EUROPEAN COMMISSION

RADIATION PROTECTION 147

Guidelines for the Regulatory Control of Consumer Products Containing Radioactive Substances in the European Union

Guidance by the group of experts established under Article 31 of the Euratom Treaty on the basis of a study carried out by

J Shaw, J Dunderdale and R A Paynter

NRPB Occupational Services Department

Directorate-General for Energy and Transport
Directorate H — Nuclear Energy
Unit H.4 — Radiation Protection
2007

Luxembourg May 2007

Foreword

The Radiation Protection Basic Safety Standards Directive 96/29/EURATOM strengthens the legal basis for the regulation of the placing on the market of consumer products containing radioactive substances. The Directive requires special regulatory initiatives to ensure that the radiation exposure of the public arising from the use and the disposal of these products is kept as low as reasonably achievable. Furthermore, the Directive requires that the authorisation of products containing radioactive substances should be subject to justification in view of the benefits offered by such particular products.

The European Commission Radiation Protection Unit regularly evaluates trends and developments concerning radioactivity in consumer products. The outcome of a recent survey (published as Radiation Protection Series No 146) shows that due to free movement of products within the European Union on the one hand and the developing technology on the other hand the number and the variety of consumer products containing radioactive substances have increased considerably.

Therefore, the European Commission initiated the establishment of the present Guidelines for the regulatory control of consumer products containing radioactive substances. The document provides the basis for harmonisation of regulatory control among Member States of the European Union. It gives advice to national competent authorities on prior authorisation procedures, criteria for control, requirements for manufacturers and importers and for labelling. Furthermore, the document makes recommendations on the exchange of information between the competent authorities of EU Member States. It advocates common procedures for type testing and an agreement on which information should be addressed to the consumers.

The Guidelines were established under a contract no. B4-3040/2002/344625/MAR/C/2002 by the UK National Radiological Protection Board (now Health Protection Agency) under the supervision of a Working Party on Consumer Products of the group of experts established under the terms of Article 31 of the Euratom Treaty. The Working Party followed the project in continuous dialogue with the Radiation Protection Unit through periodic meetings with the contractor. The full Article 31 Expert group oversaw the final version of the present document and recommended its publication.

The Radiation Protection Unit would like to thank all those involved for their most valuable contributions and personal commitment and hopes that the document will provide useful guidance in the field of consumer products containing radioactive substances for incorporation in revised Basic Safety Standards.

Augustin Janssens
Head of Radiation Protection Unit

EXECUTIVE SUMMARY

The Radiation Protection Basic Safety Standards Directive 96/29/EURATOM requires that the authorisation of consumer products containing radioactive substances should be subject to justification. The presented Guidelines for the regulatory control of consumer products containing radioactive substances provide the basis for harmonisation of regulatory control. It gives advice to national competent authorities on prior authorisation procedures, criteria for control, requirements for manufacturers and importers and for labelling. Furthermore, it advocates common procedures for type testing and an agreement on which information should be addressed to the consumers. The Guidelines were established under the supervision of a Working Party on Consumer Products established under the terms of Article 31 of the Euratom Treaty. The full Article 31 Expert group oversaw the final version of the present document and recommended its publication.

CONTENTS

1 INTRODUCTION

1.1 Overview and objectives

The objective of this document is to establish guidelines for the regulatory control of consumer products containing radioactive substances. The guidelines are intended to provide information and recommendations to enable a harmonised and uniform application of the requirements of the Basic Safety Standards Directive by the competent regulatory authorities in each member state of the European Union. The guidelines cover the following areas:

- definition of relevant products;
- requirements for prior authorisation of consumer products;
- the case for not authorising a product (prohibition);
- recommendations for product testing;
- requirements for labelling and product information; and,
- recommendations for the disposal of consumer products containing radioactive substances.

1.2 Definition of consumer products incorporating radioactive substances

Throughout these guidelines the term "consumer product" is defined as follows:

a manufactured product or appliance, or miscellaneous source, in which radionuclides are deliberately incorporated and which can be supplied to members of the public without special surveillance and control.

It follows that items containing ordinary amounts of naturally occurring radioactive materials (e.g. building materials, spa waters, minerals, foodstuffs etc) are not covered by this definition, and are therefore outside the scope of these guidelines. It should also be noted that this definition excludes products and appliances installed in public places that may give rise to radiation exposure of the public, for example exit signs containing gaseous tritium light sources in aeroplanes, theatres, etc. The scope of these guidelines is limited to those products that can be purchased without restriction by the public, not those that are intended for the use only by specialists

The types of consumer products covered by these guidelines are discussed further in Part 2.

1.3 Requirements of the Basic Safety Standards and other European Directives

All EU Member States are required to comply with the Council Directive 96/29/Euratom of 13 May 1996 published by the OJ L159 0f 29 June 1996, which sets out basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation (referred to in these guidelines as the BSS). The BSS requires prior authorisation for the deliberate addition of radioactive substances in the production and manufacture of consumer goods and the import or export of such goods, unless the practice is exempt from reporting by virtue of Article 3. The full requirements of Articles 2 to 6 of the Directive are given in an earlier report on the review of consumer products containing radioactive substances.[1]

1.3.1 EU Legislation on General Product Safety

Based on Article 95 of the Treaty establishing the European Community, the European Council and Parliament have issued a Directive on general product safety (Directive 2001/95/EC of 3 December 2001, OJ L11 of 15.01.2002).

The purpose of this Directive is to ensure that products placed on the marked are safe. The absence of EU provisions on product safety, legislation of the Member States may differ in the level of protection afforded to consumers. In order to ensure uniform consumer protection at the highest possible level, the EU has issued this Community horizontal legislation introducing general product safety requirements, laying down obligations of producers and distributors. The Directive obliges Member States to introduce actions to be taken for the exchange of information and for enforcing product safety requirements.

This Directive applies to products irrespective of their means of marketing such as distance or electronic selling.

Taking into account the difficulties to establish legislation for this rapidly evolving sector, the Directive provides a broad horizontal legislative framework.

The Directive does not explicitly refer to the existing EU radiation protection legislation but recognises the existence of Community legislation which sets out safety requirements covering specific categories of risks. However, it does not exclude consumer products containing radioactive substances.

