

MAY 2 1989

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Marvin R. Peterson

SUBJECT: COMMENTS ON IAEA SAFETY SERIES DOCUMENT ON REGULATING THE
USE OF CONSUMER PRODUCTS CONTAINING RADIOACTIVE SUBSTANCES

The IAEA has requested comments on the attached draft Safety Series Document, "Regulating the Use of Consumer Products Containing Radioactive Substances". Please note NRC staff participated in development of this draft as a member of the Advisory Committee. Comments from the Commission are to be considered by the Secretariat and an Advisory Group meeting scheduled for early 1990.

Please provide comments to the office of International Programs by close-of-business, Friday, May 19, 1989.

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SAFETY SERIES DOCUMENT

ON

REGULATING THE USE OF CONSUMER PRODUCTS CONTAINING RADIOACTIVE SUBSTANCES

DRAFT FOR COMMENTS

MARCH 1989

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FOREWORD

Luminizing properties of radioactive materials have for many decades been used in radioluminous watches and in dials for other instruments. In recent years radioactive substances have been added to ionization smoke detectors, antistatic brushes, etc. Because of the rather large scale use of such consumer products concern has been growing about the protection of the public from unnecessary radiation exposure arising from the use of these type of products.

Radiation doses to the individual members of the public may result through the use, misuse, accident and disposal of consumer products containing radioactive substances. The radiation doses, although very small, as estimated by UNSCEAR [1], cannot be avoided altogether. Members of the public in general will not be able to evaluate the significance of any radiation exposure and in many cases may not even be aware of the presence of radioactive material in a product. There is, therefore, a need for competent authorities to exercise appropriate forms of control over consumer products containing radioactive substance.

This Code of Practice has been prepared by using as a main reference the OECD/NEA Guide for Controlling Consumer Products Containing Radioactive Substances [2]. It also took into consideration the IAEA Safety Guide on the Principles for the Exemption of Radiation Sources and Practices from Regulatory Control [3].

The basis of regulatory control given in the IAEA Basic Safety Standards for Radiation Protection [4] is a system of notification, registration and licensing, which makes it possible for the competent authority to impose appropriate requirements for protection. Varying degrees of regulatory control are defined: the full system of licensing of operation involving radiation; a system of general authorization, in which the competent authority will have a general appreciation of the national situation; or, when, this level of control is not required, exemption from all the control recommended in the Basic Safety Standards.

The purpose of this Code is to provide a set of recommendations defining the policy and basic radiation protection principles to be followed when controlling such consumer products. The application of the Code and its incorporation into national regulations and practices is, of course, the responsibility of the competent authorities and depends on local socio-economic and administrative situations. It is expected, however, that the adoption of these recommendations would provide an adequate margin of safety for members of the public and could also lead to consistent national policies that will avoid difficulties in international trade, since consumer products containing radioactive materials are also exported to many countries.

This Code contains two annexes. Annex I discusses the level of radioactivity that is of no regulatory concern. Annex II gives details of the prototype tests normally carried out on ionization chamber smoke detectors.

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CHAPTER 1

SCOPE

1.01 This Code is concerned only with those products and appliances in which radionuclides have been deliberately incorporated or induced, and which can be supplied to members of the public. They are essentially beyond further control for purposes of radiation protection by the competent authority. Such products will henceforth be termed "consumer products" in this Code. Consumer products are considered regardless of the purpose for which the radionuclide is added.

1.02 The Code does not cover some products containing natural radioactive substances which have not been intentionally added, such as building materials, spa waters and geological specimens. These products will result in public exposure, but the subject of their control warrants separate consideration.

1.03 The Code does not cover medical use of radionuclides including radio-pharmaceuticals, and nuclear powered cardiac pacemakers. Radiation generating equipment, such as television receivers that emit x-rays adventitiously are also not covered in the Code.

1.04 The Code is concerned mainly with the exposure arising from consumer products of those persons who are not covered by any regulatory controls for purposes of radiation protection in normal circumstances. Members of the public come under this heading, but not workers involved in the manufacture of consumer products. These workers will normally be covered by occupational radiation protection control. However, although workers involved in handling, including servicing of the products will be covered by existing radiation protection controls in some countries, competent authorities in other countries may need to consider the exposure of such persons in their assessments of consumer products.

CHAPTER 2

INFORMATION ON SOME EXISTING CONSUMER PRODUCTS

2.01 Most of the consumer products now in existence as well as some older products no longer manufactured and supplied, but still in existence in some households, are listed in Tables 1 and 2. Certain important radiation safety aspects in the use of consumer products are discussed below:

2.02 The most widely used product is probably the ionization chamber smoke detector (ICSD) which requires a low activity of alpha emitting radionuclide, e.g. less than 40 kBq of ^{241}Am for its functioning. Annual doses to individual members of the public arising from the use of ICSDs range from 0.01 to 0.2 μSv depending on the number, location and occupancy. Although individual doses are very low, there has been a world wide concern because of the collective doses resulting from the very large number of such devices used in many countries. Their use everywhere is increasing at a very fast rate and in some countries the collective dose has exceeded or is approaching 1 man.Sv per year.

2.03 Time pieces with radioluminous paint, particularly watches which are often worn close to the body for up to 24 hours a day, are still used, although much less than in the past. Nowadays such timepieces usually contain ^3H or ^{147}Pm . Annual dose equivalent from time pieces containing ^3H or ^{147}Pm are generally of the order of 0.1 μSv but in certain cases the doses can be as high as 10 μSv .

2.04 Thoriated gas mantles in incandescent lamps are widely used in some countries. In some parts of the world such lamps are used as the main lighting in houses. In many countries, however, their use is now mainly confined to caravan users and campers. Doses to users arise from direct β and γ radiation and from inhalation and ingestion of material emitted during burning of the lamp or as a result of mantles being broken particularly when they are being removed from the lamp for replacement. Annual doses to occasional users of such lamps are of the order of a few μSv , but those who use them for lighting a home could receive much higher annual doses.

2.05 Another product which has appeared in many countries in recent years is the irradiated gemstone. Many such stones are now irradiated, to enhance their colour. However, it has recently been observed that such enhanced colour is not permanent in all cases. Irradiation by neutrons in addition produces induced activity in the stones depending on the concentration of trace elements. There have been some reports of stones being released to the public with unacceptably high levels of activity giving rise to high skin doses to the users. Such instances are rare, however, and by careful choice of stones to avoid certain impurities and by allowing sufficient time after irradiation for the short-lived nuclides to decay, stones with very little activity can be produced.

2.06 Uranium is still used to produce certain coloured enamels, usually yellow and orange shades, which have been used for cloisonne jewellery, badges, key fobs, etc. Annual doses from such key fobs which may be kept in a pocket close to the body for many hours a day could be a few μSv .

