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.

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[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

[7950-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC-2010-0292]

Consumer Product Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement; revision.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is updating its policy statement on products intended for use by the general public (consumer products). Although the NRC is not making significant changes to the policy, the Commission is generally updating the policy statement. 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 NRC's regulatory framework for exemptions.

DATES: This revised policy statement becomes effective on [INSERT DATE OF PUBLICATION].

ADDRESSES: Please refer to Docket ID NRC-2010-0292 when contacting the NRC about the availability of information for this policy statement revision. You may access information and

comment submissions related to this policy statement revision, which the NRC possesses and is publicly available, by any of the following methods:

- **Federal Rulemaking Web site:** Go to http://www.regulations.gov and search for Docket ID NRC-2010-0292. Address questions about NRC dockets to Carol Gallagher; telephone: 301-492-3668; email: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may access publicly available documents online in the NRC Library at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Shirley Xu, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-7640; e-mail: Shirley.Xu@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background.

On March 16, 1965, the Atomic Energy Commission (AEC), the NRC's predecessor agency, issued its policy statement on products intended for use by the general public (consumer products) (30 FR 3462). Under this policy, the AEC and the NRC have periodically reevaluated the overall impact to the public of products allowed to be distributed for use by the general public, which are normally used under an exemption from licensing and from all associated regulatory requirements. The NRC staff has reevaluated the policy at times and found it serves the agency well in spite of the passage of time. The policy was written in general terms, which contributed to its not needing to be revised. However, the NRC is updating the policy to include approaches and terminology more consistent with the current approach to radiation protection and to recognize relevant legislative and regulatory actions.

II. Discussion.

The 1965 policy used terms consistent with the approach to radiation protection represented primarily in the early documents of the International Commission on Radiation Protection (ICRP). These include "permissible dose to the gonads" and "permissible body burden." Newer approaches to radiation protection do not include such limits. The recommendations of the ICRP originally included control of dose to the gonads because of concern for potential genetic risks (i.e., risks to future generations). Since that time, the ICRP has updated its recommendations, which no longer include separate limits for doses to the gonads, because genetic risks are much lower than estimated at the time the policy was written.

Also, early approaches to radiation protection included limits on body burden (i.e., the amount of a radionuclide present in a person's body). In newer approaches for controlling cumulative exposure from radionuclides retained in the body, the calculated dose for the year of intake includes doses that will result from that intake in the future.

Additional updating was needed due to legislation that has been enacted since 1965. The Energy Reorganization Act of 1974 revised the Atomic Energy Act in a number of ways, primarily to separate the regulatory responsibilities from the AEC and to create the NRC. Relevant AEC policies, such as the subject policy, became the NRC's policies. Also in 1974, the Commission was given the authority to create exemptions from licensing for special nuclear material in addition to byproduct material and source material. The Commission has not issued any exemptions from licensing for products containing special nuclear material, but the revised policy recognizes the authority to do so.

Another relevant legislative action was the National Environmental Policy Act (NEPA) of 1969. In subparagraph 9(c), the policy addresses the consideration of potential impacts to the environment from the possible dispersion of radioactive material and the uncontrolled disposal of products used under exemption. This is generally the primary environmental impact to be considered when evaluating a potential exemption from licensing. Specific procedures for complying with NEPA have been developed and are addressed in part 51 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." Therefore, any rulemaking to add an exemption from licensing requirements requires NRC documentation of environmental considerations in accordance with these procedures. In addition, the responsibilities of the Federal Radiation Council are now performed within the U.S. Environmental Protection Agency (EPA).

Since the issuance of the 1965 policy, the Commission has issued class exemptions, under which additional products belonging to an identified class of products can be approved

through a licensing action, if an applicant to manufacture or distribute a product demonstrates that the product is within the class and meets certain safety criteria. This approach to exemptions from licensing is also being recognized in the policy.

Also, the safety criteria for the class exemptions include more specific criteria for accidents than were in the 1965 policy. The revised policy better addresses the level of risk that is acceptable for accident and misuse scenarios. However, the guidance remains relatively general.

The policy directly applies to any potential rulemaking to add or modify exemptions from licensing that cover consumer products and usually does not apply to individual licensing actions involving such products. However, when there is need for interpretation or judgment in the ultimate decision to approve a product, the licensing staff may look to the policy for additional direction. The policy has been reflected in the applicable provisions in the regulations, including specifically the class exemptions, so that the approval of specific products in licensing actions will be consistent with the policy.