Therefore, the product safety Directive's requirements on specific obligations and powers of Member States and on obligations of producers and distributors can be applied in the context of regulatory control of consumer products containing radioactive substances. In consequence, the requirements laid down by the product safety Directive on conformity assessment criteria and on European standards shall be considered when establishing national legislation for notification and authorisation of practices involving radioactive consumer products.

The product safety Directive lays down specific requirements for rapid exchange of information and intervention. In this context, the Commission shall promote and take part in the operation of a European network of the authorities competent in product safety. This network shall facilitate:

- The exchange of information on dangerous products, execution of joint surveillance;
- Supervision of scientific developments, exchange of expertise and best practices and cooperation in training activities;
- Establishment of risk assessments; tracing, withdrawal and recall of dangerous products;
- Development of test methods, joint testing projects and comparison of results;

Finally the product safety Directive requires that information relating to risks to consumer health available to Member States or the Commission shall in general be available to the public. In particular, the public shall have access to information on product identification, on the nature of the risk and on the measures taken.

1.3.2 EU Legislation on Toys

The radiation protection Basic Safety Standards Directive prohibits the deliberate addition of radioactivity in toys. However, the definition of toys is not provided by this Directive. It is therefore necessary to consider the Council Directive on the approximation of the laws of the Member States concerning the safety of toys (Council Directive 88/378/EEC of 3 May 1988; Consolidated text published by OJ: CONSLEG 1988L0378-02/08/1993).

The main objective of this Directive is the elimination of trade barriers for toys due to different scope and content of laws, regulations or administrative provisions on safety characteristics in force in the various Member States.

The Directive excludes a large variety of consumer products from its scope by providing a list of products not regarded as toys for the purpose of this Directive.

The Directive provides in Annex 2 for essential safety requirements for toys. Since the deliberate addition of radioactive substances is anyhow prohibited by the radiation protection Basic Safety Standards Directive, these safety requirements do not allow for the presence of any radioactivity in toys. For the definition of "Radioactivity", the toys Directive refers to the Basic Safety Standards Directive.

In order to achieve the highest level of toys safety, the Directive obliges Member States to appoint bodies competent for certification procedures and for enforcement of conformity standards regulations. The Directive requires the establishment of uniform safety standards to be applied and for a system of approval and labelling.

The Directive on toys obliges the Member States to inform the Commission every three years on the application of this Directive. Furthermore the Member States shall regularly inform the Commission about their legislative activities by the competent bodies in order to allow the Commission to verify that these procedures are correctly implemented.

Furthermore, the toys Directive provides for the establishment of a system aimed at exchanging information on restrictions for placing on the market and withdrawal of toys.

1.3.3 EU Legislation on Cosmetics

The radiation protection basic safety standards Directive requires that Member States shall not permit the deliberate addition of radioactive substances in the production of cosmetics neither the import, export or placing on the market of cosmetic products.

The BSS Directive does not provide a definition of cosmetic products. In this context, the Community has issued already in 1976 a Directive for the approximation of Member States legislation relating to cosmetic products. (Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products; Consolidated text published by OJ: CONSLEG 1976L0768 of 15/10/2003)

The overall objective of this Directive is to prevent economic barriers within the EU due to different objectives of Member States in safeguarding public health.

In this respect the Directive provides a definition of cosmetic products and excludes pharmaceutical specialities and medical products. This definition refers both to the areas of application and to the purposes of the use of cosmetics. There are cosmetic products which fall under this definition while other products containing the same substances but intended to be ingested, inhaled, injected or implanted in the human body do not come under the field of cosmetics. Consequently, the Directive provides in Annex 1 an illustrative list by category of cosmetic products and provides in Annex 2 a list of substances which must not form part of the composition of cosmetic products. In Annex 2 the cosmetic products Directive prohibits the presence of radioactivity in these products. For the definition of radioactivity Annex 2 refers to the radiation protection basic safety standards Directive 96/29/Euratom.

1.3.4 EU Legislation on Low Voltage Equipment

The Directive issued for the harmonisation of the laws of Member States relating to electrical equipment designed for the use within certain voltage limits provides for minimum requirements for the safe use of this particular group of consumer products (Council Directive 73/23/EEC of 19 February 1973 Consolidated text published in the OJ CONSLEG 1973L0023-02/08/1993).

The main objective of this Directive is to eliminate trade barriers for the placing on the market of low voltage electrical equipment due to differing national laws, regulations or administrative acts on the safety of such equipment. Some Member States legislation lays down binding provisions on safety and on the safe use of electrical equipment. Other Member States intend to achieve the same goals by providing references to technical standards. (national or international technical standards as appropriate)

The Directive obliges Member States to mutually recognise the national provisions on the safety of electrical equipment. Member States shall arrange for attesting conformity with the provisions of this Directive, applying the procedure described in an Annex of the Directive.

The Directive applies to electrical equipment designed for use between 50 and 1000 Volts. The Directive provides that electrical equipment should be designed and manufactured in such a way that temperatures, arcs or radiation cause no danger. The Directive does not refer specifically to the radiation protection Basic Safety Standards Directive.

1.4 The approach to natural radionuclides

Within the scope of the BSS, it is considered that where consumer products to which naturally occurring radioactive materials have been added. If these products give rise to a significant increase in the exposure of members of the public they should be subject to regulatory control. It is recommended, therefore, that the regulatory approach recommended in these guidelines is applied in the same way to consumer products containing artificial radionuclides and those containing naturally occurring radionuclides.

1.5 A summary of the current situation in Member States and Candidate States

A review of the availability and regulation of consumer products incorporating radioactive substances in the European Union was carried out in 2003 [1]. This report concluded that:

- With the exception of the UK, all EU Member States, Candidate States and Accession States that responded to the call for information[1] reported that they had already implemented the relevant articles of Council Directive 96/29/Euratom with regard to consumer products. However, at the time that this report was written, only Denmark and Sweden had specific legislation relating to consumer products containing radioactive materials. In other countries, the relevant articles of the Council Directive are implemented in

[1] Six countries did not supply any information to the authors of the report and hence it is not known whether the relevant articles of the Directive are fully implemented in these states.

general radiation protection legislation, and it is not certain that the requirements are effectively enforced, as there is no system for controlling the types of consumer product that are placed on the market.

