
**~~Draft~~ Regulatory Analysis for Proposed
Rulemaking – Requirements for Distribution of
Byproduct Material: (10 CFR Parts 30, 31, 32,
40, and 70)**

**U.S. Nuclear Regulatory Commission
Office of Federal and State Materials and
Environmental Management Programs**



DRAFT REGULATORY ANALYSIS

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1. STATEMENT OF THE PROBLEM

The U. S. Nuclear Regulatory Commission (NRC) conducted a systematic reevaluation of the exemptions from licensing in 10 CFR Parts 30 and 40, which govern the use of byproduct and source materials. During this reevaluation, the Commission identified several areas in which the regulations could be improved, clarified, or made more flexible, less prescriptive, up to date, and user friendly. Subsequently, the Commission also determined that certain regulations were overly burdensome or required licensee actions that are not commensurate with the associated risk. Some of these issues were addressed in an earlier rulemaking. That final rule was published October 16, 2007 (72 FR 58473).

The NRC is proposing to amend its regulations governing the use of byproduct material to make requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed. The Commission is also proposing to ~~improve safety criteria for approving products through licensing actions, and~~ redefine categories of devices to be used under exemption. This action is primarily intended to make licensing processes more efficient and effective. ~~It is also intended to improve assurance that appropriate quantities of radionuclides are approved for use under the general license in 10 CFR 31.5 and under exemptions from licensing requirements.~~ It would affect manufacturers and distributors of sealed sources and devices containing byproduct material and future users of some products currently used under general and specific license.

2. EXISTING REGULATORY FRAMEWORK

Part 30 sets out the basic requirements for licensing of byproduct material and includes a number of exemptions from licensing requirements. The exemptions are in §§ 30.14, 30.15, 30.18, 30.19, 30.20, and 30.21. The two exemptions in §§ 30.19 and 30.20, self-luminous products and gas and aerosol detectors, respectively, are class exemptions, which cover a broad class of products. Under these provisions, new products can be approved for use through the licensing process if the applicant demonstrates that the specific product meets certain safety criteria. This is in contrast to the other exemptions for which the level of safety is controlled through such limits as specification of radionuclides and quantities. Sections 30.14 and 30.18, exempt concentrations and exempt quantities, are broad materials exemptions, which allow the use of a large number of radionuclides. The specific radionuclide limits on the quantities and concentrations are contained in tables in §§ 30.71 and 30.70, respectively. The remainder of the exemptions from licensing are product specific, for which many assumptions can and have been made concerning how the product is distributed, used, and disposed.

Part 31 provides general licenses for the use of certain items containing byproduct material and the requirements associated with these general licenses. The general licenses are established in §§ 31.3, 31.5, 31.7, 31.8, 31.10, 31.11, and 31.12.

Part 32 sets out requirements for the manufacture or initial transfer (distribution) of items containing byproduct material to persons exempt from licensing requirements and to persons using a general license. It also includes requirements applicable to certain manufacturers and distributors of products and materials to be used by specific licensees. The requirements for

distributors address such measures as prototype testing, labeling, reporting and recordkeeping, quality control, and, in some cases, specific sampling procedures.

3. ALTERNATIVES CONSIDERED

3.1 No action

One alternative to proposing rule changes would be to take no action. The no-action alternative would allow current practices to continue. If NRC does not take action, there would not be any change in costs or benefits to the public, licensees or NRC. The no-action alternative would not address identified concerns.

3.2 Proposed Rulemaking to Revise 10 CFR Parts 30, 31, 32, 40, and 70

This alternative would amend 10 CFR Parts 30, 31, 32, 40, and 70 to resolve several issues related primarily to **NRC's objectives of effectiveness and openness in the regulatory process, while continuing to meet NRC's goals of ensuring adequate protection of public health and safety and increasing regulatory efficiency, effectiveness, realism, and timeliness.** ~~The environment and adequate protection in the secure use and management of radioactive materials.~~ The regulatory amendments would ~~improve the safety criteria for approving products through licensing actions,~~ improve the licensing of distribution of certain byproduct materials, add flexibility to the licensing of users of sealed sources and devices, clarify and update some regulations, as well as establish a new class exemption. These changes would affect licensees who distribute byproduct material and future users of some devices currently used under general license.

3.3 Other Alternatives

Other alternatives, such as developing or revising guidance or issuing generic communications, are not viable because these alternatives would not provide the necessary regulatory basis to mandate particular licensee actions and cannot adequately address concerns directly related to the regulations themselves. To maintain regulatory flexibility consistent with current regulatory needs, improve efficiency and effectiveness in certain licensing actions, ~~and while continuing to~~ ensure the protection of public health and safety in the future, changes in the regulations are necessary.

4. ANALYSIS OF ALTERNATIVES

Sections 4.1 through 4.408 describe each of the proposed amendments in the rule and provide discussion and in some cases, quantitative estimates of the costs and benefits to the licensees, ~~the NRC, the~~ Agreement States, and the public related to each amendment. Section 4.449 estimates the costs to NRC and Section 4.4210 estimates costs to Agreement States for rulemakings to promulgate the amendments.

Throughout this analysis, various labor rates are used. These rates are used consistently for all of the issues and their derivations are described below.

Licensee labor rates were obtained from National Wage Data available on the Bureau of Labor Statistics web site (www.bls.gov). Depending on the industry and the occupation (e.g., manufacturing, health and safety, etc.), an appropriate mean hourly labor rate is selected. The rate is then increased using a multiplier of 1.4 to account for benefits (insurance premiums, pension, and legally required benefits). Because exact hourly rates would be difficult to obtain and may not be sufficiently recent, nationwide mean hourly rates are used.

In the context of the overall, societal regulatory evaluation, NRC's fees are neither a cost nor benefit, but are considered a distributional effect. To a licensee, however, fees may have a significant impact and therefore they are mentioned, but not quantified, below in situations where they may be a significant factor.

NRC labor rates are determined per the calculation methodology in Abstract 5.2 of NUREG/CR-4627, Rev.1, "Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses." This methodology considers only variable costs that are directly related to the implementation, operation, and maintenance of the proposed requirement. Currently, this hourly labor rate for FSME is \$93.

Agreement States' labor rates vary in amount and in how each rate is determined. A survey of a particular industry would reveal a labor rate that can be compared to the NRC's labor rate, or the Bureau of Labor Statistics web site can be used to obtain an hourly labor rate. Either of these methods is likely to yield similar results. For the purpose of this analysis, the average Agreement State hourly labor rate was obtained from the Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Management, professional, and related occupations" limited to State and local government workers¹. This wage was then increased by the same factor of 1.4 described earlier to obtain an hourly labor rate of \$45 and an annual labor rate of \$80,000.

The estimation of costs for rulemaking is based on professional staff full-time equivalent (FTE). As described in the Office of Management and Budget (OMB) Circular A-76, "Performance of Commercial Activities," the number of productive hours in one year is 1,776. Therefore, a professional staff FTE is based on 1,776 hours. Costs are determined by multiplying the number of FTEs by 1,776 hours times the hourly labor rate, for NRC or Agreement States as appropriate.

For all licensee labor rates, \$43/hour is used, which is from Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Health and Safety Engineers, Except Mining Safety Engineers and Inspectors"; however, some of the actions evaluated may be conducted by lower paid employees, such as clerical staff.

This Regulatory Analysis was prepared in accordance with NUREG/BR-0058(4), "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," to support NRC's regulatory action and examine the costs and benefits of the alternatives considered by the Commission. The NRC staff has evaluated each attribute listed in Chapter Five of NUREG/BR-0184,

¹Department of Labor (U.S.), Bureau of Labor Statistics, Employer Costs for Employee Compensation, 4th Quarter 2007. Series IDs CMU3020000100000D and CMU3020000100000P.

“Regulatory Analysis Technical Evaluation Handbook.” The following attributes would be affected by the proposed rule:

- Industry Implementation and Operation – The proposed rule would improve licensing of distribution of certain byproduct materials by making the regulations more explicit, less prescriptive, clearer, more up-to-date, and in limited cases, more risk-informed. It would also allow some industrial products to be used under exemption from license instead of a general **or specific** license, which could increase the use of some products.
- NRC Implementation and Operation – The NRC would incur costs to develop a rule and to revise existing guidance. The proposed rule would result in minor effects on operating costs, improving efficiency in some regards, but adding review and reissuance of sealed source and device registration certificates.
- Other Government – Agreement States would need to amend their regulations to maintain compatibility with NRC requirements; impacts to the Agreement State regulatory programs would be minimal.
- Environmental Considerations – The proposed rule would add a new class exemption and slightly broaden the scope of another class exemption resulting in additional products being disposed of in municipal landfills and incinerators.
- Occupational Health (Accident/Event and Routine) – The proposed rule ~~would reduce likely doses to workers using some types of generally licensed devices distributed in the future.~~ It may expand the use of some types of industrial devices by providing an exemption from licensing, thus increasing the number of people exposed, but at lower levels of exposure than allowed under the general license- **under which many of these products are currently used or under a specific license.**
- Public Health (Accident/Event and Routine) – The removal of oversight for certain exempt products could result in small incremental increases in public doses.
- Regulatory Efficiency – The proposed rule would improve regulatory efficiency by ~~improving and simplifying the safety criteria,~~ removing prescriptive provisions and some unnecessary provisions, and clarifying some of the regulations. Also, adding a new class exemption and broadening another would eliminate the application of unnecessary regulatory requirements to low risk devices.
- Improvements in Knowledge – For certain issues, the proposed rule may improve the general knowledge of potential licensees/applicants.
- Other Considerations – The proposed rule could increase public confidence in the NRC by making the regulations clearer and more consistent and up-to-date. However, the risk-informing aspect could potentially have a negative impact on public confidence, since it entails reduction of regulatory control.

The above attributes are evaluated more fully in Sections 4.1 through 4.408 as they pertain to the individual issues.

