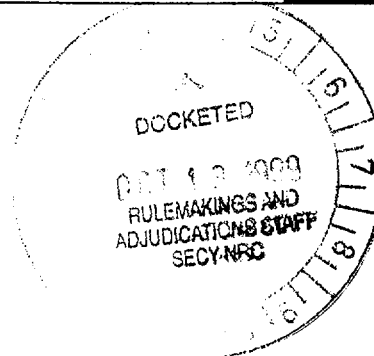


11 October 1999

Secretary
U.S. Nuclear Regulatory Commission
Washington DC
20555-0001



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

Dear Secretary:

As a manufacturer, distributor, and service provider to generally licensed thickness gauges, Honeywell-Measurex is very interested in the modifications that have been proposed for the regulations in 10 CFR Parts 30, 31, 32, 170, and 171.

We have a number of comments – some relatively minor and concerned with improving the wording, others more substantive.

1. 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.

Background: According to the material (copy attached) provided to us by Doug Broadus 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 addressed need not be 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.

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

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.)

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

2. 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.

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.

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.

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.

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.

3. 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.

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.

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.

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.

4. 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.

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.

5. 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.)
6. 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 larger, much less controlled sources of radiation?
 7. 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.
 8. During the 1 October workshop, there was much discussion of the proposed 10 CFR 32.5a(a) and (b), which address information required to be provided by device distributors to users "prior to transfer". The supplementary information that NRC provided with the proposed rules states:

While the Commission does not want to get involved with the details of licensees' business practices, it is the Commission's intent that "prior to transfer" would be before a final decision to purchase, so that the information can be considered in making that decision. The Commission seeks comment on how best to achieve and enforce this intent.

Honeywell-Measurex makes the following recommendations:

- 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.

- 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.
 - No matter what, avoid use of the phrase "prior to purchase" in the regulations. Devices may be leased, they may be loaned, etc.
 - 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.
9. 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.
10. We recommend several minor wording changes as described below:
- 10 CFR 31.5(b)(2): 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.
 - 10 CFR 31.5(c)(8)(iii): Modify 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.

- 10 CFR 31.5(c)(15): 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.

Honeywell-Measurex appreciates the opportunity to comment on the proposed regulations, both in this letter and during the 1 October 1999 workshop. We hope the input received will be useful in determining how to modify the proposed regulations to achieve the maximum US-wide improvement in safety.

Please contact me if I can provide any further information (phone: 408 864-7860, menu option 4 or email: elsa.nimmo@hmx.honeywell.com).

Sincerely,



Elsa Nimmo
Radiation Safety Officer
Honeywell - Measurex

Enclosures (not included with email):

NRC guidance on classifications for
Agreement State Compatibility

6/9/99 announcement from New York



STATE OF NEW YORK
DEPARTMENT OF LABOR
DIVISION OF SAFETY AND HEALTH
Radiological Health Unit
Building #12, Room 169
State Office Building Campus
Albany, NY 12240

6/9/99

**NOTICE TO MANUFACTURERS & DISTRIBUTORS OF RADIOACTIVE SOURCES
UNDER GENERAL LICENSE**

The New York State Department of Labor regulates the possession and use of radioactive materials for commercial and industrial purposes in New York State, and the Department has recently amended its regulations concerning measuring, gauging and controlling devices containing radioactive sources (31.5(a) devices), and exempt sources.

The purpose of this notice is to advise you of the recent changes in our regulations and to remind you of pre-existing restrictions.

Under our revised regulations, devices containing more than one millicurie of gamma-emitting radioactive material (where gamma radiation is the emission of interest), or more than one millicurie of strontium 90 or any transuranic radionuclide, may no longer be distributed under the general license and will require a specific license. Please note that this also prohibits "loaning" such devices to New York State companies, unless the company has a specific license.

Also, under pre-existing regulations, portable devices for use at temporary job sites may not be distributed under the general license to New York State companies.

Finally, the revised regulations prohibit using exempt sources in a combination that exceeds the relevant exempt quantity as a source of ionizing radiation in measuring, gauging or controlling devices.

If you would like a copy of the regulations described above please contact this office.