- Mandatory product testing is rare and generally it appears that only ionisation chamber smoke detectors (ICSD) are tested to confirm that they conform to standards. Having said that, the product standards available (NEA/OECD) are now thirty years old and reviewing may be desirable.
- Mandatory labelling of consumer products is rare and in most countries where labelling is required this only applies to ICSD.
- More than half of the countries indicated that controlled disposal (return to the supplier or to a national waste repository) is required for certain products, particularly ICSD. The others allow disposal of consumer products with the normal household waste.
- When it comes to prohibiting certain consumer products, there are major differences between the different Member States. Some countries do not prohibit any consumer products. Others prohibit, or are planning to prohibit even established products like ICSD.
- Only the Netherlands, Spain and the UK appear to have made specific assessments of maximum individual doses to the public from the use and disposal of consumer products.

2 CONSUMER PRODUCTS INCORPORATING RADIOACTIVE SUBSTANCES

As part of the recent review of consumer products in the European Union[1], each Member state, Candidate State and Accession State was asked to report on the products available in their country. Details of each consumer product reported were summarised in a table, which is reproduced in Annex 1 of the present report.

Some consumer products are widely used by the general population, for example, ionisation chamber smoke detector ICSD, whereas some are used by specialist groups only, for example weapons sights containing tritium, and thoriated tungsten welding rods. It is also recognised that some products containing radioactive material and intended for industrial use only (e.g. exit signs containing tritium) could fall into the hands of the public, perhaps via auction sites on the internet. In such cases, however, it is clear that the suppliers and manufacturers never intended these products to be consumer products. Such products, i.e. those intended for specialist and industrial use, are considered to be outside the scope of these guidelines and are not considered further.

For the purposes of these guidelines, the products available within the European Union are separated into three categories; existing products, novel products and historic products.

2.1 Existing products

Existing products are defined as those products that are being manufactured at the present time, and appear on the market. The range of existing products can be divided into the following six classes:

- ionisation chamber smoke detectors (ICSD);
- items luminised with radioluminous paint (timepieces and compasses);
- items incorporating gaseous tritium light sources (GTLS) (timepieces, compasses, fishing floats, torches, telephone dials and keyrings);
- electronic devices (lamp starters, valves, surge voltage protectors, discharge and metal vapour lamps);
- thoriated items (gas mantles, camera lenses and ophthalmic lenses); and,
- items incorporating uranium (tiles and tableware).

There are a range of views as to whether irradiated gemstones should be included in the definition of existing consumer products. Irradiation by neutron or electron beam radiation to enhance gemstone colour is standard practice in the gemstone industry, and irradiation produces radioactive activation products within the gemstone structure. So it could be argued that the irradiation process deliberately incorporates radioactive substances into the product and that irradiated gemstones are "consumer products" as defined in Part 1.2 of these guidelines. It is normal practice in the industry for the gemstones to be stored for a pre-determined length of time, to eliminate the activation products before the stones are released onto the market. This means that under normal circumstances, by the time they reach the point of sale they do not contain radioactive substances and hence do not meet the definition of consumer products given in Part 1.2. There have been a few instances of gemstones being released onto the market while still radioactive. Competent authorities and the irradiation companies should together control the release of irradiated gemstones. Hence, the practice of the irradiation of gemstones is not considered further in these guidelines. However, the import of still-active gemstones into the EU would not be considered to be acceptable and should be prohibited.

2.2 Novel products

The six classes of consumer products defined in 2.1 above have not changed for many years, although it is possible that novel products that do not fit into any of these classes could appear in the future. Also, within the six classes, novel

products do occasionally come on to the market. An example of this is the recent appearance of keyrings containing GTLS (known as "glowrings"). Part 4.1.2 of these guidelines includes recommendations on how to deal with the authorisation of such "novel products".

2.3 Historic products

Historic products are defined as those products that are not currently being manufactured and hence are no longer generally available. However, they can still appear on the market as second-hand items. The most common historic products are items luminised with radium paint. Radium-226 was used as a luminising agent in the European Union up until the late 1970s, and so a few clocks, watches and compasses luminised with radium paint remain in circulation. Other, less common, historic products include radium blankets, radium corsets, cosmetics incorporating uranium and radioluminised vending machine coins, bank cheques, identity cards and drivers' licences.

The number of historic products still in circulation is assumed to be very small and in addition, it is considered impossible to regulate the second-hand and antique market. Hence the regulation of historic products is not recommended in these guidelines. However, competent authorities should give advice to members of the public on the safe use and disposal of such products.

3 RECOMMENDED REGULATORY APPROACH

A two stage regulatory approach is recommended, consisting of two separate processes:

- justification; and,
- authorisation.

The processes are discussed further in parts 3.1 and 3.2 below. The principle of exemption and how this should be applied to consumer products is discussed in part 3.3.

3.1 Justification

The justification of types and class of practice is both a fundamental principle of radiation protection and a requirement of Article 6 of the BSS. While the principle of justification has been a key concept in radiation protection for many years, there has been much debate over the practical application of the principle. This debate has centred on the generic nature of the principle and the range of attributes that should be considered in reaching a decision. It should be noted

that justification should be applied to the practice rather than the product and hence for consumer products it should be applied to, for example, the practice of the deliberate addition of radioactive substances to ionisation chamber smoke detectors, rather than the specific product itself. It is not recommended to look into the justification of individual uses of the product. The justification exercise would look at all steps in the manufacture, use and disposal of the product and would take into account benefits and detriments to all persons involved. It is accepted now that justification is a complex subject involving more than just radiation protection issues, and that the drawing up and assessment of a justification application may be a difficult and time-consuming issue that will be very dependent on the specific requirements of the relevant national legislation.

Justification is a generic process and permits the grouping of types or classes of practices for justification purposes, when their associated benefits and detriments are similar. In the case of consumer products to which radioactive materials have been deliberately added, it is recommended that products are grouped in six separate classes, as outlined in Part 2.1 of these guidelines.

- ionisation chamber smoke detectors (ICSD);
- items luminised with radioluminous paint (timepieces and compasses);
- items incorporating gaseous tritium light sources (GTLS) (timepieces, compasses, fishing floats, torches, telephone dials and keyrings);
- electronic devices (lamp starters, valves, surge voltage protectors, discharge and metal vapour lamps);
- thoriated items (gas mantles, camera lenses and ophthalmic lenses); and,
- items incorporating uranium (tiles and tableware).

