

Policy and
Regulation of Byproduct Material and
Source Material in Products Intended
for Use by the General Public
(CONSUMER PRODUCTS)

INTRODUCTION

During the last 20 years, about 100,000,000 smoke detectors, each containing a small quantity of radioactive material, have been distributed for use in homes, office buildings, and other locations. The radioactive material is subject to regulation by the NRC but the NRC has chosen to impose no regulatory requirements on users of this "consumer product". The following discusses how the NRC regulates the manufacture and use of consumer products and the individual and collective radiation doses associated with their use.

WHAT ARE CONSUMER PRODUCTS?

The term "consumer products" does not appear in current NRC Regulations, but the subject is addressed in a Commission Notice concerning criteria for the approval of products for general public use published in the Federal Register on March 16, 1965. Initially, use of the term was limited to off-the-shelf items which were intended for use by the general public. Under this use of the term, a smoke detector was a consumer product but an uranium counterweight for use in aircraft was not a consumer product because it was intended for use only in the aircraft industry. This distinction is now seldom made for regulatory purposes and, essentially, consumer products are considered as those commodities, devices, or products that, following manufacture, can be possessed, used, transferred, or disposed of in an uncontrolled manner because persons possessing and using them are exempt from licensing requirements for byproduct or source material contained in 10 CFR Parts 30 and 40. The purpose of the exemption is to avoid the imposition of regulatory controls on consumer-users of products that are intended for wide distribution and are of very little radiation safety concern.

Examples of consumer products containing byproduct material are:

timepieces - typically use about 5 millicuries of luminous tritium paint to enable the viewer to tell time in the dark.

smoke detectors - routinely use 1 or less microcurie of Americium-241 to produce an ionized atmosphere in a detector sensitive to smoke. The detector unit contains an alarm that signals the early stage of a fire.

electron tubes - typically use a microcurie or less of krypton-85 or nickel-63 or 50 microcuries of tritium to provide more reliable performance of the tube.

Examples of consumer products containing source material are:

incandescent gas mantles - use a few milligrams of thorium; these are used extensively in gas lanterns used by campers and in gas lights such as those used to illuminate front yards of residences.

uranium counterweights - typical use is several hundred pounds of depleted uranium in wings of jet aircraft to improve performance.

NRC'S AUTHORITY TO ISSUE EXEMPTIONS

The Commission's authority to exercise regulatory control over the manufacture, distribution, and use of consumer products is provided by the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

The scope of the Commission's authority is simply that no person may conduct activities involving source, byproduct, or special nuclear material except pursuant to a general or specific license or an exemption from licensing requirements issued by the Commission.

Under the Atomic Energy Act, the Commission is authorized to exempt classes or quantities of byproduct¹ and special nuclear material² or kinds of uses or users when it makes a finding that the exemption of such classes or quantities or such kinds of uses or users will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

In the case of source material, the Act states that licenses and reports shall not be required for quantities of source material which, in the opinion of the Commission are unimportant.³

1. § 81.

2. § 57(d).

3. §§ 62 and 65.

NRC REGULATIONS FOR CONSUMER PRODUCTS

NRC regulations provide for 33 types of consumer products. These are listed in Table 1.

Provisions for consumer products have long been part of the AEC-NRC regulations. When 10 CFR Part 40 was first issued in 1947, it contained the following to accommodate ongoing uses:

- (a) Incandescent mantles.
- (b) Ceramic products.
- (c) Refractories.
- (d) Glass products.
- (e) Photographic film, negatives, and prints.
- (f) Rare earth metals and compounds, mixtures and products containing not more than 0.25% by weight thorium, uranium, or any combination of these.
- (g) Vacuum tubes.

Schedule II: Prohibited uses of uranium...

- (a) Ceramic products.
- (b) Glass products.
- (c) Photographic film, negatives, and prints.

It may be noted that three of the exempted products listed in Schedule I also appear in Schedule II. This prohibition prevented the issuance of specific licenses authorizing the receipt of uranium for purposes of manufacturing the three listed products. The prohibition was a means of conserving the supply of uranium for essential uses. Schedule II was eliminated from Part 40 in 1958 with the explanation "...At the present time the supply of uranium is such that it is no longer deemed necessary or appropriate to continue this restriction in effect."

The first exemption for byproduct material was implemented in 1951 and allowed the receipt of 0.011 millicuries of radioisotopes without an authorization certificate. The quantity allowed 0.010 millicurie of radioisotopes with a half life of 30 days
beta-gamma emitting

TABLE 1

CONSUMER PRODUCTS CONTAINING EXEMPT BYPRODUCT MATERIAL		
<u>Type of Consumer Product</u>	<u>Possession & Use Exempted By 10 CFR Section</u>	<u>Effective Date of Regulation</u>
1. Exempt Concentrations	30.14	1960
2. Timepieces (watches & clocks)	30.15(a)(1)	1961: H-3 1967: Pm-147
3. Automobile Lock Illuminators	30.15(a)(2)	1962: H-3 1965: Pm-147
4. Balances of Precision	30.15(a)(3)	1964
5. Automobile Shift Quadrants	30.15(a)(4)	1966
6. Marine Compasses and Navigational Instruments	30.15(a)(5)	1966
7. Thermostat Dials and Pointers	30.15(a)(6)	1966
8. Electron Tubes	30.15(a)(8)	1966
9. Ionizing Radiation Measuring Instruments	30.15(a)(9)	1970
10. Spark Gap Irradiators	30.15(a)(10)	1978
11. Synthetic Plastic Resins for Sand Consolidation in Oil Wells	30.16	1967
12. Exempt Quantities	30.18	1970
13. Self Luminous Products (Class Exemption)	30.19	1969
14. Gas and Aerosol Detectors (Class Exemption)	30.20	1969

TABLE 1 (cont.)