In accordance with the policy, the NRC staff has occasionally reevaluated the relevant exemptions. Three of the NRC's recent rulemaking actions included changes that reflected findings of the latest reevaluation (*see* October 16, 2007, 72 FR 58473; July 25, 2012, 77 FR 43666; and May 29, 2013, 78 FR 32310).

Finally, the example products noted in paragraphs 5 and 6 of the policy statement are revised to be more relevant and up to date. For example, thoriated tungsten welding rods, while available to the public, are used in unique, expensive equipment and are not normally used by the public in the form of consumer products. Likewise, shipping containers constructed with uranium as shielding are not used by the public in the form of consumer products. Instead, such examples as electron tubes and smoke detectors were added.

III. Summary and Analysis of Public Comments.

A proposed revision of the Consumer Product Policy Statement was published for public comment on October 14, 2011 (76 FR 63957). The comment period closed December 28, 2011, and four comment letters were received. The comment letters came from the Health Physics Society, a member of a State regulatory staff, an organization representing the industry of manufacturers and distributors, and two certified health physicists (commenting together). There was general support for the policy and the intent to update it. There were no objections to the policy or to the specific changes proposed.

One commenter noted the long history of use of certain products with low dose potential to users and stated that the NRC has had a comprehensive and successful system in place for many years for evaluating the safety of devices in broad context of use in addition to the radionuclide and activity in the product. Another expressed support for the principal considerations in the policy, stating that the changes are reasonable in light of the newer approaches to radiation protection; this commenter also stated agreement with a number of specific points such as that justifiable sources of radiation exposure of the public include those that result in an overall net benefit to society. Most comments reflected a desire for the policy to be more clear or specific, with suggestions made for including additional topics and certain definitions.

Comment: Two of the commenters thought that it would be helpful to put a specific value on certain terms in paragraph 2 of the Statement of Policy,[1] which states in part that, in general, risks of exposure will be considered acceptable if, "it is unlikely that individuals in the population will receive more than a small fraction, less than a few hundredths, of individual dose

[1] The phrase "Statement of Policy" as it is used here refers specifically to Section IV within this notice. Otherwise, the term "policy" or "policy statement" is being used.

limits in NRC regulations and as recommended by such groups as the ICRP... ” Both of these commenters believed that the use of actual numbers would be helpful and preferred that the current public dose limit be stated.

One of these commenters suggested that more specificity in paragraph 1 of the Statement of Policy would also be helpful. That paragraph states that at the present time it appears unlikely that the total contribution to exposure of the general public would exceed a “fraction of limits recommended for exposure to all radiation sources,” but if in the future radioactive materials were used in such quantities as to raise a question of the combined exposure from multiple products becoming a “significant fraction” of the permissible dose to the public, the Commission would reconsider its policy. This commenter indicated that it would be helpful if the “fraction of limits recommended for exposure to all radiation sources” could be quantified, as well as the “significant fraction…” of the public dose limit that will be used as the basis for reconsidering the policy. However, this commenter stated that there was no problem with the proposed revised policy as long as those fractions are no less restrictive than whatever is currently used.

Response: Paragraph 2 states that approval of a product depends upon both associated exposures of persons to radiation and the apparent usefulness of the product. The statement in that paragraph about a small fraction of individual dose limits in the NRC’s regulations and as recommended by such groups as the ICRP is meant to provide a general guideline on acceptable risks under routine conditions, above which an in-depth analysis and weighing of all factors would be particularly important. Paragraph 2 also addresses risks from accidents or other non-routine scenarios involving exposures to the public. These general guidelines do not mean that no comparison of the degree of benefit or usefulness to risk is made.

There is no single dose level that is acceptable for all products. For example, there are two relevant class exemptions for which dose criteria form the primary basis for approving a particular product in licensing. The associated regulations present examples of specific acceptable doses for specific classes of products. One covers self-luminous products, which can be used for a multitude of purposes. For these products, the primary routine dose criterion is 1 mrem (10 μSv)/year. The class exemption for gas and aerosol detectors allows for a more limited set of purposes, which more clearly present a benefit to society, as their purpose must be to protect health, safety, or property. The primary routine dose criterion for the gas and aerosol detector exemption is 5 mrem (50 μSv)/year. These limits are both a small fraction of the current limit for doses to the public of 100 mrem (1 mSv)/year. At the time the policy was written, the recommended limit for exposures to individual members of the public was 500 mrem (5 mSv)/year to the whole body, with additional specific organ limits. At that time, somewhat higher doses from the use of consumer products could have been acceptable. Providing general guidelines in terms of fractions of the recommended limits to the public from all sources continues to be considered the best approach, because it is appropriate for the acceptable levels to be in proportion to the overall limits and for more beneficial products to be allowed to result in a somewhat larger fraction of the overall recommended limit than products with limited benefit.