RA:jmp
cc: Agreement States

RECEIVED
JUN 21 1999
RADIATION SAFETY

9/99 from Doug Broaddus

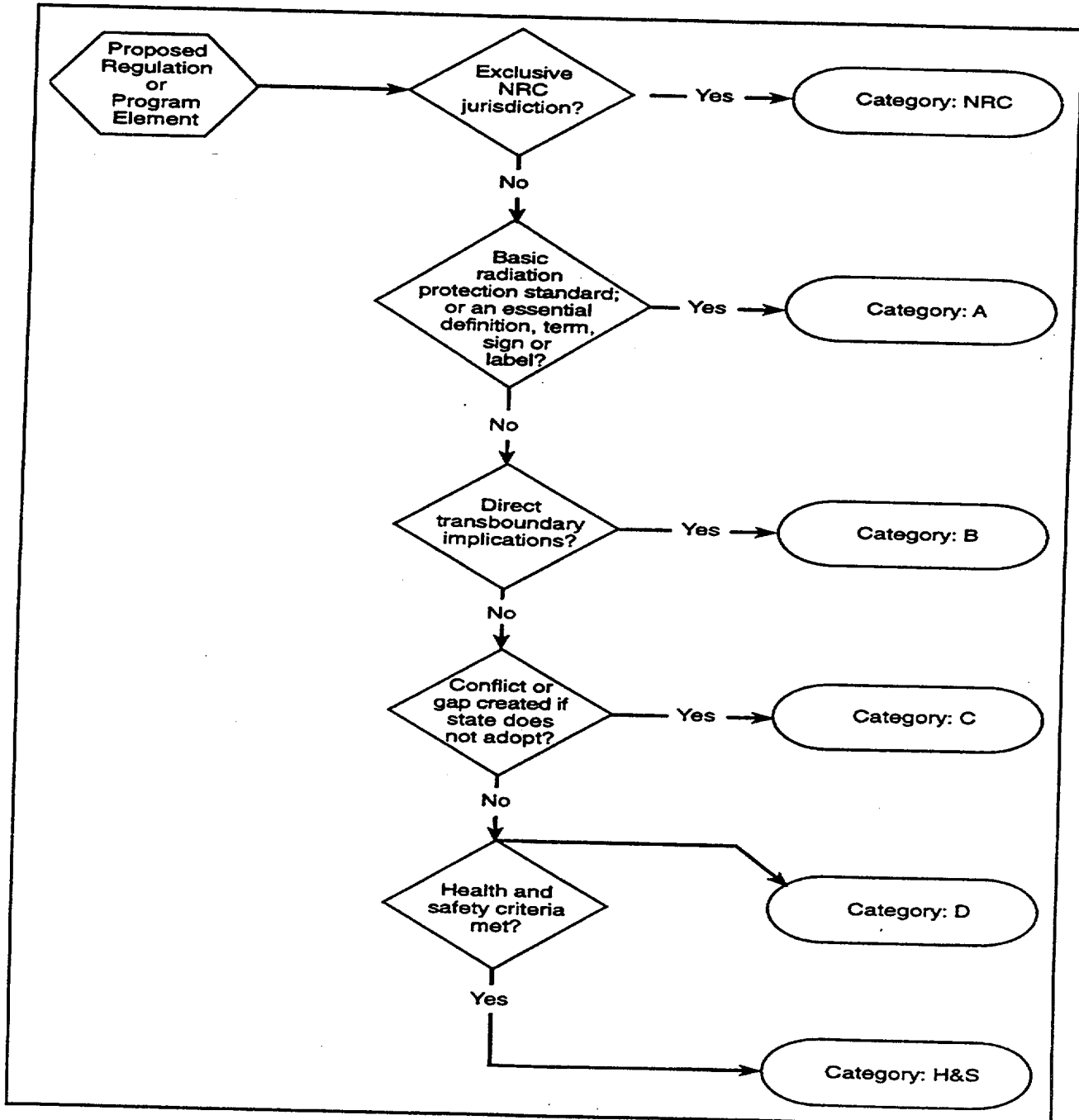
COMPATIBILITY CATEGORIES & HEALTH AND SAFETY IDENTIFICATION

The key to the categories represented by either the symbols "A", "B", "C", "D", "NRC" or "D/H&S" are as follows:

- A = Basic radiation protection standard or related definitions, signs, labels or terms necessary for a common understanding of radiation protection principles. The State program element should be essentially identical to that of NRC.
- B = Program element with significant direct transboundary 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 State to avoid conflicts, duplications or gaps. The manner in which the essential objectives are addressed need not be 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 State should not adopt these program elements.
- D/H&S = Program elements identified by H&S in the Comment column are not required for purposes of compatibility; however, they do have particular health and safety significance. The State should adopt the essential objectives of such program elements in order to maintain an adequate program.

