IAEA-TECDOC-1679

Exemption from Regulatory Control of Goods Containing Small Amounts of Radioactive Material

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Exemption from Regulatory Control of Goods Containing Small Amounts of Radioactive Material

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EXEMPTION FROM REGULATORY CONTROL OF GOODS CONTAINING SMALL AMOUNTS OF RADIOACTIVE MATERIAL

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FOREWORD

One basic requirement in the IAEA safety standards is the requirement that each State establish an effectively independent regulatory body with legal authority to conduct the regulatory process, including the granting of authorizations for a person or organization to conduct specified activities with radioactive material or equipment that generates ionizing radiation. Such regulatory control over radioactive material is necessary in view of the potentially harmful effects of exposure of persons to ionizing radiation.

In recent years, increased attention has been paid to the need for a graded approach to regulatory control, such that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation. This reflects the fact that regulatory resources are limited and need to be used in the most effective manner possible. Those situations that are potentially the most hazardous require close regulatory oversight; those that are intrinsically safe may be exempted from some or all regulatory requirements. This IAEA-TECDOC examines some of the issues that need to be considered in relation to exemption from regulatory control.

The IAEA wishes to acknowledge the contributions of the working group chaired by E. Cottens (Belgium). This working group was also tasked with preparing the illustrative assessment of electric discharge lamps containing small amounts of ^{85}Kr or ^{232}Th that is included in this publication.

The IAEA officer responsible for this publication was I. Gusev of the Division of Radiation, Transport and Waste Safety.

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1. INTRODUCTION

1.1. BACKGROUND

Small amounts of radioactive material may be added to various goods for functional reasons. Several such items are currently available for either professional or personal use. These include ionization chamber smoke detectors, thoriated-tungsten welding rods, luminous dials, electrical devices and electric discharge lamps.

Some of these goods may be intended for particular types of market such as cinemas or other places to which the public may have access, but they are unlikely to be provided directly to members of the public[1]. Other goods may be intended for wide scale use and therefore readily available on the market as consumer products[2] through commercial outlets where personal and household products are normally purchased. Members of the public may be exposed to ionizing radiation as a consequence of activities[3] such as transport, storage, use and disposal of such goods.

The IAEA safety standards provide the basic requirements for regulatory control of such goods. The most relevant documents are the Governmental, Legal and Regulatory Framework for Safety [1] and the International Basic Safety Standards (hereafter referred to as the BSS) [2]. These requirements include notification of a practice to the regulatory body and authorization of the practice by the regulatory body. Provision is made for the exemption of practices from these and other regulatory requirements based on general criteria given in the BSS or any exemption levels specified by the regulatory body on the basis of these criteria[4]. The BSS, which are jointly sponsored by the IAEA and several other international

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[1] The term "member of the public" is defined in the BSS as: "for protection and safety purposes, in a general sense, any individual in the population except when subject to occupational exposure or medical exposure." The definition is therefore dependent on the definition of occupational and medical exposures. Occupational exposure is "exposure of workers incurred in the course of their work"; medical exposure is "exposure incurred by patients for the purposes of medical or dental diagnosis or treatment; by carers and comforters; and by volunteers subject to exposure as part of a programme of biomedical research". The BSS state "employers, registrants and licensees shall ensure that workers exposed to radiation from sources within a practice that are not required by or directly related to their work have the same level of protection against such exposure as members of the public." However, it is important to clarify that such persons are still workers. This being the case, the workers involved in such places as cinemas are still occupationally exposed to radiation, even though the level of protection should be the same as that for members of the public. In particular, the dose limits for members of the public are applicable to these workers.

[2] A consumer product is defined as "a device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionizing radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale."

[3] The term "activities" is used in the BSS and includes: the production, use, import and export of radiation sources for industrial research and medical purposes; the transport of radioactive material; the decommissioning of facilities; radioactive waste management activities such as the discharge of effluents; and some aspects of the remediation of sites affected by residues from past activities. The term "practice" is also used in the BSS and means any human activity that introduces additional sources of exposure or additional exposure pathways, or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed. The main difference between these terms is that the former focuses on the action–what is being done–while the latter focuses on the exposures that will or might be received as a consequence of those actions and, as such, will be the main one used in this document.

[4] It is noted that the administrative requirements of the BSS (authorization and notification) apply to persons and organizations. Strictly therefore, exemption relates to exemption of these persons or organizations from these requirements. For convenience, however, the term is used somewhat loosely in this document, such that exemption of practices means exemption of persons or organizations undertaking activities involving these practices from these requirements.

organizations, apply to all facilities and all activities for peaceful purposes that give rise to exposure to radiation.

In the interest of harmonization of approaches among Member States, some guidance on the application of the criteria for exemption has been provided in a number of Safety Guides, e.g., Regulatory Control of Radiation Sources, IAEA Safety Standards Series No. GS-G-1.5 (2004) [3] and the Safety Guide on Application of the Concepts of Exclusion, Exemption and Clearance, No. RS-G-1.7 (2004) [4]. Nevertheless, the application of the exemption provisions in the BSS require further guidance, particularly with respect to goods containing small amounts of radioactive material. Although attempts have been made to harmonize the approaches among States and some progress has been achieved, further work needs to be done. For example, in some States such goods may be exempted from regulatory control and, in the case of consumer products, freely available to the public, while in other States their use may be subject to authorization with the consequence that they cannot be made freely available to the public. Other States may even refuse to authorize such goods, effectively resulting in their being banned. Such inconsistencies of approach may be a cause of confusion since the reasons for the different approaches will not be clear to manufacturers and suppliers of goods and the public who might use them. It may even result in questioning of the competence of the regulatory body.

Further harmonization of the regulatory approaches in Member States in the application of the exemption provision in the BSS is clearly desirable, if not essential. Such goods may be marketed globally, and lack of harmonization can be a cause of confusion among the public and others regarding the risks posed by such goods. Further harmonization would assist regulatory bodies in the efficient and effective use of their limited resources, leaving them more time to devote to those activities and practices that present more significant radiation risks. Furthermore, it would have benefits for international trade.

1.2. OBJECTIVE

This IAEA-TECDOC is directed at regulatory bodies, as well as suppliers[5] of goods containing small amounts of radioactive material. Its principal objective is to examine some of the issues that need to be considered in relation to exemption from regulatory control and to initiate discussion on how the provisions for exemption given in the BSS [2] might be applied to goods containing small amounts of radioactive material. It is anticipated that such consideration will lead to further consensus among States on how the supply of such goods to the public can be regulated and controlled. The IAEA-TECDOC considers both the administrative and the radiation protection requirements outlined in the BSS. Particular attention is given to the application of the requirement for justification because of the central role that this requirement plays in exemption and in the authorization of the supply of a consumer product containing radioactive material. Electric discharge lamps containing small amounts of ^{85}Kr or ^{232}Th are used to illustrate the type of safety assessment that might be used as a basis for decisions regarding exemption.

1.3. SCOPE

The scope of the report is restricted to finished goods (i.e. not components) that contain small amounts of radioactive material and for which exemption from regulatory control may be

[5] In the IAEA Safety Glossary, the term “supplier” includes designers, manufacturers, producers, constructors, assemblers, installers, distributors, sellers, exporters or importers of a source.

appropriate. Its focus is on the various stages following manufacture, including transport, storage, supply, use and disposal. It covers goods that may be used in places of work to which the public may have access and goods that may be supplied directly to the public as consumer products.

The report does not cover equipment which generates ionizing radiation (such as cathode ray tubes) or in which radioactive material is produced by activation (such as irradiated gemstones), which may also be sold directly to the public.

1.4. STRUCTURE

Section 2 discusses the administrative requirements given in the BSS that may apply to goods containing small amounts of radioactive material. Section 3 reviews the radiation protection requirements and Section 4 gives specific attention to the application of the requirements for justification to such goods. Section 5 discusses the provisions for exemption from the administrative requirements given in the BSS and how the criteria for exemption might be applied to goods containing small amounts of radioactive material. Section 6 provides the conclusions, summarizing the relevant points and raising the issues that need to be considered in order to achieve greater harmonization of regulatory approaches.

An example of a safety assessment for lamps containing small amounts of radioactive material is included as an Appendix to the report, and eight annexes provide supporting material.

2. APPLICATION OF ADMINISTRATIVE REQUIREMENTS

The IAEA safety standards emphasize the importance of a graded approach in the regulation of activities and practices. In particular, the General Safety Requirements, Governmental, Legal and Regulatory Framework for Safety [1] require the implementation of national policies and strategies for safety, to be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities. This requirement is also found in the BSS [2], where it is stated that "the application of the requirements of these Standards in planned exposure situations shall be commensurate with the characteristics of the practice or the source within a practice, and with the magnitude and likelihood of the exposures." A planned exposure situation is a planned situation that arises from the planned operation of a source or the planned conduct of an activity that results in or that could result in exposure. In this document, this term will be regarded as synonymous with the term 'practice'.

This requirement for a graded approach is reflected in a number of terms that are used in the BSS, namely, authorization[6] by licensing, authorization by registration, notification and exemption (these are in decreasing order of significance as far as regulatory control is concerned).

Practices that pose or are likely to pose a relatively high radiation risk are required to be subject to a system of authorization by means of licensing. This would require a detailed safety assessment prior to the issuance of a licence by the regulatory body. In addition, the licence would contain the detailed conditions that the operator (the licensee) would be required to meet and the practice would need to be subject to relatively frequent inspections by the regulatory body. Examples of such practices outside of the nuclear industry are industrial radiography, radiotherapy or situations where relatively large amounts of unsealed radioactive material are handled.

Authorization by means of registration is intended to be applied to practices of low to moderate radiation risks. The requirements for safety assessment would be less severe than those for licensing. Such authorizations may be accompanied by conditions or limitations with which the operator (the registrant) is required to comply, but again they are unlikely to be as severe as those contained in licences. Typical practices that are amenable to registration are those for which: (a) safety can largely be ensured by the design of the facilities and equipment; (b) the operating procedures are simple to follow; (c) the safety training requirements are minimal; and (d) there is a history of few problems with safety in operations. Registration is best suited to those practices for which operations do not vary significantly.

Notification of the regulatory body by a person or organization intending to undertake a practice is sufficient (i.e. authorization is not required) provided that the exposures expected to be associated with the practice are unlikely to exceed a small fraction, as specified by the regulatory body, of the relevant limits, and that the likelihood and magnitude of potential exposures and any other potential detrimental consequences are negligible. The BSS (para. 3.7) indicates that notification is required for consumer products only with respect to manufacture, assembly, maintenance, import, distribution and, in some cases, disposal. This is necessary so that the regulatory body can consider whether authorization of any of these practices is necessary.

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[6] In the IAEA safety standards [2], authorization is defined as "the granting by a regulatory body or other governmental body of written permission for a person or organization to conduct specific activities".

In situations where the radiation risks are sufficiently low as not to warrant regulatory control or regulatory control would yield no net benefit in terms of reduction of individual doses or health risks, provision is made in the BSS for exemption from the administrative requirements of authorization and notification. Even so, the provision only applies to practices that are deemed to be justified. Since exemption relates to a particular type of practice, it may be considered a generic authorization granted by the regulatory body which, once issued, releases the practice or source from the requirements that would otherwise apply and, in particular, the requirements relating to notification and authorization.

The regulatory approaches in many States do not always make a distinction between authorization by licensing and authorization by registration and often there is no provision for notification alone and sometimes no provision for exemption. In fact, in some States 'licensing' may be the only term that is used. While the use of the separate terms—authorization by licensing, authorization by registration and notification—provides clarity, it is not essential that they should all be used. What is however essential is that the regulatory body makes use of a graded approach in order to ensure that it assigns its limited resources in an appropriate way, focusing its efforts on those practices that present the highest risks and, where the risks are trivial and little or nothing can be gained from regulatory control, exempting the practice from some or all of the regulatory requirements.

As far as consumer products are concerned, the BSS require providers to ensure that such products are not made available to the public unless their use by members of the public has been justified and either their use has been exempted or their provision to the public has been authorized. These alternatives need some further clarification. In some cases, the type of product may be the subject of an existing exemption, in which case, there is no further need for the provision of that product to the public to be authorized. Such was the case with radioluminous timepieces in some States in the past. However, where there is no such existing exemption, as might be the case for a new type of product, then the provision of that product to the public would require an authorization. Once that authorization has been given, it would also be necessary to exempt its use and for that matter, its subsequent disposal, from the requirements of authorization and notification, since it would be virtually impossible to exercise regulatory control over its use and disposal. This does not mean that recommendations regarding use and disposal[7] cannot be made; what it does mean is that such recommendations cannot reasonably be subject to regulatory enforcement. This has implications for the safety assessments[8] that are necessary in determining first the justification for use and then the authorization for supply and finally the exemption for use and disposal.

Those goods that are intended for particular types of market such as cinemas, sports arenas or other places to which the public may have access are not consumer products in the sense given to this term in the BSS. While their use needs to be authorized and notified (unless exempted from these requirements) some regulatory control may be exercisable over their use and subsequent disposal and the need for this should become apparent from the results of the

[7] If, after the end of their useful life, such items are to be collected for disposal they will need to be treated as radioactive waste. In such circumstances, the safety requirements on predisposal of radioactive waste and the safety requirements on disposal of radioactive waste are fully applicable. If disused items are to be recycled, this needs to be considered a practice and regulated accordingly.

[8] Safety assessment is defined as: assessment of all aspects of a practice that are relevant to protection and safety; for an authorized facility, this includes siting, design and operation of the facility. Safety assessments considered in this document will be focused on the doses that individuals may receive under conditions of normal use, reasonably foreseeable accidents and disposal.

safety assessment. For example, a gaseous tritium light device such as a self-luminous EXIT sign installed in a place of work may be exempt from the authorization and notification requirements when in normal use, but their disposal at the end of their useful life could be subject to regulatory control if this is considered necessary by the regulatory body, based on the safety assessment. The responsibility for ensuring compliance with such exemption conditions, as with the implementation of all regulatory requirements pertaining to safety in the workplace, would fall first and foremost on the operator[9]. A similar responsibility cannot reasonably be placed on a member of the public using a consumer product.

The IAEA Safety Guide on The Management System for the Safe Transport of Radioactive Material (TS-G-1.4) [5] provides a description of how a graded approach can be applied to management systems in transport. The concepts behind the grading set out in that Safety Guide can also be applied to other areas such as notification and authorization. The Safety Guide states in paragraph A.1 that "The graded approach (also referred to as the graded process) is a process by which the scope, depth and rigour … to be applied to a specific packaging or transport related component or activity are commensurate with certain aspects, including but not limited to:

— The magnitude of any hazard (radiological and non-radiological) involved in the item's failure;

— The impacts on safety and security;

— The impact of the item's failure on the project, facility or business mission;

— Unique characteristics of the item;

— The impacts of the item's failure on other pertinent factors."

