RULEMAKING ISSUE
NOTATION VOTE

August 23, 2005 SECY-05-0151

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: PROPOSED RULE: 10 CFR PARTS 30, 31, 32, AND 150 – EXEMPTIONS FROM LICENSING, GENERAL LICENSES, AND DISTRIBUTION OF BYPRODUCT MATERIAL: LICENSING AND REPORTING REQUIREMENTS (RIN 3150-AH41)

PURPOSE:

To request Commission approval of the publication of a proposed rule in the *Federal Register* for public comment. This proposed rule includes miscellaneous amendments to Parts 30, 31, 32, and 150, regarding the use of byproduct material under exemptions from licensing and under general licenses, and regarding the requirements for those who distribute products and materials for use under exemptions from licensing.

SUMMARY:

The proposed rule would amend the regulations governing the use of byproduct material to revise requirements for reporting transfers to persons exempt from licensing, simplify the licensing of smoke detector distribution, remove obsolete provisions, and clarify certain regulatory provisions. These actions are intended to better ensure the protection of public health and safety, make the licensing of distribution to exempt persons more effective and efficient, and reduce unnecessary regulatory burden to certain general licensees. These changes would affect users of certain generally licensed devices, persons holding certain byproduct materials under exemption, and licensees who distribute byproduct material to exempt persons.

CONTACTS: Catherine R. Mattsen, NMSS/IMNS
(301) 415-6264
Andy Imboden, NMSS/IMNS
(301) 415-6128

BACKGROUND:

The staff provided the Commission with recommendations for possible improvements to the regulations governing the exemptions from licensing for both byproduct and source material in SECY-02-0196, "Recommendations Stemming from the Systematic Assessment of Exemptions from Licensing in 10 CFR Parts 30 and 40; and a Rulemaking Plan for Risk-Informing 10 CFR Parts 30, 31, and 32," November 1, 2002. These recommendations primarily resulted from a systematic assessment of the exemptions from licensing in Parts 30 and 40 of NRC's regulations, which govern the use of byproduct material and source material, respectively. The assessment of doses associated with most of these exemptions can be found in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," June 2001.

The rulemaking plan included in SECY-02-0196 addressed only the regulations governing byproduct material. The staff recommended that 16 issues be considered in the rulemaking process. The plan also discussed the possible need to make adjustments or add issues during development of the proposed rule. Additionally, in SECY-02-0196, the staff committed to further examine the issue of adequate control of generally licensed devices if quantities of byproduct material approved for use in generally licensed devices approached levels presenting security concerns.

The Commission issued a staff requirements memorandum (SRM) on November 17, 2003, which approved 12 of the individual issues for consideration in rulemaking. Additionally, the Commission directed the staff to address certain related issues specified in the SRM. The staff subsequently responded on these issues in SECY-04-0055, "Plan for Evaluating Scientific Information and Radiation Protection Recommendations," April 7, 2004, and SECY-04-0217, "Distribution of Exempt Material - Database, Dose Limits/Criteria, and Security Issues Related to Risk-Informing 10 CFR Parts 30, 31, and 32," November 18, 2004.

DISCUSSION:

The attached Federal Register notice (Attachment 1) presents a proposed rule that addresses approximately half of the original issues the Commission directed the staff to pursue in the SRM on SECY-02-0196. During the initial development of the proposed rule, the staff determined that the complexity of the rule warranted more than one rulemaking. This approach, presented in a briefing of the Commissioners' technical assistants on February 10, 2005, was selected because the staff determined that: (1) the criteria for approving products for use under general licenses or under exemptions from licensing warranted further evaluation; (2) the reevaluation of these criteria and other issues required significant additional development of their technical bases, which would significantly delay the overall rule; (3) specific immediate benefits could be gained from addressing many of the issues for which the technical basis was more straight-forward; and (4) a single rule could be overly complex, making it difficult to understand all the issues involved. Issues resolved by this initial rulemaking would not be impacted by a later resolution of remaining items. Following the briefing, the staff was advised that there were no objections to this approach of dividing the effort into separate rulemakings.

The subject proposed rule would resolve five of the issues approved by the Commission in the SRM. These issues include all of the approved issues from Option 1 and two from Option 2 of the rulemaking plan (Attachment 7 to SECY-02-0196). Proposed changes would be made to

the reporting requirements of exempt product distributors so that the information received by the NRC would be more timely, the reporting process would be more efficient, and the impact of these products on the general public could be better assessed. Additionally, licensing and enforcement experience has identified certain issues that should be simplified or clarified by rule. These improvements are part of the overall commitment to systematically assess the NRC's regulatory program to ensure the safe use and management of byproduct material.

In addition to issues listed in the rulemaking plan, the proposed rule addresses two other issues. In the section on Agreement State Implementation Issues in the rulemaking plan, the staff also indicated that consideration should be given to changing the provisions in §§ 32.11 and 32.12 (requirements for persons introducing exempt concentrations into products and materials) to make them Compatibility Category NRC. This change would make categorizations of those sections consistent with § 150.15(a)(6), which reserves to NRC the licensing of transfers to persons exempt from licensing requirements. Because this contemplated change would not alter the way these activities are currently regulated, and would only impact who would regulate these activities in the future, this action was not listed as a separate issue in the rulemaking plan. However, although compatibility category changes do not normally require rulemaking, this particular change would require revisions to certain regulations. The proposed rule includes the amendments necessary to make this change to NRC-only licensing. One additional issue, which arose after development of the rulemaking plan, involves clarification of a narrow aspect of § 31.5, which is explained in more detail below. This is also included in the subject proposed rule.

Implementing these proposed amendments to Parts 30, 31, 32, and 150 would make certain NRC regulatory actions more effective, efficient, and realistic, and enhance NRC's ability to protect public health and safety.

Issues included in this proposed rule:

(1) Improving the reporting of exempt product/material distribution, (2) Requiring NRC-only licensing of introduction of exempt concentrations, (3) Explicitly prohibiting bundling of exempt quantities, (4) Removing obsolete provisions, (5) Simplifying the licensing of smoke detector distribution, (6) Exempting most general licensees from immediate notification of losses and thefts, and (7) Clarifying requirements in § 31.5 for transfer of generally licensed devices to specifically licensed status.

Improving the reporting of exempt product/material distribution

The current reporting and recordkeeping requirements for distributors of products and materials to persons exempt from licensing in Part 30 require these licensees to maintain records of these transfers and to submit reports to NRC once every five years. This proposed rule would revise these reporting requirements from every 5 years to annually. Before 1983, these licensees were required to report annually. The requirement was changed to every 5 years in an attempt to reduce regulatory burden. However, experience has demonstrated that no significant burden reduction was achieved with the longer reporting period, because a longer record retention time was needed and compliance difficulties occurred. More significantly, the longer period has had detrimental impacts on the use and evaluation of the data available to the NRC, which has impacted the NRC's ability to assess the full impact on public health and safety. Minor changes to the content of reports would also be made. The proposed revisions to these reporting

requirements would make the NRC's ability to assess the impacts of products and materials used under exemptions from licensing more effective, efficient, realistic, and timely.

NRC licensing of introduction of exempt concentrations

Paragraph 150.15(a)(6) reserves to NRC the authority for licensing transfers to persons exempt from licensing and regulatory requirements. In a clarifying revision to that paragraph published April 16, 1969 (34 FR 6517), the reasons for NRC's retaining this authority were summarized as follows: "[T]he Commission was seeking to maintain surveillance over the safety of products containing radioactive materials, without the imposition of regulatory controls, and to be able to assess the effect of the attendant uncontrolled addition of these radioactive materials to the environment." This general intent, as well as the more specific related goals of the Consumer Product Policy (Attachment 2; discussed in SECY-02-0196), could not be well attained with multiple entities regulating such distribution. Thus, from a policy standpoint, all exempt product distributors should be licensed by the NRC, so that the national impact of products used under exemption would be known. From a regulatory standpoint, almost all distribution of byproduct material to exempt persons is required to be licensed by the NRC. However, notwithstanding § 150.15(a)(6), other provisions in NRC regulations allow Agreement States to license those who introduce byproduct material into products or materials for transfer as exempt concentrations (§ 30.14). Having this exception to NRC-only licensing of transfers of byproduct material to exempt persons creates a gap in the information available to assess the impact of exempt products, may introduce inconsistencies in the licensing process, and results in confusion concerning whether such activities require an NRC license. The proposed amendment would provide that only NRC may authorize such introduction and transfer.

No current Agreement State licensees of this type have been identified. The Agreement States were polled as to whether they had any such licensees; none were found. To supplement the license searches, members of the working group performed searches of the Thomas Register of businesses, and general online searches, and could not identify Agreement State businesses of this type.

Bundling of exempt quantities

The proposed rule would codify the Commission's position that multiple exempt quantities should not be combined. This practice circumvents the basic safety considerations relied on in issuing the exemption, and is not consistent with the required label provided by the manufacturer, which must state that "exempt quantities should not be combined." This proposed rule would amend NRC's regulations to specifically prohibit the combination of exempt quantities for the purpose of producing an increased radiation level.

Obsolete exemption provisions

Some exemptions from licensing are for obsolete products and would be discontinued. Such an exemption is no longer beneficial to the public. If the products were useful, they would still be marketed to the public because there is no regulatory burden on the end-user.

For the exemptions considered obsolete, no licensees were found who were authorized to distribute the products. Most of these exemptions are contained in § 30.15, "Certain items containing byproduct material." They are for automobile lock illuminators and shift quadrants,

thermostat dials and pointers, balances of precision, marine compasses and other navigational instruments, and spark gap irradiators containing cobalt-60. In addition, certain materials tagged with scandium-46 are allowed to be used under § 30.16, "Resins containing scandium-46 and designed for sand-consolidation in oil wells." The proposed rule would remove these exemptions, except in the case of balances of precision and marine navigational aids, where the exemption would be limited to those products already distributed, as some of these products may still be functional. Relevant distributor requirements would also be removed for these products.

Only in the case of the exemption for resins containing scandium-46 is there the potential for significant doses if used. However, resins are no longer used as the primary cementing media in oil wells. Other products, used under specific license, have replaced these resins in sand consolidation operations. Removing this exemption would further ensure that this product will not be used without a license in the future.

Smoke detector product-specific exemption

This proposed rule would simplify licensing for new applicants to initially distribute smoke detectors by establishing a new product-specific exemption for ionization chamber smoke detectors containing no more than 1 :Ci (37 kBq) of americium-241 in the form of a foil. These widely distributed and greatly beneficial devices are currently being used under the class exemption for gas and aerosol detectors. Current-day smoke detectors are very consistently designed and the NRC has developed extensive licensing experience. The establishment of a new exemption for these products would also reduce fees for initial distributors of smoke detectors.

General licensee reporting requirements

The general licenses in §§ 31.5 and 31.7 require licensees to comply with § 20.2201, which contains criteria for the reporting of lost or stolen licensed material. Some generally licensed devices contain certain radionuclides in enough quantity to meet the criteria for immediate notification. However, for certain radionuclides used by general licensees, the quantities of materials requiring immediate notification under § 20.2201 may be lower than warranted given the associated radiological risk. The regulations in §§ 31.5(c)(10) and 31.7(b) would be amended to exempt most general licensees from the immediate notification of NRC when a device is lost or stolen. However, for devices subject to registration under § 31.5(c)(13), immediate notification of losses or thefts would continue to be required. For any other lost or stolen device to which these provisions currently apply, general licensees would still be required to provide 30-day notification under §§ 20.2201(a)(ii) and 20.2201(b). This change would apply a more realistic reporting framework commensurate with general licensing and registration.

Transfer of generally licensed devices to specifically licensed status

Licensing and enforcement experience indicates that a clarification is needed to § 31.5 to address the transfer of a device from the authority provided by the general license to that of a specific license. An increased number of specific licensees have transferred their authorization to possess and use a device held under the general license to their specific licenses. Doing so allows the specific licensee to avoid paying registration fees on some devices, and is allowed under § 31.5(c)(8). However, the appropriate labeling, testing, and disposal requirements are

different for general licensees than for specific licensees. Additionally, such transfer currently requires prior written approval from NRC. The regulations would be amended to enhance regulatory clarity and to improve the ease of transfer of devices held under a general license to a specific license.

Outcome of this proposed rule: advancing NRC's strategic goals

Some of the revisions would improve NRC's ability to ensure the protection of public health and safety and the environment through the availability of more current and useful data on distributions of byproduct material. Additionally, these amendments would help to ensure that NRC actions are effective, efficient, realistic, and timely. Better data collection would improve the effectiveness and efficiency of NRC actions through the addition of certain new provisions and the elimination of certain requirements found to be no longer necessary. Based on regulatory, licensing, and enforcement experience, the staff has also identified the need to clarify regulations in response to unanticipated interpretations of certain existing regulations. Finally, the goal of ensuring openness in our regulatory process would be advanced because the NRC would have a better basis on which to inform the public about exposures resulting from the distribution of consumer products.

AGREEMENT STATE ISSUES:

In addition to having representation on the working group, the Agreement States had an early opportunity to review a copy of the draft proposed rule and Environmental Assessment (EA) posted on NRC's Technical Conference Forum.

Two States provided comment. Both supported most of the proposed revisions but were concerned with NRC making revisions to the general license requirements in § 31.5. The State of Wisconsin noted particularly the revision to § 31.5(c)(8) (delineating steps for transferring a generally licensed device to specifically licensed status) and suggested that the NRC suspend the proposed revision of § 31.5 until the Commission has evaluated a petition for rulemaking recently submitted by the Organization of Agreement States (OAS) to determine if the petition offers a better alternative. Illinois supported the revision of § 31.5(c)(8), but disagreed with that of § 31.5(c)(10) (allowing more time for reporting losses and thefts of certain generally licensed devices). With respect to the "bundling" issue, Illinois strongly supported this change and also suggested adding a clarification concerning Naturally Occurring and Accelerator-Produced Radioactive Material (NARM) and revising the labeling requirements (in § 32.19(d)(2)) so that the label would state that exempt quantities "shall" not be combined (rather than "should").

The OAS petition referred to by Wisconsin suggests that: (1) those devices used under general license and covered by the registration requirement in § 31.5(c)(13), be required to be specifically licensed instead, and (2) § 31.6 be made Compatibility Category C, instead of B. (Section 31.6 is basically a reciprocity provision for servicers of devices used under § 31.5, which involves no notification of work in other jurisdictions.) Neither of these actions, if taken, would negatively impact the changes proposed in this rule; the issues are sufficiently independent that the staff does not believe these changes to § 31.5 should await resolution of the OAS petition.

Illinois' concern with respect to the relaxation of reporting of losses or thefts relates to the inconsistencies that still exist nationally in the registration of generally licensed devices. Illinois

noted that it has a more restrictive registration program that provides a high degree of accountability and also suggested that maintaining reporting requirements for thefts is of particular importance because the occurrence of thefts potentially reflects a malicious intent and should be subject to scrutiny. In addition, the State noted the inconsistency resulting from the change to § 31.5(c)(10) in that general licensees might not report the theft or loss of a device containing the same radionuclide and quantity for which a specific licensee would report. (The staff notes that the change would in most cases simply allow somewhat more time after a general licensee becomes aware of a theft or loss; only in the case of a device being recovered during the additional time allowed would the general licensee not be required to report.) The staff recognizes the difference between general and specific licensees in this regard, does not believe it is inappropriate, and has addressed it in the supplemental information to the proposed rule. The staff does not believe that the revision to § 31.5(c)(10) would result in any increase in risk to the public; the devices for which this change is applicable present limited risks and are unlikely targets for theft for malicious use.

With regard to Illinois' suggested labeling revision, the labeling requirement in § 32.19(d) for licensees who commercially distribute exempt quantities is a notification from a licensee to a non-licensee. A revision to the exemption in § 30.18 itself is being proposed in order to make the intent demonstrated by the labeling requirement more enforceable. Amending the labeling requirement would not do so and would impose a cost on licensees who commercially distribute exempt quantities with no real benefit. In addition, the prohibition being proposed is limited in order to specifically prevent bundling of sources to create an increased radiation field. The statement, "Exempt Quantities Shall not Be Combined," would be broader than intended. The staff believes that the current required statement is more appropriate. Also, additional safety instructions are provided as appropriate for the particular type of materials. Thus, Illinois' labeling suggestion has not been added.

With regard to Illinois' comment on NARM, certain NARM is being redefined as byproduct material in the Energy Policy Act of 2005. As the regulation of NARM will change through future rulemaking as a result, no statement on NARM has been added.

STATUS OF FOLLOW-ON ACTIVITIES

During the development of this proposed rule, the staff continued to evaluate and develop those issues from the SRM to SECY-02-0196 that are not addressed in this proposed rule with a goal to prepare a second proposed rule as soon as the issues are resolved. The status of these issues is summarized as follows:

1. The staff is completing the risk assessment aspect of reviewing the quality control and prototype testing requirements and developing the best approaches to making the regulations less prescriptive in these areas.

2. The staff is developing additional technical bases to support the possible revision of the safety criteria for approving products to be used under general license or under exemption from license, as well as to establish safety criteria for the planned class exemption for industrial products. The staff is primarily concerned that higher quantities of byproduct material than currently used under these provisions could "pass" the existing criteria and believes that there may be reasons to limit quantities of materials used under exemptions and general licenses beyond just the expected resultant doses.

Any action concerning the larger-quantity generally licensed devices previously approved may be handled separately from the follow-on rulemaking arising from the subject rulemaking plan.

3. The contemplated change to broaden the class covered by § 30.20 (Issue 3 of Option 2 in the rulemaking plan) was deferred to the second rulemaking in order to first consider whether changes to the safety criteria for this exemption are warranted.

4. The staff will expand the considerations concerning making the Sealed Source and Device Registration requirements explicit in the regulations beyond those originally contemplated in developing the rulemaking plan. Additional considerations include whether or not registration certificates should have expiration dates and other alternatives to better ensure that the registration certificates are reviewed and updated as needed to ensure protection of public health and safety, as well as to provide sufficient information to all jurisdictions.

One issue, originally recommended by the staff in the rulemaking plan and approved in the SRM to SECY-02-0196, has subsequently been identified as unfounded, and will not be pursued. This issue involved the possibility of reducing radionuclide quantities allowed under the exemption for electron tubes to be closer to the lower quantities actually used because it was seen as a possible application of the as low as is reasonably achievable (ALARA) principle. However, recent and more complete information negates this premise. There are products in the marketplace with quantities up to the existing limits. Therefore, the issue is considered to be closed out, and no revision will be made to the exemption.

Finally, the staff is looking at other minor issues which might be included in the follow-on rulemaking, resulting from the ongoing work during development of the proposed rules.

RESOURCES:

The total cost to develop this rulemaking is estimated at 1.3 full-time equivalent positions and approximately $50,000 in contractor support costs. The resources to complete the action are within the approved budget for FY 2005 and FY 2006. The final rule is projected to be provided to the Commission September 2006. The information on resources and schedule reflects the current environment. If a significant amount of time (greater than 30 days) passes, or the Commission provides the staff direction that differs from, or adds to, the staff's recommended action(s), this section of the paper will need to be revisited after issuance of the draft SRM.

COMMITMENTS:

No new actions or activities committed to by the staff in this paper. Tracking for a follow-on rulemaking has been established.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register* the proposed amendments to Parts 30, 31, 32, and 150 (Attachment 1).

2. Note:

a. The Federal Register notice (FRN) provides 75 days for public comment.

b. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).

c. A draft Regulatory Analysis has been prepared for this rulemaking (Attachment 3).

d. A draft EA has been prepared for this rulemaking (Attachment 4). It will be sent to every State Liaison officer, when the rule is published.

e. NUREG-1556, Volume 8, “Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Exempt Distribution Licenses,” would require minor revisions for consistency with these proposed amendments to the regulations. Routine updating of this NUREG is due and is planned to begin following Commission action on this paper.

f. The appropriate Congressional committees will be informed of this action.

g. A press release will be issued by the Office of Public Affairs when the proposed rule is filed with the Office of the Federal Register.

h. This proposed rule amends information collection requirements. However, the burden for these revisions to information collection is insignificant and Office of Management and Budget (OMB) clearance is not required.