Paragraph 1 provides a general statement of the current level of impact from all consumer products and a level of dose from the combined effect of multiple products at which the NRC will reconsider this policy. There is no way to fully quantify the total doses that individuals in the population are likely to receive as the net effect of products distributed for use under exemptions. The policy is intended to minimize the possibility that members of the public will receive a total dose from exposure to all sources (excluding natural background and medical exposures) that exceeds the public dose limit. Putting a specific value on the significant fraction

of the public dose limit that might trigger the Commission to reconsider the policy would not be appropriate because (1) a specific value could imply a higher degree of certainty in any estimate of the actual cumulative impact than is possible, (2) the value may depend on how much other sources are expected to be contributing to the exposure of the public at any given time, and (3) the value may depend on the degree of benefit being obtained from the products most contributing to the cumulative exposure.

In general, the NRC does not expect the cumulative impact of consumer products to ever reach a level triggering a concern because the policy is designed to prevent unnecessary exposures and to keep individual doses a fraction of the public dose limit and as low as reasonably achievable. The balancing of impacts and benefits inherent in the policy is intended to ensure that only products that present a positive net benefit to society (i.e., justified products) are approved. Although justification of practice is a concept that applies to all practices involving the use of radioactive material, it is particularly relevant to the approval of consumer products in spite of the low range of acceptable doses for these products. This is primarily because a large portion of, or essentially the entire, population may be exposed. If large numbers of products were widely distributed for use by the general public, many individuals in the population would be exposed to a multitude of products and potentially receive a significant cumulative dose. The consumer market is also where unjustified products are most likely to be proposed and where any reversal of a decision on a product is most difficult to implement.

Although new products have continued to be developed and approved for use by the general public, the NRC did not need to revise the policy to be more restrictive based on the criterion in paragraph 1 of the policy. This is because, in addition to the application of the justification principle limiting the total number of products approved, some products approved and used in the past have declined in use for various reasons. In addition, as the industry has matured, the amount of radioactive material used in products has often been reduced.

Finally, this update of the policy does not constitute a substantive change to the Commission's basis for decisions in this area. There is no intent to be less restrictive as a result. For all of these reasons, no changes to the Statement of Policy have been made in response to these comments.

Comment: One commenter requested more detailed guidance on how the NRC might deny applications based on potential uses; thought that there should be definitions of "useful," "frivolous," "adornment," and "toy"; and included suggestions for such definitions. This was discussed in relation to paragraph 3 of the Statement of Policy.

Response: The NRC believes that paragraph 3 is clear. The words mentioned by the commenter are used and will be interpreted in a manner that is consistent with their normal dictionary definitions. Therefore, there is no need to add definitions to the policy.

Comment: The same commenter recommended further guidance on what is meant by "an unusual degree of utility and safety" with regard to the statement in paragraph 4 of the Statement of Policy that applications of "off-the-shelf" items that are subject to mishandling will be approved only if they are found to combine an unusual degree of utility and safety. In this context, the commenter noted that the NRC has in the past rejected products for use under exemption based on the fact that "the end use of the product could not easily be foreseen." The commenter interprets this criterion by stating, "What the NRC means by this statement is that the possible misuses of the product can be foreseen." The commenter's concerns were that distributors should not be held liable for intentional misuse of products and that products should not be banned because of the possibility of misuse.

Response: The words "an unusual degree of utility and safety" in paragraph 4 cannot be further specified so as to fit every situation. Rather, each product must be evaluated on a case-by-case basis. Paragraph 4 simply means that if a product appears to have a high likelihood of being mishandled, especially by children, it would be acceptable only if the potential doses are

relatively low and the product is unusually beneficial. The NRC notes that products are not banned based solely on the possibility that the product can be mishandled; instead, the probability of misuse and particularly the magnitude of potential doses that could occur as a result of misuse are considered. In any event, distributors are not held liable for the intentional misuse of their products that have been properly distributed.

The policy does not include a specific criterion of being able to foresee the end use of a product, although being unable to foresee the end use of a product limits the ability of the NRC to evaluate a number of considerations that *are* addressed in the policy so as to be able to determine whether the product warrants exemption from licensing. Under the policy, the likely doses, the probability and severity of accidents and misuse, and the benefits to be obtained from allowing the product to be used under exemption are factors to be considered. These factors cannot be reasonably evaluated if the ultimate uses of the product are not known.