2.07 Other products which have caused critical comment in recent years are certain camera lenses to which thorium has been added to change the optical properties of the glass, antistatic brushes containing ^{210}Po or ^{241}Am and dental products containing uranium claimed to give similar fluorescent properties as normal teeth. Thorium in lenses is not a severe problem although some reports have appeared claiming that people who use a camera a great deal could receive unacceptable doses to the eyes. Antistatic brushes containing ^{210}Po microspheres might give rise to unacceptable doses to users under certain accidental conditions. The use of uranium in dentures has caused undesirable exposures to the users [5].

2.08 Products containing gaseous tritium light sources (GTLSs) that conform with the standards for gaseous tritium light devices (GTLDs) [6] rarely cause any problem. There is some evidence, however, that some GTLDs which typically contain up to 8 GBq of ^3H do not always meet the requirements of the Standards. This could lead, in a few cases, to dose equivalents (committed from intake) higher than justified due to breakage of a GTLS.

2.09 Finally, products which give the largest doses to users are the old products containing radium, particularly pocket watches containing up to 150 kBq of ²²⁶Ra where annual dose equivalents much greater than 10 μ Sv are common and where skin doses are significant. Such products do not come onto the market very often and it would not be easy to control such sales of second hand goods. It would be very desirable, however, to control such sales if this is at all possible.

Table 1. Examples of consumer products currently available.

Product	Nuclide	Activity or mass per product	References	Notes
Ionization chamber smoke detector	^{241}Am	Up to 0.04 MBq	7,8,9,10	Some existing detectors have higher activities.
Timepieces containing radioactive paint	^3H ^{147}Pm , ^{226}Ra	Up to 280 MBq Up to 5.5 MBq Up to 5.5 kBq	11,12,13,14 15,16,17,18	Activities quoted are maximum values allowed by IAEA standard (ref 11) for wristwatches.
Higher				activities allowed for clocks. Some existing time pieces have higher activities. Radium now very little used.
Compasses containing radioactive paint	^3H ^{147}Pm ^{226}Ra ^{90}Sr	Up to 300 MBq Up to 6 MBq Up to 200 kBq [data to be provided]		Radium now very little used. ^{90}Sr not used in most countries
Other products containing radioactive paint	^3H ^{147}Pm	Up to 300 MBq Up to 4 MBq		e.g. switch markers, bell pushes, lock illuminators etc. Very few new products.
Liquid crystal display digital watches with gaseous tritium light sources (GTLSS)	^3H	4000 to 7500 MBq	10,12,18,19 6	Not available in some countries. Use declining.
Compasses containing GTLSS	^3H	up to 7500 MBq	6	
Fishing floats containing GTLSS	^3H	Up to 7500 MBq	6	Not available in some countries.
Telephone dials containing GTLSS	^3H	Up to 7500 MBq	6	Not usually on modern push button phones. Not available in some countries.
Other products containing GTLSS	^3H	Up to 7500 MBq	6	e.g. light switch markers, bell pushes, etc. Not available in some countries.
Antistatic brushes	^{210}Po ^{241}Am	Up to 18 MBq Up to 1 MBq	12,20,21	Not available in some countries

Dental products	U	Up to 0.3 mg	12,5,22,23,24	Use declining
Incandescent gas mantles	Th	1 to 1.6 kBq	12,18,25,26,27	
Optthalmic glass	Th	Up to 0.1 kBq	12,18,28,29,30, 31	
Camera lenses	Th	Up to 15 kBq	32,33	
Glassware and ceramic tableware	U Th	Up to 1kBq/g(glaze) up to 1 kBq/g (glaze)	12,34	
Ceramic tiles	U Th	up to 1 kBq/g (glaze) up to 1 kBq/g (glaze)		
Enamelled badges cloisonne jewellery	U	Up to 400 Bq/g (enamel)		
Irradiated gemstones	⁴⁶ Sc ⁵⁴ Mn ⁹⁵ Zr ⁹⁵ Nb ¹⁰³ Ru ¹¹³ Sn ¹²⁴ Sb ¹²⁵ Sb ¹³⁴ Cs ¹⁴⁴ Ce ¹⁸² Ta	20 Bq/g 13 Bq/g 3.4 Bq/g 7.4 Bq/g 0.5 Bq/g 3.3 Bq/g 1.5 Bq/g 0.85 Bq/g 3.7 Bq/g 5.3 Bq/g 150 Bq/g	35	Principal radionuclides and their respective maximum concentration are shown. At least 2 of these radionuclides typically present
Electron tubes	³ H ¹⁴ C ⁶⁰ Co ⁶³ Ni ⁸⁵ Kr ¹³⁷ Cs ¹⁴⁷ Pm	800 kBq 1700 kBq 6 kBq 35 kBq 7 kBq 40 kBq 320 kBq	12,18	Average values given in reference [12] are shown
Fluorescent lamp starter	Th ³ H	up to 0.5 Bq up to 1 MBq	12,18	
Lightning conductor attachment	²²⁶ Ra ²⁴¹ Am	Up to 40 MBq Up to 400 MBq	36	Not supplied direct to public in most countries.
Thoriated tungsten rods	Th	0.1 to 1kBq	12,37	

Note: This table does not pretend to be exhaustive as far as products or practices are concerned.
(There is some overlap with Table 2 which lists consumer products no longer produced)

Table 2

Table 2: Consumer products no longer produced in significant quantities but which have been supplied to members of the public in the past and may still sometimes be available in second-hand markets

<u>Product</u>	<u>Nuclide</u>	<u>Activity per product</u>
Ionization chamber smoke detector	^{226}Ra ^{85}Kr	Up to 550 kBq 250 MBq
Time pieces containing radioactive paint	^{226}Ra ^{90}Sr	Up to 200 kBq
Compasses containing radioactive paint	^{226}Ra	Up to 200 kBq
Other products containing radioactive paint (e.g. instrument dials, thermostat dials and pointers, car lock illuminators, bell pushes, speedometers, light switch markers)	^{226}Ra	Up to 50 kBq
Electron tubes	^{226}Ra	4 kBq
Fluorescent lamp starter	^{226}Ra	40 kBq
Vending machine coins	^{14}C	80 kBq
Bank cheques	^{14}C	0.4 kBq
Luminizing kits	^{226}Ra ^3H	Up to 100 kBq Up to 1 GBq
Electric compress (blanket)	^{226}Ra	Up to 3 MBq
Emanators, soda syphon bulbs and other devices designed to add radon to drinking water	^{226}Ra	1 kBq to 3 MBq
Ointments, creams, and powders	Natural uranium Natural thorium	
Driver's licences	^{147}Pm	40 kBq
Identity cards	^{147}Pm	40 kBq

Note: This table includes some but not all products available in the past.

CHAPTER 3

PRINCIPLES OF RADIATION PROTECTION

3.01 The IAEA/ILO/NEA(OECD)/WHO Basic Safety Standards for Radiation Protection (BSS), published in IAEA Safety Series No. 9 [4], provide guidance on regulations for radiation protection, based on the recommendations of the International Commission on Radiological Protection (ICRP) [38]. These include a system of dose limitation as discussed below.