<u>Type of Consumer Product</u>	<u>CONSUMER PRODUCTS CONTAINING EXEMPT SOURCE MATERIAL</u>	
	<u>Possession & Use Exempted by 10 CFR Section</u>	<u>Effective Date of Regulation</u>
1. Chemical mixtures, compounds, solutions or alloys containing less than 0.05% source material	40.13(a)	1961
2. Incandescent Gas Mantles	40.13(c)(1)(i)	1947
3. Vacuum Tubes	40.13(c)(1)(ii)	1947
4. Welding Rods	40.13(c)(1)(iii)	1961
5. Electric Lamps for Illuminating Purposes	40.13(c)(1)(iv)	1966
6. Germicidal Lamps, Sunlamps, and Lamps for Outdoor or Industrial Lighting	40.13(c)(1)(v)	1966
7. Rare Earth Metals and Compounds	40.13(c)(1)(vi)	1947
8. Personnel Neutron Dosimeters	40.13(c)(1)(vii)	1977
9. Glazed Ceramic Tableware	40.13(c)(2)(i)	1947
10. Piezoelectric Ceramic	40.13(c)(2)(ii)	1970
11. Glassware	40.13(c)(2)(iii)	1947
12. Glass Enamel & Glass Enamel Frit	40.13(c)(2)(iv)	1964*
13. Photographic Film, Negatives & Prints	40.13(c)(3)	1947
14. Finished Tungsten or Magnesium-Thorium Alloy Products or Parts	40.13(c)(4)	1949**
15. Uranium Counterweights for Use in Aircraft, Rockets, Projectiles & Missiles	40.13(c)(5)	1960
16. Uranium as Shielding in Shipping Containers	40.13(c)(6)	1961
17. Thorium in Finished Optical Lenses	40.13(c)(7)	1963

TABLE 1 (cont.)

CONSUMER PRODUCTS CONTAINING EXEMPT SOURCE MATERIAL		
<u>Type of Consumer Product</u>	<u>Possession & Use Exempted By 10 CFR Section</u>	<u>Effective Date of Regulation</u>
18. Thorium in Finished Aircraft Engine Parts	40.13(c)(8)	1967
19. Uranium in Fire Detection Units	40.13(d)	1964

* The exemption for glass enamel frit was suspended in 1983 and amended in 1984 to exclude further distribution of the product.

** A limited version of this exemption was issued in 1949 for 3% thorium in thoriated-tungsten, and was broadened in 1961 to its present coverage.

or less and 0.001 millicurie with a half life greater than 30 days. No alpha emitting material was allowed under the exemption. The exemption was prompted by the rapidly increasing number of requests to the AEC for authorizations to obtain radioisotopes. This exemption for small quantities of radioactive material was converted to a general license in 1956 and was re-established as exempt quantities in 1970.

The majority of the regulatory provisions for consumer products, other than those contained in Part 40 as issued in 1947, were added to the regulations in the 1960's. In nearly all instances, rulemaking action for a consumer product was initiated by a manufacturer of the product or a radioactive component of the product. This person was interested in eliminating unnecessary restrictions which hindered marketing and use of the product.

The Commission's Part 2 - Rules of Practice, has long provided in Section 2.802 that "... Any interested person may petition the Commission to issue, amend, or rescind any regulation..." In the normal course of events, as an interested person the manufacturer would submit a petition for rule making (PRM) concerning a product. The staff would then develop a paper for the Commissioners' decision on whether the requested action should be denied or whether the rule making should proceed by publication in the Federal Register of a proposed rule for public comment. Following the public comment period, the staff would prepare a second paper concerning issuance of a final rule. The Commission's judgment on the final rule was based on staff recommendations, suggestions of other Federal and State Agencies, and public comments.

The staff papers and the Federal Register notices routinely discussed the petitioner's arguments for the rule change, the apparent usefulness of the product, and the radiation doses associated with the product. These doses were usually related to recommendations issued by the Federal Radiation Council (FRC), the National Committee on Radiation Protection (NCRP), and the International Committee on Radiation Protection (ICRP). If the product appeared to have a benefit and was expected to cause doses which were only a small fraction of FRC, NCRP, and ICRP recommended limits for the public, the Commission would agree with a staff recommendation to issue the rule.

In considering PRM's, early attention was given to how useful or beneficial a product should be, particularly for a product causing very low doses. An evaluation of the benefit of a product could be a rather subjective task in the absence of guidelines.

In 1961 the Commission approved the exempt use of luminous timepieces containing tritium. At that time radium, which is not subject to AEC-NRC regulation because it is a naturally occurring radioisotope, was commonly used in luminous timepieces. Tritium was promoted as a substitute for radium and a means of reducing exposures to the public. A radiation safety summary of tritium-activated dials in luminous timepieces was part of the Federal Register notice for the proposed rule and it concluded, "... The possible radiation exposures from tritium-dial timepieces are negligible compared to those from luminous timepieces presently in use, although exposures from present luminous timepieces are relatively low. Thus, the use of tritium dial timepieces would be safe and, moreover, would be expected to result in a reduction of radiation exposure to the population."

In 1963, the Commission denied a petition requesting amendment of 10 CFR 30 to exempt from licensing and other regulatory controls the distribution, possession, and use of fish lures containing up to 15 millicuries of tritium luminescent paint. The petitioner had stated that the fish lure would be more attractive to fish inasmuch as it would be visible at night or when fishing in waters at depths where little light is present.

At the meeting at which the Commission denied the PRM for fish lures, the Commission also requested that the staff prepare recommendations on policy standards which could be applicable to proposals of a similar nature in the future involving the use of source and byproduct material in products intended for use by the general public. This request caused the development, and publication in the Federal Register with Commission approval, of the Consumer Product Criteria (published 3/16/65; copy attached as Appendix A).

With publication of the criteria, both the nuclear industry and the regulatory staff had guidance available that culminated in 13 new exemptions from licensing requirements, extension of 3 existing exemptions, and several denials or withdrawals of petitions for rule making in the period 1965-1978. No new exemptions for consumer products have been added to the NRC's regulations in the last 10 years. Although the NRC received authority in August 1974 to amend its regulations to authorize the possession and use of consumer products containing special nuclear materials, only one petition for such amendment has been submitted and it was denied (smelted alloys containing enriched U).

Table 1 lists the consumer products which are now provided for in the NRC's regulations. Over the years, other products also have received Commission and staff attention. The following is a partial listing of these products:

FISH LURES - Establishment of an exemption was denied by the Commission because of lack of benefit and possible widescale distribution and availability to children.

CUFFLINKS containing depleted uranium - Denied by the Commission because such cufflinks are adornments the use of which would result in a small increase of radiation exposure among the general public without commensurate benefit.