The proposed rule would *not* be expected to affect the following attributes:

- Offsite Property
- Onsite Property
- General Public
- Antitrust Considerations
- Safeguards and Security Considerations

A major issue here is to what extent these can be quantified. For some attributes, like NRC implementation costs, this is relatively easy. For many others, it cannot be done due to lack of information or methodological problems. However, the Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG/BR-0058, Revision 4, states: “Even inexact quantification with large uncertainties is preferable to no quantification, provided the uncertainties are appropriately considered.” In ideal circumstances, dollar amounts are added up and a “net benefit” is given -- the amount by which values exceed impacts. Often, only costs (impacts) can be quantified. In the absence of dollar estimates for benefits and costs, a regulatory analysis may be able to provide some other quantitative information, such as number of licensees likely to be affected.

Valuable information on estimating costs and benefits can be found in the Regulatory Analysis Technical Evaluation Handbook, NUREG/BR-0184.

4.0 DESCRIPTION, DISCUSSION, AND ANALYSIS OF VALUES AND IMPACTS OF THE AMENDMENTS

4.1 Sealed Source and Device Registration

The definition of “Sealed Source and Device Registry” currently appearing in § 35.2, and to be added to § 32.2, reads “*Sealed Source and Device Registry* means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.” In accordance with this definition, the certificates are to provide a sufficient summary of the safety information of the sealed source or device and the licensing and use conditions approved for the product. This information is important to the regulators in the various jurisdictions, as most sealed sources and devices are distributed into a number of jurisdictions and many are distributed nationally. This is the primary source of safety information for the regulatory bodies about products in the various categories (exempt, generally licensed, specifically licensed) manufactured outside of each jurisdiction.

4.1.1 Revise § 32.210 and Other Regulations to Make Registration Requirement Explicit

The requirements in § 32.210 provide only for voluntary registration of safety information for specifically licensed products, yet registration of many specifically and generally licensed and exempt products is conducted under current licensing practice, and fees are assessed based on whether or not a “sealed source and/or device review” is required. The products in each of these categories for which this is applicable are indicated in guidance.

The regulations governing distribution of products to be used under general license and under exemptions include requirements for information concerning safety information to be submitted by applicants and for determinations to be made by the NRC staff. This information forms the basis of the sealed source and device (SS & D) review and resultant registration. However, as a matter of licensing practice, applicants/licensees obtain sealed source and device registration certificates for most, but not all, specifically and generally licensed sealed sources and devices, and for exempt products to be distributed for use under a class exemption. For specifically

licensed products, the users must supply safety information if the manufacturer or distributor has not registered the source or device.

The rule proposes to revise § 32.210 to make the registration requirement concerning specifically licensed devices more explicit, so that it is easier for potential applicants to determine the applicable requirements and associated fees. The rule also proposes to revise the sections of Part 32 applicable to specific categories of sealed sources and devices to explicitly require that products be included in the SS & D registry, namely §§ 32.22, 32.26, new 32.30, 32.51, 32.53, 32.61, and 32.74. Also, §§ 30.19 and 30.20 would direct an applicant for a license under §§ 32.22 and 32.26 respectively to also apply for a registration certificate.

Cost Impacts:

Currently, those products for which a device evaluation and registration would be required are being evaluated and registered. The proposed rule would make this an explicit requirement rather than an administrative practice. This change is not expected to result in new or different devices requiring an evaluation and registration. The requirements are consistent with present licensing practice except for a minor change with respect to specifically licensed calibration and reference sources. This change is not expected to affect the overall number of registration certificates issued. Therefore, there are no expected costs to the manufacturers and distributors, or to the NRC from this aspect of the proposed rule. The effect of the addition of a new class exemption in proposed § 30.22 and the requirement for registration for those products (§ 32.30(c)(3)) is covered in Section 4.3.

| Costs for NRC implementation for the overall rule are discussed in Section 4.419.

Section 32.210 would remain Compatibility Category B requiring strict compatibility for those States that evaluate sealed sources and devices and Compatibility Category D for those states that do not evaluate sealed sources and devices. Revising § 32.210 and Subpart B of Part 32 would require a comparable change in some Agreement State regulations; however, each State would conduct one rulemaking following the planned revision of Parts 30, 31, 32, 40, and 70.

| The cost for the rulemaking is discussed in Section 4.4210.

Benefits:

Not only would the regulations be more explicit and understandable, but there would be better assurance that there is a sound basis for the inclusion of devices and sealed sources in the registration process. Transparency in the regulations in this regard should contribute to the efficiency and effectiveness of relevant licensing actions.

4.1.2 Revise regulations to explicitly allow for amendment, modification and revocation, review, and inactivation of SS & D registration certificates

Other provisions would be amended so as to explicitly apply to registration certificates in addition to licenses. The proposed rule would add certificates of registration to §§ 30.38, 30.39, and 30.61 concerning amendment, and modification and revocation of licenses. These actions are currently generally authorized by these provisions and others in the regulations. A new provision § 32.211 explicitly addressing inactivation of registration certificates would be added. Inactivation means that no further distribution is authorized, but information about previously

distributed products is maintained in the database. ~~Because distributors~~Distributors would be required to request inactivation of certificates for sources and devices they no longer being distributed, intend to distribute with a proposed time limit for submitting the request of 2 years after the last initial transfer ~~is included~~.

In addition, a provision for explicitly addressing review and reissuance of certificates is being proposed (§ 32.210(h)). The proposed provision in § 32.210(h) may be used to update the certificate with respect to applicable industry or NRC standards or current security concerns or to ensure the quality of the summary of safety information and the information on conditions of use contained in the registration certificate that is available to the various jurisdictions. The NRC has not generally conducted reevaluations of sealed sources or devices unless an amendment of a registration certificate has been requested or a significant problem with a product has been identified. While the current regulations provide adequate authority to do so, recalling a registration certificate for review and possible reissuance in the absence of a significant safety problem with the product would be an activity ~~not previously~~only very rarely conducted by NRC. An explicit provision in § 32.210 is considered preferable to relying on other general provisions in Part 30 such as § 30.61, for taking such an action.

Discussion of alternatives

The sealed source and device registration process is a licensing tool. However, sealed source and device registrations, unlike specific licenses, have not been issued with expiration dates. The NRC currently relies, for the most part, on certificate holders to request amendments of certificates, as appropriate, when changes are to be made. As a registration certificate, in conjunction with the license, authorizes distribution of a product, a certificate may be reevaluated at the time of license renewal. The NRC's process does not include conducting a complete reevaluation of sealed sources and devices at the time that distribution licenses are renewed. Generally, there are fewer safety significant aspects likely to change reflected in the registration certificate than those addressed in the license. Limited reviews are sometimes conducted to ensure consistency of a certificate with the license.

Many certificates are revised and updated from time to time as a result of the certificate holder requesting amendments to accommodate desired changes in a product or associated procedures or to add new products to a registration certificate covering a series of models. Corrections to update information in the certificate are also occasionally made. Certificates are also inactivated, when the distributor no longer intends to distribute a particular source or device. However, no routine NRC procedure is in place to ensure that the information is current and complete and that the licensee (certificate holder) is continuing to manufacture the product in complete compliance with the statements made at the time of issuance, or to require that certificate holders consider changes to their products or manufacturing procedures to implement improvements in technology or revised industry standards. Some certificates have been active, allowing for continued distribution, for very long periods without being reevaluated.

There may be reasons for NRC to reevaluate a sealed source or device in some circumstances with regard to either the actual design of a source or device, or such other aspects as quality assurance or information provided to the user on safe use. One factor is that the NRC is required to consider the application of industry standards, for example, as reflected in § 32.210(d). These industry standards may be updated to provide improved safety. Also, licensees are required by § 20.1101 to implement radiation protection programs and to use, to

the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA). Thus, it is appropriate for licensees to consider new developments in technology and standards as they may impact achieving ALARA in the design of products. However, because § 32.210(f) requires the certificate holder to manufacture and distribute products in accordance with the provisions of the registration certificate and any statements made in the request for registration, and no reevaluation of a source or device, once approved, is normally required, the current regulatory structure may tend to limit, rather than encourage, industry improvement.

The Commission considered how it might best provide for the update of registration certificates so as not to discourage improvement in the design of sources or devices, to more readily allow for the application of revised industry or NRC standards, and to ensure that information in the certificates is fully consistent with current practices. Related to the overall issues concerning improving products and manufacturer/distributor procedures and updating of registration certificates, the Commission also considered a number of other alternatives.

Other options considered included reviewing certificates at the time of license renewal, in part or in whole; adding separate expiration dates to certificates with typically longer terms than licenses, e.g., 10 to 20 years; and explicitly allowing licensees to make changes without NRC approval, if these changes do not reduce safety margins.

Another option considered was to explicitly require applicants/licensees to demonstrate ALARA in design of their products. As noted, licensees are required by § 20.1101 to implement ALARA in their radiation protection programs. However, with limited exceptions, the consideration or review of the concept of ALARA in the design of products is not specifically addressed in the regulations. Demonstration of achieving ALARA in the design of products is difficult and is not specifically required to be addressed in licensing in most cases. Such a process may be too burdensome and too arbitrary; however, under existing requirements, licensees should consider new developments in technology as they may impact ALARA in the design of products (and manufacturing procedures) and make improvements, as appropriate.

The Commission also considered adding separate expiration dates to ~~new~~ newly issued registration certificates only (with longer terms than the typical term for licenses, e.g., 10 to 20 years;), and having current active certificates expire through a provision in the regulations at some date (15 or 20 years) following the last issuance date on the certificate. However, problems identified with the approach of causing expiration of certificates by regulation include the fact that numerous certificates could expire within a short time of each other, especially in cases where a major distributor had updated many certificates at the same time. Additionally, without the expiration date appearing on the certificate itself, distributors may more easily miss the date for submitting timely renewal requests. The Commission does not believe it would be justified to terminate a distributor's authorization to distribute as a result of missing a date for timely renewal under this circumstance.