3.02 The system of dose limitation comprises three basic elements:

- justification of a practice;
- optimization of radiation protection; and
- limitation of individual risk.

Justification of a practice

3.03 Justification means that no practice resulting in human exposure to radiation should be authorized by the relevant competent authorities unless its introduction produces a positive net benefit. Decisions on the justification of a practice usually derive from considerations which are much broader than those based on radiation protection alone. Therefore, these decisions may well be made outside the context of regulatory control or exemption from such control.

Optimization of protection

3.04 Once a practice has been justified, it is necessary to design, plan and subsequently use the sources of exposure involved in the practice in such a way as to ensure that "exposures are as low as reasonably achievable, economic and social factors being taken into account". This means that, although the doses to the most exposed individuals, as a result of introducing a source of

exposure, have to be below the relevant dose limits, it is still necessary to "optimize" protection, that is, to reduce doses to as low as reasonably achievable.

3.05 A concept used in the optimization of protection is the health detriment. The health detriment is assumed, for the purpose of radiation protection, to be proportional to the collective dose equivalent commitment, henceforth referred to as the collective dose commitment. The unit of collective dose commitment is the man sievert (man.Sv). The collective dose commitment, rather than simply the collective dose, is the appropriate quantity since the operation of a practice in a given year may give rise to doses in the future.

3.06 Several techniques are available to carry out the analytical assessment required by the process of optimizing protection. The choice of the appropriate technique depends on the kind of parameters involved in the process and their degree of quantification. One of the techniques suggested by the ICRP when a full quantification of parameters is possible is differential cost-benefit analysis.

3.07 In differential cost-benefit analysis, the monetary value assigned to increasing the level of radiation health detriment saved, i.e. by reducing the doses, is compared with the cost of increasing the level of protection. The optimum level of protection is achieved when the next increment of expense on protection exceeds the value of health detriment thereby averted. This technique, therefore, provides a mechanism which can give indications on the correct allocation of resources in protection against ionizing radiation.

3.08 The IAEA has recommended a procedure of assigning a cost to the unit health detriment so that detriment can be "costed" and compared with costs of protection [4]. It has developed guidance on the minimum value to be assigned to the unit collective dose in the context of the control of releases of radioactive materials into the environment that have transboundary radiological significance [39] and has proposed for this purpose the minimum figure of US \$3,000 per man.Sv (in 1983 prices).

Limitation of individual risk

3.09 The limitation of individual risk is carried out by controlling the radiation doses in a group of individuals most likely to receive the highest doses from the practice. For this purpose, the concept of critical group is introduced. This group is chosen to be representative of individuals receiving the highest levels of dose from the particular practice, and is defined so that it is reasonably homogeneous with respect to factors that affect the dose received. It is also necessary to choose the time when these doses are at their maximum value. The assessment then proceeds in terms of the average individual dose in the critical group.

3.10 Unless otherwise stated, through this document the term "dose" refers to the sum of effective dose equivalent from external exposure in a given period and the committed effective dose equivalent from radionuclides taken into the body in the same period.

3.11 At present the annual dose limit to the members of the critical group is assigned as 1 mSv, averaged over the life span. The ICRP also states that it is permissible to use a subsidiary dose limit of 5 mSv in a year for some years, provided that the average annual effective dose equivalent over a lifetime does not exceed the principal limit of 1 mSv in a year [40]. With this limitation on the effective dose equivalent, the non-stochastic organ dose limit of 50 mSv in a year becomes unnecessary for most organs [41]. Since the dose equivalents in the skin and the lens of the eye are not included in the computation of effective dose equivalent for the individual [42], organ dose limits must still be used for these two tissues. The dose equivalent limit recommended by ICRP for both the skin and the lens of the eye is still 50 mSv in a year for members of the public.

CHAPTER 4

REGULATORY CONTROL

4.01 The basis of regulatory control¹ in the BSS [4] is a system of notification, registration and licensing, which makes it possible for the competent authority to impose appropriate requirements for protection. Varying degrees of regulatory control are defined: The highest of these is the full system of licensing of operations involving radiation. A lower level is a system of general authorization, in which the precise details of the operations will not normally be known, including the locations of radiation sources and the number of users, but in which the competent authority still has a general appreciation of the national situation. It may achieve this through notification and, possibly, registration, such that the general features of the operations, the total amount of sources or radioactive material in the country, and the designs of all devices approved for distribution are known. It may even require that controls remain on some aspects of source use, e.g. that disposal must be in an approved disposal facility. In some cases, even this level of control is not required, and there are then reasons for exemption from all the control recommended in the BSS.

¹The term 'control' is used in this document to mean 'restraint' rather than 'checking or verifying' (likewise for all derivations from the term such as 'controllable', 'controlled', etc.)

CHAPTER 5

EXEMPTION PRINCIPLES

5.01 It is suggested by the IAEA in the policy document on the "Principles for the Exemption of Radiation Sources and Practices for Regulatory Control", (Safety Series No. 89) [2] that, when reaching decisions on the basis of radiological protection consideration about exempting sources or practices involving radiation exposure, the competent authority should be assured that the risk and detriment² connected with the source or practices will be so small as not to warrant the application of the system of notification, registration, and licensing.

5.02 Accordingly, from a radiation protection standpoint, there are two basic criteria for determining whether or not a practice can be a candidate for an exemption from the BSS [4]:

- individual risks must be sufficiently low as not to warrant regulatory control; and
- radiation protection, including consideration of the cost of regulatory control, must be optimized (see Fig. 1).

The first aspect is addressed by defining a level of individual dose that can be taken as "trivial". The second aspect is usually addressed by using optimization analysis techniques such as cost-benefit analysis, intuitive or formal, or other methods of analysis.

² The terms 'risk' and 'detriment' are used as defined in the IAEA Radiation Protection Glossary [43]. Risk is the probability that a given individual will incur any given deleterious stochastic effect as a result of radiation exposure. Detriment is the mathematical expectation of harm (damage to health and other effects) incurred from the exposure of individuals or groups of persons in a human population to a radiation source, taking into account not only the probabilities but also the severity of each type of deleterious effect.

5.1. Individual dose considerations

5.03 For the purpose of exemption, it has been concluded that a level of individual effective dose equivalent of some tens of μSv in a year could reasonably be regarded as trivial by competent authorities. This level of dose corresponds to a few per cent of the annual dose limit for members of the public recommended by the ICRP [35] and is much smaller than any upper bound* [43] set by competent authorities for practices subject to regulatory control. Because an individual may be exposed to radiation doses from several practices that may have been judged exempt, in order to ensure that his total dose does not rise above the individual exemption dose criterion, each exempt practice should only utilize a part of that criterion, and it may be reasonable for competent authorities to apportion a fraction of that upper bound to each practice. This fractionation could lead to individual doses to the critical group of the order of 10 μSv in a year from each exempt practice.

