**Categorization by Subject of Comments on July 26, 1999 Proposed Rule on Generally Licensed Devices - 10 CFR 30, 31, 32, 170, and 171**

**Commenters**

1. Philotechnics
2. C. W. Watson & Associates
3. Central Emergency Services
4. Suburban Water Testing Laboratories
5. Republic Environmental Systems
6. Fort James Corp.
7. University of Pittsburgh
8. Boeing Company
9. Illinois
10. Northminster Presbyterian Church
11. New Jersey
12. Daniel J. Miron
13. Hewlett-Packard
14. Washington
15. Virginia Power
16. Nebraska
17. William V. Lipton
18. TN Technologies
19. University of Delaware
20. Merck Research Laboratories
21. University of Cinncinnati
22. National Automobile Dealers Association
23. James P. Roberts
24. Isolite
25. Honeywell-Measurex
26. Ohmart/VEGA
27. Metorex, Inc.
28. Steel Manufacturers Association
29. Safety Light Corp.
30. NDC Systems
31. ABB Automation, Inc.
32. Troxler
33. Nuclear Energy Institute
34. United Methodist Church in Madison
35. Detroit Edison
36. HARREL, Inc.
37. Mayo Clinic
38. AEA Technology GSA, Inc.
39. Honeywell-Measurex

These are the actual comments taken from the comment letters, excerpted and sorted by subject as organized in the Federal Register notice of final rulemaking. A few additional subheadings are added to assist the reader. The identity of the commenter in each case is

shown by the use of the numbers above appearing in parentheses at the end of each comment.

**Broad Comment about Applicability of the Requirements**

We would like to advise you that we agree with the intent of the subject NPRM. The proposed rulemaking addresses legitimate concerns, and the measures contemplated appear long overdue. We believe, however, that restricting its scope to generally licensed by-product material ignores a closely parallel problem with a more immediate and much larger potential for public exposure. (1)

After reading the material provided, I fail to see the need for the proposed regulations. The material did not document where the problems were, to what extent the problems have impacted the general public, the financial costs of implementing the rules compared to the costs of leaving the rules as they are currently written; and the potential for loss of business due to the costs of compliance with the proposed regulations. (3)

Fort James strongly supports NRC's overall approach to improving management of generally licensed sources. Because nuclear gauges are essential components of manufactunng processes used to make pulp and paper, Fort James has had a comprehensive program for managing its nuclear sources for many years. Many of the elements of the Proposal are already in the Company's program, and, in several instances, Fort James has stricter internal requirements that proposed by NRC. With the exception of one element of the Proposal (the allowable on-site storage time) as more fully discussed below, Fort James supports all the elements of the Proposal related to 10 CFR 31.5. (6)

In general, the changes appear to be reasonable and practicable. (9)

The purpose of this rulemaking is to enable regulatory agencies to better monitor certain general licensees and the devices they possess. If adopted, the rule would increase licensee awareness of the regulations that apply to possession of generally licensed devices. (9)

In the interests of simplifying the administrative burden such rulemaking would impose on the Commission, and to lessen its impact on small, non-commercial users of such devices, we respectfully request that an additional provision be incorporated in both rules that will provide:

1. That it does not apply to non-commercial enterprises, including churches and other religious institutions who employ less than 7 such devices, when such devices are limited exclusively to self-luminous exit signs.

2. Enterprises which meet the requirements of exception 1 above will receive from the Commission annual notices relative to the proper maintenance, transfer and ultimate disposal of such devices, but without requiring the payment of any fee.

In justification for the above, we would like to advise that in the case of Northminster Presbyterian Church, the self-luminous exit signs were specifically required to be installed by our local Fire Marshall. Ours is a small Church with slightly over 100 members, and a very

tight budget. Any new governmental fees such as envisioned by the proposed rules would impose a burden upon us. We believe that the proposed exception is reasonable, and respectfully request that you give it serious consideration, advising us of your decision. (10)

Does the NRC plan to reclassify any devices from their current status of specific license to general license? If so, which devices are they and how many devices will be reclassified to general license status? (11)

Does the NRC plan to reclassify any devices from their current status of general license to specific license? If so, which devices are they and how many devices will be reclassified to specific license status? (11)

Overall, I congratulate your organization for attempting to strengthen a very ailing program. I frequently converse with customers who are totally unaware of their responsibilities as ownership and job positions change frequently. We provide a suggested documented radiation safety program for our general licensees that would assist them in providing necessary regulatory information to succeeding end users and their company RSO's. As a note of interest, due to similar problems we have had internally, we implemented a transfer and tracking process for our in-house customers during the past two years that greatly mirrors the program you are working on. (13)

We generally concur with the proposed rulemaking...(15)

The *Background* section of the Proposed Rule states that generally licensed materials are "designed with inherent radiation safety features so that [they] can be used by persons with no radiation training or experience". It also states that the NRC has not inspected general licensees "because of tile small radiation risk posed by these devices". However, it is later stated that due to mishandling or improper disposal of certain generally licensed materials, "there is a potential for significant exposures" to the public. Clearly, the most appropriate course of action is to remove generally licensed status from certain devices and only allow their possession and use under the terms of a specific license. Furthermore, if the requirements associated with the use of a radioactive device are so complicated that the individual who obtains and uses it can not understand them without the assistance of a responsible person , then the device should not be generally licensed and instead should be controlled under the provisions of a specific license. (19)

Merck & Co., Inc. agrees that is prudent to require the registration of generally licensed devices that have the potential, if not handled or disposed properly, to cause exposure of the general public or widespread contamination of property. The devices listed in the proposed 10 CFR 31.5(c)(13) have the potential to cause exposure of the general public or contaminate a steel mill and should be registered. Unfortunately, parts of 10 CFR 31.5 other than registration are being revised that will apply to all generally licensed devices under 10 CFR 31.5 including static eliminators. These changes appear to be burdensome and impractical. Static eliminators containing polonium-210 are covered by 10 CFR 31.5. These devices are used in research labs, production areas, and print shops. When they are ordered, the individual placing the order may not know they are receiving a generally licensed device until it arrives. For a company such as Merck & Co., Inc. that has several thousand employees at each of its

major sites, it would be almost impossible for one "responsible" individual at each site to ensure the "day-to-day compliance" for these devices as required by the proposed 10 CFR 31.5(c)(12). The static eliminators are not labeled with a serial number. To inventory the entirety of the static eliminators on each site would prove impossible. The proposed rule appears to disregard the obstacles which are presented by having many small devices without serial numbers which are collectively used by groups of people from three different divisions which are dispersed throughout a large company. (20)

In addition, many of these devices, specifically those that present a lower risk, do not enter a site by coming through any single designated person, such as an RSO or the proposed Responsible Individual (RI). Consequently, there is no simple of fail-safe method of determining what sources have already come on site and are being used. (20)

The University of Cincinnati believes the proposed rule is inadequate. (21)

If improper disposal of a general licensed source could create a serious risk to the public then the University of Cincinnati believes the sources should be specifically licensed not generally licensed. However, if the NRC believes risks from use is the appropriate determining factor for the difference between a generally licensed and specifically licensed source, then the University of Cincinnati recommends there be different levels of general licenses, like the types for broad scope licenses. Applicable regulations should be very clear. Requirements that cover all general licensed sources should be covered in one paragraph of the regulations and requirements that are only applicable to the higher risk sources covered in a different paragraph. (21)

We have closely followed the dialogue that has led to Proposed Rule 64 FR 40295 and believe that it is appropriate to develop additional safeguards to insure that certain generally licensed measuring, gauging, and controlling devices are properly maintained and controlled to avoid any potential harm to the public. These devices have been identified as those that present a comparatively higher risk of exposure to the general public. They include devices containing minimum quantities of cesium-137, strontium-90, cobalt-60, or any other transuranic. (24)

We recommend NRC to modify its proposed regulations to include the definition of “General Licensee”, consistent with the explanation given in the comments that accompanied the proposed rules. Without a clarification to address locations and multiple buildings in a single complex, we would again expect a variety of interpretations. (25)

The need for these regulations as specified in the background information is due to the number of devices that have been lost or unaccounted for which resulted in costly clean up due to capsules being melted or ruptured. Exposure or risk to the general public has been minimal; therefore, I suggest that any rulemaking that does not directly affect the accountability issue be deleted. Additional requirements on labeling, length of storage, or the information supplied to the customer will have little or no effect on the accountability of the radioactive material. (26)

As a distributor of generally licensed devices, Metorex Inc. is deeply concerned about the proposed changes to the regulations within 10 CFR Parts 30, 31, 32, 170 and 171. (27)

NRC must implement a solution that addresses the problems of inadequate control and accountability upstream of the user, by regulating distributors and general licensees, rather than downstream, after the sources have been improperly discarded. Accordingly, we generally support NRC's proposal. (28)

We believe that NRC's current regulatory regime, contained in 10 CFR parts 30, 31, 32, 170 and 171, does not provide adequate regulatory control over generally licensed devices. Licensees can obtain certain devices easily and are not held accountable for the proper disposition of the sources they have purchased. (28)

On several occasions, generally licensed industrial devices have been improperly discarded in shipments of scrap destined for U.S. steel mills. The presence of spent radioactive sources in the ferrous scrap supply has produced significant, unanticipated economic consequences and health and safety risks to steel workers and the general public. We have noted the consequences and risks associated with orphan sources in several communications to NRC over the past eight years. (28)

SMA member companies have taken the initiative to keep radioactivity out of their mills, and have become the "second net" to catch improperly discarded sources that escape NRC's inadequate regulatory regime. Steel companies perform this function at considerable cost, as they must finance installation, use, and maintenance of detection equipment, production delays, and worker time for training and detection. (28)

The steel industry has responded to the inadequate control of licensed devices by installing sophisticated detection systems to monitor all incoming shipments of scrap. Many SMA members have also installed additional detectors at the charge bucket to improve detection. While steel mills usually detect the sources, no system is completely effective in detecting sources buried in the middle of a truck load of scrap. If a steel mill inadvertently melts a radioactive source, it can incur $10 - 24 million in unanticipated costs for decontamination, disposal of contaminated materials, and lost production time. The cost could bankrupt a minimill. (28)

The impact of radioactive sources is not only economic. The health and safety risks are evident from the several documented incidents that have occurred in the United States and worldwide where lost sources have been stolen by petty thieves, abandoned in shuttered factories, or hidden under fences and in private homes. Radioactive sources in the scrap supply also present a risk to workers, if a source is accidentally breached in a scrap shredding operation, or melted down in a steel making furnace. Fortunately, radioactive sources have not brought serious consequences for worker health and safety, so far. There is clearly a public policy interest in holding general licensees accountable for the sources they use. (28)

Under NRC's current regulatory regime for control and accountability of licensed devices, there is little economic incentive to discard generally licensed radioactive sources properly. The regulations enable members of the public to obtain a general license automatically and without filing an application. (28)

This licensing regime renders it difficult for NRC to collect information directly from holders of certain radioactive sources. Consequently, NRC does not have sufficient control over generally licensed sources, and licensees have minimal accountability. The result is that sealed sources are often improperly discarded in shipments of ferrous scrap destined for steel mills. (28)

We support recent NRC rulemakings in response to directives in the Staff Requirements Memorandum on orphan sources, because they will improve NRC's control over the sources it licenses. On August 4, 1999, NRC amended its regulations to require a limited number of general licensees (5,100 out of a total of 45,000) respond to requests from NRC to provide information concerning the devices they own. On March 9, 1999, NRC announced in a direct final rule that it is revising its enforcement policy to provide amnesty to licensees who are out of compliance but report their violations and undertake corrective action. We encourage NRC to act in an expeditious manner in implementing these final rules, and in completing the rulemaking process for those pending or not yet proposed. (28)

NRC has a statutory obligation to protect public health and safety. NRC has been aware of the lack of accountability and control in its general license program at least since 1983 when the first known inadvertent melting of a radioactive source in a steel mill occurred. It is clearly within NRC's authority to amend its licensing regime to minimize the threat that radioactive sources pose to human health and safety, the environment, and to the economic viability of steel companies. (28)

The member companies of the SMA have an interest in NRC's proposal not only because they are the unwilling recipients of improperly discarded sources, but also because they are general licensees and would therefore be held to many of the proposed new requirements. The additional burdens, including paperwork, reporting, and licensing fees, associated with NRC's proposals, comprise a modest insurance premium against the serious economic consequences, and the threat to public health and safety, that improperly discarded sources pose. (28)

We support this proposal and urge swift implementation. We appreciate the NRC staff's efforts in drafting this proposal and look forward to working with the Commissioners and staff on the issues that we have raised. (28)

A large proportion of NDC's 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. (30)

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. (30)

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. (32)

As noted in the Federal Register Notice and the "Final Report of the NRC-Agreement State Working Group to Evaluate Control and Accountability of Licensed Devices" NUREG-1551, the devices that contain the greater quantities of radioactivity are those of principal concern. NEI agrees with this philosophy which is clearly consistent with the Commission's movement towards risk-informed regulation. We support the rule as drafted and are providing responses to the five questions raised in the Federal Register notice. (33)

The proposal indicates that no negative comments were received on the proposal. Kindly amend that to cover this very, very strong protest against the proposal. (36)

I realize that this protest should have been voiced earlier. My apologies. I can only plead the general difficulty in a small company of ignoring a desk full of urgent customer matters to plow through 28 or more pages of government-eese! (36)

We are a very small company marketing a nuclear gauge, using an approved 100 mCi sealed source of Americium 241 to measure the thickness of a plastic sheet. We have been relatively inactive the past few years, but coincidentlly are just planning a major marketing push -- because the device is very serves a very useful function in a very important industry. The proposed rule will have a serious negative effect. (36)

People are already paranoid enough about anything nuclear -- as illustrated by some of the comments you cite. That is the biggest barrier we have always faced. Mention anything nuclear, and the paranoia surfaces. (36)

The function of NRC rules is not to add to this paranoia but to preserve public safety in a reasonable manner. I submit that the proposed rule is a "feel good" matter which will not really accomplish anything beyond a major increase in the costs to those who make a legitimate use of a nuclear device. (36)

Frankly, I find it difficult to imagine that anyone could ever be so boneheaded as to dispose of a nuclear device in the scrap heap. I simply don't believe that an increase in administrative costs is going to accomplish anything. What is needed is education in the proper use of the device all up and down the chain. Perhaps some very, very distinctive marking of the device would help to drive the message home. We would be most happy to participate in any program of these types, but anything that drives the cost of owning the unit up by adding another layer of governmental reporting and regulation is all it will take to eliminate a large portion of the market for a very, very worthwhile device (36)

I note that one of the cited applications for isotopes is lighting. This is in effect a consumer item. Certainly it is much more likely that someone would put a lighting device into the waste stream improperly than an instrumcnt costing several thousand dollars, such as we make. Perhaps it would make sense to handle consumer type items differently from a regulatory standpoint. (36)

By all means increase the penalties for improper disposal. Require distinctive markings, insist on proper warnings to go along with each device, insist on proper education of users - do all those things. But don't penalize the people who are not violating good practice by adding to their costs!!!!! (36)

One can certainly sympathize with the folks at the steel mills. But this rule isn't aimed at the real culprit, and there is no reason to believe it will stop the sort of thing they speak of. If some people are going to act irresponsibly, putting a burden on other people isn't going to cure things. Let the steel mills install nuclear monitoring equipment. It would be a lot more effective. (36)

We routinely accept the return, at no charge, of our gauges when they are no longer being used. The NRC should encourage others to do the same, and insist that Specific Licensees include appropriate warning and training manuals with the gauges they ship. That will be a lot more effective than adding another layer of administration. (36)

I strongly urge that this rule be rejected. (36)

Although we do not foresee any problems regarding our compliance with the proposed rulemaking, we do have two items that we believe should be addressed. Our first area of concern is the extension of the proposed rule changes, with the exception of the registration requirements, to all §31.5 generally licensed devices. The NUREG-1551 report upon which the proposed rule is based clearly states that devices not meeting the proposed registration requirements do not pose "significant health, safety, or environmental concerns," even if lost. Extending the proposed rules to all §31.5 devices seems to be contrary to the NRC's goal to move toward a risk-based approach to regulation. (37)

<u>Exit signs</u>

It is often difficult for me to believe the extent of naivety of my government. And most certainly this is one of the most ridiculous collections of data I have ever seen. The proposed rules are full of fallacies and projections that only a government employee could love. To wit:

A. As a potential general licencee, we have (5) nuclear isotope powered exit signs which would come under this regulation. My electrician tells me we can replace all five for less money than the proposed fee to license the existing units for one year. How many of the potential licensees are similar? Obviously we will not pay the fee. This begins the collapse of the number of licensees, and escalates the rate other licensees pays, which in turn snowballs in to removal of any device where a powered option is available and cost effective.

B. The Ohio Basic Building Code, patterned after BOCA, currently will not permit the installation of these exit signs anyway. Most of the Industrial States follow the BOCA pattern. This regulation went into effect approximately in 1995. The brightness required for exit, under the new codes cannot be met by these devices. Therefore most in use devices of this type are over five (5) years old. The published useful life of the devices is only ten years, at which time the device has decayed 50% over its new and safe condition of 100% of originally authorized radiation.

C. Our company is in new construction, (Architects, Engineers, and Consultants), and we have not recommended the installation of such devices since 1993, primarily due to the current requirement of registration, and later due the code requirements.

