Draft Environmental Assessment for Proposed Rulemaking – Requirements for Distribution of Byproduct Material: (10 CFR Parts 30, 31, 32, 40, and 70)

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

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1.0 Introduction

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the use of byproduct material in 10 CFR Parts 30, 31, 32, 40, and 70. These amendments would make the requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up-to-date. The Commission is also proposing to improve safety criteria for approving products through licensing actions, redefine categories of devices to be used under exemptions, add explicit provisions for the use of the sealed source and device registration process, and add flexibility to the licensing of users of sealed sources and devices. This action is primarily intended to make licensing processes more efficient and effective. It is also intended to improve assurance that appropriate quantities of radionuclides are approved for use under the general license and under exemptions from license. 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 the domestic 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, 30.18, 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 concentrations and quantities are contained in tables in §§ 30.70 and 30.71, 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 of the Commission’s regulations in Title 10 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, 31.11, and 31.12. Part 32 sets out requirements for the manufacture or initial transfer (distribution) of items containing byproduct material to persons exempt from licensing requirements and to persons using a general license.

The NRC 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 EA to be prepared. The amendments not meeting these criteria are discussed issue-by-issue, and are the focus of the EA.

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, and 32, 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 to licensees. 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. Parts 40 and 70 of the Commission's regulations would contain minor conforming amendments.

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)(3)(i) provides that amendments to Parts 30, 31, and 32 that relate to procedures for filing and reviewing applications for licenses or other forms of permission do not require an environmental assessment. Paragraph 51.22(c)(3)(iii) provides a categorical exclusion for amendments to Parts 30, 31, 32, 40, and 70 that relate to reporting. Paragraph 51.22(c)(2) provides a categorical exclusion for amendments which are corrective or of a minor or non-policy nature. Thus, such amendments do not require an EA. The proposed amendments related to when a registration certificate is issued in addition to a license to provide the authority for distribution of a sealed source or device and whether and how such certificates should be amended, revoked, reviewed, or inactivated fall into the categorical exclusion in

§ 51.22(c)(3)(i). The proposed revisions to §§ 30.6, 32.56, 40.5, and 70.5 fall under the categorical exclusion in § 51.22(c)(3)(iii). Proposed revisions to §§ 31.23, 32.1, 32.8, 32.59, and 32.303 fall under the categorical exclusion in § 51.22(c)(2), as do renaming Subparts C and D of Part 32 and moving §§ 32.72 and 32.74 to a different subpart.

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, 40, and 70 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 ensuring adequate protection of public health and safety and the environment and adequate protection in the secure use and management of radioactive materials, as well as its objectives of effectiveness and 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 overly prescriptive 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 Revisions to § 30.32(g) for Sources and Devices Not Registered by the Manufacturer or Distributor or Not Identified by the User

The proposed rule would provide flexibility in the licensing of sealed sources and devices. Sealed sources and devices present relatively limited potential for leading to any releases to the environment. The attribute most likely to be affected by these changes would be occupational exposure. As discussed briefly below, the limited changes being made in this section are unlikely to have a significant effect.

The provision in § 30.32(g)(3) provides for substituting some categories of information with other information to demonstrate the sealed source or device meets the same safety standard. This rule would extend this provision to materials covered by Part 30 prior to the final rule published October 1, 2007 (72 FR 55863).

The provision in § 30.32(g)(4) allows for the use of small calibration and reference sources for which a registration certificate has not been issued to the manufacturer or distributor without detailed safety information being submitted by the applicant. There are basic requirements

applicable to all specific licensees, such that any specific licensee should be capable of using these calibration and reference sources safely. Requiring detailed safety information from the user for such sources is unlikely to have a significant effect on occupational safety.