5.2 Collective dose considerations

5.04 A generic study of the available options (including various kinds of regulatory action) should first be made by the competent authority. If this generic study, in its early stages, indicates that the collective dose commitment resulting from one year of the unregulated practice will be less than about 1 man.Sv, it may be concluded that the total detriment is low enough to permit exemption without more detailed examination of other options.

5.05 Practical experience suggests that the cost of formal optimization procedures will be at least several thousand dollars [44,45]. The use of the IAEA minimum value of the man Sv suggested in [39] would lead to a practice-related 'trivial' collective dose for exemption purposes of the order of a few man.Sv. For continuing practices this can be interpreted as a commitment of about 1 man.Sv per year of practice.

* The upper bound is defined in Ref. [43] as a dose level established by a competent authority to constrain the optimization of protection for a given source or source type.

5.3. Other considerations

5.06 Exemption is intended for sources and practices which are inherently safe under normal and accidental conditions. Exemption must not be granted if there is a possibility of scenarios leading to doses in excess of those specified in granting the exemption.

5.07 In considering the exemption of a practice, the competent authority should aim to exempt the practice as a whole. Where this is not feasible the authority should have regard to the implications of the total effect of these exemptions across the whole practice.

5.08 The competent authority will also need to take account of the probability and severity of possible consequences of accidents or misuse. Such consideration may contra-indicate the exemption of a practice, even if it gives rise to very small doses under normal conditions.

5.09 It is recognized that competent authority may have reasons different from those concerned with radiation protection for either exempting or not exempting particular sources or practices from regulatory control. Moreover, bearing in mind the principle of justification of a practice [4], they may want to prohibit uses of radiation sources or radioactive materials even if the associated doses are trivial, e.g., for frivolous uses, or in cases where the choice of solutions not requiring the use of a radiation source or radioactive material is equally effective.

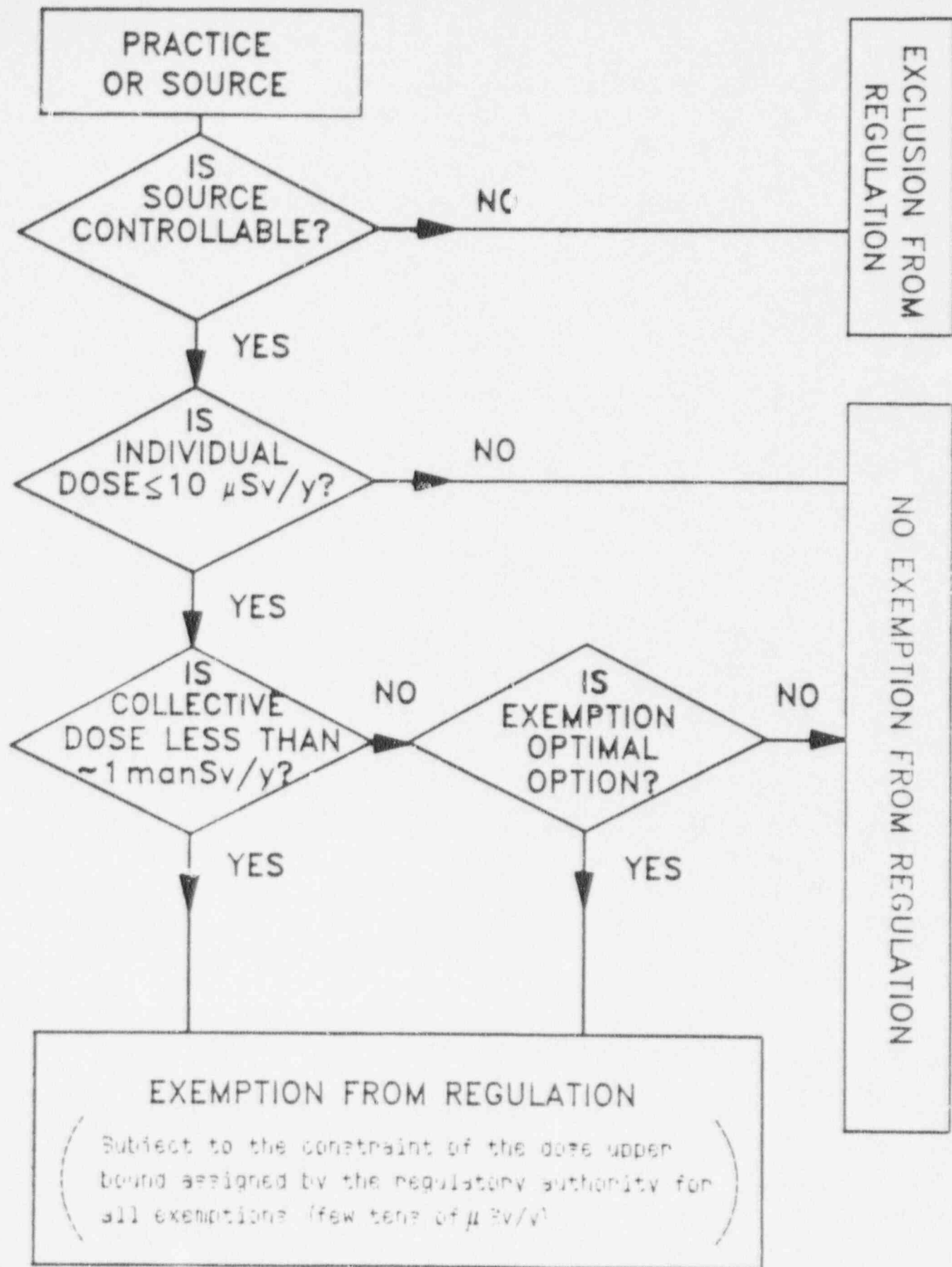


Fig.1. Exemption of a source or practice from regulatory control

CHAPTER 6

APPLICATION OF RADIATION PROTECTION PRINCIPLES TO CONSUMER PRODUCTS

6.01 The full system of licensing mentioned in Chapter 4 is not normally used for products supplied direct to the public and is not discussed further in this document. Products supplied to the public should either be authorized or exempted.

6.1 Justification of a practice

6.02 Justification is a particularly important factor in the system of dose limitation recommended by the ICRP. Various formal techniques such as cost benefit analysis or multi-attribute analysis could be used when justifying consumer products. The use of such products must be justified both for exemption and authorization.

6.1.1 Justified uses

6.03 Factors to be considered usually include, on the one hand, benefits to users of products, and to some extent benefits to manufacturers, distributors, workers involved in manufacture and distribution, and, on the other hand, detriment costs (including radiation detriment) to workers, product users and others (non-users) who may also be exposed (as a result of disposal, for example), and costs of control and protection. The most important factors are benefits to users and doses to members of the public (users and non-users). Much of the information required would be very difficult to obtain and it is considered that the formal analyses mentioned in the previous paragraph would rarely be warranted for consumer products. More qualitative and intuitive assessments of the various parameters involved in decision making will usually be adequate.