Conducting complete reevaluations of sealed sources and devices at the time of license renewal or requiring renewal of certificates through adding separate expiration dates to certificates has the advantage of providing an anticipated timeframe for reconsideration of devices/sources and the associated documentation by both the certificate holder and the NRC. Either of these approaches would likely contribute to accountability on the part of manufacturers/distributors and

to the application of ALARA to product designs, although longer time frames for renewal than the typical 10-year license term would be more likely to lead to actual improvements in products or processes versus more routine updating of documentation only. However, the timing of any renewal process may not be optimal with respect to changes that occur. Also, overall resources required for both distributors and the NRC would be greater than for the limited number of reevaluations envisioned under the proposed approach of § 32.210(h).

Consideration was also given to allowing manufacturers and distributors to make improvements without obtaining prior NRC approval. If any of the information provided in the original application is to be modified, the licensee/certificate holder must submit an application for an amendment before the change takes place. This may be an impediment to making changes, which could be safety improvements or changes that maintain the existing level of safety but reduce costs. However, it was considered difficult to develop such a provision which would not be overly complex, while both improving flexibility and ensuring that safety is maintained. In addition, eliminating some unnecessary impediments to a licensee/certificate holder making changes that do not adversely affect safety has previously been addressed in licensing practice, e.g., by keeping to a minimum, information included in the certificate concerning aspects with no safety significance.

Cost Impacts:

These proposed revisions would not change NRC's authority or specifically require any new actions on the part of certificate holders or others, except to propose that certificate holders request inactivation within two years after ceasing distribution of covered sources or devices. For most of these actions, including the requirement to request inactivation, the proposed rule would not affect the number or type of actions that occur. The provision in § 32.210(h) may be used for some additional reevaluation of registration certificates. The number of such reevaluations would vary from year to year but is expected to average 4 reviews per year, mostly dealing with certificates for devices. There are now approximately 240229 active NRC certificates, of which about 145135 are for devices. Many of these now cover a number of models.

The average effort involved in a review of an existing certificate would be less than that for a new certificate. The number of hours involved in any particular case would depend on the completeness and availability of all of the documentation on which the last issuance of the certificate was based and whether any applicable standards or industry practices have changed since that time. Only in rare cases would a sealed source or device need to be redesigned in order for the registration certificate to be reissued. Other aspects, such as quality assurance/quality control, labeling, or the operation and safety instructions to be provided to users, may occasionally need upgrading.

Costs to licensees:

The preparation of a request to register a sealed source or device or amend a certificate is estimated to average 21 hours (OMB Supporting Statement for Part 32). If the licensee's response to NRC's review/reevaluation of a certificate averages 12 hours, the average annual cost to licensees would be:

$$4 \text{ reviews/year} \times 12 \text{ hr/review} \times \$43/\text{hour} = \sim\$2,100$$

Other potential costs are more difficult to quantify. However, consideration of licensee costs would be made on a case-by-case basis in requiring any changes to be made beyond documentation, so as not to impose any unreasonable costs.

A small number of licensees who are certificate holders in Agreement States may be impacted by equivalent requirements for inactivation.

Costs to NRC:

The number of reissuances per year is estimated to average approximately 4; however, as these would selectively involve mostly certificates for devices (for which the review is more complex), the average number of hours per action would be greater than the overall average for both sources and devices, and is estimated for purposes of this Regulatory Analysis at 24 hours. The annual cost would be approximately:

$$4 \text{ reviews and reissuances} \times 24 \text{ hours/reissuance} \times \$93/\text{staff hour} = \sim\$9,000$$

NRC could also incur minor administrative costs associated with replacing SS & D registrations with a somewhat increased number of updated or inactivated SS & D certificates from Agreement States that issue certificates in the SS & D database.

Costs for NRC implementation are discussed in Section 4.119.

Costs to Agreement States:

Some of the Agreement States have some process in place to review the certificates, typically at the time of license renewal, at least to ensure that the information contained is complete and consistent with current distribution. (Although manufacturers and distributors are required to manufacture, distribute, and service sources and devices in compliance with any statements made in the request for registration and the provisions in the certificate (§ 32.210(f)), sometimes a licensee may make a change resulting in an inconsistency with its previous commitments.) In some cases, information from inspections or other reports concerning failures or compliance concerns are also considered with respect to the need for revising the certificate.

Some form of reevaluation of SS & D certificates by the Agreement States that issue them would be encouraged. A limited number of actions may result from changes being ~~made~~ **considered** in ~~this a separate~~ **action** ~~and others~~ to the general license program. Sections 30.38, 30.39, and 30.61 are currently Compatibility Category D and are anticipated to remain Compatibility Category D. Therefore, no specific cost to Agreement States is attributed to this change, although some costs would result for Agreement States that issue registration certificates if they increase efforts to review and reissue, or inactivate certificates. Of the proposed amendments related to this issue, only § 32.210 and the new § 32.211 involving inactivation of certificates are a Compatibility Category B for those States that conduct evaluations of sealed sources and devices. NRC is seeking to establish consistency in the practice of inactivation of certificates, so that it is clear to all of the jurisdictions which sealed sources and devices are authorized for continued distribution. Inactivation can be a simple administrative action, once the cessation of distribution is identified. In some cases, time might be spent evaluating such things as the availability of authorized servicers for devices currently in use; however, the issue of maintaining

the adequacy of service providers exists irrespective of an inactivation process. These provisions would require a comparable change in some Agreement State regulations; however, each State would conduct one rulemaking following the planned revision of Parts 30, 31, 32, 40, and 70. The cost for the rulemaking is discussed in Section 4.4210.

Benefits:

These explicit provisions concerning review and inactivation of registration certificates and the addition of registration certificates to the provisions for amendment and revocation would provide a clearer basis for these Commission actions, contributing to the efficiency and effectiveness of the regulatory program concerning manufacture and distribution of sealed sources and devices. The addition of inactivation provisions to Agreement State regulations would improve the information on currently authorized distribution in the registry and may improve the identification of issues concerning the availability of authorized servicers.

An SS & D certificate review process would provide an orderly approach to ensuring that the industry adjusts to a changing environment and/or standards. It would be less disruptive to industry (both distributor and user industries) than revoking or invalidating certificates on a certain date. For example, it was determined that devices that had been approved for use under the general license in § 31.5 in some cases contained inappropriately high amounts of a radionuclide of concern than is currently acceptable given the change in the security environment. One certificate that allowed for a Category 2 quantity of americium-241 was revoked. Others may be invalidated by a separate rulemaking to restrict quantities of materials in devices authorized under § 31.5. ~~Also, in another aspect of this proposed rule, discussed under Section 4.6 of this document, the Commission is proposing to revise the safety criteria in § 32.51 for approval of devices to be used under § 31.5 (and equivalent Agreement State regulations). The Commission is planning to apply these revised criteria to devices approved in the future and not immediately (or in a specific time frame) require all current distributors of such devices to demonstrate that their products meet the revised criteria. The Commission would instead expect to use the provision in proposed § 32.210(h) to consider whether changes are needed on a case-by-case basis. A specific request for comment on this is included in the proposed rule notice.~~

The process of reviewing certificates could make distributors more accountable. It would allow case-by-case consideration of the impacts of requiring an actual change to the design of a sealed source or device and time for the distributor to propose acceptable changes. The authority to distribute would continue while the review process was ongoing.

Other possible improvements may result from review and updating of registration certificates. These could include: improvement in a product design or associated required procedures, including greater consideration of the ALARA philosophy in the design of devices, potentially leading to exposure averted, and improvements in the quality of the summary of safety information and the information on conditions of use contained in the registration certificate that is available to the various jurisdictions (NRC and the States), potentially contributing to confidence in the regulatory program. Any improvement in the information provided to users as instructions on the safe use of a product could also provide benefits in terms of exposure averted.

4.2 Revisions to § 30.32(g) for Sealed Sources and Devices Not Registered by the Manufacturer or Distributor or Not Identified by the User

The current § 30.32(g) assumes that either (1) sealed sources and devices are registered by the manufacturer or distributor or (2) the user can specify which sealed sources and devices it intends to use and provide all of the same safety related information that the manufacturer or distributor would have provided if the products had been registered. A recent exception to this was made for legacy sealed sources and devices containing naturally occurring and accelerator-produced radioactive material (NARM). That provision, in § 30.32(g), also requires applicants to specify which sealed sources and devices it will use before the license (or amendment to license) is obtained.

There are a number of reasons that a manufacturer or distributor may not have registered a sealed source or device, i.e., (1) it was manufactured before the SS & D registry was fully implemented; (2) guidance in NUREG-1556, Vol. 3, Rev. 1, exempts it from the need for a SS & D registration process; or (3) it is a source or device being developed for a custom user.

If a sealed source or device is not registered, the user must provide the information listed in § 32.210(c). In some cases, it is difficult, or even impossible, for a user to provide some of the types of information required, such as what prototype tests were conducted and the results of those prototype tests. Although the criterion in this provision (§ 32.210(c)) is that there is sufficient information to provide reasonable assurance that the radiation safety properties of the sealed source or device are adequate to protect health and minimize danger to life and property, this provision has been interpreted to mean that information in all of the listed categories must be submitted to support the finding, irrespective of the risk or complexity of determining that the standard has been met.

The proposed rule includes the following provisions:

§ 30.32(g)(3) - would extend the provision for providing alternative information on NARM legacy sealed sources and devices to all legacy sealed sources and devices containing byproduct material.

§ 30.32(g)(4) – would add a provision for limited information for certain smaller unregistered calibration and reference sources.

§ 30.32(g)(5) – would add a provision to allow for constraints to be proposed and approved as a basis for licensing the use of sealed sources and devices in lieu of identifying all individual items.

The change to § 30.32(g)(3) extends a provision for legacy sealed sources and devices with 11e.(1) byproduct material (byproduct material covered by Part 30 prior to the addition of NARM). This simply allows alternative information (to that specified in § 32.210(c)) to be provided to support the safety finding on the product.

The addition of § 30.32(g)(4) would provide that smaller calibration and reference sources can be licensed for use under a specific license without an evaluation of the safety properties. Sealed source registration certificates have sometimes not been issued for small sources of this type under current licensing practice. (The exact criteria proposed for the exclusion is somewhat different than those in the current guidance.) Although some review of the proposed design and manufacturing methods would be part of licensing a manufacturer/distributor of such sealed

sources, the degree of evaluation does not rise to the level of needing registration of the safety information of the sealed source.