This approach is based on the fact that products within a particular class of consumer product have similar benefits and detriments, e.g. a benefit by the user, economic benefits to the manufacturer and supplier, and similar potential doses associated with their use and disposal. However, the regulatory authority may still require a full justification case for any proposed unusual or novel product that is identified as having an unusually high dose detriment or other disadvantage.

The assessment of whether the deliberate addition of radioactive substances to a particular class of product is justified can be problematic. The regulatory authority will need to decide whether the benefit provided by the addition of radioactive materials outweighs any detriment. The benefits of products with a safety role, e.g. ICSDs, are easy to identify and hence it may be concluded that the deliberate addition of radioactive material to this class of product is justified. The benefits of other products (e.g. items incorporating GTLS) are more difficult to quantify and this has resulted in subjective decisions and a fragmented approach across Europe. However, the fact that there is a demand for a product indicates that the purchaser perceives there to be a benefit in its use, even though the benefit may be perceived by others to be trivial. In other cases, for example the deliberate addition of uranium and thorium to tableware and tiles, it

could be argued that the addition of radioactive material has no practical benefit, and that there are means of achieving the same colouration without using radioactive material.

The previous report[1] indicated that many member states of the EU already consider the deliberate addition of radioactive substances to certain classes of consumer goods (e.g. ICSD, radioluminised timepieces and compasses) to be a justified practice and have in place prior approval procedures for these products.

Finally, it should be noted that the practice of deliberately adding radionuclides to certain types of product is not justified, and such practices should be prohibited. This is discussed further in 3.1.1 below.

3.1.1 Prohibition

The deliberate addition of radioactive substances in the production of toys, personal ornaments and cosmetics is not considered to be justified. The production, import and export of such items is also explicitly prohibited by the BSS.

3.2 Authorisation

Having decided that the deliberate addition of radioactive material to a particular class of product is justified, the next step is authorisation of the production, manufacture, import or export of an individual product. Although a class of product, e.g. ICSD, may be deemed justified, some individual ICSDs may not be authorised because they do not meet the required standard.

The BSS requires the prior authorisation of the deliberate addition of radioactive substances in the production and manufacture of consumer goods, and the import and export of such goods. The authorisation of the production, manufacture, import and export of consumer products should take account of a number of factors, in particular the design, and (potential) doses during use and as a consequence of disposal.

Authorisation is defined as permission granted in a document by the competent authority, on application, or granted by national legislation, to carry out a practice or any other action within the scope of the Directive. It follows that authorisation is a regulatory process that requires the potential supplier or manufacturer to apply to the competent body for authorisation to place a product on the market, and to supply any required supporting information on design criteria, performance testing etc with the application. Although the manufacture of consumer products will inevitably involve exposure to workers national legislation already addresses this exposure route through occupational exposure legislation. These guidelines will therefore recommend an authorisation process that only covers public exposure, either as a result of use or disposal. It will be assumed that exposures associated with manufacture will be covered by other legislation.

It is recommended that the principle of prior authorisation is applied to the placing on the market of new consumer products and also to those that are already on the market. For these existing consumer products, an interim period

should be set after the introduction of any regulations, to allow the manufacturer, importer or supplier time to apply for authorisation.

3.3 Exemption

The BSS defines exempted products as those where the annual dose is less than a few tens of micro-Sieverts. It also gives exemption values in terms of total activity and activity concentrations (if a source is less than either values it can be considered to be exempt from regulatory control). However, these values are derived from occupational exposure scenarios and are not always appropriate for consumer products. It is considered that the exemption values set out in the BSS are not quite useful for consumer products and that product–specific authorisation levels (specified either in terms of activity per item or, when applicable, activity concentration) should be used in the authorisation process. The levels should be chosen by calculating the activity at which routine use and disposal of a product will result in individual doses that satisfy recommended constraints (see Part 4.3.1 below).

Although the BSS also considers collective dose in the consideration of regulatory significance, this is not thought to be appropriate in the case of consumer products. While individual doses are low the number of users may be very high. However, it is noted that, for some products, the collective benefit also increases with the number of users. It is recommended therefore that the concept of collective dose is not considered in the authorisation process.

4 RECOMMENDED CRITERIA OF APPROVAL FOR AUTHORISATION

The recent review of the use of consumer products[1] indicated that although the majority of countries had an authorisation system in place for the manufacture of consumer products incorporating radioactive substances, very few took into account potential doses to the users of the products doses arising from disposal. An effective authorisation system should consider each of these areas as well as construction standards, if available, and should be capable of being applied equally effectively and without prejudice to novel products in addition to the well-established ones. This section considers the requirements for an effective authorisation system and proposes a straightforward procedure that satisfies these requirements.

It should also be noted that, if each country develops its own authorisation system, there is a possibility that some products will be authorised in one

member state, but prohibited in another. Use of the system of authorisation outlined below will increase harmonisation between member states.

4.1 Recommended system of authorisation

The responsibility for applying for, and obtaining, authorisation for the deliberate addition of radioactive substances to a consumer product lies with the manufacturer or, in the case of imported products from outside the EU, the importer/supplier. The areas to be considered by the competent authority in assessing the authorisation of the manufacture, production or placing on the market of a product should be:

- doses arising from the use and disposal of the product;
- whether the product is designed to ensure that doses to the user are optimised;
- the standards of construction, i.e. the durability of the product under tests that represent credible use and misuse (prototype testing); and,
- labelling and product information.

Each of these is considered in detail in part 4.2 below.

The authorisation scheme should require the manufacturer, importer or supplier to provide evidence that requirements in each of these areas have been met. The recommended means of achieving this for existing products and novel products is described below.

4.1.1 The use of pro-forma authorisations for existing products

Obtaining authorisation for the supply of well-established products such as ICSDs should be a relatively straightforward process. These products should be constructed to established international standards and the manufacturers should regularly test the products to ensure compliance with the standards. Likewise the doses arising from their use and disposal are well-documented. Provided that existing products meet the requirements of the relevant standards, authorisation should be granted automatically. Manufacturers, importers or suppliers of existing products would be required to provide evidence that the product complies with the requirements of the standard, using a simple pro-forma approach.

Alternatively, the use of generic authorisation by a system of type approval could be utilised by competent authorities. In this case, provided that the manufacturer, importer or supplier was able to meet the conditions specified in the generic authorisation, the product would be considered to be authorised automatically, without the need for application to the competent authority. However, there could be problems in trading between member states if one state authorises a product by type approval, whilst another does not.