6.04 For each product considered to be beneficial, the collective dose commitment resulting from normal use, likely accidents and disposal, and also the doses to a typical individual user and to the most exposed individual user should be estimated. Competent authorities may decide that in some cases, particularly where products are likely to be sold in very large numbers, the estimated collective dose commitment could be significant and should therefore be taken into account in the justification procedure. In a few cases, products might not be authorized if the relevant collective dose commitment were unacceptably high. In most cases, however, the collective dose commitment is likely to be considered insignificant and it would not be necessary to include collective dose in the justification procedure. In these cases, a necessary and sufficient condition for the exemption or authorization of a justified consumer product is that the individual doses are lower than the appropriate values given in 6.3.

6.05 The doses resulting from the misuse of a product and/or accidental damage to the product, should also be estimated and taken into account when considering the approval or exemption of that product.

6.1.2 Orders of Benefit

It is proposed that there should be two orders of benefit:

- a) higher benefit - category I products (all safety devices, e.g. all products specifically designed to prevent injury to people);
- b) lower benefit - category II products (all other products not considered unacceptable in principle, or not otherwise unjustified).

6.06 A higher dose to users is considered acceptable from products contributing to safety (category I) than from other products (category II).
(See 6.3.1 and 6.3.2)

6.1.3 Unjustified uses

6.07 There are some products in which the presence of radioactive material would appear to be of no benefit to the users of those products, and therefore should be considered unacceptable in principle. A definitive list cannot be given, because competent authorities may need to exercise judgement in particular cases. Examples of such consumer products which are already considered unacceptable in some countries are those designed for irradiating the human body (apart from those prescribed by a qualified medical practitioner), children's toys, art forms and articles for personal adornment. In the case of gemstones which have been irradiated by neutrons, the competent authority should ensure that quality assurance programmes are set up to check that released stones are below the level of radioactivity that is of regulatory concern (see Annex I). The distribution to the public of radioactive sources not incorporated in the construction of complete consumer products is also unacceptable in principle, because in this case the subsequent use, and the associated risks could not normally be anticipated and the benefit could not be predicted in advance. A further reason is that hazards are in general reduced when radioactive sources are incorporated in complete devices.

6.1.4 Non-radioactive alternatives

6.08 The existence of non-radioactive alternative products must be considered when justifying a product. It would not be necessary, however, particularly at low levels of radiation hazard, to refuse to exempt or authorize a product containing a radioactive substance solely on the grounds that there were non-radioactive alternatives. The existence of the latter should not, therefore lead to automatic rejection of the radioactive product, but the choice of the radioactive alternative must be properly justified. Relative costs, reliability and any detriment associated with the alternative should also be considered.

6.09 When making comparisons it needs to be established that the alternative fulfils the same function as the radioactive product. For example, phosphorescent paints are now used to luminize some time pieces; however, such time pieces will remain luminous for only a few hours when placed in the dark. Therefore, phosphorescent paint cannot always be considered a true

alternative to radioactive paints. Another example is the optical smoke detector. Both optical and ionization chamber smoke detectors respond to smoke but their responses are not the same. The optical type reacts quicker to slow-burning fires but slower to fast-burning fires where it could be argued that a fast response is more important. An example of a radioactive product which is considered by many to have no advantage over the non-radioactive alternative is a lightning conductor with radioactive attachments.

6.2 Optimization of protection

6.2.1 General

6.10 Formal decision-aiding techniques, such as cost-benefit analysis, have been used as a support in optimizing the radiological protection of the public, i.e. in satisfying the requirement that all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account. The use of such techniques may be warranted when large investments in radiological protection are being considered, when individuals are being exposed at levels close to statutory limits, or when collective doses are likely to be large. On the other hand, if the estimated collective dose is small it may not be worthwhile to optimize on the basis of cost-benefit analysis, because the cost of the effort to carry out such an analysis would exceed the value of any reduction of collective dose. This is often the case with radioactive consumer products, and for optimizing radiation protection for such products it would normally be appropriate to use a more qualitative approach.

6.2.2 Important factors relating to optimization of protection for consumer products

6.11 Important factors which affect optimization include the following:

- a) selection of the radionuclide with the shortest half-life consistent with the useful life of the product, and the lowest radiation energy;

- b) use of minimum activity necessary for the product to function effectively;
- c) selection of the chemical and physical form of the radionuclide which provides the highest degree of intrinsic safety under normal and accidental conditions;
- d) limitation of access to the radioactive substance without the use of special tools;
- e) experience of other products, particularly similar products, that have been assessed previously.

6.3 Limitation of individual and collective doses

6.3.1 Exempt products

6.12 Some individuals could be exposed to radiation from many products, most of them being non-safety products (category II). To ensure that annual doses to such users of all exempt products are not more than a few tens of μSv (see Chapter 5), it is recommended that for a product to be exempt, the annual dose equivalent to the most highly exposed individual should be less than about $1\mu\text{Sv}$ for each non-safety product and less than about $10\mu\text{Sv}$ for each safety product. In both cases the estimated collective dose should be of the order of 1 man.Sv per year or less. Dose equivalents to the skin and lens of the eye and the dose equivalent as a result of accidents and misuse should be in accordance with sections 6.3.3 and 6.3.5.

6.3.2 Authorized products

6.13 Authorization should be considered for products when the annual dose to the most highly exposed individual is greater than 1 or $10\mu\text{Sv}$ (for non-safety and safety products respectively) and/or when the collective dose is greater than 1 man.Sv . For many products currently on the market annual doses to the most highly exposed individuals are less than 1 or $10\mu\text{Sv}$. There are some, however where this is not the case, e.g. where thoriated gas mantles are used continuously for lighting in homes. In such cases doses to typical users should be used in the assessment.

6.14 Since the net benefit from the radioactive material in most non-safety consumer products will, in general, be small, the maximum dose to an individual from a single Category II authorized product should be restricted to a level corresponding to a low level of risk. This should also avoid the simultaneous exposure to several consumer products, and possibly to other sources, resulting in ICRP dose limits being exceeded. It is recommended that the effective dose equivalent (external or committed from intake) to a typical individual user of a Category II authorized product from normal use should be less than about 5 μ Sv in a year.

6.15 Since there is a higher order of benefit associated with products which contribute towards safety, a higher annual dose equivalent is permitted for Category I products. It is recommended that the effective dose equivalent to a typical user of a Category I authorized product should be less than about 50 μ Sv in a year (i.e. a factor of 10 higher than the dose level for a Category II product). It should be noted that there are likely to be relatively few Category I products and the eventuality of a simultaneous exposure to several products of this category appears rather remote. Also, optimization of protection will normally lead to doses substantially below the dose level of about 50 μ Sv.