The addition of § 30.32(g)(5) would also provide some flexibility to applicants and license reviewers in the licensing of the use of sealed sources and devices. It would provide an option whereby the exact sealed sources or devices to be used need not be identified in all cases.

Cost Impacts:

There are no costs anticipated beyond that for NRC implementation of the rule and Agreement State rulemakings for compatibility. Paragraph 30.32(g) is classified as Compatibility Category C. Both the NRC and Agreement States would incur costs associated with the rulemaking. These are discussed in Sections 4.119 and 4.1210.

These changes are not expected to increase occupational doses. Paragraph 30.32(g)(3) has the same standard for approval using alternative information to support the approval. With respect to § 30.32(g)(4), calibration and reference sources meeting the criteria of exclusion from registration (in proposed § 32.210(g)(1), i.e., 37 MBq (1 mCi) of β/γ -emitters; or 0.37 MBq (10 μ Ci) of α -emitters) should be able to be handled safely by any specific licensee. Under § 30.32(g)(5), adequate constraints would be added to the license to assure that the safety properties of the sealed sources and devices are adequate given the training and experience and facilities and equipment of the licensee.

Benefits:

These amendments would simplify the licensing of users of sealed sources and devices under certain circumstances.

It may prevent some licensees from disposing of and replacing some sources or devices when renewing their licenses because they cannot supply the information identified in § 32.210(c).

It would eliminate the need in some cases of issuing exemptions from § 30.32(g) and the associated preparation of environmental assessments.

For licensees/applicants, it is estimated that an average of 10 hours would be saved if an exemption from § 30.32(g) is not needed as a result of these provisions.

For NRC, it is estimated that an average of 10 hours per licensing action, plus an additional 10 hours for the environmental assessment, would be saved as a result of not needing an exemption from § 30.32(g).

In the case of small unregistered calibration and reference sources licensed for use under § 30.32(g)(4), it is estimated that an average of 5 hours would be saved by the applicant and a similar amount for NRC.

For situations where the new § 30.32(g)(5) is used, the complexity of this aspect of the license review process might be somewhat increased, but for some cases for which it is currently very difficult for the applicant to identify all sealed sources and devices they intend to use, a

significant simplification would result. Overall, a significant savings in time for both applicants and the NRC is expected.

Under Compatibility Category C, Agreement States do not have to have exactly the same requirements. At least some of the States may not have had the same lack of flexibility in this area that developed at NRC. However, some savings to Agreement States and their applicants may result, if the States incorporate similar provisions.

4.3 Create § 30.22 for New Class Exemption and §§ 32.30, 32.31, and 32.32, Requirements for a License, Safety Criteria, and Conditions of a License to Distribute Devices

A new provision, § 30.22, would be created to establish a new class exemption for certain industrial products initially transferred from a § 32.30 licensee. Licensing requirements for distribution of devices for use under the new exemption would be comparable to those imposed on specifically licensed distributors of gas and aerosol detectors used under § 30.20 (and equivalent Agreement state provisions). These regulations would be:

§ 32.30 would be created to establish distributor requirements for exempt industrial devices.

§ 32.31 would be created to establish new safety criteria.

§ 32.32 would be created to establish the specific conditions of the license.

Under these proposed provisions, some manufacturers and distributors of generally licensed devices would apply to have their current products approved for use under the new exemption. In the future, there may be some expansion of markets for these types of products as a result of the elimination of regulatory requirements on the users, particularly given the uncertainty in future costs of radioactive waste disposal. These licensing provisions would apply to distributors nationally, as licensing the distribution of products used under an exemption from license is reserved to NRC. Distributors of products used under a general license may be licensed by the Agreement States. As some States have not taken over the review of sealed sources and devices for registration, some of the Agreement State licensees distributing generally licensed devices for use under § 31.5 may already have obtained an SS & D certificate from NRC.

It is expected that some existing licensees would seek to change the status of their devices so that their future customers would be exempt from licensing. It is estimated that approximately 10 existing licensees would apply in the 2-3 years following the rule change and an additional 3 new applicants for exempt distribution licenses per year would result. However, there is uncertainty in these numbers as they are projections of future voluntary actions. The requirements would be the same for those in Agreement States as those in NRC States. However, there may be some additional cost for those in Agreement States as a result of dealing with two different regulatory bodies. Distributors of exempt products in Agreement States must also have a license from the State authorizing possession and use. For some distributors who currently do not distribute any products for use under an exemption, NRC fees may be a factor in deciding whether to distribute a product under an exemption or continue to distribute it as a generally licensed device. Annual fees are significantly less for small entities than for large entities; thus, this would be less of a factor for small entities.

There are no non-rulemaking alternatives that could accomplish the same result. However, there are other approaches in changing the regulations that could be used to reduce the burden

on users of industrial devices and allow for the expanded use of such products. These include establishing a number of product-specific exemptions, revising the general license to reduce requirements for certain devices, or establishing a new general license with more limited requirements commensurate with the level of risk of the devices covered.

One should note that the cost/benefit situation for exempting an industrial product is different than that for exempting a consumer product. In the case of a consumer product, the practice (the manufacture and use of a particular product) does not occur in the absence of a regulatory provision reasonably available to the general public. Thus, all exposures (and any other impacts) from the potential practice, including those during manufacture of a product, are attributable to the provision, as are all benefits to society from the use of the product. In the case of industrial products, considerations include: How practical is the use of the product under the specific provisions of the general license? What is the burden of the particular requirements of the general license? Will more benefit to society result with a reduction in the burden to users? What additional impacts would occur if used under an exemption, for example, from 100% uncontrolled disposal of the products? In either case, it is difficult to quantify many of the impacts and benefits with any certainty, in part, because most depend on the projection of quantities of products to be distributed. However, most impacts and benefits are in fact proportional to the number distributed, i.e., when larger numbers of a product are used, more people are exposed, but more benefit to society results.

Cost Impacts:

Costs to Licensees (Manufacturers and Distributors)

There are no projected costs to licensees from the rule. The rule does not impose any new requirements on existing licensees.

However, some current licensees may choose to expend resources to change the regulatory status of their product. Also, manufacturers and distributors who do not apply for a license to distribute their products under the exemption may lose some market share to those who do.

Products would be evaluated for use under the exemption and a new certificate would be issued. The affect on fees would depend on whether an NRC SS & D certificate is replaced or only a new one is obtained, as there is a significant annual fee for each certificate. The average time for preparation and review of an SS & D certificate has been previously estimated (OMB Supporting Statement for 10 CFR Part 32) at 21 hours for the applicant and 21 hours for NRC. These vary depending on the nature of the action, whether it is a sealed source or a device, and whether a dose assessment is required. The products involved here are devices with relatively low risk but a complex set of exposure scenarios to evaluate; a somewhat above average estimate of 24 hours per submittal by the applicant is used. The estimate for preparing the license application is also higher than the average estimated in the OMB Supporting Statement for NRC Form 313.

For those specifically licensed distributors who choose to apply for a license under § 32.30, the following costs are estimated.

This would be a voluntary expenditure in order to obtain an overall benefit. This one-time expenditure combined with Benefits to Existing Licensees/Distributors would result in a net benefit to existing licensees.

Illustrative estimate of application costs for these assumptions:

8 licensees in Agreement States
2 current NRC licensees
Average of 2 device certificates per licensee

NRC Exempt-Distribution License Required:

10 applications x 8 hours/application x \$43/hour = ~\$3,400

Device Evaluation Required:

20 registrations x 24 hours/device x \$43/hour = ~\$21,000

Total: ~\$24,000

Fees associated with these licenses and registration certificates could be more significant costs than those estimated.

Costs to NRC:

10 applications x 8 hours/application x \$93/staff hour = ~\$7,400

20 evaluations x 21 hours/evaluation x \$93/staff hour = ~\$39,100

Total: ~\$46,500

Costs to Agreement States

Agreement State licensing and inspection programs would only be impacted to the extent that a few of their general license distributors might possibly change completely over to exempt distribution, which would be covered by an NRC license. Even in this case, their possession and use would still be under an Agreement State license.

In addition, both the NRC and Agreement States will incur costs associated with a rulemaking.

These are discussed in Sections 4.119 and 4.1210.

Costs to public

There are some limited expected costs to the public from this aspect of the proposed rule due to contaminated scrap; however, due to the uncertainty in the probability and extent of such incidents, an actual cost is not estimated.

Occupational Health/Public Health

As this would likely increase the market in affected devices, and would ultimately lead to the development of additional devices, potential increases in the number of persons exposed would

result. The safety criteria associated with this exemption would limit routine exposures to no more than $200 \mu\text{Sv}$ (20 mrem ~~$(200 \mu\text{Sv})$~~ /year (in a work environment) and also control disposal and accident risks. Actual exposures would typically be expected to be lower than those in the safety criteria.

This proposed class exemption, like the two existing class exemptions, requires applicants to estimate the quantity of byproduct material to be distributed annually, and the quantities of units likely to be in one location. This aids in the estimation of doses likely to occur in a number of the scenarios required to be analyzed, including specifically doses from disposal of the product.

Environmental Considerations

This provision would increase the number of products allowed to be disposed as ordinary trash. The new exemption would minimize residential use, by limiting it to products normally used in an industrial setting. Because of this, broadly distributed consumer products would not be included. Increases in the number of “exempt” devices containing byproduct material of about 10 percent might be expected.

The safety criteria would ensure that future doses from disposal are unlikely to exceed $10 \mu\text{Sv}$ (1 mrem ~~$(10 \mu\text{Sv})$~~ /year from as many items of one product likely to be disposed at one landfill or municipal incinerator. This should minimize environmental effects of increased numbers of products being disposed in landfills and at incinerators.

Benefits:

Benefits to Licensees/Users

There would be no direct effect on current licensees general or specific. However, future users of devices approved for use under the exemption would benefit from not having the requirements of the general license or, in some cases, a specific license. Some current general licensees would be expected to return generally licensed devices to the vendor and obtain devices covered under the exemption, when they become available. Also, NRC may choose to exempt previously distributed items when a model is approved for use under the exemption.