COORDINATION:

The Office of the General Counsel has no legal objection to the proposed rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

/RA/

Luis A. Reyes
Executive Director
for Operations

Attachments:
1. Draft Federal Register Notice
2. Consumer Product Policy
3. Draft Regulatory Analysis
4. Draft Environmental Assessment

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 31, 32, and 150

RIN: 3150 - AH41

Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the use of byproduct material to revise requirements for reporting transfers to persons exempt from licensing, simplify the licensing of smoke detector distribution, remove obsolete provisions, and clarify certain regulatory provisions. These actions are intended to better ensure the protection of public health and safety in the future, make the licensing of distribution to exempt persons more effective and efficient, and reduce unnecessary regulatory burden to certain general licensees. These changes would affect licensees who distribute byproduct material to exempt persons, users of some generally licensed devices, and some exempt persons.

DATES: Submit comments by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit comments specific to the information collection aspects of

this rule by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments received after these dates will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before these dates.

ADDRESSES: You may submit comments by any of the following methods. Please include the number RIN 3150-AH41 in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available to the public in their entirety on the NRC rulemaking website. Personal information will not be removed from your comments.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: SECY@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking website at http://ruleforum.llnl.gov. Address questions about our rulemaking website to Carol Gallagher at (301) 415-5905; e-mail cag@nrc.gov. Comments can also be submitted via the Federal eRulemaking Portal at http://www.regulations.gov.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone (301) 415-1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101.

You may submit comments on the information collections by the methods indicated under Paperwork Reduction Act Statement.

Publicly available documents related to this rulemaking may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), Room O1 F21, One

White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents, including comments, may be viewed and downloaded electronically via the NRC rulemaking website at http://ruleforum.llnl.gov.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/adams.html. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Catherine R. Mattsen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Mail Stop T8F3, Washington, DC 20555-0001, telephone (301) 415-6264, e-mail, crm@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction.

The Commission has authority to issue both general and specific licenses for the use of byproduct material and also to exempt byproduct material from regulatory control under section 81 of the Atomic Energy Act of 1954, as amended (hereafter, "the Act"). A general license is provided by regulation, grants authority to a person for certain activities involving byproduct material, and is effective without the filing of an application with the Commission or the issuance of a licensing document to a particular person. Requirements for general licensees appear in the regulations and are designed to be commensurate with the specific circumstances covered by each general license.

In considering its exemptions from licensing, the Commission is directed by the Act to make "a finding that the exemption of such classes or quantities of such material or such kinds of uses or users will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public." As beneficial uses of licensed material were developed and experience grew, new products intended for use by the general public were invented and the regulations were amended to accommodate the use of new products. The Commission currently has 15 exemptions from licensing for byproduct material in its regulations, most of which were added by 1970.

The Commission has conducted a systematic reevaluation of the exemptions from licensing in parts 30 and 40 of NRC's regulations (in Title 10 of the Code of Federal Regulations), which govern the use of byproduct and source materials. A major part of the

effort was an assessment of the potential and likely doses to workers and the public under these exemptions. The assessment of doses associated with most of these exemptions can be found in NUREG-1717[1], "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," June 2001. For some exemptions, the difference between potential (possible under the conditions of the exemption) and likely doses is significant because actual use of the exemption is limited or nonexistent, or significantly lower quantities are used in products than is potentially allowed under the exemption.

This proposed action concerns only conclusions of the reevaluation of regulations governing byproduct material. Any potential revisions to the regulations governing source material would be addressed in the future. In addition to the exemptions themselves, the NRC has reviewed the existing regulations governing the distribution of byproduct material to persons for use under the exemptions.

Generally, the systematic assessment of exemptions determined that no significant problems exist with the current uses of byproduct materials under the exemptions from licensing. Actual exposures of the public likely to be occurring are in line with Commission policy concerning acceptable doses from products and materials used under exemptions from licensing. However, in some cases, the regulatory constraints and controls in place may not be

---

[1]Copies of NUREGs may be purchased from the Superintendent of Documents, U. S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and/or copying for a fee at the NRC public Document Room, One White Flint North, 11555 Rockville Pike, Public File Area O1-F21, Rockville, MD.

adequate to fully ensure that the health and safety of the public will continue to be protected to the extent considered appropriate for practices occurring under exemptions from licensing.

Although presenting very low risks of significant individual doses to members of the general public, exempt products are a source of routine exposure to the public. A substantial portion of the population uses and enjoys benefits from exempt products, such as smoke detectors, but, at the same time, receives some radiation exposure from those products.

The Commission has also decided to make the regulations more flexible, user-friendly, and performance-based, and to improve its ability to risk-inform its regulatory program. These concepts have been considered in developing potential revisions to the regulatory program in the area of distribution of byproduct material to exempt persons.

The Commission is also proposing revisions to certain general licenses within this same rulemaking. There are also some areas where the regulations are not clear or explicit. This leads to inefficiencies in the regulatory process and can lower public confidence. Thus, some clarifications are also being proposed.

In addition to the issues addressed by this proposed rule, the Commission is considering other issues that may be addressed in a future rulemaking to further amend parts 30, 31, and 32.

B. Regulatory Framework.

The Commission's regulations in part 30 contain the basic requirements for licensing of byproduct material. Part 30 includes a number of exemptions from licensing requirements in

§§ 30.14, 30.15, 30.16, 30.18, 30.19, 30.20, and 30.21. These exemptions allow for certain products and materials containing byproduct material to be used without any regulatory requirements on the user. The two exemptions in §§ 30.19 and 30.20, for 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 is within the class and meets certain radiation dose criteria. This contrasts with 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 these concentrations and quantities are contained in tables in §§ 30.70 and 30.71, respectively. The remaining exemptions from licensing are product specific, for which many assumptions can and have been made concerning how the product is distributed, used, and disposed.

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

Part 32 sets out requirements for the manufacture or initial transfer (distribution) of items containing byproduct material to persons exempt from licensing requirements and to persons using a general license.

Part 150 sets out regulations for all States that have entered into agreements with the Commission under subsection 274b of the Act (Agreement States).

II. Proposed Actions

This proposed rule would make a number of revisions to the regulations governing the use of byproduct material under exemptions from licensing and under general licenses and to the requirements for those who distribute products and materials for use under exemptions from licensing. The changes are intended to better ensure the protection of public health and safety in the future and improve the efficiency and effectiveness of certain licensing actions.

A. Improved Reporting of Distribution to Persons Exempt from Licensing Requirements.

The current reporting and recordkeeping requirements for distributors of products and materials to persons exempt from licensing in part 30 (contained in §§ 32.12, 32.16, 32.20, 32.25(c), and 32.29(c)) require these licensees to maintain records of these transfers and to submit reports to NRC once every five years. The reports must indicate the total quantity of byproduct material and/or the total number of exempt units listed by type transferred during the reporting period. The breakdown of the information by year is not required. These reports are also required when filing for license renewal or notifying the Commission of a decision to cease authorized activities.

The resulting reports are not timely and informative enough for NRC to fully determine the products and amount of byproduct material distributed annually for exempt use. This limits the NRC's ability to evaluate the overall net impact of these practices on public health and safety. Because the date of reporting for each licensee is different and the information is not necessarily reported by year, it is difficult to estimate the amount or types of products/materials

containing byproduct material distributed each year or to see any trends. Also, the information is not very current. The limitations of the information about the products/materials and quantities distributed for use under exemption greatly impacted the effort involved in developing the dose assessments in NUREG-1717 and contributed to the uncertainties in the results.

Before 1983, reporting of transfers of exempt byproduct material was required on an annual basis. The regulations were amended in 1983 to change the reporting requirement to once every 5 years to minimize administrative burden. However, subsequent experience with the 5-year reporting frequency has shown that it does not provide NRC with complete, accurate, or timely information on products and materials containing byproduct material distributed for use under exemptions from licensing. Reevaluation of the reporting requirements also suggests that annual reporting may be administratively more efficient for both the NRC and affected licensees than the current requirement. Experience shows that there have been more implementation problems under the current scheme than with annual reporting. For example, because of the long interval between reports, licensees frequently forget to file reports in compliance with the regulations. This lapse sometimes results in the need for requests for additional information to be sent so that an application for renewal or termination of license can be processed. The long interval between reports also leads to licensee inefficiencies in collecting the data.

The proposed rule would require that material transfer reports covering transfers made during the calendar year be submitted annually by January 31 of the following year. These reports would also be required 30 days after ceasing authorized activities, rather than at the point of notifying the Commission of the decision to cease authorized activities. The reports would no longer be required when filing for license renewal. In the first report made after the proposed change, licensees would also be required to submit information on transfers made since the previous report. Routine annual reporting should be more straightforward and easier

for licensees to comply with than consolidating and reporting five years of distribution information. This approach is expected to impose a minimal burden and be more efficient for both the NRC and licensees, particularly given the current state of information technology. A recent change to the Commission's regulations allows electronic submission as an alternative to standard mail submission, which reduces administrative costs.

In addition to the lengthy period between the current reports, certain information is not always clear in the reports, making it more difficult to use the information. The proposed rule would make these reporting provisions more specific. The report would be required to include reference to the specific exemption provision under which the products/materials are being distributed and clearly identify the specific licensee submitting the report, including the license number.

The current regulations require the licensee to identify the product distributed. However, this is done in a number of ways, some of which require the NRC to refer to other documents to obtain the information needed to fully interpret what is being distributed. The proposed rule would add model numbers, when applicable, to the required information. Licensees have frequently included model numbers in the reports, but often as the only identification of the type of product being transferred. The proposed rule would eliminate these inefficiencies without making a significant change to licensees' reporting burden. The address to which reports are to be sent would also contain the line, "ATTN: Document Control Desk/Exempt Distribution," to make the internal distribution of the documents within NRC more efficient. The requirement for licensees to send an additional copy of the reports to the appropriate Regional office would be removed. Under NRC's internal procedures, the information would be electronically distributed to the Regional offices. These factors are expected to make the reporting process more efficient and to improve the quality of the information submitted.

As a result of these proposed changes, the NRC would receive information on distribution to exempt persons that is more useful for evaluating both potential individual doses to the public from multiple sources and collective doses to the public from these products and materials than that provided under the existing regulations. The NRC would have a stronger basis for informing the public concerning such exposures. These changes would also provide a better basis for considering any future regulatory changes in this area and in allocating NRC resources. Finally, the period of retention for records, proposed to remain at one year after transfers are included in a report, would be up to four years shorter than under existing requirements.

B. NRC Licensing of the Introduction of Exempt Concentrations.

For most exemptions from licensing in part 30, distributors must have an NRC license even if they are in Agreement States. Reporting requirements for these licensees provide the NRC with national data on products and materials containing byproduct material distributed to persons exempt from licensing and regulation. There are two exemptions for which this is not the case. The first of these, § 30.16, "Resins containing scandium-46 and designed for sand-consolidation in oil wells," would be removed, as noted below, because it is obsolete. The second is § 30.14, "Exempt concentrations," for which those who introduce byproduct material into products or materials are licensed under § 32.11 or similar Agreement States regulations. The concentration limits applicable to this exemption from licensing are contained in § 30.70, "Schedule A – Exempt concentrations," and equivalent Agreement State regulations.

The provisions that allow Agreement State licensing of the introduction of byproduct material into products and materials in exempt concentrations for transfer to persons exempt from licensing were added to NRC regulations in 1963, soon after the regulations governing the Agreement State program were established in 1962 (10 CFR part 150). At the time, the only practices being regulated under these provisions related to quality control procedures and other radiotracer activities. Exempt concentrations were permitted to be introduced into oil, gasoline, plastics, and similar commercial and industrial items. Also, at the time these provisions were added, it was expected that the NRC would develop a system with the Agreement States to obtain copies of the transfer reports submitted to the Agreement States by their licensees so that NRC would have national information on distribution. Such a system was never implemented.

The exempt concentration provision in § 30.14 is a general materials exemption that is not limited to a particular use. It allows for various practices to be evaluated by the NRC or an Agreement State on a case-by-case basis through the licensing process. A number of different practices have been evaluated and conducted under § 32.11, including the neutron irradiation of gemstones, silicon semiconductor materials, and luggage and cargo in an airport explosive detection system, resulting in induced radioactivity in the products. These practices involved consideration of issues not anticipated in the early 1960's, including the extensive national distribution of the products. For the case of irradiation of gemstones, the NRC has since required authorization by an NRC license.

Section 30.14 also contains an exemption from licensing by NRC (in paragraph (c)) for manufacturers, processors, or producers in Agreement States if the introduction of byproduct material into their product or material is conducted by a specific licensee whose license authorizes this introduction. Currently, this authority may be provided under either an NRC license or an Agreement State license.

Information on all distributions to exempt persons is important for NRC to effectively and efficiently assess the overall impact to the public nationally. NRC licensing of all such distribution would facilitate this process. Also, the concentration limits in § 30.70 do not provide the sole assurance of protection of public health and safety. The evaluation done in connection with the licensing process is also important. The current situation of multiple jurisdictions potentially issuing these licenses may allow for some inconsistency in the licensing process.

The proposed rule would require that the entity introducing byproduct material into products and materials for use under the exempt concentration provisions have an NRC license specifically authorizing this introduction. Specifically, the proposed rule would make §§ 32.11 and 32.12 Compatibility Category NRC (i.e., reserved to NRC). (For a brief explanation of compatibility categories see the Agreement State Compatibility section.) This change to NRC-only licensing would also require amendment of other provisions in the regulations. Thus, the proposed rule would revise the wording of the exemption in § 30.14(c), § 32.11, the prohibition in §§ 30.14(d) and 32.13, and the reciprocity provision in § 150.20 accordingly, so that only NRC may authorize the introduction of byproduct material into products and materials to be distributed for use under § 30.14 and equivalent Agreement State regulations.

Section 32.11 would be revised to exempt Agreement State licensees from § 30.33(a)(2) and (3). Consistent with the practice for other distributors of byproduct material to exempt persons in Agreement States, who have possession and use of the material authorized by an Agreement State license and distribution authorized by an NRC license, the possession and use of the byproduct material to be introduced could remain under an Agreement State license. In that case, provisions similar to § 30.33(a)(2) and (3) would apply under the Agreement State license.

Currently, the only known entities licensed under § 32.11 or equivalent regulations of the Agreement States are a small number of radiotracer firms, who introduce byproduct material into such materials as gas and oil, and steel companies, who use sources to monitor the wear of refractory lining in blast furnaces resulting in infrequent but expected instances of slight contamination of some steel. The Agreement States were requested to provide information on the number of licensees of this type in 2002 and 2005. No licensees were identified.

The exemption in § 30.14(c) was added specifically for persons in Agreement States because of the provision in § 150.15(a)(6), which reserves for NRC the authority for licensing transfers to exempt persons. The proposed rule would further revise the exemption in § 30.14(c) to also apply to manufacturers, processors, or producers in non-Agreement States who use a radiotracer firm or other § 32.11 licensee to introduce byproduct material into their products. The intent of the regulations in § 32.11 is to allow a licensee to introduce byproduct material into products and materials held by others who are not required to have a license, thus, there is no reason to limit this provision to persons in Agreement States. Therefore, § 30.14(c) would be amended to delete the reference to the Agreement States.

C. Bundling of Exempt Quantities.

In accordance with § 30.18, “Exempt quantities,” a person is exempt from the requirements for a license to the extent that person receives, possesses, uses, transfers, owns, or acquires byproduct material in individual quantities, each of which does not exceed the applicable quantity set forth in § 30.71, Schedule B. However, a person who commercially distributes materials to another person for use under § 30.18 must first obtain a distribution

license from NRC in accordance with § 32.18, “Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license.”

Paragraph (c) of § 32.18 prohibits the distributor from incorporating the exempt byproduct material into any manufactured or assembled commodity, product, or device intended for commercial distribution. However, there is no stated prohibition regarding such application by the end-user who is not commercially distributing the product.

NRC became aware that some persons holding byproduct material under the exemption in § 30.18 had been combining (bundling) multiple exempt quantities within an individual device that had not been evaluated and approved by the NRC. The devices were manufactured without radioactive material, but were designed to use multiple exempt quantity sources of byproduct material. After first becoming aware of the bundling issue, NRC originally determined in June 1994, that, under certain limited circumstances, bundling of exempt sources did not present a health and safety hazard and therefore no action was taken. Later, the NRC became concerned that the number of exempt sources bundled in these devices could reach a point where a general or specific license would normally be required. If the bundled sources were considered exempt, NRC would have no mechanism to ensure their safe possession, use, and disposal. As a result, NRC issued a generic letter in 1999, “NRC Generic Letter 99-01: Recent Nuclear Material Safety and Safeguards Decision on Bundling Exempt Quantities, May 3, 1999,” to clarify that bundling was not appropriate under the existing regulation. This position is supported by the language in § 32.19(d)(2), which directs the distributor to provide a label or accompanying brochure with any distributed exempt quantities that includes the statement: “Exempt Quantities Should Not be Combined.” However, the NRC believes that the regulations in § 30.18 should be amended to specifically prohibit bundling under the exemption. The proposed rule would revise

the exempt quantities provision in § 30.18 to explicitly prohibit combining sources to create an increased radiation level.

The original basis for the quantities chosen for the exemption in § 30.18 was the more restrictive of: (1) the quantity of material inhaled by a reference individual exposed for one year at the highest average concentration permitted in air for members of the general public in unrestricted areas at the time; or (2) for gamma emitters, the quantity of material that would produce a radiation level of 1 mR/hr at 10 cm from a point source. It was reasoned that under the conditions of the exemption, it is unlikely that any individual would inhale (or ingest) more than a very small fraction of any radioactive material being used or receive excessive doses of external radiation when realistic source-to-receptor distances and exposure times are assumed. Should bundling be permitted, NRC cannot assure that the exposures would not exceed the levels originally intended under the exemption. In addition, there would be some potential that disposal of devices containing multiple exempt sources through ordinary commercial waste streams or metal recycling channels could result in inappropriate contamination of property.

Because of the NRC's 1994 determination that, under certain limited circumstances, bundling of exempt sources did not present a health and safety hazard, the May 3, 1999, generic letter affirmed that NRC did not plan to take any action regarding the devices initially produced for use with a limited number of exempt quantity sources or their users unless a radiological safety hazard were to be identified. Because NRC has no indication that significant exposures are resulting or will result from the continued use of the devices evaluated in 1994, the proposed amendment would allow continued use of those devices. This exclusion is intended to avoid imposing a regulatory burden on those persons who otherwise might be impacted by this clarification in the regulation who are continuing to use devices in use before the generic letter

was issued. Additionally, this regulation is not intended to impact normal storage methods of the materials held under the exemption in § 30.18.

D. Obsolete Provisions.

Some exemptions from licensing are considered obsolete in that no products are being distributed for use under the exemption. In some cases, no products covered by the exemption remain in use. Generally, this has occurred because new technologies have made the use of radioactive material unnecessary or less cost-effective.

The Commission is proposing to delete exemptions for products that are no longer being used or manufactured, or to restrict further distribution while allowing for the continued possession and use of previously distributed items. These exemptions in part 30 are for: automobile lock illuminators (§ 30.15(a)(2)), balances of precision (§ 30.15(a)(3)), automobile shift quadrants (§ 30.15(a)(4)), marine compasses (§ 30.15(a)(5)), thermostat dials and pointers (§ 30.15(a)(6)), spark gap irradiators (§ 30.15(a)(10)), and resins containing scandium-46 (Sc-46) for sand consolidation in oil wells (§ 30.16). Of these, only the exemption for resins containing scandium could result in significant doses, which might be of concern, if it were used.