The requirements for transport include radionuclide values (the A values) that allow the amount of material in transport to be expressed on a common hazard scale. These are based on scalable models, such that they can be applied over a very wide range of hazards (over 10 orders of magnitude). This conversion to a hazard index is used throughout the transport requirements as the basis for applying the graded approach to all aspects of the requirements. As an example, packages for low hazard contents (such as Type A packages) are self-approved by users and subject to verification by authorities through inspection regimes, packages for large sources (such as Type B (U) packages) may require approval by one regulator and packages for nuclear material (such as Type AF packages) require approval in every State in which they are used.

The quantity of material normally found in goods that are the subject of this document is a small fraction of the limit for the lowest grade of transport package (several orders of magnitude below the limit). Radioactive material in these quantities can typically be moved as though it were a package, with limited marking and documentation requirements and self-certification of all of

[9] An operator is any organization or person applying for authorization or authorized and/or responsible for nuclear, radiation, radioactive waste or transport safety when undertaking activities or in relation to any nuclear facilities or sources of ionizing radiation. This includes, inter alia, private individuals, governmental bodies, consignors or carriers, licensees, hospitals, self-employed persons, etc. It is a term used to indicate the organization or person with the primary responsibility for safety [GSR Part 1]. In the context of the BSS, it may be taken as equivalent to the terms employer, licensee and registrant, as the case may be. However, it also relates to the person ultimately responsible for safety at work, irrespective of whether the person has been authorized to undertake a practice or been exempted from authorization by the regulatory body.

the safety related aspects of the transport. An exception is when Special Form Radioactive Material is being carried. In this case the manufactured enclosure of the material requires the approval of one regulatory body for worldwide use.

Currently the requirements for transport do not extend the graded approach to the low levels being considered in this document; however proposals for doing so are under consideration. Before such requirements can be put in place a methodology for applying them that has global acceptance is required.

3. APPLICATION OF RADIATION PROTECTION REQUIREMENTS

The three basic requirements of radiation protection are: justification of practices, optimization of protection and safety and compliance with dose limits. With the types of goods in question, doses are expected to be well below the dose limits, so consideration will only be given here to the first two requirements, the emphasis however being on the first because of its importance in the context of exemption and the authorization of the provision of consumer products to the public.

3.1. JUSTIFICATION OF PRACTICES

The requirement for justification is both simple and logical in concept: practices are required to produce a positive net benefit to the exposed individuals or to society. This concept though is not unique to radiation safety. All decisions concerning the adoption of a particular human activity involve a balancing of costs (including detriments) and benefits. Often, this balancing is done implicitly. The BSS however explicitly require a demonstration of a positive net benefit before a practice can be authorized by the regulatory body. As far as consumer products are concerned, the BSS state that the justification for their use by members of the public has to be approved by the government or regulatory body. Generally, the responsibility will fall on the regulatory body. This however presents the regulatory body with some difficulty, because the competence of the regulatory body is in assessing the radiation detriment associated with a given type of practice and it is unlikely to have any special competence in assessing other types of detriment or in determining benefit. Sometimes, the radiation detriment will be a small part of the total detriment, which would in fact generally be the case with consumer products (because they would present a trivial risk). Overall justification thus goes far beyond the scope of radiation protection. It is for this reason that the regulatory body should focus specifically on ensuring that the benefit exceeds the radiation detriment that might be caused by the introduction of the practice.

For example, in the case of a device containing a gaseous tritium light source, the regulatory body should only concern itself with the risk from the tritium in normal use, in accidental conditions and following disposal, because it is these matters that are within its competence. It is not within its competence to assess the more ‘conventional’ risks such as those arising from broken glass following an accident or to take decisions on the basis of these risks.

As far as assessing the benefit is concerned, which is an integral part of determining whether the device is justified, the regulatory body may well wish to set up some mechanism for reflecting the views of potential users to assist it in determining the degree of benefit.

It should be noted that the requirement for justification relates to their being a net benefit from the particular type of device. It does not concern itself with whether or not there are alternative ways of achieving the same or a similar benefit. Thus, to search for the best of all the available alternatives is a task that is beyond the responsibility of the regulatory body — the existence of a non-radioactive alternative which gives a similar benefit is irrelevant in the decision-making process.

The BSS require “the government or regulatory body, as appropriate, [to] ensure that provision is made for the justification of any type of practice and for review of the justification, as necessary, and [to] ensure that only justified practices are authorized.” Thus determination of the justification for a particular practice is to be undertaken prior to

authorization. Although not explicitly stated in the BSS, practices that need only be notified to the regulatory body also have to be shown to produce a positive net benefit.

The BSS specifies certain types of practices that are not justified. These include:

- The deliberate addition of radioactive substances to food, feed, beverages or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a person;

- The frivolous use of radioactive substances in commodities or in products such as toys and personal jewellery or adornments, which result in an increase in activity, by the deliberate addition of radioactive substances.

Although provision is made in the BSS for the exemption from the regulatory requirements of practices that pose a trivial level of risk, justification for such practices is still required to be demonstrated. Clearly though, if the risk is indeed trivial then the benefit need not be substantial in order for the practice to be shown to be justified. Thus, with consumer products, although some regulatory bodies might be tempted to accept only those products that are potentially life-saving or prevent injury or illness (because radiation safety is concerned with protection against risks to health) this would not seem to be appropriate. There are many human activities that are not life-saving or prevent injury but entail risks to health. The benefits from a practice could therefore be of many different types, not just possible saving of life or prevention of injury or illness, but also technical benefits, prevention of property damage, improvements in security or simply improvements in the quality of life.

The justification is normally applied to a type of practice and therefore need not be applied to each and every application for authorization or candidate for exemption. In fact, the existence of a technical standard for a particular type of practice may often be taken to indicate that the type of practice is justified.

3.2. OPTIMIZATION OF PROTECTION AND SAFETY

Demonstration of net benefit is not in itself sufficient for a practice to be authorized. The BSS also require the regulatory body to establish and enforce requirements for the optimization of protection and safety and authorized persons to ensure that protection and safety is optimized.

Optimization of protection and safety is the process of deciding on the level of protection that needs to be applied in order to obtain the maximum net benefit. Thus, both justification of a practice and optimization of the protection and safety measures to be applied in the practice involve the balancing of radiological detriment against benefit; the former, however, simply requires there to be a positive net benefit, while the latter requires the net benefit to be maximized.

Optimization of protection and safety is implemented through attention to the design and configuration of goods. It can also be applied through the use of procedural controls. However, if procedural controls are necessary in order for protection to be optimized, then the practice would clearly not be a candidate for exemption. In the case of the goods under consideration in this document, the emphasis needs to be on their design and configuration . Important factors that are relevant in this context to the optimization of protection and safety include the following:

(a) Selection of the most appropriate radionuclide with respect to the half-life, radiation type, energy and activity necessary for the product to function effectively;

(b) Selection of the chemical and physical forms of the radionuclide that provide the highest degree of intrinsic safety under both normal and accident conditions and for disposal;

(c) Configuration of the product;

(d) Prevention of access to the radioactive substance without the use of special tools;

(e) Use of experience with other products, particularly similar products, that have previously been assessed; and

(f) Verification of quality.

3.3. COMPARTMENTALIZING THE ANALYSIS

The term ‘practice’ focuses attention on those planned situations where there is an increase in radiation exposure (see footnote 3). Goods containing radioactive material are likely to go through a number of stages during which they will result in radiation exposure, from manufacture, through distribution and supply, to use and eventual disposal. Each stage will involve different groups of individuals and different benefits to those individuals. In some cases, the groups exposed will be essentially workers, e.g. in manufacture and transport, and the benefits to these workers will be one of employment. Following the supply of, say, a consumer product to the public, the groups will be mainly those individuals who use the product and obtain the benefit from that use, although there will of course be some collateral exposure of others who receive no benefit, for example, as a consequence of disposal.

Clarification of these various phases and separate analysis of each of these phases would seem to be essential, particularly to avoid any inequity that might otherwise arise, for example in the application of the requirement for justification to avoid the situation where the benefits are received by one group at the expense of exposure of another group. This is particularly the case with consumer groups. Indeed, the BSS specifically state that justification relates to the ‘use’ of a consumer product**.** Here the distribution of risks and benefits are largely coincident. Justification for manufacture or transport, for example, both of which may require specific authorization, is a separate matter. Inclusion of the benefits of employment to those involved in the manufacture, transport and supply of the products and the associated radiological detriment in an overall analysis may well lead to incorrect decisions.

This compartmentalization of the analysis is entirely consistent with the requirements of the BSS where para. 3.1 specifically indicates that production, supply, transport, use, etc. are practices.

3.4. SAFETY ASSESSMENT

The safety assessment is an essential input to the determination of the justification of a practice and in the optimization of protection. It covers the doses that are likely to be received from normal use, reasonably foreseeable accidents and disposal. The assessed doses have to be compared with any established dose criteria, particularly those for exemption in the case of goods containing small amounts of radioactive material.

Some goods, such as consumer products, are likely to be used singly or in small numbers. Other goods, such as those installed in places of work to which the public may have access, may be used in greater quantities. For example, large numbers of ionization chamber smoke detectors may be used as part of a complete fire protection system in a large bookshop or hotel. Several self-luminous EXIT signs containing tritium may be used in an aircraft, cinema or hospital. This needs to be taken into account in the assessment.

Separate safety assessments are necessary in dealing with the storage and transport of bulk quantities of goods containing individually small amounts of radioactive material. Such assessments will indicate whether a limit needs to be placed on the numbers of goods being stored or transported in order to ensure that the criteria for exemption are not exceeded. As indicated in the paragraph above, the starting point for the safety assessment would normally be the numbers of items typically transported or stored together; the analysis can then be expanded to calculate maximum allowable numbers of goods in transport or storage.

An example of a safety assessment is given in the Appendix.

4. APPLICATION OF THE REQUIREMENT FOR JUSTIFICATION

The manufacturer, or, in the case of imported goods, the supplier, needs to provide the regulatory body with sufficient documentation to enable it to review and assess the proposed product. The documentation provided normally includes the following:

(a) A description of the item, its intended uses and benefits, the radionuclide(s) incorporated and the function served by the radionuclide(s). Documentary evidence that the radioactive material fulfils its function also needs to be provided;
(b) The activity of the radionuclide(s) to be used in the product;
(c) Justification of the choice of a radionuclide, particularly relative to the hazard associated with and the half-lives of other radionuclide(s);
(d) The chemical and physical forms of the radionuclide(s) contained in the item;
(e) Details of the configuration and design of the item, particularly as related to the containment and shielding of the radionuclide in normal and adverse conditions of use and disposal, and the degree of accessibility to the radioactive material;
(f) The quality testing and verification procedures to be applied to radioactive sources, components and finished products to ensure that the maximum specified quantities of radioactive material or the maximum specified radiation levels are not exceeded, and that devices are constructed according to the design specifications;
(g) A description of the prototype tests for demonstrating the integrity of the product in normal use and for possible misuse and accidental damage, and the results of these tests;
(h) External radiation levels arising from the product and the method of measurement;
(i) Safety assessments arising from normal use, possible misuse and accidental damage and disposal and, if applicable, servicing and repair (see the example in the Appendix);
(j) The anticipated useful lifetime of the product and the total number of items expected to be distributed annually;
(k) Information about any advice to be provided on the correct use, installation, maintenance, servicing and repair of the item;
(l) An analysis to demonstrate that the item is inherently safe (i.e. will not result in significant doses to individuals in the event of reasonably foreseeable accidents); and
(m) Information on how the product is intended to be labelled.

If the risk associated with the use of a consumer product is trivial, for the product to be exempt from the regulatory requirements, there is no need for any hazard warning label, such as one might find on intrinsically unsafe products such as weed killer. However, the BSS do require providers of consumer products to provide clear and appropriate information and instructions with consumer products relating to (a) correct installation, use and maintenance of the product; (b) servicing and repair; (c) the radionuclides and their activities at a specified date; (d) dose rates in normal operation and during servicing and repair; and (e) required or recommended options for recycling or disposal. The first two requirements would normally apply to any consumer product, whether or not it contains radioactive material and may have associated safety benefits. The third and fourth requirements are more concerned with consumer choice than safety. The fifth requirement may also have associated safety benefits, but these would need to be carefully examined as disposal with normal household waste would normally be anticipated in the safety assessment. If such disposal presents an unacceptable level of risk, authorization of supply to the public would not seem appropriate. Furthermore, collection of large quantities of waste consumer products may pose more significant risks than if they were disposed of separately with household waste. It is noted that some States recommend the collection of alkaline batteries at the end of their useful lives. However, this is rather different from the situation with consumer products containing small

amounts of radioactive material that present a negligible risk as alkaline batteries may cause injury if disposed of carelessly.

All of this information, including the safety assessment, needs to be provided by the manufacturer or supplier and made available to the regulatory body. The regulatory body would need to critically evaluate the information, particularly the safety assessment, and seek any additional information it considers necessary as input to the decision on justification and eventually whether exemption can be granted.

Despite best efforts to guarantee objectivity in the evaluation of justification, it is recognized that this will not be easy to achieve. One of the reasons is that it is often not possible to quantify both costs and benefits in units that are directly comparable, such as lives or money. Determination of benefit would therefore normally involve making a judgement on behalf of society. Because of the difficulties involved in this (see above), there is value in the regulatory body setting up a mechanism for obtaining input from individuals or bodies reflecting the interests of those who might use the goods; in the case of consumer products, this would mean consumer interest groups and individuals. This could be done through a committee reflecting such interests or through some other means of consultation. Such a mechanism would help to avoid decisions being made based on the subjective judgement of the regulatory body alone[10]. The IAEA is preparing detailed guidance on the application of the requirement for justification of practices [6].

Clearly, if the use of a particular good is considered not to be justified, then it would follow that the other stages—manufacture, importation, transport, etc. — are also not justified. Although this is obvious, it needs to be said in order to ensure that clarity is maintained over how the requirement for justification is to be applied to goods containing radioactive material. In particular, the importance of maintaining the focus, first and foremost, on the intended use and benefit from that use is critical. On the other hand, if a particular good is considered to be justified, then it would normally follow that the other stages — manufacture, importation, transport, etc. — are also justified.

[10] In a market economy, it is the consumer who is “sovereign” and the benefit of a particular product for the consumer is reflected in the degree to which the consumer is willing to purchase the product. However, the consumer is effectively “ignorant” of the risks that radiation would present in the case of a consumer product containing radioactive material, and it is this “gap” in the consumer’s knowledge that the regulatory body through the regulatory process fills. If the regulatory body imposes its own feelings about benefit, then it is effectively denying the consumer the right to remain “sovereign”. It is for that reason that the regulatory body needs to focus on the risks associated with the product and obtain the views of consumers on the benefit that they feel they would receive.