The Commission did, however, include a criterion in the regulations of being able to foresee the end use of a product for approval of specific products proposed for use under the class exemption for self-luminous products. These regulations specifically provide that the NRC may deny an application for a distribution license if the end uses of the product cannot be reasonably foreseen. The commenter is incorrect, however, in the interpretation of this criterion in the regulations that this means that possible misuses of the product can be foreseen. This criterion is not related primarily to misuse, but rather to the ability to project how people are likely to be exposed to the radioactive material within or the radiation produced by a product, as well as the conditions under which the product would be used. Self-luminous products in particular have a wide range of potential applications, some of them frivolous, and might easily be widely used for purposes other than those originally intended if not clearly designed for a specific use. This criterion also ensures that the uses (not the occasional misuse) of radioactive material in products are justified. The NRC considers the potential for unintended end uses that

may occur on a widespread basis differently from misuse or “mishandling” as used in paragraph 4 of the policy, although the NRC recognizes that, in some cases, a product with relatively wide open end uses might also be more likely to be misused.

Comment: With regard to paragraph 8 of the Statement of Policy, which discusses the use of other limitations, such as quality control and testing, considered important to health and safety, one commenter suggested that the phrase “radiation doses to users” be used in place of “health and safety.”

Response: The commenter did not provide a basis for this suggested change. In addition, the suggested replacement words would not be appropriate, as it is not only doses to users that are relevant, but also doses to others who may be exposed at any time throughout the lifecycle of the product.

Comment: With regard to subparagraph 9(b), which states that a principal consideration in evaluating proposals for the use of radioactive materials in consumer products is the potential total cumulative radiation dose to individuals in the population who may be exposed to radiation from a number of products, one commenter asked the following questions: What method is used to determine the type and number of products? How are the number and type of products a person is exposed to controlled? Is this possibly misinterpreted to be “from a number of pathways” available from the product?

Response: The phrase “from a number of products” in subparagraph 9(b) is not misinterpreted to be from a number of pathways from the same product, but rather concerns exposures from many products. Subparagraph 9(b) covers an overall intent to reduce the likelihood that large segments of the population would receive a significant cumulative radiation dose from being exposed to many exempt products. Because products approved for use under exemptions from licensing are no longer under any regulatory control, the number and type of products a person is exposed to cannot be controlled nor determined. Instead, the NRC

collects information on the total number of the various types of products distributed and looks broadly at the overall impact of all products being distributed. A complete reevaluation of the number and type of products a person may be exposed to is not conducted each time a petition is received for an exemption for a new product.

New products expected to be widely distributed and to expose much of the population warrant a more careful weighing of impacts and benefits, and more attention to ensuring that doses will be as low as is reasonably achieveable (ALARA), if the product is approved, than those that are likely to have limited distribution. This helps ensure minimization of the likelihood that large segments of the population would receive a significant cumulative radiation dose from being exposed to many exempt products.

Comment: One commenter asked for further information on the criteria used to evaluate public benefit mentioned as a principal consideration in evaluating a product in subparagraph 9(d) of the Statement of Policy.

Response: Benefits come in a wide variety of ways and some are not quantifiable. The benefits that may accrue to society from a particular product must be evaluated on a case-by-case basis; this often involves an exercise in judgement. International guidance recognizes that government authorities must make value judgments in determining whether a practice is justified (i.e., the benefit outweighs the harm). Due to the low doses that normally result from products used under exemptions from licensing, it would not be necessary for the benefit of a product to accrue to the individuals exposed; rather, any benefits to society as a whole can be considered.

Comment: One commenter asked what criteria are used to determine if children can access a product.

Response: Aspects such as product size and likely storage or use locations might be factors affecting accessibility to children. Again, consideration of such matters requires

judgment and evaluation on a case-by-case basis. It would not be possible for the NRC to establish generic criteria that could be applied to every situation.

Comment: One commenter suggested that subparagraph 10(d) of the Statement of Policy, which concerns the potential of a radionuclide to cause internal doses, be reworded to replace the term “exposures” with the term “doses” to be consistent with ICRP and National Council on Radiation Protection and Measurements (NCRP) terminology.

Response: The NRC agrees that the word “dose” is more appropriate than “exposure” in some instances in the policy, including in subparagraph 10(d), and has made such changes.