The following discusses typical costs for general licensees which would no longer be incurred by users under the exemption

Currently, generally licensed devices are required to be disposed of as low-level radioactive waste, although some with shorter-lived materials may be allowed to decay instead (after return to the distributor). The proposed rule would allow certain industrial devices to become exempt from licensing, and therefore, disposal of such devices would be as ordinary trash. Users would benefit by no longer having to pay for disposal (usually indirectly as they usually transfer devices back to vendors or may also transfer to waste brokers). The affected devices would not need disposal for some time in the future, after distributors have applied for and obtained exempt status for their devices and sold devices for use under the exemption, and after those devices have subsequently been used for their useful life, which in some cases is more than 10 years. Currently, disposal options for low level radioactive material are limited. As of June 30, 2008, the Barnwell site can only accept waste from organizations located in South Carolina, Connecticut, and New Jersey, the three states that make up the Atlantic Interstate Low-Level

Radioactive Waste Management Compact. The costs of low level waste disposal several and more years in the future is highly uncertain; thus no quantification of this benefit has been conducted, but may be substantial. Also, the uncertainty in the cost of future disposal in itself affects the market for such devices; thus, eliminating the requirement for controlled disposal may allow for more people to enjoy the benefits of the products.

Under the proposed solution, future users (including some current general licensees) would no longer have to leak test the devices. However, only approximately 10 percent of these devices are estimated to require a leak test and/or operational test. It is assumed that a leak or operational test is performed every six months, if required. Six-month testing intervals are the default unless the manufacturer requests otherwise. Typically, the licensee swipes the device, then sends the swipe to be analyzed. Analysis services range in price from \$35 - \$40 per kit depending on the number of kits. The savings from not performing leak tests are estimated to be:

$$2 \text{ leak tests/device-year} \times (\$40/\text{kit}/2 \text{ wipes}) = \$40/\text{device-year}$$

It is assumed that sources that require leak tests are in devices that need to be checked for proper operation. The savings from no longer having to perform this activity is estimated to be:

$$2 \text{ tests/device-year} \times 0.1 \text{ hour/test/operational check} \times \$43/\text{hour} = \$8.60/\text{device-year}$$

Currently, general licensees are required to maintain records of leak tests and device operation tests performed. The records are required to be maintained for three years. It is assumed that it takes approximately 0.1 hour per device to file and maintain the appropriate records. The time saved from no longer having to perform this activity is estimated to be:

$$2 \text{ leak tests/device-year} \times 0.1 \text{ hour/record} \times \$43/\text{hour} = \$8.60/\text{device-year}$$

In addition, users (currently generally licensed) would no longer have to file the required transfer reports with the NRC (under § 31.5(c)(8) and (9)). Agreement States are likely to require similar reports under compatibility requirements. The total annual amount saved from no longer having to file reports is estimated below. Based on information from the current OMB clearance for 10 CFR Part 31, it takes 0.6 hours per report. Therefore the reduction in cost, or savings, is estimated to be:

$$0.6 \text{ hour/transfer report} \times \$43/\text{hour} = \$26/\text{transfer report}$$

As static eliminators containing polonium-210, which need replacing annually, are a type of device likely to be affected, the number of transfer reports relative to the number of devices in use would be higher than the overall ratio currently under § 31.5.

There are a few additional reporting requirements such as change of address (§ 31.5(c)(14)), bankruptcy (§ 30.34(h)), accidents (§ 31.5(c)(5)), and loss or theft of sources (§§ 20.2201 and 20.2202). However, since these are likely to be less frequent events (requiring reports), the impact would be small by comparison with the above quantified costs.

A current requirement in § 31.5(c)(12) is that general licensees must appoint an individual responsible for having knowledge of appropriate regulations, and that person is to assure day-to-

day compliance with the regulations. This requirement would no longer apply under the proposed solution. Therefore, future users, including some current general licensees, would save by not having to pay a person to perform these duties. It is recognized that this person performs other duties that would require his/her employ for those duties; however, it is assumed that this person spends 4 hours/year attending to the required duties.

$$4 \text{ hours/year} \times \$43/\text{hour} = \$172/\text{user-year}$$

As § 31.5 is now a Compatibility Category B, the Agreement States should have equivalent requirements. Any new exemption would also require equivalent provisions in Agreement State regulations. Thus, the change in status should result in similar cost savings per licensee.

Illustrative annual cost savings to future users for the following assumptions:

- 50,000 devices used by 5000 users;
- 10,000 transfers (those currently reportable under § 31.5)/year;
- 10% of devices require semiannual leak testing
- 10% of devices require semiannual operational testing

5,000 leak test kits	x \$40	=	\$200,000
5,000 devices tested/year	x \$8.60	=	\$43,000
5,000 devices tested for operation/year	x \$8.60	=	\$43,000
10,000 transfer reports/year	x \$26	=	\$260,000
5,000 responsible individuals	x \$172	=	<u>\$860,000</u>
Total			~\$1,400,000

This does not include the unquantified savings in disposal costs, which may be quite significant.

The proposed rule is likely to change user prices slightly. Currently, some manufacturers and distributors of generally licensed devices offer to take back the devices for replacement of the decayed source or disposal. This disposal service is sometimes reflected in the initial sale price. If such devices become exempt from regulation, this disposal service would no longer be required. As such, there may be a slight decrease in the price of the device. A major portion of the cost of the device is for materials (radioactive source and other). Another large contributor to the cost of the device is from insurance and bonding. These portions of the cost would remain, whether the device is generally licensed or exempt. Therefore, there may only be a slight decrease in the cost of the devices.

Benefits to Licensees/Distributors

Distributors are likely to have slightly reduced reporting and recordkeeping costs. Currently, licensees are required to submit quarterly transfer reports under § 32.52, both to NRC and to any Agreement States into which they are transferring devices. Manufacturers and distributors of these products would be required to submit reports of transfer to the NRC annually (proposed § 32.32(c)). Additionally, records of the transfers for exempt products are required to be maintained for 1 year versus 3 years for generally licensed devices (under § 31.5). Reporting requirements for the new class exemption would be less than for generally licensed devices.

A significant reporting and recordkeeping cost for distributors is labeling. This would also be a requirement for the proposed class exemption. Therefore, there would not be a savings associated with this aspect of the recordkeeping. Although there are a number of distributor requirements that would change relative to reporting and recordkeeping, as noted above, the annual costs after the initial changes are made when revising the license would be very similar to current costs.

The most significant benefit to manufacturers and distributors would be increased sales. The extent that the changed status of the product affects future sales will vary depending on the type of device and the circumstances of its use. This benefit cannot be quantified in any realistic manner.

Benefits to NRC/Benefits to Agreement States

The NRC and the Agreement States would benefit from the proposed provision by a reduction in paperwork (reviewing reports, tracking devices, etc.) associated with generally licensed devices. If this change resulted in 10,000 fewer devices sold per year for use under § 31.5 and equivalent Agreement State provisions, a total time saved by NRC and Agreement State staff would be approximately 500 hours annually dealing with reports associated with potentially impacted generally licensed devices. NRC has approximately 20 percent of general licensees. Therefore, the regulatory agencies would save approximately the following annual amount:

$$100 \text{ hours/year} \times \$93/\text{staff hour} = \$9,300/\text{year}$$

$$400 \text{ hours/year} \times \$45/\text{hour} = \$18,000/\text{year}$$

Benefits to Public

It is likely that persons previously not obtaining and using the subject devices under general license would now purchase some of the devices for use. Examples of such persons would be garage/car repair shop owners, photo finishing establishments, laboratories and analytical services, and others. Costs associated with general licenses to possess and use the devices might have been an issue that prevented such persons from owning a device. The use of these products by these types of businesses should lead to benefits to society as a whole.

~~4.4 Revise the Safety Criteria for the Existing Class Exemptions~~

~~The safety criteria for the current class exemptions are based on outdated dose calculation methodology, are limited to addressing the dose from a single unit in the case of disposal, and, in the case of the criteria for gas and aerosol detectors, §§ 32.26, 32.27, and 32.28 do not adequately control the maximum quantities of byproduct material that could be approved for use under the exemption in § 30.20 (and equivalent Agreement State provisions).~~

~~The following revisions to the safety criteria are proposed:~~

~~Revise § 32.23 by removing organ dose limits and terminology derived from the International Commission on Radiation Protection (ICRP) 2 dose limitation methodology, combining criteria in columns I and II of the existing table in § 32.24, changing the negligible~~

~~probability accident criterion, and requiring consideration of the likely number of units present for all scenarios.~~

~~Remove § 32.24, as a table is not needed for the simplified approach to § 32.23.~~

~~Revise § 32.26 to add a specific quantity limit related to radionuclides of concern.~~

~~Revise § 32.27 by removing organ dose limits (except for skin from misuse) and terminology derived from ICRP-2 dose limitation methodology; changing the negligible probability accident criterion; adding a misuse criterion with a specified scenario, and requiring consideration of the likely number of units present for all scenarios.~~

~~Remove § 32.28, as a table is not needed for the simplified approach to § 32.27.~~

Cost Impacts:

~~These changes would affect future distribution and not require reevaluation of any devices currently approved for distribution. Thus, they would have no direct cost on any current licensees. They may limit future development of such products, with associated impacts on distributor and user industries.~~

~~Both the NRC and Agreement States will incur costs associated with a rulemaking. These are discussed in Sections 4.11 and 4.12.~~

Benefits:

~~These changes would simplify the criteria by eliminating most separate organ dose limits, and provide more flexibility for applying the latest dose calculation methodology based on ICRP recommendations. These changes should improve the efficiency and effectiveness of future NRC licensing actions under these provisions, although no specific cost savings can be quantified.~~

~~Some factors in the revisions would tend to be somewhat less restrictive, others, more restrictive. Overall, for the common scenarios of exposure, risk levels would be essentially unchanged. However, the addition of a specific quantity limit in § 32.26 for radionuclides of concern and the specific misuse scenario would improve assurance that gas and aerosol detectors approved in the future do not contain more than an appropriate quantity of byproduct material for use under exemption from licensing. The benefits of controlling quantities are: (1) assuring that exempt products do not present a practical source of radioactive material for malicious use; (2) minimizing risks associated with devices becoming subject to scrap metal recycling, such as property damage due to contamination resulting from smelting, (3) further controlling overall impacts to waste disposal workers, (4) minimizing overall impacts to the environment from uncontrolled disposal of products used under exemptions from licensing, and (5) minimizing the potential problems of products exempted by NRC being detected at and sometimes rejected for disposal in landfills and municipal incinerators by State and local restrictions.~~

4.54.4 Revise § 30.20 Wording to be Less Restrictive on Purpose of Detectors

The exemption in § 30.20 provides for persons without a license to receive, possess, use, transfer, own, or acquire byproduct material, in gas and aerosol detectors *designed to protect life or property from fires and airborne hazards*, provided that the detectors are manufactured,

processed, produced, or initially transferred in accordance with a specific license. Products similar to those allowed under this exemption, but not quite fitting the “class,” cannot be approved under this exemption. One example is drug detectors which were rejected for distribution under this exemption because they were not “designed to protect life or property from fires and airborne hazards.”

