.5.

We appreciate the opportunity to provide these comments to you. If you have any questions, please feel free to contact me.

Sincerely,

Stephen A. Browne
Corporate Radiation Safety Officer

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