D. As Engineers, we are familiar with other industrial sources used as BETA gages (for thickness), gas Chromatography (for molecular identification), point source, (for level detection) and other uses where radiation is cost effective, and accurate. However in each case, there are alternatives that can be used without licensing Fees. When taken over a ten year useful life, the licensing fee is substantial when performing life cycle cost analysis. (2)

We believe that the result of this proposed rule will leave the NRC with progressively less to regulate, and fewer licensees to share in the cost. Page 40297 states that the fee could be some what higher in the final rule, (i.e.) by using a formula of cost divided by licensees. Since I am telling you we will convert, this statement must be changed to “will” vs the conditional “could”. And you well know we will not be the only ones to scrap out devices to avoid the fee. Further, we will cease to recommend any nuclear device for industrial use where a non nuclear substitute is available. (2)

If the intent of this proposed rule is to eliminate all nuclear devices possible, then this is a good first step toward that goal. (2)

Based upon my understanding of sales volume, smoke detector ionization sensors, represent a larger share of radiation devices in use, and including them in the regulations would make your divisor considerably larger thus reducing the fee substantially. However, confronting the general public with such and idea wold seem to be politically unwise. (2)

In any event the inclusion of “EXIT” signs in this proposed rule and fee structuring is ridiculous. You obviously needed the inclusion to increase the divisor, a goal it will not achieve. (2)

We currently use radioactive powered exit signs in all of our fire stations. The rationale for the use of these devices is that they will always work as they are not power dependent, and they are easier to maintain in that we do not have to replace burned out bulbs in the exit signs. (3)

I have been following the recent rulings by the NRC regarding gauging, measuring, and controlling devices. In general, those devices should have additional safeguards for the safety of the general public as they contain minimum quantities of cesium-137, strontium-90, cobalt-60, or other transuranic materials. Do to the nature of these materials, I agree they may require tighter/different regulations. I do however, find that CFR 31.5 is too broad and combines many different products including H3 into the same categories as those listed above. This causes confusion to the general licensees when they receive a letter similar to the one sent by the NRC dated August 12, 1999. We received many calls from confused/concerned customers that have installed self-luminous signs questioning how this ruling affects them. (23)

We suggest that devices containing byproduct material such as H3 and manufactured to produce light, e.g. self-luminous devices, be placed in their own category. This would benefit the general licensees understanding of the law by clearly stating the regulations for their use and proper disposal of the devices. (23)

However, it has become equally apparent that CFR 31.5 covers too wide a spectrum of products for effective control and regulation. It would be far easier for general licensees to understand their responsibilities and obligations if they didn't have to decipher what does and does not apply to them. The August 12, 1999 mailing to NRC General Licensees which included FR Vol. 64, No. 149 and Fr Vol. 64, No. 142 is a good example of this problem. Based on the large number of calls that we received from general licensees of self-luminous signs, we can attest to the confusion that this mailing caused. We suggest that "byproduct material contained in devices designed and manufactured for the purpose of ..... producing light" be removed from 10 CFR 31.5 and reclassified into a new category. In so doing, the safeguards and regulations appropriate to those devices can be clearly stated, thereby making it easier for the general licensees who possess them to understand their obligations and thus help insure that the devices are handled, used, and eventually disposed of in the proper manner. (24)

I firmly believe, as I stated in that meeting that Self-Luminous Exit Signs do not belong in Part 31.5. Unlike the other devices that are listed in 31.5, Self-Luminous Exit Signs save lives and energy. We estimate there are currently close to a million such signs in use in North America. The number of incidents that are recorded as a percentage of these signs in use is negligible. It is our understanding that even the most recent incidents in New Jersey, where juveniles stole self-luminous signs from a construction site and unlawfully dismantled them, resulted in a radiological dose to the individuals involved that was nil or below background levels.
I therefore believe that Self-Luminous Exit Signs should be exempt from general license requirements. The 25 year history of these signs supports this conclusion. (29)

I note that one of the cited applications for isotopes is lighting. This is in effect a consumer item. Certainly it is much more likely that someone would put a lighting device into the waste stream improperly than an instrumcnt costing several thousand dollars, such as we make. Perhaps it would make sense to handle consumer type items differently from a regulatory standpoint. (36)

Applicability to power reactors

The proposed rule should clearly exempt 10CFR50 licensed power reactor facilities from the proposed requirements for registration and tracking of general licensed measuring, gauging or controlling devices. (15)

A definition for measuring, gauging, or controlling devices should be included in 10CFR30. For example, the stations may have radiation monitoring system calibration or check sources that meet the radioactivity requirements for registration, but should not be considered measuring, gauging, or controlling devices. (15)

The proposed rulemaking imposes a registration fee and administrative requirements on those who possess these devices under a general license. It is unclear, however, whether these requirements apply to the holder of an operating license. While appropriate for a person who is not subject to the strict controls of an operating license, these requirements would be an unnecessary burden to a power reactor licensee. For example:

- A power reactor operating license generally requires the leak testing of sources exceeding a specified threshold, with a contamination limit of 0.005 microcurie. Sources found to have contamination exceeding this limit must be reported to the Commission on an annual basis. Power reactor licensees should not have to also meet the 30-day reporting requirements of 10 CFR 31.5. In addition, the proposed rulemaking would require that the report include, "a plan for ensuring that the premises and environs are acceptable for unrestricted use..." This has the potential to impose an unnecessary burden on a power reactor licensee who is using this device within its restricted area.
- The proposed rulemaking will not allow a licensee to hold a device that is not in use for more than 2 years. Although this is a reasonable requirement for a licensee without a radiation protection program, it is an unnecessary burden on a power reactor licensee who has adequate storage facilities.
- The requirement for annual registration, with payment of a fee, would impose an unnecessary burden on a person who already maintains an operating license.

Although the requirements of 10 CFR 31.5 do not seem designed for persons who would be allowed to possess these devices under their operating licenses, the applicability of 10 CFR 31 is not clear. This should be corrected through an explicit statement in the regulations that these requirements are limited to those who cannot possess this device under the provisions of a specific or operating license. (17)

**This commenter (#35) has the same comment as #17, above.** As the holder of a power reactor operating license, under 10 CFR Part 50, Detroit Edison is allowed to receive and possess, at the Fermi 2 site, whatever types, forms, and quantities of source, byproduct, and special nuclear material that are needed to operate Fermi 2. This includes devices that may be possessed under a general license of 10 CFR 31. As a power reactor licensee, however, these devices are included in our radiation protection program, which provides for the proper receipt, use, accountability, and transfer of these devices, as well as leak testing, if the quantity of radioactive material exceeds a threshold quantity. These controls assure that these devices do not create a radiological hazard while in our possession, and that their transfer is limited to authorized recipients. (35)

The proposed rulemaking imposes a registration fee and administrative requirements on those who possess these devices under a general license. It is unclear, however, whether these requirements apply to the holder of an operating license. While appropriate for a person who is not subject to the strict controls of an operating license, these requirements would be an unnecessary burden to a power reactor licensee. For example:

- Fermi 2 is required to leak test sources exceeding a specified threshold, with a contamination limit of 0.005 microcurie. Sources found to have contamination exceeding this limit must be reported to the Commission on an annual basis. Power reactor licensees should not have to also meet the 30-day reporting requirement of 10 CFR 31.5. In addition, the proposed rulemaking would require that the report include "a plan for ensuring that the premises and environs are acceptable for unrestricted use..." This has the potential to impose an unnecessary burden on a power reactor licensee who is using this device within its restricted area.
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- The requirement for annual registration, with payment of a fee, would impose an unnecessary burden on a person who already maintains an operating license. (35)

Although the additional requirements of 10 CFR Part 31 do not seem designed for persons who would be allowed to possess these devices under their operating licenses, the applicability of 10 CFR Part 31 is not clear. This should be corrected through an explicit statement in the regulations that these requirements are limited to those who cannot possess this device under the provisions of a specffic or operating license. (35)

<u>Specific licensees</u>

Honeywell-Measurex recommends that the proposed rules be modified to require the annual registration of devices and sources of the radionuclides and activities specified by 10 CFR 31.5(c)(13)(i) that are possessed by Specific Licensees. (25)

According to the article titled *Radioactive Material in Recycled Metals* (April 1995 issue of Health Physics, authored by Joel Lubenau and James Yusko), naturally occurring radioactive material (NORM) is the largest single contributor to the problem of radioactive contamination in metal scrap. Unfortunately, NRC has not been given authority to regulate the use of radioactive material if it happens to be naturally occurring or accelerator-produced. We see this limitation on NRC's jurisdiction to be a serious problem in itself and an issue that should be reviewed. For purposes of this discussion, we note that the exclusion of NORM limits the potential for this particular set of proposed rules to solve the original problem. (25)

However, the proposed rules in their current form also ignore a large fraction of sources and devices containing radionuclides that are major contributors to the metal scrap problem and that NRC **does** have clear authority to regulate. Specifically Licensed devices generally contain larger quantities of the same radionuclides (e.g. Co-60 and Cs-137) that have been identified for special requirements in the proposed rules for General Licensees and device manufacturers. (25)

To the best of my knowledge, no data presented at any of the meetings or in any of the papers on the topic have ever shown that loss of source/device control is limited to General Licensees. Whenever the justification for ignoring Specific Licensees in the proposed rules has been addressed, much has been made of the ongoing contact between the licensee and NRC. We believe that this ongoing contact is greatly overstated. In fact, many Specific Licensees go years between inspections and license renewals – ample time for organizational changes that compromise source/device accountability. (25)

For these reasons, Honeywell-Measurex believes there is no basis for requiring special registration, labeling, etc. for Generally Licensed devices when there are no comparable regulations for sources and devices with the same radionuclides that happen to be held under Specific Licenses. (25)

Do not adopt regulations for Generally Licensed devices that are stricter than those for applied to Specifically Licensed sources and devices (see discussion under Items 2 and 6). For example, if distributors of Generally Licensed devices are required to provide information on disposal options and estimated costs, this information should certainly be required to be provided to distributors of Specifically Licensed sources and devices. (25)

Incorporation into a Specific License

The requirement to obtain written NRC approval prior to transferring an item to a licensee's specific license will be unnecessarily costly, time consuming, and cumbersome. When the specific license already authorizes possession of the type of material in question, a notification to the NRC of the transfer, in lieu of obtaining permission, will still enable NRC to track the devices. A notification in this case will be more cost effective and efficient for industry. (8)

Many institutions incorporate generally licensed material into their specific licenses and thereby provide strict controls on their use and disposal. The regulations should clearly state these incorporated devices shall be exempt from the Part 31 requirements if incorporated into a specific license. (19)

The University of Cincinnati believes that a specific licensee should be allowed to incorporate generally licensed sources under their specific license, thereby eliminating the need for the general license. If the NRC accepts this suggestion, the University of Cincinnati believes that the transfer from a general license to a specific license could be done during the initial contact with the responsible individual. (21)

## B. Comments Relating to Specific Provisions of the Proposed Amendments

### Requirements for General Licensees

10 CFR 30.31

The registration of particular general licenses is mentioned in 30.31(b); however, the registration requirements are buried in 31.5(c)(13). These are not easily located especially by

general licensees who do not regularly read the regulations. Make “Registration” a separate paragraph with bold type heading. (7)

10 CFR 30.34(h)(1)

Bankruptcy reporting

The current rule requires that all licensees notify the NRC of such situations. I strongly believe the current provision, if properly communicated to customers at the time of the sale, prompts the customer in meeting other regulatory requirements identified in 31.5 for transfer of location or ownership. I would suggest leaving the rule in 30.34 as is and adding a reference to other requirements associated with transfer of ownership of regulated materials that may be affected by the bankruptcy of the general licensee's company. (13)

Bankruptcy notification would bring to NRC's attention facilities in which there is an increased likelihood of lost or improperly discarded sources. The requirement imposes little additional burden on licensees, and the possibility that they could lose their sources is heightened following bankruptcy. Therefore, it would not be unreasonable to require all licensees to comply with this requirement. (28)

10 CFR 31.1 and 31.2

Clarification of which regulations apply

Sections 31.1 and 31.2 -- both state the purpose is to clarify which parts apply to general licensees -- my response would be put all the items that apply to a general licensee in one place so that a booklet can be given to a general licensee by the NRC or manufacturer and the general licensee will have all the information necessary in one place. (5)

Requirements that cover all general licensed sources should be covered in one paragraph of the regulations and requirements that are only applicable to the higher risk sources covered in a different paragraph. (21)

10 CFR 31.5(b)(2)

Recommend modify to read:
*The general license in paragraph (a) of this section applies only to byproduct material contained in devices which have been received from one of the specific licensees described in paragraph (b)(1) of this section or through transfer made under paragraph (c)(9) of this section.* (25)

10 CFR 31.5(c)(2) through (c)(4)

Inventory
The requirement for a six month physical inventory is implied but not stated. It should be clearly stated and the licensee must be required to verify, as a minimum, the name plate

information (i.e., manufacturer, model and serial number, assay date, isotope, activity, location of device). (18)

10 CFR 31.5(c)(5)

Reporting of failures or accidents

This is a trivial point but the verb is "dispose" not "dispose of". The sentence in this section should read "The device may be disposed by transfer ..." (14)

10 CFR 31.5(c)(8)

Transfer or disposal of devices

In the summary and discussion, on page 40299 item (3) first paragraph, general licensee can transfer a device directly to a waste collector for disposal and also to other specific licensees with NRC approval. In the second paragraph, the recipient can be "a part 32 licensee, a part 30 waste collection licensee, or ...". However, the actual text in proposed 31.5(c)(8)(i) is unclear. Should this read "...to a person authorized to receive the device by a specific license issued under parts 30 and 32 of this chapter that authorizes waste collection..." or should it read "...issued under parts 30 and 32 of this chapter, [or] part 30 of this chapter that authorizes waste collection .... "? If this second wording is correct, then (8)(iii) would only apply to specific licensees other than part 30 or 32 and therefore could more clearly read "...Shall obtain written NRC approval before transferring the device to any specific licensee not covered in (8)(i)." (7)

Review of specific part 30 licenses for vendors which we return sources to shows an authorized use “For storage as radioactive wastes.” Though the intent may be the same, is this the same as authorizing waste collection? A general licensee verifying a recipient’s license prior to transfer may have a problem with interpreting this properly. (7)

Section 31.5(8)(iii) While the Boeing Company understands the NRC desire to track certain generally licensed devices, we think the requirement to obtain written NRC approval prior to transferring an item to a licensee's specific license will be unnecessarily costly, time consuming, and cumbersome. When the specific license already authorizes possession of the type of material in question a notification to the NRC of the transfer, in lieu of obtaining permission, will still enable the NRC to track the devices. A notification in this case will be more cost effective and efficient for industry. (8)

From page 40307, first column (8)(ii) and (iii). Item (ii) describes a requirement for the general licensee to furnish a report to the NRC within 30 days after the transfer of a device to a specific licensee. Item (iii) tells the general licensee that they "Shall obtain written NRC approval before transferring the device to any other specific licensee. This is quite confusing to me. If item (iii) is referring to the specific licensee providing a replacement device in item (ii) then this should either be stated as such in (iii), or item (iii) should be included in point (ii) instead of standing on its own. Please clarify this point for our customers. (13)

Proposed 31.5(c)(8)(ii) -- the information requested should be "The identification of the device, source holder, and source by manufacturer's name, model number(s), and serial number(s), as appropriate." Each of these items could be separated from the others when "discovered" and a search of the database would find only the number entered. If there are multiple numbers, all should be entered. (14)

10 CFR 31.5(c)(8)(iii): How will written approval be obtained prior to transferring the device to a specific licensee? (18)

We recommend that NRC define “replacement devices” in Section 31.5(c)(8)(ii)) and the word “replaced” in Section 32.52(a)(3). (25)

Suggest modify (iii) to read:
*Shall obtain written NRC approval before transferring the device to any specific licensee not listed in paragraph (c)(8)(i) of this section.* (25)

Metorex recommends that the term "replacement device" in section 31.5(b)(8)(ii) be better defined. Does this term imply a replacement of one device with an identical device or is it simply replacement with a like device which is also generally licensed? Further, if the "replacement device" is identical, is it expected to have the same source serial number? (27)

ABB recommends that the NRC clarify the definition of “replacement device” in § 32.52 and § 31.5. Confusion is likely to arise under the current wording. ABB, for example, foresees several scenarios that may be considered “replacements.” The situations include: replacements of sources alone, replacements of sources and devices, replacements of devices keeping the same sources, and upgrades of devices on the same measurement system or platform. Further confusion may arise from the time frame of the replacement. (31)

We recommend that NRC clearly define “replacement devices” in Section 31.5(b)(8)(ii)) and the word “replaced” in Section 32.52(a)(3). We routinely ship out replacement devices and/or sources to load into a device. If the device is undergoing a standard reload with a new source, is this a “replacement” since it is a different source? In addition it would be difficult to track what specific source is replacing another source. This should be a user responsibility and not a vendor responsibility. (38)

<u>10 CFR 31.5(c)(9)</u>

<u>Transfer to another GL at same site</u>

Section 31.5(c)(9)(i) - The person having authority to take required action -- This is a very broad statement....this should be a management person as in EPA permits or OSHA Std, a certified statement is required by a president/owner/etc. (5)

NRC should require general licensees who take over facilities containing devices to provide the name of the new RI and BRI. NRC should also require that the responsible individual RI and BRI have knowledge of the device, general license, and relevant regulations. (28)

10 CFR 31.5(c)(12)

Responsible individual

31.5(c)(12): I agree with the proposed requirement to have each general licensee have an individual assigned to the day-to-day compliance duties. I do not agree with using the term "responsible individual" since the licensee is ultimately responsible for the devices, not this individual. Although the proposed rule states that the general licensee is responsible, there may
be some confusion regarding these responsibilities. (12)