SELF-LUMINOUS SCREWS - Denied by the Commission because the "end-use" of the product could not be foreseen and the screws could be used in toys and adornments or for frivolous purposes.

RADIO DIALS and MARKERS - Following comments on a proposed rule, in 1966 the Commission deferred action on the request. Comment opposing the use of tritium on radio dials and markers questioned whether the usefulness of tritium on the dials and markers would justify increased exposure of the general public from widespread use of tritium for this purpose.

DEPLETED URANIUM in INDUSTRIAL PRODUCTS - In 1975 the Commission considered petitions for exempting the use of depleted uranium in commercial products for mass-volume applications. The Commission denied the request for exemption because "...These petitions indicate that the potential exists for widespread distribution of uranium in industrial products or devices and, absent regulatory control over ultimate disposal of these products or devices, ultimate entry of the uranium into scrap-processing systems."

TECHNETIUM-99 and LOW-ENRICHED URANIUM as Residual Contamination in SMELTED ALLOYS - In 1986, following receipt of nearly 4,000 public comments opposing a proposed rule for exemption of smelted alloys containing residual contamination in the form of low-enriched uranium and/or technetium-99, the Commission withdrew the proposed rule with the explanation that "... The proposed rule is being withdrawn in favor of developing an integrated federal policy which would establish consistent guidelines for dealing with the more general issues of decontamination and decommissioning of nuclear facilities as well as the recycling and reuse of decontaminated lands, facilities, materials, and equipment." The petition had been submitted by the Department of Energy and the exemption would have allowed the Department to recycle contaminated smelted alloys salvaged from its uranium enrichment facilities. The commenters objected to, among other things, the possible use of contaminated steel to make frying pans and other cooking utensils.

PROMETHIUM-147 Use in LUMINOUS WATCH DIALS - was denied by the Commission in 1965. This position was reversed in 1967 following approval of this use by the IAEA, ENEA, and several European countries.

NEPTUNIUM-237 (0.05 uc) in WATCHES - The ²³⁷Np-237 was to be used to provide a time-base reference source. Following NRC issuance of a Draft Environmental Statement and development of a staff recommendation to deny the PRM because of the absence of a demonstrated need (benefit), the petitioner withdrew the PRM.

PHOTOIDENTIFICATION CARDS CONTAINING 1 uCi Pm-147 - The Pm-147 was for use in verification of credential authenticity. Following NRC issuance of a Draft Environmental Statement and proposed development of a staff recommendation to deny the PRM because of the absence of a demonstrated need (benefit), the petitioner withdrew the PRM.

Other products which were discussed with the staff by potential petitioners include (a) radioactive lightning rods, (b) security tags to prevent shoplifting, (c) "tags" for detonators to aid in detecting concealed bombs, and (d) grave markers to assist in precise location of coffins. Following the discussion of the expected content of a PRM, no petitions were submitted for these products.

NRC regulations contain one exemption for a consumer product which permits persons possessing the product prior to 1983 to continue such possession but does not permit further manufacture or import for distribution of additional products for use under the exemption. This is the exemption for the possession and use of glass enamel and glass enamel frit containing small amounts of source material. The exemption was issued in 1964. The source material was used to produce brightly colored surfaces on consumer products such as cloisonne jewelry. The exemption was suspended in 1983 and amended in 1984 with the explanation that the amendment "... is intended to prevent unnecessary radiation exposure that may be received by artists who use these materials or by consumers who use the products containing these materials."

As mentioned above, no new exemptions for consumer products have been added to NRC regulations in the last 10 years. This probably is due to two factors.

The first factor is the 1969 issuance of the class exemption for self-luminous products and the class exemption for gas and aerosol detectors. Each class exemption covers a variety of products. The class exemption for self-luminous products set out the concept of safety criteria (radiation dose and dose commitment limits for individuals) that consumer products containing tritium, krypton, or promethium-147 must meet under conditions of use and disposal. The class exemption for gas and aerosol detectors carried the concept one step further by not specifying the byproduct material that may be used in the consumer product, but rather charged the manufacturer (license applicant) with exercising care in selection of the type and quantity of the radionuclide and in the design and construction of containment and shielding features used to meet the safety criteria. Both class exemptions provide for consideration of the probability and consequences of failure of containment, shielding, or other safety features of the product.

The second factor is the National Environmental Policy Act of 1969 (NEPA). The principal objective of NEPA is to build into the agency decision-making an appropriate and careful consideration of environmental aspects of proposed actions.

As part of its policy and procedures for achieving this objective, NRC requires that an environmental report be submitted by any person petitioning the NRC to establish an exemption from licensing for the use of radioactive material in a product. The report must identify environmental impacts, alternatives to avoid or mitigate adverse environmental effects, and benefits and costs of the proposed action. The NRC staff uses the petitioner's environmental report plus other available sources of information to prepare a draft environmental impact statement and the notice of proposed rule making. All comments, public and others, are

considered in preparing a final environmental impact statement and a notice of effective rule making that make an exemption a codified portion of the Commission's regulations. A potential petitioner may view preparation of an environmental report as a formidable task. Guidance for the petitioner is provided in Regulatory Guide 6.7, "Preparation of an Environmental Report to Support a Rule Making Petition Seeking an Exemption for a Radionuclide Containing Product."

LICENSING

The exemptions with respect to consumer products extend only to possession, use, transfer, and disposal. As a general rule, persons manufacturing or otherwise introducing byproduct material or source material into a consumer product or importing the products for distribution, must possess an NRC license issued pursuant to 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," or 10 CFR Part 40, "Domestic Licensing of Source Material." Two exceptions to the general rule are the regulatory provisions for exempt concentrations (§30.14) and for resins containing scandium-46 and designed for sand-consolidation in oil wells (§30.16). In those two cases, either the NRC or an Agreement State may issue the specific license authorizing transfer of the byproduct material for possession exempt from regulations.

At the end of 1988 there were 159 NRC specific licenses in force to import, manufacture, or distribute consumer products containing byproduct material, the majority of these being for distribution of smoke detectors, self-luminous products, small quantities, electron tubes and timepieces. A much smaller number of licenses were in force permitting the import for distribution or manufacture of consumer products containing source material.

A 1987 survey of licenses showed that the majority of the products are manufactured in the U.S., with about 18% imported from the following countries: Switzerland, Japan, France, England, West Germany, Hong Kong, Sweden, and Finland.