NUREG-1717 describes the various products covered by the individual exemptions in the second subsection of each section for a particular exemption. Some of the conclusions in that report concerning distribution are:

(1) On § 30.15(a)(2): It is believed that automobile lock illuminators containing H-3 (tritium) or promethium-147 have never been manufactured for commercial use;

(2) On § 30.15(a)(3): Tritium is not currently being used on balances of precision;

(3) On § 30.15(a)(4): It is believed that automobile shift quadrants containing tritium are not being manufactured, nor have they ever been manufactured, for commercial use;

(4) On § 30.15(a)(5): Apparently, domestic manufacture and import of marine compasses and other navigational instruments that contain tritium has ceased;

(5) On § 30.15(a)(6): Tritiated paint is not currently being used on thermostat dials and pointers, primarily because electronic displays are now available for illumination purposes. Neither are gaseous tritium light sources used for thermostat dials or pointers;

(6) On § 30.15(a)(10): Spark gap irradiators containing cobalt are designed to minimize spark delay in some electrically ignited commercial fuel-oil burners by generating free electrons in the spark gap. The irradiators are no longer being manufactured, only about 100 irradiators were in stock in 1994, and no plans had been made to distribute them for use. The original manufacturer is no longer in business. The number of irradiators actually distributed is unknown, but is not thought to be significant. [Note: there are products referred to as “spark gaps” or “spark gap tubes,” a category of electron tube, covered by the exemption in § 30.15(a)(8), which should not to be confused with the specific product covered by § 30.15(a)(10)]; and

(7) On § 30.16: Resins as the primary cementing media are no longer used.

With the exception of resins covered by § 30.16, only NRC licenses distributors of these products. The primary bases for determining that products are obsolete are NRC’s records on its licensees. Industry contacts were also used to collect historical information concerning the use of the various products.

The NRC expects that the distribution of thermostat dials or pointers, spark gap irradiators, and resins containing Sc-46 for sand consolidation in oil wells ceased so long ago that it is highly unlikely that any remain in use. This may or may not be the case for balances of precision and marine compasses distributed for use under § 30.15(a)(3) and (5). As noted, automobile lock illuminators and automobile shift quadrants were likely never commercially distributed for use under exemption. The exemptions for automobile lock illuminators, automobile shift quadrants, thermostat dials or pointers, spark gap irradiators, and resins containing Sc-46 for sand consolidation in oil wells would be removed. The exemptions for balances of precision and marine compasses and other navigational instruments would be retained for previously distributed products only. This language is not being retained for the other five exemptions considered obsolete. However, in the unlikely event that persons still possess any of these products, this action is not intended to change the regulatory status of any products previously distributed in conformance with the provisions of the regulations applicable at the time.

Specific requirements for manufacturers and initial distributors of products that are no longer being manufactured or distributed would also be deleted. These include § 32.17 for the manufacture or distribution of resins containing Sc-46 and the prototype test procedures for automobile lock illuminators specified in § 32.40 and required by § 32.14(d)(2).

In the case of the resins containing Sc-46 for sand consolidation, this action would provide assurance that health and safety are adequately protected from possible future distribution. Only preliminary dose estimates were made for this exemption. These preliminary estimates indicated a potential for exposures higher than is appropriate for materials being used under an exemption. However, the preliminary dose estimates were not refined or included in NUREG-1717, because the exemption was no longer being used.

Deleting these unnecessary provisions would simplify the regulations by eliminating extraneous text. Also, the Commission periodically reevaluates the exposure of the general public from all products and materials distributed for use under exemption, to ensure that the total contribution of these products to the exposure of the public will not exceed small fractions of the allowable limits. Eliminating obsolete exemptions would add to the assurance that future use of products in these categories would not contribute to exposures of the public and would also eliminate the need to reassess the potential exposure of the public from possible future distributions of the products.

E. New Product-Specific Exemption for Smoke Detectors.

One of the most widely distributed products used under an exemption from licensing is the ionization chamber smoke detector commonly used in residences. These smoke detectors are currently used under the class exemption in § 30.20 for gas and aerosol detectors and equivalent regulations of the Agreement States. This class exemption was established in April 1969. Section 30.20 also covers chemical agent detectors and allows for new detectors with similar purposes to be licensed for distribution without a new exemption from licensing being established by rulemaking.

The specific requirements for obtaining a license to manufacture, process, produce, or initially transfer gas and aerosol detectors intended for use under § 30.20 are currently contained in § 32.26. Conditions of licenses are contained in § 32.29 including requirements for quality control, labeling, recordkeeping, and reporting of transfers. NRC's licensing of a new initial distributor of smoke detectors involves an evaluation to determine that certain safety

criteria (contained in §§ 32.27 and 32.28) are met. The safety criteria for gas and aerosol detectors include: (1) radiation dose limits for individuals from normal handling, storage, use, and disposal of these products; and (2) radiation dose limits for individuals, in conjunction with approximate associated probabilities of occurrence, for accidents.

Residential ionization chamber smoke detectors and some similar smoke detectors have been manufactured and used for many years. Current designs are very consistent, using 0.9 to 1 μCi (33 to 37 kBq) of americium-241 (Am-241) contained in a foil, surrounded by an ionization chamber. Earlier designs used larger quantities of americium and, in some cases, other radionuclides. Residential ionization chamber smoke detectors (and similar detectors) represent a well established practice with consistency in the design of products and with extensive licensing experience. Potential doses from the distribution, use, handling, and disposal of these detectors has been estimated in NUREG/CR-1156, "Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am-241," November 1979, in NUREG-1717, and in various license applications. The estimated doses under normal, routine conditions are well under the safety criterion for routine use of 5 mrem/year (50 μSv/year) whole body, and the associated individual organ limits.

This proposed rule would establish a specific exemption from licensing requirements for ionization chamber smoke detectors containing no more than 1 μCi (37 kBq) of Am-241 in the form of a foil and designed to protect life and property from fires. This is intended to apply to ionization smoke detectors whose primary function is the protection of life and property. The exemption for ionization chamber smoke detectors would be added to § 30.15(a) as § 30.15(a)(7). The primary difference between this proposed exemption and the existing class exemption in § 30.20 is that an applicant for a license to distribute smoke detectors for use under this exemption would not be required to submit dose assessments to demonstrate that

doses from the various stages of the life cycle of the product do not exceed certain values. The applicant would still be required to submit basic design information consistent with that required from applicants to distribute products for use under other product-specific exemptions, specifically for those products used under § 30.15. The requirements for applicants to distribute these products are contained in § 32.14. The primary emphasis of these requirements is to provide assurance that the byproduct material is properly contained within the product and will not be released under the most severe conditions encountered in normal use and handling. Requirements for those licensed under § 32.14 are contained in §§ 32.15 and 32.16. These latter requirements address quality assurance, labeling, recordkeeping, and reports of transfer. The labeling requirement for smoke detectors under the current regulation in § 32.29(b) is more specific than those in § 32.15(d). In order that the more specific labeling requirement be retained, essentially the same details would be added to § 32.15(d) as applicable specifically to ionization chamber smoke detectors. A minor change (i.e., not referring to 10 CFR 32.27) would be made to be consistent with the new regulatory requirements.

It is the NRC staff's licensing practice to issue licenses for the distribution of products to be used under a class exemption only after a Sealed Source and Device (SS & D) review and registration in the SS & D. This is not the practice for products to be distributed for use under a product-specific exemption. Because of this, the proposed revision would also reduce both application and annual fees for distributors of smoke detectors. There is a separate application fee in § 170.31, associated with device review and registration, which would no longer apply. Also, in § 171.16, there are different annual fees based on whether a device has been evaluated for registration in the SS & D. The primary difference is the elimination of the fee for holding a registration certificate. For small entities, reduced fees apply; therefore, the affect of this change on fees would be smaller.

The effect of this change would be to reduce the regulatory burden and the fees for new applicants for licenses to distribute ionization chamber smoke detectors. Additionally, the change would reduce the NRC staff time needed to review these applications, because an evaluation of dose assessments would no longer be included. Current distributors of ionization chamber smoke detectors using no more than 1 μCi of Am-241 (37 kBq) may also amend their licenses and SS & D registrations to change the regulatory status of their products in order to reduce their annual fees. Given the wide distribution this product has already experienced, this change is not expected to affect the overall number of ionization chamber smoke detectors distributed in the future. Thus, a more efficient regulatory process would be used without any impacts to the health and safety of the public or the environment.

F. General Licensees and Immediate Notification of Losses and Thefts.

Two of the NRC's general licenses are established in § 31.5, "Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere," and in § 31.7, "Luminous safety devices for use in aircraft." General licensees under §§ 31.5 and 31.7 are exempt from part 20 except for § 20.2201, "Reports of theft or loss of licensed material," and § 20.2202, "Notification of incidents." Some devices used by general licensees contain quantities of radionuclides meeting the criterion in § 20.2201(a)(1)(i) for immediate notification if lost or stolen. It would seem inappropriate for sources whose inherent risk might warrant immediate notification if lost or stolen to be used under a general rather than a specific license. The NRC staff believes that, for certain radionuclides used by general

licensees, the quantities of materials requiring immediate notification under § 20.2201(a)(1)(i) may be lower than warranted given the associated radiological risk.

This proposed rule would exempt general licensees under §§ 31.5 and 31.7 from the requirement in § 20.2201(a)(1)(i) for immediate notification, except with regard to devices meeting the requirements for registration in § 31.5(c)(13)(i). For those devices for which immediate notification is no longer required, the 30-day notification requirement in § 20.2201(a)(1)(ii) would still apply, unless the device has been recovered beforehand. If a telephone report is required under § 20.2201(a), a written report is also required under § 20.2201(b).

The criteria for immediate reporting of lost or stolen devices in § 20.2201(a)(1)(i) are 1,000 times the quantities in Appendix C to part 20, "Quantities of Licensed Material Requiring Labeling." These limits are based on the most restrictive chemical and physical form and are related to the risks from inhalation or ingestion. The general licenses in §§ 31.5 and 31.7 cover only certain categories of devices, for which incidents involving inhalation or ingestion of the byproduct material within the device are unlikely. Also, these devices are designed to be safely used by persons untrained in radiological protection.

General licensee personnel would not be expected to have the same level of familiarity with the regulations as specific licensee personnel, even though § 31.5 general licensees are required by § 31.5(c)(12) to have an individual responsible for having knowledge of the appropriate regulations and requirements. None of the generally licensed devices present an imminent danger to health and safety; most are required, among other things, to meet a safety criterion of no person likely to receive a dose in excess of 15 rem (150 mSv) whole body under severe accident conditions; others present a lower risk. Also, generally licensed devices

covered by this change do not contain the types and quantities of radioactive material that are considered to be of concern for possible intentional misuse in a radiological dispersion device. However, generally licensed devices meeting the requirement for registration may result in significant contamination and expensive cleanup if smelted. Therefore, the general licensees under § 31.5 would not be exempted from the immediate notification of loss or theft with respect to devices requiring registration.

G. Specific Licensees and Generally Licensed Devices - Clarification.

Following a revision to the general license provided by § 31.5 (65 FR 79161; Dec. 18, 2000) that became effective in February 2001, an increased number of specific licensees transferred their authorization to possess and use some devices under the § 31.5 general license to the authority provided by their specific license. These transfers were made primarily to avoid the cost of the new registration fees for some of these devices in addition to their specific license fees. There are also other, non-fee-related reasons why one would make such a transfer. There has been some confusion as to the applicability of some requirements with respect to the transfer of a device from a general licensee to a specific licensee when the same entity holds both licenses, and as to exactly what is necessary to comply with existing requirements related to both types of license.

The general license in § 31.5, under paragraph (c)(1), requires that the original label on the device be maintained. This label, among other things, indicates the general license regulatory status of the device and provides safety instructions or reference to operating and service manuals. Instructions to the general licensee may not be appropriate for the use of the

device under a specific license. For example, instructions may indicate that the general licensee may not conduct its own leak tests, but must have an appropriate specifically licensed service company do so. Also, under a specific license, different labeling requirements are applicable (§ 20.1904, “Labeling containers”). It is not acceptable for a device being held under a specific license (SL) to be labeled in accordance with § 32.51(a)(3), i.e., a general license (GL) label. Thus, if a device is to be transferred from GL status to SL status, the label needs to be changed to comply with the appropriate labeling requirement.

A specific licensee would conduct its own maintenance activities including required leak tests, but may need information from the manufacturer concerning the appropriate methods for the particular device. This information may not have been provided to the entity as a general licensee, depending on the device and what has been determined to be appropriate activities for a general licensee. Thus, a specific licensee may need to contact the manufacturer to obtain the proper procedures for conducting required leak tests and other activities.

A specific licensee may have provisions in its license that authorize the quantities of the radionuclides used in a generally licensed device. The licensee needs to verify that the conditions of the specific license authorize the possession and use of the device or apply for an appropriate amendment to the license.

Paragraph (c)(8) of § 31.5 specifies acceptable specifically licensed recipients of devices covered by this general license and requires that a general licensee report to the NRC transfers of devices to specific licensees. The address for reporting includes an attention line to Document Control Desk/GLTS. GLTS refers to the General License Tracking System, which includes information on devices in use under §§ 31.5 and 31.7. In order for this database to be kept up-to-date, transfers to specific licensees must be reported and the devices removed from

the database. Paragraph (c)(8)(iii) of § 31.5 requires written approval from the NRC for transfers to any specific licensee not identified in paragraph (c)(8)(i). Thus, a general licensee who wishes to transfer a device to any other specific licensee, even if that licensee is the same entity and the effect is only to transfer to a specifically licensed status, must obtain approval for the transfer. In this way, the NRC can verify that the specific license authorizes this use and can ensure that the licensee is fully aware of its responsibilities under both the general and specific license with respect to the device. In addition, the NRC can update the GLTS.

This proposed rule would explicitly set out the required actions for this type of transfer. It would also remove the necessity of obtaining prior written NRC approval under these circumstances. Paragraph 31.5(c)(8)(iii) would be revised to include details concerning the required actions for a specific licensee to transfer a device held under this general license to the authority provided by the specific license. With these additional details included in the regulation, it is not considered necessary for the specific licensee to obtain prior written approval.

III. Early Agreement State Participation

The working group involved in the preparation of this proposed rule included a member who was appointed by the Organization of Agreement States (OAS), as well as the Conference of Radiation Control Program Directors (CRCPD). This proposed rule and its draft Environmental Assessment were also provided to the Agreement States during their development via the use of the NRC Technical Conference Forum Website and notification to the States of their availability.

Two States provided comments. Both supported most of the proposed revisions but were concerned with NRC making revisions to the general license requirements in § 31.5. The State

of Wisconsin noted particularly the revision to § 31.5(c)(8) and suggested that the NRC suspend the proposed revision of § 31.5 until the Commission has evaluated a recently submitted OAS petition for rulemaking to determine if the petition offers a better alternative. Illinois supported the revision of § 31.5(c)(8), but disagreed with that of § 31.5(c)(10), which would allow longer time for some general licensees to report losses and thefts under Part 20. Illinois also suggested revising the labeling requirements (in § 32.19(d)(2)) so that the label would state that exempt quantities "shall" not be combined (rather than "should").

The NRC has determined that the actions suggested by the OAS petition, if taken, would not negatively impact the proposed changes in this action; the issues are sufficiently independent that the NRC does not believe these changes should await resolution of the petition.

The NRC does not believe that the revision to § 31.5(c)(10) would result in any increase in risk to the public. Reports are required immediately or within 30 days depending on radionuclide and quantity, after the loss or theft becomes known to the licensee. The change simply allows the longer time period for some additional devices. No effective change in the likelihood of the notification resulting in recovery of the devices is anticipated, and, as discussed above, the devices for which this change is applicable present limited risks in any case.

The labeling requirement in § 32.19(d) is a notification from a licensee to a non-licensee. The label provides information to the user; however, this direction is not enforceable. A revision to the exemption in § 30.18 itself is being proposed in order to make the intent demonstrated by the labeling requirement more enforceable. Amending the labeling requirement would not do so and would impose a cost on licensees who commercially distribute exempt quantities with no real effect.

IV. Summary of Proposed Amendments by Section

10 CFR 30.14(c) - Would revise the exemption for manufacturers, processors, and producers to require that the licensed entity must be an NRC licensee, and clarify that the exemption applies in all jurisdictions.

10 CFR 30.14(d) - Would revise the prohibition on introducing exempt concentrations to apply to all persons except those authorized by an NRC license.

10 CFR 30.15(a) - Would (1) remove exemptions for automobile lock illuminators, automobile shift quadrants, thermostat dials and pointers, and spark gap irradiators; (2) limit the exemptions for balances of precision and marine compasses and other navigational instruments to products previously distributed; and (3) add an exemption for ionization chamber smoke detectors containing no more than 1 μCi of Am-241 in a foil.

10 CFR 30.16 - The exemption for resins containing Sc-46 for sand consolidation in oil wells would be removed.

10 CFR 30.18 - Would revise the exempt quantities provision by adding an explicit prohibition in a new paragraph (e) against combining sources to create an increased radiation level.

10 CFR 31.5(c)(8)(ii) - Would resolve a minor ambiguity with respect to addressing reports.

10 CFR 31.5(c)(8)(iii) - Would revise transfer provisions to explicitly state actions necessary for transfer of devices from general license to specific license status and remove the need for written NRC approval in that case.

10 CFR 31.5(c)(10) - Would exempt these general licensees from immediately reporting thefts and losses under § 20.2201(a)(1)(i) except regarding registerable devices.

10 CFR 31.7(b) - Would exempt these general licensees from immediate reporting of thefts and losses under § 20.2201(a)(1)(i).

10 CFR 32.11(a) - Would be revised to exempt Agreement State licensees from § 30.33(a)(2) and (3).

10 CFR 32.12 - Would revise the period of reporting for material transfers to annual and make minor changes to the content of reports.

10 CFR 32.13 - Would revise the prohibition on introducing exempt concentrations to apply to all persons except those authorized by an NRC license.

10 CFR 32.14(d) - Would remove the reference to § 32.40.

10 CFR 32.15(d) - Would add specific labeling requirements for smoke detectors distributed for use under § 30.15 consistent with that currently applicable under the gas and aerosol detector provisions in § 32.29.

10 CFR 32.16 - Would revise the period of reporting for material transfers to annual, make minor changes to the content of reports, and remove reference to § 32.17.

10 CFR 32.17 - Requirements for distribution of resins containing Sc-46 for sand consolidation in oil wells would be removed.

10 CFR 32.20 - Would revise the period of reporting for material transfers to annual and make minor changes to the content of reports.

10 CFR 32.25(c) - Would revise the period of reporting for material transfers to annual and make minor changes to the content of reports.

10 CFR 32.29(c) - Would revise the period of reporting for material transfers to annual and make minor changes to the content of reports.

10 CFR 32.40 - Prototype test requirements for automobile lock illuminators would be removed.

10 CFR 150.20(b) - Would remove provision for transfers to persons exempt under § 30.14 from the reciprocity provision for Agreement State licensees.

V. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is proposing to amend 10 CFR parts 30, 31, 32, and 150 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

VI. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" which became effective on September 3, 1997 (62 FR 46517), NRC program elements (including regulations) are placed into compatibility categories A, B, C, D, NRC or adequacy category H&S. Compatibility Category A are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt category A program elements in an essentially identical manner in order to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner.

Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, above, and, thus, do not need to be adopted by Agreement States for purposes of compatibility. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the Atomic Energy Act of 1954, as amended, or provisions of Title 10 of the Code of Federal Regulations. These program elements should not be adopted by the Agreement States. Health and Safety (H&S) are program elements that are required because of a particular health and safety role in the regulation of agreement material within the State and should be adopted in a manner that embodies the essential objectives of the NRC program.

The proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. The revisions to parts 30 and 31 would be classified as Compatibility Category B and the revisions to §§ 32.13 and 150.20 would be classified as Category C. Sections 32.11 and 32.12 would be changed from Compatibility Categories C/B and C respectively to Category NRC. Section 32.17 is Compatibility Category B. Sections 32.15, 32.16, 32.20, 32.25, and 32.29 are classified as Compatibility Category NRC. The existing compatibility designation for these regulations are not affected.