4.1.2 The authorisation of novel products

For novel products, pro-forma or generic authorisation would be inappropriate, as there would be no product-specific standards available. Manufacturers, importers or suppliers of novel products would be required to submit individual applications for authorisation to the competent authority in each country. The scope of information required by the competent authority, to enable them to decide whether supply of the product is authorised, is outlined below:

- a description of the product and its intended use, including the function served by the incorporated radioactive substances;
- the radionuclide(s) used, their chemical and physical form, and the total activity or activity concentration;
- the case for using the radionuclide and activity chosen;
- the maximum external radiation dose rate from the product, together with details of how this was measured;
- a risk assessment demonstrating that doses to the public from use, disposal and reasonably foreseeable incidents (e.g. misuse and breakage) will not exceed the recommended dose constraints (given in part 5.3.1 of these guidelines);
- drawings showing the construction of the product, and, where appropriate, the radioactive source(s);
- details of any quality control procedures to be applied to the components, the finished product, and, where appropriate, the radioactive source(s);
- details and results of prototype tests carried out;
- details of the labelling and product information that will be supplied to the consumer; and,
- the arrangements for disposal of the product.

While some of this information is relatively straightforward, other aspects (e.g. risk assessment and prototype testing) are more complex. It is recommended that the applicant is required to seek the assistance of a qualified expert in assembling the application.

It is important that a consistent approach to the authorisation of novel products is applied in all Member States, otherwise a situation could arise where a product is authorised in one state but prohibited in another. To ensure a consistent approach it is recommended that Member States exchange information regarding applications for novel products.

4.1.3 The authorisation of products sold on the "World Wide Web"

In theory, the authorisation of Internet sales should work in the same way as for products sold in a shop. If the products are manufactured within the EU, the manufacturer would be responsible for making an application for authorisation to the competent authority in each country to which they would deliver the product. If the product is manufactured outside the EU, the Internet site selling it would be responsible for application, as they are the supplier/importer. However, it is recognised that the authorisation of products sold on the Internet presents problems. It is difficult to exercise control over the sale of products that may, in many cases, be produced outside the EU, and sold on many different websites. The exchange of information between Member States is vital in ensuring that consumer products sold on the Internet come to the attention of competent authorities.

4.2 General criteria for justification and authorisation

4.2.1 Acceptability

Consumer products containing radioactive substances will be defined as acceptable, providing that:

- they fall into one of the classes of product to which the deliberate addition of radioactive materials is deemed to be justified (see Part 3.1);
- there is a perceived benefit from their use that is more than just aesthetic (see discussion below); and,
- there is no suitable non-radioactive alternative (see discussion below).

It is considered that the frivolous uses of radioactive material in a consumer product, i.e. a product where the radioactive material serves no apparent purpose or is for aesthetic purposes only, would not be acceptable. It is recommended that clear advice on this matter is produced, perhaps in the form of a list of the types of products which are considered to be to be in a category of so-called "costume jewellery".

If there is a non-radioactive product that provides the same or greater benefit then it is doubtful that the radioactive product could be considered to be acceptable. However, this requires careful consideration. For example, a smoke detector incorporating an optical detector might not, at present, be considered as a suitable non-radioactive alternative to an ICSD, because it does not detect certain types of fire as well as an ICSD. In the same way, it can be considered that a photoluminescent watch does not present an equivalent non-radioactive alternative to a radioluminescent watch, as it does not glow all the time, and hence its benefit to some users might be reduced. The relative cost of the non-radioactive product should also be a factor for consideration.

4.2.2 Dose constraints

The following dose constraints are proposed:

- the effective dose to users and non-users of the product arising from normal use and disposal should not exceed 10 micro-Sieverts per year, and in the case of partial body exposure, 1% of organ dose limits for members of the public; and,
- the dose to users and non-users of the product arising from reasonably foreseeable accidents or misuse should not exceed the appropriate public dose limit.

For existing products, the activity limits in the product standards should be set such that these dose constraints will not be exceeded under conditions of normal use (including uncontrolled disposal), misuse and reasonably foreseeable accidents.

For novel products, the applicant would be expected to provide a detailed risk assessment, demonstrating that the dose constraints could not be exceeded. The risk assessment should consider both normal use (including uncontrolled disposal) and reasonably foreseeable incidents.

4.2.3 Optimisation of doses by design

The recommended design criteria for existing products should be included in the product standards. This may include requirements specific to that class of product, for example, specifying a particular radionuclide that may be used. Other, more general, requirements are outlined below. These may apply to both existing and novel products:

- any sealed sources must conform to ISO 9978;
- the activity or activity concentration must be as low as reasonably achievable for satisfactory function;
- any GTLS must contain less than 2% tritiated water;
- the accessible surface dose rate must not exceed a given limit;
- where appropriate, the rate of radioactive leakage from the product must not exceed a given limit;
- the product must be designed to prevent easy access to the radioactive components; and,
- the outer casing should be designed to prevent breakage as far as practicable.

4.2.4 Standards of construction and prototype testing

For existing products, authorisation would be subject to evidence that the prototype tests specified in the appropriate standard had been passed.

For novel products, the competent authority should be satisfied that the applicant had chosen appropriate prototype tests. The authorisation of the novel product would be subject to evidence that the product had passed these tests.

4.2.5 Labelling and product information

The supply of information to the user of the product is considered to be very important. The source housing or mounting and the outside of the product should be labelled where practicable and meaningful (e.g. to avoid misuse). The format of the labelling should comply with the requirements for the labelling of other potentially dangerous goods. In addition, the packaging of the product should include a warning label and instructions for safe use and disposal

5 THE NEED FOR A HARMONISED APPROACH WITHIN THE EUROPEAN UNION

In order to prevent barriers to trade between member states, it is important that any system of prior authorisation for the sale of consumer products is applied consistently across the European Union. For existing products, the prospect for a consistent approach is good, provided that clear guidance is issued by the EU and observed by each member state. However, the authorisation of novel categories of product may present problems.

5.1 Recommendations for the exchange of information between member states

In order to maintain up to date information on the availability of existing consumer products, and the introduction of novel products, it is recommended that there is a mechanism for the exchange of information between member states. It is recommended, therefore, that the EC seeks the following information from each of the twenty-five Member States and four Candidate States:

- details of the competent authority that is responsible for the regulation of consumer products, including contact names, telephone numbers and email addresses; and,
- a list of the types of consumer product known to be available in each country, (including those sold via the internet) with as much information as

possible about the range of radionuclides and activities incorporated in each type of product.