One question: If a licensee holds both a general license and a specific license, can the "responsible individual" be someone other than the RSO listed on the specific license? (12)

The method of appointing a "responsible person" needs to be modified. The proposed rule requires the general licensee (purchaser/transferee) of any generally licensed material to assign a responsible person but does not insure that the purchaser has selected an appropriate or willing individual. The rule must include a provision to require (and document) that the general licensee has obtained permission from the proposed responsible person to be listed as such. The responsible person can not fulfill their duties unless they are aware that they have been named and are aware that generally licensed material has been acquired. (19)

The proposed rule states that the responsible person must have the "authority for taking required actions to comply with appropriate regulations" implying authority over the actions of the user (general licensee) of the licensed device. It also implies liability in the case of misuse or improper disposal. The rule further states that the appointment of the responsible person "does not relieve the general licensee of responsibility". This is contradictory. The rule should be revised to state that the responsible person acts solely in an advisory role and that the general licensee alone is responsible for complying with regulations and liable for misuse or improper disposal. (19)

Suggest revise to: **Any general licensee required to register devices in accordance with paragraphs (c)(13),** shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of responsibility in this regard. (20)

The University of Cincinnati agrees with the requirement that general licensees designate a responsible individual. A second or backup responsible individual should not be required. Timely notification of the designated responsible individual by the specific licensed distributor or the NRC is a must. Notification prior to receipt of the generally licensed item is preferred; however, if notification occurs after receipt it should have to occur quickly (e.g., within 30 or 60 days of receipt). Notification must be ensured by returned receipt of acknowledgment and must include a copy of applicable regulations and general license requirements. (21)

We recommend that NRC expand the definition of the “individual responsible” in Section 31.5(c)(12) to explicitly address:

- The fact that this individual does not necessarily have to work on site at the place of use of the device(s). Without this clarification, there is a strong probability that there would be varying interpretations, including ones to require the individual to work on site or and/or to restrict the use of the device to times when that individual is physically present. In our experience, some of the best radiation safety programs are ones that are very centralized (e.g. the 3M radiation safety program) and we think it is important that any new rules explicitly permit such programs.
- Whether the individual must be an employee of the General Licensee. (There are good arguments on both sides of this question; Honeywell-Measurex makes no suggestion beyond recommending that the regulations address and clarify this point to minimize chances for varying interpretations among regulatory agencies.) (25)

We agree that there needs to be a clearly defined person responsible for all devices that contain radioactive material. Some of the discussion on this issue mentions the need for a named backup individual. We feel that this is unnecessary. What would help accountability is a clear understanding that the management at each licensee site is aware of these requirements much in the way OSHA and EPA requirements are the ultimate responsibility of the owner or plant manager. (26)

Metorex feels that it should be possible for a non-employee to be the responsible individual for a registered device, Section 31.5(c)(12). In many cases, a small company holds the device and the concepts of the regulations are not well enough understood by the management of the company. Hiring a consultant would greatly improve their awareness of the regulations and would better achieve the goals of this regulation. Section 31.5 (c )(12) points out that appointment of this individual does not relieve the general licensee of the responsibility for enforcement of the conditions of the license. (27)

The SMA supports the proposed requirement of designating a responsible individual (“RI") for ensuring compliance with NRC regulations, in instances where the licensee is a firm or organization. Furthermore, any limitations on operational flexibility imposed by designating an RI and BRI would be negligible compared to the risk to the licensee company from lost sources. (28)

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. (30)

ABB agrees with the objectives behind requiring a Responsible Individual be assigned for each General Licensee. We believe that this requirement alone will lead to significant increases in control of devices at the General Licensee's locations. However, there needs to be some clarification with respect to the requirements for establishing this position. Particularly, make clear if the individual needs to be at the location of the devices under his/her responsibility and if the individual needs to be an employee of the General Licensee. (31)

ABB believes that the Responsible Individual should be allowed to both be at a location separate from the devices (i.e. a corporate individual responsible for many company sites) and be from outside of the General Licensee's company (i.e. a consulting organization). For either situation to be permitted there must be the obvious requirements that the individual is physically able and has the appropriate authority from the General Licensee to perform all required duties. Not allowing either of these situations would put restrictions on General Licensees that are not applicable to Specific Licensees. A Specific Licensee's Radiation Safety Officer, a position of significantly greater responsibility, is permitted to be at a location separate from the materials on the license and is also permitted to be from outside of the organization. Further, these restrictions would not promote the objective of the proposed changes, control and accountability of Generally Licensed devices. (31)

10 CFR 31.5(c)(13)

Registration

Since the intent of these proposed regulations is to increase the oversight of 5100 licensees with 20,000 sources deemed higher risk, Paragraphs 31.5(c)(12), (c)(14), and (c)(15) should only be applicable to general licensees who must register under paragraph 31.5(c)(13), and not to all general licensees. Otherwise, the burden is imposed upon 40,000 general licensees with 580,000 devices. Group these paragraphs with the registration requirements or reference the applicability to 31.5(c)(13), such as “(12) General licensees who are required to register under paragraph (c)(13)(i) shall appoint....” (7)

It is my opinion that once a registration policy and annual fees are implemented for certain general licensees that these licenses should be changed to a new category of specific licensees for these devices (a device specific license). This would be consistent with other license types that present a potential higher risk and are assessed an annual fee. The idea that some general licensees would be regulated differently than other could potentially cause more problems than it solves. One problem would be additional work for the NRC from general licensees submitting registrations for devices that are not required to be registered under the proposed rule. This is illustrated by the fact that at least one person that commented on the NRC rulemaking web site mistakenly thought that tritium "EXIT" signs would have to be registered. A few questions: If a licensee possesses devices that need registration along with devices that do not need registration, do all the devices need to be registered? Would specific
license holders have to pay the registration fee? 31.5(c)(13)(iii)(E) and (F) require "certification by the responsible representative of the general licensee." Do 31.5(c)(13)(iii)(E) and (F) require this "certification" by the licensee's management or the "responsible individual"? The NRC requires specific licensee's management to review and sign all licensing actions. It is not clear to me who is responsible for doing the certifying in these paragraphs. (12)

The problem of distributors or "intermediates". Beyond the technicality that anyone possessing or storing the device before its final installation is also a general licensee, the focus needs to be on the end user. The use of a "registration card" similar to the common warranty card that comes with nearly every appliance should be instituted. The registration card should have the appropriate device, source holder, and source model and serial numbers pre-printed. The end user need only fill in the facility information and address it to the appropriate agency. The manufacturer continues to report "distributions", the agency cross checks the distributions against end user cards, and follows up with the manufacturer or distributor if all devices leaving the manufacturer are not reported to be installed after some appropriate time. (14)

(Mentioned at the public meeting) Charge fees every four years to lessen the cost of collection. Sounds good except that the issue is "contact" with the general licensee. The annual fee collection is also the opportunity to jog the general licensee on "responsible individual", leak testing, inventory, storage limitation, etc. It is also easier on the budget to keep the fee relatively constant and "low". (14)

Metorex is concerned about the requirement in the new paragraph 31.5(c)(13)(ii) that the user will be required to respond to the notification within 30 days. In the first round of notifications, this requirement could cause substantial burden for the manufacturers and distributors. As the NRC already recognizes, there are many general licensees who do not realize the requirement(s) imposed by a general license. These users will contact the manufacturers and/or distributor of the device and look for assistance in providing the required information. If all the notifications are mailed simultaneously, this may cause an undue burden on the supplier. We hope that this will be taken into account and that the NRC will provide the extra time required for the first round of registrations. (27)

We support any registration format that simplifies licensees' reporting requirements while maintaining the quality of the data being reported, because it will encourage more licensees to report. We agree with NRC's proposal to send registration request forms to licensees to verify, correct and/or add to the information provided, similar to automobile registration renewals. (28)

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 many posses. 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, 199 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. (30)

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 about several aspects of the proposed rule that seem particularly unnecessary and inappropriate. (32)

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. (32)

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. (32)

10 CFR 31.5(c)(13)(i)

Registration Criteria

What criteria will be used to amend 30.5(c)(13)(i) to add additional devices to the list of devices that require registration? These criteria should be specified so that knee jerk reactions by the NRC to improper management, use or disposal of certain generally licensed devices does not occur. (12)

Personally, I would like to see 63Ni added to the list of those radioactive elements targeted for registration and tracking. I say this because of the expected improvement in the NRC's ability to track our devices once they leave our control. I have been contacted by too many customers who have inherited their devices without receiving necessary regulatory information from the previous owners. These customers learn of those requirements only by chance or when a state regulatory agency representative shows up at the door. A $420 annual fee is cheap compared to the panic these customers experience. (13)

(Raised at public meeting) Exempting "robust" sources. We oppose this idea. This rule is based on a history of smelted sources, among other concerns. So-called "robust" sources are not smelter-proof. If radioactivity is present, the risk is present and some enterprising soul will someday find a way, probably inadvertently, to defeat whatever safety barriers have been put in place. (14)

It is unclear whether any of the devices (e.g., exit signs, static eliminators, or thickness gages) potentially used at dealerships would make them subject to the proposal's physical inventory, annual registration, and/or fee requirements. Surely such requirements would be excessive given the nature of these devices and their use. On the other hand, additional specific licensee requirements designed to ensure that their customers receive adequate, life-of-product information on the proper use and disposal (or transfer) of these devices, would be consistent with accepted product stewardship best practices. (22)

**Devices containing radioactive material below the defined limit** – Since the purpose of these regulation changes is to increase the accountability of devices, the limit for Cs-137 that requires registration should be lowered. Currently some manufacturers are attempting to

circumvent the rules and the interest of public health and safety by packaging or directing other people to repackage exempt quantities of radioactive material. If the proposed rule were to state that any quantity of Cs-137, Co-60, Sr-90, Am-241 or any other transuranic distributed under 31.5 would require registration, the loophole that allows significant quantities to be unaccounted for and improperly disposed of could be closed. This would still allow for the use of individual exempt quantities of material to be used as calibration or check sources. (26)

The proposed rule would require all general licensees to register. This requirement will help NRC ensure that all licensees are held accountable for their sources. A system that holds only a portion of licensees accountable could create an incentive for some licensees to try to opt out of the regulatory net by arguing that the registration system does not apply to them. (28)

There does not appear to be a strong technical justification for the types and quantities of devices that require the annual registration and fee. Many of the sources that we provide for the devices meet special form requirements and have achieved the appropriate ANSI/ISO classification for use. They are designed and constructed to withstand hypothetical accident conditions and extreme environments of use. They are normally a double or triple encapsulation making it impossible to inadvertently open up a capsule. All of these characteristics significantly minimize any safety implications even if the device were abandoned or lost. These physical considerations do not appear to have been considered in establishing registration requirements. (38)

10 CFR 31.5(c)(14)

Change of address reporting

From page 40307, third column, point (14) "Shall report changes of address...". The requirement for reporting changes of addresses do not provide for the exemption from reporting if the device is transferred to the specific licensee in order to obtain a replacement device from the same specific licensee as previously described in point (8)(ii). Should the same provision be made in point 14 if a replacement is purchased from the same specific licensee? (13)

10 CFR 31.5(c)(15)

2-Year storage period

Our company is a small laboratory using several electron capture detectors on gas chromatographs. These detectors each contain 8mCi of 63Ni. The radioactive isotope is a replaceable foil located inside the detector. The user ships the device out to an approved facility for replacement of the foil and or internal cleaning. (4)

It is not uncommon for these devices to be stored for periods exceeding two years and then be put back into use for special projects. For instance, the Safe Drinking Water Act specifies testing for contaminants on three and nine year intervals. While some devices may be in use during this time frame, other devices may be in storage for use during the peak demand time. In addition, a device needing foil replacement may be kept on hand to minimize down time.

The device is eventually shipped out for foil replacement while another device is kept in service. (4)

I can understand the desire to avoid individuals stockpiling unusable devices as a means of avoiding proper disposal, however an electron capture detector can be stored for more than two years and still be in usable condition. It would be unreasonable to require the disposal of the detector simply because it hasn't been used for two years. (4)

While an electron capture detector in need of service still has value to a laboratory, other devices may not. From reading the proposed regulations it seems that a substantial number of devices are unaccounted for at the present time. At least some of these devices may have found their way to other general licensees capable of caring properly for the devices. Owners of such devices when faced with a two year maximum storage time may be reluctant to admit the presence of all of the devices on the premises, in particular, any devices they may have acquired without authorization. In such cases the two year maximum holding time may actually run contrary to the purpose of the proposed rule and encourage some to withhold disclosing the presence of these devices or improperly dispose of the devices. (4)

I believe that accounting for all of the devices is far more important than time restrictions on device storage. Please consider eliminating the time restrictions on storage of devices or alternately, consider exempting devices with replaceable isotopes from the time based storage rule. (4)

**Fort James urges the Commission to limit this provision to nuclear sources that have been removed from service and are either awaiting transfer back to a specific licensee for disposal or have been temporarily removed from service.** There are two reasons for this request.

A. Because NRC's Proposal would provide for procedures to assure that sources (including those kept in storage) would be properly managed, there is no compelling reason to limit storage time for unused sources to two years.

In this Proposal, NRC would establish several procedures to assure that all generally licensed sealed sources would be properly managed. These include appointment of a responsible person at each facility who would manage all on-site sources; even those kept in storage. The proposed registration procedures would further assure that all generally licensed sources would be properly inventoried, and none, even those in storage, would be overlooked. With these procedures in place, there is no reason to limit storage time to two years.

Fort James agrees with NRC, however, that sources removed from service for transfer to a properly licensed disposer should be returned as soon as possible. In this scenario, a shorter time frame, such as six months, seems adequate.

For sources that have been temporarily removed from service but will eventually returned to active use, the two-year period should apply. This would allow licensees to remove sources into storage while a production process is being reconstructed or while a new application for the nuclear device is being built. The two-year limit would

discourage licensees from holding a discontinued sealed source indefinitely to avoid proper disposal.

B. Some sealed nuclear gauges are essential spare parts for production processes.

There are some applications where nuclear gauges are essential to the operation of process equipment. An example would be a gauge to control the level of material inside a chemical reactor. In several instances, there is no feasible alternative to a nuclear gauge measuring device. If the level gauge fails, the equipment must be shut down until the gauge is replaced. In this case, it is essential to have an on-site spare.

It would be excessively restrictive if the two-year storage requirement were to apply to this situation. A facility would be forced to recycle a new, unused gauge and purchase a new one merely because an arbitrary time limit had passed. (6)

Move the sentences regarding testing during storage to 31.5(c)(2) as subparagraph (iii), which covers testing requirements. (7)

The proposed regulation states that [the licensee] "May not hold devices that are not in use for longer than 2 years." What must be done with a device after two years of storage? A general licensee who receives a copy of these regulations after the final rule will not have the comments as outlined on page 40299 paragraph (2) to guide him. Therefore, for clarity, the regulation should state possible actions such as

a. Disposal of device via an authorized licensee
b. Send the device back to the supplier (or authorized licensee) for interim storage (The supplier may not want to provide this service and/or almost certainly will impose a storage charge)
c. Request an exemption from this paragraph from the NRC (will a "timely request" prevent enforcement action until the request is acted upon?)