5. EXEMPTION FROM REGULATORY CONTROL

5.1. CRITERIA FOR EXEMPTION

From Chapter 4 it is clear that consideration of justification of a type of practice is necessary as a prelude to determining the degree of regulatory control, if any, that needs to be applied. Application of a graded approach to regulatory control will lead, in some cases, to the conclusion that a particular practice may be exempted from the administrative requirements of authorization and notification. As we have already seen, if the use of a consumer product containing radioactive material is considered to be justified, then it will normally be necessary for the use and disposal of that product to be exempted.

As laid down in the BSS, the general criteria for exemption are that:

(a) Radiation risks arising from the practice or a source within a practice are sufficiently low as not to warrant regulatory control, with no appreciable likelihood of situations that could lead to a failure to meet the general criterion for exemption; or

(b) Regulatory control of the practice or the source would yield no net benefit, in that no reasonable control measures would achieve a worthwhile return in terms of reduction of individual doses or of health risks.

The BSS further note that the criteria for exemption can be considered to be met if, under all reasonably foreseeable circumstances, the annual effective dose expected to be incurred by any member of the public from the practice or source within the practice is of the order of 10 μSv or less in a year. To take into account low probability scenarios, the BSS suggest that a different criterion could be used, namely that the effective dose expected to be incurred by any member of the public for such low probability scenarios does not exceed 1 mSv in a year. A safety assessment would normally be the means by which compliance with these criteria would be shown. It is important to underline that these dose values are not limits, although they do reflect international consensus.

Based on these criteria, derived values of total activity and activity concentration for several hundred radionuclides have been calculated and the values are given in Schedule 1 of the BSS. These values can be used for exempting justified practices automatically, without further consideration, in particular, without the need for a safety assessment[11]. The methodology used for determining the exemption values for radionuclides has been documented in reference [7]. The reason why the values may be used ‘without further consideration’ is because the methodology used in calculating the values is highly conservative.

Some regulatory bodies have adopted these values into their regulatory process simply because they can be used ‘without further consideration’ but they have not provided for the flexibility inherent in the general criteria for exempting higher quantities, where appropriate, and the specific provisions in the BSS relating to devices containing sealed radioactive sources. The automatic exemption values relate to radioactive material in whatever form they might exist, whether as sealed sources or as unsealed radioactive material.

[11] The reason why no safety assessment is necessary is because that assessment has already been done and has involved the use of models that are sufficiently pessimistic such that all reasonably foreseeable situations have been covered. This being the case, it is clear that higher total activities or activity concentrations could be accepted for exemption, provided that specific safety assessments have been conducted and shown that the general criteria for exemption will be met.

The provisions specifically relating to devices containing sealed radioactive sources are outlined in para. I-6 of Schedule I of the BSS. These are as follows:

"Exemption may be granted subject to conditions specified by the regulatory body, such as conditions relating to the physical or chemical form of the radioactive material, and to its use or the means of its disposal. In particular, such an exemption may be granted for equipment containing radioactive material that is not otherwise exempted [by the provisions above relating to the total activity or activity concentration] provided that:

(a) The equipment containing the radioactive material is of a type approved by the regulatory body;

(b) The radioactive material:

  (i) Is in the form of a sealed source that effectively prevents any contact with the radioactive material and prevents its leakage; or

  (ii) Is in the form of an unsealed source in a small amount such as sources used in radioimmunoassay;

(c) In normal operating conditions the equipment does not cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 μSv/h at a distance of 0.1 m from any accessible surface of the apparatus;

(d) Necessary conditions for disposal of the equipment have been specified by the regulatory body."

It is noted that this particular provision for exemption only gives examples of the sort of conditions that might apply. As we have already seen, conditions relating to disposal may be appropriate in the context of the exemption of goods that are to be used in the workplace such as a cinema, because these can be enforced. In general though, conditions relating to disposal would not be appropriate in the context of consumer products containing radioactive material, unless they relate to providing advice to the public on the appropriate means of disposing of the products at the end of their useful life rather than defining an obligation.

During the development of the 1996 edition of the IAEA Regulations for the Safe Transport of Radioactive Material (TS-R-1), the dose criterion of 10 μSv in a year was used to derive exemption levels specific to transport. The values of total activity and activity concentration were very similar to those for moderate quantities given in the BSS[12]. These BSS values were therefore adopted for use in transport [8].

5.2. SCOPE FOR HARMONIZATION OF APPROACHES TO EXEMPTION

The provisions in the BSS already indicate that consensus among Member States has been achieved regarding:

(a) The level of dose that may be used for the purpose of exemption;

[12] Two sets of values of total activity and activity concentration are now given in the BSS for many radionuclides. The first relates to moderate quantities (at the most of the order of 1 tonne) and it is these that are used for exemption in the transport. The other relates to bulk amounts (with no limit on quantity).

(b) The total activities and activity concentrations of many radionuclides that may be used without further consideration in exempting moderate and bulk quantities of radioactive material; and

(c) The criteria for exempting devices containing sealed radioactive sources.

Harmonization of regulatory approaches however depends on the implementation of these provisions through national regulations. Further harmonization would depend on whether agreement can be obtained in the application of the criteria for exempting particular types of goods containing sealed radioactive sources. In particular, consideration would need to be given to whether type approval of goods in one State could be accepted in other States, or, at least, whether the safety assessment that has been used as the basis of type approval in one State could be used for the purpose of granting type approval in another, thereby avoiding the need for the regulatory body to spend effort in assessing the radiological impact of goods for which the risk have already been shown to be trivial. This would necessitate international agreement on the approaches to be used in determining the benefit associated with the use of goods and in undertaking the safety assessment.

5.3. EXEMPTION OF LARGE NUMBERS OF GOODS CONTAINING RADIOACTIVE MATERIAL

So far, this document has focused on the end use of single items containing radioactive material. Consideration of the requirements that apply to large quantities of goods, particularly in storage or transport, is necessary. While the amount of radioactive material in each individual item may be small, much larger amounts of radioactive material are likely to be stored in the warehouses of suppliers and, in the case of consumer products, on shop premises[13]. Exemption of the use of a particular type of good does not necessarily mean that other stages of the supply chain are also exempted. These stages will need to be assessed separately and, based on a consideration of the doses that might be received during normal operations and in the event of an accident such as fire. On the basis of the assessment, the regulatory body may decide that authorization is necessary, using a graded approach; alternatively, the regulatory body may decide to exempt quantities of goods up to a maximum number provided it can be shown that the general criteria for exemption are met i.e. that the radiation risks are insufficient to warrant regulatory control or that regulatory control measures would achieve no worthwhile benefit.

A number of studies have been published reviewing the safety of goods containing small amounts of added radioactive material. Several of these show that, even when present in large numbers, such goods are inherently safe and meet the dose criteria for exemption during their entire life cycle [9–20].

6. CONCLUSIONS

Various types of goods containing small amounts of radioactive material are produced for the global market. Some are intended for use by professional bodies, such as in cinemas and sports arenas, and may lead to public exposure; others are intended to be sold directly to the public (i.e. consumer products).

[13] The manufacturing process may involve the handling of relatively large quantities of radioactive material and non-trivial doses to workers. For these reasons, the manufacture of such items is normally authorized by the regulatory body and is therefore not considered here.

The BSS require a graded approach to regulatory control and this is reflected in the administrative requirements, which, starting with the most complex, are authorization by licensing, authorization by registration, and notification. As part of this graded approach, provision is made for exemption from these administrative requirements.

Demonstration that the benefit is greater than the radiation detriment (justification) for the use of a product containing radioactive material, whether in a place of work or by a member of the public, is always required, even if the provision for exemption is used.

In the particular case of consumer products, the justification has to be approved and either their use has to be exempted or their provision to the public authorized.

Criteria for exemption are given in the BSS. The basic criteria are that the radiation risks are very low or regulatory control would yield no real benefit. These criteria are expressed in terms of doses to individuals and these doses, in turn, have been used to derive total activities and activity concentrations of radionuclides, which, provided the practice is justified, can be used without further consideration.

These derived values are not limits and the term 'without further consideration' needs to be stressed. The BSS also provides for exemption of higher quantities. However, a specific safety assessment would be required in order to demonstrate that the basic criteria for exemption are met. This would involve consideration of different scenarios related to normal use, reasonably foreseeable accidents and disposal.

The BSS also provide for the exemption of equipment containing sealed radioactive sources, the equipment being of a type approved by the regulatory body. There is a limit on dose rate outside the equipment, but no limit on the activity of the sealed source. Thus, for example, ionization chamber smoke detectors containing higher levels of activity than those defined for exemption without further consideration can be exempted provided that the conditions are met and they are of a type approved by the regulatory body.

Consumer products are normally sold singly or in small numbers to members of the public and in general there would be no need to do a safety assessment which assumes the presence of more than a few products of a given type. However, multiple products may be stored, for example in shops and warehouses, or transported. Separate safety assessments may be required in order to determine whether these practices could be exempted subject, for example, to limits on the numbers present at any one time. Exemption of a particular consumer product does not automatically imply exemption of bulk storage or transport.

The case of goods containing small amounts of radioactive material that are intended for use in places of work to which the public may have access such as public buildings, hotels and cinemas is somewhat different from that with the specific case of consumer goods[14]. In principle, such places can be subject to regulatory control and therefore, depending on the results of the safety assessment, while their use may be exempted, their disposal need not necessarily be. For example, the exemption may only relate to installed devices and when they are removed, exemption would no longer apply. However, it is stressed that the

[14] Consumer products can of course be used in such places and the arrangements would be the same as they are with their use by the public, i.e. if their supply to the public has been authorized and their use exempted, then this would also be the case if they are used in the workplace.

imposition of restrictions on the ultimate disposal of such goods needs to be considered only if the outcome of the safety assessment indicates that the dose criterion may be exceeded.

Authorization of the supply of consumer products, exemption from authorization, approval of justification and type approval of equipment containing sealed radioactive sources are all matters for the regulatory body. Determining the justification of the use of a product alone can involve significant effort, particularly in the case of consumer products, where consultation with interested parties may be necessary in order to obtain more objective information on benefit. As a consequence, the provisions for exemption may well militate against the overall objective of the graded approach which is to assist regulatory bodies in directing their attention to those situations that pose the highest risks and to keep to a minimum their effort on those that pose a minimal risk. Put bluntly, it may be easier for the regulatory body to refuse to authorize the supply and to exempt the use than to make use of the provisions that are available for authorizing the supply and exempting the use.

By refusing to authorize the supply and to exempt the use of these goods, the regulatory body may also feel that it is protecting itself from criticism by those who vociferously oppose anything associated with the use of ionizing radiation. Alternatively, the regulatory body may decide only to adopt the values that can be used 'without further consideration' and not make use of the flexibility that is inherent in the general provisions for exemption. The feeling may be that these values are internationally accepted, can be used without further consideration, and are unlikely to result in criticism if used.

It is important to remember the limited role of the regulatory body in these matters. The regulatory body does not have any responsibility in setting societal standards with regard to what may or may not be sold to and used by the public. Its primary role is to ensure that any goods destined for sale to the public that contain small amounts of radioactive material are inherently safe; consumer decisions will subsequently determine if the product is competitively priced and useful.

Thus, although the BSS and other Safety Standards reflect the consensus of Member States and are intended to lead to harmonization of approaches, this clearly has not happened with goods containing small amounts of radioactive material. The different approaches, while understandable, may however not be in the interests of the public and others whom the regulatory body is intended to serve. Whatever the reason for the differences, there clearly would be value in considering whether there is scope for improving the situation.

This lack of harmonization is not helpful, particularly these days in view of the global marketing of goods, including via the internet. Regulatory bodies have a shared interest in adopting a harmonized approach to regulating radiation safety. Those who might use goods containing small amounts of radioactive material also have an interest in a harmonized approach — to avoid confusion that might otherwise arise because of the different approaches and to avoid inadvertently being out of compliance with national requirements when moving from one State to another.

An internationally accepted example of a harmonized approach to regulating radiation safety is with the IAEA Transport Regulations [7]. Thus, for example, once a decision on exemption for the transport of a certain thing has been granted by a regulatory body in one State, the results of the safety assessment may be acceptable to regulatory bodies in other IAEA Member States.

The benefits of greater harmonization are:

(a) Reduction of the effort required by the regulatory body in implementing the provisions for approval of justification, authorization of supply and exemption;

(b) Avoidance of the confusion over the significance of the radiological hazards created in the minds of the public over the differences in approaches among States;

(c) Facilitating international trade.

An example of the utility of harmonized standards for international trade is highlighted in the Safety Guide on Application of the Concepts of Exclusion, Exemption and Clearance, RS-G-1.7. This Safety Guide provides values of activity concentration that, if applied, would not require any further action (e.g. to reduce exposures) for materials containing radionuclides at activity concentrations below the values quoted. In particular, national and international trade in commodities containing radionuclides with activity concentrations below the values of activity concentration provided should not be subject to regulatory control for the purposes of radiation protection.

Harmonization is an issue that needs to be approached from an international perspective and must involve consultation with all interested parties including suppliers, regulatory bodies and consumer groups. The following key issues need to be addressed in order to obtain the desired harmonization of approaches:

(a) Harmonization of how safety assessments are to be conducted — the scenarios, models and parameters to be used — and eventually the acceptance of a safety assessment conducted in one State according to the agreed approach by regulatory bodies in other States. In the case of those practices which involve a low level of risk and are inherently safe, such an understanding would represent a significant saving of regulatory resources that could be more usefully deployed elsewhere. Safety assessments cover both a single item, particularly in the case of consumer goods, and multiple items, for example in a store. Consideration would need to be given to normal use, reasonably foreseeable accidents and disposal. In the case of consumer goods, uncontrolled disposal with normal household refuse would need to be considered.

(b) Development of guidance on the application of the exemption provision given in paragraph I-6 of the BSS relating to equipment containing sealed sources. One issue here is how the IAEA definition of sealed source relates to that given by ISO; another is whether an ampoule containing a radioactive gas such as tritium or ^{85}Kr can be regarded as a sealed source.

(c) Development of international technical standards for a type of product that has been authorized in a number of Member States covering such things as design, radionuclide, activity, nature of the (sealed) source, performance requirements under test conditions, etc. A number of such standards have been developed covering such things as gaseous tritium light devices [9], cardiac pacemakers [10][15] and ionization chamber smoke

[15] Strictly, cardiac pacemakers containing batteries powered by a radioactive source do not fall into the categories of goods being considered here. The activity of the radionuclide used was high and, furthermore, they are neither consumer products nor products for use in the workplace. The standard however does illustrate the sort of technical safety standard that might be produced for such goods.

detectors [11]. These standards were prepared many years ago and have not been reviewed since they were published. The development of technical standards for more recent innovations, such as lamps containing krypton-85, could also be considered. Such technical standards would be indicative of the fact that the goods in question have been accepted as justified in a number of States and therefore provide confidence regarding their justification and that protection is optimized in goods complying with the standard.