For most Member States and Candidate States, this information is already available in the recent review of consumer products[1], but the EC should verify the information provided to ensure that it is up to date.

It is also recommended that the competent authority in each Member State and Candidate State should:

- provide the EC with an annual statement of the products newly authorised for placing on the market in that member state during the year; and,
- notify the EC if it receives information on any new classes of consumer product placed on the market, or if it receives information about any new products that are significantly different to existing products of that class.

5.2 Recommendations for European Standards on consumer products containing radioactive substances

Part 3 of these guidelines recommends a system of prior authorisation for consumer products, and Part 4 goes on to recommend that authorisation should be granted to products which meet certain criteria. These would include limits on the activity in a single product, set such that the user of the product would not exceed appropriate dose constraints, and in the case of currently existing classes of product, compliance with specified product standards and the passing of appropriate prototype tests. It is important that the criteria of acceptability and the product standards are set out clearly, to ensure a consistent approach to authorisation by all member states.

At present there are three international standards for consumer products:

- Radiation Protection Standards for Gaseous Tritium Light Devices (GTLD) NEA/OECD, 1973; and
- Recommendations for Ionization Chamber Smoke Detectors (ICSD) in Implementation of Radiation Protection Standards. NEA/OECD, 1977.
- Radioluminescence for time measurement instruments - Specifications. ISO 3157:1991(E)

Further details regarding the scope and content of these documents are given in the review of consumer products in the European Union[1].

The first two of these documents are now more than twenty-five years old. In addition, there are no standards for the other classes of consumer product defined in Part 1.2 of these guidelines. It is recommended, therefore, that updated European or international standards for ionisation chamber smoke detectors, radioluminous items, items incorporating GTLS, electronic valves and thoriated items are now produced. It is worth noting that in the UK, NRPB has

published standards for ICSD, radioluminous timepieces, timepieces containing GTLS, compasses containing GTLS and thoriated gas mantles[2].

It is outside the scope of these guidelines to recommend exactly what should be contained in these new standards, but an example of a standard for ICSD, based on that published by NRPB, is given in Annex 3, for guidance.

6 RECOMMENDATIONS FOR THE DISPOSAL OF CONSUMER PRODUCTS

The approach to the disposal of consumer products currently varies considerably across the member states of the EU. While some countries require the products to be returned to the supplier/manufacturer after use, others accept that such products are essentially beyond regulatory control when sold and hence may be disposed of with other domestic waste. The latter approach has been justified by the fact that potential doses arising from uncontrolled disposal are generally very low. However, such an approach is inconsistent with the increasing requirements for the efficient disposal of waste and the recycling of products. A recent EC directive on waste electrical and electronic equipment (known as the WEEE directive)[3] requires waste electrical and electronic products containing radioactive components to be collected separately and any radioactive components with activities above the exemption levels given in the BSS to be removed.

Hence it is recommended that mechanisms for the collection, recycling and controlled disposal of such products be encouraged. While it is not practicable to enforce the public use of specified routes of disposal, the provision of collection points for specific products (e.g. ICSDs) at public waste collection facilities will encourage responsible disposal. The authorisation process should also ensure that the impact of the uncontrolled disposal of products remains low.

[2] Documents of the NRPB, Vol. 3 No 2, Board Statement on Approval of Consumer Goods containing Radioactive Substances, ISBN 0-85951-350-5, 1992

[3] Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003, on waste electrical and electronic equipment.

7 SUMMARY AND CONCLUSIONS

The objectives of these guidelines are stated in Part 1.1. The following sections reiterate and summarise the recommendations in relation to these objectives.

7.1 Definition of relevant products and scope of regulatory guidelines

7.1.1 It is recommended that, in the context of these guidelines, the term "consumer product" be defined as follows:

a manufactured product or appliance, or miscellaneous source, in which radionuclides are deliberately incorporated and which can be supplied to members of the public without special surveillance and control.

7.1.2 The supply and use of the following is outside the scope of these guidelines:

- specialist and industrial use products (e.g. thoriated welding rods);
- historic consumer products (e.g. watches luminised with radium); and,
- irradiated gemstones to the extent they are no longer radioactive when placed on the market.

7.2 Requirements for prior authorisation of consumer products

7.2.1 A two stage regulatory approach is recommended, consisting of two separate processes:

- justification and,
- authorisation.

7.2.2 It is recommended that regulatory authorities do not require a justification case for each individual type of product, but rather group products into the following six classes when considering justification:

- ionisation chamber smoke detectors (ICSD);
- items luminised with radioluminous paint (timepieces and compasses);
- items incorporating gaseous tritium light sources (GTLS) (timepieces, compasses, fishing floats, torches, telephone dials and keyrings);
- electronic devices (lamp starters, valves, surge voltage protectors, discharge and metal vapour lamps);

- thoriated items (gas mantles, camera lenses and ophthalmic lenses); and,
- items incorporating uranium (tiles and tableware).

In determining whether the deliberate addition of radioactive substances to a particular class of product is justified the regulatory authority will need to decide whether the benefit provided by the addition of radioactive materials outweighs any detriment.

7.2.3 It is recommended that the production, manufacture, import or export of consumer products is subject to prior authorisation by national competent authorities.

7.2.4 It is recommended that the areas to be considered by the competent authority in assessing the authorisation of the manufacture, production or placing on the market of a product should be:

- (potential) doses arising from the use and disposal of the product;
- whether the product is designed to ensure that doses to the user are optimised;
- the standards of construction, i.e. the durability of the product under tests that represent credible use and misuse (prototype testing); and,
- labelling and product information.

Part 4.2 of this report details the general criteria for authorisation.

7.2.5 To facilitate the process of authorisation, it is recommended that new European Standards for each class of existing consumer product be produced. Authorisation for the manufacture, import and sale of existing products will then be automatically granted to those products that meet the requirements of these standards. For these existing consumer products, an interim period should be set after the introduction of any regulations, to allow the manufacturer, importer or supplier time to apply for authorisation.