In our case, the University possesses several gas chromatographs with generally licensed Ni-63 electron capture sources which have not been used for more than two years. However, research interests change and the units may well be utilized again. As a policy, we continue to perform leak tests at six month intervals to assure no source degradation and to confirm the device and/or researcher is still present. Once the device is no longer useful, we remove the source and either dispose of it or return it to the device manufacturer. (7)

Persons holding generally licensed devices that have been in storage for more than 2 years will be in immediate noncompliance if this rule is implemented in its present form. Public safety will be better served if general licensees are given a reasonable amount of time after implementation of this rule to properly dispose of the material. If the storage provisions become effective 2 years after the passage of the rule, general licensees with material currently in storage will have the same amount of time as general licensees with newly acquired devices to arrange for proper disposition of the devices. (8)

Continuing on page 40307, point (15): This, of course, may generate more business for us but I question the short time period of 2 years as the life expectancy of our devices is in the decades and different product life expectancies vary depending on equipment type and half-life of the radioactive materials in them. I would much prefer to see that customers be required to maintain the current wipe test frequency during storage. This keeps the customer knowledgeable of the device's ownership and location. If the agency does allow a 2 year exemption of testing during storage, then I would suggest building upon the proposal and require a wipe test be performed at the time of removal from storage by an authorized organization, forbidding installation or use of the device until acceptable results are obtained. (13)

10 CFR 31.5(c)(15): Devices in storage should still be required to be subject to six month physical inventory requirements. (18)

The statement in the proposed role that "general licensees are unlikely to keep a device unused for more than 2 years" is inaccurate. The imposition of a two-year limit on storage would be a hardship for the university research community. It is often the nature of scientific research in a university setting for radioactive devices to be used intermittently. For instance, funding of grants to conduct research utilizing generally licensed devices is sometimes not forthcoming and a device may need to be stored until the project is again funded. One common laboratory device is the liquid scintillation counter which usually contains a generally licensed external radiation standard. The proposed rule might require disposal of this expensive piece of lab equipment which, almost certainly, would be used at a future time. The University recommends that the permitted storage time period be changed to 5 years. (19)

Proposed 10 CFR 31.5(c)(15) requires that a general licensee not hold devices that are not in use for longer than two years. Again, this would also prove burdensome. Generally licensed devices may placed in storage and not be used for a period of more than 2 years. The owner may intend to use the device at a later date. This proposed rule would preclude this activity and would require the general licensee to dispose and re-purchase the generally licensed device. In the case of a static eliminator, it would be very difficult for the responsible individual to determine when such a device has been held in storage for longer than 2 years. (20)

The additional regulatory burden required by the Proposed Rule is not warranted in light of the following. Typically, the devices employed by the pharmaceutical industries, as with many other industries, are those which present a lower risk. These devices are sealed sources which are designed to be inherently safe with regard to radiation safety. These devices are manufactured and distributed without serial numbers. Therefore, to require a general licensee to inventory and assure that devices are not stored for more than two years poses an undue regulatory burden. (20)

Suggest revise to: **10 CFR 31.5(c)(15)(i)** May not hold devices that are not in use for longer than 5 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph (c)(2) of this section need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person and have not been tested within the required test interval, they must be tested for leakage before being put back into service. (ii) **For generally licensed**

**devices distributed without an affixed serial number, 10 CFR 31.5(c)(15)(i) is not applicable.** (20)

Modify to read:
*May not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph (c)(2) of this section need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage (devices containing only krypton need not be tested for leakage) before use or transfer and the shutter tested before use. (25)*

Exposure or risk to the general public has been minimal; therefore, I suggest that any rulemaking that does not directly affect the accountability issue be deleted. Additional requirements on labeling, length of storage, or the information supplied to the customer will have little or no effect on the accountability of the radioactive material. (26)

These rules place an arbitrary limit on the storage of devices not in service. Clarification needs to be made for devices that may be out of service but are planned to be reused at a future date that could be several years. In addition, for some critical applications a spare device might be kept in storage for years. It is also possible for a general licensee to possess a device that is kept in secure storage because there is no path for disposal or transfer. Am-241 is an example of what would be orphaned waste. The portions of this rule that require a responsible individual and reporting will be sufficient to ensure accountability of sources in storage. (26)

We support the proposed requirement to limit the period during which a device may be stored and unused to two years. We agree that when a device is not used for a prolonged period of time, it is susceptib!e to neglect and improper disposal. In fact, some licensees store sources as a way of avoiding the costs of proper disposal. This provision would compel licensees to decide whether to use, return, or properly dispose of their sources, and would hold licensees accountable for their decisions. (28)

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. (30)

<u>10 CFR Part 170</u>

<u>Registration Fee</u>

We believe that the result of this proposed rule will leave the NRC with progressively less to regulate, and fewer licensees to share in the cost. Page 40297 states that the fee could be some what higher in the final rule, (i.e.) by using a formula of cost divided by licensees. Since I am telling you we will convert, this statement must be changed to “will” vs the conditional “could”. And you well know we will not be the only ones to scrap out devices to avoid the fee.

Further, we will cease to recommend any nuclear device for industrial use where a non nuclear substitute is available. (2)

If the intent of this proposed rule is to eliminate all nuclear devices possible, then this is a good first step toward that goal. (2)

Based upon my understanding of sales volume, smoke detector ionization sensors, represent a larger share of radiation devices in use, and including them in the regulations would make your divisor considerably larger thus reducing the fee substantially. However, confronting the general public with such and idea wold seem to be politically unwise. In any event the inclusion of “EXIT” signs in this proposed rule and fee structuring is ridiculous. You obviously needed the inclusion to increase the divisor, a goal it will not achieve. (2)

Also, suggests that there are alternatives for thickness gauges, gas chromatographs, level detectors, etc. and that a fee charged over a ten-year life could significantly affect life cycle cost analysis. (2)

Significant numbers of people will go to nonradioactive alternatives, reducing the number of people to collect fees from, leading to higher fees, and further reduction in use of products; suggests fees for smoke detectors would increase the numbers to divide costs among. (2)

We believe that the result of this proposed rule will leave the NRC with progressively less to regulate, and fewer licensees to share in the cost. Page 40297 states that the fee could be some what higher in the final rule, (i.e.) by using a formula of cost divided by licensees. Since I am telling you we will convert, this statement must be changed to “will” vs the conditional “could”. And you well know we will not be the only ones to scrap out devices to avoid the fee. Further, we will cease to recommend any nuclear device for industrial use where a non nuclear substitute is available. (2)

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**Are the proposed fees reasonable?** No, they are not reasonable. The intent of having a single fee for a registrant makes sense. But, if the registrant has only one small device and the fee is much more than the device, where is the incentive to use the device? Also, using the exit signs as an example again, does the fee recognize that the consumer purchased the device to improve the safety of a building for the general public? (3)

Would specific license holders have to pay the registration fee? (12)

Personally, I would like to see $^{63}$Ni added to the list of those radioactive elements targeted for registration and tracking. I say this because of the expected improvement in the NRC's ability

to track our devices once they leave our control. I have been contacted by too many customers who have inherited their devices without receiving necessary regulatory information from the previous owners. These customers learn of those requirements only by chance or when a state regulatory agency representative shows up at the door. A $420 annual fee is cheap compared to the panic these customers experience. (13)

Charge fees every four years to lessen the cost of collection. Sounds good except that the issue is "contact" with the general licensee. The annual fee collection is also the opportunity to jog the general licensee on "responsible individual", leak testing, inventory, storage limitation, etc. It is also easier on the budget to keep the fee relatively constant and "low".(14)

10 CFR 170.31(3)(Q): The NRC has always had in rule the requirement and ability to maintain accountability of general license devices via the manufacturer's required general license distribution reports. It is unclear as to the rationale of an annual $420 fee. It is suggested that this be an initial start up fee and that further evaluation for maintenance/inspection fees be conducted after the program has been in place for a few years. (18)

NRC proposes a registration fee of $420 per licensee to cover NRC's costs of the registration program. The SMA believes this to be a modest and reasonable fee for all licensees, including small businesses. (28)

The current regulatory regime has shifted the costs of lax accountability and control onto steel makers, insurers, and the taxpayers. General licensees do not pay directly for their licenses. The cost has instead fallen on steel producers to detect the sources, on the steel producers and taxpayers to arrange for proper disposal, and on steel producers and their insurers to pay the cost when a source is inadvertently melted. The cost has also fallen on the general public, in the form of increased risk to health and safety from unanticipated exposure to dangerous levels of radioactivity. General licensees, who benefit economically from the manufacture, sale and/or use of radioactive devices, should be required to shoulder their fair share to protect the public. Accordingly, an annual fee in the neighborhood of $420 is not only equitable, but entirely reasonable. (28)

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. (32)

We have evidently been included in this mailing because the church has two self-luminous exit signs. My best interpretation of the proposed fee schedule indicates that the church could be required to pay an annual registration fee of $420 for the privilege of continuing to use these two signs. (34)

It seems self-evident that this ruling has the potential to penalize many small institutions unreasonably. If the regulation fee passes as proposed, and the fee will be required of us, kindly be advised that we will no longer have the signs. (34)

Single fee per registrant.

Makes sense but if significant fee for small device no incentive to use, even if beneficial as in safety improvement with use of self-luminous exit signs. (3)

**Requirements for Distributors**

10 CFR 32.51(a)(4) and (5) and 32.51a(c)

Labeling

As recommended by George Brown of Ohmart at the 1 October workshop, Honeywell-Measurex recommends that the wording in the proposed 10 CFR 32.51(a)(4) be changed to replace the word "permanent" with the word "durable". Obviously, distributors of these devices must be able to remove the labeling as required by 10 CFR 20.1904(b) when we remove the radioactive source and are ready to scrap a source housing. If we have truly added "permanent" markings, this will not be possible. (25)

I suggest that any rulemaking that does not directly affect the accountability issue be deleted. Additional requirements on labeling, length of storage, or the information supplied to the customer will have little or no effect on the accountability of the radioactive material. (26)

Additional rulemaking on labeling is unnecessary and should be considered as part of the device registration. All containers or devices are required to be labeled now by 10CFR 20.1904(a). The wording that refers to *permanent, embossed or engraved* will result in confusion. Many components that would be shipped as part of the manufacturing process would be labeled and contain no radioactive material. Any label must be removable to meet the requirements of 10CFR20.1904(b). (26)

The SMA supports the requirement of additional labelling on source housing. Steel companies have received on several occasions improperly discarded sources and source housings on which the label has been removed. A marking of the serial number on the source housing would alert NRC and the public to the existence of the missing source. (28)

The SMA also supports the requirement that labels be embossed, etched, stamped, or engraved on the devices, for the reasons NRC listed in its proposal. Permanent labeling would help alleviate the problem of removed labels. It would also help prove criminally improper disposal, as the effort and deliberation required to remove such labelling would indicate the willfulness of the offense. (28)

ABB requests that the Commission replace the term "permanent label" [32.51(a)(5)] with the term "durable label." This change would reflect the apparent intent of the proposed rules without conflicting with the requirements of Part 20.1904(b), which requires removal of labels.

A “durable label” also implies that labels on a device could be changed to reflect new source serial numbers, as this information is required to be on the label. Many of ABB’s devices allow for the interchanging of sources without replacement of the entire device. In this situation, the source serial number is likely to change many times in the lifetime of the device and hence the device labels will be changed many times as well. (31)

Frankly, I find it difficult to imagine that anyone could ever be so boneheaded as to dispose of a nuclear device in the scrap heap. I simply don't believe that an increase in administrative costs is going to accomplish anything. What is needed is education in the proper use of the device all up and down the chain. Perhaps some very, very distinctive marking of the device would help to drive the message home. We would be most happy to participate in any program of these types,.. (36)

Require distinctive markings, insist on proper warnings to go along with each device, insist on proper education of users - do all those things. But don't penalize the people who are not violating good practice by adding to their costs!!!!! (36)

10 CFR 32.51a(a) and (b)

Information to be provided to users (prospective customers)

If the intent of the rules changes are to make sure that general licensee's know the rules, follow labeling requirements, and dispose of their devices properly, then it would make more sense to make sure that all general licensee's know what is expected of them. We did not receive any information from the manufacturer, distributor, or supplier on any of these items regarding the illuminated exit signs that we purchased. Complete instructions, including the regulatory requirements, should be packaged with all devices so that consumers know what is expected of them. (3)

The companies selling devices containing these sources sell to the individual researcher or department within the institution. The information required to be provided under 32.51a is included with the documentation accompanying the device and often the "responsible individual" representing the institution normally does not receive it. In practice, the researcher/department does not read the information since it is not applicable to the operation of the instrument, and the institution is oftentimes unaware that the device is in its possession. Only one of the six vendors noted above routinely notifies us when a new source comes onto campus. Copies of recent notification letters are attached and demonstrate that it really doesn't know who to notify, though it made a good guess is addressing it to the radiation safety office. Your own mailing of this proposed rule was sent to a formerly independent institution which is now under our umbrella, and also to a researcher who retired several years ago. In both cases, the mailing was forwarded to our office by mail room staff who recognized that mail from the NRC usually comes to us. (7)

IDNS recommends that NRC require distributors to include information about NRC fees and the likelihood of agreement state fees in the information provided to prospective customers pursuant to 10 CFR 32.51a(a) and (b). We have experienced situations where licensees became resentful when learning after buying expensive equipment that they were also subject

to regulatory fees. The department believes that advance notice of the possible existence of fees would lead to better cooperation and reduce the potential for unauthorized transfer of devices. (9)

The information provided to recipients of the generally licensed devices should also include a Safety Analysis Summary (SAS) for each general licensed device transferred. The SAS should provide information that would be useful to regulating agencies and end users during normal use and accident conditions. The NRC recognizes the fact that general licensees have no radiation background and should, therefore, recognize that general licensees would not be able to answer any questions raised by the employees about the hazards associated with routine use of the device or working in the area of such a device. Additionally, the general licensee would not know how to deal with incident involving their device. A well thought out SAS should provide this information and during an incident would provide general recommendations that should be taken to reduce contamination and unnecessary radiation exposure. This information could be used by the general licensee in a manner similar to Material Safety Data Sheets which many industrial facilities use routinely. (11)

§ 32.51a(a): The manufacturer should be required to provide the required information to the "responsible individual" not "to each person that to whom a device is to be transferred." The NRC should supply, upon request, the manufacturer with the name of the "responsible individual" for a general licensee. This would assure that the responsible individual is aware of all new generally licensed devices that are purchased. This would also help the NRC maintain licensee accountability. (12)

From page 40301 of the proposed rule changes, third column "...The distributor would also be required to provide copies of additional applicable sections of the regulations..." This would be in addition to section 31.5 which will be required to be given to the customer prior to the product's transfer. I have a concern over the amount of paperwork thrown at a proposed customer. I believe Section 31.5 is critical for review prior to the sale but I think additional information could be provided with the product at time of delivery. If the intention is to communicate necessary information, we may be able to better accomplish this if we could indicate that further necessary regulatory requirements are specified with the delivery of the product and the end user is responsible for compliance with all regulatory information provided. (13)

I would also recommend a validation form be sent along with section 31.5 to end users purchasing all general license devices, requiring the user to sign the form indicating they had received, read, understood, mid would comply with the regulation(s) provided. People have a much greater tendency to read and comply with something if they must put their signature to it. (13)

Continuing with the same paragraph on page 40301, the last sentence in the paragraph reads "In addition, the distributor would furnish the name, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained." I question the value of indicating a person's name instead of the title "Director". At least one of the agreement states has asked me not to include the state director's name in my quarterly reports and I feel it should be the same for the information we provide our customers. (13)

In 32.51a(a), the last sentence of the paragraph reads, "The required information includes-" and then lists a copy of 31.2, 30.51 20.2201...in line (2). I wonder why the requirements in this section do not match the information general licensees are responsible for as defined ill the proposed section 31.2 on page 40306? (13)

Continuing with 32.51a(a). Line (3) of the required information to be provided to general licensees states "A list of the services that can only be performed by a specific licensee". Please explain what this means. If the section refers to sales of general license devices would it not be better to identify the restrictions of the general licensee as opposed to the allowances of the specific license? If not, who determines the list of services that can only be performed by a specific license? This pertains to point 32.51a(b)(2) as well, which is a copy of the same point. (13)

I am very confused over the wording in the proposed change in 32.51a(b). The current requirement clearly allows for furnishing a copy of the general license contained in the Agreement State's regulation equivalent to 31.5, or alternatively, furnishing a copy of the NRC's 31.5 (along with other specific information) to persons in Agreement States. The proposed rule may imply in section 32.51a(b) and (b)(1) that this will continue but it is not clear. I believe the intention was to continue making the alternative possible and, if so, I suggest proposed 32.51a(b)(1) be changed to state that the supplier may alternatively furnish a copy of the NRC's 31.5, as now provided for. (13)

Making a requirement for the distributor of the generally licensed source to provide applicable regulations to the general licensee is insufficient. If the regulations are part of a large packet of information they are too easily overlooked. Also, if the individual is unfamiliar with regulations the significance of the information may not be understood. (21)

The NRC has concluded that some general licensees are:

- Unaware of the rules that apply to the possession of generally licensed devices.
- Unable to account for their devices.

