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

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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, some 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~~,~~ and to 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.