7.2.6 It is considered that the exemption levels set out in the BSS are not quite useful for consumer products. Rather than using the nuclide-specific exemption levels given in the BSS, product–specific authorisation levels (specified either in terms of activity per item or, where appropriate, activity concentration) should be used in the authorisation process. The levels should be chosen by calculating the activity at which routine use and disposal of a product will result in individual doses that satisfy recommended constraints. It is also recommended that the concept of collective dose is not considered in the authorisation process.

7.2.7 Authorisation of novel products will be subject to the product meeting criteria set down by the competent authority. It is important that a consistent approach to the authorisation of novel products is applied in all Member States, otherwise a situation could arise where a product is authorised in one state but prohibited in another. To ensure a consistent

approach it is recommended that Member States exchange information regarding applications for novel products.

7.2.8 In order to maintain up to date information on the availability of existing consumer products, and the introduction of novel products, it is recommended that there is a mechanism for the exchange of information between member states. It is recommended, therefore, that the EC seeks the following information from each of the twenty-five Member States and four Candidate States:

- details of the competent authority that is responsible for the regulation of consumer products, including contact names, telephone numbers and email addresses; and,
- a list of the types of consumer product known to be available in each country (including those sold via the internet) with as much information as possible about the range of radionuclides and activities incorporated in each type of product.

For most Member States and Candidate States, this information is already available in the recent review of consumer products[1], but the EC should verify the information provided to ensure that it is up to date.

7.2.9 It is also recommended that the competent authority in each Member State and Candidate State should:

- provide the EC with an annual statement of the products newly authorised for placing on the market in that Member State during the year; and,
- notify the EC if it receives information on any new classes of consumer product placed on the market, or if it receives information about any new products that are significantly different to existing products of that class.

7.3 Prohibition

7.3.1 The deliberate addition of radioactive substances in the production of toys, personal ornaments and cosmetics is not considered to be justified and hence the production, import and export of such items should be prohibited.

7.4 Recommendations for product testing

7.4.1 It is recommended that the product standards (see 7.2.5 above) include specifications for tests on prototype products. For existing products, authorisation would be subject to evidence that the prototype tests specified in the appropriate standard had been passed. For novel

products, the competent authority should be satisfied that the applicant had chosen appropriate prototype tests. The authorisation of the novel product would be subject to evidence that the product had passed these tests.

7.5 Requirements for labelling and product information

7.5.1 It is recommended that the source housing or mounting and the outside of the product should be labelled where practicable and meaningful. The format of the labelling should comply with the requirements for the labelling of other potentially dangerous goods.

7.5.2 It is also recommended that the packaging of the product should include a warning label and instructions for safe use and disposal.

7.6 Recommendations for the disposal of consumer products containing radioactive substances

7.6.1 It is recommended that mechanisms for the return of products to the suppliers be encouraged. While it is not practicable to enforce the public use of specified routes of disposal, the provision of collection points for specific products (e.g. ICSDs) at public waste collection facilities will encourage responsible disposal. The authorisation process should also ensure that the impact of the uncontrolled disposal of products remains low.

ANNEX 1

DETAILS OF CONSUMER PRODUCTS AVAILABLE WITHIN THE EUROPEAN UNION

This table summarises the information provided by member states and candidate states in the recent review of consumer products in the European Union[1].

Table 1 Reported products

Product	Radionuclides reported	Activities reported	Potential annual individual doses from use	Potential annual individual doses from disposal
ICSD	Americium-241	15 kBq to 2.7 MBq	<1 μSv effective dose from 40 kBq source [3,4]	<1 μSv effective dose[3]
	Radium-226	3 kBq		
	Plutonium-239	175 kBq to 175 MBq		
Timepieces incorporating radioluminous paint	Tritium	5 to 925 MBq	<1 μSv effective dose and ≤2.9 mSv equivalent dose to skin[3]	<1 μSv effective dose[3]
			≤ 22 μSv effective dose and ≤10.6 mSv equivalent dose to skin[5]	
	Promethium-147	0.05 to 18 MBq	<1 μSv effective dose and ≤0.35 mSv equivalent dose to skin[3]	<1 μSv effective dose[3]
	Radium	5 to 50 kBq		

[4] Eleveld H and Pruppers M J M, Schattingen van de individuele en collectieve doses als gevolg van consumentenproducten waarin radioactieve stoffen zijn verwerkt, Rijksinstituut voor Volksgezondheid en Milieu, RIVM report 610310 005, May 2000

[5] Paynter R A, Shaw P V, Dunderdale J, Ely S Y and O'Mahony M T, The use of radioactive materials in the luminising of watches, NRPB Contract Report M-863, 1997

Product	Radionuclides reported	Activities reported	Potential annual individual doses from use	Potential annual individual doses from disposal
Compasses incorporating radioluminous paint	Tritium Promethium-147 Radium Carbon-14	5 to 250 MBq 0.05 to 220 MBq up to 400 MBq up to 3.5 MBq		
Clock faces in car fascias incorporating radioluminous paint	Radium-226	No information		
Timepieces incorporating GTLS	Tritium	up to 1 GBq	<1 μSv effective dose and ≤0.9 mSv equivalent dose to skin[3] <1 μSv effective dose[6]	<1 μSv effective dose[3]
Compasses incorporating GTLS	Tritium	up to 13 GBq	<1 μSv effective dose and ≤4 μSv equivalent dose to skin[3]	<1 μSv effective dose[3]
Fishing floats incorporating GTLS	Tritium	0.1 GBq to 28 GBq		
Torches incorporating GTLS	Tritium	No information		
Keyrings incorporating GTLS	Tritium	up to 17.5 GBq		

Product	Radionuclides reported	Activities reported	Potential annual individual doses from use	Potential annual individual doses from disposal
Telephone dials incorporating GTLS	Tritium	No information		
Fluorescent lamp starters	Tritium	up to 11 kBq	<1 μSv effective dose[5]	
	Krypton-85	20 to 200 Bq	<1 μSv effective dose[5]	
	Thorium-232	up to 70 Bq		
Surge voltage protectors	Tritium	up to 3 GBq		
	Krypton-85	20 to 50 Bq		
	Promethium-147	up to 300 kBq		
	Radium-226	No information		
Electronic valves	No information	No information		
Discharge/metal vapour lamps	Krypton-85	0.75 to 15 kBq		
	Th-232	5 to 3500 Bq		
Thoriated incandescent gas mantles	Thorium	0.5 to 4 kBq	≤130 μSv effective dose depending on age[3] <1 μSv effective dose[5]	<1 μSv effective dose[3]
Thoriated opthalmic lenses	Thorium	up to 500 kBq		
Thoriated camera lenses	Thorium	up to 2 kBq		