The proposed rule would replace the wording in § 30.20, “designed to protect life or property from fires and airborne hazards,” with less restrictive wording to allow other potential applications under an existing framework, which has safety criteria that adequately protect public health and safety.

Cost Impacts:

Currently, devices such as drug detectors are generally licensed for use per the requirements of § 31.5 (and equivalent Agreement State provisions). A change to § 30.20 would allow such devices to be used by persons exempt from licensing requirements. Some manufacturers and distributors of generally licensed devices may apply to have their current products approved for use under the expanded exemption. In the future, there may also be some expansion of markets for these types of products as a result of the elimination of regulatory requirements on the users, particularly given the uncertainty in future costs of radioactive waste disposal. The licensing provisions in §§ 32.26, 32.27, 32.28, and 32.29 apply to distributors nationally, as licensing the distribution of products used under an exemption from license is reserved to the NRC. Distributors of products used under a general license may be licensed by the Agreement States. As some States have not taken over the review of sealed source and devices for registration, some of the Agreement State licensees distributing generally licensed devices for use under § 31.5 may already have obtained an SS & D certificate from NRC. Products would be evaluated for use under the exemption and a new certificate would be issued. The affect on fees would depend on whether an NRC SS & D certificate is replaced or only a new one is obtained, as there is a significant annual fee for each certificate. The average time for preparation and review of an SS & D certificate has been previously estimated (OMB Supporting Statement for 10 CFR Part 32) at 21 hours for the applicant and 21 hours for NRC. These times vary depending on the nature of the action, whether the certificate is for a sealed source or a device, and whether a dose assessment is required. The products involved here are devices with relatively low risk but a complex set of exposure scenarios to evaluate; a somewhat above average estimate of 24 hours per submittal by the applicant is used. The estimate for preparing the license application in this case is also higher than the average estimated in the OMB supporting Statement for NRC Form 313.

Costs to Licensees/Distributors

There are no projected costs to licensees from the rule. The rule does not impose any new requirements on existing licensees.

For those specifically licensed distributors who choose to apply for a license under § 32.26 as a result of this change, the following costs would be expended:

Illustrative estimate of application costs for these assumptions:

- 3 Agreement State licensees
- 1 current NRC licensee

NRC E-Distribution License Required:

4 applications x 8 hours/application x \$43/hour = ~\$1,400

Device Evaluation Required:

4 registrations x 24 hours/device x \$43/hour = ~\$4,100

Total/year: ~\$5,500

Fees associated with these licenses and registration certificates could present more significant costs than those estimated.

Costs to NRC:

4 applications x 8 hours/application x \$93/staff hour = ~\$3,000

4 evaluations x 21 hours/evaluation x \$93/staff hour = ~\$7,800

Total/year: ~\$11,000

There are no costs to Agreement States other than the rulemaking. Both the NRC and Agreement States will incur costs associated with a rulemaking. These are discussed in Sections 4.119 and 4.1210.

Costs to Public

There are some limited potential costs to the public from this aspect of the proposed rule due to contaminated scrap; however, due to the uncertainty in the probability and extent of such incidents, an actual cost is not estimated.

Occupational Health/Public Health

As this would likely increase the market in affected devices, some increases in the number of persons exposed are expected. The safety criteria associated with this exemption would limit routine exposures to no more than 5 mrem (50 μ Sv)/year and also control ~~disposal and~~ accident risks. Actual exposures are typically lower than those in the safety criteria. The proposed revised scope of purposes for the detectors is “designed to protect health, safety, or property.” This ensures that any product approved for use under the expanded scope of the exemption would be expected to provide a significant benefit to society, thus ensuring a reasonable cost/benefit for the individual product.

Environmental Considerations

This provision would increase the number of devices allowed to be disposed as ordinary trash. ~~However, the safety criteria would also be improved to ensure that future~~ Estimated doses from disposal ~~are unlikely to exceed 5 mrem (50 μ Sv)/year from as many items of one product likely to be disposed at one landfill~~ landfills or municipal ~~incinerator~~ incinerators for detectors previously distributed for use under this exemption have been low. The types of additional detectors anticipated are likely to be used in smaller numbers than the initial products used under this

exemption, i.e., smoke detectors. This should ~~minimize~~limit increases in environmental effects of increased numbers of detectors being disposed.

Benefits:

Benefits to Licensees/Users

There would be no direct effect on current general or specific licensees. However, future users of devices approved for use under the exemption would benefit from not having the requirements of the general license, or in some cases, a specific license. Some current general licensees would be expected to return generally licensed devices to the vendor and obtain devices covered under the exemption, when they become available.

As discussed in Section 4.3, there are a number of costs incurred by general licensees, which would not be incurred by future users under an exemption from licensing. The following discusses typical costs for general licensees, which would no longer be incurred by users under the exemption. Costs per device, per general licensee, and per report are the same as assumed under Section 4.3.

Currently, generally licensed devices are disposed of as low-level radioactive waste, although some with shorter-lived materials may be allowed to decay instead (after return to the distributor). The proposed rule would allow certain devices to become exempt from licensing, and therefore, disposal of such devices would be as ordinary trash. Users would benefit by no longer having to pay for disposal (usually indirectly as they usually transfer devices back to vendors or may also transfer to waste brokers). The affected devices would not need disposal for some time in the future, after distributors have applied for and obtained exempt status for their devices and sold devices for use under the exemption, and after those devices have subsequently been used for their useful life, which in some cases is more than 10 years. Currently, disposal options for low level radioactive material are limited. As of June 30, 2008, the Barnwell site can only accept waste from organizations located in South Carolina, Connecticut, and New Jersey, the three states that make up the Atlantic Interstate Low-Level Radioactive Waste Management Compact. The costs of low level waste disposal several and more years in the future is highly uncertain; thus no quantification of this benefit has been conducted, but may be substantial. Also, the uncertainty in the cost of future disposal in itself affects the market for such devices; thus, eliminating the requirement for controlled disposal may allow for more people to enjoy the benefits of the products.

Under the proposed solution, users exempt from regulation would no longer have to leak test the sources. It is assumed that a leak test, if required, is performed every six months. Six-month testing intervals are the default unless the manufacturer requests otherwise. Typically, the licensee swipes the device, then sends the swipe to be analyzed. Analysis services typical price is \$35 to \$40 per kit depending on the number of kits.

$$\frac{2 \text{ tests/kit}}{2 \text{ test/year}} \times \$40/\text{kit} = \$40/\text{device-year}$$

Some devices are also checked for proper operation if used under the general license. The savings from no longer having to perform this activity is estimated to be:

$$2 \text{ tests/device-year} \times 0.1 \text{ hour/operational check} \times \$43/\text{hour} = \$8.60/\text{device-year}$$

Currently, general licensees are required to maintain records of leak tests and device operation tests performed. The records are required to be maintained for 3 years. It is assumed that it takes approximately 0.1 hour per device to file and maintain the appropriate records. The time saved from no longer having to perform this activity is estimated to be:

$$2 \text{ leak tests/device-year} \times 0.1 \text{ hour/record} \times \$43/\text{hour} = \$8.60/\text{device-year}$$

In addition, users would no longer have to file the required transfer reports with the NRC. Agreement States mostly require similar reports, as a result of compatibility requirements.

$$0.6 \text{ hour/transfer report} \times \$43/\text{hour} = \$26/\text{transfer report}$$

There are a few additional reporting requirements such as change of address (§ 31.5(c)(14)), bankruptcy (§ 30.34(h)), accidents (§ 31.5(c)(5)), and loss or theft of sources (§§ 20.2201 and 20.2202). However, since these are likely to be infrequent events (requiring reports), the impact would be small by comparison.

A current requirement in § 31.5(c)(12) is that general licensees must appoint an individual responsible for having knowledge of appropriate regulations, and that person is to assure day-to-day compliance with the regulations. This requirement would no longer apply under the proposed solution. It is recognized that this person normally performs other duties that would require his/her employ for those duties; however, it is assumed that this person spends 4 hours/year attending to the required duties. Therefore, current general licensees and other future users would save by not having to pay a person to perform these duties.

$$4 \text{ hours/year} \times \$43/\text{hour} = \$172/\text{user-year}$$

As § 31.5 is now a Compatibility Category B, the Agreement States should have equivalent requirements. Any new exemption would also require equivalent provisions in Agreement State regulations. Thus, the change in status should result in similar cost savings per user in Agreement States.

Illustrative annual cost savings to future users for the following assumptions:

- 5,000 devices used by 1,000 users;
- 500 transfers/year;
- 10% of devices require semiannual leak testing
- 10% of devices require semiannual operational testing

500 leak test kits	x \$40	=	\$20,000
500 devices tested/year	x \$8.60	=	\$4,300
500 devices checked for operation/year	x \$8.60	=	\$4,300
500 transfer reports/year	x \$26	=	\$13,000
1,000 responsible individuals	x \$172	=	<u>\$172,000</u>
Total			~\$214,000

This does not include the unquantified savings in disposal costs which may be quite significant.

