POLICY ISSUE
(Notation Vote)

September 18, 2013 SECY-13-0100

FOR: The Commissioners

FROM: Mark A. Satorius
Executive Director for Operations

SUBJECT: UPDATED POLICY STATEMENT ON CONSUMER PRODUCTS

PURPOSE:

To request Commission approval to publish a final revision to the Commission's 1965 Consumer Product Policy Statement in the *Federal Register*. This paper does not address any new commitments or resource implications.

SUMMARY:

This paper presents a draft final revision updating the Commission's Consumer Product Policy Statement. A proposed revision of the Consumer Product Policy Statement was published for public comment by the Office of Federal and State Materials and Environmental Programs (FSME) on October 14, 2011 (76 FR 63957). The revision will reinforce the Commission's current policy regarding approval of the use of radioactive material in products intended for use by the general public (consumer products) without the imposition of regulatory controls on the consumer-user. As there has been no significant change in the Commission's direction and decisions in this regard and no new concerns of the staff, no substantive changes have been made. Updates reflect the current approach to radiation protection and methodology, legislation that has been enacted since the policy was published in 1965, and subsequent approaches taken in the U.S. Nuclear Regulatory Commission's (NRC) regulatory framework for exemptions.

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BACKGROUND:

In a staff requirements memorandum (SRM) dated February 3, 2010, "Staff Requirements-SECY-09-0035 Proposed Rule: Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70 (RIN 3150-AH91)," NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML100341324 the Commission approved the staff's recommendation to publish proposed amendments to Parts 30, 31, 32, 40, and 70 of Title 10 of the *Code of Federal Regulations* (10 CFR) in the *Federal Register,* subject to certain modifications. In that SRM, the Commission also directed the staff to update the 1965 Consumer Product Policy Statement (the policy or the 1965 policy).

The Atomic Energy Commission (AEC) published the policy on March 16, 1965 (30 FR 3462). The purpose of the policy was to set forth the essential terms of the Commission's approach 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. These products are normally used under an exemption from licensing and from all associated regulatory requirements.[1]

The policy incorporates the three fundamental principles of radiation protection, as recommended by the International Commission on Radiological Protection (ICRP): justification of a practice, optimization of protection (the As Low As Reasonably Achievable (ALARA) principle), and application of dose limits to individuals. For example, the policy specifically provides that approval of a proposed consumer product will depend upon both associated exposures of persons to radiation and the apparent usefulness of the product. The policy calls for monitoring the amounts of radioactive materials being distributed for use by the general public and reconsidering the policy if there is any indication that materials in products reaching the public may result in a significant fraction of the permissible dose.

In the past, the staff has undertaken various efforts to re-evaluate exemptions from licensing, including those for consumer products, as well as to re-evaluate the policy. Initially, the AEC staff evaluated the exemptions for consumer products in conjunction with the development of the original policy. Soon after its creation, the NRC began a major effort to collect information and reevaluate the use of radioactive material in consumer products.[2] A more rigorous evaluation of the doses from consumer products, as well as identification of alternatives and discussion of cost/benefit considerations, was published in NUREG/CR-1775, "Environmental Assessment of Consumer Products Containing Radioactive Material," dated October 1980 (ADAMS Accession No. ML082910862). In conjunction with that effort, the staff also developed plans to revise the policy as well as to codify the approval criteria in 10 CFR Parts 30 and 40.

[1] Note that while products not intended for use of the general public, particularly other exempt products, do not come under the policy, they may result in exposures to the public. An example is counterweights installed in aircraft (exempt under 10 CFR 40.13(c)(5)). Decisions on these products should generally provide similar protection to members of the general public, although workers may be exposed to somewhat higher doses.

[2] In connection with that effort, a symposium was held in February 1977 in Atlanta, Georgia, cosponsored by the NRC and other federal agencies. In August of 1978, a compendium of papers on the subject was published as NUREG/CP-0001, "Radioactivity in Consumer Products"; ADAMS Accession No. ML052650521 (NUREG/CP-0003 in paperbound version).