Specific information about the compatibility or health and safety components assigned to this rule may be found at the Office of State and Tribal Programs website, http://www.hsrd.ornl.gov/nrc/home.html.

VII. Plain Language

The Presidential Memorandum dated June 1, 1998, entitled, “Plain Language in Government Writing” directed that the Government’s writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31883). The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the ADDRESSES heading above.

VIII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would amend its regulations governing the use of byproduct material to revise reporting of transfers to persons exempt from licensing, simplify the licensing of smoke detector distribution, remove obsolete provisions, and make some clarifications to the regulations. None of these actions constitute the establishment of a standard that establishes generally applicable requirements.

IX. Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, not to prepare an environmental impact statement for this proposed rule because the Commission has concluded on the basis of an environmental assessment that this proposed rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment. The following is a summary of the Environmental Assessment: Many of the individual actions being proposed are the type of actions described in the categorical exclusions of § 51.22(c)(1) and (3). In addition, the proposed rule would remove provisions applicable to practices that no longer exist, establish a separate exemption from licensing for ionization smoke detectors containing no more than 1 μCi of americium-241, explicitly prohibit combining exempt quantity sources, and require NRC licensing of the introduction of exempt concentrations into products and materials. The removal of unused provisions would not result in a change to any practices except to ensure that these activities do not resume in the future without reconsideration by the Commission. The new exemption for smoke detectors is not expected to have any impact on the design or number of smoke detectors distributed to the public. The prohibition on combining exempt quantities reinforces the intent of existing regulations. The safety standards related to the exempt concentration provisions would not change. The Commission has concluded that none of these actions would have any significant impacts to the environment or otherwise include any condition requiring consultation under section 102(2)(C) of NEPA.

The determination of the Environmental Assessment for this proposed rule is that there will be no significant impact to the public or the environment from this action. However, the

general public should note that the NRC welcomes public participation. Comments on any aspect of the Environmental Assessment may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of the Environmental Assessment and this proposed rule to every State Liaison Officer and requested their comments on the Environmental Assessment. The Environmental Assessment may be examined at the NRC Public Document Room, O-1F23, 11555 Rockville Pike, Rockville, MD. Single copies of the environmental assessment are available from Andy Imboden of the Office of Nuclear Material Safety and Safeguards, telephone (301) 415-6128, e-mail, asi@nrc.gov.

X. Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This proposed rule decreases the burden on general licensees to report losses and thefts under § 20.2201(a). It makes minor revisions to the burdens on licensees for reporting and recordkeeping under §§ 31.5, 32.12, 32.16, 32.20, 32.25(c), and 32.29(c). It reduces the burden for new applicants to distribute ionization chamber smoke detectors by allowing them to obtain licenses under § 32.14 rather than § 32.26. The public burden for this information collection is estimated to average 1 hour per request. Because the burden for these revisions to the information collections is insignificant, Office of Management and Budget (OMB) clearance is not required. Existing requirements were approved by the Office of Management and Budget, approval numbers 3150-0001, 3150-0014, 3150-0016, and 3150-0120.

Send comments on any aspect of this collection of information, including suggestions for reducing the burden, to the Information and Records Management Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to bjs1@nrc.gov.

XI. Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XII. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading. The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. The regulatory analysis can also be viewed and downloaded electronically via the NRC rulemaking website at http://ruleforum.llnl.gov. Single copies of the regulatory analysis are available from Catherine R. Mattsen, telephone (301) 415-6264, e-mail, crm@nrc.gov of the Office of Nuclear Material Safety and Safeguards.

XIII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. A significant number of the licensees affected by this action would meet the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121. However, none of the proposed revisions to the regulatory program would result in a significant economic impact on the affected entities.

XIV. Backfit Analysis

NRC has determined that the backfit rule does not apply to this proposed rule; therefore, a backfit analysis is not required for this proposed rule because it does not involve any provisions that would impose backfits as defined in Chapter I.

Lists of Subjects

10 CFR Part 30 - Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 31 - Byproduct material, Criminal penalties, Labeling, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment.

10 CFR Part 32 - Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 150 - Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear materials, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR Parts 30, 31, 32, and 150.

PART 30 - RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for part 30 continues to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 30.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. In § 30.14, paragraphs (c) and (d) are revised to read as follows:

§ 30.14 Exempt concentrations

* * * * *

(c) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and parts 31 through 36 and 39 of this chapter to the extent that this person transfers byproduct material contained in a product or material in concentrations not in excess of those specified in

§ 30.70 and introduced into the product or material by a licensee holding a specific license issued by the Commission expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(d) No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.11 of this chapter.

3. In § 30.15, paragraphs (a)(2), (a)(4), (a)(6), and (a)(10) are removed and reserved, paragraphs (a)(3) and (a)(5) are revised, and paragraph (a)(7) is added to read as follows:

§ 30.15 Certain items containing byproduct material.

(a) * * *

(2) [Reserved]

(3) Balances of precision containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before (insert effective date of rule).

(4) [Reserved]

(5) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before (insert effective date of rule).

(6) [Reserved]

(7) Ionization chamber smoke detectors containing not more than 1 microcurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

* * * * *

(10) [Reserved]

* * * * *

§ 30.16 [Removed]

4. Section 30.16 is removed.

5. In § 30.18, paragraph (a) is revised and paragraph (e) is added to read as follows:

§ 30.18 Exempt quantities.

(a) Except as provided in paragraphs (c) through (e) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 30 through 34, 36, and 39 of this chapter to the extent that such person receives,

possesses, uses, transfers, owns, or acquires byproduct material in individual quantities, each of which does not exceed the applicable quantity set forth in § 30.71, Schedule B.

* * * * *

(e) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in § 30.71, Schedule B, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this part.

PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

6. The authority citation for part 31 continues to read as follows:

Authority: Secs. 81, 161, 183, 68 Stat. 935, 948, 954, as amended (42 U.S.C. 2111, 2201, 2233); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

7. In § 31.5, paragraphs (c)(8)(ii), (c)(8)(iii) and (c)(10) are revised to read as follows:

§ 31.5 Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.

* * * * *

(c) * * *

(8) * * *

(ii) Shall, within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the Director of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/GLTS. The report must contain --

(A) The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

(B) The name, address, and license number of the person receiving the device (license number not applicable if exported); and

(C) The date of the transfer.

(iii) Shall obtain written NRC approval before transferring the device to any other specific licensee not specifically identified in paragraph (c)(8)(i) of this section: however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

(A) Verifies that the specific license authorizes the possession and use, or applies and obtains an amendment to the license authorizing the possession and use;

(B) Removes the label otherwise required by paragraph (c)(1) of this section and replaces it with an appropriate label to comply with § 20.1904 of this chapter;

(C) Obtains information from the manufacturer (or initial transferor) concerning maintenance such as leak testing that would be applicable under the specific license; and

(D) Reports the transfer under paragraph (c)(8)(ii) of this section.

* * * * *

(10) Shall comply with the provisions of §§ 20.2201 and 20.2202 of this chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of parts 19, 20, and 21 of this chapter. However, only losses and thefts of devices meeting the registration criteria in § 31.5(c)(13)(i) must be reported by telephone immediately under § 20.2201(a)(1)(i).

* * * * *

8. In § 31.7, paragraph (b) is revised to read as follows:

§ 31.7 Luminous safety devices for use in aircraft.

* * * * *

(b) Persons who own, receive, acquire, possess or use luminous safety devices under the general license in this section are exempt from the requirements of parts 19, 20, and 21 of this chapter, except that they shall comply with the provisions of §§ 20.2201 and 20.2202 of this chapter. With respect to devices meeting the criteria for immediate notification in § 20.2201(a)(1)(i), telephone notification within 30 days under § 20.2201(a)(1)(ii) is required.

* * * * *

PART 32 - SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

9. The authority citation for part 32 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

10. In § 32.11, paragraph (a) is revised to read as follows:

§ 32.11 Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license.

* * * * *

(a) Satisfies the general requirements specified in § 30.33 of this chapter; *provided, however,* that the requirements of § 30.33(a)(2) and (3) do not apply to an application for a license to introduce byproduct material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material

containing the byproduct material, if the possession and use of the byproduct material to be introduced is authorized by a license issued by an Agreement State;

* * * * *

11. Section 32.12 is revised to read as follows:

§ 32.12 Same: Records and material transfer reports.

(a) Each person licensed under § 32.11 shall maintain records of transfer of byproduct material and file a report with the Director of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the byproduct material is transferred for use under § 30.14 of this chapter or equivalent regulations of an Agreement State.

(b) The report must identify the:

(1) Type and quantity of each product or material into which byproduct material has been introduced during the reporting period;

(2) Name and address of the person who owned or possessed the product or material, into which byproduct material has been introduced, at the time of introduction;

(3) The type and quantity of radionuclide introduced into each product or material; and

(4) The initial concentrations of the radionuclide in the product or material at time of transfer of the byproduct material by the licensee.

(c)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after (Insert the effective date of this rule), the licensee shall separately include data for transfers in prior years not previously reported to the Commission or to an Agreement State.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.11 shall file a report for the current calendar year within 30 days after ceasing distribution.

(d) If no transfers of byproduct material have been made under § 32.11 during the reporting period, the report must so indicate.

(e) The licensee shall maintain the record of a transfer for a period of one year after the transfer is included in a report to the Commission.

12. Section 32.13 is revised to read as follows:

§ 32.13 Same: Prohibition of introduction.

No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under § 30.14 of this chapter or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.11.

13. In § 32.14, paragraph (d) is revised to read as follows:

§ 32.14 Certain items containing byproduct material; Requirements for license to apply or initially transfer.

* * * * *

(d) The Commission determines that the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

14. In § 32.15, paragraph (d) is revised to read as follows:

§ 32.15 Same: Quality assurance, prohibition of transfer, and labeling.

* * * * *

(d)(1) Label or mark each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified.

(2) For ionization chamber smoke detectors, label or mark each detector and its point-of-sale package so that:

(i) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:

(A) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(B) The name of the radionuclide (“americium-241" or “Am-241") and the quantity of activity; and

(C) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) of this chapter or equivalent regulations of an Agreement State.

(ii) The labeling or marking specified in paragraph (d)(2)(i) of this section is located where it will be readily visible when the detector is removed from its mounting.

(iii) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(A) The name of the radionuclide and quantity of activity;

(B) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) or equivalent regulations of an Agreement State; and

(C) The following or a substantially similar statement:

THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.

(iv) Each detector and point-of-sale package is provided with such other information as may be required by the Commission.

15. Section 32.16 is revised to read as follows:

§ 32.16 Certain items containing byproduct material: Records and reports of transfer.

(a) Each person licensed under § 32.14 shall maintain records of all transfers of byproduct material and file a report with the Director of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under § 30.15 of this chapter, giving the specific paragraph designation, or equivalent regulations of an Agreement State.

(b) The report must include the following information on products transferred to other persons for use under § 30.15 or equivalent regulations of an Agreement State:

(1) A description or identification of the type of each product and the model number(s), if applicable;

(2) For each radionuclide in each type of device and each model number, if applicable, the total quantity of the radionuclide;

(3) The number of units of each type of product transferred during the reporting period by model number, if applicable.

(c)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after (Insert the effective date of this rule), the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.14 shall file a report for the current calendar year within 30 days after ceasing distribution.

(d) If no transfers of byproduct material have been made under § 32.14 during the reporting period, the report must so indicate.

(e) The licensee shall maintain the record of a transfer for a period of one year after the transfer is included in a report to the Commission.

§ 32.17 [Removed]

16. Section 32.17 is removed.

17. Section 32.20 is revised to read as follows:

§ 32.20 Same: Records and material transfer reports.

(a) Each person licensed under § 32.18 shall maintain records of transfer of material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.18 of this chapter or the equivalent regulations of an Agreement State and

stating the kinds, quantities, and chemical and physical form of byproduct material transferred.

(b) The licensee shall file a summary report with the Director of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the materials are transferred for use under § 30.18 or equivalent regulations of an Agreement State.

(c) For each radionuclide in each chemical and physical form, the report shall indicate the total quantity of each radionuclide and the chemical and physical form, transferred under the specific license.

(d)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after (Insert the effective date of this rule), the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.18 shall file a report for the current calendar year within 30 days after ceasing distribution.

(e) If no transfers of byproduct material have been made under § 32.18 during the reporting period, the report must so indicate.

(f) The licensee shall maintain the record of a transfer for a period of one year after the transfer is included in a summary report to the Commission.

18. In § 32.25, paragraph (c) is revised to read as follows:

§ 32.25 Conditions of licenses issued under § 32.22: Quality control, labeling, and reports of transfer.

* * * * *

(c) Maintain records of all transfers and file a report with the Director of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under § 30.19 of this chapter or equivalent regulations of an Agreement State.

(3) The report must include the following information on products transferred to other persons for use under § 30.19 or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product and the model number(s);

(ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide;

(iii) The number of units of each type of product transferred during the reporting period by model number.

(4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after (Insert the effective date of this rule), the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.22 shall file a report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of byproduct material have been made under § 32.22 during the reporting period, the report must so indicate.

(6) The licensee shall maintain the record of a transfer for a period of one year after the transfer is included in a report to the Commission.

19. In § 32.29, paragraph (c) is revised to read as follows:

§ 32.29 Conditions of licenses issued under § 32.26: Quality control, labeling, and reports of transfer.

* * * * *

(c) Maintain records of all transfers and file a report with the Director of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under § 30.20 of this chapter or equivalent regulations of an Agreement State.

(3) The report must include the following information on products transferred to other persons for use under § 30.20 or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product and the model number(s);

(ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide;

(iii) The number of units of each type of product transferred during the reporting period by model number.

(4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after (Insert the effective date of this rule), the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.26 shall file a report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of byproduct material have been made under § 32.26 during the reporting period, the report must so indicate.

(6) The licensee shall maintain the record of a transfer for a period of one year after the transfer is included in a report to the Commission.

§ 32.40 [Removed]

20. Section 32.40 is removed.

PART 150 - EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

21. The authority citation for part 150 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 274, 73 Stat. 688 (42 U.S.C. 2201, 2021); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Sections 150.3, 150.15, 150.15a, 150.31, 150.32 also issued under secs. 11e(2), 81, 68 Stat. 923, 935, as amended, secs. 83, 84, 92 Stat. 3033, 3039 (42 U.S.C. 2014e(2), 2111, 2113, 2114). Section 150.14 also issued under sec. 53, 68 Stat. 930, as amended (42 U.S.C. 2073). Section 150.15 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 150.17a also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 150.30 also issued under sec. 234, 83 Stat. 444 (42 U.S.C. 2282).

22. In § 150.20, paragraph (b)(3) is revised to read as follows:

§ 150.20 Recognition of Agreement State licensing.

* * * * *

(b) * * *

(3) Shall not, in any non-Agreement State, in an area of exclusive Federal jurisdiction within an Agreement State, or in offshore waters, transfer or dispose of radioactive material possessed or used under the general licenses provided in this section, except by transfer to a person who is specifically licensed by the Commission to receive this material.

* * * * *

Dated at Rockville, Maryland, this_____ day of_____, 2005.

For the Nuclear Regulatory Commission.

_____

Annette Vietti-Cook,
Secretary of the Commission.

ATOMIC ENERGY COMMISSION

USE OF BYPRODUCT MATERIAL AND SOURCE MATERIAL

Products Intended for Use by General Public (Consumer Products)

Criteria for the approval of products intended for use by the general public containing byproduct material and source material. This notice sets forth the essential terms of the Commission's policy with respect to approval of the use of byproduct material and source material in products intended for use by the general public (consumer products) without the imposition of regulatory controls on the consumer-user. This is accomplished by the exemption, on a case-by-case basis, of the possession and use of the approved items from the licensing requirements for byproduct and source material of the Atomic Energy Act of 1954, as amended, and of the Commission's regulations "Licensing of Byproduct Material", 10 CFR Part 30 and "Licensing of Source Material", 10 CFR Part 40.

1. At the present time it appears unlikely that the total contribution to the exposure of the general public to radiation from the use of radioactivity in consumer products will exceed small fractions of limits recommended for exposure to radiation from all sources. Information as to total quantities of radioactive materials being used in such products and the number of items being distributed will be obtained through record-keeping and reporting requirements applicable to the manufacture and distribution of such products. If radioactive materials are used in sufficient quantities in products reaching the public so as to raise any question of population exposure becoming a significant fraction of the permissible dose to the gonads, the Commission will, at that time, reconsider its policy on the use of radioactive materials in consumer products.

2. Approval of a proposed consumer product will depend upon both associated exposures of persons to radiation and the apparent usefulness of the product. In general, risks of exposure to radiation will be considered to be acceptable if it is shown that in handling, use and disposal of the product it is unlikely that individuals in the population will receive more than a small fraction, less than a few hundredths, of individual dose limits recommended by such groups as the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and the Federal Radiation Council (FRC), and that the probability of individual doses approaching any of the specified limits is negligibly small. Otherwise, a decision will be more difficult and will require a careful weighing of all factors, including benefits that will accrue or be denied to the public as a result of the Commission's action. Factors that may be pertinent are listed in paragraphs 9 and 10, below.

3. It is considered that as a general rule products proposed for distribution will be useful to some degree. Normally the Commission will not attempt an extensive evaluation of the degree of benefit or usefulness of a product to the public. However, in cases where tangible benefits to the public are questionable and approval of such a product may result in widespread use of radioactive material, such as in common household items, the degree of usefulness and benefit that accrues to the public may be a deciding factor. In particular, the Commission considers that the use of radioactive material in toys, novelties, and adornments may be of marginal benefit.

4. Applications for approval of "off-the-shelf" items that are subject to mishandling especially by children will be approved only if they are found to combine an unusual degree of utility and safety.

5. The Commission has approved certain long standing uses of source material, most of which antedate the atomic energy program. These include:

(1) Use of uranium to color glass and glazes for certain decorative purposes;

(2) Thorium in various alloys and products (gas mantles, tungsten wire, welding rods, optical lenses, etc.) to impart desirable physical properties; and

(3) Uranium and thorium in photographic film and prints.

6. The Commission has also approved the use of tritium as a substitute luminous material for the long standing use of radium for this purpose on watch and clock dials and hands.

7. The Commission has approved additional uses of byproduct and source material in consumer products. These include the following:

(1) Tritium in automobile lock illuminators;

(2) Tritium in balances of precision;

(3) Uranium as shielding in shipping containers; and

(4) Uranium in fire detection units.

8. In approving uses of byproduct and source materials in consumer products, the Commission establishes limits on quantities or concentrations of radioactive materials and, if appropriate, on radiation emitted. In some cases other limitations, such as quality control and testing, considered important to health and safety are also specified.

PRINCIPAL CONSIDERATIONS WITH RESPECT TO EVALUATION OF PRODUCTS

9. In evaluating proposals for the use of radioactive materials in consumer products the principal considerations are:

(a) The potential external and internal exposure of individuals in the population to radiation from the handling, use and disposal of individual products;

(b) The potential total accumulative radiation dose to individuals in the population who may be exposed to radiation from a number of products;

(c) The long-term potential external and internal exposure of the general population from the uncontrolled disposal and dispersal into the environment of radioactive materials from products authorized by the Commission; and

(d) The benefit that will accrue to or be denied the public because of the utility of the product by approval or disapproval of a specific product.

10. The general criteria for approval of individual products are set forth in paragraph 2, above. Detailed evaluation of potential exposures would take into consideration the following factors together with other considerations which may appear pertinent in the particular case:

(a) The external radiation levels from the product.

(b) The proximity of the product to human tissue during use.

(c) The area of tissue exposed. A dose to the skin of the whole body would be considered more significant than a similar dose to a small portion of the skin of the body.

(d) Radiotoxicity of the radionuclides. The less toxic materials with a high permissible body burden, high concentration limit in air and water, would be considered more favorably than materials with a high radiotoxicity.

(e) The quantity of radioactive material per individual product. The smaller the quantity the more favorably would the product be considered.