Except for the cases of exempt concentrations and scandium-46 resins, the Commission has not transferred to an Agreement State regulatory authority over distribution of consumer products. The Commission has retained the right to regulate through its licensing and inspection processes the transfers by a manufacturer/

distributor of consumer products. The decision not to transfer regulatory authority over the distribution of consumer products to Agreement States was originally made in 1962 and was based on the recognition that such products will be sold unregulated in interstate commerce to the general public throughout the U.S. It was felt that retaining regulatory control at the Federal level was essential for maintaining uniform standards for design and labeling and for assessing the total effect of the uncontrolled release of radioactive materials to the environment.

QUANTITIES OF BYPRODUCT AND SOURCE MATERIAL USED IN CONSUMER PRODUCTS

The Commission's regulations in Part 32 have long required specifically licensed manufacturers/distributors of consumer products to report to the NRC(AEC) the number of units and the quantities of byproduct material transferred. Prior to 1983, these reports were submitted annually. In 1983 the reporting requirements were amended to change the reporting period from 1 year to 5 years or at time of license renewal in order to reduce administrative effort associated with the reports. The reporting requirements have been used to collect information about the extent of use of products for which NRC has exempted the user from regulatory controls.

The change in reporting requirements has complicated interpretation of distribution data although the submitted reports still provide an indication of the number of units and the quantities of byproduct material distributed for exempt use. Table 2 is a listing of reported and recorded information about the more widely distributed consumer products containing byproduct material.

Although Commission regulations have required reports from distributors/^{of products}containing byproduct material (smoke detectors, self-luminous products, etc.) no similar requirement has been imposed on distributors of consumer products containing source material (gas mantles, welding rods, etc.). The absence of a reporting requirement for source material is a result of specific provision in Section 65 of the Atomic Energy Act of 1954, as amended, that the Commission shall not require reports with respect to unimportant quantities of source material.

The absence of reporting requirements for consumer products containing source material has not prevented the development of estimates on distribution. These estimates are used in NUREG/CR-1775, "Environmental Assessment of Consumer Products Containing

Radioactive Material," and include annual distribution of:

(a) 25,000,000 incandescent mantles containing thorium, (b) 5,200,000 thoriated welding rods, and (c) 38.7 million porcelain teeth containing 15.4 pounds of uranium.

TABLE 2
 QUANTITIES DISTRIBUTED*

GAS and AEROSOL DETECTORS: (See attached bar graph.)

Over a 16 year period (1971 through 1986) 92,085,000 smoke detectors containing 320.4 curies Am-241 were distributed; also, 124,000 units containing 1.2 curies Ni-63.

SELF-LUMINOUS PRODUCTS (Including timepieces):

Over a 17 year period (1970 through 1986) more than 150,000,000 units containing 1,380,000 curies H-3 were distributed; also 7,000,000 units containing 4,000 curies Pm-147.

EXEMPT QUANTITIES:

Over a 15 year period (1972 through 1986) the following:

<u>Radionuclide</u>	<u>Millicuries</u>	<u>Radionuclide</u>	<u>Millicuries</u>
Am-241	0.001	Kr-85	25.9
Ba-133	41.5	Mn-54	3.8
C-14	35.	Na-22	0.231
Ca-45	0.204	Ni-63	3.66
Cd-109	9.1	P-32	66.4
Ce-144	0.07	Pb-210	0.116
Cl-36	0.2	Pm-147	1.41
Co-57	21.7	Po-210	2.64
Cr-51	4155.	Rb-106	0.006
Cs-137	220.	S-35	29.5
Fe-55	29.4	Sn-113	38.9
Fe-59	219.	Sr-90	10.0
H-3	78,600.	Tc-99	0.083
I-125	7,110.	Tl-204	81.
I-129	0.346	Ta-182	0.025
I-131	10,000.	Zn-65	3.6
Ir-192	0.0099		

*Data Source: Materials Licensing Branch, NMSS
 Internal Memorandum dated 2/18/87.,

TABLE 2 (cont.)