The provision in § 30.32(g)(5) also provides flexibility to licensing the use of sealed sources and devices by allowing for constraints on the number and type of sealed sources and devices and the conditions under which they will be used to provide the basis for licensing the user in lieu of identifying each specific sealed source and device to be used. This provision is also not expected to significantly affect occupational doses for workers at licensed facilities, or any other environmental factors.

There are no reasonable alternatives to amending the regulations to add such flexibility. There is not a significant environmental impact from the preferred action compared to the no-action alternative and this aspect of the rulemaking is not likely to affect any environmental resources.

5.2 Establish a New Class Exemption for Certain Industrial Products

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

§ 32.30 would be created to establish distributor requirements for exempt industrial devices.
§ 32.31 would be created to establish new safety criteria.
§ 32.32 would be created to establish the specific conditions of the license issued under § 32.30.

The creation of §§ 32.30, 32.31, and 32.32 would establish the requirements for manufacturers and distributors of certain industrial devices to be used under the new exemption.

Of the various revisions in this proposed rule, this provision has the most potential for producing environmental impacts. Creating an exemption from licensing results in products being released from any further regulatory control. This results in these products being disposed of without regard to radioactivity. While many devices of the types likely to be distributed under this exemption are currently being used under the general license in § 31.5 (and equivalent Agreement State provisions), these are required to be disposed of as low level radioactive waste (and usually, though not uniformly are). Also, providing an exemption from licensing is likely to significantly increase the number of these types of devices distributed in the future. The ultimate disposal of these devices is the most significant factor in evaluating the environmental impacts of this action.

The limitation of this exemption to industrial products unlikely to be routinely used in the home and the provisions in §§ 32.30, 32.31, and 32.32 are key to whether the resulting environmental impacts could be significant. The proposed requirements to approve a device for use under the proposed exemption include the analysis of numerous scenarios through which exposures are expected to occur. These include those expected in various routine situations, as well as accident scenarios. Each of the criteria related to these scenarios limits the potential for significant risks from some aspect of the marketing, distribution, installation, use, servicing and disposal of the devices. Of particular importance with regard to environmental considerations

are: (1) the requirement that it is unlikely that the dose to a suitable sample of the group of individuals expected to be most highly exposed from disposal of the quantities of products likely to accumulate in the same disposal site will exceed 10 μSv (1 mrem) in any one year; (2) the limitation of quantity allowed to be in any device to no more than 10^{-4} times the Category 2 limit in Appendix E of Part 20 (related to the International Atomic Energy Agency (IAEA) categorization of sources of radionuclides of concern); (3) the requirement that certain doses would not be exceeded in specified misuse scenarios involving the unshielded source.

With respect to the first of these, the total quantity expected to be distributed annually must be provided and this would be considered in the projection of the total number of devices likely to accumulate in a single landfill, municipal incinerator, or, if applicable, recycling center. This limit is very low because persons exposed to radioactive material through disposal scenarios are exposed to all materials which end up in ordinary trash. The intent is that the combined effect of the disposal of all materials exempt from regulatory control will not result in exposures to persons, such as waste collectors and waste workers at municipal incinerators, of more than 1 mSv (100 mrem)/year. It is also intended to control exposures to others such as people who may live at the site of a closed landfill in the future; however, waste collectors or waste workers are typically the most exposed population as a result of uncontrolled disposal.

The proposed limit noted in item (2) above is to provide added assurance that quantities of byproduct material in exempt devices would not provide a realistic source of radioactive material for persons with malicious purposes.

The misuse scenario in item (3) above is intended to essentially limit the quantity of any radionuclide which could be in any device, regardless of any shielding and containment designed to limit the exposures from the source in the device. This has a number of intended benefits including minimizing impacts to the environment.

