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October 11, 1999

Secretary  
United States Nuclear Regulatory Commission  
Washington DC  
20555-0001

Subject: Proposed Changes to 10 CFR Parts 30, 31, 32, 170 and 171

Dear Secretary:

NDC is a manufacturer and distributor of thickness gauges to persons holding general licenses under authority of 10 CFR 31.5. The company has been in this business for over 35 years, and we take great pride in offering our gauges and services to a wide range of industries. A large proportion of NDCs' business is provided to medium and small businesses. NDC is concerned that the proposed regulations, as published in the Federal Register, will create a major impact to our customers and potentially to NDC. NDC believes that accountability of radioactive sources is needed but the proposed rules will have little if no effect on the true intention of ensuring accountability of orphaned sources.

**Requirements for General Licenses subject to registration.** NDC believes that the NRC currently has the necessary authority and resources in place to effectively run the program. The effect of the registration is to improve accountability. Currently NDC Systems as well as all manufacturers provide transfer and sales information to the NRC for generally licensed devices within the NRC's authority. Regulations do not require the reporting of gauges that are sold to specific license holders. Specific licensees may have line items in their license, which identify the exact number of devices the licensee may possess. Alternatively, a specific licensee may have no limit imposed on the number of devices of a certain type, which can be in their possession at any given time. The only method the NRC has in place for the tracking of material for specific licensees is through inventories, and reliance on the integrity of the licensee. NDC Systems is of the belief that the proposed regulations create a third class of license holders, who will be subject to more restrictive regulations, with less reliance placed on the integrity of the licensee. Nevertheless, if the NRC does proceed with the proposed rule, it should do so in a less burdensome manner. As was suggested during the October 1, 1999 public meeting on the proposed rule, the NRC should adopt a four-year registration requirement instead of an annual registration requirement. Such a requirement would substantially reduce financial and other impacts on stakeholders while, combined with the other reporting requirements contained in the rule (i.e., report of transfer and disposal) meet NRC accountability needs. Only after experience with such a rule should the NRC consider a more burdensome requirement.

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**Appointment of Responsible Individual (RI).** NDC agrees that the need for a responsible individual is important but as interpretation currently, appears to be overly restrictive for general license holders. Specific licensees currently are authorized to appoint a RSO (Radiation Safety Officer), which is a non-employee of the company or institution. The purpose of the sealed source and device registry is to permit manufacturers the ability to distribute radioactive devices, which are inherently safe, and require no training by the users. This section appears to be more restrictive for general license holders in that an employee may not have the same level of training and experience of a consultant or professional health physicist. Based on experience with specific licenses we recommend that General Licensees be authorized to appoint a Responsible Individual, who is a non-employee.

**Vendor Requirements and Timing of Information to Customers.** NDC believes that the additional requirement of providing specific information to the customers is vague and unnecessary. These additional requirements will create unnecessary burden to the customer and creates contractual problems, which should not be regulated by the NRC. NDC provides radioactive devices to OEM's (Original Equipment Manufacturers) who in turn supply an end user with the device built in the system. Mutually competing commercial interests prevent an OEM from supplying the end user's location prior to shipment. Therefore, NDC is unaware of the end users location prior to shipment of the device. NDC would recommend that the required information be supplied to the end user prior to shipment of the device. This would allow the customer to make an informed decision while excluding the NRC from involvement in contract disputes.

**Storage of Radioactive Material.** NDC asks the commission to extend the storage of radioactive devices to three years. This would allow customers to maintain a spare probe. The spare probe would be on the same schedule for leak testing and would ensure that the probe was accounted.

NDC would like to thank the commission for the opportunity to comment on the proposed regulations. NDC hopes the commission has the insight and trust in generally licensed individuals and customers to see that the rule is overly restrictive and burdensome to all stakeholders.

Sincerely,

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