TOTAL ACTIVITY AND UNITS SOLD FOR Am-241 UNDER 10 CFR 32.26

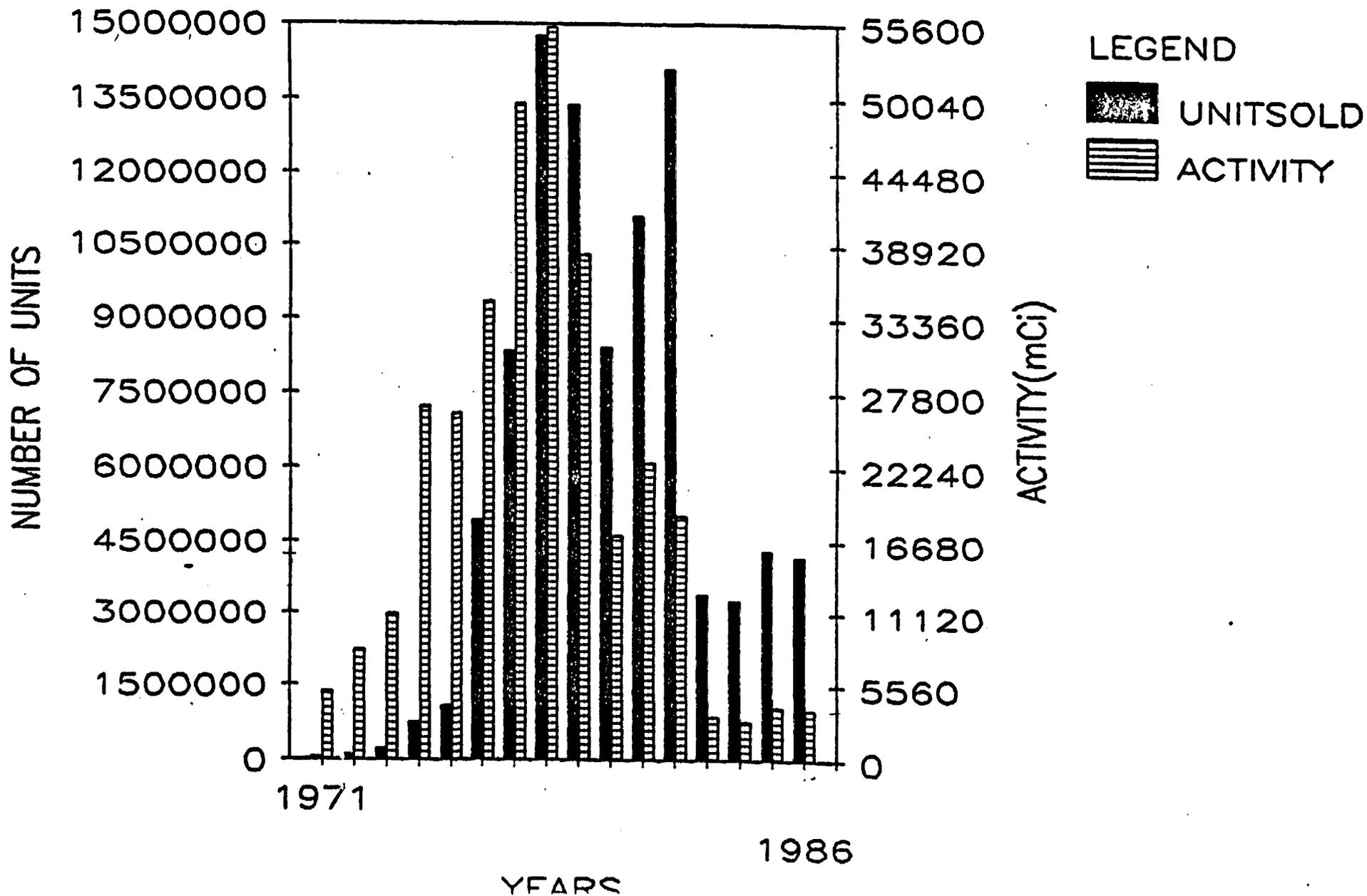


TABLE 2 (cont.)

QUANTITIES DISTRIBUTED

ELECTRON TUBES:

Over a 17 year period (1970 through 1986) the following:

<u>Radionuclide</u>	<u>Millicuries</u> <u>x 10³</u>	<u>Number of Units</u> <u>In Millions</u>
H-3	5,245.	133.
Cs-137	0.279	0.272
Co-60	0.148	0.519
Kr-85	334.	1,182.
Ni-63	1.21	1.185
Pm-147	186.	33.3

EXEMPT CONCENTRATIONS:

Over a 16 year period (1971 through 1986) the following:

<u>Radionuclide</u>	<u>Millicuries</u>	<u>Radionuclide</u>	<u>Millicuries</u>
Au-198	27.	H-3	7990.
Br-82	10.7	Hg-203	1193.
C-14	7.5	I-125	18700.
Cs-134	43.	I-131	185.
Cs-137	7.2	Kr-85	128.
Fe-55	6.7	P-32	2880.
Co-60	3,800.	Sn-113	8.11
Fe-59	17.9	Sr-90	0.0385

ASSESSMENTS of PUBLIC EXPOSURE from CONSUMER PRODUCTS

By NCRP

The increased use of consumer goods which emit ionizing radiation prompted the National Council on Radiation Protection and Measurements (NCRP) to establish Scientific Committee 28 in 1972. This Committee was assigned responsibility for estimating "Radiation Exposure from Consumer Products and Miscellaneous Sources."

The primary goal of the Committee was to identify consumer products that could be sources of ionizing radiation and to provide quantitative data on the range of typical dose equivalents to members of the population from each such source. To the extent possible, the Committee was also asked to provide information to assist in making decisions on whether a given application involving radiation exposure might better be replaced by some other method of accomplishing the same task without involving irradiation of the population.

The results of Committee 28's effort were published as NCRP Report No. 56 in 1977.

The Report covered approximately 25 sources including television receivers, tobacco products, luminous timepieces, and glass and ceramics. The data showed that the total average annual contribution to the whole-body dose equivalent to the U.S. population from consumer products was less than 5 mRem. The data also indicated that consumer products which were subject to NRC control contributed only a small fraction of the 5 mrem. The major contributors were television receivers and building materials.

In 1987 the NCRP updated and superseded Report No. 56 (1977) by issuance of NCRP Report No. 95, "Radiation Exposure of the U.S. Population from Consumer Products and Miscellaneous Sources." A summary of the number of people exposed to each source evaluated in the report, an estimate of the resulting

dose equivalents to the exposed population, and an estimate of the average annual collective effective population dose equivalent (based upon an assumed U.S. population of 230 million) are presented in Table 5.1 of the report. A copy of Table 5.1 is shown on the following page. Those consumer products which are subject to NRC regulation are identified with an "x".

By Science Applications, Inc.

Under contract to NRC, Science Applications, Inc. prepared a report on consumer products. The report was published in 1980 as NUREG/CR-1775, "Environmental Assessment of Consumer Products Containing Radioactive Material." The report was intended as a supporting document for an NRC generic environmental impact statement (GEIS) on consumer products. The GEIS was not issued and so NUREG/CR-1775 has not served its primary intended purpose. However, the report is quite comprehensive and useful when considering the impact of NRC regulated consumer products.

The approach followed in the report is to assess each important consumer product individually in separate sections. Each section provides the information needed to arrive at a comprehensive assessment of each consumer product. First, a general overview or background information on the product is given, including product descriptions, distribution, life span uses, and other pertinent data. Following the general overview, a discussion of the environmental impact of the product due to manufacture, distribution, use, and disposal is given. The particular benefits derived from the use of the product are discussed, as are the adverse impacts of product use, including both radiological and non-radiological aspects. The radiological impacts are expressed in terms of dose commitments and health