6.3.3. Doses to the skin and lens of the eye

6.16 Compliance with the effective dose equivalents detailed in 6.3.1 and 6.3.2 will ensure that doses to single organs are well below the ICRP limits for members of the public, and it is only necessary to consider separately those organs which are not included in the calculation of effective dose equivalent, i.e. the skin and lens of the eye. As discussed in Chapter 3, the non-stochastic limits for members of the public for the skin and lens of the eye are assumed to be 50 mSv a year. However, to cover the possible contribution from several sources, the annual dose equivalents to the skin and lens of the eye should not exceed 5 mSv for a single product of either category. Where the skin is non-uniformly irradiated, such as might occur through wearing some radioluminous watches, the average dose over 1 cm² in the region of the highest dose should be estimated and related to the above restriction (see paragraph 183 of reference [38]).

6.3.4 Exposure of non users

6.17 The effective dose equivalent to the most highly exposed individual non-user (e.g. another member of the user's household or an individual living close to an urban landfill or incinerator of domestic waste) is likely to be much lower than that to the individual users, and no assessment of individual dose would normally be necessary. Since non-users receive no benefit, competent authorities should make occasional reviews to establish that doses to individual non-users are much lower than the relevant dose restrictions for users. Doses to non-users should of course be included in any estimates of collective dose.

6.3.5 Accidents and misuse

6.18 It is general practice for manufacturers to inform their customers on how to use products correctly, and some manufacturers also explain how to avoid damaging the containment of the radioactive substance with a view to preventing unnecessary exposure. Although this will help to reduce the probability of accidents and misuses, it cannot be assumed that a consumer will necessarily follow explanations given by a manufacturer. There is no way of ensuring that any products will be used in the manner intended by the manufacturer. However, because adequate and clear instructions can play a significant role in reducing the risk of accidents and misuses, manufacturers should be strongly encouraged to supply their products with such clear instructions.

6.19 Products should only be exempted or authorized if the expected frequency and severity of accidents and misuses is low. In these circumstances, the annual effective dose equivalent limit for members of the public of 1 mSv (or 5 mSv) and 50 mSv for the skin and the lens of the eye should be used as a guide when assessing the significance of doses that might be received as a result of misuse or accidents. The likely frequency should be taken into account as well as the doses. When the estimated doses from accidents and misuse are close to the limits, the product should not be exempt and only in particularly justified cases should it be authorized.

CHAPTER 7

REQUIREMENTS FOR THE COMPETENT AUTHORITY

7.1 Prior exemption and authorization scheme

7.01 It is impossible to ensure that consumer products, once supplied, are used in the manner intended by the manufacturer, or that they will be disposed of in any recommended fashion. It would be impracticable, therefore, to contemplate exercising control over doses to persons after the sale of the goods. The only practicable way to ensure compliance with the three principles of the ICRP system of dose limitation is a system of prior assessment. The value of such a system is that doses can be assessed before new products are supplied, and unjustified products should never appear on the market.

7.02 The competent authority should therefore set up an exemption and authorization system. This system should include assessments of consumer products to establish which products are exempt (see Chapters 5 and 6), which are authorized (see Chapter 6), and which should not be supplied to the public.

7.2 Types of product

7.03 In general, there will be four classes of product to assess:

- A) novel products of a given type which have not previously been considered and are not already on the market; this includes new applications of radionuclides in a form or of a type not covered by an existing assessment;
- B) products of a given type which have been previously exempted or authorized (e.g. a new model of an ionization chamber smoke detector);
- C) products already on the market before a prior exemption and authorization scheme has been established by the competent authority;

D) products already supplied to the public but no longer marketed.

7.2.1 Novel products (class A)

7.04 Exemption or authorization should be given only after the competent authority is satisfied that the principles relating to justification, optimization and dose limitation outlined in Chapter 3 of this Code are complied with. The assessment to show compliance should include estimated annual doses to individuals from normal use and disposal and also those resulting from accidents and misuses. Collective doses resulting from normal use, accident, and disposal should also be estimated as necessary.

7.05 Labelling, if required, should be in accordance with Chapter 10 of this Code.

7.06 Although specific standards for such products may not exist, it may be appropriate to demonstrate compliance with general standards [6].

7.2.2 Products of a given type already exempted or authorized (class B)

7.07 If radiological safety standards laying down design criteria, upper limits of activities, tests, maintenance procedures, etc are available, the applicant should demonstrate that the product is in conformity with the standards. The competent authority should verify the quality of the assessment and the objectivity of the demonstration.

7.08 If such standards are not available, the competent authority should take into account the assessment which has previously been carried out and used as the basis for granting the first exemption or authorization.

7.09 Labelling, if required, should be in accordance with Chapter 10 of this Code.

7.2.3 Products already on the market without authorisation or exemption
(class C)

7.10 In the case of products that are already on the market at the time when the prior exemption and authorization scheme is established, competent authorities should normally allow further supplies of such products for a definite period (e.g. 1 year after the scheme comes into operation). This time should be sufficient to enable manufacturers to carry out design modifications if necessary and demonstrate that their products conform with these recommendations. In exceptional circumstances, when it is known that the risks associated with a given product are unacceptable, competent authorities should give consideration to prohibiting further supplies of the product immediately, or perhaps recalling the products. Therefore, the assessment should emphasize the risk from individual dose rather than from collective dose.

7.11 The competent authority should work towards the establishment of safety standards, if they do not exist, for products already on the market, in order to distinguish between safe and unsafe products.

7.2.4 Products already supplied to the public but no longer marketed (class D)

7.12 Unless the individual radiological risk is high, no regulatory action is required for products already in the hands of the public, although in some cases surveys and assessments to estimate the degree of radiological detriment associated with these products may be appropriate. Table 2 is included to make competent authorities aware of what products have been available in the past. Many of these products will still be owned by members of the public and some of them will occasionally be sold as second-hand goods in markets, jumble sales, second-hand shops and auctions. Since it is usually these older products that give rise to the largest doses to purchasers, competent authorities should include such products sold as second-hand goods in their exemption and authorization scheme if this is practicable. The competent authority may wish to inform the public as to the recommended method of disposal of such products.

CHAPTER 8

REQUIREMENTS FOR MANUFACTURERS AND IMPORTERS

8.01 The manufacturer, importer or other applicant should provide the competent authority with sufficient documentation and certification to enable it to review and assess the proposed product. This document should normally include information on the following:

8.02 A description of the product, its intended use and benefit, its expected life time of use, and the function served by the radionuclide(s). Documentary evidence that the radioactive material fulfils its function should also be given.

8.03 The concentration and activity of the radionuclide(s) to be used in the product. The applicant should justify the choice of a radionuclide, particularly in relation to other radionuclides that could be of lower toxicity, e.g. emits less penetrating radiation and/or have shorter half-lives. The reason for choosing radioactive material in preference to a non-radioactive alternative may also be outlined.

8.04 Whether the product contributes to safety or not (see 6.1.2) and comparisons with any non-radioactive alternatives. The manufacturer or importer should demonstrate that the doses that may be received from the use comply with appropriate dose limits and that the disposal of the product complies with the requirements given in Chapter 12.