(d) Development of guidance on justification of practices with specific consideration of goods, including consumer products, which may cause exposure of members of the public. Such guidance could discuss the various stages from manufacture through use to disposal delineating or compartmentalizing the scope of the justification analysis. It could also discuss the role of the regulatory body with regard to detriment, clarifying that the regulatory body needs to focus only on radiation detriment. It could also discuss how information on benefit may be obtained through appropriate consultations with interested parties.

Work on addressing some of these topics is already underway within the IAEA Secretariat, in cooperation with other relevant international organizations.

Consideration could be given to the establishment of an international forum for considering the justification for novel uses of small amounts of radioactive material in goods. Bearing in mind that, for the purposes of exemption, the radiation risks would normally be trivial, international consensus is a realistic ambition. There are after all many types of goods on the market that present far more serious risks. While this may well be difficult to achieve, it would avoid having divergent approaches among regulatory bodies and an associated negative impact on global trade.

Change will not take place until the need for change is widely recognized and accepted, and greater harmonization is unlikely to occur unless regulatory bodies recognize that greater harmonization is both desirable and beneficial. This publication is intended to contribute to greater harmonization in the approach to issues such as the role of the regulatory body in approving the supply of goods containing small amounts of radioactive material to the public, the application of the graded approach and prioritizing the resources of the regulatory body to ensure that those practices that represent the greatest hazard receive the greatest attention. Such harmonized approach is necessary in light of the widespread use of these goods and the potential for many similar goods to be manufactured and sold directly to the public in the future.

APPENDIX
SAFETY ASSESSMENT: RADIOLOGICAL ASSESSMENT ON LAMPS CONTAINING SMALL AMOUNTS OF RADIOACTIVE ^{85}Kr AND/OR ^{232}Th

I.1. INTRODUCTION

High intensity discharge lamps (HID-lamps) produce bright white light with a high intensity in an energy efficient manner. These lamps are typically used in large numbers in public and professional environments such as shops, warehouses, hotels and offices. They are also used in outdoor applications to illuminate streets, buildings, statues, flags, gardens and further as architecture lighting. They also have applications associated with film projection in cinemas, manufacture of semiconductors, fluorescence endoscopy and microscopy, schlieren photography, hologram projection, UV-curing, sky beamers and car headlights. Some types of HID-lamps, as well as certain other lighting products, contain radioactive material for functional reasons[16,17].The radionuclides that are typically applied in HID-lamps are ^{85}Kr and ^{232}Th.

Once the manufacture of HID-lamps is completed, they are made available in large quantities to a global market. Several steps lead towards end-use. The first step is the logistic process involving transport and warehouse storage. Before being supplied, HID-lamps may be assembled into light fixtures, commonly referred to as luminaires. The subsequent sale, installation, replacement, service, repair and maintenance of lamps or luminaires typically involve members of the public, as these lamps are supplied to clients in large numbers. In these many steps members of the public may not necessarily be aware of their (potential) exposure to the radiation emitted by ^{85}Kr or ^{232}Th. Members of the public are not the only persons exposed during end-use, but also workers in the lighting industry and other professionals involved in the chain of events described above.

I.2. OBJECTIVE OF THE RADIOLOGICAL ASSESSMENT

This radiological assessment is aimed at demonstrating that the use of HID-lamps containing small quantities of ^{85}Kr or ^{232}Th is justified and to provide evidence that these items can be made available to a global market without any restrictions as the consequences of exposure for members of the public are well within the boundaries of the dose criteria for exemption from further regulatory concern[18].

Throughout this report the term ‘high intensity discharge lamp’ (or ‘HID-lamp’) refers specifically to an electric discharge lamp in which the light-producing arc is stabilized by wall temperature and the arc has a bulb wall loading in excess of 3 W/cm^2 [21]. It produces light by means of an electric arc between tungsten electrodes housed inside a transparent or translucent arc tube made of quartz glass or alumina ceramics. This tube is filled with both inert gas and metal/metal salts. The gas facilitates the arc's initial strike. Once the arc is formed, it heats and evaporates the metal/metal salts forming a plasma which greatly

[16] Annex I shows examples and an overview of the types of HID-lamps evaluated in this study.

[17] Annexes II and III describe the use of radioactive material in starters or glow-switches that are part of fluorescent lamp systems; Annexes II and IV describe the use of radioactive material in QL-induction lamps.

[18] The criteria for exemption are described in the IAEA Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources [2]. The dose criteria for exemption are described in Schedule I of these Standards. Further guidance material on the regulatory control of radiation sources and in particular consumer goods is found in the IAEA Safety Guide on Regulatory Control of Radiation Sources [3].

increases the intensity of light produced by the arc and reduces its power consumption. High-intensity discharge lamps are a type of arc lamps.

I.3. SCOPE OF THE ASSESSMENT

The scope of this radiological assessment is restricted to lamps that:

(a) Contain ^{85}Kr in a permanently sealed capsule or contain ^{232}Th in a closely bonded solid form within a permanently sealed capsule;

(b) Do not need further steps of manufacture;

(c) Do not, as a single item, exceed the exemption level for total activity in Schedule I of the Basic Safety Standards [2].

- Current exemption level for ^{85}Kr activity is 10 000 Bq;
- Current exemption level for ^{232}Th (mother nuclide) activity is 10 000 Bq;

(d) Exceed or are likely to exceed the exemption level for total activity when multiple numbers of items are involved within a practice.

I.4. RADIATION PROTECTION REQUIREMENTS, JUSTIFICATION AND OPTIMIZATION

The main reason for using HID-lamps is that they are capable of producing high intensity light in a highly energy efficient manner. In addition, the high intensities produced by HID-lamps can neither be produced by alternative technologies. These products are typically applied in a professional environment.

Therefore, important reasons for the industry [22] for placing these products on the market are:

(a) To promote the use of energy efficient lighting systems;

(b) To provide savings in term of energy and cost;

(c) To help EU Member States to meet the Kyoto Protocol targets on CO_2 emission reductions.

I.5. USE OF HID-LAMPS CONTAINING SMALL AMOUNTS OF RADIOACTIVE MATERIAL IN PROFESSIONAL APPLICATIONS

HID-lamps containing small amounts of radioactive material are mostly used for their capability to produce light with high intensities in a highly energy efficient manner. Its compactness and point-like centered light provide very good optical control to direct the light to where it is needed. In professional lighting, luminaires with HID-lamps are typically used many hours per day (12 hours per day) and burn on average 4 000 hours per year. Lamps are not only applied in new installation (10–20% of the volumes sold) but are also provided in large numbers to replace old lamps (80–90% of the volumes sold). Typical applications,

properties and main benefits are described below and examples of these lamps are shown in Annex I.

- **Shops** HID-lamps (in the range of 20 to 150W) are used frequently applied in shops and shop windows. Powerful focal light can be produced without generating excessive heat.

- **High ceiling buildings** HID-lamps are also used in high ceiling buildings, e.g. supermarkets, shopping malls, train stations, airports and other public areas. The compact HID sources make it possible to direct the light downwards in a controlled manner. Due to its high power, a relatively low number of lamps is required to illuminate such areas.

- **Outdoor** HID-lamps are used in a high variety of outdoor environments. Examples are parking lots, sport fields, road lighting, other urban areas, buildings and objects. Powerful point sources (50 to 2 000W) provide good optical control to distribute the light in the most optimal way or to make a directed floodlight on a building, object or area.

- **Entertainment** In studios, theatres, film sets and big events powerful beams are needed to create dramatic effects. The generation of powerful beams without concomitant excessive heat production is an important reason to apply HID-lamps. Especially in the highest power area, HID lamps are the only solution to produce the required light intensities.

- **Automotive** HID-lamps help in increasing the driving safety of cars by offering higher lumen output for headlamps (twice as much as halogen lamps provide), increasing the illuminated area of the roads, enabling earlier recognition of road and street markings. Lower power consumption and longer lamp life are also particular advantages of the discharge automotive lamp.

- **Special applications in industrial processes** For curing (i.e. hardening of paint or other chemicals), manufacturing of semiconductors, photo-biochemical processes (e.g. generation of vitamins) or disinfection, special UV-light producing HID lamps are used. The high intensity of the produced light and the relative compactness of the lighting system are the main benefit for such HID-lamps.

I.6. BENEFITS OF USING HID-LAMPS AND COMPARISON TO ALTERNATIVE LAMP TECHNOLOGIES

A major benefit of this technology is that light of a desired spectral quality and high intensity is produced in a very energy efficient manner. The light yield of HID-lamps is typically 90–100 lumen per watt and is substantially higher compared to the performance of that of halogen lamps (20–30 lumen per watt). As this energy-saving technology is ubiquitously available in society, the utilization of this lamp technology makes an important contribution to a reduction of CO_2-emission and helps society towards achieving the objectives of the Kyoto Protocol [22].

Economic reasons also justify the use of HID-lamps. Energy saving is next to an environmental argument, also an economical argument for using HID-lamps. When alternatives are used, more lamps as well as more energy would be needed to produce the

equal amount of required light. The use of HID lamps is also economical as the average lifetime of up to 20 000 hours is considerably longer compared to the average life expectancy of halogen lamps (2 000 hours).

Other energy efficient alternatives, such as fluorescent lamps, produce more diffuse light rather than focused high intensity light and do not provide the same ambience compared to HID-lamps. Also the compactness of HID-lamps is in many instances an advantage or even an essential requirement.

More recent developments show that LED-technology is becoming increasingly more available in modern life. This energy saving technology is currently, however, not a suitable alternative for many HID-applications. This is in particular the case for applications requiring high intensity light. The main reason hampering the application of LED in high intensity applications is the management of the heat produced in the lamp during light generation. This is in particular the case for high power applications. Taking the recent developments in LED-technology into account, it can be anticipated that LED-technology may become a suitable alternative for certain HID-applications in the future. Even if LED-technology would replace HID-technology in new lamp systems, it will take many years to replace the latter technology due to the relatively long replacement cycles and the long lifetimes of relatively expensive professional luminaires.

An overview of the currently available electric lamp technologies is given in Annex II. In fluorescent lamp systems small amounts of radioactive materials (such as ^{3}H or ^{85}Kr) may be used in starters or glow-switches that are required to ignite the lamp. Further details of this system and the justification for using small amounts of radioactive material are provided in Annex III.

I.7. TECHNICAL REASONS FOR UTILIZING RADIOACTIVE MATERIAL IN HID LAMPS

I.7.1. Functional reasons for applying ^{85}Kr in HID lamps

Light is produced in the discharge or arc tube of the lamp. Ignition of the lamp cannot occur without a starting aid helping towards the formation of an arc between the electrodes in the burner. The arc tube is a sealed compartment filled with a noble gas mixture containing small amounts of the radioactive noble gas ^{85}Kr. Krypton-85 provides the starter aid function by supplying free electrons. The outer glass bulb envelopes and protects the arc tube and other lamp components. This outer compartment is, just as the arc tube, a sealed and gas tight compartment.

Some types of HID-lamps do not have an outer envelope, but consist of a single compartment. These so called ‘burner only lamps’ produce light in the same way as the lamps described above and an example is shown in Annex I. Another example of ‘burner only lamps’ is the QL-induction lamp shown in Annex IV. The operating principle differs from that of HID-lamps, but QL-lamps also require ^{85}Kr as an ignition aid[19].

[19] QL-lamps are compared to HID-lamps provided in relatively limited amounts to the market. This study evaluates HID-lamps but is equally applicable to QL-lamps. Differences of QL-lamps compared to HID-lamps are addressed in Annex IV.

The added ^{85}Kr-activity is optimized in such a way that only the required quantity is present in order to guarantee lamp ignition throughout the anticipated lifetime of up to 20,000 hours.

The choice of ^{85}Kr as a radionuclide is, compared to other radionuclides, also the most optimal choice for this application since the selected radionuclide (i) must be a noble gas; (ii) emits predominantly or exclusively electrons; (iii) emits no or with a relative low emission probability penetrating gamma radiation; and (iv) has a half-life that is compatible with the need to provide sufficient electron supply throughout the expected life time of the item.

I.7.2. Functional reasons for applying ^{232}Th in HID-lamps

Thorium-232 has been used in electrode systems internationally for several decades in various high performance and special lighting products as the common state of the art of science and technology. The deliberate addition of ^{232}Th to these products is indispensable for their function and high performance.

Thorium-232 is a naturally occurring radioactive material and is added to the lamp as thoriated tungsten electrodes, or less frequently in the form of $^{232}ThO_2$ coated tungsten, or as ^{232}Th-iodized admixture in the filling depending on the type and application of the light source. Important advantages of deliberately adding ^{232}Th (or $^{232}ThO_2$) to the tungsten of the electrode are to improve the metallurgical properties and to increase the stability of the electric arc between the electrodes. Due to the presence of ^{232}Th, the lifetime of the electrodes is prolonged as less material is lost and lumen maintenance over lamp life is better, as less electrode material evaporates and do not darken the glass bulb.

I.8. NON-RADIOACTIVE ALTERNATIVES AS A POTENTIAL REPLACEMENT FOR RADIOACTIVE MATERIALS IN HID-LAMPS

I.8.1. Alternative non-radioactive ignition aids as a potential replacement for ^{85}Kr technology.

There is a continuous effort from the industry to develop non-radioactive alternative ignition aids, such as UV-enhancers. However, they do not perform with equal reliability compared to the current ^{85}Kr-technology. Another disadvantage is that it is impossible to equip smaller lamps of this product range with UV-enhancers. In addition, this alternative is more expensive to produce. The limited radiological consequences of the items evaluated in this study are neither a justification to substantially increase investment that may, but not necessarily, lead towards the development of a reliable alternative at reasonable cost. In conclusion, no reliable and reasonable non-radioactive HID-alternatives are available to date and in the foreseeable future.

I.8.2. Alternative non-radioactive elements as a potential replacement for ^{232}Th

Replacing ^{232}Th by non-radioactive elements like Lanthanum and Hafnium is not possible because of vaporisation and other differences in metallurgical properties. To date, no other elements with similar characteristics as ^{232}Th were found. In lamp development there is continuous search for possibilities to decrease or eliminate the ^{232}Th in the lamps.

