
**Regulatory Analysis for Final 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**



**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 Title 10 of the *Code of Federal Regulations* (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 amending 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 redefining categories of devices to be used under exemption. This action is primarily intended to make licensing processes more efficient and effective. It will affect 1) manufacturers and distributors of sealed sources and devices containing byproduct material and 2) future users of some products currently used under general and specific license.

2. EXISTING REGULATORY FRAMEWORK

Part 30 of 10 CFR 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 of 10 CFR 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 of 10 CFR sets out requirements for the manufacture or initial transfer (distribution) of items containing byproduct material to 1) persons exempt from licensing requirements and 2) 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 making rule changes would be to take no action. The no-action alternative would have allowed current practices to continue. If NRC does not take action, there would be no change in costs or benefits to the public, licensees or NRC. The no-action alternative would not address identified concerns.

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

This alternative will 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 the environment and adequate protection in the secure use and management of radioactive materials. The regulatory amendments will 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 will 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, 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 5.1 through 5.8 describe each of the 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 5.9 estimates the costs to NRC and Section 5.10 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 1.5 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 requirement. Currently, this hourly labor rate for FSME is \$114.

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 of \$33.17 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 1.5 described earlier to obtain an hourly labor rate of \$50 and an annual labor rate of \$89,000.

The estimation of costs for rulemaking is based on professional staff full-time equivalent (FTE). Based on actual data from NRC's time and labor system, the number of hours in 1 year that directly relate to implementation of assigned duties is 1,451; this excludes hours on such things as leave, training, and completing administrative tasks. Therefore, an NRC professional staff FTE hour rate is based on 1,451 hours. As described in the Office of Management and Budget (OMB) Circular A-76, "Performance of Commercial Activities," the number of productive hours in 1 year is 1,776. As this actual value is likely to vary from State to State and no specific data are available, the FTE costs for the Agreement States are based on the number of hours estimated in OMB Circular A-76. Costs are determined by multiplying the number of FTEs by 1,451 hours or 1,776 hours times the hourly labor rate, for NRC or Agreement States, as appropriate.

For all licensee labor rates, \$55/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";² 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,

¹ Department of Labor (U.S.), Bureau of Labor Statistics, Employer Costs for Employee Compensation, September 2010, Table 3 - Employer costs per hour worked for employee compensation and costs as a percent of total compensation: State and local government workers, by major occupational and industry group, September 2010.

² Department of Labor (U.S.), Bureau of Labor Statistics. Occupational Employment Statistics, Occupational Employment and Wages, May 2009 17-2111 Health and Safety Engineers, Except Mining Safety Engineers and Inspectors. Mean hourly wage is $\$36.45 \times 1.5 = \$55/\text{hour}$.

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

- Industry Implementation and Operation –The final rule will 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 will 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 will incur costs to develop a rule and to revise existing guidance. The final rule will 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 will need to amend their regulations to maintain compatibility with NRC requirements; impacts to the Agreement State regulatory programs will be minimal.
- Environmental Considerations – The final rule will 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 final rule 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 final rule will improve regulatory efficiency by removing prescriptive provisions and some unnecessary provisions, and clarifying some of the regulations. Also, adding a new class exemption and broadening another will eliminate the application of unnecessary regulatory requirements to low risk devices.
- Improvements in Knowledge – For certain issues, the final rule may improve the general knowledge of potential licensees/applicants.
- Other Considerations – The final 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 5.1 through 5.8 as they pertain to the individual issues.

The final rule is *not* 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, quantification 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.

5. DESCRIPTION, DISCUSSION, AND ANALYSIS OF VALUES AND IMPACTS OF THE AMENDMENTS

5.1 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 as follows: “*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.

5.1.1 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 review and resultant registration. However, as a matter of licensing practice, applicants/licensees obtain sealed source and device (SS & D) 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 will 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 will also 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 will 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 will be required are being evaluated and registered. The final rule will 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 final rule. The effect of the addition of a new class exemption in § 30.22 and the requirement for registration for those products (§ 32.30(c)(3)) is covered in Section 5.3.

Costs for NRC implementation for the overall rule are discussed in Section 5.9.

The relevant portions of § 32.210 will 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 will require a comparable change in some Agreement State regulations; however, each State will conduct one rulemaking following the planned revision of Parts 30, 31, 32, 40, and 70. The cost for the rulemaking is discussed in Section 5.10.

Benefits:

Not only will the regulations be more explicit and understandable, but there will 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.