In addition to the specific provisions being proposed with this new exemption, there are a number of other factors which contribute to the conclusion that adding this exemption would not lead to significant impacts to the environment. The Commission has a consumer product policy which calls for the Commission to monitor the overall impact of its exemptions from licensing. The Commission evaluated the potential exposure impacts from consumer products in the early ’60’s, again in the late ‘70’s, and more broadly of all of its exemptions in the ‘90’s. The second of these analyses was published as NUREG/CR-1775, “Environmental Assessment of Consumer Products Containing Radioactive Material,” in 1980. As noted in the Background section of this document, the dose assessments from the latest of these evaluations were published as NUREG-1717 in 2001. NUREG-1717 also includes dose assessments for some devices which are likely candidates for being approved for use under this new class exemption; these assessments estimated exposures from these devices if they were used under an exemption from license.

Related to the consumer product policy, the Commission has reporting requirements for the distribution of byproduct material nationally, through which it can monitor the amount of byproduct material distributed under the exemptions from licensing, which will ultimately be disposed as ordinary trash. Although currently there are no equivalent reporting requirements for the distribution of source material, the Commission has obtained more limited information on the types and quantities of source material being distributed for use under exemptions as input for these types of evaluations.

The intent of this monitoring of distribution is to be able to ensure that members of the public are unlikely to be routinely exposed to more than 1 mSv (100 mrem)/year from the net effect of various sources of materials released from regulatory control. The Commission's policy (March 16, 1965; 30 FR 3462) is for consumer products to routinely expose users to only a small fraction of this limit such that the net effect of multiple exempt products should still be a fraction of the public dose limit, so that those who live on decommissioned sites or are exposed to effluents from licensed facilities are still unlikely to be routinely exposed to more than 1 mSv (100 mrem)/year. The proposed dose criterion for routine use conditions is 200 μSv (20 mrem)/year; however, this exemption, unlike most of the Commission's exemptions, is limited to industrial devices, not including commonly used consumer products.

The conclusion of each of the evaluations of the overall effects of the Commission's exemptions was that the Commission's policy on consumer products has been adequate to maintain routine exposures from exempt products to a fraction of the public dose limit. (That limit was 500 mrem (5 mSv)/year at the time of the first two evaluations.)

The results of the systematic assessment of exemptions, of which NUREG-1717 was a part, showed that many of the earlier established exemptions had declined in use or become completely obsolete. For a number of the source material exemptions, non-radioactive lanthanum has been replacing thorium in large part. These exemptions for thorium-containing products were relatively large contributors to the exposures of the public (in some cases occupationally exposed populations) at one time. Although some products, such as smoke detectors are currently distributed in the millions per year, for many exemptions, there has been a downward trend in distribution. Also, in a recent final rule published October 16, 2007 (72 FR 58473), several obsolete exemptions were removed further assuring that the covered products will no longer be distributed. In that rule, the Commission also improved the reporting requirements in Part 32 in order to improve the ability of the Commission to ensure compliance with the constraints in the exemptions and with the conditions of the license and to see trends in the future. Therefore, the Commission has enhanced its ability to ensure that the net effects of products distributed for use without regulatory control are consistent with the intent of the Commission's consumer product policy.

There are no viable alternatives to rulemaking to establish a broadly applicable exemption from licensing. The conclusion of the Commission is that this new class exemption, if established with the additional provisions noted here, would not result in significant potential for leading to inappropriate exposures to members of the public from the net effect of materials released from regulatory control, and is unlikely to significantly affect other environmental resources.

5.3 Revise the Safety Criteria for the Existing Class Exemptions

The safety criteria for the current class exemptions are based on outdated dose calculation methodology, are limited to addressing the dose from a single unit in the case of disposal, and, in the case of the criteria for gas and aerosol detectors, § 32.26, 32.27, and 32.28 do not adequately control the maximum quantities of byproduct material that could be contained in a detector approved for use under the exemption in § 30.20 (and equivalent Agreement State provisions). The regulations governing the approval of products for use under the class exemption (in § 30.19 and equivalent Agreement State provisions) for self-luminous products

are in §§ 32.22, 32.23, and 32.24. The proposed changes would apply to new products approved in the future under these provisions.