(f) Form of material. Materials with a low solubility in body fluids will be considered more favorably than those with a high solubility.

(g) Containment of the material. Products which contain the material under very severe environmental conditions will be considered more favorably than those that will not contain the material under such conditions.

(h) Degree of access to product during normal handling and use. Products which are inaccessible to children and other persons during use will be considered more favorably than those that are accessible.

(Sec. 161, 68 Stat. 948; 42 U.S.C. 2201. Administrative Procedure Act, sec. 3, 60 Stat. 238; 5 U.S.C. 1002)

Dated at Washington, D.C., this 8th day of March 1965.

For the Atomic Energy Commission.

W. B. McCOOL,
Secretary.

[F.R. Doc. 65-2616; Filed, Mar. 15, 1965; 8:45 a.m.]

DRAFT REGULATORY ANALYSIS

for

AMENDMENT to

10 CFR Parts 30, 31, 32, and 150

for

CERTAIN EXEMPTIONS AND GENERAL LICENSE PROVISIONS

DRAFT REGULATORY ANALYSIS

TABLE OF CONTENTS

1 STATEMENT OF THE PROBLEM AND OBJECTIVES

The Nuclear Regulatory Commission (NRC) conducted a systematic reevaluation of the exemptions from licensing in 10 CFR Parts 30 and 40, which govern the use of byproduct and source materials. During this reevaluation, the Commission identified several areas in which the regulations could be improved, clarified, or made more flexible and user friendly.

Of particular importance, exempt distribution reports, as currently required at 5-year intervals, do not provide timely information that is necessary for NRC to assess the health impacts of these programs on the public health and safety. Difficulties exist in reporting because the required date for reporting by each licensee is different and the information is not necessarily reported by year. This makes it difficult to estimate the amount or types of products/materials containing byproduct material distributed each year or to see any trends in the market. Additionally, distribution information that is recorded by licensees in Agreement States is not currently being provided to the NRC. In order for NRC to effectively and efficiently evaluate the overall impact to the public nationally as part of carrying out the Commission's policy on products distributed for use by the general public, timely and complete information is needed.

The Commission has periodically reevaluated the exposure of the general public from all products and materials distributed for use under exemption, in order to ensure that the total contribution of these products to the exposure of the public will not exceed small fractions of the allowable limits of exposure for the public. Regulations regarding exempt quantities are not explicit to prevent combining (bundling) of sources, thus the NRC cannot provide assurance that exposures would not exceed the levels originally intended under the exemption. Some of the regulations in § 30.15 and § 30.16 currently contain some obsolete provisions, i.e., no products are being distributed for use under certain exemptions. Eliminating obsolete exemptions adds to the assurance that future use of products in these categories would not contribute to exposures of the public.

Some regulations are overly burdensome or require licensee actions that are not commensurate with the associated risk. For example, adequate information is available concerning the potential doses to the public from the use of smoke detectors, that the requirements to distribute these products no longer need to include the development and submittal of dose assessments. Residential ionization chamber smoke detectors, and some similar smoke detectors, have been manufactured and used for many years. Current designs are very consistent. Licensing a new initial distributor of smoke detectors currently requires a dose evaluation to demonstrate that certain safety criteria are met. The estimated doses under normal, routine conditions are well under the safety criterion for routine use of 5 mrem/year (50 μSv/year) whole body, and the associated individual organ limits. In addition, general licensees under §§ 31.5 and 31.7 are required to immediately notify the NRC if devices containing certain quantities of radionuclides are lost or stolen. For certain radionuclides, the quantities of materials requiring immediate notification under § 20.2201(a)(1)(i) may be lower than warranted given the associated radiological risk. Revision to these requirements can reduce licensees' and NRC and Agreement States' burdens while still maintaining the health and safety of the public and the environment.

There has been some confusion as to the applicability of some requirements with respect to the transfer of a device from a general licensee to a specific licensee when the same entity holds

both licenses. Currently, written approval from the NRC is required for this type of transfer. Clarification in the regulation would improve regulatory efficiency.

The NRC is proposing to amend its regulations governing the use of byproduct material to revise reporting of transfers to persons exempt from licensing, simplify the licensing of smoke detector distribution, remove obsolete provisions, and clarify some of the regulations. These actions are intended to better ensure the protection of public health and safety in the future, make the licensing of distribution to exempt persons more effective and efficient, and reduce unnecessary regulatory burden to certain general licensees.

2 EXISTING REGULATORY FRAMEWORK

Part 30 sets out the basic requirements for licensing of byproduct material and includes a number of exemptions from licensing requirements. The exemptions are in §§ 30.14, 30.15, 30.16, 30.18, 30.19, 30.20, and 30.21. The two exemptions in §§ 30.19 and 30.20, self-luminous products and gas and aerosol detectors, respectively, are class exemptions, which cover a broad class of products. Under these provisions, new products can be approved for use through the licensing process, if the applicant demonstrates that the specific product meets certain safety criteria. This is in contrast to the other exemptions for which the level of safety is controlled through such limits as specification of radionuclides and quantities. Sections 30.14 and 30.18, exempt concentrations and exempt quantities, are broad materials exemptions, which allow the use of a large number of radionuclides. The specific radionuclide limits on the quantities and concentrations are contained in tables in §§ 30.71 and 30.70, respectively. The remainder of the exemptions from licensing are product specific, for which many assumptions can and have been made concerning how the product is distributed, used, and disposed.

Part 31 provides general licenses for the use of certain items containing byproduct material and the requirements associated with these general licenses.

Part 32 sets out requirements for the manufacture or initial transfer (distribution) of items containing byproduct material to persons exempt from licensing requirements and to persons using a general license. The requirements for distributors address such measures as: prototype testing, labeling, quality control, and, in some cases, specific sampling procedures. The requirements for distribution to general licensees include material transfer reports on a quarterly or annual basis. The requirements for distribution to exempt persons include material transfer reports on a five-year interval, and when applying for renewal or termination of a license.

Part 150 sets out regulations for all States that have entered into agreements with the Commission under subsection 274b of the Act (Agreement States).

3 IDENTIFICATION OF ALTERNATIVE APPROACHES TO THE PROBLEM

3.1 No Action

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

3.2 Proposed Rulemaking to Revise 10 CFR Parts 30, 31, 32, and 150

This alternative is to amend 10 CFR Parts 30, 31, 32, and 150 to resolve seven issues related primarily to the goals of ensuring public health and safety and increasing regulatory efficiency, effectiveness, realism, and timeliness. The proposed regulatory amendments would improve reporting requirements, improve licensing of distribution of certain byproduct materials, clarify some regulations, eliminate obsolete provisions, as well as establish a specific product exemption. These changes would affect licensees who distribute byproduct material to exempt persons, users of some generally licensed devices, and some exempt persons.

3.3 Other Alternatives

Other alternatives such as developing or revising guidance, issuing generic communications, etc., are not viable because these alternatives would not provide the necessary regulatory basis to mandate particular licensee actions. To maintain regulatory flexibility consistent with current regulatory needs and ensure the protection of public health and safety in the future, changes in the regulations are necessary.

4 DESCRIPTION, DISCUSSION, AND ANALYSIS OF VALUES AND IMPACTS OF PROPOSED PROVISIONS

Sections 4.1 through 4.7 describe each of the proposed amendments in the rule and provide estimates of the costs and benefits to the licensees, NRC, Agreement States, and the public related to each amendment. Section 4.8 estimates the costs to NRC and Section 4.9 estimates costs to Agreement States for rulemakings to promulgate the amendments.

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

Licensee labor rates were obtained from National Wage Data available on the Bureau of Labor Statistics web site (www.bls.gov). Depending on the industry and the occupation (e.g., manufacturing, health and safety, etc.), an appropriate mean hourly labor rate is selected. The rate is then increased using a multiplier of 1.4 to account for benefits (insurance premiums, pension, and legally required benefits). The 1.4 multiplier was determined by reviewing Employer Costs for Employee Compensation tables for 2004 for the same industries and occupation groups also available on the Bureau of Labor Statistics web site. Because exact hourly rates would be difficult to obtain and may not be sufficiently recent, nationwide mean hourly rates are used.

Licensee fees were obtained from 10 CFR 170.31 and 171.16. It is recognized that the fees are periodically adjusted, most recently on May 26, 2005 (70 FR 30527), and fluctuate from year to year based on many factors. For the purpose of this analysis, the fees are assumed to remain unchanged over the next three years. In the context of the overall, societal regulatory evaluation, NRC's fees are neither a cost or benefit, but are considered a distributional effect. To a licensee, however, fees may have a significant impact and therefore they are discussed in detail below.

NRC labor rates are determined per the calculation methodology in Abstract 5.2 of NUREG/CR-4627, Rev.1 "Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses." This methodology considers only variable costs that are directly related to the implementation, operation, and maintenance of the proposed requirement. Currently, this hourly labor rate for NMSS is $87.

Agreement States' labor rates vary in amount and in how each rate is determined. A survey of a particular industry would reveal a labor rate that can be compared to the NRC's labor rate, or the Bureau of Labor Statistics web site can be used to obtain an hourly labor rate. Either of these methods is likely to yield similar results. For the purpose of this analysis, the average Agreement State hourly labor rate was obtained from the Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Management, professional, and related occupations" limited to State and local government workers[1]. This wage was then increased by the same factor of 1.4 described earlier to obtain an hourly labor rate of $43 and an annual labor rate of $76,000.

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

For all other labor rates or fees that are specific to an issue, the source is provided within the specific issue (Sections 4.1 through 4.7).

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

- Industry Implementation and Operation – The proposed rule would improve reporting requirements and improve licensing of distribution of certain byproduct materials. For example, manufacturers and distributors of smoke detectors would no longer have to perform a dose assessment, nor pay certain fees.

---

[1]Department of Labor (U.S.), Bureau of Labor Statistics, Employer Costs for Employee Compensation, 4th Quarter 2004. Series IDs CMU3020000100000D and CMU3020000100000P.

- C NRC Implementation and Operation – The NRC would incur costs to develop a rule and to revise existing guidance. The proposed rule would result in small reductions in operating costs.
- Other Government – Agreement States would need to amend their regulations to maintain compatibility with NRC requirements; the only impacts to the Agreement State regulatory program would be a small reduction in reports received.
- Regulatory Efficiency – The proposed rule would improve regulatory efficiency by simplifying the licensing of smoke detectors, removing obsolete provisions, and clarifying some of the regulations.
- C Improvements in Knowledge – The proposed rule would allow NRC to better track products and materials distributed for use under exemptions from license and better estimate the impacts of these products and materials. For certain issues, the proposed rule may improve the general knowledge of licensees (e.g., clarify the required actions for transfers from general license to specific license).
- Other Considerations – The proposed rule could increase public confidence in the NRC by assuring that exempt persons and the public are not being exposed to material that could possibly yield a dose in excess of limits contained in policy guidance for exemptions.

The above attributes are evaluated more fully in Sections 4.1 through 4.7 as they pertain to the individual issues.

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

- C Public Health (Accident/Event and Routine)
- C Occupational Health (Accident/Event and Routine)
- C Offsite Property
- C Onsite Property
- C General Public
- C Antitrust Considerations
- C Safeguards and Security Considerations
- C Environmental Considerations

4.1 Revise §§ 32.12, 32.16, 32.20, 32.25(c), and 32.29(c) for Reporting Requirements

Sections 32.12, 32.16, 32.20, 32.25(c), and 32.29(c) require that specific licensees (manufacturers and distributors) maintain records of transfer of material to exempt persons and file a report with the Director of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a). A copy of the report must also be sent to the appropriate NRC Regional Office.

The usefulness of information collected through reports of byproduct material in products and materials being distributed to exempt persons could be improved by changing the period of reporting to every calendar year rather than every 5 years (and when filing an application for renewal or termination of the license). This change would provide product distribution information that is more useful for evaluating potential individual doses to the public from multiple sources and collective doses to the public from exempt products and materials than

under the existing regulations. Because the date of reporting for each licensee is different and the information is not necessarily reported by year, it is difficult to estimate the amount or types of products/materials containing byproduct material distributed each year or to see any trends. Also, the information is not current. It is more difficult for NRC to track when reports are due, particularly now that this type of license is typically issued for 10 years rather than 5 years. The deficiency may not always be noted unless a renewal or termination of license is being processed. Reporting annually would eliminate these difficulties and would not significantly change the reporting burden for these licensees.

In addition to the lengthy period between reports, certain information is not always clear in the reports, making it more difficult to use the information. The proposed rule would make these reporting provisions more specific, to include the specific exemption provision under which the products/materials are being distributed, the model numbers, when applicable, and clear identification of the specific licensee submitting the report including the license number.

The proposed rule would also revise §§ 32.12, 32.16, 32.20, 32.25, and 32.29 to include in the address, "ATTN: Document Control Desk/Exempt Distribution" on the annual reports. The requirement to provide copies to the Regions would be eliminated, and the frequency of reporting would be changed to annual.

The following number of licensees are likely to be affected by the above changes. The following information (with the exception of § 32.12) was obtained from the Licensing Tracking System as of December 2004. Licensees reporting under § 32.12 were identified through ADAMS searches for the appropriate type of licenses.

§ 32.12	2	licensees
§ 32.16	43	licensees
§ 32.17	0	licensees
§ 32.20	25	licensees
§ 32.25	11	licensees
§ 32.29	27	licensees

The above numbers sum to 108 licensees. However, five of these licensees distribute products under two sections.

Cost Impacts:

Costs to Licensees (Manufacturers and Distributors)

> The proposed rule would require annual reports instead of a 5-year reporting period. Efficiency and accuracy in compiling annual reports are expected, because it is likely that less time would be needed to compile annual reports compared to locating and compiling accurate information for five years for current reporting requirements. Thus, the costs to licensees are expected to be minimal or non-existent.

Costs to NRC and Agreement States

> The NRC would incur costs from the rulemaking which are discussed in Section 4.8. Although NRC would receive a greater number of reports per year, the amount of data

would be similar and no additional costs to NRC are expected. The proposed rule would require more specific information, identification of the specific exemption provision, the model numbers of products, and the license number of the reporting licensee. The handling and use of the information would be more efficient and effective overall.

Section 32.12 would become Compatibility Category NRC; the impacts of that are addressed in Section 4.2. Sections 32.16, 32.20, 32.25, and 32.29 are already Compatibility Category NRC. Therefore, this proposed rule change would not result in any costs to the Agreement States.

Costs to the Public

There are no expected costs to the public from the proposed rule.

Benefits:

The revisions are expected to make the reporting process more efficient and could improve the quality of the information. Annual reporting would also provide information on distribution that is more useful for evaluating potential individual doses to the public from multiple sources and collective doses to the public from exempt products and materials than under the existing regulations. The NRC would have a better basis on which to inform the public concerning these exposures. These changes would also provide a better basis for considering any future rulemaking in this area and in allocating NRC resources. Finally, the period of retention for records, though still one year after transfers are included in a report, would be as much as 4 years shorter. The amount of information required to be kept at any one time would be up to 2 years of transfers records rather than 6 years of transfers.

4.2 Revise § 30.14 to Make Exempt Concentrations NRC Only

Section 30.14 states that any person is exempt from the requirements for a license to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in concentrations not in excess of those listed in § 30.70. The requirements for a license to introduce exempt concentrations into products are specified in § 32.11. Section 32.12 requires that each person licensed under § 32.11 maintain records of transfer of material and file a report with the Director of Nuclear Material Safety and Safeguards, and send a copy of the report to the appropriate NRC Regional Office.

Paragraph 30.14(c) exempts a manufacturer, processor, or producer of a product or material in an Agreement State from the requirements for an NRC license to the extent that he transfers byproduct material contained in a product or material in concentrations not in excess of those specified in § 30.70 and introduced into the product or material by a licensee holding a specific license issued by an Agreement State, the Commission, or the Atomic Energy Commission expressly authorizing such introduction. Currently, there is no process in place by which Agreement States provide copies of transfer reports to the NRC. The exemption in § 30.14(c) was added specifically for persons in Agreement States, because of the provision in § 150.15(a)(6), which reserves to NRC the authority for licensing transfers to exempt persons.

Paragraph 30.14(d) and § 32.13 prohibit introduction of byproduct material into products and materials that may be transferred to persons exempt under § 30.14 or equivalent regulations without a specific license authorizing the introduction. Currently this license may be an NRC or Agreement State license.

In order for NRC to effectively evaluate the overall impact to the public from exempt distribution, all distribution for use under exemptions from licensing should be licensed by NRC. Thus, the proposed rule would make §§ 32.11 and 32.12 Compatibility Category NRC and revise the wording of the exemption in § 30.14(c), § 150.20, and the prohibition in §§ 30.14(d) and 32.13 accordingly, so that only NRC may authorize the introduction of byproduct material into products and materials to be distributed for use under § 30.14 and equivalent Agreement State regulations. For clarification, § 30.14(c) would also be revised to apply to manufacturers, processors, or producers in non-Agreement States who use a radiotracer firm or other § 32.11 licensee to introduce byproduct material into their products.

Cost Impacts:

Cost to Licensees (Manufacturers and Distributors)

If §§ 32.11 and 32.12 become Compatibility Category NRC, then any entity licensed under equivalent regulations of an Agreement State would be required to obtain an NRC license. The NRC has been unable to identify any such licensees. However, there is considerable uncertainty as to whether there are any licensees to be impacted. In order to consider the potential impact if there were affected licensees, the costs are estimated based on an assumption that there are three times as many Agreement State licensees as NRC licensees. As there are two NRC licensees, the number of Agreement State licensees is assumed to be six. As a result of this proposed change, the following costs are projected for six affected licensees in Agreement States:

E-Distribution License Required:

Effort to prepare the application:

7 hours/application[2] x $44/hour[3] — $300/application

6 applicants x $300/application = $1,800

The estimated effort to prepare an application comes from a generic number that is the average based on all applications submitted to NRC by applicants for a variety of materials licenses, amendments of licenses, and renewals of licenses over a given time

[2]OMB Clearance No. 3150-0120, "Final Supporting Statement for NRC Form 313 Application for Material License and NRC Form 313A Training and Experience and Preceptor Statement."

[3]Department of Labor (U.S.), Bureau of Labor Statistics, Occupational Employment and Wages, May 2004. Standard Occupational Classification (SOC) System Code Number 17-2111 "Health and Safety Engineers, Except Mining Safety Engineers and Inspectors," national hourly mean wage, plus benefits.

period. Some applications are more complex and require more effort to develop. Others may require less time to develop. Because the licensees considered by this proposed change are already Agreement State licensees, the effort to become an NRC licensee is assumed to be minimal; therefore, the generic number provided in the OMB supporting statement was used.

Licensees are required to pay a fee for the application:

$8,000 application fee[4] x 6 applicants — $48,000

E-Distribution Annual Fees:

$11,100 annual fee[5] x 6 licensees = $66,600/year

It is noted that some Agreement States charge fees, while others do not. Therefore, for some licensees, the cost of fees to NRC may be partially offset by fees no longer paid to a State. Also, there are other costs associated with complying with the requirements of an NRC license, but these costs are expected to be essentially the same as currently applicable under Agreement State licenses.

Section 32.12 requires that transfer reports be filed with the NRC. Section 32.12 is currently Compatibility Category C, so reporting requirements may not be identical. However, Agreement State licensees would be expected to be filing transfer reports to their appropriate state government. The proposed rule would not be expected to result in significantly different cost for filing of reports.

Costs to NRC and Agreement States

If there are licensees in Agreement States impacted by this proposed change, the NRC would incur annual costs associated with the review of the E-Distribution license applications, in addition to the review, filing, and retention of reports.

Effort to review the applications:

7 hours/application[6] x $87/hour — $600/application

6 applications x $600/application = $3,600

---

[4]§ 170.31, "Schedule of fees for material licensees and other regulatory services, including inspections, and import and export licenses," Item 3.I (Byproduct Material)

[5]§ 171.16, "Annual Fees: Material Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC," Item 3.I (Byproduct Material)

[6]OMB Clearance No. 3150-0120, "Final Supporting Statement for NRC Form 313 Application for Material License and NRC Form 313A Training and Experience and Preceptor Statement."