5.1.2 Revise Regulations to Explicitly Allow for Amendment, Modification and Revocation, Review, and Inactivation of SS & D Registration Certificates

Other provisions will be amended so as to explicitly apply to registration certificates in addition to licenses. The final rule will 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 will be added. Inactivation means that no further distribution is authorized, but information about previously distributed products is maintained in the database. Distributors will be required to request inactivation of certificates for sources and devices that they no longer intend to distribute. The usual time limit for submitting the request will be 2 years after the last initial transfer. However, the final rule recognizes that the decision to cease distribution may occur after 2 years have passed since the last transfer and allows 90 days after the determination that no more transfers will be made to request inactivation of the certificate.

In addition, a provision for explicitly addressing review and reissuance of certificates is being added (§ 32.210(h)). The new provision in § 32.210(h) may be used to 1) update the certificate with respect to applicable industry or NRC standards or current security concerns or 2) 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 is an activity 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 when the certificate holder requests amendments to 1) accommodate desired changes in a product or associated procedures or 2) 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 in order 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. For example, such circumstances might involve: 1) the actual design of a source or device, 2) quality assurance programs, or 3) information to be 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 1) reviewing certificates (in part or in whole) at the time of license renewal; 2) adding separate expiration dates to certificates with typically longer terms than licenses, e.g., 10 to 20 years; and 3) 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 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 both provide the certificate holder and the NRC with the advantage of an anticipated timeframe for reconsideration of devices/sources and the associated documentation. Either of these approaches would likely contribute to accountability on the part of manufacturers/distributors and to the application of ALARA to product designs. However, 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 chosen 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 revisions will 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 normally within 2 years after ceasing distribution of covered sources or devices. For most of these actions, including the requirement to request inactivation, the final rule will 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 will vary from year to year, is expected to be small, and for purposes of illustration is assumed to average four reviews per year, mostly dealing with certificates for devices. There are now approximately 225 active NRC certificates, of which about 132 are for devices. Many of these now cover a number of models.

The average effort involved in a review of an existing certificate will be less than that for a new certificate. The number of hours involved in any particular case will 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 will 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 will be:

$$4 \text{ reviews/year} \times 12 \text{ hr/review} \times \$55/\text{hour} = \sim\$2,600$$

Other potential costs are more difficult to quantify. However, consideration of licensee costs will 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 uncertain and assumed for illustrative purposes to average approximately four; however, as these will selectively involve mostly certificates for devices (for which the review is more complex), the average number of hours per action will 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 will be approximately:

$$4 \text{ reviews and reissuances} \times 24 \text{ hours/reissuance} \times \$114/\text{staff hour} = \sim\$11,000.$$

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 5.9.

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, to at least 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 will be encouraged. Paragraph (h) of § 32.210 will be Compatibility Category C, meaning that the essential objectives should be adopted by those States that conduct evaluations of sealed sources and devices. 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 will result for Agreement States that issue registration certificates if they increase efforts to review and reissue, or

inactivate certificates. Of the final amendments related to this issue, only § 32.210 (with the exception of new paragraph (h)) 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 will require a comparable change in some Agreement State regulations; however, each State will conduct one rulemaking following the planned revision of Parts 30, 31, 32, 40, and 70. The cost for the rulemaking is discussed in Section 5.10.

Benefits:

These explicit provisions concerning review and inactivation of registration certificates and the addition of registration certificates to the provisions for amendment and revocation will provide a clearer basis for these Commission actions. Thus the provisions will contribute 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 will 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 will provide an orderly approach to ensuring that the industry adjusts to a changing environment and/or standards. It will 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 some devices that had been approved for use under the general license in § 31.5 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. The process of reviewing certificates could make distributors more accountable. It will 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 will continue while the review process was ongoing.

Other possible improvements may result from review and updating of registration certificates. These could include: 1) 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 2) 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.

5.2 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: 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 final rule includes the following provisions:

§ 30.32(g)(2) - will extend the provision for providing alternative information on NARM legacy sealed sources and devices (previously in § 30.32(g)(3)) to all legacy sealed sources and devices containing byproduct material.

§ 30.32(g)(3) – will add a provision for limited information for certain smaller unregistered calibration and reference sources.

§ 30.32(g)(4) – will 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, when doing so is not feasible.

The change reflected in § 30.32(g)(2) 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 a new § 30.32(g)(3) will 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 for the exclusion are somewhat different than those in the current guidance.) Although some review of the proposed design and manufacturing methods will 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)(4) will also provide some flexibility to applicants and license reviewers in the licensing of the use of sealed sources and devices. It will 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 will incur costs associated with the rulemaking. These are discussed in Sections 5.9 and 5.10.