The proposed solution is likely to change prices to users slightly. Currently, manufacturers and distributors of generally licensed devices offer to take back the devices for replacement of the decayed source or disposal. This disposal service is sometimes reflected in the initial sale price, or sometimes recouped in the price of devices replacing the ones being returned. If such devices become exempt from regulation, this disposal service would no longer be required. As such, there may be a slight decrease in the price of the device. A major portion of the cost of the device is for materials (radioactive source and other). However, another large contributor to the cost of the device is from insurance and bonding. These portions of the cost would remain, whether the device is generally licensed or exempt. Therefore, there may only be a slight decrease in the cost of the device.

Benefits to Licensees/Distributors

Distributors are likely to have slightly reduced reporting and recordkeeping costs. Currently, NRC licensees distributing devices for use under § 31.5 are required to submit quarterly transfer reports under § 32.52, both to NRC and to any Agreement States into which they are transferring devices. In addition, they are required to provide information to customers prior to transfers of devices by § 32.51a (and equivalent Agreement state provisions). Manufacturers and distributors of exempt products, including gas and aerosol detectors (§ 30.20) are required to submit reports of transfer to the NRC annually (§ 32.29). Additionally, records of the transfers for exempt products are required to be maintained for 1 year versus 3 years for generally licensed devices (under § 31.5). Distributors may also benefit from an increase in sales. No attempt has been made to quantify this benefit.

A significant reporting and recordkeeping cost for distributors is labeling. However, similar labeling requirements apply to distributors of gas and aerosol detectors. Therefore, there would not be a savings associated with this aspect of the recordkeeping. Although there are a number of distributor requirements that would change relative to reporting and recordkeeping, as noted above, the annual costs after the initial changes are made when revising the license, and for applicants for products to be used in the future, would be similar to current costs, although somewhat reduced.

Benefits to NRC/Agreement States

The NRC and the Agreement States would benefit from the proposed solution by a reduction in paperwork (e.g., reviewing reports, tracking devices) associated with devices now required to be used under the general license. Also, a limited savings in inspection costs could result, but is unlikely to be significant. General licensees are subject to inspections, but not routinely inspected. Those using the types of devices likely to change to an exempt status are unlikely candidates for inspection.

Benefits to Public

As noted, markets for such devices might expand. Costs associated with general licenses to possess and use the devices might have been an issue that prevented some potential users from obtaining the devices. As more of these devices are apt to be used in the future as a result of the elimination of regulatory requirements on users, more benefit would accrue to the public.

from the use of the devices. The products would be required to provide some protection to health, safety, or property.

~~4.6 Revise the Safety Criteria for Devices to be Used under the General License in § 31.5~~

~~This proposal would be to amend § 32.51 to make the safety criteria simpler, allow for the use of more up-to-date dose calculation methodology, reduce the dose criterion for untrained workers, and limit the quantities of radionuclides of concern that can be obtained from § 32.51 licensees (and Agreement State equivalent licensees) in devices approved in the future.~~

~~This proposal would revise the safety criteria to change the routine dose limit to 1 mSv (100 mrem)/yr and accident criterion to 100 mSv (10 rem); add an explicit requirement to consider multiple devices; add a specific quantity limit related to radionuclides of concern; and remove references to § 32.24 and § 20.1201(a). These changes are only for approvals of new products for future distribution to § 31.5 general licensees and those under equivalent regulations of the Agreement States. However, as noted under Section 4.1.2, the Commission may on a case-by-case basis require consideration of the revised safety criteria for continued distribution of devices approved for use some time in the past during a reevaluation of the safety information in the registration certificate. There is a specific question for comment in this regard in the proposed rule.~~

~~The separate rulemaking to put a quantity limit into § 31.5 would restrict all future distribution to persons generally licensed under § 31.5.~~

Cost Impacts:

~~These changes would affect future distribution. The Commission would not require reevaluation of any devices currently approved for distribution, unless reevaluation of older device registration certificates are conducted as discussed under Section 4.1.2. Thus, it would have no immediate direct cost on any current licensees. It may, however, limit future development of these types of products, with associated impacts on distributor and user industries.~~

Benefits:

~~This proposal would provide for improved health and safety of persons who use generally licensed devices under § 31.5 and equivalent Agreement State regulations. In addition, reducing the criterion for routine use to 1 mSv (100 mrem)/year and clarifying that contributions to dose from multiple devices must be considered would reduce acceptable radiation fields around the devices, thus, tending to reduce doses to others besides the direct users.~~

~~This proposal would simplify the safety criteria, such that licensing actions under this section would be more efficient and effective.~~

~~This proposal may contribute to the development of devices with better safety features, such as better shielding or less hazardous radionuclides, as distributors attempt to achieve a generally licensed status for devices developed in the future.~~

~~If a less restrictive limit is made effective in § 31.5, the quantity limit in proposed § 32.51(a)(2)(v) would limit the quantity of radionuclides of concern approved for use in the future for use under § 31.5 (and equivalent Agreement State provisions). As proposed, it is only more restrictive than the separate limit proposed for § 31.5 for devices using more than one radionuclide, as it would apply a “rule of ratios” to the quantity limit.~~

4.74.5 Update the Regulations on Certain Static Eliminators and Ion Generating Tubes

This proposal would be to replace the general license in § 31.3 with an exemption from licensing in § 30.15(a)(2); thus, there would be clear requirements in the regulations for any applicant to distribute such products in the future (under §§ 32.14, 32.15, and 32.16). The products are consumer products and have essentially been regulated in the past as if they were exempt from regulation, in spite of there being no exemption from Parts 19, 20, and 21 stated in § 31.3.

Cost impacts:

This change is intended to have no effect on current distributors or users of these products. No costs are anticipated beyond the overall costs of the NRC rulemaking and implementation, discussed in Section 4.149, and Agreement State rulemaking discussed in Section 4.1210.

It is, however, possible that the one NRC licensee would choose to amend its license to reduce its fees, resulting in one time costs to that licensee and the NRC.

Benefits:

Removing the inconsistency in regulating these products and clarifying the regulations should contribute to public confidence and make any future licensing decisions in this regard more efficient and effective.

4.86 Revise Part 32 to Remove Prescriptive Requirements for Distributors of Certain Generally Licensed Devices and Exempt Products

The requirements for manufacturers of exempt and generally licensed products are in some cases very prescriptive, particularly in the areas of prototype testing and quality control requirements. The regulations would be made less prescriptive and continue to contain general requirements and may provide standards by which performance may be judged rather than specifying details of procedures that must be followed. Regulatory guidance would be provided on acceptable approaches to meeting the requirements. It may also be possible to allow licensees to submit assurance programs that verify product integrity in lieu of specific quality control procedures.

In the case of generally licensed products, regulations that are candidates for modification include those for prototype test procedures (§§ 32.53(d)(4), 32.57(d)(2), 32.61(e)(4), 32.101, 32.102, and 32.103). There are specified sampling or testing procedures as a means of quality control for certain exempt products and generally licensed products (§§ 32.15(a)(2) and (3) and (c)(2), 32.55(a) through (d), 32.59, 32.62(a) through (e), and 32.110).

The following revisions are proposed:

Revise § 32.15(a), (b), and (c) to remove specific procedures.

Revise § 32.53(b)(5) to remove the reference to § 32.55.

Revise § 32.53(d)(4) to remove reference to § 32.101 and add § 32.53(e) to add prototype testing requirement without details of procedures to be followed.

Revise § 32.55 to remove specified acceptance sampling procedures and revise the acceptance criterion.

Revise § 32.57(d)(2) to remove reference to § 32.102 and add § 32.57(e) to add prototype testing requirement without details of procedures to be followed.

Revise § 32.59 for clarification.

Revise § 32.61(e)(4) to remove reference to § 32.103 and add § 32.61(f) to add prototype testing requirement without details of procedures to be followed.

Revise § 32.62(c), (d), and (e) to revise and clarify quality assurance requirements and revise the acceptance criterion.

Remove § 32.101.

Remove § 32.102.

Remove § 32.103.

Remove § 32.110.

The revision or supplementation of the following guidance documents would include example acceptable approaches: NUREG-1556, Vol. 16, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees" and NUREG-1556, Vol. 8, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses Authorizing Distribution to Exempt Person."

Cost Impacts:

Cost to applicants/licensees

The only change that affects existing licensees is the revision of the acceptance criterion from 10% risk of more than 5% defectives to 5% risk, expressed as 95 percent confidence. Current licensees are likely achieving this as a result of other factors. There are no current NRC licensees under §§ 32.53, 32.57, or 32.61. A very small number are expected to be in the Agreement States under any of these provisions. The NRC has 46 licensees under § 32.14; some of these would no longer have NRC oversight of their quality assurance/quality control requirements as a result of changes discussed in Section 4.97.2. There are no Agreement State licensees equivalent to § 32.14, as NRC retains authority over exempt distribution licensing.

It is not expected that the revisions would significantly affect the cost to the applicants, although there might be a small increase as a result of having to address more specifics of the procedures to be followed.

Cost to NRC

Some additional effort would be involved in updating the two relevant guidance documents. Some additional time may be required of NRC license reviewers for a very small number of license applications.

Cost to Agreement States

Some additional time may be required of Agreement State license reviewers for a very small number of license applications.

Benefits:

Less prescriptive, more flexible regulations would be more performance-based. Applicants would be free to propose alternative methods to those presented in guidance to satisfy the requirements in the regulations. The requirements would continue to provide adequate assurance that the products being distributed meet performance standards. The performance standard would be somewhat revised to reduce the risk of defective products being distributed. Any new industry standards would more easily be accommodated.

The Code of Federal Regulations would be reduced by several pages.