Comment: This commenter also recommended that the NRC consider quantification of both external doses and internal doses (from inhalation, ingestion and dermal absorption) when evaluating new consumer products.

Response: The NRC does quantify both external and internal doses when evaluating new consumer products. Much of the policy, however, is intentionally general with respect to the use of the terms “exposures” and “doses.” These terms cover both external or internal exposures. In subparagraph 9(a), the policy specifies consideration of both external and internal exposures.

Comment: One of the comment letters recommended recognition of an AEC/NRC practice that has evolved subsequent to 1965 to require, when practical, labeling or marking of the product, stating that this practice is consistent with the ALARA principle and recognizes the consumers' and others' interest in radiation. This comment letter made the point that labeling of the product and its point-of-sale package enables consumers and others to make informed decisions about acquisition, use, and disposal of the product, and also noted an assumption that omission of the recognition of current NRC labeling and marking requirements in the published policy update was an oversight and not a change in policy about informing the public.

Response: Labeling was not mentioned in the policy because it is not a factor in considering the initial approval of a product for use under an exemption, but a consideration as to what the NRC should require of manufacturers and distributors when they subsequently distribute an approved product. Impacts to health and safety are controlled through both constraints in an exemption and the requirements placed on the manufacturers and distributors. Examples of typical distributor requirements are among the topics in paragraph 8 of the Statement of Policy. The NRC agrees that labeling may be an important matter and has added mention of labeling to that paragraph.

The NRC notes that, while labeling was considered an important issue for some products, the agency has not had a uniform policy of always requiring labeling of consumer or other products for the purpose of informing purchasers and others of the presence of radioactive material. In the past, the Commission was more inclined to require labeling when it was a matter of safety (i.e., when a user may reasonably minimize one's exposure with proper handling). This practice is indeed consistent with the ALARA principle. The description in the comment letter of the evolving practice of requiring labeling, when practical, is correct, at least as new exemptions were added. With the recent revisions made to 10 CFR part 40 (May 29, 2013; 78 FR 32310), this practice has been more uniformly applied by adding labeling requirements for some older exemptions from licensing.

The draft Statement of Policy published for public comment has been further revised to clarify points not addressed by the comments. Most importantly, in the area of accident risks in paragraph 2 of the draft Statement of Policy, the upper limit of potential doses to individuals was characterized as approaching a level that could cause immediate effects being negligible. This has been revised to state that the probability of individual doses exceeding a level that could cause effects for which there is a threshold dose must be negligible.

IV. Statement of Policy.

Products Intended for Use by the General Public (Consumer Products)

Criteria for the approval of products containing radioactive material and intended for use by the general public.

This section sets forth the essential terms of the Commission's policy with respect to approval of the use of byproduct material, source material, and special nuclear 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, source, or special nuclear material of the Atomic Energy Act of 1954, as amended, and of the Commission's regulations in 10 CFR part 30, "Licensing of Byproduct Material," 10 CFR part 40, "Licensing of Source Material," or 10 CFR part 70, “Licensing of Special Nuclear Material.”

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 a fraction 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 recordkeeping and reporting requirements applicable to the manufacture and distribution of such products. Periodically, the NRC staff conducts an overall reevaluation of this information to estimate the range of likely doses to the population. If radioactive materials are used in sufficient quantities in products reaching the public so as to raise any question of the combined dose from multiple consumer products becoming a

significant fraction of the permissible dose to members of the public, 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, and adding a new exemption from licensing provision to the regulations, depends 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 in the NRC's regulations and as recommended by such groups as the ICRP, the NCRP, and the EPA, and that the probability of individual doses exceeding the limits is low. 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. However, in any case, the probability of individual doses exceeding a level that could cause effects for which there is a threshold dose must be negligible, even in the event of severe accidents involving the numbers of a product that may be present during distribution.

3. 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 a product may result in widespread use of radioactive material, such as in common household items, the degree of usefulness and benefit 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, many of which predate the atomic energy program. These include:

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

(b) Thorium in various alloys and products (e.g., gas mantles, optical lenses, tungsten wire in such things as electric lamps and vacuum tubes) to impart desirable physical properties.

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:

(a) Tritium and other radionuclides in electron tubes;

(b) Americium-241 in smoke detectors; and

(c) Thorium and uranium in piezoelectric ceramic, which is used in many electronic products and other consumer products.