The following revisions are proposed:
Revise definition of "*dose commitment*" in § 32.2.
Revise § 32.23 by removing organ dose limits and terminology derived from International Commission on Radiological Protection (ICRP) 2 dose limitation methodology, combining criteria in columns I and II of the existing table in § 32.24, changing the negligible probability accident criterion, and requiring consideration of the likely number of units present for all scenarios.
Remove § 32.24, as a table is not needed for the simplified approach to § 32.23.
Revise § 32.26 to add a specific quantity limit related to radionuclides of concern.
Revise § 32.27 by removing organ dose limits (except for skin from misuse) and terminology derived from ICRP-2 dose limitation methodology; changing the negligible probability accident criterion; adding a misuse criterion with a specified scenario, and requiring consideration of the likely number of units present for all scenarios.
Remove § 32.28, as a table is not needed for the simplified approach to § 32.27.

Removing some of the individual organ limits would be somewhat less restrictive than the current criteria, but other changes would be more restrictive. In particular, the applicant would now have to estimate the potential doses resulting from disposal of its products to be used under § 30.20 to show that it is unlikely that the dose to a suitable sample of the group of individuals expected to be most highly exposed from disposal of the quantities of units likely to accumulate in the same disposal site will exceed 50 μSv (5 mrem) in any one year. The existing requirement contains a 5 mrem/year dose criterion (with additional organ dose limits) but it applies only to the disposal of a single unit. In addition, a provision to evaluate certain misuse scenarios involving the unshielded source and show that certain exposure limits would not be exceeded is also intended to control the quantity of byproduct material that may be contained in a detector approved for use under § 30.20. In the proposed revision to § 32.23, the disposal criterion of 10 μSv (1 mrem)/year would also now apply to disposal of the quantities of units likely to accumulate in the same disposal site rather than disposal of a single unit.

Overall these changes are expected to be more restrictive as to the quantities of materials that could be approved for use in a detector to be used under §§ 30.19 and 30.20 (and equivalent Agreement State regulations) without unduly limiting the development of new products in the future that may provide significant benefits to the public. These revisions are therefore protective of the environment, but do not result in a significant change to current practices. There is no environmental impact from the preferred action compared to the no-action alternative and this aspect of the rulemaking is not likely to affect any environmental resources.

5.4 Remove Unnecessary Limitations from the Class Exemption for Gas and Aerosol Detectors

The exemption in § 30.20 and equivalent Agreement State regulations provide for persons without a license to receive, possess, use, transfer, own, or acquire byproduct material, in gas and aerosol detectors *designed to protect life or property from fires and airborne hazards*, provided that the detectors are manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.26. Products similar to those allowed under this exemption, but not quite fitting the "class" cannot be approved under this exemption.

One example is drug detectors, which were rejected for distribution under this exemption because they were not "designed to protect life or property from fires and airborne hazards."

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

As discussed under Section 5.3, the safety criteria for this exemption are also being revised. Although a wider class of products would be covered by the exemption, potentially leading to increased numbers of products being distributed under this provision in the future, and ultimately disposed without regard to radioactivity, the revisions to §§ 32.26 and 32.27 should provide improved assurance that the quantities of byproduct material distributed for use under this exemption (and equivalent Agreement State provisions) will be adequately controlled.

The additional considerations discussed under Section 5.2 concerning the Commission's consumer product policy, the evaluations of the overall impact of distribution of products for use under exemptions from licensing, and the fact that distribution under many other exemptions has declined are also applicable to considering the impacts of the potential increase in the types of products being approved for use under § 30.20 and equivalent Agreement State regulations.

The conclusion of the Commission is that expanding the scope of this exemption, while also adding the provisions discussed under 5.3, would not significantly increase the potential for inappropriate exposures to members of the public from the net effect of materials released from regulatory control, would not significantly increase occupational or public exposures, and is unlikely to significantly affect other environmental resources.