4.97 Make the Requirements for Distributors of Exempt Products More Risk-informed

The level of control over the distribution of the various exempt products and materials is not commensurate with the associated risk, particularly in the areas of prototype testing and quality assurance/quality control. Some existing requirements may be unnecessary given the risk associated with the particular product. The products for which requirements would be removed have been evaluated as to their inherent risk and how much this risk could change if adequate prototype testing is not performed or an appropriate level of quality assurance/quality control is not used by the manufacturer.

4.97.1 Revise § 32.14 to Make the Requirements for Prototype Tests for Distribution of Exempt Products More Risk-Informed

Some existing requirements may be unnecessary given the risk associated with the particular product. In this rule, the NRC proposes to revise Part 32 requirements for prototype tests for exempt products to be more risk-informed by eliminating some of the individual requirements. These requirements are in § 32.14(b)(4) and relate to the product-specific exemptions under § 30.15 (and equivalent regulations of the Agreement States).

This proposal would revise § 32.14(b)(4) to make exceptions to prototype testing requirements.

Cost Impacts:

No costs are anticipated for applicants/licensees. There would be no costs to NRC beyond rulemaking and implementation costs discussed in Section 4.44-9. There would be no costs to Agreement States, as these are NRC only provisions.

Minimal additional incremental increases in doses to the public could result, if a larger number of products experience failure. Minimal potential for increases in doses to a fraction of users could result, usually no more than a fraction of 10 μSv (1 mrem ~~(10 μSv)~~/year. Overall, an insignificant risk to the public would result even if removal of oversight results in lower quality designs.

Benefits:

Unnecessary regulatory burden during the application process on distributors of certain types of exempt products containing byproduct material would be reduced.

It is estimated that 3 hours would be saved per future applicant. A similar amount would be saved by NRC per application. Typically, it is estimated that eight applicants per year would be affected.

Using those assumptions, \$43/hour for applicants, and \$93/staff hour for NRC, savings to applicants would be approximately \$1,000/year and for NRC, approximately \$2,200.

The applicants would also have more flexibility in determining the approach to any prototype testing.

4.97.2 Revise § 32.14 to Make the Requirements for Quality Control for Distribution of Certain Exempt Products More Risk-Informed

Existing requirements for distributors of byproduct material to exempt persons include: specified sampling procedures (§§ 32.15(a)(2) and (3), and 32.110) and submittal of quality control procedures (§ 32.14(b)(5)). These are requirements related to the product-specific exemptions under § 30.15 (and equivalent regulations of the Agreement States).

This proposal would eliminate individual requirements if not justified, based on risk as follows: Revise § 32.14 (b)(5) to make exceptions to requirements to submit quality control procedures for review.

Revise § 32.15, to qualify the **condition of license for maintaining** quality assurance **requirementspractices** so as to limit ~~them~~ to ~~these~~**products for which such** procedures **established in the license are required**. This accommodates the exceptions made in § 32.14(b)(5).

Cost Impacts:

No costs to applicants/licensees are anticipated. There would be no costs to NRC beyond rulemaking and implementation costs discussed in Section 4.44-9. **However, some current licensees may choose to amend their licenses to remove conditions in the license, which would no longer be required, resulting in small administrative costs to those licensees and to NRC.** There would be no costs to Agreement States as these are NRC only provisions.

Minimal potential for increases in doses to a fraction of users could result, usually no more than a fraction of **10 μ Sv** (1 mrem ~~(10 μ Sv)~~)/year, as well as potential for increases in the probability of failures sometimes resulting in somewhat higher exposures. Overall, an insignificant risk to the public would result even in the unlikely event that removal of oversight results in poor quality control activities.

Benefits:

Unnecessary regulatory burden on distributors of certain products containing byproduct material would be reduced.

It is estimated that 3 hours would be saved per future applicant. A similar amount would be saved by NRC per application. Typically, it is estimated that eight applicants per year would be affected.

Using those assumptions, \$43/hour for applicants, and \$93/staff hour for NRC, savings to applicants would be approximately \$1,000/year and for NRC, approximately \$2,200.

There are currently 46 licensees under § 32.14, many of whom would be free to make adjustments in their quality assurance/ quality control procedures ~~without amending their license.~~ (Any amendments to license would be limited to removing conditions of the license to conduct QC as previously committed to.) No attempt has been made to quantify this benefit. However, as this is an ongoing effect, the overall benefit for this change would be greater than that concerning prototype tests discussed in Section 4.97.1.

NRC inspection costs would be slightly reduced or time would be allotted to more risk-significant activities.

4.108 Minor Clarifying or Administrative Revisions

Other minor revisions are proposed to better organize, clarify, or update the regulations in these parts, such as the renaming of Subparts C and D and the movement of §§ 32.72 and 32.74 from Subpart B to Subpart C. These two sections would be moved because they do not cover generally licensed items. Minor conforming amendments are included in Parts 40 and 70 because the delineation of the delegation of licensing programs to the Regions is written broadly in these parts.

Cost Impacts:

No costs are anticipated beyond the costs of inclusion in the rulemaking. Overall costs for NRC and Agreement State implementation are discussed in Sections 4.119 and 4.12-10. Such changes constitute a small portion of the implementation costs.

Benefits:

Improvements of this type in the regulations contribute to efficiency and effectiveness and to public confidence.

4.149 Development and Implementation Costs

NRC development costs are the costs of preparation of a regulation before its promulgation and implementation. Such costs may include expenditures for research in support of this regulatory action, publishing notices of rulemaking, holding public meetings, responding to public comments, and issuing a final rule. NRC implementation costs are those “front-end” costs necessary to effectuate the action; they may arise from the necessity of developing procedures and guidance to assist licensees in complying with the final action. All costs associated with pre-decisional activities are viewed as “sunk” costs and are excluded from NRC implementation costs.

Developmental and implementation costs within the scope of this analysis are the costs of proceeding with a rulemaking, as well as efforts on guidance development associated with this rule. These are mainly costs of the effort of NRC professional staff members in the Office of Federal and State Materials and Environmental Management Programs expended in developing the rule.

Approximately 1 FTE is estimated for the analysis of comments and development of the final rule. One NRC professional staff member costs \$165,200/FTE

NRC staff would need to update existing guidance in the NUREG-1556 series related to distribution licensing to reflect the revisions to the regulations. NUREG-1556, Vol. 3, Rev. 1, “Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration;” NUREG-1556, Vol. 8, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses;” and NUREG-1556, Vol. 16, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licenses” would require minor revisions or supplementation. If the changes for this rule are made within overall revisions of these NUREGs, the additional updating needs should be a relatively limited cost impact as a result of this proposed rulemaking.

4.1210 Costs to Agreement States of Compatible Regulations

Costs would be incurred by the Agreement States for development and implementation of compatible regulations. The costs would vary significantly by State because of differences in internal procedures for developing regulations. Some rule changes would be required to meet Compatibility Category ~~A or~~ B for certain revisions. As these need to be essentially word-for-word compatible, the process should be relatively simple. One provision, § 30.32(g), is a Compatibility Category C; this may also result in some revision of the Agreement State regulations. For this proposed rule, the NRC assumes an average of 0.1 FTE at \$80,000/FTE for each state. There are currently 3537 Agreement States; therefore, the total cost for all Agreement States would be approximately \$280300,000.

5. DECISION RATIONALE

The assessment of costs and benefits discussed above, quantitatively when possible and qualitatively otherwise, leads the Commission to the conclusion that the overall impacts of the

proposed rulemaking would be ~~assurance of the protection of public health and safety in the future,~~ more effective and efficient licensing of distribution to exempt persons and to generally licensed persons, and a reduction in undue burden to certain distributor licensees, ~~and some other specific licensees, without a reduction in the protection of public health and safety in the future.~~ Currently, some of the regulations are unclear or contain unnecessary burden relative to the very small risk associated with a product. Although there are apparent costs associated with some of the amendments, the Commission believes that these costs will be outweighed by those non-quantifiable costs associated with regulatory efficiency ~~and protection of the health and safety of the public.~~ This rule would advance ~~to varying degrees the Commission's goals concerning safety, efficiency, timeliness, security,~~ the Commission's objectives of effectiveness and openness.

The largest single cost would be implementation of the proposed rulemaking by the NRC and the Agreement States. However, by handling several issues together, the Commission minimizes its costs as well as costs for the Agreement States.

6. IMPLEMENTATION

The NRC's schedule for implementation of this rulemaking calls for the effective date of the rule to be in 201~~0~~¹ for the NRC's jurisdiction and full implementation by the Agreement States by 201~~3~~⁴. The applicable guidance documents are NUREG-1556, Vol. 3, Rev. 1, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration;" NUREG-1556, Vol. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses;" and NUREG-1556, Vol. 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licenses." These all have additional updating needs and should be revised as part of a broader update following the issuance of the rule. There are no changes requiring entirely new guidance; i.e., nothing that would necessitate having guidance available in draft for comment along with the proposed rule. Details of procedures being removed from the regulations would be added to the applicable guidance when revised as examples of acceptable approaches; however, these details are currently in the regulations. Some revisions to these three documents are needed as a result of this rule for consistency with revisions to the exemptions and requirements for the various categories of distributors.

For all changes that affect Compatibility Category B or Compatibility Category C requirements, Agreement States have 3 years to make changes to their affected regulations.

This regulatory action is not expected to present any significant implementation problems. Affected licensees will be sent a copy of the final *Federal Register* Notice.

7. IMPLICATIONS FOR OTHER FEDERAL AGENCIES

Promulgation of this proposed rule would have no adverse effects on other Federal agencies.

8. EFFECT ON SMALL ENTITIES

The proposed rule would not significantly impact small or large entities.

References

Department of Labor (U.S.), Bureau of Labor Statistics, Employer Costs for Employee Compensation. Management, professional, and related occupations, State and local government wages. Series IDs CMU3020000100000D and CMU3020000100000P, 4th Quarter 2007. <www.bls.gov>.

Department of Labor (U.S.), Bureau of Labor Statistics, May 2004 National Occupational Employment and Wage Estimates. Standard Occupational Classification (SOC) System Code Number 17-2111 "Health and Safety Engineers, Except Mining Safety Engineers and Inspectors." <www.bls.gov>.