These changes are not expected to increase occupational doses. Paragraph 30.32(g)(2) has the same standard for approval using alternative information to support the approval. With respect to § 30.32(g)(3), calibration and reference sources meeting the criteria of exclusion from registration (in § 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)(4), adequate constraints will 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 will 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 will eliminate the need in some cases of issuing exemptions from § 30.32(g).

For licensees/applicants, it is estimated that an average of 10 hours will 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 will be saved as a result of not needing an exemption from § 30.32(g). In the Regulatory Analysis for the proposed rule, it was also estimated that an additional 10 hours per such licensing action would be saved as a result of no longer having to prepare environmental assessments for the actions. However, most, if not all, of these exemptions that would no longer be required would have fallen under a recently added categorical exclusion in § 51.22(c)(25); thus, this additional benefit is no longer applicable.

In the case of small unregistered calibration and reference sources licensed for use under § 30.32(g)(3), it is estimated that an average of 5 hours will be saved by the applicant and a similar amount for NRC.

For situations where the new § 30.32(g)(4) 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 will 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.

5.3 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, will 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 will 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 will be:

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

§ 32.31 will be created to establish new safety criteria.

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

Under these provisions, some manufacturers and distributors of generally licensed devices will 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 will 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 will seek to change the status of their devices so that their future customers will be exempt from licensing. It is estimated that approximately 10 existing licensees will apply in the 2 to 3 years following the rule change, and an additional three new applicants for exempt distribution licenses per year will result. However, there is uncertainty in these numbers, as they are projections of future voluntary actions. The requirements will 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 will be less of a factor for small entities. The lack of complete consistency in the general license provisions among the Agreement States would tend to make a conversion to use under exemption more desirable.

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 will 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 will be evaluated for use under the exemption and a new certificate will be issued. The affect on fees will 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 will be a voluntary expenditure in order to obtain an overall benefit. This one-time expenditure combined with Benefits to Existing Licensees/Distributors will 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 \$55/hour = ~\$ 4,400

Device Evaluation Required:

20 registrations x 24 hours/device x \$55/hour = ~\$26,000

Total: ~\$30,000

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 \$114/staff hour = ~\$ 9,100

20 evaluations x 21 hours/evaluation x \$114/staff hour = ~\$48,000

Total: ~\$57,000

Costs to Agreement States:

Agreement State licensing and inspection programs will only be impacted to the extent that a few of their general license distributors might possibly change completely over to exempt distribution, which will be covered by an NRC license. Even in this case, their possession and use will 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 5.9 and 5.10.

Costs to public:

There are limited potential costs to the public from this aspect of the final rule due to devices being smelted and contaminating metals. The technology of detecting radioactive sources in the metals recycling industry has improved and includes multiple points of detection during the process. While the small quantities that may be approved for use under the exemption may be less likely to be detected, the potential for significant resulting contamination is also limited. Due to the uncertainty in the probability and extent of such incidents, an actual cost is not estimated.

Occupational Health/Public Health:

As this will likely increase the market in affected devices and will ultimately lead to the development of additional devices, potential increases in the number of persons exposed will result. The safety criteria associated with this exemption will limit routine exposures to no more than 200 μ Sv (20 mrem)/year (in a work environment) and also control disposal and accident risks. Actual exposures are typically expected to be lower than those in the safety criteria.

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

The safety criteria will ensure that future doses from disposal are unlikely to exceed 10 μSv (1 mrem)/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 will be no direct effect on current licensees general or specific. However, future users of devices approved for use under the exemption will benefit from not having the requirements of the general license or, in some cases, a specific license. Some current general licensees will 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 will 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 rule will allow certain industrial devices to become exempt from licensing; therefore, such devices will be disposed of as ordinary trash. Users will 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 will 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 Richland, Washington facility can only accept low-level radioactive waste from Rocky Mountain Low-Level Radioactive Waste Compact and Northwest Interstate Compact States, of which there are 11. Although a facility has not yet been opened, the Texas Low-Level Radioactive Waste Disposal Compact will accept waste from Texas and Vermont. Therefore, a majority of the States either use a waste broker for disposal,

or send their wastes to the facility in Clive, Utah, operated by Energy Solutions. However, the Clive, Utah facility cannot accept sealed sources.

