

~~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 ~~general~~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, ~~most~~many of which ~~ant~~predate 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 illuminator~~electron tubes;

~~(2) Tritium~~(b) Americium-241 in ~~balances of precision~~;

~~(3) Uranium as shielding in shipping containers~~smoke 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~~ ~~would~~ ~~will~~ 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.