However, that revision was not undertaken in light of higher priority actions and given that the results of the environmental assessment were generally favorable.[3]

In 1990, the Commission published a much broader policy, the Below Regulatory Concern (BRC) Policy (55 FR 27522; July 3, 1990), in an attempt to make all decisions concerning releases from regulatory control more efficient and more consistent, indicating that the BRC policy superceded the subject policy. However, the Commission chose criteria that many stakeholders believed would not adequately protect public health and safety and the quality of the environment, with the ultimate result that the BRC Policy was revoked by the Energy Policy Act of 1992 (Public Law 102-486, October 24, 1992). Thus, the 1965 policy has remained in effect.

In the 1990s, the staff began an evaluation of all exemptions from licensing, including those for consumer products and others not included in the earlier efforts. This effort, which was initiated in connection with the BRC policy, was done in large part to determine whether the major revision of 10 CFR Part 20 (56 FR 23409; May 21, 1991) had affected any conclusions concerning the exemptions and whether the exemptions needed modification. The dose assessments were published in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," dated June 2001 (ADAMS Accession No. ML01198433). The recommendations of the staff as a result of the overall evaluation were provided to the Commission 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" (ADAMS Accession No. ML021650518). That paper addressed all but three of the exemptions, noting that those three were being considered along with broad jurisdictional issues by the Jurisdictional Working Group established as a result of SECY-99-259, "Exemption in 10 CFR Part 40 for Materials less than 0.05 Percent Source Material - Options and Other Issues Concerning the Control of Source Material." Subsequent efforts on those issues ultimately resulted in the legislative proposal currently before the Commission concerning the definition of source material.

Three rulemakings evolved from the systematic assessment of exemptions. Two of these rulemakings concerned the regulation of byproduct material.[4] The third rule concerned the regulation of source material. Although the 1965 policy indicated that, "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," such recordkeeping and reporting requirements had previously only been implemented in the regulations governing the distribution of byproduct material. The source material rule, "Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions," was published as a final rule on May 29, 2013 (78 FR 32310). That rule, among other things, establishes basic

[3] One change that did arise from that effort was the suspension and then elimination of an exemption for glass enamel and glass enamel frit in 1984 as an unjustified use of radioactive material. Only products of that type manufactured before July 25, 1983, are exempt under 10 CFR 40.13(c)(2)(iv).

[4] "Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," was published as a final rule on October 16, 2007 (72 FR 58473) and "Requirements for Distribution of Byproduct Material" was published as a final rule on July 25, 2012 (77 FR 43666).

distributor requirements for products containing source material, including recordkeeping and reporting, as envisioned by the 1965 policy.

Additional actions recommended by the staff in SECY-02-0196 included revision of the provisions for exempt quantities and exempt concentrations to present a more consistent level of risk based on the newer dosimetric methodologies and of the safety criteria for the two existing class exemptions for consistency with the newer dose methodologies and terminologies. These actions were delayed until the broader implications of ICRP-103, "The 2007 Recommendations of the International Committee on Radiological Protection," are analyzed and the dose conversion factors based on ICRP-103 are calculated.

A proposed revision of the Consumer Product Policy Statement was provided to the Commission for information by memorandum dated September 20, 2011 (ADAMS Accession No. ML112280545), and published for public comment by FSME on October 14, 2011 (76 FR 63957). The comment period closed December 28, 2011, and four comment letters were received. The comments were generally supportive of the policy and the intent to update it. Minor changes have been made to the updated policy as a result of comments received. A discussion of the comments appears in the notice (Enclosure 1).

DISCUSSION:

The policy remains important because, although presenting very low risks of significant individual doses to members of the general public, consumer products containing radioactive material are a source of routine exposure to the public. A substantial portion of the population uses and enjoys benefits from consumer products such as smoke detectors, and consequently receives a small radiation exposure from those products. Well-informed regulatory decisions in this area may have a significant effect on minimizing cumulative exposures to the public. The doses likely to result from exempt products depend not only on limitations within the exemption itself, such as radionuclide quantity limits, but also on requirements placed on the distributor, such as following approved quality control procedures or providing information to the user on the safe use of a product.

As directed by the SRM, the staff has prepared a simple update of the policy (i.e., entailing no significant changes in direction and no change in scope). In planning the update, the staff considered whether any enhanced public participation should be requested in connection with this effort, given the nature of the policy, but did not recommend doing so because no change in direction was planned. Also, no significant public comments related to the policy had been received in response to the three recent rulemakings that implemented many of the recommendations of the systematic assessment of exemptions.