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 it 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 chosen solution, future users (including some current general licensees) will 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 6 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 \$20 - \$40 per kit, depending on the number of kits. The savings from not performing leak tests are estimated to be:

$$2 \text{ leak tests/device-year} \times (\$40/\text{kit}) = \$80/\text{device-year}$$

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:

$$2 \text{ tests/device-year} \times 0.1 \text{ hour/test/operational check} \times \$55/\text{hour} = \$11/\text{device-year}$$

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:

$$2 \text{ leak tests/device-year} \times 0.1 \text{ hour/record} \times \$55/\text{hour} = \$11/\text{device-year}$$

In addition, users (currently generally licensed) will 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:

$$0.6 \text{ hour/transfer report} \times \$55/\text{hour} = \$33/\text{transfer report}$$

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

$$4 \text{ hours/year} \times \$55/\text{hour} = \$220/\text{user-year}$$

The general license in § 31.5 was Compatibility Category B for about 10 years, but the Commission recently decided to change it to Compatibility Category C. In some States, some of these devices would have required a specific license, but for those devices covered by the general license, the applicable requirements in many of the Agreement States were equivalent, because of the previous compatibility requirement. Exemptions are Compatibility Category B, so the new exemption will require equivalent provisions in Agreement State regulations. Thus, the change in status should result in similar cost savings per general licensee. For those using such devices under a specific license, cost savings will be greater, but are not estimated.

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

10,000 leak test kits x \$40	=	\$400,000
5,000 devices tested/year x \$11	=	\$ 55,000
5,000 devices tested for operation/year x \$11	=	\$ 55,000
10,000 transfer reports/year x \$33	=	\$330,000
5,000 responsible individuals x \$220	=	<u>\$1,100,000</u>
Total		~\$1,900,000

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

The 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 will no longer be required. Therefore, 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 will 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 Agreement States into which they are transferring devices. Manufacturers and distributors of

these products will be required to submit reports of transfer to the NRC annually (§ 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 will be less than for generally licensed devices.

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

The most significant benefit to manufacturers and distributors will be increased sales. Additionally, for those devices not uniformly covered by general license in all jurisdictions, the complexity of dealing with this and the effects on sales will be removed. 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 will benefit from the new provision by a reduction in paperwork (reviewing reports, tracking devices, etc.) associated with generally licensed devices (and to a limited extent, specifically 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 will be approximately 500 hours annually dealing with reports associated with potentially impacted generally licensed devices. NRC has approximately 20 percent of such general licensees. Therefore, the regulatory agencies will save approximately the following annual amount:

100 hours/year x \$114/staff hour	=	\$11,400/year
400 hours/year x \$50/hour	=	\$20,000/year

Benefits to Public:

It is likely that persons previously not obtaining and using the subject devices under general license will now purchase some of the devices for use. Examples of such persons are 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.

5.4 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 final rule will replace the wording in § 30.20, “designed to protect life or property from fires and airborne hazards,” with less restrictive wording. This will 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 will 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 will be evaluated for use under the exemption and a new certificate will be issued. The affect on fees will 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 will 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 \$55/hour = ~\$ 1,800

Device Evaluation Required:

4 registrations x 24 hours/device x \$55/hour = ~\$ 5,300

Total/year: ~\$ 7,100

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 \$114/staff hour	=	~\$ 3,600
4 evaluations x 21 hours/evaluation x \$114/staff hour	=	~\$ 9,600
Total/year:		~\$13,000

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 5.9 and 5.10.

Costs to Public:

There are some limited potential costs to the public from this aspect of the final 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 will likely increase the market in affected devices, some increases in the number of persons exposed are expected. The safety criteria associated with this exemption will limit routine exposures to no more than 5 mrem (50 μ Sv)/year and also control accident risks. Actual exposures are typically lower than those in the safety criteria. The 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 will be expected to provide a significant benefit to society, thus ensuring a reasonable cost/benefit for the individual product.

Environmental Considerations:

This provision will increase the number of devices allowed to be disposed as ordinary trash. Estimated doses from disposal at landfills or municipal 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 limit increases in environmental effects of increased numbers of detectors being disposed.

Benefits:

Benefits to Licensees/Users:

There will be no direct effect on current general or specific licensees. However, future users of devices approved for use under the exemption will benefit from not having the requirements of the general license, or in some cases, a specific license. Some current general licensees will 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 5.3, there are a number of costs incurred by general licensees, which will not be incurred by future users under an exemption from licensing. The following discusses typical costs for general licensees, which will 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 5.3.