As discussed above, the effort to review an application is a generic number that is the average based on all applications reviewed by the NRC from applicants for materials licenses over a given time period. Some applications are more complex and require more effort to review. For the purpose of this analysis, the generic number provided in the OMB supporting statement was used.

The NRC would also incur the cost from this rulemaking process, which is discussed in Section 4.8.

Paragraphs 30.14(c) and 30.14(d) are Compatibility Category B requiring essentially identical wording. Revising §§ 30.14(c) and 30.14(d) would require a comparable change in Agreement State regulations; however, each State would conduct one rulemaking following the planned revision of Parts 30, 31, 32, and 150. The cost for the rulemaking is discussed in Section 4.9.

Costs to the Public:

There are no expected costs to the public from the proposed rulemaking.

Benefits

The benefits of the proposed regulation would be that the NRC could more effectively evaluate the overall impact to the public from exempt distribution by having the necessary information on a national level. Additionally, it would improve the efficiency, and possibly the consistency, of regulation, because one entity, the NRC, would have responsibility for handling exempt distribution licenses for byproduct material. Currently, there are approximately 100 total NRC licenses for distribution of byproduct material to exempt persons, none known amongst all the Agreement States. [Some States have similar requirements governing the distribution of Naturally Occurring and Accelerator-Produced Radioactive Material (NARM), which does not come under the authority of the NRC.] This change would also remove a source of confusion concerning whether an NRC license is required.

4.3 Revise § 30.18 to Preclude Combining Multiple Exempt Quantities

Section 30.18 states that a person is exempt from licensing requirements to the extent that such a person possesses, uses, transfers, owns, or acquires byproduct material in individual quantities, each of which does not exceed the applicable quantity in § 30.71, Schedule B (i.e., an "exempt quantity"). However, there is no restriction as to the total quantity that may be possessed and used at any one time. The exemption in § 30.18 is based, in part, on the safety properties inherent in a single exempt quantity. The radiological assessment in NUREG-1717 shows there is a potential safety hazard if multiple exempt sources (for some radionuclides) are combined and used in a device.

In 1999, the NRC issued Generic Letter 99-01 to notify materials licensees about an Office of Nuclear Material Safety and Safeguards decision concerning combining (bundling) exempt quantities. The NRC stated that it does not authorize: (a) the bundling of exempt quantities of byproduct material; (b) any program advising persons to combine exempt quantity sources; and

(c) the possession and use of bundled exempt sources, in unregistered devices, by persons exempt from licensing. The generic letter also addressed concerns about protection of property, by articulating the preferred labeling and disposal practices. Since that time, the NRC has denied all requests to manufacture and distribute devices that have source holders to accommodate multiple exempt quantity sources, i.e., bundling of exempt quantity sources. Therefore, it is assumed for the purposes of this analysis that since 1999, both manufacturers and distributors and users of exempt devices are in "compliance" with NRC regulations and do not bundle multiple sources for the purpose of use in a device, except in cases previously approved by the NRC. These latter devices were "grandfathered" by the generic letter, subject to the user maintaining control of these devices.

The proposed rule would clarify the regulations in § 30.18 to better ensure that persons will not combine or bundle exempt sources in the future. The proposed rule would also codify the "grandfathering" of those devices placed in use before May 3, 1999.

The added language in the rule would ensure that bundling is prohibited. Although similar information was communicated in a generic letter, generic letters are not enforceable. By amending the regulation, the prohibition against the practice of bundling becomes legally binding and enforceable, which provides the assurance that these practices would not occur. Moreover, a regulation would preclude the need for future follow-up generic letters on the issue.

Cost Impacts:

Costs to Exempt Persons (Users)

Since the issuance of Generic Letter 99-01, it is assumed that licensees and users are complying with the provisions of § 30.18 as interpreted in that notification. In addition, instructions in the generic letter designed to ensure protection of property are assumed to already be adopted by licensees and users of these devices. At least with regard to the manufacture and distribution of unapproved devices designed for the use of bundled exempt quantity sources, it is unlikely that these practices would be ongoing without NRC becoming aware. The proposed rule would clarify that bundling of exempt quantity sources for use in a device used by exempt persons is not permitted. Therefore, there are no expected costs to the users of exempt devices using exempt quantity sources from the proposed rule.

Costs to Licensees (Manufacturers and Distributors)

There are no expected costs to manufacturers and distributors from the proposed rule since they are already required to state on a label or in a brochure "Exempt Quantities Should Not be Combined" and this revision reflects current policy.

Costs to NRC and Agreement States

There are no expected costs to the NRC from the proposed rule, except the cost of rulemaking, which is discussed in Section 4.8.

Section 30.18 is Compatibility Category B requiring essentially identical wording. Revising § 30.18 would require a comparable change in Agreement State regulations;

however, each State would conduct one rulemaking following the planned revision of Parts 30, 31, 32, and 150. The cost for the rulemaking is discussed in Section 4.9.

Costs to the Public

There are no expected costs to the public from the proposed rule.

Benefits:

The NRC and the Agreement States would have regulatory assurance that exempt persons and the public are not being exposed to quantities that could possibly yield a dose in excess of limits contained in policy guidance for exemptions. In addition, as it is preferable not to dispose of devices containing multiple exempt sources through ordinary commercial waste disposal or metal recycling channels because of the presence of radioactive material, this prohibition will ensure that property is protected from inadvertent contamination. The public will benefit from this prohibition due to potentially reduced doses for the device users, and the due consideration of property protection.

4.4 Revise Regulations to Remove Obsolete Provisions

The exemptions in § 30.15 provide for persons to receive, possess, use, transfer, own, or acquire certain products containing byproduct material. Of interest are those products no longer being used or manufactured. The general reason for their obsolescence is because of new technologies that have made the use of radioactive material unnecessary or less cost-effective. Candidate exemptions are: automobile lock illuminators (§ 30.15(a)(2)), balances of precision (§ 30.15(a)(3)), automobile shift quadrants (§ 30.15(a)(4)), marine compasses (§ 30.15(a)(5)), thermostat dials and pointers (§ 30.15(a)(6)), spark gap irradiators (§ 30.15(a)(10)), and resins containing Sc-46 for sand consolidation in oil wells (§ 30.16). The Commission is proposing to delete exemptions for these products or to prohibit further distribution while allowing for the continued possession and use of previously distributed items.

For products no longer being manufactured, but for which some products may remain in use, the proposed rule would prohibit further distribution, i.e., §§ 30.15(a)(3) and (a)(5). For those products believed to never have been distributed or for which it is otherwise unlikely that any remain in use, the proposed rule would remove the provisions, i.e., §§ 30.15(a)(2), (a)(4), (a)(6), and (a)(10).

Section 30.16 contains a provision for synthetic plastic resins containing scandium-46 for sand consolidation in oil wells. Based on preliminary dose estimates not included in NUREG-1717, this is the only one of these exemptions that could result in significant doses. Based on recent information, there is no such resin in use. Therefore, the proposed rule would remove § 30.16.

Part 32 contains regulations specifically for manufacturers and distributors of these products. Therefore, the proposed rule would remove the associated requirements for prototype test procedures in §§ 32.14(d)(2) and 32.40, and the requirements for a license to produce or initially distribute resins containing scandium-46 in § 32.17.

Cost Impacts:

Costs to Licensees (Manufacturers and Distributors)

There are no manufacturers or distributors for these products.

Costs to NRC and Agreement States

The NRC would incur costs from the rulemaking which are discussed in Section 4.8.

Sections 30.15, 30.16, and 32.17 are Compatibility Category B requiring essentially identical wording. Revising §§ 30.15 and 30.16, and removing § 32.17 would require comparable changes in Agreement State regulations; however, each State would conduct one rulemaking following the planned revision of Parts 30, 31, 32 and 150. The cost for the rulemaking is discussed in Section 4.9.

Costs to the Public

There are no expected costs to the public from the proposed rulemaking.

Benefits:

Deleting these unnecessary regulations would simplify the regulations by eliminating extraneous text. This would eliminate the need to reassess the potential exposure of the public from these exemptions for possible future distributions of the products. Also, these exemptions would no longer need to be considered when assessing the total potential doses to the public from multiple sources. There would also be a small reduction of effort in the process of renewing OMB clearance for the reporting and recordkeeping requirements contained in Part 32. In a planned future effort, the NRC is considering making revisions to the requirements for distributors with respect to quality control and sampling, and for applicants for distribution licenses to make them less prescriptive and more risk-informed. In that action, the consideration for such changes would not need to address the requirements being removed in this action. Additionally, there is a potential benefit to the public from the elimination of future exposures. Based on preliminary dose estimates performed for the exemption for resins containing Sc-46 for sand consolidation in oil wells (§ 30.16), potential exposures could be higher than is appropriate for exempt materials. As a result of this proposed action, members of the public would be assured that future exposures would not occur.

4.5 Revise § 30.15 to Add a Product-Specific Exemption for Smoke Detectors

Ionization chamber smoke detectors have been manufactured and used for many years. Users of these smoke detectors currently qualify under an exemption at § 30.20. Specifically, § 30.20 exempts from licensing requirements persons that receive, possess, use, transfer, own, or acquire byproduct material, in gas and aerosol detectors designed to protect life or property from fires. The specific requirements to obtain a license to manufacture, process, produce, or initially transfer gas and aerosol detectors intended for use under § 30.20 are contained in

§ 32.26. Specific conditions of licenses are stated in § 32.29 and include requirements for quality control, labeling, recordkeeping, and reporting of transfers.

The current designs of residential ionization chamber smoke detectors are very consistent, using 0.9 to 1 FCi of americium-241 (Am-241) contained in a foil, surrounded by an ionization chamber. Based on information in NUREG-1717, as well as other documents, the estimated doses under normal, routine conditions are well below the safety criterion for routine use of 5 mrem/year (50 FSv/year), and the associated individual organ limits.

The proposed rule would establish a specific exemption from licensing requirements for ionization chamber smoke detectors. Specifically, § 30.15(a)(7) would be added to create a specific exemption for ionization chamber smoke detectors containing no more than 1 FCi of Am-241 in the form of a foil and designed to protect life and property from fires. Paragraph 32.15(d) would be revised to include more specific labeling requirements for smoke detectors consistent with those currently applicable under the gas and aerosol detector provisions.

The primary difference between this proposed exemption and the existing class exemption is that an applicant for a license to distribute smoke detectors for use under this exemption would not be required to submit dose assessments to demonstrate that doses from the various stages of the life cycle of the product do not exceed certain values. The applicant would still be required to submit basic design information consistent with that required from applicants to distribute products under other product-specific exemptions, specifically for those products used under § 30.15.

The effect of this proposed rule is to reduce the regulatory burden for new applicants for licenses to distribute ionization chamber smoke detectors, including the associated fees, while still providing assurance that the byproduct material is properly contained within the product and will not be released under the most severe conditions encountered in normal use and handling. The fees would be reduced because under current licensing practice, a product-specific exemption does not require a Sealed Source and Device (SS&D) certificate for the product. Although license fees fluctuate, typically the fee for a distributor of a product under a class exemption is higher than for a distributor of a product used under a product-specific exemption.

Costs and benefits are estimated below for 10 existing licensees and 3 new applicants per year (based on a review of licensing action data for FY02 through FY04 for Program Code 3255). It is expected that some existing licensees would seek to change the status of their licenses so that they would no longer have to pay certain annual fees (a significant savings). Also, it is assumed that the NRC would continue to receive new applications at the current rate. However, there is uncertainty in these numbers as they are projections of future voluntary actions. Furthermore, the estimations presented below are for large entities; annual fees are different for small entities.

Cost Impacts:

Costs to Licensees (Manufacturers and Distributors)

> There are no expected costs to licensees from the proposed rule. The proposed rule would 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 in order to reduce their annual fees. As this would be a voluntary expenditure in order to obtain an overall benefit, this expenditure is covered under Benefits to Existing Licensees to estimate a net benefit to existing licensees.

Costs to NRC

From Existing Licensees:

The NRC would incur costs from the review of the license and SS&D certificate amendments that might be submitted by existing licensees. These costs are recovered from the annual fees paid by the licensees. If a significant number of licensees choose to change the status of their product as a result of this proposed change to the regulation, annual fees in the future may be affected; however, such an impact is not estimated in this analysis.

In order to illustrate the potential overall impact of this revision, NRC assumes that 10 current licensees, who are not small entities, amend their license in the first year or two after the rule is effective. The cost for the NRC to review amendments is estimated as follows.

7 hours/amendment[7] x $87/hour x 10 licensees ─ $6,000, a one time cost

From the Rulemaking:

The NRC would incur costs from the rulemaking which are discussed in Section 4.8.

Costs to Agreement States

Section 30.15 is Compatibility Category B requiring essentially identical wording. Adding § 30.15(a)(7) would require a comparable addition to Agreement State regulations; however, each State would conduct one rulemaking following the revision of Parts 30, 31, 32, and 150. The cost for the rulemaking is discussed in Section 4.9. As §§ 32.14 and 32.26 are Compatibility Category NRC, there would be no impact on Agreement State licensing.

Costs to the Public

There are no expected costs to the public from the proposed rulemaking.

[7]OMB Clearance No. 3150-0120, "Final Supporting Statement for NRC Form 313 Application for Material License and NRC Form 313A Training and Experience and Preceptor Statement."

Benefits:

Benefit to New Applicants (Manufacturers and Distributors)

The effect of this change is to reduce the regulatory burden for new applicants to distribute ionization chamber smoke detectors, as well as the associated fees.

For this product-specific exemption, applicants would no longer have to perform a dose assessment as previously required. OMB Supporting Statement 3150-0001 estimates that applicants spend an average of 21 hours preparing the required information for a sealed source and device evaluation. A majority of this time is spent on the dose assessment. For the purpose of this analysis, it is assumed that licensees spend approximately 50 percent of their time on dose assessments. Because a dose assessment would no longer be required, applicants' burden would be reduced by 50 percent (i.e., roughly 11 hours saved). Thus, 11 hours saved at $44/hour[8] for a cost savings of $440/applicant for the development of an application. In addition, the fee associated with a device evaluation ($19,300 in 2005),[9] would no longer be required. A different application fee would also apply. Using FY 2005 fees, the application fee would be $8,000[10] instead of $13,500.[11] This would be a net reduction in application fees of $24,800 for each applicant and a total of $25,240 saved at the time of application once labor costs are accounted for.

These applicants would also have reduced net annual fees as licensees. Because a device evaluation would no longer be required, the proposed change would result in a savings equal to the amount of the annual fee for an active SS&D certificate ($24,600/year in 2005),[12] and a saving in the applicable annual fee. The applicable annual fee would be $11,100 (in 2005).[13] The annual fee for a licensee who distributes

---

[8]Department of Labor (U.S.), Bureau of Labor Statistics, Occupational Employment and Wages, May 2004. Standard Occupational Classification (SOC) System Code Number 17-2111 "Health and Safety Engineers, Except Mining Safety Engineers and Inspectors," national hourly mean wage, plus benefits.

[9]§ 170.31, "Schedule of fees for material licensees and other regulatory services, including inspections, and import and export licenses," Item 9.A (Devices).

[10]§ 170.31, "Schedule of fees for material licensees and other regulatory services, including inspections, and import and export licenses," Item 3.I.

[11]§ 170.31, "Schedule of fees for material licensees and other regulatory services, including inspections, and import and export licenses," Item 3.H.

[12]§ 171.16, "Annual Fees: Material Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC," Item 9.A (Devices).

[13]§ 171.16, "Annual Fees: Material Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC," Item 3.I.

a device that requires a device evaluation is $18,300 (in 2005).[14] Thus, a net reduction in annual fees of $31,800/licensee.

Over the past three fiscal years, the NRC has received eight applications for new licenses to manufacture or distribute smoke detectors.[15] For the purpose of this regulatory analysis, it is assumed that three applications per year would be submitted to the NRC, maintaining the current rate. The annual cost savings to new applicants are estimated to be:

3 applicants/year x 11 hours saved/applicant x $44/hour ─ $1,500

Plus, $24,800 x 3 applicants/year = $74,400

For a total of about $75,900 saved/year by applicants, plus continuing savings as licensees depending on the fluctuation of the applicable fees.

Benefit to Existing Licensees (Manufacturers and Distributors)

Existing licensees would be afforded the flexibility to change the status of their license (i.e., from § 32.26 to § 32.14), allowing their SS&D registration to be made inactive, if they so choose. For those existing licensees choosing to do so, they would no longer have to pay the annual fee for holding a registration certificate ($24,600 in 2005). A change in the regulatory status of the license would also reduce the annual fees. Annual fees are currently $18,300/year[16] but would decrease to $11,100/year[17] under this change. Using 2005 fees, this would be a resultant annual savings of $31,800.

In order to do so, the licensee would have to get an amendment to the certificate and its license. Although there is no fee for these amendments, a licensee would incur costs to prepare the amendment. OMB Supporting Statement 3150-0120 estimates that an applicant/licensee would spend an average of 7 hours to fill out the health and safety portion of an application, and does not differentiate between an application and an

---

[14]§ 171.16, "Annual Fees: Material Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC," Item 3.H.

[15]Number of applications based on review of licensing action data for FY02 through FY04 for Program Code 3255.

[16]§ 171.16, "Annual Fees: Material Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC," Item 3.H (Byproduct Material – Require Device Evaluation)

[17]§ 171.16, "Annual Fees: Material Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC," Item 3.I (Byproduct Material – Do Not Require Device Evaluation)

amendment. For current licensees wishing to distribute their smoke detectors under a product-specific exemption, the amendment process would be mostly administrative in nature. Therefore, it is estimated that it would take licensees a total of 7 hours to prepare and submit both the license amendment request and the device registration certificate amendment request. The licensee's effort is estimated as follows:

7 hours/amendment[18] x $44/hour[19] = $308, a one-time cost

For a rough indication of overall savings to existing licensees:

7 hours/amendment x $44/hour x 10 licensees — $3,000 one-time cost incurred

To obtain an annual savings:
Elimination of an annual fee of $24,600 and a $7,200 decrease in another annual fee for 10 licensees. This would result in a benefit of $318,000 per year for 10 licensees starting roughly one year after promulgation of the final rule; however, these fees would be expected to change from year to year.

Currently there are 27 licensees under § 32.26, most of which distribute smoke detectors. A few of these distributors are small entities. For them, the benefit from changing from a § 32.26 license to a § 32.14 license would be limited to reducing their annual fee either $2,300 or $500 under current licensing policy and the 2005 fee schedule, depending on which size category they fall into, because of inactivating their SS&D certificate. (Fees for small entity categories are provided in § 171.16(c) and size standards are established in § 2.810).

Benefit to NRC

From New Applicants:

A device evaluation would no longer be required; however, the time expended by the NRC staff to review a future license application of this type would increase slightly because the license reviewer would now also have to review and verify certain information about the device that would otherwise be included in the SS&D review. NRC estimates that it currently takes 34 hours for NRC to review such an application. Under this change, the reduction in staff burden is estimated by eliminating the 21-hour effort needed to perform a device evaluation, but increasing NRC effort to review a license application by 6 hours. The net decrease in burden would be 15 hours. NRC would save:

---

[18]OMB Clearance No. 3150-0120, "Final Supporting Statement for NRC Form 313 Application for Material License and NRC Form 313A Training and Experience and Preceptor Statement."

[19]Department of Labor (U.S.), Bureau of Labor Statistics, Occupational Employment and Wages, May 2004. Standard Occupational Classification (SOC) System Code Number 17-2111 "Health and Safety Engineers, Except Mining Safety Engineers and Inspectors," national hourly mean wage, plus benefits.

3 applications/year x 15 hours saved/application x $87/hour ─ $3,900 saved/year

Benefit to Agreement States

There are no benefits to Agreement States because §§ 32.26 and 32.14 are NRC-only provisions.