Source	Number of people exposed in the United States	Average annual dose equivalent to the exposed population ^a	Remarks	Average annual effective dose equivalent to the exposed population ^a	Average annual effective dose equivalent to the U.S. population ^a	Annual collective effective population dose equivalent (person-Sv) ^b
Electronic products						
Unwanted byproduct x rays						
Television receivers	230,000,000	<0.01 mSv	Whole body exposure	<0.01 mSv	<0.01 mSv	<2,300
Video display terminals	50,000,000	<0.01 mSv	Whole body exposure	<0.01 mSv	<0.01 mSv	<500
Intentional x rays						
Airport luggage inspection systems	30,000,000	0.021 μSv	Whole body exposure	0.021 μSv	0.0027 μSv	0.6
Radioactive materials						
Processed radioactive materials						
Radioluminous products						
Luminous watches and clocks						
* H activated watches	10,000,000	1.04 μSv	Whole body exposure	1 μSv	0.05 μSv	12
	750,000					
* ²²⁷ Pm activated watches	3,700,000	0.4 μSv	Whole body exposure	0.4 μSv	0.014 μSv	3.2
	4,400,000					
* Static eliminators	40,000	3.2 μSv	Whole body exposure	3.2 μSv	0.0003 μSv	0.13
* Electron tubes	230,000,000	0.04 μSv	Whole body exposure	0.04 μSv	0.04 μSv	10
* Gas and aerosol detectors	100,000,000	0.08 μSv	Whole body exposure	0.08 μSv	0.03 μSv	8
* Check sources	800,000	0.01-1 mSv	Whole body exposure	<0.01 mSv	<0.04 μSv	<8
Natural radioactive materials						
Tobacco products						
Tobacco products	50,000,000	160 mSv	Bronchial epithelial dose equivalent	X ^c	X	X
Building materials	120,000,000	0.07 mSv	Whole body exposure	0.07 mSv	0.035 mSv	8,400
Domestic water supplies	230,000,000 ^d	0.15-0.9 mSv ^e	Bronchial epithelial dose equivalent	0.01-0.06 mSv ^f	0.01-0.06 mSv	2,300-14,000
Highway and road construction materials	5,000,000	0.04 mSv	Whole body exposure and gonadal dose equivalent	0.04 mSv	0.0008 mSv	200
Mining and agricultural products						
Fertilizer products						
Fertilizer products	200,000,000	0.005-0.05 mSv ^g	Whole body exposure and ingestion dose from food	0.005-0.05 mSv	<0.01 mSv	<2,000
Combustible fuels						
Coal						
Coal	230,000,000	0.3-3 μSv ^h	Exposure is to several organs	0.3-3 μSv	0.3-3 μSv	80-700
Natural gas						
Heaters						
Heaters	16,000,000	0.22 mSv	Bronchial epithelial dose equivalent	0.018 mSv ⁱ	0.0012 mSv	290
Cooking ranges	125,000,000	0.05 mSv		0.004 mSv ⁱ	0.002 mSv	800
Liquefied petroleum gas	18,000,000	0.016 mS		0.0013 mSv	0.0001 mSv	23
Glass and ceramics						
* Dental prostheses	45,000,000	7 mSv	Basal mucosa dose equivalent	0.0007 mSv ^j	0.00014 mSv	30
* Ophthalmic glass	60,000,000	40 mSv	Corneal germinal dose equivalent	<0.004 mSv ^j	<0.001 mSv	<200
Thorium products						
* Gas mantles	50,000,000	0.002 mSv	Whole body exposure plus selected organ dose equivalent	0.002 mSv	0.0004 mSv	86
* Tungsten welding rods	300,000	0.16 mSv	Whole body exposure plus selected organ dose equivalent	0.16 mSv	0.0002 mSv	50
* Fluorescent lamp starters	50,000,000	0.0002 μSv	Whole body exposure plus selected organ dose equivalent	0.0002 μSv	0.00004 μSv	<0.01
Miscellaneous sources						
Aircraft transport of radioactive material						
Passengers	14,000,000	2.3 μSv	Whole body exposure	2.4 μSv	0.13 μSv	30
Pilots	15,000	0.7 μSv				
Attendants	20,000	35 μSv				

^a 1 mSv = 100 mrem.
^b 1 person-Sv = 100 person-rem.
^c Data necessary to convert the organ dose to an effective dose equivalent are not currently available (See Section 3.2.1).
^d Although some radon is present in all domestic water supplies, those members of the population using groundwater sources would be expected to receive the largest doses from this source.
^e Estimates of the population dose equivalent vary so widely that only a range can be given at the present time.
^f Based on a weighting factor of 0.08 (See Section 3.2.3).
^g Based on a weighting factor of 10⁻⁴ (See Section 3.2.7.4).
^h Based on a weighting factor of 10⁻⁴ (See Section 3.2.7.5).

effects, where appropriate, due to exposures received by the population of concern during the life span of the product. Included in the discussion of radiological impacts is the disposal of the product in landfills and by incineration, as well as the consequences of possible accidents or misuses of the product.

The assessments indicate that radioluminous timepieces, gas mantles, welding rods and electron tubes are among the greatest contributors to doses to the public from consumer products which are subject to NRC regulation. Each of the four types of products causes an estimated 1,000 person-rem (10 person-Sv) or more annual dose to the total population.

The following Table 3 combines information from NUREG/CR-1775 and NCRP Report No. 95 to illustrate the quantities of radioactive material in a product, numbers of exposed persons, and individual and collective doses.

TABLE 3 - RADIATION EXPOSURE FROM CERTAIN CONSUMER PRODUCTS

Consumer Product	Radionuclide & Average Content	Number of people exposed in the United States	Average annual effective dose equivalent to exposed person	Annual collective effective dose equiv.
Incandescent Gas Mantles	Th 0.036 uCi (325 mg)	50,000,000	0.2 millirem (0.002 mSv)	8,600 person-Rem (86 person-Sv)
Welding rods	Th 0.029 uCi (260 mg)	300,000	16 millirem (0.16 mSv)	5,000 person-Rem (50 person-Sv)
Timepieces	H-3 1.85 mCi	10,750,000	0.1 millirem (1 uSv)	1,200 person-Rem (12 person-Sv)
	Pm-147 0.045 mCi	8,100,000	0.04 millirem (0.4 uSv)	320 person-Rem (3 person-Sv)
Gas and Aerosol Detectors	Am-241 3.5 uCi	100,000,000	0.008 millirem (0.08 uSv)	800 person-Rem (8 person-Sv)
Electron tubes	H-3: 21 uCi	230,000,000	0.004 millirem (0.04 uSv)	1,000 person-Rem (10 person-Sv)
	C-14: 47 uCi			
	Co-60: 0.17 uCi			
	Ni-63: 0.91 uCi			
	Kr-85: 0.18 uCi			
	Cs-137: 1.1 uCi			
Pm-147: 8.7 uCi				

References - The data on radionuclide and content are from NUREG/CR-1775, "Environmental Assessment of Consumer Products Containing Radioactive Material." The data on exposed population and doses are from NCRP Report No. 95, "Radiation Exposure of the U.S. Population from Consumer Products and Miscellaneous Sources."