I.9. CONSIDERATIONS FOR TECHNICAL DESIGN AND MANUFACTURE

I.9.1. Technical design and quality assurance

HID light sources (overview and pictures shown in Annex I) generally consist of an arc tube (quartz glass or ceramic material) containing the radioactive material (^{85}Kr or ^{232}Th) and an outer envelope of quartz or other glass material with one or two bases for electrical and mechanical contact with the luminaires. Lamp bases are generally made of ceramic material and/or metal with insulating material and withstand high temperatures. The purpose of the arc tube is to maintain over a prolonged lifetime a vacuum tight noble gas environment for the electric arc, to preserve the filling during operation and to resist high temperatures as well as high temperature gradients. The pressure in the arc tube under normal conditions is typically a few hundred mbar below atmospheric pressure. The primary function of the outer envelope (outer jacket) is to protect and maintain an inert atmosphere for the arc tube and its mechanical and electrical supportive metal/glass components. Sealing of envelopes are very well engineered and controlled processes.

Some types of HID-lamps do not have an outer envelope, but consist of a single compartment. These so called 'burner only lamps' produce light in the same way as the lamps described above and an example is shown in Annex I. These burners also require a conditioned environment and for this functional reason need always to be assembled into closed luminaires. Another example of 'burner only lamps' is the QL-induction lamp shown in Annex I. The operating principle differs from that of HID-lamps, but QL-lamps also require ^{85}Kr as an ignition aid.

The ^{232}Th amount in the lamp electrodes depends on the lamp wattage. It is fixed and insoluble bounded in the Tungsten matrix. The mass concentration of $^{232}ThO_2$ in the tungsten electrode material is in the range of 1–2% by weight.

In certain lamp types, $^{232}ThI_4$ is used in the filling up to only a few tenths of micrograms.

I.9.2. Quality assurance programme

Produced HID-lamps are subject to a quality assurance programme in order to guarantee leak tightness of critical seals as well as product quality and safety throughout the entire life cycle of the items. This programme consists of running tests as well as type and design tests (see [21] for the definitions of these tests).

The purpose of the leakage tests is to demonstrate that lamps retain their integrity and that the arc burner remains permanently sealed with the purpose to contain ^{85}Kr and hence to maintain its functionality. Functional tests can be considered equal to the ISO-norm designed for leakage testing of sealed radioactive materials [23] as lamps having a leaky arc tube fail to ignite according to the specified quality criteria. In fact the US Nuclear Regulatory Commission allows the use of functional tests to demonstrate the leak tightness of lamps containing byproduct materials when applying for a distribution license [24]. The excerpt on the use of functional tests is provided in Annex V.

The mechanical product safety of HID-lamps is tested according to the requirements laid in International Electrotechnical Norms IEC 62035 [21]. Temperature tests are part of both the functionality and safety test programme.

In addition, a programme of tests is used to ensure that packages of lamps are protected during transport until the end-user.

I.10. RUNNING TESTS DURING LAMP MANUFACTURE (INCLUDING LEAKAGE TEST)

The manufacturing process of each lamp is concluded with a functional running test. This test comprises of full light up and the evaluation of several photometric (e.g. lamp light output level, colour and temperature) and electrical parameters (e.g. starting capability, lamp voltage, lamp wattage).

Photometric and electrical parameters are measured on lamps at full operation when the arc tube temperature reaches or exceeds 1 000 °C. These parameters are highly dependent on the arc tube filling gas as well as outer jacket pressure; arc tubes with insufficient leak tightness will be rejected as they will fail to meet the high performance specifications.

I.10.1. Mechanical safety tests

Representative samples of produced lamps are subjected to a mechanical type test (torque or pull test) to ensure that they do not rupture during installation, when handled by the end-user or during replacement. Additional criteria are described for lamps applied in open luminaires. Under these circumstances the outer glass bulb should contain the arc tube particles and other components if the inner tube ruptures in the event of abnormal lamp failure. When applied in an outdoor environment, such lamps must also be resistant to moisture and water droplets. Testing methods and criteria are defined in IEC 62035 and ANSI/IEC C78.62035 Standards [21], together with sampling rates and acceptable quality levels (AQL).

I.10.2. Temperature test

Lamp ignition at –30 °C is a design test requirement according to the IEC Standard [21] and this test is commonly used in Europe as well. The lamp body develops a very rapid temperature increase to a maximum value of approximately 1 000 °C at the hottest part and a minimum value of about 150 °C at the lamp base. This so-called glow wire test for lamp bases is described in [21].

I.10.3. Testing packages of lamps for transport

A number of standard tests are used to ensure that packages of lamps are protected during transport until the end-user. This program of tests is executed for every new lamp type or new package design and includes conditioning, drop, rolling, toppling, vibration, stacking and impact tests. The test programme used by one of the members of the European Lamp Company Federation (ELC) is described in Annex VI. This programme is derived from relevant ISO-norm requirements. Other ELC-members use similar test programmes.

I.11. RADIOACTIVE PROPERTIES

I.11.1. Radioactive properties of ^{85}Kr

Krypton-85 is a radioactive noble gas that decays with a half-life of 10.7 years and emits beta-radiation with a maximum energy of 687 keV [25, 26]. In 0.4% of its transformations, ^{85}Kr also emits gamma-radiation with an energy of 514 keV [25].

I.11.2. Radioactive properties of ^{232}Th

Thorium-232 is a natural occurring radioactive material with a low specific activity. It is purified from the progenies by chemical separation before the manufacture of lamps. Therefore the ^{232}Th mother activity is taken as the reference value.

After separation, the amount of radiation (produced by the progenies) within the thoriated electrode is considerably reduced for several years but of course, the progenies will grow up and will reach up to 75 % of the mother nuclide activity (^{232}Th) in a time period of 15 years (conservative estimate for the lifetime of the lamp) [16]. The whole ^{232}Th decay chain is shown in Annex VII.

I.11.3. ^{85}Kr-activity in HID-lamps

The ^{85}Kr-activity in individual HID-lamps does not exceed the exemption level [2] for total ^{85}Kr-activity of 10 000 Bq. The incorporated activity depends on the ^{85}Kr-activity concentration in, and pressure of, the noble gas mixture and the arc tube volume. The incorporated ^{85}Kr-activity varies from a value of about 50 Bq up to a value of 10 000 Bq. The noble gas mixtures used in manufacture have an ^{85}Kr-activity concentration that typically varies between 0.65 to 11 MBq per litre of gas, equaling to concentrations ranging from to 3 E+ 5 to 70 E+5 Bq per gram[20]. If concentrations below the exemption level were to be used, the desired incorporated ^{85}Kr-activity would not be obtained in the arc tube.

I.11.4. ^{232}Th-activity in HID-lamps

Table I.1 shows the maximal values for ^{232}Th activity and specific activity in ^{232}Th-containing lamps.

TABLE I.1. THE MAXIMAL VALUES FOR ^{232}Th ACTIVITY AND SPECIFIC ACTIVITY IN ^{232}Th-CONTAINING LAMPS

Nuclide	max. Activity	Specific Activity	Specific Activity
^{232}Th	4 500 Bq	max. 6 Bq/g	max. 72 Bq/g
		based on the weight of the lamp	based on the weight of the electrode

Note: An exemption level for ^{232}Th (including all progeny) of 4 700 Bq can be derived from the exemption level described in Schedule I of the BSS [2].

^{232}Th-containing items exceed the exemption level for the specific activity (1 Bq/g).

I.11.5. Operational dose rates close to pallet stacked with lamps containing ^{85}Kr

Operational dose rates were not evaluated for individual lamps, but for the situation in which lamps are typically packed in large numbers on a pallet for transport or stored in a warehouse. The maximum activity that can be stored on a pallet depends on lamp dimensions, incorporated activity and package size. Using this criteria, 18 MBq ^{85}Kr was found to be the

[20] For this calculation, argon is assumed to be the carrier in the noble gas mixture. Other noble elements may be used in other applications.

maximum amount that can be stored on a pallet[21]. For determining the operational dose rates, the following conservative approach was applied: a pallet is assumed to contain an activity of 20 MBq ^{85}Kr and this activity is uniformly distributed over a cubic volume of 1 m^3.

The radionuclide ^{85}Kr is contained in the arc tube of the lamp. The arc tube and the glass envelope have in total a thickness of at least 1.0 mm and will, therefore, provide effective shielding against the emitted beta-radiation [26]. This is also the case for 'burner only lamps'. The stopping of beta-particles generates, however, bremsstrahlung and this production is relatively important since the beta-particle emission probability (100%) is relatively high compared to the emitted gamma-radiation (0.4%). The bremsstrahlung contribution is considered equal to that of gamma emission [27]. In summary, when lamps are intact only photon radiation contributes to the dose in the surrounding environment.

The codes of the programme Microshield Version 8.01 (Grove Software Inc., Lynchburg, USA 2008) were used to calculate the contribution of the emitted gamma-radiation to the ambient dose equivalent rate at 10 mm depth and the directional dose equivalent rate at 0.07 mm depth as defined in [28][22]. The calculated values are multiplied with a factor 2 in order to take the bremsstrahlung contribution into account. Both operational radiation protection quantities increase with a value of 50 nSv per hour. At a distance of 1 meter from the surface of the pallet both dose rates increase with a value of 8 nSv per hour.

I.11.6. Operational dose rates close to pallet stacked with lamps containing ^{232}Th

Operational dose rates were evaluated for individual lamps and for the situation in which lamps are typically packed on a pallet for transport or stored in a warehouse. The maximum activity for a single lamp is 4 500 Bq ^{232}Th (which relates to about 1 g of ^{232}Th). The maximum activity that can be stored on a pallet depends on lamp dimensions, size of package and incorporated activity. Using this criteria, 0.1 MBq ^{232}Th was found to be the maximum amount that can be stored on a pallet[23]. To determine the operational dose rates, the following conservative approach was applied: a pallet is assumed to contain an activity of 0.1 MBq ^{232}Th and this activity is uniformly distributed over a cubic volume of 1 m^3.

The radionuclide ^{232}Th is contained in the electrodes of the lamp which causes low dose rates also by gamma-radiation of the daughter nuclides. Alpha and beta radiation is shielded fully; gamma radiation is shielded partly by the Tungsten and the quartz glass bulb(s). The resulting external gamma radiation caused by the daughter nuclides is negligibly low, because of the high self-absorption in the heavy Tungsten matrix and the age of the ^{232}Th.

Thus only the emitted external gamma radiation will contribute to the dose in the surrounding environment close to lamps. The codes of the programme Microshield Version 8.03 (Grove Software Inc., Lynchburg, USA 2008) were used to calculate the ambient dose equivalent rate

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[21] Analysis of the complete ^{85}Kr-lamp portfolio of the involved members of the European Lamp Companies Federation (ELC) revealed that a total activity of 18 MBq is the maximum activity that can be packed onto a pallet; this amount equals 9 000 lamps of a particular lamp type, each containing 2 000 Bq ^{85}Kr.

[22] Where applicable in this study, this programme was also used to calculate the effective dose and the equivalent skin dose as defined in ICRP-74 [29].

[23] The type of lamps evaluated in this study each contains an activity of maximum 4 500 Bq and up to 6 lamps can be packed on a pallet. Analysis of the complete ^{232}Th lamp portfolio revealed that a total activity of 0.1 MBq is the maximum activity that can be packed onto a pallet; this amount equals 100 lamps, each containing 1 000 Bq ^{232}Th which is more than the average of transported lamps.

at 10 mm depth and the directional dose equivalent rate at 0.07 mm depth as defined in ICRP -51 [28].

For a single lamp both operational dose rates increase up to 123 nSv per hour at a distance of 0.1 m and up to 1 nSv per hour at 1 m.

For a pallet of lamps both operational dose rates increase with a value of 47 nSv per hour. At a distance of 1 meter from the surface of the pallet both dose rates increase with a value of 8 nSv per hour.

I.12. RADIOLOGICAL ASSESSMENT ON LAMPS WITH ^{85}KR

I.12.1. Exposure scenarios and pathways of exposure to ^{85}Kr

The radiological assessment was made for the entire life-cycle of lamps that do not need any further steps of manufacture. To this end, various exposure scenarios were developed to representatively describe the various phases of the life cycle of the product. Not only normal scenarios, but also potential and accidental exposure situations were developed for this analysis. Due to the radioactive properties of the noble ^{85}Kr-gas, the (potential) exposure pathways for ^{85}Kr are:

- Exposure to external radiation of emitted gamma rays and beta particles, and
- Submersion when ^{85}Kr is released into the environment.

I.12.2. Normal exposure conditions

During normal use, ^{85}Kr is contained within the arc tube of the lamp and exposure due to submersion of ^{85}Kr does not occur. The physical properties of the lamp provide effective shielding against the emitted beta-particles. The stopping of beta-particles generates bremsstrahlung and this production is relatively important since the beta-particle emission probability (100%) is relatively high compared to the emitted gamma-radiation (0.4%). The bremsstrahlung contribution is considered equal to that of gamma emission [27]. In summary, during normal conditions of exposure to ^{85}Kr, persons can only be externally exposed to photon radiation.

I.12.3. Exposure in accident conditions

The scenario to describe accidents is loss of containment of the otherwise occluded radioactive gas. In a conservative approach it is assumed that all lamps involved in a particular accident scenario will instantaneously release their ^{85}Kr-content into the environment. As ^{85}Kr is a noble gas, submersion will be the dominant exposure pathway contributing to the dose of exposed persons.

I.13. LIFE CYCLE OF LAMPS

Following manufacture the life cycle of a lamp comprises of the following elements:

(i) Transportation

(ii) Warehouse storage,

(iii) Assembly of lamps into luminaires as well as installation, servicing, maintenance, repair, replacement and sale,

(iv) End-use and, finally

(v) Disposal of used lamps.

I.13.1. Transport

The occupational and public radiation doses resulting from transport operations with lamps containing radioactive material have been evaluated in a study funded by the European Commission [17]. Risk analysis showed that estimated contribution of such shipments to the effective dose of involved employees does not exceed 1 µSv per year under normal circumstances. The resulting increase of the effective dose for members of the public is not expected to be higher than 10 nSv per year. The radiological consequences of a transport accident were also evaluated in this study according to the Q-system described in the advisory material published by the IAEA for the Safe Transport of Radioactive Material [30]. The instantaneous release of a consignment of 20 pallets of lamps products equaling to an activity of 400 MBq ^{85}Kr results in an estimated equivalent skin dose of 16 µSv and an increase of the effective dose of about 0.3 µSv (see Annex VIII for details of calculation). Analysis of reported transport accidents with consumer goods containing radioactive material shows that substantial release of radioactive material have an infrequent occurrence [17]. It is, therefore, unlikely that a person is involved in such an accident more than once in his lifetime.

In a recent study, the radiological impact during transportation of lamps containing ^{85}Kr was re-evaluated in detail for a variety of representative transport and distribution scenarios [20]. The transport scenarios included road, sea and air transport of manufactured products and road transport of disused lamps. Evaluation of both routine and accident scenarios demonstrated again that the criteria of exemption were not exceeded under the various evaluated transport conditions.