Benefits to the Public

There are no expected benefits to the public from the proposed rule. Savings experienced by manufacturers and distributors may be passed on to the consumer; however, given the large number of detectors sold, this is not expected to have a significant impact on prices.

4.6 Revise §§ 31.5 and 31.7 to Exempt Some General Licensees from Immediate Notification Requirement in § 20.2201(a)(1)(i)

Currently §§ 31.5(c)(10) and 31.7(b) require that general licensees comply with the provisions of §§ 20.2201 and 20.2202 for reporting the theft or loss of licensed material and radiation incidents, but exempt them from the remainder of the requirements of 10 CFR Parts 19, 20, and 21. In particular, § 20.2201(a)(1)(i) requires that each licensee must notify NRC by phone immediately after its occurrence becomes known to the licensee of any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to Part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas. The licensee must report to NRC by phone within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in Appendix C to Part 20 that is still missing at this time (§ 20.2201(a)(1)(ii)). In addition, a written report is required within 30 days of making the phone call (§ 20.2201(b)).

This proposed rule would exempt general licensees under §§ 31.5 and 31.7 from the requirement in § 20.2201(a)(1)(i) for immediate notification, except with regard to devices meeting the requirements for registration in § 31.5(c)(13)(i). For those devices for which immediate notification is no longer required, the 30-day telephone notification requirement in § 20.2201(a)(1)(ii) would still apply. The proposed devices for which the general licensee would be exempted would be devices containing 1 Ci or more of tritium (mostly exit signs), 1 Ci or more of Kr-85, 10 mCi or more of Pm-147, 0.1 mCi or more of Po-210, and 1 mCi or more of Cd-109, as well as a small number of devices containing a few other radionuclides. The number of devices for which the timing for reporting losses or thefts would be affected by the proposed rule is estimated to be over 500,000. However, only roughly 20 immediate reports of losses and thefts of devices are made by general licensees per year, according to NMED (Nuclear Material Event Reports), the database that includes information on these reports.

The proposed revision would serve to give general licensees more time to report. In the case where a device is found or recovered before the making of the 30-day telephone report, no call or followup written report would be required.

Cost Impacts:

Costs to General Licensees (Users)

There are no expected costs to the general licensees from the proposed rule.

Costs to Specific Licensees (Manufacturers and Distributors)

Those licensed under § 32.51 and equivalent regulations of the Agreement States would have to update the information provided to their customers (i.e., updated copies of § 31.5 and equivalent Agreement State regulations) under § 32.51a(a) and (b). It is assumed that adequate implementation transition time would be allowed by the NRC and the Agreement States. Thus, this change is not expected to cause any incremental cost. Also, this would be a single action, though necessary because of both this issue and the issue discussed in section 4.7 below.

Costs to NRC and Agreement States

The NRC would incur costs from the rulemaking which are discussed in Section 4.8.

Sections 31.5 and 31.7 are Compatibility Category B requiring essentially identical wording. Revising §§ 31.5(c)(10) and 31.7(b) would require a comparable revision to Agreement State regulations; however, each State would conduct one rulemaking following the planned revision of Parts 30, 31, 32, and 150. The cost for the rulemaking is discussed in Section 4.9.

Impacts to Public Health (Accident/Event)

Although timely notification of NRC or the Agreement States is intended to provide an opportunity for taking action to recover devices to prevent unnecessary exposure to radiation as well as prevent sources from ending up in scrap, this revision is not expected to have a negative impact on public health. None of the generally licensed devices present an imminent danger to health and safety. Most are required to meet a safety criterion of no person likely to receive a dose in excess of 15 rem (150 mSv) whole body under severe accident conditions. Reporting for the devices presenting the most significant, though still small, risks are not being revised. Also, generally licensed devices covered by this change do not contain the types and quantities of radioactive material that are considered to be of concern for possible intentional misuse in a radiological dispersion device. The change in notification requirements is not expected to have a significant impact on the recovery of affected lost or stolen devices. Thus, elimination of the requirement for immediate notification for certain lost or stolen generally licensed devices would not impose additional health concerns on the public or affect the environment.

Costs to the Public

There are no expected costs to the public from the proposed rulemaking.

Benefits:

The proposed rule seeks to eliminate the burden associated with immediate notifications commensurate with the associated risk. Approximately 20 immediate reports of losses and thefts per year are made by general licensees (including Agreement State general licensees). This number does not include specific licensee reports concerning devices they possess under a general license, because these reports are identified in the data base by the specific license. It should be noted that the practice of immediate notification is when the licensee becomes aware that the device is missing, often long after the actual loss occurred. General licensees are likely to have different methods for internal audits and inventorying than specific licensees, such that the time before losses are discovered may be longer. As a result, the likelihood of devices being found because of more timely reporting is smaller than for specifically licensed devices.

Two of the most widely distributed devices under § 31.5 are EXIT signs and static eliminators. Many of the 20 annual reports are likely to involve one of these devices. (General licensees that possess devices that are required to be registered are more likely to be the ones reporting losses, even though they represent a smaller fraction of generally licensed devices than those covered by this proposed rule.) Therefore, for the purpose of the regulatory analysis, it is estimated that there would be 12 fewer reports per year required on an immediate basis as a result of the proposed rule (3 by NRC licensees and 9 by Agreement State licensees). Historically, the portion of devices reported lost or stolen in immediate reports and reported found or recovered in 30-day follow-up reports is roughly one third. Thus, in roughly 4 instances per year, neither a telephone call nor written report would be required. In 8 more instances, more time would be provided to make the required reports.

Benefit to Licensees

> Licensees would experience savings for no longer making 4 immediate phone calls and 4 written reports per year, each of which has been estimated to take 3 hours effort.[20] Annual savings are estimated as follows:
>
> 8 reports/year x 3 hours/report x $44/hour[21] — $1,100/year; roughly $300 for NRC and $800 for Agreement States
>
> This does not account for instances where reports are still required, though not immediately. It is considered a further benefit to the licensees to have more time before being required to make a report. It may also be somewhat easier on an ongoing basis for "responsible individuals" (required by § 31.5(c)(12)) not to prepare and maintain plans for immediate reporting capability.

---

[20]OMB Clearance No. 3150-0014, "Final OMB Supporting Statement For 10 CFR Part 20 'Standards for Protection Against Radiation' Revision to Clearance Extension," Table 1.

[21]Department of Labor (U.S.), Bureau of Labor Statistics, Occupational Employment and Wages, May 2004. Standard Occupational Classification (SOC) System Code Number 17-2111 "Health and Safety Engineers, Except Mining Safety Engineers and Inspectors," national hourly mean wage, plus benefits.

Benefit to NRC and Agreement States

NRC and the Agreement States would experience savings as a result of no longer receiving and acting on 4 immediate reports per year and 4 written reports. The annual savings are estimated as follows:

8 reports/year x 3 hours/report[22] x $87/hour ─ $2,100/year

Additionally, the NRC and Agreement States would benefit from not having to a do a resource-intensive response if the device is found/recovered by the licensee within the 30-day window. Follow-up investigations depend heavily on the nature of the incident and resources spent vary widely; therefore, they are not quantified for this analysis.

Benefit to the Public

There is no expected benefit to the public from the proposed rule.

4.7 Revise § 31.5(c)(8) to Clarify General Licensee Transfer to Specific Licensee Status

Following a revision to the general license in § 31.5 that became effective in February 2001, an increased number of specific licensees transferred their authorization to possess and use some devices under the § 31.5 general license to the authority provided by their specific license. This was primarily to avoid paying the new registration fees for some of these devices.

Although there are provisions in the regulations related to the required actions, there has been some confusion as to the applicability of some requirements with respect to the transfer of a device from a general licensee to a specific licensee when the same entity holds both licenses.

Paragraph 31.5(c)(8) specifies acceptable specifically licensed recipients of devices covered by the general license and lays out requirements for the transfer of the devices. For example, it requires that a general licensee report to the NRC transfers of devices to specific licensees. It also requires written approval from the NRC for transfers to any specific licensee not included in § 31.5(c)(8)(i). Thus, the general licensee who wishes to transfer a device to any other specific licensee, even if that licensee is the same entity and the effect is only to transfer to a specifically licensed status, shall obtain approval for the transfer. The Commission can then verify that the specific license authorizes such use, ensure that the licensee is fully aware of its responsibilities under both the general and specific license with respect to the device, and make updates to its tracking system.

The proposed amendment would clarify the required actions for this type of transfer. It would also remove the necessity of obtaining prior written NRC approval under these circumstances. Paragraph 31.5(c)(8)(iii) would be revised to include details concerning the required actions for

[22]OMB Clearance No. 3150-0014, "Final OMB Supporting Statement For 10 CFR Part 20 'Standards for Protection Against Radiation' Revision to Clearance Extension," Table 3.

a specific licensee to transfer a device held under this general license to the authority provided by his specific license. By including these additional details in the regulation, it is not considered necessary for the specific licensee to obtain prior written approval.

Cost Impacts:

Costs to Licensees (Specific Licensees)

There is no cost to the specific licensees wishing to transfer the regulatory status of their generally licensed devices. The actions described in proposed revised § 31.5(c)(8)(iii) are necessary to comply with all current applicable requirements related to both the general license and the specific license.

Costs to Specific Licensees (Manufacturers and Distributors)

Those licensed under § 32.51 and equivalent regulations of the Agreement States would have to update the information provided to their customers (i.e., updated copies of § 31.5 and equivalent Agreement State regulations) under § 32.51a(a) and (b). It is assumed that adequate implementation transition time would be allowed by the NRC and the Agreement States. Thus, this change is not expected to cause any incremental cost. Also, this would be a single action, though necessary because of both this issue and the issue discussed above in section 4.6.

Costs to NRC and Agreement States

The NRC would incur costs from the rulemaking which are discussed in Section 4.8.

Section 31.5 is Compatibility Category B requiring essentially identical wording. Revising § 31.5(c)(8) would require a comparable revision to Agreement State regulations; however, each State would conduct one rulemaking following the planned revision of Parts 30, 31, 32, and 150. The cost for the rulemaking is discussed in Section 4.9.

Costs to the Public

There are no expected costs to the public from the proposed rulemaking.

Benefits:

The proposed rule would remove the necessity of obtaining prior written NRC approval when a specific licensee transfers a generally licensed device to itself such that it would be covered by the provisions of his specific license. As a result, there would be a reduction in burden to the licensees from obtaining approval, and a reduction in burden to the NRC from granting approval. This scenario is not expected to occur frequently. It is assumed that it occurs approximately five times per year.

Benefit to Licensees

Licensees would be relieved of the need to make a request to NRC to transfer the material. Annual savings are estimated as follows:

5 requests/year x 1 hour saved/request x $44/hour[23] ─ $200 saved/year

Additionally, licensees would more easily understand the applicable requirements and procedures and would not need to contact NRC for clarification.

Benefit to NRC and the Agreement States

The NRC and the Agreement States would no longer receive requests from licensees to transfer generally licensed devices under the provisions of their specific license. Therefore, the NRC's burden would be reduced by approximately one hour per request:

5 requests/year x 1 hour/request x $87/hour ─ $400/year

Similarly, Agreement States would experience a small reduction in burden. For the purpose of this analysis, it is assumed that there are three times as many general licensees in Agreement States as in NRC regulated states. Therefore, the reduction in burden for all Agreement States would be approximately three times as much as for the NRC.

Also, there should be a reduction in phone and email inquiries concerning if and how such a transfer can be made and in problems that arise when licensees misinterpret what needs to be done, are not fully aware of their responsibilities, and possibly omit some of the necessary steps such as reporting under § 31.5(c)(8)(ii). The clarification of licensee responsibilities would also make enforcement of these requirements easier.

Benefit to the Public

There are no expected benefits to the public from the proposed rule.

4.8 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

[23]Department of Labor (U.S.), Bureau of Labor Statistics, Occupational Employment and Wages, May 2004. Standard Occupational Classification (SOC) System Code Number 17-2111 "Health and Safety Engineers, Except Mining Safety Engineers and Inspectors," national hourly mean wage, plus benefits.

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 Nuclear Material Safety and Safeguards expended in developing the rule.

The estimated total cost of the rulemaking is 1.3 professional staff years (FTE) and $50,000 in contractor assistance. One NRC professional staff member costs $156,600/FTE. The total cost of development for the NRC is estimated to be approximately $250,000. These are "sunk" costs for developing the proposed rule. Approximately 0.3 FTE remain for the development of the final rule ($47,000).

NRC staff would need to update existing guidance in the NUREG-1556 series related to exempt distribution licensing to reflect the revisions to the regulations. NUREG-1556, Vol. 8 would require minor revisions. Because there is a routine update planned for the NUREGs in this series, there is no cost impact as a result of this proposed rulemaking for implementation.

4.9 Costs to Agreement States of Compatible Regulations

Costs would be incurred by the Agreement States for development and implementation of compatible regulations. The costs would vary significantly by State because of differences in internal procedures for developing regulations. Some rule changes would be required to meet Compatibility Category B for certain revisions. As these need to be essentially word-for-word compatible, the process should be relatively simple for this part. For this proposed rule, the NRC assumes an average of 0.1 FTE at $76,000/FTE for each state. There are currently 33 Agreement States; therefore, the total cost for all Agreement States would be approximately $250,000.

4.10 Quantifiable Costs

Table 4.1 presents the quantified impacts of the proposed rule in current dollars. Numbers in parentheses are negative and represent a net benefit. Accordingly, numbers not in parentheses are positive and represent a net cost. As noted in previous sections, this rule may have significant distributional financial effects on certain categories of licensees. Distributional effects are not included in the table below.

Table 4.1 Quantifiable Costs (Benefits) of Proposed Rule (thousands of $)

Section of RA	Initial (One Time) Costs	Annual Costs
4.1 – Revise Exempt Distribution Reporting Requirements	-	-
4.2 – Change Exempt Concentrations to NRC-Only	6	-
4.3 – Prohibit Combining Exempt Quantities	-	-
4.4 – Remove Obsolete Provisions	-	-
4.5 – Product-Specific Smoke Detector Exemption	9	(5)
4.6 – Exempt Most General Licensees from Immediate Notification	-	(3)
4.7 – Clarify General License to Specific License Transfer	-	(1)
4.8 – NRC Rulemaking Activities	47	-
4.9 – Agreement State Rulemaking Activities	251	-
Total	313	(9)

The net present value of the costs and benefits in Table 4.1 at a discount rate of 3% for a 10-year period is $234,000. The net present value of the costs and benefits in Table 4.1 at a discount rate of 7% per year for a 10-year period is $248,000. As discussed in the decision rationale (Section 5), the quantifiable costs and benefits are a small portion of the overall considerations. For example, the data quality gained from revising exempt distribution reporting requirements (Section 4.1) is impossible to obtain under the current regulatory structure. The limitations of the information about the products/materials and quantities distributed for use under exemption greatly impacted the cost of developing the dose assessments in NUREG-1717 and contributed to the uncertainties in the results.

4.11 Uncertainty

There are a number of uncertainties contained in this regulatory analysis. The costs and benefits, where quantified, are based on an assumed number of licensees or applicants. Some of the numbers were obtained from the review of licensing action data, whereas others are assumptions. When possible, specific data was used. Other costs and benefits are not easily quantifiable, and therefore, are assessed qualitatively. These factors combine to make this regulatory analysis highly uncertain. However, the uncertainty is not so great as to affect the ability to evaluate this rule. Further study of the variability of the unknown factors would not elucidate any valuable insights, and the conclusions presented are not sensitive to the uncertainty itself.

Estimations of efforts to prepare applications, amendments, dose assessments, reports, etc., are based on current OMB supporting statements. Although OMB supporting statements are based on a few years of licensing action data, they represent averages and not best estimates. The licensing action data itself, i.e., hours charge to TAC numbers, may be inaccurate.

The labor rates are based on national mean (average) wage rates published by the Bureau of Labor Statistics, and then adjusted to account for indirect labor costs. This process for estimating labor rates introduces statistical uncertainty, because of the variability of both wages and indirect labor costs. Further uncertainty is introduced due to time lags. The most current set of wage data available from the Bureau of Labor Statistics was published in May 2005, but is based on older data (May 2004). In addition, another time lag exists between the preparation of this regulatory analysis and the effective date of this rule, approximately 2007 - 2008. These factors collectively contribute to uncertainty in estimating the labor rates.

The annual fees and NRC's labor rate change periodically, and although these numbers are accurate at the present time (FY05), they are expected to fluctuate in the future. There is no reliable method to predict NRC's annual fees in advance of their publication each fiscal year, and none is attempted in this document. Because the annual fees are a significant factor in this regulatory analysis and they vary greatly from year to year, it should be recognized that there is considerable uncertainty in the overall analysis.

5 DECISION RATIONALE

The assessment of costs and benefits discussed above, quantitatively when possible and qualitatively otherwise, leads the Commission to the conclusion that the overall impacts of the proposed rulemaking would be assurance of the protection of public health and safety in the future, more effective and efficient licensing of distribution to exempt persons, and a reduction in undue burden to certain general licensees. Currently, some of the regulations are unclear, provide for obsolete activities, or contain unnecessary burden relative to the very small risk associated with a product. Although there are apparent costs associated with some of the amendments, the Commission believes that these costs will be outweighed by those non-quantifiable costs associated with regulatory efficiency and protection of the health and safety of the public. The largest single cost would be to the NRC and to Agreement States from implementation of the proposed rulemaking. However, by handling several issues together, the Commission would minimize its costs as well as costs for the Agreement States.

6 IMPLEMENTATION

NRC's schedule for completion of this rulemaking calls for a final rule to be published in 2006 or 2007. The applicable guidance document, NUREG-1556, Vol. 8, would be revised as part of its routine updating following the issuance of the rule. Revisions are needed for consistency with revisions to the exemptions and associated distributor requirements. No new guidance is needed.

One of the proposed changes would require that persons currently authorized by an Agreement State to introduce byproduct material into a product or material and to transfer ownership or

possession of the product or material containing the byproduct material to persons exempt under § 30.14 or equivalent regulations become NRC licensees. It appears that there are no current Agreement State licensees that would be affected by this change. If any such licensees are identified, the Commission would add transition provisions to allow adequate time for any Agreement State licensees affected by this proposed change to apply for and obtain an NRC license under § 32.11, so that a smooth transition would result without any interference with the conduct of their business.

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

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

7 IMPLICATIONS FOR OTHER FEDERAL AGENCIES

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

8 EFFECT ON SMALL ENTITIES

The proposed rule would not significantly impact small or large entities. The proposed rule would result in a net savings to licensees. The maximum number of licensees impacted by a proposed change is 103, many of which are not small entities. The proposed change for this case is simply limited to a change in reporting requirements (i.e., minimal impact on licensees).

REFERENCES

Code of Federal Regulations, *Title 10, Energy,* Part 20, "Standards for Protection Against Radiation."

Code of Federal Regulations, *Title 10, Energy,* Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."

Code of Federal Regulations, *Title 10, Energy,* Part 31, "General Domestic Licenses for Byproduct Material."

Code of Federal Regulations, *Title 10, Energy,* Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," Subpart A, "Exempt Concentrations and Items."

Code of Federal Regulations, *Title 10, Energy,* Part 150, "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters under Section 274."

Code of Federal Regulations, *Title 10, Energy,* Section 170.31, "Schedule of Fees for Materials Licenses and Other Regulatory Services, Including Inspections, and Import and Export Licenses."

Code of Federal Regulations, *Title 10, Energy,* Section 171.16, "Annual Fees: Materials Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC."

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 2004. <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>.

Executive Office of the President, Office of Management and Budget (OMB). Circular A-76, "Performance of Commercial Activities." May 29, 2003 including technical correction made August 15, 2003.

Executive Office of the President, Office of Management and Budget (OMB). Clearance No. 3150-0001, "Final Supporting Statement for 10 CFR Part 32 "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material."