To remedy these concerns, the NRC should require specific licensees to undertake increased outreach efforts aimed at making general licensees better aware of their regulatory responsibilities. This can best be done using simple, straightforward, device specific fact sheets. Requiring specific licensees to distribute copies of the NRC's regulations is of little value to small business general licensees who lack the expertise to interpret rules or who, for a variety of reasons, may be unaware of the devices they use. The NRC also should endeavor to outreach to general licensees by working with and through industry trade associations and trade press. (22)

I suggest that any rulemaking that does not directly affect the accountability issue be deleted. Additional requirements on labeling, length of storage, or the information supplied to the customer will have little or no effect on the accountability of the radioactive material. (26)

I agree with the intent of this portion of the proposed rule to try and make sure a person purchasing a device with radioactive material and their management understands all of the

implications and requirements of owning a device containing radioactive material. Too many times I meet individuals who think that a device is possessed under the manufacturer's general license. The rule as worded is too vague as to the timeframe and as to what level of documentation is required to ensure that the information has been given to the customer. As a distributor we can only make a good faith effort to get the information to the end user. (26)

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. (30)

We routinely accept the return, at no charge, of our gauges when they are no longer being used. The NRC should encourage others to do the same, and insist that Specific Licensees include appropriate warning and training manuals with the gauges they ship. That will be a lot more effective than adding another layer of administration. (36)

With the proposal to identify a responsible individual, it should be made clear that it is not the vendor's responsibility to assess the competency or reporting structure of the organization. We will provide whatever name is supplied to us by the user. (38)

Although the intent of NRC is to educate the end user of the requirements for a generally licensed device, we do not believe the proposal is necessary. It is difficult to implement, will not increase safety and it will be unenforceable. (38)

The requirement for certain information to be provided to the end user "prior to transfer" is vague on when the information is to be given to the prospective user. In addition providing the information to the personnel making the decision to use the device still allows that the information may not get to the individual that will be ultimately responsible for compliance. It will be difficult to demonstrate compliance that the information was given by the vendor and then reviewed by the end user. Does a record need to be kept showing the information was sent which is then auditable? (38)

We agree that the potential user should be made aware that there are regulatory requirements inherent in the use of the device, however this is normally covered in the sales brochures. The specific requirements and copies of regulations should be given at time of sale with the product. We do not support providing estimated disposal costs as it will be difficult to determine those as they vary significantly over time and contracts/vendors. In addition the requirement to provide disposal costs to general licensees would be more restrictive than what is currently required for a specific licensee. Disposal costs are not required to be given to a specific licensee. (38)

We believe the current requirement to provide information with the device is adequate. The additional information proposed to be given to the end user will not significantly increase compliance. However enforcement of the existing requirements will meet the intent of the proposed requirement. (38)

Disposal information

Section 32.51a(b)(3) requires information on acceptable disposal options including estimated costs of disposal. Estimated costs of disposal should be deleted. Disposal availability and costs for disposal change continually and any estimated costs are likely to be meaningless at actual time of disposal. (15)

Information on "acceptable disposal" can not be accurately provided by the vendors. The lifetime of many of the applicable sources/devices can be upwards to 30+ years. Right now, we can not assuredly state that there will be viable disposal options next year, let alone 30 years from now. It is important to remember that the willingness and ability of a vendor, or other Specific Licensee, to accept sources from a General License is dependent on the options for ultimate disposal of the sources. For example, there are not viable disposal options for Am-241 for most companies. The situation for radioactive waste disposal is currently so tumultuous that any information that a vendor would supply regarding source transfer/disposal availability or cost is subject to being very wrong and possibly misleading. Therefore, the vendors should not be required to provide this potentially wrong and misleading disposal information. (31)

In addition the requirement to provide disposal costs to general licensees would be more restrictive than what is currently required for a specific licensee. Disposal costs are not required to be given to a specific licensee. (38)

10 CFR 32.52(a) and (b)

Material transfer reports

Part 31.5(a) states general-licenses are issued to commercial and industrial firms research, education, and medical institutions, individuals in the conduct of their business. As a large research, education, and medical institution, the University of Pittsburgh currently has 80 liquid scintillation counters containing generally licensed Ra-226, Ba-133, Cs-137 or Eu-152 sources with activity less than 30 uCi. In addition, we possess 11 gas chromatographs containing generally licensed Ni-63 sources with activity less than 15 mci. These devices were manufactured by six different vendors. (7)

The vendors need to be educated that it is the institution, not the individual or department, which holds the general license. In order to make your database as accurate as possible, Form 653 should make this clear. (7)

The proposed requirements at 10 CFR 32.51(a)(4) and (5) appear to clarify what NRC expects of manufacturers regarding labeling of devices. We recommend the same clarification be extended to material transfer reports required by 10 CFR 32.52(a)(1) and (b)(1). Specifically,

we recommend that material transfer reports provide the model and serial number of the item of primary regulatory interest (for example the device or a separable source housing). This would provide more specific guidance than is now proposed at 10 CFR 32.52(a)(1)(iv) and (b)(1)(iv). IDNS believes that more specific instructions for reporting serial numbers would increase the likelihood that a serial number on file with a regulatory agency matches one on a corresponding label. (9)

Page 40308, section 32.51a(a) "Conditions of licenses". I could not find the term “intermediate person" defined in any of the regulations I have accessed. During the October 1 workshop, I was informed that intermediate persons referred to general licensees who receive a radioactive device but are not the ultimate user. The term does not, from what I gathered, refer to holders of materials licenses to receive and redistribute general license devices. I request that the term be defined in section 32 for clarity. (13)

Proposed 32.52 (a)(1) and (b)(1) -- the required report should specify the type, model, and serial numbers of the device, source holder, and source, as appropriate. Many devices have multiple (different) serial numbers used to identify the various components. Any of these numbers could be reported by themselves at different times leading to mis-identification of transfers, returns, and deliveries. All numbers associated with a device should be reported. (14)

Proposed 32.52 (a)(3) and (b)(3) -- rather than presuppose a source will be returned immediately (not always the case) the rule should require that returned sources be reported in the manufacturer's quarterly report when actually received (not in anticipation). As written, a source could be removed from the database, yet never be sent back. Reports should be precise; what was sent out, what was received. We are interested in knowing for what the general licensee is accountable. It doesn't matter if the source is the first of its kind, a "direct replacement", a "spare part", or the last of its kind (removal) at the facility. This subsection should read "If a device is returned by the general licensee, the report must ..." (14)

On reporting specific location of use rather than mailing address of location of use (discussed at public meeting): Identifying the precise physical location. This is "nice to have" information if the agency intends to routinely inspect the facility. We believe the burden of locating the device should fall on the general license. If the general licensee cannot locate a device in a timely manner, it should be presumed "lost" and the appropriate fine would be in order! (14)

We recommend that NRC define “replacement devices” in Section 31.5(c)(8)(ii)) and the word “replaced” in Section 32.52(a)(3). We see several likely sources of confusion in the current wording:

- **Model, activity, and radionuclide confusion**: Assuming both AAAA and BBBB are models designated on Sealed Source and Device Evaluations approved for distribution by Honeywell-Measurex:
    - If Honeywell-Measurex shipped a customer a Model BBBB to replace a Model AAAA, does that ever constitute a “replacement” under the two sections cited above? If yes, under what circumstances must or can it be considered a replacement?

    - If Honeywell-Measurex shipped a customer a 1 Ci Kr-85 Model BBBB to replace a 0.5 Ci Kr-85 Model BBBB does that constitute a “replacement” under the two sections cited above?
    - If Honeywell-Measurex shipped a customer a Pm-147 Model BBBB to replace a Kr-85 Model BBBB does that constitute a “replacement” under the two sections cited above?
- **Chronology confusion:** During discussions with NRC at the 1 Oct workshop, it became clear that the NRC representatives present did not consider a device to be a “replacement” (per Sections 31.5(c)(8)(ii)) and 32.52(a)(3)) unless the original device had been received by the Specific Licensee **before** that Specific Licensee shipped another device as its replacement. This view was new to us. We believe that, unless clarified, this point is likely to be one that confuses device distributors, end users, and regulators. We recommend that the definitions of the terms “replacement devices” and “replaced” be added to the regulations to address this issue explicitly. (25)

  We note that if a device is considered a “replacement” only in cases when we ship it **after** we’ve received the original device, then Honeywell-Measurex would only inform NRC of the serial numbers of replaced sources/devices on an exception basis. This is because our “replacement” devices are nearly always shipped before the original device is taken out of service and shipped from the user site. (25)

In addition, Metorex urges the NRC to move as quickly as possible to the electronic submission of all the information required on the quarterly reports. Most manufacturers and distributors of the generally licensed devices currently have the information in a computer database. The transcription of the information to printed reports and then entry into a central database can result in substantial errors. In addition, the use of electronic reporting will substantially reduce the amount of time (and thus the cost) required to report the information both on the part of the NRC and the reporting company. (27)

We support any registration format that simplifies licensees' reporting requirements while maintaining the quality of the data being reported, because it will encourage more licensees to report. We also support allowing licensees to report the required information to NRC without a form, assuming that the information is properly recorded and preserved. (28)

ABB recommends that the NRC clarify the definition of “replacement device” in Part 32.52 and Part 31.5. Confusion is likely to arise under the current wording. ABB, for example, foresees several scenarios that may be considered “replacements.” The situations include: replacements of sources alone, replacements of sources and devices, replacements of devices keeping the same sources, and upgrades of devices on the same measurement system or platform. Further confusion may arise from the time frame of the replacement. Frequently a “replacement source” may be at a customer’s site for some time prior to removal and transfer of the old source. This procedure is necessary due to the nature of the measurement process and the associated industry. Thus, a replacement source may not be able to be directly associated with a particular returned source for several months. The final definition of “replacement devices” needs to address some of the uncertainties in these different procedures. (31)

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. (32)

(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. (32)

(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. (32)

(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. (32)

We recommend that NRC clearly define “replacement devices” in Section 31.5(b)(8)(ii)) and the word “replaced” in Section 32.52(a)(3). We routinely ship out replacement devices and/or sources to load into a device. If the device is undergoing a standard reload with a new source, is this a “replacement” since it is a different source? In addition it would be difficult to track what specific source is replacing another source. This should be a user responsibility and not a vendor responsibility. (38)

The timing of a replacement is not clear in the proposed regulation. We do not routinely receive back the old source until the new source has been installed in the device. When would this be required to be reported? (38)

10 CFR 32.52(c)

Recordkeeping

The SMA supports the extension of the time period throughout which licensees must retain records on final disposition of devices, from three to five years after the expected useful life of the device or final disposition. We do not believe it is appropriate to include the phrase "if known," because licensees should be assumed to have knowledge of the useful lives of the devices in their possession and their final disposition. (28)

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. (32)

## C. Comments on Compatibility Category for Agreement States

The supplementary information is unclear on how general licensees in Agreement States must demonstrate that they can account for devices and are knowledgeable of the applicable requirements. Specifically, it does not say if NRC intends to request that Agreement States track general licensees and individual devices. Since establishing a tracking system is a significant undertaking, we recommend that NRC clarify its expectations of the Agreement States in this regard. (9)

The NRC intends to classify 10 CFR 31.5 as Category C requirement for Agreement State compatibility. This is inappropriate and inconsistent in that this change will have significant direct trans-boundary implications. The Agreement State program element should be essentially identical to that of the NRC and thus should be a Category B requirement. (18)

The state of New York has prohibited the distribution of generally licensed devices in their state. The states of Louisiana and California have requested (but have not implemented in rule) that general license devices distributed in their respective states obtain a specific license. I agree with accountability but I strongly disagree with inconsistent application among Agreement States and the voiding of generally licensed devices. Agreement States are in essence voiding other Agreement States SSD registry reviews and technical positions. (18)

NRC states it is planning to classify Section 31.5 as Category C for Agreement State compatibility. We believe this is inappropriate and detrimental to safety and we request that NRC classify this section as Category B. (25)

**Background:** According to the material (copy attached) provided to us by Doug Broaddus of the NRC at the 1 October 1999 workshop, the compatibility categories have the following meanings:

A = Basic radiation protection standard or related definitions, signs, labels or terms necessary for a common understanding of radiation protection principles. The State program elements should be essentially identical to that of NRC.

B = Program element with significant direct trans-boundary implications. The State program element should be essentially identical to that of NRC.

C = Program element, the essential objectives of which should be adopted by the States to avoid conflicts, duplications or gaps. The manner in which the essential objectives are addresses need not he the same as NRC, provided the essential objectives are met.

D = Not required for purposes of compatibility.

NRC = Not required for purposes of compatibility. These are NRC program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the AEA or provisions of Title 10 of the Code of Federal Regulations. The States should not adopt these program elements.

Section 31.5 establishes the General License for people purchasing, leasing, or otherwise possessing industrial thickness gauges. Section 31.6 establishes the General License for Agreement State Specific Licensees to install and service Section 31.5 gauges within non-Agreement States. **(25)**

**Category C for Agreement State compatibility is inappropriate because** these General Licenses (and the restrictions they contain) have major and direct trans-boundary implications. (25)

To illustrate this with a real example, consider the State of New York. New York recently adopted regulations different from the existing or proposed NRC regulations in Section 31.5. A copy of the 6/9/99 announcement from New York is attached. (Note that affected firms based outside New York had no advance notice of this regulatory change and no opportunity to comment.) (25)

Under the regulations that are New York's current version of 10 CFR 31.5, Industrial Code Rule 38.41(b), certain devices (gamma gauges, Sr-90, transuranics) may no longer be possessed under a General License within the State of New York. (25)

This change affects some of our New York customers who have been required to apply for and obtain Specific Licenses for these gauges. Honeywell-Measurex and our competitors will be affected in terms of providing additional customer support for licensing, assuring shipments don't occur before we have Specific License verification, and added record keeping. (25)

However, our concern with Agreement State variations on 10 CFR 31.5 is not the just the possibility of new Specific License requirements for certain gauges. Again, using New York as the example, we'd like to show a seemingly unintended, but real consequence of permitting different Agreement State versions of 10 CFR 31.5. (25)

In non-Agreement States, Honeywell-Measurex provides gauge service to end users under 10 CFR 31.6. This permits us to work under the detailed terms of our Specific License for gauge service, issued by the Agreement State of California, without needing to apply for a Specific License from NRC and without being required to work under reciprocity. (25)

Like most other Agreement States, New York regulations contain a provision similar to 10 CFR 31.6:
*Section 38.15(b): Any holder of a license or permit issued by….the United States Nuclear Regulatory Commission, any Agreement State…which authorizes the holder to manufacture, install or service a device of the type which is generally licensed and specified in Table 3, Item (b) of this Part (rule), may install or service such device without obtaining a license from the commissioner, provided that:….*
Under New York's new version of 10 CFR 31.5 (General License for gauge users), the regulation quoted above no longer authorizes Honeywell-Measurex to provide installation or on-going service to New York end users of our Sr-90 and Am-241 gauges. New York's version of reciprocity (Section 38.15(a)) requires filing for permission a minimum of seven days in advance of the activity and is limited to 30 days of work per calendar year. Because we have employees who live and report to work on a daily basis at end-user sites in New York State, these reciprocity provisions are too restrictive to be useful on an ongoing basis. (25)

As a result, Honeywell-Measurex and others will be required – if we wish to continue to offer service to all our customers -- to apply for a Specific License from the State of New York. We have to do this although we already have Specific Licenses (issued by NRC or Agreement States) that were designed to regulate our installation and service activities throughout the US. (25)

To compound the particular problem in New York, we have found that the agency would not accept the very detailed license commitments and terms approved by California. New York appears to require a Specific License for service that contains commitments and restrictions unique to New York. Since we have established all of our procedures (training, certification, instrument, badging, record keeping, etc.) considering our California license requirements, it will require significant time and resources to develop a separate program for employees who will work in New York. (We have hundreds US service employees who are involved in the present safety program.) We are still in the process of trying to resolve this problem and plan to visit with the New York agency later this month. (25)

If, under Category C compatibility for 10 CFR 31.5, other Agreement States eliminate the General License for certain gauges, those states and the out-of-state service providers working within those states will be involved in the time-consuming process of negotiating new Specific Licenses (in duplication of existing licenses). This will not be a trivial undertaking, as the licenses are generally quite complex. (25)

Based on these trans-boundary licensing considerations, Honeywell-Measurex believes that it is inappropriate under current NRC guidelines to classify Sections 31.5 and 31.6 as Category C for Agreement State compatibility. We urge that Sections 31.5 and 31.6 be classified as Category B for Agreement State compatibility. (25)

**Category C for Agreement State compatibility is counter-productive in terms of safety because** just as regulatory agencies do not have unlimited personnel and resources, firms that manufacture, distribute, and service 10 CFR 31.5 type gauges are also faced with real limits. The time radiation safety personnel spend attempting to comply with any Agreement States' unique versions of 10 CFR 31.5 (and 31.6) is directly at the expense of efforts that are meaningful to product safety, to training, to following up with customers who have not returned devices, etc. (25)

Likewise, if Category C is designated for compatibility, regulators in Agreement State are likely to spend significant time and resources developing variations on NRC's 10 CFR 31.5 wording. Agreement State agencies are also likely to spend significant time and resources in processing licenses applications for activities and procedures that were already thoroughly reviewed by NRC or other Agreement States. (25)

To use a concept popular in business today, the time radiation safety professionals (employed by licensees and by regulatory agencies) spend applying for, processing, and issuing Agreement State service licenses to duplicate existing NRC or Agreement State licenses is non-value-added in terms of safety. (25)

Based on promoting the best use of resources in the interest of overall safety, Honeywell-Measurex urges that Sections 31.5 and 31.6 be classified as Category B for Agreement State compatibility. (25)

These rules need to have the highest level of compatibility to ensure consistency of notification and traceability through the initial shipment and original installation of the device. This should guarantee that at least the first movement of the device is recorded with consistency and accuracy. (26)

We routinely deal with all of the Agreement States and find it very difficult to keep abreast of most rule changes. There is no mechanism in place for someone who is not a licensee in a particular state to be made aware of any changes of staff and rules. We send letters annually to all of the Agreement States asking for changes in the rules. Many times we only hear if they want a fee paid. (26)

I am keenly aware of State's rights issues and the home rule debate but the lost or non-accountability of radioactive material is a serious matter that is contrary to the basic principles of radiation safety, which would require type A compatibility. At the least it has significant transboundary implications and should be considered type B compatibility. (26)

Metorex feels very strongly that all of the changes to Section 31.5 must have a classification of Category B for Agreement State Compatibility, as these changes will have distinct trans-boundry implications. (27)

Section 31.5 establishes the General License for people purchasing, leasing, or otherwise possessing systems for the determination of quantitative or qualitative chemistry. Section 31.6 establishes the General License for Agreement State Specific Licensees to install and service Section 31.5 gauges within non-Agreement States. (27)
**Category C for Agreement State compatibility is inappropriate because** these General Licenses (and the restrictions they contain) have major and direct trans-boundary implications. (27)

To illustrate this with a real example, consider the State of New York. New York recently adopted regulations different from the existing or proposed NRC regulations in Section 31.5. (Note that affected firms based outside New York had no advance notice of this regulatory change and no opportunity to comment.) (27)

Under the regulations that are New York's current version of 10 CFR 31.5, Industrial Code Rule 38.41(b), certain devices (gamma gauges, Sr-90, transuranics) may no longer be possessed under a General License within the State of New York. (27)

This change affects some of our New York customers who have been required to apply for and obtain Specific Licenses for these gauges. Metorex and our competitors will be affected in terms of providing additional customer support for licensing, assuring shipments don't occur before we have Specific License verification, and added record keeping. (27)

If, under Category C compatibility for 10 CFR 31.5, other Agreement States eliminate the General License for certain gauges, those states and the out-of-state service providers working within those states will be involved in the time-consuming process of negotiating new Specific Licenses (in duplication of existing licenses). This will not be a trivial undertaking, as the licenses that are generally quite complex. (27)