I.13.2. Warehouse storage

Exposure to lamps containing radioactive materials which are stored in a warehouse is an occupational exposure scenario. The adopted scenario to evaluate the exposure of employees was similar to that described in [17]. When assuming an annual occupational exposure of 400 h at 1 m distance from a pallet of lamps with a total activity of 20 MBq ^{85}Kr, the incurred effective dose will be less than 4 µSv per year[24]. For an accident scenario in a warehouse the same scenario as described above for transport was adopted. The resulting estimated equivalent skin dose and effective dose will not exceed 16 µSv and 0.3 µSv respectively (see Annex VII for calculation details).

The recently conducted transport study described above also included the evaluation of routine and accident scenarios in a warehouse [20]. Also under these circumstances the estimated doses did not exceed the dose criteria for exemption.

[24] The assumed exposure time at 1 meter for a pallet is twice as long as the 200 h of exposure time assumed for operators working near a non-dispersible source in [14].

I.13.3. Professional use

During scenarios describing professional use other than warehouse storage, employees will work close to a pack of lamps and will pick up and manually handle a substantial number of lamps as part of their daily work. Examples of such use are:

- Assembly of lamps into luminaires,
- Installation,
- Replacement,
- Service repair and maintenance, and
- The retailer who is selling lamps.

According to workplace scenarios described in [14], not only external exposure of the whole body to a pack of lamps needs to be evaluated, but also the exposure of hands and the skin must be evaluated. The annual increase of the effective dose of employees exposed to the photon radiation emitted from a pack of lamps will be less than 4 µSv when the same conservative scenario described for warehouse storage was adopted.

During manual handling any surface of the skin can only be exposed to the radiation emitted by a single lamp. As a consequence, any surface of the skin will not be in close contact to an ^{85}Kr activity exceeding the exemption level of 10 000 Bq defined in Schedule I of the Basic Safety Standards [2]. The skin is, due to the lamp design and configuration, effectively protected against the emitted beta-radiation that would otherwise dominantly contribute to the equivalent skin dose. When assuming an annual exposure time of 10 hours for direct contact during manual handling as defined in [14], an equivalent skin dose of up to 1 µSv can be calculated[25] (see Annex VII for calculation details).

The radiological consequences resulting from an accident scenario will be of limited importance if only one pallet of lamps is involved. The dose contributions of exposed persons will be no more than the doses estimated for transport or warehouse accidents.

I.13.4. End-use

End-users benefit from the light produced by the lamps and but are also potentially exposed to the emitted gamma radiation of the lamps. In this phase of the lamp life-cycle, members of the public are, at a distance of a few meters, exposed to a substantially smaller number of lamps compared to that packed on a pallet. The same ‘dilution’ applies to an accident scenario in which a few lamps might lose their integrity. When relating this exposure condition to smaller numbers of lamps to the warehouse exposure scenarios, it can be deducted that the annual dose for members of the public will not exceed a value of 1 µSv per year. These dose estimates are in line with those published by the European Commission [18] and the Dutch National Institute for Public Health and the Environment [31].

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[25] Calculations were done for a typical lamp described having a diameter of 2 cm. The arc tube containing ^{85}Kr is centered in the middle of the lamp, is 1 cm long and has a diameter of 0.7 cm and contains an activity of up to 300 Bq. For a conservative assumption, the dose rate is calculated at 1 cm distance from a point source having an ^{85}Kr-activity of 10 000 Bq.

I.13.5. End of life — treatment and disposal

Collection & recycling

At the end of lamp life it depends on the national requirements on how to proceed with lamp disposal. According to the legislation in many States (e.g. WEEE in the EU States) [32] collection is mandatory for all lamps. Incandescent lamps are excluded from this requirement.

In the recycling process the lamps are treated and useful materials are recovered as recycled materials. Due to the mercury content in the lamps, this work is done in well ventilated environments with a negative pressure compared to the employees' environment thus preventing inhalation of any vapor content of the lamps by the employees [33]. This measure will also minimize the risk of exposure of workers to ^{85}Kr.

Recycling process of ^{85}Kr-containing products

Many of the lamps contain small amounts of ^{85}Kr and mercury. As most of the ^{85}Kr-lamps are HID-lamps, they are normally very compact and difficult to disassemble, especially the burners (or discharge tubes) that are made of quartz or ceramic material and contain the radioactive material. Because of these characteristics, the burners are crushed and then recycled or disposed for controlled landfill. As a consequence of crushing, ^{85}Kr is eventually released into the environment.

Recycling process of ^{85}Kr-containing products

Due to the ventilation measures taken at the workplace, the workplace ^{85}Kr concentration will be of little relevance to contribute to the effective dose[26].

The crushing will ultimately lead to the release and subsequent dilution of ^{85}Kr into the atmosphere. The effect of this environmental release is insignificant compared to the concentration of 1 Bq/m^3 already present in the atmosphere due to other man-made activities [34]. The Dutch National Institute for Public Health and the Environment estimated that the effective dose of members of the public will increase with a value of around 2 pSv per year when the ^{85}Kr activity of 1 million light products (equivalent to an activity of 20 GBq) is released into the atmosphere during waste processing [31][27].

Disposal: Landfill

Waste treatment employees and members of the public visiting land fill sites that are externally exposed to disposed intact lamps, cannot be expected to incur a higher dose compared to employees involved in transport or logistic work in a warehouse. Waste treatment will ultimately lead to release and dilution of ^{85}Kr into the atmosphere. The resulting environmental effects are described above in the paragraph 'Recycling process of ^{85}Kr containing products'.

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[26] According to German regulations (Strahlenschutzverordnung) employees do not need to be considered exposed workers if the ^{85}Kr concentration at the workplace does not exceed 1 E+6 Bq/m^3. It is not realistic to assume that this concentration will be exceeded in a recycling facility because of the amount of HID-lamps processed. This is due to the well confined environment in which lamps are crushed.

[27] According to German regulations (Strahlenschutzverordnung) the maximum ^{85}Kr concentration is limited to 1 E+4 Bq/m^3 when the emitted volume does not exceed 1 E+4 m^3/h. Under these circumstances, the effective dose for a member of the public at the point of emission will be restricted to 0.3 mSv per year.

The radiological consequences of disposing disused lamps in landfill waste have been investigated in a recent study [20]. The study shows that in order to exceed the dose criteria for exemption, the number of disposed lamps needs to excessively exceed the estimated amounts disposed on landfill. In other words, the radiological consequences of landfill disposal are insignificant.

Disposal: Incineration

An alternative treatment includes incineration as part of the total generic disposal stream in a State. This case was evaluated by the Dutch RIVM studies of 2000 and 2002 [31, 35] of which the outcomes are taken over in the EU Review 146 on radiation protection [18]. Waste treatment will ultimately lead to release and dilution of ^{85}Kr into the atmosphere. The resulting environmental effects are described above in the paragraph 'Recycling process of ^{85}Kr containing products'.

I.14. COMPARISON TO EXEMPTION LEVELS (SEE REF. [14])

The European Commission's publication Radiation Protection 65 [14] describes the principles and methods for establishing exemption values. In this study, the critical exposure pathways determining the ^{85}Kr-exemption levels for activity concentration and total activity were found to occur during normal conditions in a workplace environment. The critical pathway determining the exemption value for ^{85}Kr activity concentration (100 000 Bq/g) is external exposure to gamma-radiation emitted from a 100 liter gas cylinder. For the dose estimation the European Lamp Company Federation assumed the cylinder to contain 2.7 GBq ^{85}Kr when filled under pressure of 150 bar[28] with an activity concentration of 100 000 Bq per gram of gas. In other words, the activity present in a 100 liter cylinder containing an exempt ^{85}Kr-concentration is equal to that of 135 pallets of lamps each containing 20 MBq ^{85}Kr. At a distance of 1 meter from such a model cylinder, the ambient dose equivalent rate at 10 mm depth increases with a value of about 0.7 µSv per hour (only gamma-emission taken into account). Although the activity concentration of the lamp filling gas is about ten-fold higher than the exemption level, the resulting increase of the ambient dose equivalent rate at 10 mm depth at 1 m distance from a pallet of lamps will be more than one hundred fold lower (8 nSv per hour) compared to that of the smaller sized model cylinder.

The critical exposure pathway determining the exemption level for total ^{85}Kr activity (of 10 000 Bq) is based on external exposure of the skin to the emitted beta-radiation during handling of a source [14]. Although the total activity within a practice may exceed the exemption level, a person will only handle lamps with an activity of no more than 10 000 Bq. In addition, the lamp design and configuration was demonstrated to effectively attenuate the beta-particles. Moreover, the skin surface cannot be contaminated as ^{85}Kr is a noble gas. This comparison shows that skin exposure is not a critical exposure pathway when handling lamps containing ^{85}Kr.

The critical exposure pathways determining the exemption levels for activity and activity concentration are relevant for workplace scenarios. Comparison with the presented radiological assessment for lamps containing ^{85}Kr shows, however, that the assumptions for the radioactive materials used for these workplace scenarios do not apply for the radiological

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[28] This assumption is based on the properties of gas cylinders typically used for lamp manufacture. Such cylinders are delivered with a pressure of 150 bar and with the noble gas Argon as the carrier gas.

assessment of critical groups of members of the public exposed to these types of items containing radioactive material.

I.15. ASSESSMENT ON LAMPS WITH ^{232}TH

I.15.1. Exposure scenarios and pathways of exposure to ^{232}Th

The radiological assessment was made for the entire life-cycle of lamps that do not need any further steps of manufacture. To this end various exposure scenarios were developed to representatively describe the various phases of the life cycle of the product. Not only normal scenarios, but also potential and accidental exposure situations were developed for this analysis. Due to the radio physical properties of ^{232}Th, the (potential) exposure pathways are: external exposure to alpha-, beta-, gamma- radiation when ^{232}Th is released into the environment due to an accident (crash and fire scenario).

I.15.2. Normal exposure conditions

During normal use, ^{232}Th is contained within the electrodes and within the arc tube of the lamp and exposure due to alpha- and beta- radiation by ^{232}Th and its progenies does not occur. The physical properties of the lamp provide effective shielding against the emitted alpha and beta-particles. Therefore, under normal conditions of use persons can only be externally exposed to the gamma-radiation emitted by the progenies of ^{232}Th.

I.15.3. Exposure in accident conditions

The external gamma radiation and furthermore the alpha- and beta-radiation on the surface of the thoriated Tungsten is taken into account after lamp breakage. Incorporation by inhalation is not possible, because ^{232}Th is fixed bounded in the Tungsten matrix or in a solid form. Contamination is also not relevant with these thoriated electrodes, because the activity is fixed bounded and therefore smear-resistant. The ingestion case is possible if a complete electrode is swallowed which is, however, very unlikely, in particular for large electrodes.

If during the crash scenario fire also occurs the inhalation pathway is taken into account because ^{232}Th-particles at the surface can leave the solid matrix.

I.16. LIFE CYCLE OF LAMPS.

Following manufacture the life cycle of a lamp involves the following steps:

(i) Transportation,

(ii) Warehouse storage,

(iii) Assembly of lamps into luminaries as well as installation, servicing, maintenance, repair, replacement and sale,

(iv) Operation by end-user and, finally

(v) Disposal of used lamps.

I.16.1. Transport

The occupational and public radiation doses resulting from transport operations with lamps containing radioactive material have been evaluated in a study funded by the European Commission [20]. Risk analysis showed that estimated contribution to the effective dose of employees involved in the transport of such lamps under normal circumstances is far below 1 µSv per year. Indeed, the resulting increase of the effective dose for members of the public is not expected to be higher than 10 nSv per year. The radiological consequences of a transport accident were also evaluated in this study according to the Q-system described in the advisory material published by the IAEA for the safe transport of radioactive material [30]. The release of a consignment of 20 pallets of lamp products with an activity of 2 MBq ^{232}Th results in an estimated equivalent skin dose of 5.2 µSv and an increase of the effective dose of approximately 0.52 µSv for the employee when collecting the lamp parts by hand. The case of fire is explained under warehouse accident. (See Annex VIII for details of calculation).

In a recent study, the radiological impact during transport of lamps containing ^{232}Th was re-evaluated in detail for a variety of representative transport and distribution scenarios [20]. The transport scenarios included road, sea and air transport of manufactured products and road transport of disused lamps. Evaluation of both routine and accident scenario's demonstrated again that the criteria of exemption were not exceeded under the various evaluated transport conditions.

I.16.2. Warehouse storage

Exposure to lamps containing radioactive materials stored in a warehouse is an occupational exposure scenario. The scenario to evaluate the exposure of employees was similar to that described in [17]. When assuming an annual occupational exposure of 400 h at 1 m distance from a pallet of lamps with a total activity of 0.1 MBq ^{232}Th, the incurred effective dose will be less than 1 µSv per year[29]. For an accident scenario in a warehouse the broken lamp scenario as described for transport can be applied. For the fire scenario the estimated equivalent skin dose and effective dose will not exceed 0.0001 µSv and 5 µSv respectively by using a very conservative calculation. In the fire scenario, the inhalation pathway is the dominant one. The effective dose through inhalation doesn't exceed 5 µSv. (See Annex VIII for details of calculation).

In the recently conducted transport study described above also included the evaluation of routine and accident scenarios in a warehouse [20]. Also under these circumstances the estimated doses did not exceed the dose criteria for exemption.

I.16.3. Professional use

During scenarios describing professional use other than warehouse storage, employees will work close to a pack of lamps and will pick up and manually handle large numbers of lamps as part of their daily work. Examples of such use are:

- Assembly of lamps into luminaries,
- Installation,

[29] The assumed exposure time at 1 meter for a pallet is twice as long as the 200 h of exposure time assumed for operators working near a non-dispersible source in [14].

- Replacement,
- Service repair and maintenance,
- The retailer who is selling lamps.

According to workplace scenarios described in [14], not only external exposure by the pack of lamps needs to be evaluated but also the exposure of hands and the skin must be evaluated. Realistic exposure parameters (time, distance and shielding, low number of lamps at one time) were taken into account, which limit the exposure in practice. The annual increase of the effective dose of employees exposed to the gamma radiation emitted from lamps will be less than 6 µSv at a distance of 0.2 m and 0.23 µSv for 1.0 m. The dose contributions of exposed persons do not exceed the doses estimated for transport or warehouse accidents. (See Annex VIII for details of calculation).

I.16.4. End-use

End-users benefit from high efficient light items but they are exposed to the emitted external gamma-radiation of the ^{232}Th progenies from a certain distance. In this phase of the lamp life-cycle, members of the public are usually at a distance of a few meters exposed to a substantial smaller number of lamps compared to that packed on a pallet. In an accident scenario are also just one or few lamps in concern. Therefore compared to the warehouse and transport accident scenarios the resulting annual dose for members of the public will be significantly lower and will not exceed a value of 1 µSv annually. These dose estimates are in line with those published by the U.S. Nuclear Regulatory Commission [16] (See Annex VIII for details of calculation).