Executive Office of the President, Office of Management and Budget. OMB Clearance No. 3150-0014, "Final OMB Supporting Statement For 10 CFR Part 20 "Standards for Protection Against Radiation' Revision to Clearance Extension."

Executive Office of the President, Office of Management and Budget (OMB). Clearance No. 3150-0120, “Final Supporting Statement for NRC Form 313 Application for Material License and NRC Form 313A Training and Experience and Preceptor Statement.”

Nuclear Regulatory Commission (U.S.) (NRC). Generic Letter 99-01, “Recent Nuclear Material Safety and Safeguards Decision on Bundling Exempt Quantities.” NRC: Washington, D.C. May 3, 1999.

Nuclear Regulatory Commission (U.S.)(NRC). NUREG-1717, “Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials,” NRC: Washington, D.C. June 2001.

Nuclear Regulatory Commission (U.S.)(NRC). NUREG/BR-0058 Revision 4, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” NRC: Washington, D.C. September 2004.

Nuclear Regulatory Commission (U.S.)(NRC). NUREG/BR-0184, “Regulatory Analysis Technical Evaluation Handbook, Final Report,” NRC: Washington, D.C. January 1997.

Nuclear Regulatory Commission (U.S.)(NRC). NUREG/CR-4627 Revision 1, “Generic Cost Estimates: Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses,” NRC: Washington, D.C. February 1989.

Nuclear Regulatory Commission (U.S.)(NRC). SECY-02-0196, “Recommendations Stemming from the Systematic Assessment of Exemptions from Licensing in 10 CFR Parts 30 and 40; and a Rulemaking Plan for Risk-informing 10 CFR Parts 30, 31, and 32.” NRC: Washington, D.C. November 1, 2002.

Environmental Assessment for Proposed Rulemaking – Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements (10 CFR Parts 30, 31, 32, and 150)

Draft Report

U.S. Nuclear Regulatory Commission

Table of Contents

1.0 Introduction.

The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the use of byproduct material in 10 CFR Parts 30, 31, 32, and 150. These amendments would revise reporting of transfers to persons exempt from licensing, revise reporting requirements of some general licensees, simplify the licensing of smoke detector distribution, remove obsolete provisions, and make some clarifications to the regulations in these parts. These actions are intended to better ensure the protection of public health and safety in the future, make the licensing of distribution to exempt persons more effective and efficient, and reduce unnecessary regulatory burden to certain general licensees. These changes would affect licensees who distribute byproduct material to exempt persons, users of some generally licensed devices, and some exempt persons. The NRC has prepared this environmental assessment (EA) to determine whether the promulgation of this rule will have any significant environmental impact.

1.1 Background.

The Commission's regulations for byproduct material are in Part 30 (in Title 10 of the Code of Federal Regulations), which sets out the basic requirements for licensing of byproduct material and includes a number of exemptions from licensing. These exemptions allow for certain products and materials containing byproduct material to be used without any regulatory requirements imposed on the user. These exemptions are in §§ 30.14, 30.15, 30.16, 30.18, 30.19, 30.20, and 30.21. The two exemptions in §§ 30.19 and 30.20, for 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.

Other parts would be affected by this rulemaking. Part 31 provides general licenses for the use of certain items containing byproduct material and the requirements associated with these general licenses. The general licenses are established in §§ 31.3, 31.5, 31.7, 31.8, 31.10, and 31.11. Part 32 sets out requirements for the manufacture or initial transfer (distribution) of items containing byproduct material to persons exempt from licensing requirements and to persons using a general license. Part 150 provides regulations for all States that have entered into agreements with the Commission in accordance with subsection 274b of the Atomic Energy Act, and would also be amended where relevant to the changes made in Parts 30 and 32.

The NRC has conducted a systematic reevaluation of the exemptions from licensing in Parts 30 and 40 of NRC’s regulations, which govern the use of byproduct and source material. A major part of the effort was an assessment of the potential and likely doses to workers and the public under these exemptions. The assessment of doses associated with most of these exemptions can be found in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Material," June 2001. Also in the past few years, several issues have been identified where improvements could be made to the regulations governing these products. The amendments considered in this document largely stem from this analysis.

1.2 Document Organization.

This EA presents a discussion of the basic subjects specified in 10 CFR 51.30. It is organized to best accommodate the proposed rule's complexity. This complexity is due to the Commission's decision to aggregate multiple issues into this single rulemaking, with the purpose of minimizing the costs of its activities. The proposed rule is therefore best understood and discussed as a collection of autonomous small issues. If taken independently, many of the amendments being proposed meet the criteria for categorical exclusion – as detailed below – and do not require an environmental assessment to be prepared. The amendments not meeting these criteria are discussed issue-by-issue, and are the focus of the environmental assessment.

A discussion of the need for the proposed actions is contained in Section 2.0. The applicability of categorical exclusions to certain amendments is discussed in Section 3.0. For those issues where a categorical exclusion does not apply, a discussion of the proposed actions and their alternatives is presented generically in Section 4.0, and specifically on an issue-by-issue basis in Section 5.0 along with their environmental impacts. The conclusion is in Section 6.0. A list of agencies and persons consulted and an identification of sources used are contained in Sections 7.0 and 8.0, respectively.

2.0 Need for the Proposed Action.

Based on the NRC's review of regulations that govern the licensing, manufacture, use, and disposal requirements for byproduct material as contained in 10 CFR Parts 30, 31, 32, and 150, it was determined that several of its regulations are in need of revision. Internal analyses have identified regulations that can be improved because they are less effective than intended, or unnecessarily burdensome. Additionally, interactions with the licensed community have identified regulations that require additional clarification. Therefore, Federal action is needed to address the need for the NRC to update and clarify certain regulations, improve efficiency in the licensing of material transfer to exempt persons, and relieve licensees of unnecessary reporting requirements. If enacted, changes to these regulations would better ensure the protection of public health and safety in the future and improve the effectiveness and efficiency of certain licensing actions.

3.0 Applicability of Categorical Exclusion for Certain Amendments.

Many of the proposed amendments, if taken independently, belong to a category of actions that the Commission has determined to be a categorical exclusion, having found that these types of actions do not individually or cumulatively have a significant effect on the human environment. Therefore, this EA is not required to evaluate these amendments further.

The categorical exclusion in § 51.22(c)(1) includes amendments to Part 150 as not requiring an environmental assessment.

The categorical exclusion in § 51.22(c)(3) provides that amendments to Parts 30, 31, and 32 that relate to recordkeeping and reporting – paragraphs (ii) and (iii), respectively – do not require an environmental assessment. The proposed amendments that would revise the reporting for material transfers from a 5-year period to annual are therefore covered by this categorical exclusion. Proposed amendments to these affected recordkeeping and reporting requirements are in §§ 32.12, 32.16, 32.20, 32.25(c), and 32.29(c). The proposed amendments that would exempt some general licensees from immediate notification requirements are also covered by this categorical exclusion, specifically the proposed amendments to §§ 31.5(c)(10) and 31.7(b).

The amendment to § 31.5(c)(8) would eliminate a reporting requirement for general licensees who transfer a device from a general to a specific license, and is covered by this categorical exclusion.

4.0 The Proposed Action and Alternatives: Generic Discussion.

Under the proposed action, the NRC would amend certain sections of 10 CFR Parts 30, 31, 32, and 150 by rulemaking in accordance with the Administrative Procedure Act of 1946, as amended. The alternatives to rulemaking would be to take no action, or to take various non-rulemaking actions. Non-rulemaking alternatives include: generic letters, information notices, guidance documents, and direct one-on-one contact with licensees.

Rulemaking is the NRC's preferred alternative because it best resolves the need for action for these issues consistent with the Agency's goals of protecting the public health and safety, increasing regulatory effectiveness, efficiency, and realism, and ensuring openness in the regulatory process. In general for these issues, rulemaking establishes regulations which can be made enforceable; affords opportunity for public involvement; and are readily available to regulators, licensees, and the general public.

For issues inherent in the regulations themselves – such as obsolete provisions – no non-rulemaking alternatives can realistically address the issue. For other issues, there may be realistic non-rulemaking solutions, but these have drawbacks as explained below.

The no-action alternative is to keep the status quo. The no-action alternative would not address identified concerns. Specific details of the implications of the rulemaking, non-rulemaking alternatives, and the no-action alternative are discussed below, issue by issue.

5.0 The Proposed Actions, Alternatives, and Environmental Impacts: Discussion of Specific Issues.

5.1 Revise 10 CFR 30.14 to Make Exempt Concentrations NRC Only.

Section 30.14 provides that any person is exempt from the requirements for a license to the extent that this person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in concentrations not in excess of those listed in § 30.70. Licenses to transfer or introduce byproduct material for commercial distribution in a product or material may be issued by the NRC or one of the more than 30 Agreement States. With respect to exempt products, the ability for an Agreement State to authorize these distributors is relatively unique, whereas the NRC routinely reviews applications for licenses to distribute products containing byproduct material to exempt persons.

The provision allowing Agreement State licensing of products and materials used under the § 30.14 exemption was promulgated with the intent that the States and the NRC would develop a system whereby the NRC would obtain information on distribution and NRC would still be able to track nationwide distribution. No such process has been developed; as a result there is a gap in NRC information on nationwide distribution of exempt products. The no-action alternative would leave this gap in NRC information. Similarly, although non-rulemaking methods could improve communication of information on distribution, there is no other alternative to rulemaking as effective in obtaining data that is complete, comprehensive, and timely. For example, guidance documents could be used to recommend communication methods to be used between the States and the NRC, but the NRC can not enforce compliance with the guidance documents.

The no-action and non-rulemaking alternatives would also not address any potential inconsistencies in licensing approach or confusion caused by this exception to the otherwise NRC-only licensing of byproduct material distribution to exempt persons.

The no-action and non-rulemaking alternatives would continue current licensing practices; licenses for introducing exempt concentrations could be issued by either the NRC or an Agreement State. There is no difference in standards for a license from the NRC or from an Agreement State, licenses from both jurisdictions are essentially equivalent, and all users regardless of location are exempt from licensing.

The proposed action would consolidate, within the NRC, all distributor licensing of byproduct material to exempt persons. Therefore, all information regarding nationwide distribution would be in one place and would be more easily tracked. The existing concentration limits and prohibitions would be retained for these products and materials. Because no changes would be made to any provision that regulates the physical nature of this category of products, the proposed action would not affect any environmental resources.

5.2 Revise 10 CFR 30.18 to Preclude Combining Multiple Exempt Quantities.

Section 30.18 provides an exemption from licensing for a person who receives, possesses, uses, transfers, owns, or acquires byproduct material in individual quantities each of which does not exceed the applicable quantity set forth in § 30.71, Schedule B. The material limits in § 30.71 were established for individual sources. The combining or "bundling" of multiple sources into devices to make use of an increased radiation field was not anticipated in the development of the byproduct material limits. A person wishing to commercially distribute or initially transfer these products containing byproduct material must obtain an exempt distribution license from NRC in accordance with § 32.18. Paragraph (c) of § 32.18 prohibits the distributor from incorporating the exempt byproduct material into any manufactured or assembled commodity, product, or device intended for commercial distribution. Also, a license condition is imposed on the distributor in § 32.19(d)(2) to label the byproduct material to include the words, "Exempt Quantities Should Not Be Combined." However, there is no provision in § 30.18 to explicitly prohibit the user from combining multiple exempt quantities.

The NRC staff determined that the bundling of exempt quantities is "inconsistent with existing regulations" (NRC Generic Letter 99-01: Recent Nuclear Material Safety and Safeguards Decision on Bundling Exempt Quantities, May 3, 1999). The letter indicated that the NRC would consider rulemaking to clarify the regulatory status of combined exempt quantities and to assure the protection of the public health and safety with consideration of property protection. Because the generic letter has already been issued, and the users are exempt from licensing, there is no realistic non-rulemaking alternative available for this issue. The no-action alternative would be to continue to rely on the generic letter to communicate the NRC's position on this issue. However, generic letters are not binding or enforceable for non-licensees and may be less effective over time.

The proposed rule would clarify the regulations in § 30.18 to better ensure that persons will not combine or bundle exempt sources in the future. To the NRC's knowledge, no person exempt from licensing has combined multiple exempt quantities in devices for purposes of creating an increased radiation level since the issuance of the generic letter in 1999. The proposed action would prevent the past practice of bundling from recurring. It would provide better assurance that devices with bundled sources, equivalent to larger quantity sources than permitted under the exemption, would not be created and ultimately disposed of in landfills and metals recycling

waste streams. The prohibition of bundling would therefore be protective of the environment, but without a significant change to current practices. There would be no environmental impact from the proposed action compared to the no-action alternative and the proposed rule is not likely to affect any environmental resources.

5.3 Revise 10 CFR 30.15 and 30.16 to Remove Obsolete Provisions.

The existing § 30.15 establishes an exemption from licensing for many products containing byproduct material. The specific provisions of § 30.15 evaluated in this document are: § 30.15(a)(2) – automobile lock illuminators, § 30.15(a)(3) – balances of precision, § 30.15(a)(4) – automobile shift quadrants, § 30.15(a)(5) – marine compasses and other marine navigational instruments, § 30.15(a)(6) – thermostat dials and pointers, and § 30.15(a)(10) – spark gap irradiators. The existing § 30.16 establishes an exemption from licensing for resins containing scandium-46 and designed for sand-consolidation in oil wells. These provisions are for products that have never been used, are no longer being used, or are no longer being manufactured.

NRC's proposed action is to delete exemptions and distributor requirements for the above products. No non-rulemaking alternatives can feasibly attain this purpose. The proposed action is not intended to change the regulatory status of any products previously distributed in conformance with the provisions of the regulations applicable at the time. Therefore, the proposed rule would retain the exemptions for balances of precision and marine compasses and other navigational instruments, but the exemption would be constrained to products that were distributed before the effective date of the final rule.

All other obsolete exemptions considered in this rulemaking would be eliminated in full. Although thermostat dials or pointers, spark gap irradiators, and resins containing Sc-46 for sand consolidation in oil wells have been distributed in the past, their distribution ceased so long ago that it is highly unlikely that any are still being used. These products are no longer in use because their function have been replaced by other products due to external factors such as economic considerations or technical advances, making their fulture use unlikely. Automobile lock illuminators and automobile shift quadrants were never distributed commercially. A regulatory exemption was pursued for these products before a market could be developed; none ever materialized.

Because the exemptions that would be removed by this action are obsolete, and in all cases no products are currently being distributed, the only notable distinction between the no-action alternative and the proposed rulemaking is that the latter would prohibit future distribution without NRC reevaluation. However, future distribution is unlikely in the no-action alternative because the products are outmoded. Therefore, it is unlikely that the proposed rulemaking would affect any environmental resources.

5.4 Revise 10 CFR 30.15 to Add a Product-Specific Exemption for Residential Smoke Detectors.

The existing § 30.20 provides an exemption from licensing for a person to receive, possess, use, transfer, own, or acquire a gas and aerosol detector. One of the most widely distributed consumer products containing byproduct material, currently used under this class exemption, is the ionization chamber smoke detector. These products have been used for residential fire protection purposes for many years and have demonstrated through extensive licensing experience that they meet adequate design and safety criteria. The vast majority of U.S. homes

have one or more ionization chamber smoke detectors, and the total number in use is most likely to be considerably more than 100 million (NUREG-1717, pp. 2-217).

Under the no-action alternative, the requirements for a specific license to initially transfer, manufacture, process, or produce smoke detectors, as well as other gas and aerosol detectors containing byproduct material used under § 30.20, are located in § 32.26. New applicants must demonstrate that their device meets the safety requirements of §§ 32.26, 32.27, and 32.28. Once a license is issued, all manufacturing must be done in accordance with § 32.29. Because this issue has no realistic non-rulemaking alternative, the no-action alternative is the only alternative to rulemaking.

Under the proposed action, NRC would establish a product-specific exemption under § 30.15(a)(7) for ionization chamber smoke detectors that contain no more than 1 microcurie (μCi)(37 kBq) of americium-241 (Am-241) in the form of a foil. New applicants seeking to manufacture or initially distribute these devices under § 30.15(a)(7) would have to meet the application requirements of § 32.14. Once the application requirements have been met and a license issued, all manufacturing must be done in accordance with the requirements of § 32.15. Under the proposed action, the current regulatory structure remains for the class of gas and aerosol detectors: smoke detector licensees/applicants may choose for their product to be distributed for use under either the class exemption in § 30.20 or the product-specific exemption under § 30.15(a)(7).

For the purposes of assessing environmental impact, the primary difference between the two regulatory schemes would be regarding new applicants. Under the proposed amendment, new applicants would not be required to submit dose assessments as part of the application process. These dose assessments are intended to demonstrate the doses that result during various life stages of the product do not exceed certain values. This has been thoroughly evaluated in NUREG/CR-1156, “Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am-241,” November 1979, and in NUREG-1717, “Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials,” June 2001. The applicant would still be required to submit basic device design information for the product consistent with product-specific distribution regulations under § 32.14 (which are similar to § 32.26). Specific requirements applicable to the licensed distributor are similar to § 32.29 and are contained in § 32.15. However, the labeling requirements for smoke detectors under the current regulation are more specific than those in § 32.15(d). In order that the more specific labeling requirement be retained, essentially the same details would be added to § 32.15(d) for ionization chamber smoke detectors. The proposed action is unlikely to have any effect on the design of the device compared to the no-action alternative.

The proposed action is not expected to result in any significant changes in the number of ionization chamber smoke detectors on the market. Because the dose assessment and its review would not be performed, a new applicant under the proposed rule would have a lower regulatory burden. However, given the very large number of smoke detectors distributed annually, the difference in regulatory cost per unit between the current and proposed regulations is negligible, and therefore unlikely to appreciably affect the number of smoke detectors on the market.

There is no identifiable environmental impact from the proposed action compared to the no-action alternative. Therefore, the proposed rule is not likely to affect any environmental resources.

6.0 Conclusion.

The NRC is proposing to amend its regulations governing the use of byproduct material in 10 CFR Parts 30, 31, 32, and 150. This document was prepared so that environmental impacts would be considered as part of the decision-making process. This assessment discusses the impacts of the proposed rulemaking under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51. Many of the individual amendments being proposed belong to a category of actions which the Commission, by §§ 51.22(c)(1) and 51.22(c)(3)(ii) and (iii), has declared to be a categorical exclusion and found that it is not possible for these types of actions to individually or cumulatively have a significant effect on the human environment. The other proposed amendments in this overall rulemaking would not affect any environmental resources, and therefore this rulemaking does not warrant the preparation of an environmental impact statement. Accordingly and appropriately, a finding of no significant impact (FONSI) will be published in the *Federal Register* concurrently with the publication of the proposed rule for public comment.

7.0 List of Agencies and Persons Consulted.

The NRC staff has determined that the proposed action is not a type of activity that has potential to cause effects on historic properties because it is a procedural action. Therefore, no further consultation is required under Section 106 of the National Historic Preservation Act. Additionally, the NRC staff has determined that Section 7 consultation with the U.S. Fish and Wildlife Service is not required because the proposed action is procedural in nature and will not affect listed species or critical habitat.

8.0 Sources Cited.

Code of Federal Regulations, Title 10, Energy, Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."

Code of Federal Regulations, Title 10, Energy, Part 31, "General Domestic Licenses for Byproduct Material."

Code of Federal Regulations, Title 10, Energy, Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," Subpart A, "Exempt Concentrations and Items."

Code of Federal Regulations, Title 10, Energy, Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," Subpart A, "National Environmental Policy Act – Regulations Implementing Section 102(2)."

Atomic Energy Commission (U.S.) (AEC). Washington, D.C., "Use of Byproduct Material and Source Material, Products Intended for Use by General Public (Consumer Products)." *Federal Register*: Vol. 30, No. 50, pp. 3462–3463. March 16, 1965.

Nuclear Regulatory Commission (U.S.) (NRC). NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," NRC: Washington, D.C. June 2001.

Nuclear Regulatory Commission (U.S.) (NRC). NUREG/CR-1156, "Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am-241," November 1979.