8.05 The chemical and physical form of the radionuclides to be applied to or incorporated in the product.

8.06 Details of the construction and design of the product particularly as related to containment and shielding of the radionuclide under normal and adverse conditions of use and disposal and the degree of access to the radioactive substance.

8.07 The quality control procedures to be applied to radioactive sources, components and the finished products, to assure that maximum specified quantities of radioactivity and radiation levels are not exceeded, and devices are constructed according to design specifications.

8.08 Dose assessments, including estimated individual and collective doses from normal use, misuse and accidents and disposal. The external radiation level from the product and the method of measurement should be provided.

8.09 The total numbers of the product expected to be distributed annually.

8.10 Instructions to be provided to customers for use, installation, and maintenance.

8.11 A safety analysis evaluating the likelihood consequences of misuse, damage or failure.

8.12 Description of tests for demonstrating the radiological integrity of the product in normal use, misuse, and accidental damage. Results of these tests.

8.13 Details on information to be provided to customers concerning the radioactive material in advertising matter, technical and maintenance instructions, guarantee certificates, etc.

8.14 Information on how it is intended to label the product (See Chapter 10).

8.15 A description of the anticipated method of disposal, and expected radiation doses from disposal (see Chapter 12).

CHAPTER 9

TESTING AND QUALITY CONTROL REQUIREMENTS

9.01 The safety assessment of a product or type of product is based on the assumption that the product will contain certain safety features and will behave as specified during normal use, in abnormal situations, and after disposal. The competent authority should establish a system which assures that those assumptions used in the safety assessment relating to the design of the product are valid. This is usually accomplished through a three-tiered system of control.

9.1 Safety performance specifications

9.02 These are requirements applied to products or types of products to enhance safety. While it is not feasible to recommend requirements for specific types of products in a general guide of this nature, such requirements typically include specifications for radiation levels or radionuclide content, durability of the source, solubility or dispersibility of the radionuclide, fire resistance etc.

9.2 Prototype tests

9.03 These are laboratory tests developed to determine that the materials of construction and methods of manufacture are such that the ultimate product or its components will meet the safety performance specification as well as any other design requirement which might be imposed on the product. Such tests should confirm some of the assumptions used in the safety assessment related to the design safety of the product prior to authorizing distribution of the product to consumers.

9.04 As an example, Annex II gives the detailed prototype tests recommended by the OECD/NEA for ionization chamber smoke detectors. Where standards incorporating detailed prototype tests exist, competent authorities should assess these tests and may decide that compliance with the standard is obligatory for both exempt and authorized products.

9.3 Quality control

9.05 This consists of statistical sampling of products, components, materials and manufacturing methods coupled with a test regimen sufficient to confirm that the products are within the specifications of the prototype. The number of products selected for testing should be such that there is only a small probability that a defective product will be released to the public.

CHAPTER 10

CONSUMER PRODUCTS LABELLING REQUIREMENTS

10.01 Many radioactive consumer products currently on the market are not labelled. For consumer products that comply with the criteria on dose restriction outlined in this Code, labels are not essential to safety, but they are desirable to identify the product and reduce the risk of misuse. It is recommended, therefore, that for authorized consumer products, information that is observable at the time of purchase, e.g. on the packaging, should indicate that the product contains radioactive material and has been assessed and authorized by the competent authority. This information should also be on the product itself except when the competent authority agrees that it is not practical to do this. However, in such cases the package should be labelled; for example, thorium gas mantles cannot be labelled, but the packages can.

10.02 It would not normally be necessary to label exempt products.

10.03 Any guidance that is considered desirable for the purpose of reducing exposures due to accident, misuse or disposal (see 6.3.5 and Chapter 12) should be given on the package, in the accompanying instructions and, if appropriate, on the product itself. In particular, consumers should be advised to avoid inhalation or ingestion of the radioactive material in the product.

CHAPTER 11

SURVEILLANCE AFTER EXEMPTION OR AUTHORIZATION

11.1 Retrospective reviews

11.01 It is recommended that the competent authority keeps records of which products are exempt and which products are authorized. Periodic reviews should be carried out to determine that individual doses are being maintained within the restrictions established in the authorization or are below the value for exemption. These reviews should include effective dose equivalents to individual users and non-users from specific products. The reviews should also include results of investigations of accident and examples of misuse.

11.02 Estimates should also be made of the collective dose equivalents for types of consumer product (e.g. all ICSDs supplied to the public). On rare occasions it may be necessary for a competent authority to limit further supplies of a product if the collective dose is deemed to be too significant, or if a new product becomes available which causes lower radiation doses or does not contain radioactive material.

11.03 The appropriateness of standards used by competent authorities when considering a consumer product for exemption or authorization should also be reviewed periodically (e.g. every 10 years).

11.2 Periodic revision of authorizations

11.04 It is recommended that the authorization granted for any product should be for a fixed number of years (e.g. 5), to be decided upon by the competent authority, or a shorter time if changes are proposed that could result in increased doses to users or non-users. Applicants should seek reapproval after the time decided by the competent authority or when any significant change to the product has been proposed.

CHAPTER 12

DISPOSAL OF PRODUCTS

12.01 No new product should be exempt or be authorized if it is considered necessary, in order to limit doses to acceptable levels, to specify operational procedures to be followed for dealing with its disposal. From a practical point of view, no administrative system appears possible to ensure controlled disposal of products which are in the hands of the general public.

12.02 Generally with the levels of activity normally encountered in consumer products, no advantage relevant to radiological protection is to be gained by recommending the return of waste products to a manufacturer or other authorized recipient. Nevertheless, for reasons of general policy some competent authorities may advise users of products to dispose of them by other means than as household refuse. Not all users would follow this advice, however, and nearly all consumer products are likely to be disposed with normal household rubbish; this must be taken into account in the analysis. When calculating collective doses, it is therefore necessary to take into account the radiological impact resulting from disposal in landfills and that resulting from incineration and other forms of disposal.

CONCLUSIONS

It is expected that if the recommendations in this Code relating to exemptions and authorizations are carried out, then most consumer products currently on the market will be exempt products. A relatively few will be authorized products. This could occur for products such as thoriated gas mantles when annual dose equivalents to the most highly exposed individuals are much greater than $10\mu\text{Sv}$, and for products such as ionization chamber smoke detectors where individual dose equivalents are very low, but collective doses could exceed 1 man.Sv per year. There may also be some authorized products where individual doses and collective doses are low but where anticipated doses as a result of accidents approach the annual dose limits recommended by ICRP for members of the public.

The essential difference between exempt and authorized products is that the assessment of the former, particularly for further examples of a product already assessed to be exempt should be a much simpler process. The other main difference is that exempt products would not necessarily be labelled but authorized products would carry a label.