I.16.5. End of life: treatment and disposal

Collection and recycling – legal aspects

At the end of the lamp life it depends on the national requirements on how to proceed with the lamp disposal. According to the legislation in many States (e.g. WEEE in the EU States) [32] collection is mandatory for all lamps. Incandescent lamps are excluded from this requirement. Fluorescent lamps represent the largest part of the mix put on the market.

In the recycling process the lamps are treated and useful materials are recovered as recycled materials. Due to the mercury content in the lamps, this work is done in well ventilated environments with a negative pressure compared to the employees' environment thus preventing inhalation of any vapour content of the lamps by the employees [33]. This measure will also minimise the risk of contamination of the workplace with ^{232}Th and thereby minimize the exposure risk of the employees.

Recycling process of ^{232}Th-containing products

Many of the lamps contain small amounts of ^{232}Th and mercury. As most of the ^{232}Th-lamps are HID lamps, they are normally very compact and difficult to disassemble, especially the burners (or discharge tubes) that are made of quartz or ceramic material and contain the ^{232}Th-material. Because of these characteristics, the burners are either left intact or are crushed and then recycled or disposed for controlled landfill. In the first case the radioactive material remains contained in the burner, while in the second case the ^{232}Th can be released: in case of thoriated tungsten electrodes, some material parts will still be protected/sealed by glass, whereas other parts are not.

Another important fact is that all HID lamps are processed in a similar way, so in the average mix with non-^{232}Th containing products, ^{232}Th materials will be a non-significant part of the total volume.

Disposal: municipal waste landfill

When end-of-life lamps are directly sent to a municipal waste landfill, the resulting annual doses are below 0.1 µSv [16]. In the unlikely case that someone swallows a thoriated lamp electrode (intake by ingestion) on a landfill site, the resulting dose of 0.4 µSv (calculated by [14]) doesn't exceed the dose criteria. (See Annex VIII for details of calculation).

The radiological consequences of disposing disused lamps in land fill waste have been investigated in a recent study [20]. The study shows that in order to exceed the dose criteria for exemption, the number of disposed lamps needs to excessively exceed the estimated amounts disposed on land fill. In other words, the radiological consequences of land fill disposal are insignificant.

Disposal: incineration

An alternative way of treatment includes incineration as part of the total generic disposal stream in a State. This case was evaluated by the Dutch RIVM studies of 2000 and 2002 [31, 35] of which the outcomes are taken over in EU Review 146 on radiation protection [18]. The resulting dose of the study was 0.0002 µSv by incineration of 20 MBq ^{232}Th for members of the public.

I.17. CONCLUSION

This radiological assessment demonstrated that the use of radioactive ^{85}Kr and/or ^{232}Th in HID-lamps is justified and optimized. The radiological consequences for members of the public, including the lighting industry and other involved professionals, were demonstrated to be insignificant during the entire life cycle of the lamps, including waste disposal. This study also demonstrated that the applied scenarios and exposure pathways, to derive the exemption levels specified in the Basic Safety Standards, are of little relevance in the case of the evaluation of the radiological consequence for members of the public when exposed to items under normal as well as accident scenarios. In conclusion, this study provides support for the idea that the ^{85}Kr and ^{232}Th containing items can be made available to a global market without any restrictions. This free trade is possible as the consequences of exposure to members of the public are well within the boundaries of the dose criteria for exemption.

Additionally, several published independent studies on lamps containing thoriated electrodes (see [16, 17, 31, 35]) demonstrate the safe nature of the items produced by the lamp industry during all aspects of their life cycle. The exposure risk for any member of the public is far below the 10 µSv per year.

The results from previously published studies concerning the different pathways of exposure scenarios with electrical lamps are summarized in the figure below.

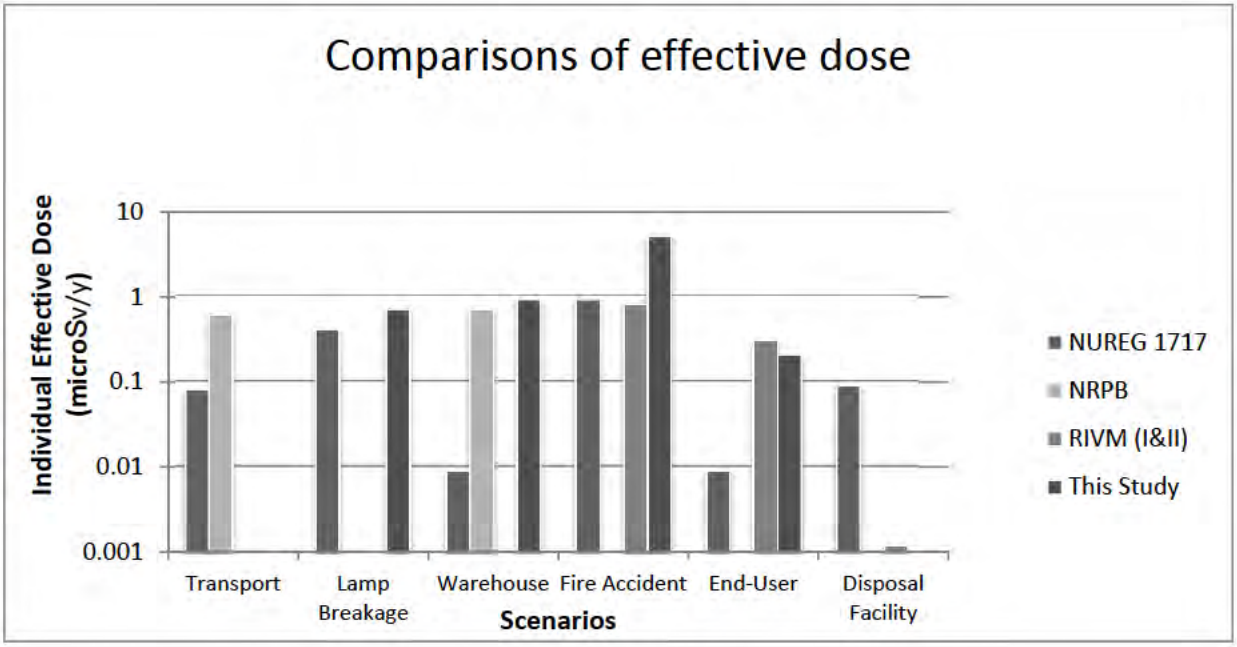

FIG. A-1. Comparisons of effective dose from various studies.

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ANNEX I.
TYPICAL EXAMPLES OF LAMPS CONTAINING ^{85}K AND ^{232}TH

FIG. I-1. Typical example of an HID-lamp containing an inner quartz glass arc tube, a quartz glass outer envelope and an Edison fitting. (Image courtesy of Philips)

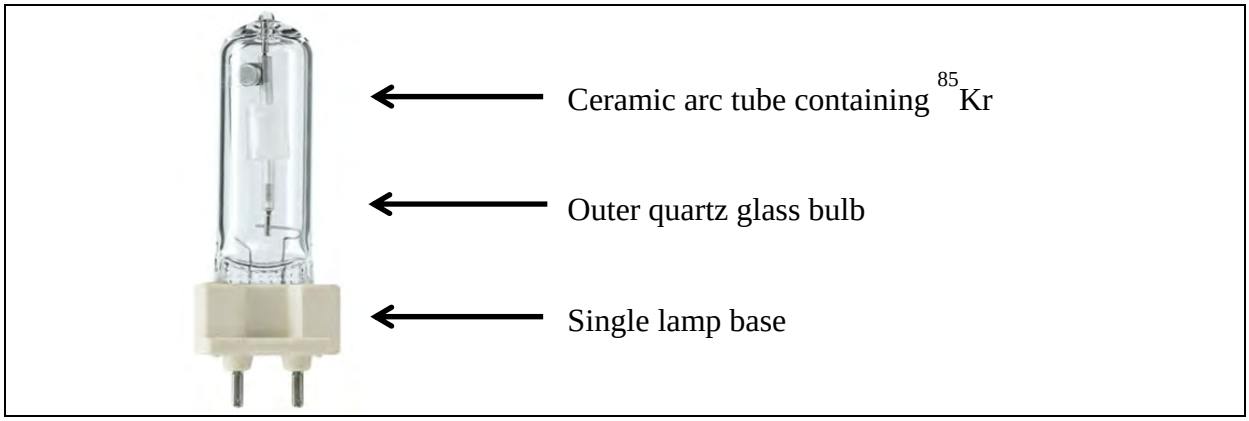

FIG. I-2. Typical example of a single ended HID-lamp containing an inner ceramic arc tube and a quartz glass outer envelope. (Image courtesy of Philips)

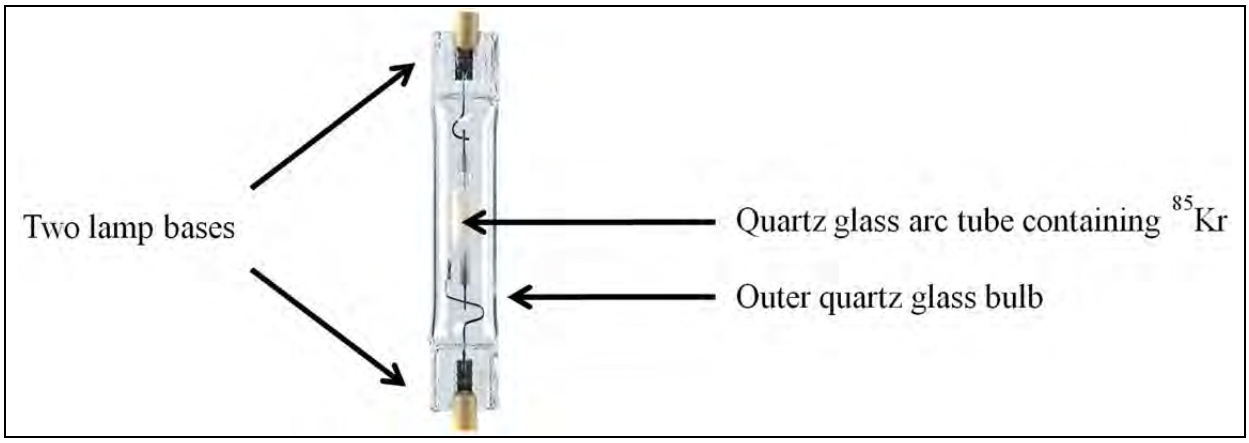

FIG. I-3. Double ended HID-lamp containing an inner ceramic arc tube and a quartz glass outer envelope. (Image courtesy of Philips)

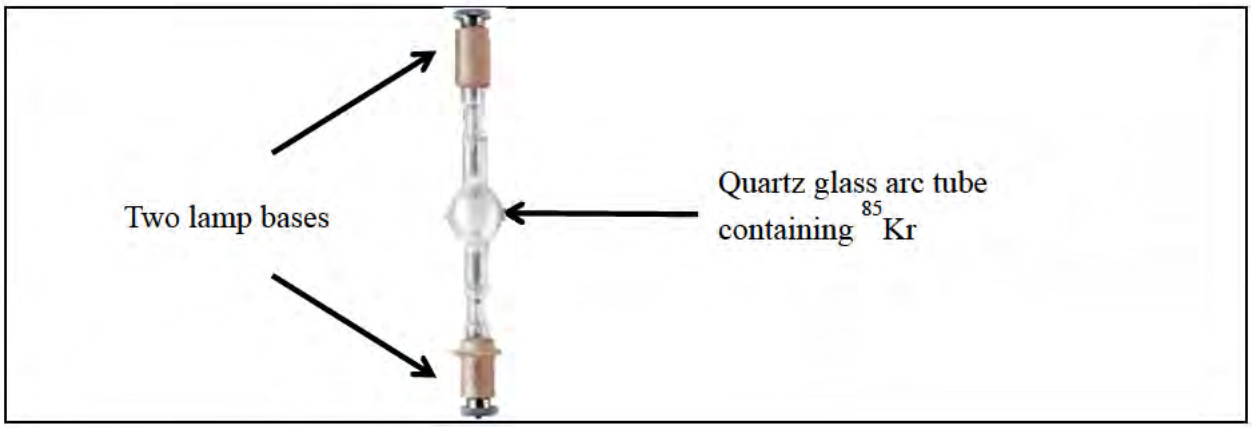

FIG. I-4. Typical example of a 'Burner only' HID-lamp without an outer envelope. (Image courtesy of Philips)

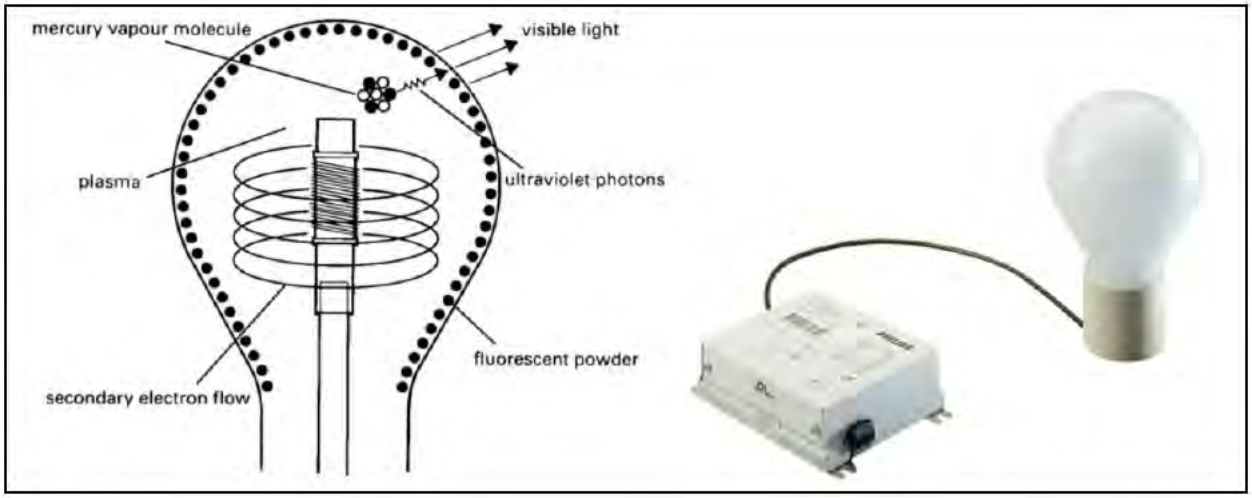

FIG. I-5. QL-induction Lamps containing ^{85}Kr. (Image courtesy of Philips)