Based on these trans-boundary licensing considerations, Metorex believes that it is inappropriate under current NRC guidelines to classify Sections 31.5 as Category C for Agreement State compatibility. We urge that Sections 31.5 and 31.6 be classified as Category B for Agreement State compatibility. (27)

**Category C for Agreement State compatibility is counter-productive in terms of safety because** just as regulatory agencies do not have unlimited personnel and resources, firms that manufacture, distribute, and service 10 CFR 31.5 type gauges are also faced with real limits. The time radiation safety personnel spend attempting to comply with any Agreement States' unique versions of 10 CFR 31.5 (and 31.6) is directly at the expense of efforts that are meaningful to product safety, to training, to following up with customers who have not returned devices, etc. (27)

Likewise, if Category C is designated for compatibility, regulators in Agreement State are likely to spend significant time and resources developing variations on NRC's 10 CFR 31.5 wording. Agreement State agencies are also likely to spend significant time and resources in processing licenses applications for activities and procedures that were already thoroughly reviewed by NRC or other Agreement States. (27)

To use a concept popular in business today, the time radiation safety professionals (employed by licensees and by regulatory agencies) spend applying for, processing, and issuing Agreement State

service licenses to duplicate existing NRC or Agreement State licenses is non-value-added in terms of safety. (27)

Based on promoting the best use of resources in the interest of overall safety, Metorex urges that Sections 31.5 and 31.6 be classified as Category B for Agreement State compatibility. (27)

The proposed changes to 10 CFR 31.5 are currently identified as Category C for Agreement State Compatibility. ABB feels that the implicit trans-boundary effects of the current and proposed rules require Compatibility Category B for effective implementation nationwide. As ABB understands the categorization, Agreement State Compatibility Category C program elements must meet the objectives of the NRC element, but the means to meet the objectives need not be the same. This implies that there could and, as past history has shown, likely will be significant deviations from the NRC among Agreement States with respect to how these objectives are implemented. Category B program elements, on the other hand, are defined as having significant trans-boundary implications and the Agreement States' element should be essentially identical. (31)

One important concept that seems to have been overlooked by the NRC in Agreement State compatibility classification is the fact that the devices of concern in the regulation are distributed from vendors located all over the country to General Licensees located all over the country. This type of distribution network makes any rules affecting the distributors and the recipients inherently trans-boundary, and thus appropriately subject to Category B Classification. Uniformity among NRC and Agreement State Regulations is particularly important to vendors in that we must be knowledgeable of the regulations and interpretation nuances of the regulations of all Agreement States to provide accurate and complete information to the General Licensees. Successful implementation of the objectives of the proposed changes require that the elements of Part 31.5, Part 32.51, and Part 32.52 be classified as Category B for Agreement State compatibility. (31)

NRC states it is planning to classify Section 31.5 as Category C for Agreement State compatibility. We believe this is inappropriate as there are significant trans-boundry considerations (38)

There are some recent inconsistencies in how certain gauges/devices are handled by individual agreement states. Some states are requiring that some generally licensed devices now be specifically licensed. This is basically ignoring the SSDR information and review performed by another agreement state and/or NRC and the resulting conclusion and approval that the device meets all the requirements to be generally distributed. This results in states not accepting the SSDR for an already assessed device and spending time and resources to perform another review. This is inefficient and counter productive to safety. (38)

It is very difficult and sometimes impossible to stay current with all the various amendments and differences betweeen state regulations. As a result it is very possible that a generally licensed device could be shipped to a user in an agreement state that now requires a specific license for the end user. This would result in both the distributor and user being out of compliance. Consistency in the regulations important to safety should be a fundamental practise. (38)

Consistency in the regulations significantly improves the chance of compliance by both the end user and the distributor thereby increasing safety. If the states and NRC have inconsistent levels of concern over the same device, ie it could be generally licensed in one state and specifically

licensed in another then the public and users get conflicting views on whether or not it is safe. We strongly urge that Sections 31.5 and 31.6 be classified as Category B for Agreement State compatibility. (38)

I'm forwarding a copy of a letter Honeywell-Measurex (& others) sent to the NY Dept of Labor. (39)

It is relevant the issue of state variations in the definition of GL devices & compatibility levels for 10 CFR 31.5 & 31.6. (39)

In the letter, Honeywell-Measurex & a number of other companies filed for an exception in NY. This is an obvious example of the transboundary implications to 10 CFR 31.5 & 31.6. As Honeywell-Measurex & many others stated in oral and written comments, requiring Agreement States to adopt program elements that are identical to 31.5 and 31.6 is justified. (39)

Sorry if I am boring everyone with the same story over & over again, but we find variations in these particular portions of state regulations to be very detrimental -- they certainly undermine our ability to establish a comprehensive, consistent radiation safety program. We want to do everything we can to make sure our problems are not ignored. (39)

[28 October 1999

Mr. Peter Chiefari
Assistant Division Director, Safety & Health
New York State Dept. of Labor
Building #12
State Office Building Campus
Albany, NY 12240

Subject: Application for Variation from Section 38.15(b) of 12 NYCR 38 for Activities to be Conducted in New York

Dear Mr. Chiefari:

As described in Section 38.2 of 12 NYCR 38, we request a variation from a portion of the regulations. Specifically, we request a variation from Section 38.15(b), which states:

> *Any holder of a license or permit issued by the State Department of Health, the New York City Department of Health, the United States Nuclear Regulatory Commission, any Agreement State, or any licensing nonagreement State which authorizes the holder to manufacture, install or service a device of the type which is generally licensed and specified in Table 3, Item (b) of this Part (rule), may install or service such device without obtaining a license from the commissioner, provided that:*
>
> > *such person shall file a report with the commissioner within 30 days after the end of each calendar quarter in which any device is transferred to or installed within the commissioner's jurisdiction. Such report shall contain the name and address of each person receiving such a device, shall identify the type of device or devices so transferred, and shall state the quantity and type of radioactive material contained in such device or devices;*

*any such device is installed and serviced in accordance with the terms of the license or permit issued to such person;*

*such person shall assure that any labels required to be affixed to any such device shall bear a statement that reads "Removal of this label is prohibited"; and*

*the person to whom such holder transfers any such device or on whose premises such holder installs or services any such device has a copy of the general license requirements or the equivalent requirements outlined in Table 3, Item (b) of this Part (rule).*

While in all other ways remaining subject to each condition stated in Section 38.15(b) above, we request permission to conduct the described activities **involving any device which New York, any other Agreement State, or the Nuclear Regulatory Commission has approved for distribution to General Licensees.**

**Reasons for request:**

(a) Apparently unintended effect of recently adopted regulations: With the New York's recent elimination of certain devices from those that may be held under a General License, Section 38.15(b) no longer authorizes us to provide installation or on-going service to New York users of several of our devices (e.g. devices containing > 1 mCi of Sr-90 or Am-241).

The New York Department of Labor used a notice (dated 9 June 1999; copy attached) to inform manufacturers and distributors of generally licensed devices about eliminating the general license for certain devices. From the content of that notice and discussions with Radiological Health Unit staff members, we understand that the Department of Labor did not specifically intend to alter the regulations that had permitted manufacturers and distributors to conduct service to devices in New York.

(b) Operating under reciprocity not feasible: Reciprocity [Section 38.15(a)] normally requires filing for permission a minimum of seven days in advance of the activity and, is limited to 30 days of work per calendar year. In many cases, we have employees who live and report to work on a daily basis at end-user sites in New York State. The 30-day limit is insufficient to permit the required tests for source leakage and for shutter and indictor function. Advance scheduling is also nearly impossible because (in many cases), the device is essential to the customer's process and is kept running as many hours per day as possible. This means that the safety tests are "scheduled" on the fly when there is an interruption in the customer's operation.

For these reasons, the reciprocity provisions are too restrictive to be useful on an ongoing basis.

(c) Not productive in terms of safety: In order to continue to provide service to all of our customers in New York, we will need to apply for and obtain Specific Licenses. Since we already have very detailed licenses approved by NRC or by other Agreement States, we see no improvement to safety that is likely to result from this process. Radiation Safety personnel employed by the Department of Labor and by manufacturer/distributors will spend time on the license application and on each later amendment and renewal. Whether regulator or device-distributor, that time could far more be productively be spent on issues that will truly improve safety.

Note that each person listed below represents a **separate** NRC or Agreement State specific licensee and this exception request is on behalf of each of those licensees. (Additional copies of the letter with the individual signatures will follow this one.)

We hope you will approve our request. Please contact us if we can provide further information on this request or the nature of our businesses.

Sincerely,


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CC: Charles Burns, Associate Radiophysicist, NY Dept. of Labor

Attachment: *Notice to Manufacturers & Distributors of Radioactive Sources Under General License* (9 June 1999)] (39)

Other comments concerning transboundary activities.

The Department of Nuclear Safety recommends that NRC clarify how the proposed rulemaking would apply to transboundary activities. It appears that NRC intends to apply 10 CFR 31.5(b)(2) to use of portable devices by agreement state general licensees at temporary job sites in NRC jurisdiction. If so, 10 CFR 31.5(b)(2) would require agreement state licensees to seek assistance from distributors to transfer devices from agreement states to NRC jurisdiction. We recommend that supplementary information for the final rulemaking explicitly describe the conditions under which an agreement state licensee would be allowed to use a portable generally licensed device in an area of NRC jurisdiction. (9)

Portable and "mobile fixed" gauges allowed under general license. There are obvious transboundary implication to this practice and, as noted in the Federal Register notice, reciprocal recognition of the general license is not provided (and should NOT be). In our opinion, portable and "mobile fixed" gauges should be under specific license only. (14)

Timing of adoption of requirement for augmented material transfer reports

The Illinois Department of Nuclear Safety does not agree that such accelerated implementation is vital to establishing a nationally expanded general license program. We have administered a registration program for several years that is similar to the one now proposed by NRC. This experience shows that while the additional information proposed for 10 CFR 32.52(a) and (b) is desirable, it is not absolutely necessary. (9)

In practice, the information currently provided by distributors is marginally adequate for a registration program. Although we agree with NRC that transfer reports should contain the additional information proposed, we recommend that the requirement be phased in by the agreement states over the normal three-year adoption period. We believe this is adequate to accomplish NRC's goal of providing increased oversight. (9)

We believe an accelerated implementation date for Agreement States (one year instead of three) is an extra burden especially because the rule demands an infrastructure (a state registration program) which may not already exist. While our database and annual survey of general licensee is adequate for a start, other aspects of the registration program require we also institute a fee. Any fee based program receives extra (and lengthy) scrutiny in our state and while this is certainly an important new program, we may not be able to justify the haste in setting it up fully. We support the normal three year period for achieving compatibility. However, for our several manufacturers, we can apply appropriate license conditions to cause the necessary compliance if need be. (14)

Need to have three years to implement. It would be difficult for all of the Agreement States to have the regulations changed so that the NRC and all Agreement States could implement this on the same date. (16)

## D. Comments on Specific Questions Posed

*1. The Commission seeks comment on whether the registration requirement should include a provision that would require the general licensee to complete registration by a certain time, whether or not the NRC requests registration.*

No, the commission should not require registration until the NRC requests it. This sort of requirement would increase paperwork for all involved parties that may not be needed until a determination has been made that the information is needed to satisfy a requirement of the regulations. (3)

Registration should include a deadline. (5)

General licensees should be required to register their general licensed devices within 30 days of taking possession of the device, regardless of whether or not the NRC requests this information through a mailing or questionnaire. This requirement should be clearly stated in the regulation along with information required for registration and the address where the registration information and fees are to be sent. This portion of the registration rule should be part of the information required to be provided by the distributor or licensee authorized to transfer the general licensed device to a general licensee. Since the registration mailings will probably not be sent out certified mail, there is no guarantee or way to prove that every general licensee received the registration questionnaire. This may be used as an excuse by some general licensees for not registering their general licensed devices. The registration questionnaire should be viewed as an additional service provided by the NRC and not required of the NRC. It is the general licensees responsibility to make sure their general licensed devices are registered, with or without the registration questionnaire and the regulations should clearly state that fact. (11)

It is already apparent from a reading of the public letters posted to the NRC rulemaking website that some general licensees, for whom this rule does not apply, have already been confused and assumed that it does apply. It is inappropriate to cause them to attempt to register unnecessarily. Registration should be a response to NRC or Agreement State directive based on agency assessment of the devices received. On the other hand, once notified that a registration is required by the agency, it would be appropriate to indicate how soon the process must be completed (or proof of prior disposal or transfer provided) before escalated enforcement begins. In simplest terms, no time limit should be placed on a general licensee that has not been notified that registration is required. (14)

Once the NRC or an Agreement State notifies a entity that they need to register the device a timeline should be set and penalties imposed if not met. But if a entity is unaware that a device should be registered because they have not been notified by a manufacturer, distributor, NRC or Agreement State it would be unfair to impose a penalty on them. (16)

If general licensees are to become more responsible then the University of Cincinnati believes that a sufficient and specific time period for initiating the registration process should be set; however, the burden for the initial implementation should not be placed on the general licensee. The initial burden should be on the NRC, associated agreement state or the specific licensee distributor. At least one of these groups should be required to contact the general licensee and ensure a

responsible individual is aware of the process and requirements. Many of the non-compliances with the general license regulations are believed to be due to ignorance (i.e., individual not aware the instrument contains a radiation source and/or not aware that the radiation source is "generally licensed" making the user/owner is subject to specific regulations). An individual or organization that does not know they have a general licensed source will not, because of new regulations, become knowledgeable. If the NRC insists that the only solution is to place the burden on the general licensee then ignorance should not result in enforcement action. (21)

NRC must make it absolutely clear to all licensees that they are not excused from reporting requirements if NRC fails to contact them. New licensees should be required to register before receiving their sources. The registration requirement should include a provision that requires all general licensees to complete registration before twelve months after the date of the previous registration certificate, or within twelve months of the receipt of a device subject to registration whichever came first. (28)

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. (32)

The general licensee should be required to submit the registration information within a reasonable time period alter the initial transfer of the device. If the general licensee has any devices that require registration in its possession and control on the effective date of this rule, the licensee should have six months to either submit the registration information or transfer the devise to another approved licensee. (33)

*2. The Commission requests comment on whether it is appropriate for new devices obtained by registrants to be registered when the annual reregistration is carried out without the NRC having earlier contact after additional devices are received. Earlier contact could be made either by an acknowledgment by NRC to the user or by a required response from the general licensee to account for the additional device(s).*

Yes, it makes sense that the logical time to add or subtract devices would be at the annual re-registration. This would provide only one information flow, which will reduce paperwork, cost of implementation, and the chance for errors and/or loss of materials. (3)

I am not sure I understand this, but when the annual re-registration is done, all devices should be on that list even if a new device was received days before. (5)

In our experience, it is sufficient to reconcile the device inventory records with general licensees annually. We believe that more frequent regulatory contact with general licensees is time consuming and unnecessary. We reconcile the records as part of a “self-inspection” (mail survey), which is similar to NRC’s proposed “reregistration” (64 FR 40304). (9)

General licensees should be required to register their general licensed devices within 30 days of taking possession of the device, regardless of whether or not the NRC requests this information through a mailing or questionnaire. This requirement should be clearly stated in the regulation along with information required for registration and the address where the registration information and fees are to be sent. This portion of the registration rule should be part of the information required to be provided by the distributor or licensee authorized to transfer the general licensed device to a general licensee. Since the registration mailings will probably not be sent out certified mail, there is no guarantee or way to prove that every general licensee received the registration questionnaire. This may be used as an excuse by some general licensees for not registering their general licensed devices. The registration questionnaire should be viewed as an additional service provided by the NRC and not required of the NRC. It is the general licensees responsibility to make sure their general licensed devices are registered, with or without the registration questionnaire and the regulations should clearly state that fact. (11)

We believe annual "confirmation" of information initially provided to us in the manufacturer's "quarterly report" is adequate. Requiring additional "receipt" or "transfer" reports from the general licensee needs to tempered with two thoughts: keep it simple (how about requiring manufacturer's to include "warranty" type registration cards with the pre-typed model(s), and serial number(s) to mail off to the agency?) and verifiable (disposition of licensed sealed sources is verified by contacting the recipient, not by accepting the word of the transferor; in this case accepting the manufacturer's statement on a quarterly report that a certain source has been transferred back from a general licensee is what provides us assurance the source is not left sitting in the "bone yard"). In simplest terms, make sure the general licensee's responses on the annual re-registration make sense based on what the manufacturers tell you; follow-up if they don't. (14)

We agree with the concept of an acknowledgement letter when the device is shipped to a facility. Billing can occur with annual re-registration. (16)

As indicated in response to question 1 the general licensee should be submitting the appropriate registration information within a reasonable time period after the initial transfer of the devise. This would allow for prompt and continuous information on the devices. For device(s) the general licensee has in its position on the date the rule becomes effective, the general licensee has six months to either transfer the device(s) or to submit the registration information. Any device that is transferred during this time period would trigger a submittal of registration information by the new possessor of the device. (33)

*3. The Commission solicits comment on whether general licensees should be required to assign a backup responsible individual (BRI).*

No, the requirement is not needed. General licensee's should be advised of the need to have responsible individual(s), and they should be encouraged to have one, or more, backups available. Most of the licensee's will be responsible. (3)

I would think most general licensees are small businesses, to have a second person responsible may not be realistic. Management is ultimately responsible and the people listed should reflect that fact. (5)

IDNS believes that appointment of a backup responsible individual is overly complicated and unnecessary for this class of byproduct material. As noted in the supplementary information (64 FR 40299), a general licensee would be required to replace the responsible individual to maintain compliance with proposed 10 CFR 31.5(c)(12). (9)