ANNEX 1

LEVEL OF RADIOACTIVITY THAT IS OF NO REGULATORY CONCERN

For radioactive substances used in work places, it is common for any solid substance having an activity concentration of less than 100 Bq g^{-1} to be considered as being of no regulatory concern. [46]

It is considered that the value of 100 Bq g^{-1} is too high to be considered as being of no regulatory concern for some consumer products, particularly those which may be used close to the body for up to 24 hours a day. Competent authorities may therefore decide on a lower value.

It is suggested that the level of radioactivity for solid substances in consumer products, which is considered to be of no regulatory concern, should be less than a value between 1 and 10 Bq g^{-1} of source material, e.g. activity concentration of the luminous paint in a watch; higher levels might be appropriate for ^3H and ^{14}C . Competent authorities should devise methods of checking such low levels of activity concentration.

Although most consumer products contain solid materials, there are some containing gases and there could possibly be some containing liquids. Competent authorities should also, therefore, decide on levels of radioactivity in gases and liquids which are considered to be of no regulatory concern.

ANNEX II

PROTOTYPE TESTS FOR IONIZATION CHAMBER SMOKE DETECTORS (ICSDs)

The following is a modified form of the annex to "Recommendations for ionization chamber smoke detectors in implementation of radiation protection standards", published by OECD/NEA in 1977 [7]. This is reproduced as an example of a typical set of tests that could be carried out. Values in mrem/h and μCi in the original document have been converted to $\mu\text{Sv/h}$ and Bq respectively.

1. PRELIMINARY TESTS ON ICSDs

These shall include:

- a) general inspection noting any obvious design defects. The competent National Authorities shall be satisfied that the ICSD is so constructed that under normal conditions of use, direct contact with the radioactive source(s) shall be impossible, that the ionization chamber for single station ICSDs shall be sufficiently tamper-proof, and that the source(s) will not become detached or suffer loss of integrity in ordinary use during the lifetime of the ICSD;
- b) measurement of external dose rates. The competent National Authorities shall be satisfied where appropriate that the external dose rate averaged over 10 cm^2 is less than $1\text{ }\mu\text{Sv/h}$ at 0.1 m from the surface of the device.
- c) measurements of radioactive contamination on the external surfaces and those accessible during maintenance operations of the ICSD. The ICSD shall be deemed to have failed if the levels exceed a mean of 0.4 Bq/cm^2 for α -emitters or 4 Bq/cm^2 for β -emitters on all examined surfaces.

2.1 ADDITIONAL TESTS ON ICSDs

The competent National Authorities shall be satisfied that the source(s) will not become detached or suffer loss of integrity as a result of the following tests. A separate ICSD shall be used in each test.

- a) Temperature: The ICSD shall be cooled to -25°C , kept at this temperature for one hour, then allowed to return to ambient temperature. It will then be heated to 100°C , kept at this temperature for one hour, then allowed to return to ambient temperature.
- b) Impact: The equipment and procedure for the impact test is a modified form of those described in ISO 2919. A steel hammer weighing 0.5 kg shall be dropped from a height of 0.5 m on to the ICSD which is positioned on a steel anvil so as to suffer the maximum damage.
- c) Drop: The ICSD shall be dropped from a height of 10 m on to a hard unyielding surface so as to suffer the maximum damage. This test may be relaxed for single station ICSDs where a 4 m drop test is considered sufficient.
- d) Vibration: If the ICSD has not been successfully subjected to a vibration test which is specified in a national or international standard concerned with the proper functioning of the ICSD then the following test shall be applied. The ICSD shall be vibrated sinusoidally in a direction perpendicular to its normal plane of fixation; the frequency of vibration being swept from 5 to 60 Hz at a rate of 4 octaves/hour. The peak acceleration shall be 0.24 g for the range 5-20 Hz, 0.40 g for 20-40 Hz and 0.51 g for 40-60 Hz.

Two sweeps through the range shall be made and the ICSD shall then be vibrated for one hour at any resonant frequencies found, the peak acceleration being $0.7 \gamma f \text{ ms}^{-2}$, where f is the resonant frequency.

2.2 ADDITIONAL TESTS ON SOURCES

- a) Maintenance: In addition to the ISO/C 32222 classification tests, two sources mounted in their holders shall be subjected to twice the number of cleaning operations to be carried out during the expected lifetime of the ICSD according to the instructions of the manufacturer. The sources shall be considered to have passed this test if they have maintained their integrity.

2.3 EVALUATION

- a) Sources containing solid radioactive substances

Following each test wipe or immersion leak tests shall be carried out according to the recommendations and methods described in ISO DTR 4826 (April 1975). The wipe test shall be carried out over the source(s) and the inactive surfaces of the detector paying particular attention to the source holder. The immersion test shall be carried out using the complete detector. If the removed activity is less than 185 Bq from each source, then the source shall be considered to have retained its integrity.

- b) Sources containing krypton-85 gas

Following each test, the activity of the source(s) shall be determined by appropriate means to confirm that rupture of the source(s) has not occurred. Leak tests shall then be carried out on the source(s). If the detected leak rate corresponds to less than 4 kBq per day from each source, then the source shall be considered to have retained its integrity.

3.1 TEST FOR THE EFFECTS OF FIRE

The competent National Authorities shall be satisfied that the source(s) in an ICSD will not result in an unacceptable level of contamination in the event of a fire. A fire test shall therefore be carried out on the complete ICSD or on the source(s) mounted in their source holders in the

presence of parts of the ICSD which are sufficiently representative of the whole ICSD. Air shall be passed through the furnace for the duration of the test at a flow rate of 1 to 5 l/min and condensed and filtered before release to atmosphere. The ICSD (or the parts thereof) shall be heated from room temperature to 600°C and retained at this temperature for one hour.

If the sum of the activity remote from the source(s) (that is, that which is in the condenser and on the filters and in the debris) and that removed from the source(s) and holder(s) either by wipe or by immersion leak testing (using the methods and procedures described in ISO DTR 4826), exceeds 185 Bq per source, then the source(s) shall be considered to result in an unacceptable level of contamination.

ICSDs containing Kr-85 need not be subjected to this test.

3.2 HIGH TEMPERATURE INDUSTRIAL FIRE AND INCINERATION TEST

The competent National Authorities shall be satisfied that the source(s) in an ICSD will not result in an unacceptable release of activity to atmosphere in the event of a high temperature fire (for industrial ICSDs) or of incineration of waste (for single station ICSDs). A high temperature fire and incineration test shall therefore be carried out on the complete ICSD or on the source(s) mounted in their source holders in the presence of parts of the ICSD which are sufficiently representative of the whole ICSD. The procedure shall be the same as that described in paragraph 3.1 except that the ICSD (or the parts thereof) shall be heated to 1200°C and retained at this temperature for one hour.

If the activity detected in the condenser and on the filters exceeds 1 per cent of the activity of the ICSD (radioactive daughters of Ra-226 are excluded) then the source(s) shall be considered to result in an unacceptable release of activity to atmosphere.

ICSDs containing Kr-85 need not be subjected to this test.

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