November 4, 2013

MEMORANDUM TO: Mark A. Satorius
Executive Director for Operations

FROM: Richard J. Laufer, Acting Secretary /RA/

SUBJECT: STAFF REQUIREMENTS – SECY-13-0100 – UPDATED POLICY STATEMENT ON CONSUMER PRODUCTS

The Commission has approved publication of the final revision to the Commission's 1965 Consumer Product Policy Statement in the *Federal Register* subject to the attached edits.

Attachment: Edited version of the Consumer Product Policy Statement

cc: Chairman Macfarlane
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
CFO
OCA
OPA
Office Directors, Regions, ACRS, ASLBP (via E-Mail)
PDR

[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.~~ The u~~U~~pdate~~s~~ reflect~~s~~ ~~the~~ our 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 subsequently, the NRC have periodically reevaluated the overall public safety 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~~ periodically and found that it has serve~~s~~d the agency well ~~in spite of~~ and withstood the passage of time. The policy was written in general terms, which contributed to its ~~not needing to be revised~~ continuance of use. However, the NRC is updating the policy to include approaches and terminology more consistent with the agency's current approach to radiation protection and to recognize relevant legislative and regulatory actions taken since the policy was originally issued.

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~~ apply such ~~limits~~ standards. 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 radiation protection is achieved by summing the dose from external radiation and the doses from inhaled and ingested radioactive material ~~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~~ is needed due to Federal 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 former 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 proposing 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 reflected 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 as off-the-shelf items, ~~are used in unique, expensive equipment and~~ are

not ~~normally~~ intended for widespread personal or household use ~~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 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

[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.

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~~ allow for a comparison of the degree of benefit or usefulness to risk for each product ~~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~~ As a result, somewhat higher doses from the use of consumer products could have been acceptable at that time. 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. Some of t~~T~~he words mentioned by the commenter are used in the policy 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. However, the NRC must be able to determine whether the product warrants exemption from licensing ~~although~~ and 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 judg~~e~~ment. 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. Labeling is, however, a consideration in determining requirements for 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~~ The Nuclear Regulatory Commission (NRC) issues this Policy Statement to set forth its 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 International Commission on Radiological Protection ~~(~~ICRP~~)~~, the National Council on Radiation Protection and Measurements ~~(~~NCRP~~)~~, and the U.S. Environmental Protection Agency ~~(~~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, and 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 ~~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 societal 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