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 final rule will allow certain devices to become exempt from licensing; therefore, such devices will be disposed of as ordinary trash. Users will 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 will 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 Richland, Washington facility can only accept low-level radioactive waste from Rocky Mountain Low-Level Radioactive Waste Compact and Northwest Interstate Compact States, of which there are 11. Although a facility has not yet been opened, the Texas Low-Level Radioactive Waste Disposal Compact will accept waste from Texas and Vermont. Therefore, a majority of the States either use a waste broker for disposal, or send their wastes to the facility in Clive, Utah, operated by Energy Solutions. However, the Clive, Utah facility cannot accept sealed sources. 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 it 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 chosen solution, users exempt from regulation will no longer have to leak test the sources. It is assumed that a leak test, if required, is performed every 6 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 \$20 to \$40 per kit depending on the number of kits purchased.

$$\frac{2 \text{ tests/year/device}}{1 \text{ test/kit}} \times \$40/\text{kit} = \$80/\text{device-year}$$

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:

$$2 \text{ tests/device-year} \times 0.1 \text{ hour/operational check} \times \$55/\text{hour} = \$11/\text{device-year}$$

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:

$$2 \text{ leak tests/device-year} \times 0.1 \text{ hour/record} \times \$55/\text{hour} = \$11/\text{device-year}$$

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

$$0.6 \text{ hour/transfer report} \times \$55/\text{hour} = \$33/\text{transfer report}$$

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 will 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 will no longer apply under the chosen solution. It is recognized that this person normally performs other duties that will 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 will save by not having to pay a person to perform these duties.

$$4 \text{ hours/year} \times \$55/\text{hour} = \$220/\text{user-year}$$

The general license in § 31.5 was Compatibility Category B for about 10 years, but the Commission recently decided to change it to Compatibility Category C. In some States, some of these devices would have required a specific license, but for those devices covered by the general license, the applicable requirements in many of the Agreement States were equivalent, because of the previous compatibility requirement. Exemptions are Compatibility Category B, so the new exemption will require equivalent provisions in Agreement State regulations. Thus, the change in status should result in similar cost savings per general licensee. For those using such devices under a specific license, cost savings will be greater, but are not estimated.

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

1000 leak test kits x \$40	=	\$ 40,000
500 devices tested/year x \$11	=	\$ 5,500
500 devices checked for operation/year x \$11	=	\$ 5,500
500 transfer reports/year x \$33	=	\$ 16,500
1,000 responsible individuals x \$220	=	<u>\$220,000</u>
	Total	~\$288,000

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

The chosen solution will likely cause a slight change in prices for users. 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, or sometimes recouped in the price of devices replacing the ones being returned. If such devices become exempt from regulation, this disposal service will no longer be required. Therefore, 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 will 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. Additionally, for those devices not uniformly covered by general license in all jurisdictions, the complexity of dealing with the differences in regulations in various jurisdictions and the effects on sales will be removed. No attempt has been made to quantify these benefits.

A significant reporting and recordkeeping cost for distributors is labeling. However, similar labeling requirements apply to distributors of gas and aerosol detectors. Therefore, there will not be a savings associated with this aspect of the recordkeeping. Although there are a number of distributor requirements that will 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, will be similar to current costs, although somewhat reduced.

Benefits to NRC/Agreement States:

The NRC and the Agreement States will benefit from the chosen 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 it 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 will accrue to the public from the use of the devices. The products will be required to provide some protection to health, safety, or property.

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

This rule will 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 5.9, and Agreement State rulemaking discussed in Section 5.10.

However, the one NRC licensee may need to amend its license at the time of its next renewal, resulting in onetime costs to that licensee and the NRC, and with an associated change to the fees.

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.

5.6 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 will be made less prescriptive and continue to contain general requirements and in some cases provide standards by which performance may be judged rather than specifying details of procedures that must be followed. Regulatory guidance will be provided on acceptable approaches to meeting the requirements. Licensees may also be allowed 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 being made:

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 will include examples of acceptable approaches: 1) NUREG-1556, Vol. 16, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees" and 2) 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 percent risk of more than 5 percent defectives to 5 percent 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 equivalent provisions to these. The NRC has 49 licensees under § 32.14; some of these will no longer have NRC oversight of their quality assurance/quality control requirements as a result of changes discussed in Section 5.7.2. 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 will 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 will 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 will be more performance-based. Applicants will be free to propose alternative methods to those presented in guidance to satisfy the requirements in the regulations. The requirements will continue to provide adequate assurance that the products being distributed meet performance standards. The performance standard will be somewhat revised to reduce the risk of defective products being distributed. Any new industry standards will more easily be accommodated.