CONSUMER PRODUCTS of CURRENT PARTICULAR INTEREST

Radioactive Gems

In 1986 the NRC became aware that large quantities of irradiated gems, particularly topaz, were on the U.S. retail market from both foreign and domestic sources. The gems had been irradiated in reactors to enhance their color. Irradiation of the gems induces low levels of radioactivity which is subject to NRC regulation. Licensing of the distribution of the gems has been performed under 10 CFR Section 32.11 and under the conditions established in the licenses, the gems are not expected to cause annual doses in excess of 1 millirem whole body dose equivalent.

In authorizing distribution of gems under §32.11 it has been necessary to waive the requirement that the subject radioactive material not be incorporated into any product designed for application to a human being.

Explosive Detection Systems

The Federal Aviation Administration (FAA) has been developing, and has applied for an NRC license to use, an explosive detection system (EDS) which uses thermal neutron activation to inspect airline baggage. The purpose of the system is to detect contraband explosives placed in airline baggage.

Exposure of the baggage to the neutrons is expected to reveal materials high in nitrogen (which is found in most explosives). The neutrons also cause low level concentrations and quantities of other radionuclides and exposure of the public. The largest potential radiation exposure to passengers appears to be due to transport of gold jewelry. When gold is passed through the EDS, the radioisotope gold-198, half life 2.3 days, is produced. The potential dose from wearing a 40-gram gold medallion after

passing through the EDS was evaluated. The total beta particle dose at a depth of 0.007 cm beneath the skin next to the jewelry is estimated to be about 0.7 mrad if the item would be worn continuously for approximately 10 days after the baggage is claimed.

An NRC environmental assessment of the EDS estimates a collective dose to the public of 9 person-rem/unit/year.

CONFORMANCE OF REGULATORY PRACTICES FOR CONSUMER PRODUCTS
WITH THE PROPOSED NEW BROAD POLICY ON EXEMPTIONS:

On December 12, 1988, the NRC published in the Federal Register an advance notice of intent to develop a broad policy statement on exemptions from regulatory control for practices whose health and safety impacts could be considered below regulatory concern. The policy statement is intended to provide for more consistent regulatory actions in connection with exemptions from various Commission requirements.

Regulatory practices concerning consumer products are one group of actions which are expected to be covered by the new policy. Accordingly, it is of interest to evaluate the acceptability of the existing regulatory exemptions for products under the provisions of the proposed broad policy. For purposes of this evaluation it is assumed that regulatory actions on (a) each of the 33 types of consumer products in Table 1, (b) licensing of the distribution of gemstones under a waiver from a prohibition on products applied to humans, and (c) licensing of the use of the Explosive Detector System at airports, make up a total of 35 "practices." And, although the published statement may be open to interpretation on some points and is yet to be firmed up on others, the following are assumed to apply:

1. Justification - There should be some expectation of net benefit for the practice.
2. Dose limits - It should appear unlikely that the dose from this practice, when combined with likely doses from other exempted practices, will exceed 100 mrem/year effective dose equivalent.
3. ALARA - A cost-benefit analysis should show that imposition of regulatory controls after distribution of the product would not be cost effective.

4. Distribution - There should be adequate regulatory controls on distribution of the product and a means of monitoring distribution.
5. Risks from accidents - The estimated risk from accidents involving an exempted product should be acceptable.

Determinations of justification may be affected by Commission decisions on specific criteria for exclusions from exemption, such as (a) continuing the custom of excluding the intentional introduction of radioactive material into toys, and into products for ingestion, inhalation, or direct application to the skin, or (b) finding categorically unjustified uses where there are clear economical alternatives and no unique benefits from using radioactive material.

Under the proposed policy, depending on the circumstances either a detailed cost-benefit analysis may be needed or a simple analysis may suffice to determine ALARA with respect to regulatory controls after distribution. With respect to other aspects of the practice, a simple analysis will satisfy ALARA concerns if individual doses are unlikely to exceed 10 mrem/year and the collective dose is small. Collective doses should be compared with two values which are under consideration: 100 person-rem and 1,000 person-rem. If the simple analysis indicates individual and collective doses greater than these limits, then a detailed cost-benefit analysis is needed to satisfy ALARA concerns.

No specific criteria have been proposed in the policy statement concerning acceptability of accidents risks. For the purposes of this evaluation, the safety criterion used in the class exemptions for self-luminous products (§32.23) and for gas and aerosol detectors (§32.27) will be applied: the probability is negligible (i.e., not more than once per year per million units distributed) that a person would receive in excess of 15 rem effective dose equivalent.

Conclusions of evaluation of present practices

General observation - The majority of the 35 practices appear consistent with the guidance of the proposed broad policy. This is not unexpected because of the general agreement between the proposed policy and the consumer product criteria policy that was published in 1965 (copy in Appendix A). However, there are several instances where some of the 35 practices may not fully satisfy all aspects of the five points listed above for the proposed policy. The possible departures from the five points are:

1. Justification -

The question of "net benefit" is raised by the use of uranium compounds to produce pigmented glazes for glassware and ceramic pottery and tableware and to color decorative glassware. Part 40 has allowed for these uses since its first issuance in 1947. A conservative estimate of radiation doses to users of radioactive tableware in feeding establishments indicates about 34 mrem/yr to dishwashers, 8 mrem/yr to waiters and 0.2 mrem/hr to patrons.¹ Since the use of uranium in these products results in little or no benefit in terms of health or well-being of the public, and since suitable substitutes for uranium exist for this application, it can be concluded that the exposures incurred as a result of product distribution and use, while low in most cases, are unnecessary and unwarranted. While manufacture and distribution of these products may be limited at present by the marketplace, unlike glass enamel frit (amended in 1984 to prohibit further distribution), the regulations do not prohibit distribution.

1. NUREG/CR-1775, p. 8-5.

A question of "net benefit" also is raised by the irradiation of gemstones to enhance their color and value but also causing very low level effective dose equivalents to users. To date, this question has been resolved in favor of continuing the distribution, which occurs both domestically and internationally, under conditions imposed on the specifically licensed distributors.