8. In approving uses of byproduct, source, or special nuclear material in consumer products, the Commission establishes limits on quantities or concentrations of radioactive materials and, if appropriate, on radiation emitted. In the case of class exemptions covering a class of products, specific safety criteria are included in the regulations, which require the applicant to evaluate many pathways of exposure of the public. In some cases, other limitations considered important to health and safety, such as quality control and testing, are also specified. In most cases, labeling of the product, when practical, or the point-of-sale packaging is required to inform purchasers and others of the presence of radioactive material.

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, storage, and disposal of individual products;

(b) The potential total cumulative 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 dose to 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 usefulness 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. Detailed evaluation of potential doses will take into consideration the following factors, together with other considerations that 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) Potential of the radionuclides to cause doses from intakes. Materials that result in lower cumulative dose when taken into the body would be considered more favorably than materials that result in higher doses from intakes.

(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 and the environment will be considered more favorably than those with a high solubility.

(g) Containment of the material. Products that 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 that are inaccessible to children and other persons during use will be considered more favorably than those that are accessible.

Dated at Rockville, Maryland, this_____ day of_____, 2013.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission

~~**USE OF BYPRODUCT MATERIAL AND SOURCE MATERIAL**~~

Products Intended for Use by the General Public (Consumer Products)

Criteria for the approval of products containing radioactive material and intended for use by the general public ~~containing byproduct material and source material~~.

This ~~notice~~ section sets forth the essential terms of the Commission's policy with respect to approval of the use of byproduct material ~~and~~, source material, and special nuclear 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, or special nuclear material of the Atomic Energy Act of 1954, as amended, and of the Commission's regulations in 10 CFR part 30, "Licensing of Byproduct Material~~",~~," 10 CFR ~~Part 30 and~~ part 40, "Licensing of Source Material~~", 10 CFR Part 40.~~," or 10 CFR part 70, “Licensing of Special Nuclear Material.”

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~~a fraction 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~~recordkeeping and reporting requirements applicable to the manufacture and distribution of such products. Periodically, the NRC staff conducts an overall reevaluation of this information to estimate the range of likely doses to the population. If radioactive materials are used in sufficient quantities in products reaching the public so as to raise any question of ~~population exposure~~the combined dose from multiple consumer products becoming a significant fraction of the permissible dose to members

of the ~~gonads~~public, 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~~, and adding a new exemption from licensing provision to the regulations, depends 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 in the NRC's regulations and as 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),~~EPA, and that the probability of individual doses ~~approaching any of~~exceeding the ~~specified~~ limits is ~~negligibly small~~low. 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~~. However, in any case, the probability of individual doses exceeding a level that could cause effects for which there is a threshold dose must be negligible, even in the event of severe accidents involving the numbers of a product that may be present during distribution.

3. ~~It is considered that as a general rule products~~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, mostmany of which antpredate the atomic energy program. These include:

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

(2b) Thorium in various alloys and products (e.g., gas mantles, tungsten wire, welding rods, optical lenses, etc.tungsten wire in such things as electric lamps and vacuum tubes) 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:

(1a) Tritium and other radionuclides in automobile lock illuminatorselectron tubes;

(2) Tritiumb) Americium-241 in balances of precision;

(3) Uranium as shielding in shipping containerssmoke detectors; and

(4) Uranium in fire detection units.

(c) Thorium and uranium in piezoelectric ceramic, which is used in many electronic products and other consumer products.

8. In approving uses of byproduct and, source materials, or special nuclear material in consumer products, the Commission establishes limits on quantities or concentrations of

radioactive materials and, if appropriate, on radiation emitted. In the case of class exemptions covering a class of products, specific safety criteria are included in the regulations, which require the applicant to evaluate many pathways of exposure of the public. In some cases, other limitations~~, such as quality control and testing,~~ considered important to health and safety, such as quality control and testing, are also specified. In most cases, labeling of the product, when practical, or the point-of-sale packaging is required to inform purchasers and others of the presence of radioactive material.

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, storage, and disposal of individual products;

(b) The potential total ~~accumulative~~cumulative 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~~dose to 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~~ usefulness 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~~doses w~~ould~~ill take into consideration the following factors, together with other considerations ~~which~~that 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~~Potential of the radionuclides~~. The less toxic materials with a high permissible body burden, high concentration limit~~ to cause doses from intakes. Materials that result in ~~air and water,~~lower cumulative dose when taken into the body would be considered more favorably than materials ~~with a high radiotoxicity~~that result in higher doses from intakes.

(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 and the environment will be considered more favorably than those with a high solubility.

(g) Containment of the material. Products ~~which~~that 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~~that are inaccessible to children and other persons during use will be considered more favorably than those that are accessible.