The *Code of Federal Regulations* will be reduced by several pages.

5.7 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 will 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.

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

Some current requirements are considered unnecessary given the risk associated with the particular product. In this rule, the NRC will 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 rule will revise § 32.14(b)(4) to make exceptions to prototype testing requirements.

Cost Impacts:

No costs are anticipated for applicants/licensees. There will be no costs to NRC beyond rulemaking and implementation costs discussed in Section 5.9. There will 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 μ Sv (1 mrem)/year. Overall, an insignificant risk to the public will 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 will be reduced.

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

Using those assumptions, \$55/hour for applicants, and \$114/staff hour for NRC, savings to applicants will be approximately \$1,300/year and for NRC, approximately \$2,700.

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

5.7.2 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 rule will eliminate individual requirements considered unjustified 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 practices so as to limit it to products for which such procedures are required. This accommodates the exceptions made in § 32.14(b)(5).

Cost Impacts:

No costs to applicants/licensees are anticipated. There will be no costs to NRC beyond rulemaking and implementation costs discussed in Section 5.9. However, some current licensees may choose to amend their licenses to remove conditions in the license, which will no longer be required, resulting in small administrative costs to those licensees and to NRC. There will 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 μSv (1 mrem)/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 will 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 will be reduced.

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

Using those assumptions, \$55/hour for applicants, and \$114/staff hour for NRC, savings to applicants will be approximately \$1,300/year and for NRC, approximately \$2,700.

There are currently 49 licensees under § 32.14, many of whom will be free to make adjustments in their quality assurance/ quality control procedures. (Any amendments to licenses will be limited to removing conditions of the license to conduct QC in the manner to which the licensee previously committed.) No attempt has been made to quantify this benefit. However, as this is an ongoing effect, the overall benefit for this change will be greater than that concerning prototype tests discussed in Section 5.7.1.

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

5.8 Minor Clarifying or Administrative Revisions

Other minor revisions are being made 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 will 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 5.9 and 5.10. 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.

5.9 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 \$165,400/FTE.

NRC staff will need to update existing guidance in the NUREG-1556 series related to distribution licensing to reflect the revisions to the regulations. Specifically, 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” will require minor revisions or supplementation. As the changes for this rule are being made within overall revisions of these NUREGs, the additional updating needs should be a relatively limited cost impact as a result of this final rulemaking. The staff is also preparing interim guidance for use until the completion of the updates of the relevant volumes of NUREG-1556. This effort was done in parallel with the development of relevant revisions to the NUREGs to minimize the added resources from development of the interim guidance.

5.10 Costs to Agreement States of Compatible Regulations

Costs will be incurred by the Agreement States for development and implementation of compatible regulations. The costs will vary significantly by State because of differences in internal procedures for developing regulations. Some rule changes will be required to meet Compatibility Category B for certain revisions. As these need to be essentially word-for-word compatible, the process should be relatively simple. Two provisions, §§ 30.32(g) and 32.210(h), are Compatibility Category C; this may also result in some revision of the Agreement State regulations. For this final rule, the NRC assumes an average of 0.1 FTE at \$8,900/FTE for each State. There are currently 37 Agreement States; therefore, the total cost for all Agreement States will be approximately \$329,000.

6. 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 final rulemaking will be 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. This rule will advance the Commission's objectives of effectiveness and openness.

The largest single cost will be implementation of the final 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.

7. IMPLEMENTATION

The NRC's schedule for implementation of this rulemaking calls for the effective date of the rule to be in 2012 for the NRC's jurisdiction and full implementation by the Agreement States by 2015. The applicable guidance documents are: 1) NUREG-1556, Vol. 3, Rev. 1, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration;" 2) NUREG-1556, Vol. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses;" and 3) 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 are being revised as part of a broader update. There are no changes requiring entirely new guidance; i.e., nothing that necessitated having guidance available in draft for comment along with the proposed rule. Details of procedures being removed from the regulations are being added to the applicable guidance as revised to provide examples of acceptable approaches; however, these details have generally been in the regulations for many years. 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. As these will not be completed by the time the final rule is published, interim guidance is to be published concurrently with the final rule.

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.

8. IMPLICATIONS FOR OTHER FEDERAL AGENCIES

Promulgation of this final rule will have no adverse effects on other Federal agencies.

9. EFFECT ON SMALL ENTITIES

The final rule will not significantly impact small or large entities.

10. 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>.