Product	Radionuclides reported	Activities reported	Potential annual individual doses from use	Potential annual individual doses from disposal
Tableware incorporating U or Th	Uranium / thorium	Up to 10%; or		
	Uranium / thorium	up to 0.5 Bq/g		
Ceramic tiles incorporating U or Th	Natural uranium	0.1 to 2 mg/cm^2	1 μSv effective dose[5]	
	Radium-226	25 - 80 Bq/kg	<1 μSv effective dose[5]	
	Thorium-232	50 - 70 Bq/kg		
	Uranium-238	60 - 80 Bq/kg		
	Potassium-40	200 - 400 Bq/kg		

ANNEX 2

AN EXAMPLE OF A STANDARD FOR IONISATION CHAMBER SMOKE DETECTORS (ICSD)

Introduction

1. Ionisation chamber smoke detectors (ICSD) containing radioactive sources are an important application of ionising radiation and are widely available. Their use is important both in protecting property, and more importantly in saving lives.

2. The EU has considered this class of consumer product and has concluded that it meets the requirements for an acceptable product. Properly constructed ICSD present no significant hazard to the public. However, the radiation doses that might be received during normal use, or as a result of accidental damage or misuse, must be kept as low as reasonably achievable and should not exceed the dose criteria established by the EU. It is considered that demonstration of compliance with the requirements set out in these standards is sufficient evidence to demonstrate compliance with these principles. In order for manufacturers or suppliers of ICSD to obtain prior authorisation for the manufacture, import and sale of their product, it will be sufficient for them to provide evidence of compliance with these standards.

3. These standards include design and construction requirements that will ensure that doses are as low as reasonably achievable.

Scope

4. These standards detail the radiation protection requirements for ICSD. The standards relate to those ICSD intended for use by the general public in their own homes.

5. The standards do not cover the protection of persons normally handling ICSD as a result of their occupation (manufacturers, distributors, maintenance engineers etc), neither do they specifiy requirements for the storage and transport of ICSD.

Definitions

6. *Ionisation chamber smoke detector (ICSD)* - this is a device intended for the detection of combustion products. It contains an ionisation chamber and a radioactive source. Entry of the combustion products into the ionisation chamber affects the ionisation current and this in turn triggers an alarm.

7. *Sealed source* - this is a radioactive source sealed in a capsule or having a bonded cover, the capsule or cover being strong enough to prevent

contact with and dispersion of the radioactive material under the conditions of use and wear for which the sealed source was designed. This definition includes cut foil sources where the radioactive material is sandwiched between inactive layers.

9. *Source holder* - this is the mechanical support for the sealed source.

Principal specifications

10. The radioactive source(s) used in an ICSD shall be americium-241 sealed source(s) conforming to the relevant requirements of ISO standard 9978. The tests specified in the ISO standard shall be applied to the sealed source mounted in its source holder.

11. The total activity of the source(s) shall be as low as reasonably achievable consistent with the reliable function of the ICSD and shall not exceed 40 kBq.

12. Under normal conditions of use, direct contact with the radioactive source shall be impossible. The design of the device shall also discourage persons from attempting to gain access to the radioactive source and should be reasonably tamper-proof.

13. ICSD (or parts of ICSD where permitted) shall satisfy the tests specified below.

Prototype tests

14. The following tests shall be carried out on a prototype of each ICSD submitted for approval. A separate ICSD may be submitted for each test. The source shall not become detached or suffer loss of integrity as a result of each test.

Temperature

The ICSD shall be cooled to -25ºC, kept at this temperature for one hour and then allowed to return to ambient temperature. It shall then be heated to 100ºC, kept at this temperature for one hour and then allowed to return to ambient temperature.

Impact

The equipment and procedure for the impact test shall be those described in ISO 2919. A steel hammer of mass 0.5 kg shall be dropped from a height of 0.5 m on to the ICSD, which should be positioned on a steel anvil.

Drop

The ICSD shall be dropped from a minimum height of 4 m on to a hard, unyielding surface.

Vibration

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 per hour. The peak acceleration shall be 2.4 m s^{-2} for the range 5 to 20 Hz, 4 m s^{-2} for the range 20 to 40 Hz and 5.1 m s^{-2} for the range 40 to 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 $0.7\sqrt{f}$ m s^{-2}, where f is the resonant frequency.

Evaluation

Following each of the above four tests, wipe or immersion tests shall be carried out. The wipe test shall be carried out over each source 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 200 Bq from each source, then the source shall be considered to have retained its integrity.

Tests for the effects of fire

A fire test shall be carried out on the complete ICSD or on the source mounted in its source holder in the presence of parts of the ICSD which are sufficiently representative of the whole device. Air shall be passed through the furnace for the duration of the test at a flow rate of 1 to 5 litres per minute, and condensed and filtered before release to atmosphere. The ICSD (or its parts) shall be heated from room temperature to 600ºC and retained at this temperature for one hour. If the sum of the activity remote from the source (ie that which is in the condenser, on the filters and in the debris) and that removed from the source and holder (either by wipe or immersion testing) is less than 200 Bq, then the ICSD shall be considered to have passed the test.

Incineration test

A high temperature fire and incineration test shall be carried out on the complete ICSD or on the source mounted in its source holder in the presence of parts of the ICSD which are sufficiently representative of the whole device. The procedure shall be the same as that described in *Tests for the effects of fire,* except that the ICSD (or its parts) shall be heated to 1200ºC and retained at this temperature for one hour. If the activity detected in the condenser and on the filter is less than 1% of the activity of the ICSD, then the ICSD shall be considered to have passed the test.

Marking and labelling of ICSD

15. The ionisation chamber of each ICSD shall bear a label with the trefoil symbol and the word "radioactive". This label shall be clearly visible on removing any cover or housing of the ICSD. The outer housing of the ICSD should be marked in the same way.

16. The packaging of the product should include a warning label and instructions for safe use and disposal.

Quality control

17. The production of an ICSD shall be subject to adequate quality control procedures. Applicants for authorisation will be expected to provide descriptions of such procedures, indicating the methods employed to ensure that each ICSD manufactured is within the specification of the prototype.