5.5 Revise the Safety Criteria for Devices to be Used under the General License in § 31.5 (and equivalent provisions of the Agreement States)

The requirements for a license to manufacture or initially transfer devices containing byproduct material to persons generally licensed under § 31.5 and equivalent Agreement State regulations are established in § 32.51. This proposal would amend § 32.51 to make the safety criteria simpler, allow for the use of more up-to-date dose calculation methodology, reduce the dose criterion for untrained workers, and limit the quantities of radionuclides of concern that can be obtained from § 32.51 licensees (and Agreement State equivalent licensees) in devices approved in the future.

This proposal would revise the safety criteria to reduce the routine dose limit to 1 mSv (100 mrem)/yr and the accident criterion to 100 mSv (10 rem); add an explicit requirement to consider multiple devices; add a specific quantity limit related to radionuclides of concern; and remove references to § 32.24 and § 20.1201(a). These changes are for approvals of new products for future distribution to § 31.5 general licensees and those under equivalent regulations of the Agreement States.

A quantity limit similar to the one proposed here for future approvals is being considered separately by the Commission for direct application in § 31.5. If that provision is not enacted, or a less restrictive provision is made effective, the proposed limitation on quantity in § 32.26 would specifically control quantities of "radionuclides of concern" in devices approved in the future.

The most significant change in these revised provisions is the reduction to the standard for acceptable dose for use of devices under the general license in § 31.5 (and equivalent Agreement State provisions). This would affect both occupational and public doses from devices approved under the revised regulation.

While these devices are required to be returned to a vendor or transferred to a waste broker and ultimately disposed as radioactive waste, it is believed that there is less compliance with disposal requirements for devices used under general license than for those used under specific license, i.e., a larger fraction of general licensees than specific licensees are projected to dispose of devices improperly. Thus, improvements to reduce quantities or exposure rates from generally licensed devices may result in a small reduction to the environmental effects of improper disposal.

This aspect of the proposed rule is therefore protective of the environment. There are no non-rulemaking alternatives to accomplish this result. There is no environmental impact from the preferred action compared to the no-action alternative and the rulemaking is not likely to affect any other environmental resources.

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

This proposal would be to replace the general license in § 31.3 with an exemption from licensing in § 30.15(a)(2). As a result, there would be clear requirements in the regulations for any applicant to distribute such products in the future (under §§ 32.14, 32.15, and 32.16). The products are consumer products and have essentially been regulated in the past as if they were exempt from regulation.

Although this is also adding a new exemption to the regulations, these products have been distributed essentially without further regulatory control for use under the general license in § 31.3 (and equivalent Agreement State provisions). The only difference is that there are, in fact, some regulatory requirements applicable to any general license and thus more readily available recourses available to NRC with use under a general license; however, given that no mechanism exists in the regulations to directly identify users of products under this general license, the difference in regulatory status of the products presents little practical difference in the level of control. The potential doses from the use of the covered products under exemption from licensing have been estimated to be very low; dose estimates for some of these products are also presented in NUREG-1717. The important aspect under the existing provisions and under the proposed action is the licensing requirements placed on the distributor. The requirements would remain essentially the same as in current practice, but would be explicit to ensure consistency. Achieving this noted benefit cannot be accomplished under any non-rulemaking alternative.

There is no environmental impact from the preferred action compared to the no-action alternative and the rulemaking is not likely to affect any environmental resources.

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

The requirements for manufacturers of exempt and generally licensed products are in some cases very prescriptive, particularly in the areas of prototype testing and quality control requirements. The regulations would be made less prescriptive, but continue to contain general requirements and provide standards by which performance may be judged rather than specifying details of procedures that must be followed (except for the specific requirements being removed in connection with the risk-informing issue discussed in section 5.8 of this document). Regulatory guidance would be provided on acceptable approaches to meeting the requirements. It may also be possible to allow licensees to submit assurance programs that verify product integrity in lieu of specific quality control procedures.