We recommend that NRC adopt the rulemaking with no provision requiring identification of a backup responsible individual. If NRC determines after a few years of experience that a problem exists, the provision may be added then. (9)

We agree with the NRC-Agreement State Working Group's recommendation 3.1 listed in NUREG-1551, regarding Increased Regulatory Oversight, that there should be a Responsible Individual (RI) and Back-up Responsible Individual (BRI) for each general license. Unlike a specific license, where there would be a Radiation Safety Officer and Authorized Users, there may be only one person who has a real understanding that the device is generally licensed and contains a radioactive source. When this RI leaves or is let go, the general licensed device may be the farthest thing from his mind. This has occurred on many occasions in New Jersey and ultimately led to abandonment of the devices which found their way into the public domain. (11)

I am against assigning a backup responsible individual (BRI). The NRC does not require, by regulation, that specific licensees assign a backup RSO, which I think would be equivalent to a BRI. (12)

Since we normally do not require assistant radiation safety officers for specific licensees, it seems incongruous to do the equivalent for general licensees. In other words, "no". (14)

It is not necessary to add a backup responsible individual at this time. It will be very helpful to have a responsible individual named. (16)

A second or backup responsible individual should not be required. (21)

Honeywell-Measurex recommends that there be no added requirement for General Licensees to appoint a backup responsible individual. We note that Specific Licensees, even those with significant quantities of radioactive material in a variety of physical forms, are not uniformly required to name a backup Radiation Safety Officer. Even if this requirement were limited to General Licensees with one or more of the devices identified in 10 CFR 31.5(c)(13)(i), it would not make sense. Why should a licensee with as little as 0.1 mCi of Sr-90, sealed and contained in a device that has been evaluated and approved, have requirements that are stricter than those applied to licensees with much large, much less controlled sources of radiation? (25)

We agree that there needs to be a clearly defined person responsible for all devices that contain radioactive material. Some of the discussion on this issue mentions the need for a named backup individual. We feel that this is unnecessary. What would help accountability is a clear understanding that the management at each licensee site is aware of these requirements much in the way OSHA and EPA requirements are the ultimate responsibility of the owner or plant manager. (26)

Metorex is opposed to the concept of requiring a backup individual for the responsible individual. First, the requirement of a backup would make this class of registration more restrictive than the current specific license. Further, many generally licensed devices are possessed by very small companies and the inclusion of a backup individual would be impractical. (27)

Licensees should also be required to designate a backup responsible individual ("BI") to take over responsibilities of the RI if he or she leaves the company. This is a routine operational practice at SMA member companies, and it would significantly enhance licensee accountability if required and enforced at all licensee facilities. Furthermore, any limitations on operational flexibility imposed by designating an RI and BRI would be negligible compared to the risk to the licensee company from lost sources. (28)

The general licensee should have an officer of the organization who is accountable for registered devices under the organization's control. The officer need not be the backup responsible individual (BRI) responsible for knowing the regulations. However, this individual should be knowledgeable of the devices that are in the general licensee's control and should be responsible for authorizing the transfer of registered devices to other licensee(s). (33)

We do not support the requirement for a backup responsible individual. This would make the requirements for a generally licensed device more restrictive than the requirements for a specific device. In addition the majority of our end users are very small companies and having a second designated individual is impractical. (38)

*4. The Commission seeks comment on how best to achieve and enforce the intent that full disclosure of information required to be provided to general licensee customers by distributors be made early enough to be considered in a decision to purchase. For example: Would it be better to use the words, "prior to purchase" in the regulatory text?*

**Should information be provided to potential general licensee's earlier?** Yes. The consumer should have all information available to them PRIOR to their making a purchase that would make them a party to these regulations. If the purchase of a regulated device is $200.00, and it costs $420.00 to register it and another $250.00 to dispose of it properly, then the consumer may make the decision to purchase an alternative type of device. The proposed rules will probably force some manufacturers out of business, as the consumers will not purchase their products due to the regulatory requirements and costs of these proposed rules. Unfortunately, some of these products are superior to the alternatives-specifically the use of radioactive powered exit signs vs. electrically powered exit signs. (3)

A distributor should assure itself and its responsibility to the NRC and the general public that a general licensee has all the necessary information and is in compliance before the device is shipped. This can be done by the certification statement made by the president/owner that compliance is achieved the device can be sent. Similar to an EPA permit which requires everything be done before a process starts. (5)

IDNS agrees with NRC's intent to require distributors to disclose full information about usage limitations and regulatory responsibilities to prospective customers. Furthermore, we agree with NRC that this should be done well in advance of transfer. We recommend that NRC require

distributors to provide the information prescribed at 10 CFR 32.51a(a) and (b) at the time that purchase or other acquisition arrangements are under negotiation (64 FR 40301). This would allow a prospective customer to back out of a deal if regulatory requirements were felt to be onerous. (9)

We recommend that NRC amend 10 CFR 32.51a(a) and (b) to require that described information be provided "at the time that purchase or other acquisition arrangements are made." We believe that this language would convey NRC's intent regarding early provision of information more clearly than the proposed and more general requirement "before the device may be transferred." (9)

Before they are allowed to ship a general licensed device, distributors should be required to obtain from the recipient, a signed "Certification Statement", that they acknowledge the fact that they have received copies of the regulations and other pertinent information, and that they are aware of the rights and responsibilities of a general licensee. This "Certification Statement" should also be required for all transfers of general licensed devices (i.e., distributor to initial recipient, initial recipient to subsequent recipients, etc.). Without some kind of signed documents, how can anyone prove that they were or were not properly informed of their obligations as a general licensee. Ultimately, it boils down to what evidence would a court require to prove responsibility for an abandoned general licensed device and any damages resulting from that device. (11)

We support use of the term "prior to purchase" as the clearest wording of the intent of the rule. (14)

The information should be provided to the customer before the contract is signed to purchase the device. The buyer should sign a statement indicating that he is aware of the responsibilities of purchasing a generally licensed device and the fee associated with owning the device. (16)

Reconsider the likely effectiveness of this proposal. During the workshop, Dr. Jonathan Fortkamp of ABB noted that the end-user personnel involved in decisions to purchase would often be purchasing agents and would rarely include anyone concerned with the information NRC proposes distributors provide. We agree with Dr. Fortkamp's comment. The devices ABB, Honeywell-Measurex, and others distribute are embedded in very large, very complex and costly process control systems (typically cost hundreds of thousands of dollars). The license requirements and source disposal options are unlikely to influence decisions to acquire such systems. Note that in many cases, a process control system (including the original radioactive source) will be used for several decades. (25)

No matter what, avoid use of the phrase "prior to purchase" in the regulations. Devices may be leased, they may be loaned, etc. (25)

If regulations similar to those proposed are to be adopted, Honeywell-Measurex urges that NRC add language so that compliance with the requirement can be inspected. For example, NRC could require distributors to maintain records showing the required information was sent, including date sent and the end-user address used. We recommend this because compliance with regulations costs licensees. We believe it is important to avoid establishing regulations that "punish" conscientious licensees while ignoring sloppy operators. (25)

Metorex is concerned about the implication of the change to 32.51a(a) and (b). This change requires notification prior to the transfer of the generally licensed device and the comments suggest

using the words "prior to purchase". Clarification is required regarding the method and extent of the notification. Is the proof of mailing such a notice prior to the shipment of a unit sufficient or is a document signed by a responsible individual required. Further, the phrase "prior to purchase" is ambiguous. In most cased, there are many steps in the purchase process, the quotation, the order the delivery and finally the invoice. In other cases, the devices are not purchased, but rather leased. In all of these cases, the point of "purchase" is ambiguous. Thus, Metorex feels that the proper point of notification is prior to the transfer. (27)

Prospective licensees should be notified of general license requirements before purchase of devices. By providing notice of the regulations and potential cost of proper disposal, the prospectixe general licensee can make an informed decision before purchase. (28)

The NRC proposes that certain information be provided to General Licensees “before the device may be transferred.” The information to be provided includes the relevant regulations, a list of services that must be done under a Specific License, and disposal information. In the Discussion segment of the Federal Register Notice, the Commission states their intent is for the vendor to provide this requested information “before a final decision to purchase.” ABB feels that it is unreasonable and ineffective to provide the requested information during the purchase decision. ABB also believes that it is unreasonable to require the vendors to provide information on “acceptable disposal” to the General Licensees. (31)

ABB Automation does not only sell sources and devices, but entire measurement, control, and actuation systems. These systems frequently cost in the hundreds of thousands of dollars and are a major investment decision for large corporations. The negotiations for purchase of the systems may span several years and involve numerous individuals, most of whom would not be concerned with the information proposed to be provided. Further, the individuals within the General Licensee’s company for which the information would be useful might not even be aware of the purchase decisions being considered. Along the same lines, ABB’s Radiological Operations Center, the organization that would be responsible for providing the information to the General Licensee, is not currently aware of all sales efforts that are underway within ABB. It would be a substantial, and we believe inefficient, effort to train the full sales staff of ABB and provide them with appropriate information. ABB recommends that the information outlined above be provided to the General Licensees at the time of source transfer or at any time prior to transfer per the request of the prospective General Licensee. (31)

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 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. (32)

Full disclosure is the norm in the United States. Therefore, the distributor should provide the required information as part of the proposal to the general licensee. In addition, the general licensee should be permitted to return a device to the distributor within a fixed period of time if the general licensee believes it did not fully understand the responsibilities of device ownership prior to the purchase. (33)

The requirement for certain information to be provided to the end user “prior to transfer” is vague on when the information is to be given to the prospective user. In addition providing the information to the personnel making the decision to use the device still allows that the information may not get to the individual that will be ultimately responsible for compliance. (38)

*5. The Commission seeks comment on the advantages and disadvantages of implementing a national database of general licensees and their devices.*

The advantage of a national database would be that their would be one central location with information on who had devices, and what type of devices. The disadvantages include: the cost to set up such a database; the stigma of having your company's name in the database; the potential for receipt of unsolicited comments from readers of the database; and the potential for misuse of the database by outsiders. (3)

It appears this is redundant. The agency already requires the distributor to keep lists and the agency has access to those lists, why does it need another database of the same information. (5)

The Department of Nuclear Safety supports in principle the concept of a national database of general licensees and devices. As alluded to above, the concept would be especially useful if NRC does not intend to request that agreement states track general licensees and individual devices. IDNS is willing to provide data for a national database when NRC has addressed the access and security questions raised at 64 FR 40303. In our opinion, a national database would be implemented most effectively if each agency maintained its own data. (9)

We are concerned, however, about the cost of a national database. NRC describes a lack of funds for startup of an expanded general license program at the federal level (64 FR 40297). Since Illinois general licensees already pay registration fees, we cannot ask them to contribute additional money for startup of a national database. (9)

We also believe a new database may or may not be effective during the first five years of operation. Our experience has revealed difficulties with our database that have been overcome only with time and experience. We are, therefore, reluctant to exchange our existing database for one introduced by NRC until the new national database has been proven effective over several years at no additional cost to our regulated community. (9)

A national database of general licensees and their devices would be extremely valuable to the NRC in helping to track who has what devices and where they are located. This database along with

NRC's expanding Nuclear Materials Events Database can be extremely helpful to the NRC and the States in tracking responsible parties when abandoned general licensed devices are discovered. (11)

We have concerns about the cost effectiveness of centralizing existing resources. First, we would most likely continue to maintain our "local" database in support of our general license registration program, a compatibility requirement! Therefore, our data would be "duplicated" somewhere else, unnecessarily (and we certainly shouldn't have to pay for it). Second, electronic communication makes the search for serial number identification "fast", even among numerous agencies and manufacturers possessing the "pieces of the puzzle". Third, the need for a database search presupposes that a "serial number" has been identified. For this to happen, the device or source must have been interdicted and presumably safeguarded. There should be no need for urgency in identifying the responsible party. (The urgency should be in safeguarding the source which doesn't require knowing who to blame.) The serial number and the physical characteristics of the source or device should narrow it down to the manufacturer who can either identify the general licensee or pay for the source recovery themselves. The BIG concern, a smelted source, cannot be found by using a database. Finally, if a national database is established, who is going to pay for its maintenance, including assuring that data input is prompt, especially given the rarity of the events that it would facilitate? (14)

A national database for GL's would be great but it may be too large and cumbersome to work efficiently. Who would have authority to make changes? How would changes and additions be made? Would all devices be included? Would we be able to see that a particular device was returned to the distributor or manufacturer? (16)

The University of Cincinnati believes a centralized database covering both NRC and agreement states is a good idea. However, there must be a mechanism to ensure accuracy and completeness of the data in the database. Recently, the University of Cincinnati was supplied a list of generally licensed sources by the Ohio Department of Health which the Ohio Department of Health stated was supplied by the NRC and that was suppose to be a complete listing of generally licensed sources at the University of Cincinnati. It was impossible to determine if the list was complete. For many of the sources, the data was incomplete making it impossible to distinguish between sources and determine double entries. Also, some data was notably inaccurate, e.g., microcurie sources were listed as millicuries. (21)

We recommend that the proposed rules require a nationwide database, instead of multiple databases created and maintained by NRC and by individual Agreement States. Our basis for these recommendations is given below. (25)

Contrary to the recommendations of both the metals industry and the device distributors, the proposed regulations would not create a nationwide database that consistently tracks sealed sources/devices. (25)

Individual Agreement State databases will be less effective in terms of having useful information on source/device location: With a single database, it is possible to detect and investigate when one device/source is mistakenly reported to be in two or more separate locations at one time. This type of error can very easily happen, e.g. when someone is not conscientious about replacing

source/device identity labels following a source/device replacement. The multiple database approach virtually guarantees that the assorted databases will end up with contradictory information. For there to be any hope of having valid information in a variety of databases, NRC and Agreement States would periodically need to compare their data and attempt to reconcile discrepancies – a difficult and very time-consuming activity. (25)

In addition to the problems of data integrity that are inherent in maintaining separate databases, Agreement State databases will require an inefficient, duplicative use of limited resources, both initially as new databases are developed and ongoing, as those databases are maintained. (25)

The most important part of trying to maintain accountability is the formation of a national database. Multiple State run databases would only lead to high cost and difficulty in maintaining the integrity of the database. A database of all general licensed devices requiring registration would not be that large considering that it would be smaller than most States' automobile licensing databases. The cost cannot be that high. Given your estimate of 5000 affected licensees, a portion of the proposed fee of $50 each would result in $250,000 of annual income to construct and maintain this database. The States could be required to submit the data and pay for part of the funding or they could defer and let their licensee file directly with the NRC. (26)

Metorex strongly supports the concept of a National Database for all licensed devices instead of multiple databases created and maintained by the NRC and individual Agreement States. A National database will give the interested community one source of information regarding any licensed device. This will ultimately be much more efficient (and less costly) than maintaining multiple separate databases. Metorex currently supplies all of the requested information in the quarterly reports and in fact routinely supplies the serial number of the source installed in the device. Thus, we would have no objection to including this piece of information as it could help locate the licensee of a source that is discovered in an inappropriate location. (27)

In its July 26, 1999 proposal, NRC stated that it is exploring the possibility of establishing a national database of generally licensed sources. Such a database could assist steel companies, the States, and others in finding the licensees of lost sources. The SMA supports this database and offers to work with the agency in its implementation. NRC should make as much data publicly available on a Web site, as possible, so that members of the public can trace the ownership of sources they find. If there is information in NRC's files that cannot be released to the public, for business proprietary or national security reasons, then NRC should have control over the information, but be required to assist in finding the owners of "lost" sources when there is an emergency notification. (28)

The proposed rule changes establish a tracking database for generally licensed devices. ABB believes in the objectives of this database, namely to be able to track source/device distribution, use, transfers, and disposals. However, for such a database to be truly effective in meeting these objectives, it must be a single database for the entire nation. The establishment of individual databases by each Agreement State would not only lead to higher costs for each registrant, but would result in 32 separate and incomplete databases. The proposed system, namely reports of individual transfers to individual organizations, is essentially the same type of system that is in effect now, and it has obviously been proven ineffective. (31)

An effective system of tracking requires a single group collecting and soliciting information, maintaining the database, and disseminating information as necessary. Further, a single database is the only effective way to reconcile discrepancies among reports in or out of separate Agreement States. ABB recommends that the proposed rules require a single nationwide database for tracking all applicable sealed sources and devices. (31)

NEI supports the concept of a national database for devices that require registration. The list needs to be comprehensive and include the devices that are regulated by the Agreement States. NEI recommends that the database include: type of devise, manufacturer's name, model number, serial number, and registered general licensee. In addition, general licensees should have the option to add to the database other devises that do not require registration. (33)

This national registry would provide one location for tracking the owners of any devices that are found and for obtaining background information on any devises that are lost or stolen. The database should be publicly accessible and searchable in a read only mode. It would provide ready access to state and local officials in tracking or locating owners of devices. The major difficulty with the database would be maintaining it. (33)

We support the establishment of one national database instead of separate databases maintained by each Agreement state A national database allows for one organization to enter the data resulting in less errors and more consistency. With one database for all devices, any discrepancies can be quickly found and followed up on. This would result in quicker response times when a device appears to be lost or unaccounted for. In addition it would be a waste of resources and a significant duplication of effort to have 30 plus separate databases created. (38)

AEA Technology has experience in establishing similar databases and could provide assistance if NRC would like support. (38)