In preparing the update, the staff identified and reviewed a number of documents, mostly in draft, of several national and international organizations that contain related matter. The goal of this review was to identify any related issues for consideration and to avoid unnecessary inconsistencies. The staff notes that these organizations generally do present standards for consumer products separate from standards that apply to all exempted products and give significant emphasis to the justification of practice principle discussed below. No changes have been made in the updated policy based on this review.

The staff provided the draft updated policy to the Interagency Steering Committee for Radiation Standards for review and comment. No comments were received.

As noted, one of the fundamental principles of radiation protection is justification of practice. This principle leads to some restrictions on products with frivolous purposes. While the policy does not include the term "justification of practice," the intent is captured through consideration of the degree of benefit or usefulness of a product to the public and indicates that the use of radioactive material in toys, novelties and adornments may be of marginal benefit.[5] Note there is no absolute ban on these categories of products. Some draft international documents do contain such a ban; however, these documents either exclude the applicability of consumer product criteria to irradiated gemstones, or treat activated products separately from products to which radioactive material has been added for a purpose rather than simply as a result of a treatment.

There are products that are exempt from regulatory control in other countries, but not in the United States. This situation unavoidably results from the differing judgments made concerning justification of practice by various regulatory authorities (e.g., the United Kingdom has authorized the distribution of key rings containing tritium). These products are sometimes sold in the United States. Although these sales cannot be completely prevented, any widespread distribution can generally be identified and stopped; thus, the goal of minimizing the number of widely distributed products is nonetheless achieved.

The staff believes that despite the age of the policy, its content continues to be generally appropriate and consistent with the Commission's and the ICRP's recommended framework for radiation protection, in that it incorporates the three fundamental principles of radiation protection. As a result, the staff is recommending relatively minor changes to the policy, primarily to (1) make its terms consistent with the current approach to radiation protection and methodology; (2) recognize legislation that has been enacted since the policy was published in 1965; and (3) recognize the subsequent approach of establishing class exemptions from licensing in lieu of numerous individual product exemptions.

With regard to the changes to radiation protection methodology and terminology, the policy currently includes the terms "permissible body burden" and "permissible dose to the gonads" which derive from early approaches to radiation protection, as presented by the ICRP in 1959. Newer approaches to radiation protection do not include such limits. The discussion in the revised policy briefly explains why these two particular terms are no longer used. All of the later recommendations of the ICRP use a more integrated approach to the estimation of and protection against radiation exposures. The basic approaches of summation of external and internal doses resulting from intakes of radioactive materials and integrating doses to various tissues were incorporated into 10 CFR Part 20 in the 1991 revision cited above. The ICRP has continued to reevaluate and update its dose assessment methodologies and terminology.

[5]The NRC's policy of limiting the use of radioactive material in "frivolous" products comes not only from the basic radiation protection principle of "justification of practice," but also from an intent to minimize the number of widely distributed products, so as to better ensure that public doses are appropriately limited given exposure to multiple sources (and not be faced with difficult decisions in the future concerning more useful products). An example of the application of the policy's concept of justification and the limited benefit seen in adornments was the Commission's denying of a petition (PRM-40-12) for an exemption for cuff links containing depleted uranium (34 FR 6870, April 24, 1969, and 35 FR 11275, July 14, 1970).

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The updated policy includes only the general terms “exposure” and “dose” to avoid possible conflicts with specific regulatory requirements; this approach is intended to provide a flexible policy allowing the Commission and the staff to use up-to-date dosimetric approaches.

The staff notes that at the time the policy was written, the limit for doses to individuals in the general public recommended by various groups, such as the ICRP, the National Council on Radiation Protection and Measurements, and the Federal Radiation Council was 500 mrem/year (5 mSv/year). Consistent with later recommendations of some of these groups, the 1991 revision of 10 CFR Part 20 established a public dose limit of 100 mrem/year (1 mSv/year) (§ 20.1301). However, as the policy does not state explicit dose limits, it has not become inconsistent with these changes in dose limits. The update to the policy continues with the basic standard that exposures from a product should contribute only a small fraction of the dose limits for the public, in order to maintain its flexibility.