Volume 5, Governmental Relations and Public Affairs
Adequacy and Compatibility of Agreement State Programs
Handbook 5.9 Exhibit

**Exhibit
Flow Chart**



COMpatibility CATEGORIES AND COMMENTS

REGULATION	TITLE	COMPATIBILITY CATEGORY	COMMENTS
§30.31	Types of Licenses	C	Based upon Handbook 5.9, Part II, "Categorization Criteria," Section (C), this provision is identified as Category C because its absence could potentially impair effective communication regarding the different types of licenses used on a nationwide basis. The essential objectives of this provision are the identification and definition of the two types of licenses -- general and specific.
§30.34(h)(1)	Terms and conditions of licenses	D/H&S	<p>Based upon Handbook 5.9, Part II, "Categorization Criteria," Section (E), Paragraph (h)(1), is designated "H&S." This provision assists in establishing a minimum level of safety for devices containing agreement materials that are distributed nationwide by reducing the likelihood of public overexposure. The essential objective of this requirement is to assure that specific and certain general licenses provide the appropriate regulatory agency notification of a petition for bankruptcy under any chapter of title 11 of the United States Code.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not provide the notification of bankruptcy, there is the possibility that the regulatory agency will not be alerted to a potential abandonment of licensed material. The abandonment of licensed materials could lead to the potential for exposures in excess of 10 CFR Part 20 limits.</p>
§31.1	Purpose and scope	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§31.2	Terms and conditions	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§31.5(a)	Certain measuring, gauging or controlling devices	C	Based upon Handbook 5.9, Part II, "Categorization Criteria," Section (C), this provision is identified as Category C to establish a minimum level of safety for certain devices that are distributed nationwide. The essential objectives of paragraph (a) are to assure the proper identification of the devices addressed by this provision (e.g., devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness), the identification of the persons who can receive these devices, and the regulations of these devices through a general or specific licensing mechanism.
§31.5(b)	Certain measuring, gauging or controlling devices	C	Based upon Handbook 5.9, Part II, "Categorization Criteria," Section (C), (2)(f), this provision is identified as Category C to establish a minimum level of safety for the devices identified in paragraph (a). The essential objectives of paragraph (b) are to assure that the receipt of the devices listed in paragraph (a) are limited to those who receive them through an authorized transfer and that the devices are as authorized by a 10 CFR 32.51 or equivalent Agreement State license.

REGULATION	TITLE	COMPATIBILITY CATEGORY	COMMENTS
§31.5(c)	Certain measuring, gauging or controlling devices	C	<p>Based upon Handbook 5.9, Part II, "Categorization Criteria," Section (C), this provision is identified as Category C to assist in the establishment of a national program for the accountability of the devices identified in paragraph (a) and to establish a minimum level of safety for these devices.</p> <p>The essential objectives of paragraph (c) include ensuring that:</p> <p>(1) Devices covered by paragraph (a) are accounted for, not abandoned, leak tested at the appropriate intervals (if applicable), operating properly, and transferred to or disposed of by persons authorized to receive the device;</p> <p>(2) Persons who acquire, receive, possess, use, or transfer the devices listed in paragraph (a) comply with all instructions and precautions provided by the labels;</p> <p>(3) Licensees comply with the appropriate regulations and requirements, and retain responsibility for the device;</p> <p>(4) Devices that are not operating properly are removed from use and repaired or disposed of by an authorized individual. Also, that appropriate regulatory agency is notified and proper decontamination is completed; and</p> <p>(5) Licensees can account for these devices and are knowledgeable of the applicable requirements. Accountability for devices and knowledge of the applicable requirements on the part of licensees with devices considered to present a higher risk relative to other devices in this category should be attained, in part, through periodic contact with the regulatory body.</p>
§31.5(d)	Certain measuring, gauging or controlling devices	C	<p>Based upon Handbook 5.9, Part II, "Categorization Criteria," Section (C), this provision is identified as Category C to establish a minimum level of safety and to assure accountability for the devices identified in paragraph (a). The essential objectives of paragraph (d) is to establish that the manufacture and import of devices is not authorized by paragraph (a).</p>
§32.51	Byproduct material contained in devices for use under §31.5; requirements for license to manufacture or initially transfer	B	<p>Based upon Handbook 5.9, Part II, "Categorization Criteria," Section (C), these provisions were identified as Category B because they establish requirements for products that are distributed nationwide.</p>

REGULATION	TITLE	COMPATIBILITY CATEGORY	COMMENTS
§32.51a (a)-(d)	Same: Conditions of licenses		
§32.52(a)-(c)	Same: Material transfer reports and records		
Part 170	Fees for facilities, materials, import and export licenses, and other regulatory services under the atomic energy act of 1954, as amended	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
Part 171	Annual fees for reactor operating licenses, and fuel cycle licenses and materials licenses, including holders of certificates of compliance, registrations, and quality assurance program approvals and government agencies licensed by NRC	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.