A question of "net benefit" also accompanies the use of uranium in teeth (under §40.13(a)). The only benefit is strictly of a cosmetic nature in that the uranium causes artificial teeth to have a fluorescent quality similar to natural teeth. This cosmetic quality may be essential to certain persons such as those before the cameras in the television or film industry.

2. Dose limits - With one possible exception, all the 35 practices appear to cause less than 100 mrem/year effective dose equivalent. That possible exception is the use of uranium counterweights in aircraft. As stated in the Statement of Considerations when expanding that exemption in 1961,²

"...Is highly unlikely that any individual would be exposed to a radiation dose in excess of one-tenth the occupational dose limits of 10 CFR Part 20. The radiation dose rate at the surface of the counterweight is about 130 mr/hr of beta-gamma radiation, of which the gamma component contributes only 2.7 mr/hr. Film badge data and handling time studies indicate that it is probable that the yearly dose to the hands would not exceed 5 rems, from handling incident to storage, installation, and removal of counterweights in aircraft. Ten percent of the Part 20 limit for exposure of the hands and forearms of individuals in a restricted area is 7.5 rem per year. The whole body dose is unlikely to exceed a small fraction of the dose limit for individuals in unrestricted areas."

2. 26 FR 7143, August 9, 1961.

It may be noted that when this exemption was established, uranium counterweights were not considered to be "consumer products" because they were intended for use by a limited industry. An examination of this use, particularly at aircraft manufacturing plants, may be in order to determine whether the 100 mrem/year limit is likely to be exceeded.

3. ALARA - Simple analyses for the 35 practices indicate no case where imposition of regulatory controls after distribution would be cost effective.

The application of the ALARA principle to products causing individual annual doses greater than 10 mrem/yr or large annual collective doses may relate to the following:

Welding rods 5,000 person-rem and 2.4 - 88 mrem individual

Timepieces - H-3..1,200 person-rem

Timepieces - Pm-147 ... 320 person-rem

Electron tubes 1,000 person-rem

Gas & Aerosol detectors

(smoke detectors) 800 person-rem

Dental prostheses..... 30,000 person-rem

Gas mantles8,600 person-rem

The above products are addressed in NUREG/CR-1775, "Environmental Assessment of Consumer Products Containing Radioactive Material" and in NCRP Reports 56 and 95.

Aircraft counterweights, because of possibly exceeding the individual annual dose criterion of 10 mrem/yr, may qualify for a detailed cost-benefit analysis.

4. Distribution - Generally acceptable controls apply to the 35 practices although two changes could be considered:
(a) amendment of Part 40 so that control over manufacture and distribution more closely parallels Part 30, and (b) require annual reports of transfers of all distributors of exempt products.

5. Risks from accidents - A possible question is raised by gas mantles. The above criterion of 15 rem could be exceeded if a small child were to ingest a gas mantle. The calculated dose to the child would be 16 rem.³ Although the probability of occurrence is difficult to predict, the likelihood of its occurrence combined with the 16 rem dose results in an acceptable risk.

Additional comment

On at least one occasion (uranium in mass-volume applications) a petition for rulemaking was denied⁴ because of concern about ultimate entry of the uranium into scrap-processing systems. On another occasion, when approving an exemption of certain aircraft engine parts containing nickel-thoria alloy⁵, the Commission considered whether the exemption could ultimately result in contamination by thorium of materials used in construction of nuclear reactors. In the latter case it was stated:

"...In order to continue verification that contamination of reactor construction materials by thorium or other similar impurities does not occur or build up over an extended period of time, the Commission will arrange periodically to sample reactor construction materials for thorium and other contaminants. If this periodic sampling shows an increasing thorium level in such materials, the regulation set forth below may be amended from time to time to effect licensing controls to prevent the thorium contained in discarded nickel-thoria aircraft engine parts from contaminating materials used for construction of nuclear reactors."

This interest in matters other than those that directly cause radiation exposure to persons presumably will be considered when determining the justification and net benefit of a practice.

3. NUREG/CR-1775, p. 5-25

4. 40 FR 2209, January 10, 1975.

5. 32 FR 15872, November 18, 1967.

U. S. ATOMIC ENERGY COMMISSION

(Reprint from Federal Register) 30 F.R. 3462, March 16, 1965

ATOMIC ENERGY COMMISSION USE OF BYPRODUCT MATERIAL AND SOURCE MATERIAL

Products Intended for Use by General Public (Consumer Products)

Criteria for the approval of products intended for use by the general public containing byproduct material and source material. This notice sets forth the essential terms of the Commission's policy 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. 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 material of the Atomic Energy Act of 1954, as amended, and of the Commission's regulations "Licensing of Byproduct Material", 10 CFR Part 30 and "Licensing of Source Material", 10 CFR Part 40.

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 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 and reporting requirements applicable to the manufacture and distribution of such products. If radioactive materials are used in sufficient quantities in products reaching the public so as to raise any question of population exposure becoming a significant fraction of the permissible dose to the gonads, 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 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 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), and that the probability of individual doses approaching any of the specified limits is negligibly small. 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.

3. It is considered that as a general rule 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 of which antedate the atomic energy program. These include:

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

(2) Thorium in various alloys and products (gas mantles, tungsten wire, welding rods, optical lenses, etc.) 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:

(1) Tritium in automobile lock illuminators;

(2) Tritium in balances of precision;

(3) Uranium as shielding in shipping containers; and

(4) Uranium in fire detection units.

8. In approving uses of byproduct and source materials in consumer products, the Commission establishes limits on quantities or concentrations of radioactive materials and, if appropriate, on radiation emitted. In some cases other limitations, such as quality control and testing, considered important to health and safety are also specified.

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 and disposal of individual products;

(b) The potential total accumulative 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 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 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 would take into consideration the following factors together with other considerations which 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 of the radionuclides. The less toxic materials with a high permissible body burden, high concentration limit in air and water, would be considered more favorably than materials with a high radiotoxicity.

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

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

(Sec. 161, 68 Stat. 948; 42 U.S.C. 2201. Administrative Procedure Act, sec. 3, 60 Stat. 238; 5 U.S.C. 1002)

Dated at Washington, D.C., this 8th day of March 1965.

For the Atomic Energy Commission.

W. B. McCool,
Secretary.

[F.R. Doc. 65-2616; Filed, Mar. 15, 1965; 8:45 a.m.]

Appendix A