The primary relevant legislative actions are the Energy Reorganization Act of 1974 (ERA) and the National Environmental Policy Act of 1969 (NEPA). The ERA revised the Atomic Energy Act in a number of ways, primarily to separate the regulatory responsibilities from the AEC and to create the NRC. Under the ERA, relevant AEC policies such as the subject policy became the NRC’s policies. Updating the policy to reflect that transfer removes any uncertainty as to whether it is in fact current NRC policy. The discussion in the notice of the revised policy indicates that procedures for carrying out the requirements of NEPA are contained in 10 CFR Part 51. In accordance with 10 CFR Part 51, the NRC would prepare the appropriate documentation (environmental assessment or environmental impact statement) in proposing any new exemption from licensing. Also, 10 CFR 51.68, “Environmental Report – Rulemaking,” requires petitioners for rulemaking requesting, among other things, exemptions from licensing to submit a separate document entitled, “Petitioner’s Environmental Report.” Although the NRC may accept such a petition under 10 CFR 2.802, “Petition for rulemaking,” without an environmental report, it facilitates the NRC’s ability to evaluate such a petition if the petitioner provides significant information on the potential impacts of the requested exemption.

With respect to the third reason for changes noted above, two class exemptions that include consumer products were established by the AEC in 1969. The class exemption approach was developed because industry was submitting numerous petitions for rulemaking to add exemptions from licensing including many for a variety of self-luminous products. These exemptions allow new products within a class to be approved by the staff in a licensing action rather than by rulemaking and, because of this, were designed to reflect the principles of the policy. Justification of practice is ensured for gas and aerosol detectors by limits to the purposes of the detectors along with the safety criteria. For self-luminous products, the purpose is simply producing light. Therefore, additional controls were included in the regulations to ensure that the products are justified. These provisions are 10 CFR 30.19(c), which limits the exemption with respect to frivolous purposes and toys and adornments, and 10 CFR 32.22(b), which indicates the Commission may disapprove products for which the end use cannot be reasonably foreseen.

Because most new products have been developed for use under these class exemptions, the policy has not been used very often in recent years to evaluate newly developed products. The policy, however, was used in conducting the overall reevaluations of consumer products

noted in the *Background* section of this paper. The safety criteria associated with the class exemptions include more specific criteria for accidents than in the existing policy. The revised policy addresses the use of class exemptions by better reflecting the level of risk that is acceptable for accident and misuse scenarios, as well as acknowledging the use of safety criteria in the regulations governing distribution for use of products under class exemptions. However, the guidance provided by the policy remains relatively general.

In addition, some of the examples of exempt products noted in the policy were replaced with more current or more appropriate ones; for example, smoke detectors were added and uranium as shielding in shipping containers was removed.

The draft final "Statement of Policy" (Section IV of the notice) showing changes made to the original 1965 policy is provided for ease of review (Enclosure 2).

AGREEMENT STATE REVIEW

Although the approval of products for use under exemptions from licensing is an activity reserved to the NRC, the draft final updated policy was provided to the Agreement States to provide an opportunity for comment. Four comments were received. The Organization of Agreement States (OAS) and the Commonwealth of Virginia submitted comments in the form of a markup of the Statement of Policy section. The State of Arkansas agreed with the OAS comments and expressed a concern that some of the wording concerning benefit, particularly paragraph 3 of the Statement of Policy, was not clear, and did not convey appropriate assurance that products are thoroughly evaluated for justification. The State of Wisconsin also agreed with the OAS comments and had additional editorial suggestions.

A few minor changes were made. However, most of the comments were not accepted, because they were outside the scope of the proposed policy changes.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication, in the *Federal Register*, the update to the Policy Statement on Consumer Products (Enclosure 1).

2. Note:

   a. That the revised policy will be effective upon publication in the *Federal Register*.

   b. That a press release will be issued by the Office of Public Affairs when the revised policy is filed with the Office of the Federal Register.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

/RA Mike Weber for/

Mark A. Satorius
Executive Director
for Operations

Enclosures:
1. Draft *Federal Register* Notice of Updated Policy Statement on Consumer Products
2. Markup showing changes of the "Statement of Policy" from the 1965 policy

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