## E. Additional Comment on Implementation Issues

Is there a way for general licensee's to request a list of devices that should be in their possession? This would be a great benefit to the "responsible individual" once these proposed rules are implemented. (12)

We recommend that the NRC develop a list of §31.5 licensed devices and make the list readily available to the public, possibly via the NRC web site. The list should contain the manufacturer, model number, and brief description of the device and should also state whether the device meets the registration criteria. This would assist current general licensees in identifying §31.5 devices already their possession. (37)

## F. Comment on Enforcement and Civil Penalties

Can the past inspection and enforcement history of a specific license be used to escalate the enforcement actions against the general license and vice versa? If so, is there precedence set for such actions? (12)

Once the NRC or an Agreement State notifies a entity that they need to register the device a timeline should be set and penalties imposed if not met. But if a entity is unaware that a device should be registered because they have not been notified by a manufacturer, distributor, NRC or Agreement State it would be unfair to impose a penalty on them. (16)

Many of the non-compliances with the general license regulations are believed to be due to ignorance (i.e., individual not aware the instrument contains a radiation source and/or not aware that the radiation source is "generally licensed" making the user/owner is subject to specific regulations). An individual or organization that does not know they have a general licensed source will not, because of new regulations, become knowledgeable. If the NRC insists that the only solution is to place the burden on the general licensee then ignorance should not result in enforcement action. (21)

By all means increase the penalties for improper disposal. (36)

We do not feel the civil penalties proposed for the loss or unauthorized disposal reflect real safety implications. In the case of Po-210, the safety hazard involved is minimal. (38)

Although the current NRC regulations allow the use and distribution of generally licensed devices (ie they were assessed as having no significant safety risk when used by personnel without specialized training) it appears as though we are creating a new class of license. Although a license is not required, there are still several requirements the user has to meet prior to getting the device, in essence there are additional prerequisites that must be accomplished by the vendor and end user prior to receiving the device. Many of these prerequisites are going to be difficult to demonstrate compliance. (38)

## G. Comments Outside the Scope of the Rulemaking

We believe, however, that restricting its scope to generally licensed by-product material ignores a closely parallel problem with a more immediate and much larger potential for public exposure. (1)

This problem concerns depleted uranium (DU) aircraft counterweights. Counterweights, made of extremely dense material such as DU, are used to balance the control surfaces of ailerons and elevators to facilitate hydraulic adjustments during flight. When properly marked by a licensed manufacturer, depleted uranium counterweights are currently exempted from all licensing requirements as an "unimportant quantity" while installed on a plane or stored or handled incident to installation or removal. The implication, confirmed verbally by the NRC staff, is that when counterweights are removed from service, they lose their exemption. This means that when a fleet is "set down" or a plane is scrapped out, hundreds to thousands of pounds of DU counterweights suddenly become source material requiring a license. When this happens, they are generally in the possession of an organization that has no license and no knowledge of the hazards of the material or of any regulatory requirements. Over the past nine months, we have conducted extensive informal industry surveys that confirm widespread unawareness of responsibilities and the controls that are applicable to depleted uranium aircraft counterweights. (1)

A general license cannot be invoked to control this material because the amount of DU that can be possessed under a general license is limited to 15 pounds. Very few counterweights weigh less

than this, e.g. a 1524834-101 counterweight for the L-1011 weighs about 11 pounds. In contrast, an AMC-7226 counterweight from a DC-10 weighs approximately 191 pounds. Most DU counterweights for wide-body aircraft weigh between 20 and 50 pounds. Collectively, the quantities at issue almost always exceed the general license limit because a "ship set" of counterweights includes many counterweights and cumulatively weighs over 1,000 pounds for most aircraft models. (1)

Depleted uranium counterweights were once widely used on the L-1011 Tristar, the DC-10 and the Boeing 747 wide-body commercial aircraft. DU was also used on general aviation planes such as the JetStar. Many military and naval aircraft employed DU for their counterweights. The A-7, F-111, C-5A, C-130, C-141, P-3C, S-3B are examples. Some, like the C-141, continue to use DU counterweights. Others, like the S-3B, are having their counterweights converted to tungsten. Some, like the A-7, have passed out of U.S. service to our allies, along with their DU components. So far we have been unable to locate an authoritative and comprehensive listing of all the planes for which DU counterweights were manufactured and distributed. Researching this may be complicated by the facts that some counterweights were manufactured in Canada and that a primary domestic producer, National Lead of Albany, went out of business in the 80's and decommissioned its Colonie, NY plant. As a result, DU counterweights may be in service on additional commercial aircraft types. (1)

The use of depleted uranium for counterweights fell from favor, and today counterweights for new production aircraft are made from tungsten. A legacy of depleted uranium counterweights remains on the older planes. The total amount of these DU counterweights is difficult to determine accurately because the quantity varies for each different model of the wide-body types. We used parts listings and structural drawings to determine the amount of DU in ship sets of counterweights for representative L-1011, DC-10, 747 and JetStar aircraft. Based on the numbers of these planes in existence and a survey of the quantities of some of the counterweights in the inventories of aviation parts suppliers, we estimate that as many as two million pounds may be in service, world-wide, for commercial aircraft. As these planes approach the end of their economical service life, DU counterweights are beginning to enter uncontrolled disposal channels in a rapidly increasing stream. (1)

The average of ages of existing wide-body commercial aircraft are 22.9 years for the L-1011, 23.4 years for the DC-10, and 15.8 years for the 747. Increasing numbers of these planes are now being "set down", "parted-out" and scrapped. Major airlines are knowledgeable enough to insure appropriate disposal of their surplus counterweight spares, although, in the process, they usually store the (now non-exempt) counterweights for prolonged periods without a license. The fate of counterweights entering parts and salvage channels generally consists of abandonment or of transfer to unlicensed operators and disposal in municipal and industrial landfills and other sites. Thousands of pounds are now being so disposed. It is clear that many of these companies are unaware of proper storage and disposal requirements. (1)

Depleted uranium counterweights often remain on aircraft that are retired from service and consigned to long-term storage, parts recovery, or salvage. DU counterweights are corrosion prone but are plated and painted to retard oxidation. When they cease to be maintained in airworthy condition and subjected to systematic inspection, release of radioactive uranium oxides is highly probable. Although military aircraft are not subject to FAA inspection and maintenance directives,

recent observations of the C-141 maintenance program confirm that without on-going surveillance, corrosion of DU counterweights can progress to the point where radiological contamination of maintenance facilities and long-term storage areas is threatened. This potential for environmental release could be minimized by terminating the exemption of counterweights on aircraft that are not in active use. (1)

The findings of the NRC Study of Conformity with General License Conditions apply even more emphatically to the possessors of DU counterweights. Ignorance of the hazards and properties of the material and of regulatory controls on alteration, transfer and disposal are virtually total. During our inquiries, responsible managers have casually explained their company's regular procedures for turning over hundreds and thousands of pounds to unlicensed salvage operators and scrap dealers. They obviously have no idea that they are doing anything wrong or violating regulatory requirements. Although counterweights manufactured after 31 December 1969 were required to be marked "Unauthorized Alterations Prohibited", we have received anecdotal reports of individuals sawing up counterweights and using them for "bucking bars" to set rivets. State and municipal officials have begun to encounter abandoned counterweights at airports and discarded in trash dumpsters. (1)

A recent incident involving a DU counterweight is illuminating. On 28 July 1999, the NRC published, in its Daily Events Report, an incident in which some Air Force mechanics at Robbins Air Force Base removed a DU counterweight from a C-141 aileron with a hammer and chisel, scattering a small quantity of dust and debris. This incident is now the subject of a formal investigation because someone at the scene was aware of the hazard. The irony of this level of response, while hundreds of thousands of pounds of the same material are being released into the public domain, speaks for itself. (1)

Several complimentary regulatory responses to this situation may be appropriate. The existing regulations urgently require clarification of a number of issues including the point, and the circumstances under which, the exemption from licensing ceases, the length of time counterweights for which there is no demand or use can be stored as exempt material, the extent to which DU-bearing aircraft leaving service can be transferred to unlicensed parts dealers and salvage operators, and the need for radiological surveillance of long-term aircraft storage parks and facilities where counterweights have been stored for protracted periods under unmonitored conditions. As an attachment to this letter, some of these points are defined and discussed in more detail. Many of these issues closely parallel the ones that are being addressed in the current rule-making. This circumstance suggests the alternatives of expanding its scope or of initiating a separate one along similar lines. (1)

In the interim, it is clear that some immediate notification is necessary to advise the organizations currently in possession of depleted uranium aircraft counterweights of their responsibilities to the public. The aviation community is a tightly regulated and law-biding one. There are extremely effective channels of communication with its primary regulator, the Federal Aviation Administration. Perhaps the NRC could take advantage of these existing channels by encouraging the FAA to issue an appropriate advisory bulletin informing the aviation community of its responsibilities for managing depleted uranium counterweights. An effective and practical solution must clearly involve the active participation of the aviation community and must be based on a detailed understanding of the realities that govern its daily activities and operations. (1)

The management of depleted uranium aircraft counterweights is a real problem that merits serious regulatory review. At this stage, it can probably be brought under control, and previous inappropriate disposals and releases can be corrected and remediated. (1)

UNRESOLVED ISSUES AND QUESTIONS RE DEPLETED URANIUM AIRCRAFT COUNTERWEIGHTS

1. When an airline or operator "sets down" a fleet of DU-bearing aircraft, how long does it have to effect disposition of spare parts inventories of DU counterweights before it needs to apply for a source material license to maintain possession of them? Based on informal conversations with the NRC staff and with state regulators, one interpretation is that DU counterweights lose their exemption from licensing when they are no longer intended for their original use. Criteria based upon intent (such as intent to sell surplus counterweights to another operator) tend to be difficult to enforce. As aging planes are retired and "parted out", spare parts inventories will predictably swell even as real demand disappears, along with the number of aircraft to be supported. This development would reflect the fact that it may be cheaper to store DU counterweights indefinitely rather than to pay the costs of authorized disposal. Frequency of demand or period of non-use might afford one objective tool for determining the credibility of a representation of intent for future use. The NRC encountered an analogous problem in enforcing its requirement that licensees clean up and decommission their unused facilities. Licensees deferred clean-up costs by claiming possible future uses. The NRC finally promulgated the "Timeliness Rule", which requires that, if a licensed facility has remained idle for two years, the decommissioning process must be initiated. Perhaps, by analogy, DU aircraft counterweights should lose their exemption from licensing if they have not been used in flight (or, for a particular part number, have experienced no demand) for a specified period. Another objective indication of intended use relates to how the part is managed. Modern commercial aircraft incorporate over one million different parts. They are almost always managed by an automated data processing system. All parts are classified in such a system as either "repairable" or "consumable". Another common industry term for parts that may be economically repairable is "rotable". "Consumable" parts, on the other hand, that do not meet criteria for airworthiness are automatically directed to disposal channels. The "system" will not allow the issuance of a repair order for a "consumable" part. Categorization of DU counterweights as "consumable" parts in an organization's ADP system is therefor a clear indication that such a part loses its exemption from licensing as soon as it is removed from an aircraft.

2. Presumably, the exemption from licensing for DU counterweights, stored incident to installation on an aircraft, applies to counterweights in the inventories of aviation parts dealers who are attempting to sell them back to operators and maintenance organizations for their originally intended use. Do such counterweights, that are held in storage for a specified period without being sold, lose their exemption from licensing, requiring the aviation parts dealer to apply for a source material license or to transfer the parts to an appropriate special licensee, e.g. for controlled disposal?

3. Can DU counterweights in the possession of a salvor, scrap dealer, or parts broker be considered as exempt from licensing because of a (theoretical) possibility of future use on

an aircraft? Such organizations often acquire parts (such as DU counterweights) that they do not expressly want because they are included in a large-scale consignment, transaction, or inventory transfer along with other high demand parts. An important factor in making such a determination should be the recognition that the Federal Aviation Administration requires a documentation of airworthiness for all parts used on an aircraft. This is effected by means of a completed FAA Form 8130-3 (Airworthiness Approval Tag) (or JAA Form One or equivalent for foreign carriers) that must accompany the part. Counterweights coming out of a tear-down facility would have to be shipped to an FAA licensed repair station for inspection, repair (if required), and issuance of the FAA Forms 8130-3 before they could be put to their original intended use. This is an expensive procedure and is not economically justified by the current negligible demand for DU counterweights. If a scrap or parts dealer accepted a consignment of material from an aircraft tear-down facility and did not obtain accompanying FAA Forms 8130-3 for the counterweights, it would be a good indication that there was no realistic prospect for their reuse. In fact, transfers of counterweights, without Forms 8130-3, from a tear-down activity to an unlicensed scrap or parts dealer is probably inconsistent with the intent of the regulations. From the time that DU counterweights are removed from an aircraft and enter either parts or salvage channels, the possessor should bear the burden of demonstrating a realistic probability of reuse, either by obtaining Forms 8130-3 immediately upon transfer or by other affirmative means.

4. Do DU counterweights installed on an aircraft lose their exemption from licensing if they remain installed on an aircraft that is placed in long-term storage, "moth-balled", or transferred for "parting out" or salvage? Aircraft that are not maintained in airworthy condition and subjected to periodic inspections and maintenance will eventually experience corrosion of counterweights and release of radioactive oxide onto storage areas and into the adjacent environment. The FAA defines an aircraft as a device intended for flight, so aircraft taken out of service cease to be aircraft in its view. If installation, even on a non-operational aircraft, qualifies the counterweights for exemption from licensing, it means that the parts company performing a tear-down could remove engines, avionics and other high value components for refurbishment and reuse and leave the counterweights attached to the carcass consigned for scrapping. At what point does the stripped aircraft cease to be an aircraft? Can the DU counterweights be left attached to a bare airframe or a subassembly and legally abandoned?

5. Under the proposed rule-making, devices containing by-product material that were stored for two years without being used are going to require disposition. By analogy, should depleted uranium counterweights installed on aircraft parked in long-term storage and not flown for a specified period lose their exemption? Would the owner/operator of the storage facility be required to obtain a source material license, remove the counterweights and place them in controlled storage, or perform periodic radiation monitoring and surveillance to insure against release of corrosion products into the environment?

6. Military aircraft with DU counterweights, e.g. the A-7 Corsair, have been transferred to allied governments through foreign military sales. The gaining organizations are not always aware of the presence of the DU or of the controls that are appropriate. The notifications and information requirements that are appropriate to such transfers should be established. (1)

With establishing 10 CFR 31.5c(13)(i) registration requirements of 10 mCi for Cs-137, 1.0 mCi for Co-60, 0.1 mCi for Sr-90 and 1.0 mCi of Am-241 or any other transuranics the NRC has left the issues of exempt quantity distribution unaccounted for. (18)

Certain industrial gauge manufacturers have distributed gauges with exempt quantities of sources above the regulatory limits specified under 10 CFR 30.18 and 30.71, Schedule B (i.e., 10 mCi of Cs-137). In addition, distributions were being made without an exempt quantity distribution license. Apparently, approval had been granted that would allow distribution of gauges where 10 individual (and more) 10 mCi of Cs-137 sources are used. It is our understanding that the manufacturer sold the device to a customer (without the exempt quantity sources, which are purchased from a third party) thereby circumventing the exempt quantity license and the Sealed Source and Device (SSD) registry requirements. It remains unclear how certain manufacturers of industrial gauges use 10 CFR 30.15 (c)(9)(ii) as a basis for distributing gauges when this section clearly applies to "...measuring instruments containing, for the purposes of internal calibration or standardization...). The appropriate section should be as defined under 10 CFR 31.5 "...measuring, gauging or controlling devices." This is again brought to NRC's attention since we continue to have concerns with the "loop hole" in the regulations and that this "uncontrolled" distribution by certain manufacturers will increase the lack of accountability of radioactive material. (18)

The NRC's May 3, 1999, Generic Letter 99-01, addressed some of this issue; however, NRC and Agreement States have issued SSD registries that allow these devices to be relocated by the end user and are exempt from leak test requirements and potentially certain reporting requirements. (18)

Over the past years we have attended numerous meetings and workshops in which the steel manufacturers association have complained that the NRC and manufacturer's of devices have not maintained adequate accountability of radioactive material. This exempt quantity distribution approach taken, by certain manufacturers, is not only inappropriate but will perpetuate the already existing concerns regarding the lack of accountability of licensed devices. (18)

The NRC must continue to address those issues outlined in the "Final Report of NRC-Agreement State Working Group to Evaluate Control and Accountability of Licensed Devices" (NUREG-1551). The report clearly outlined and identified the need for regulatory agencies (both federal and state) to strive toward more effectively utilizing existing avenues in rule to address the entire issue of radioactive material accountability consistently. (18)

The current rules remain open to interpretation with regard to exempt quantities and the proposed rule has become so extreme that some sections require more information of general licensees than from existing specific licensees. The NRC must establish some sense of consistency in order to meet the goals and objectives outlined in SECY-97-273 dated November 26, 1997. Some examples of inconsistency between general and specific are as follows:

| General Licensee will be required to have: | Specific Licensee: |
|---|---|
| A responsible person and backup responsible person. | One contact person - the RSO |
| Model and Serial Numbers, Isotope, Activity and Quantity | Generic without this information |
| Report replacements, returns and disposals | Not required until termination (18) |

The NRC recently also issued a final rule providing for the occasional solicitation of information from general licensees, when such information cannot be obtained from or by specific licensees. 64 Fed. Reg. 42269, et seq. (August 4, 1999). With respect to small business general licensees (as with any government paperwork requirement), these solicitations should be conducted only when absolutely necessary. (22)