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

The following revisions are proposed:
Revise § 32.15(a), (b), and (c) to remove specific procedures.
Revise § 32.53(b)(5) to remove the reference to § 32.55.
Revise § 32.53(d)(4) to remove reference to § 32.101 and add § 32.53(e) to add prototype testing requirement without details of procedures to be followed.
Revise § 32.55 to remove specified acceptance sampling procedures and revise the acceptance criterion.
Revise § 32.57(d)(2) to remove reference to § 32.102 and add § 32.57(e) to add prototype testing requirement without details of procedures to be followed.
Revise § 32.59 for clarification.
Revise § 32.61(e)(4) to remove reference to § 32.103 and add § 32.61(f) to add prototype testing requirement without details of procedures to be followed.
Revise § 32.62(c), (d), and (e) to revise and clarify quality assurance requirements and revise the acceptance criterion.
Remove § 32.101.
Remove § 32.102.
Remove § 32.103.
Remove § 32.110.

These revisions would primarily remove details of procedures to be followed from the regulations. The standards for acceptance sampling would also be revised to reduce the number of defective units likely to be distributed for use under the product-specific exemptions in § 30.15 and some of the general licenses in Part 31 (and equivalent Agreement State regulations). Oversight of how licensees conduct these procedures, however, may be completely removed in the case of some of the products covered by § 30.15 as discussed in the following section.

No impacts to environmental resources would be expected from taking a more performance-based approach for exercising oversight over these procedures.

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

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

Prototype tests:
In this rule, the NRC proposes to revise Part 32 requirements for prototype tests for exempt products to be more risk-informed by eliminating some of the individual requirements. These requirements are in § 32.14(b)(4) and relate to the product-specific exemptions under § 30.15 (and equivalent regulations of the Agreement States). This proposal would revise § 32.14(b)(4) to make exceptions to prototype testing requirements.

Quality Control:
Existing requirements for distributors of byproduct material to exempt persons include specified sampling procedures (§§ 32.15(a)(2) and (3), and 32.110) and submittal of quality control procedures (§§ 32.14(b)(5)). These are requirements related to the product-specific exemptions under § 30.15 (and equivalent regulations of the Agreement States). This proposal would eliminate individual requirements if not justified, based on risk, by revising § 32.14 (b)(5) to make exceptions to requirements to submit quality control procedures for review, and § 32.15, to accommodate the exceptions made in § 32.14(b)(5).

Removing oversight of prototype testing could have negative effects on the quality of product designs. Removing oversight of quality control could have negative effects on manufacturing quality, i.e., a larger number of items distributed for use under these exemptions may not be manufactured exactly as designed. However, the Commission has evaluated the inherent risk of these products and how much this risk could change if adequate prototype testing is not performed or an appropriate level of quality assurance/quality control is not used by the manufacturer. The Commission has concluded that the potential increase in doses to the public are very small, usually less than 10 μSv (1 mrem)/year, even if removing oversight results in significant changes to the conduct of manufacturers in these areas. No other environmental resources are expected to be affected by this aspect of the proposed rule.

6.0 Conclusion

The NRC is proposing to amend its regulations governing the use of byproduct material in 10 CFR Parts 30, 31, 32, 40, and 70. 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)(2) and 51.22(c)(3)(i) 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 significantly 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. 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 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."

Code of Federal Regulations, Title 10, Energy, Part 40, "Domestic Licensing of Source Material."

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)."

Code of Federal Regulations, Title 10, Energy, Part 70, "Domestic Licensing of Special Nuclear Material."

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/CR-1775, "Environmental Assessment of Consumer Products Containing Radioactive Material," prepared by D. W. Buckley, R. Belanger, P. E. Martin, K. M. Nicholaw, and J. B. Swenson, Science Applications, Inc., October 1980.

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