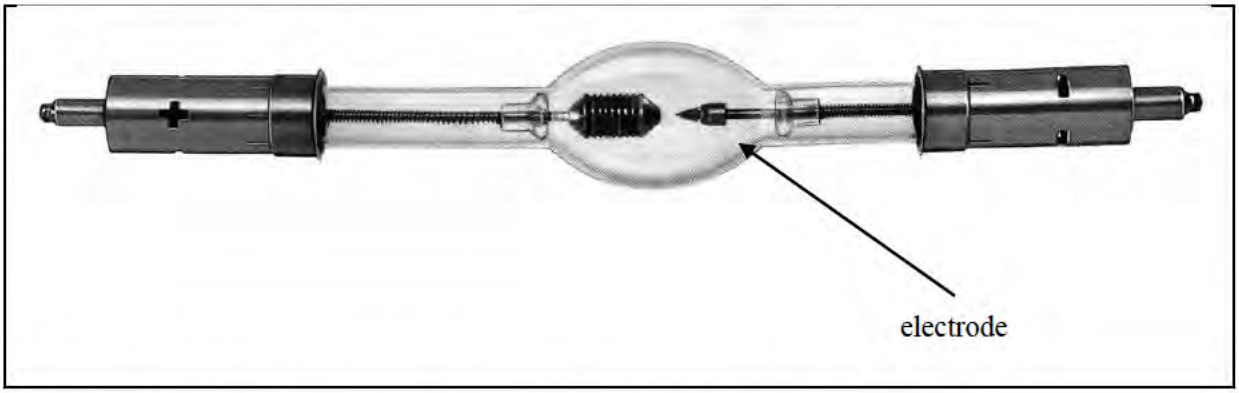

FIG. I-6. Xenon short arc lamp with a thoriated tungsten electrode (cathode). (Image courtesy of Osram)

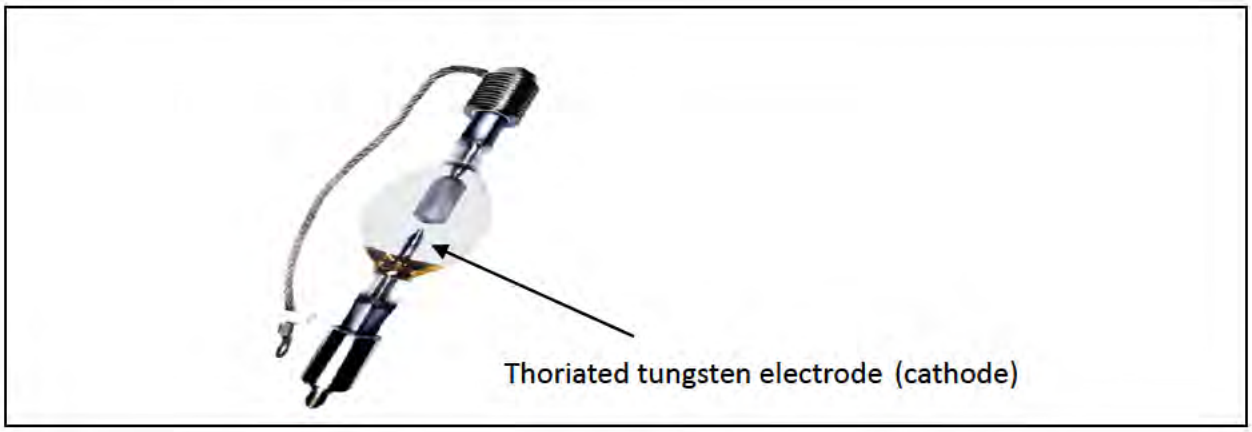

FIG. I-7. Mercury short arc lamp with a thoriated tungsten electrode. (Image courtesy of Osram)

FIG. I-8. Automotive Xenon lamp with thoriated tungsten electrodes. (Image courtesy of Osram)

FIG. I-9. Metal halide lamp with thoriated tungsten electrodes (Image courtesy of Osram)

TABLE I-1. OVERVIEW OF LAMPS CONTAINING ^{85}Kr

Type of lamp	**Typical application**	**Typical ^{85}Kr-activity per item**	**Maximal ^{85}Kr-activity per item**
Metal halide lamps or arc tubes Fig. I-1, I-2, I-3, I-4	Shop lighting; Hotel and restaurant lighting; Office lighting; Stadium lighting; Street – area lighting.	100 – 2 500 Bq	< 10 000 Bq
Entertainment short arc lamps Fig. I-4	TV / Film studio lighting Stage / Concert lighting Sport Event lighting	1 500 – 9 500 Bq	< 10 000 Bq
QL-induction lamp Fig. I-5	High-bay indoor and outdoor applications	1 000 – 5 000 Bq	< 10 000 Bq

TABLE I-2. TYPICAL EXAMPLES AND OVERVIEW OF HID-LAMPS CONTAINING ^{232}Th

Type of HID lamp	**Electric Power consumption per item**	**Typical Activity per item**	**Max. Activity per item ^{232}Th**	**Typical application**	**Information on the radio nuclides**
Xenon short arc lamps Fig. I-6	50 – 12 000 W	50 – 500 Bq	< 2 000 Bq	Architecture lighting Classic film projection Light guide applications Solar simulation Light houses, sky beamer	^{232}Th (mother activity) (max. 2 weight-% ThO_2 in Tungsten) Max. activity concentration per electrode: 72 Bq/g ^{232}Th
Mercury short arc lamps Fig. I-7	50 – 25 000 W	100 – 1 000 Bq	< 4 500 Bq	Manufacture of semiconductors Fluorescence endoscopy Fluorescence microscopy Schlieren photography Hologram projection UV curing	^{232}Th ($^{232}ThO_2$) doped tungsten electrodes ^{232}Th ($^{232}ThI_4$) in salts ^{232}Th in coating material of tungsten electrodes Functions: (1) Reduces the electron discharge level at the cathode, start aid, prolongs life span (2) Improves metallurgical qualities (3) Improves colour properties of light output
Automotive Xenon lamps Fig. I-8	2 – 35 W	0.1 – 0.5 Bq	< 1 Bq	Car headlight	
Metal halide lamps Fig. I-9	20 – 5 000 W	10 – 80 Bq	< 100 Bq	Shop lighting Hotel and restaurant lighting Office lighting Stadium lighting Street –Area lighting	Special types with $^{232}ThI_4$ max. 0.04 weight-% of the lamp filling (< 0.05 Bq)

TABLE I-3. CALCULATION OF THE ^{232}Th ACTIVITY (A) PER LAMP

$A = m_{\text{electrode, filling}} \times A_{\text{Specf}} \times R_{^{232}\text{Th/ThO2}} \times c_{^{232}\text{Thw}}$

$m_{\text{electrode, filling}}$ = Weight of the electrode or filling in which the ^{232}Th is embedded [g]

A_{Specf} = Specific Activity of pure ^{232}Th = 4 058 [Bq/g]

$R_{^{232}\text{Th/ThO2}}$ = Relation ^{232}Th / $^{232}ThO_2$ = 0.88 (^{232}Th is embedded in the form of $^{232}ThO_2$)

$c_{^{232}\text{Thw}}$ = Concentration of ^{232}Th (here $^{232}ThO_2$) in the embedded solid by weight

Example:

Electrode m = 0.1 g

$c_{^{232}\text{Thw}}$ = 2% (0.02)

A = 7.1 [Bq]

ANNEX II.
OVERVIEW OF LAMP TECHNOLOGIES

II-1. INCANDESCENT LAMPS

This is the oldest electric lamp technology: a coiled wire of tungsten emits light by passing an electric current through the wire. Due to the low efficiency, the lamps (bulbs) used for general lighting, principally in households, are currently being phased-out globally.

Typical parameters:

Temperature of the coil is 2 700 K;

Lamp life is 1 000 h (at end of life the coil breaks, weakened by evaporation of the tungsten);

Lamp efficacy is 10 lm/W for 230 V systems and 15 lm/W for 110 V systems;

Colour rendition: 100.

II-2. HALOGEN LAMPS

Same technical principle as used in incandescent lamps, but enhanced with a halogen cycle in the bulb by which evaporated tungsten is brought back to the coil. By this principle, halogen lamps last longer, operate at a higher temperature (3 000 K) and have a higher efficacy compared to incandescent lamps. Advantages of the lamps are the easy switch on/off and dimming.

Typical parameters:

Temperature of the coils is 2 700–3 300 K;

Lamp life is 1 000–5 000 h;

Lamp efficacy is 10 to 25 lm/W, depending on operating voltage and lamp wattage;

Colour rendition: 100.

II-3. FLUORESCENT LAMPS/SYSTEMS IN WHICH THE STARTER/GLOW-SWITCH CONTAINS LLR

Fluorescent lamps are low pressure gas-discharge lamps in which an electric current excites mercury to emit UV-light. The emitted UV-light is subsequently transformed by the fluorescent powder that is coated onto the internal lining of the tube, into visible light. The lamps have a high efficacy (50–100 lm/W) and a good colour rendition of 80–90. Due to the relatively large surface they give a diffuse light compared with point sources e.g. HID, halogen, LED's. This technology is utilized in 3 main groups of lamps, namely:

- Fluorescent tubes,
- Non-integrated compact fluorescent lamps, and
- Integrated compact fluorescent lamps.

The lamp system consists of a fluorescent tube, a starter and a ballast. The starter or glow-switch is needed to ignite the lamp. Certain starters may contain small amounts of radioactive material (^{3}H or ^{85}Kr), whereas some non-radioactive alternatives do already exist. Further details on the fluorescent lamp systems and on the justification for applying radioactive material in starters and glow-switches is given in Annex III.

II-4. FLUORESCENT TUBES

This is the original fluorescent lamp type and consists of a straight tube and operates at wattages typically varying from 15–85 W.

Typical lamp parameters:

Colour temperature: wide range from warm white (2 700 K) to cold bluish light (17 000 K), plus coloured lamps;

Lamp life is 10 000–20 000 h;

Lamp efficacy is 90 lm/W;

Colour rendition: 80–90.

II-5. COMPACT FLUORESCENT NON-INTEGRATED LAMPS

Around 1980 it became technically possible to make smaller tubes and to bend them into smaller, compact lamps. The lamps operate in a wattage range of 5 to 26 W and are predominantly applied in a professional environment.

Typical lamp parameters:

Colour temperature: wide range of whites plus coloured lamps;

Lamp life is 6 000–10 000 h;

Lamp efficacy is 65 lm/W (slightly less efficient compared to classic fluorescent tubes. Internal reflections occur due to the bending of the tube);

Colour rendition: 80–90.

II-6. COMPACT FLUORESCENT INTEGRATED LAMPS

Similar to the non-integrated version but in these lamps the tube, glow-switch and ballast are integrated into the lamp. These lamps, well known as ‘energy-savers’, are mainly used in households. The wattage is limited to 23 W. (23 W lamps have an equivalent efficacy compared to a 100 W incandescent lamp).

Typical lamp parameters:

Colour temperature: wide range of whites;

Lamp life is 6 000–10 000 h;

Lamp efficacy is 60–70 lm/W (slightly less efficient compared to classic fluorescent tubes. Internal reflections occur due to the bending of the tube);

Colour rendition: 80–90.

II-7. QL-INDUCTION LAMPS

QL-induction lamp is another type of fluorescent lamp but operates on a different principle. This type of lamp contains a small amount of ^{85}Kr. Further details are described in Annex IV.

Typical parameters:

Colour temperature: range from warm white (2 700 K) to daylight (6 500 K);

System life is 50 000 to 60 000 h;

System efficacy is 80 lm/W;

Colour rendition: 85.

II-8. HID-LAMPS (see Appendix)

Typical parameters for HID-lamps containing small amounts of radioactive material:

Colour Temperature is 2 700–20 000 K (6 500 K is equal to daylight);

Lamp life is typically 10 000 to 25 000 h;

(Special lamps can have a lamp life of less than 1 000 h due to the required heavy load of some applications).

Lamp efficacy is 70–120 lm/W;

Colour rendition: 70–90.

II-9. LEDs (LIGHT EMITTING DIODES)

Over the last decades the development of LEDs has evolved rapidly. White light can be produced efficiently. Warm white light is produced with less efficacy compared to cold white light. Whereas LEDs have become more efficient in making light, the heat management remains the biggest problem of this technology. Contrary to ‘conventional’ light sources, LEDs have to dissipate the main part of the heat (i.e. energy loss) into the plate on which they are mounted. This makes it difficult to pack a lot of LEDs closely together in order to obtain the same high intensity light produced by HID sources. This is in particular the case for systems designed to replace the higher wattage HID-applications. The first LED alternatives are now appearing on the market and have comparable performances compared to low wattage HID-lamps.

Typical parameters:

Colour temperature: any desired type, but warm white is produced with less efficacy compared to ‘cold’ white light types;

Lamp life is more than 15 000 h;

Lamp efficacy is 60–100 lm/W;

Colour rendition: 70–95.

II-10. GLOSSARY

Colour rendition	The degree to which colours look natural under the light; the higher the better and 100 is the maximum value (= sunlight, black body radiator).
Colour temperature	Tc [K]: Indication of the light colour compared with a black body radiator expressed in degrees kelvin [K].
Efficacy [lm/W]:	Used to express the amount of light (lumen or lm) yielded per unit watt.
Lumen [lm]	The amount of light emitted by a light source expressed in the unit lumen (lm).
Temperature [B]	Quantity temperature expressed in degrees kelvin (K).
Power [W]	Quantity power (or energy supplied per unit time) to the lamp expressed in units watt (1 watt (W) = 1 joule per second).

ANNEX III.
JUSTIFICATION FOR USING STARTERS AND GLOW-SWITCHES CONTAINING SMALL AMOUNTS OF RADIOACTIVE MATERIAL (^{3}H OR ^{85}Kr) IN FLUORESCENT LAMPS

Fluorescent lamps are low pressure gas-discharge lamps in which an electric current excites mercury to emit UV-light. The emitted UV-light is subsequently transformed by the fluorescent coating into visible light. This technology is utilized in 3 main groups of lamps, namely:

- Fluorescent tubes,
- Non-integrated, and
- Integrated compact fluorescent lamps.

The main application of the conventional tube systems (see Fig. III-1 in Annex III) is used in the professional market e.g. parking lots, warehouses, offices etc. The luminaires have also some domestic applications e.g. in the cellar or garage. Non-integrated compact fluorescent lamps (see Fig. III-2 in Annex III) are principally used in professional applications such as shops, corridors in office buildings, outdoor security lighting. In households these types of lamps can be applied for desk illumination purposes. The integrated compact fluorescent lamps, well known as 'energy-savers', are mainly used in households.

The main benefits of fluorescent lamps are that they produce light with a high efficacy (50–100 lm/W) and a good colour rendition of 80–90. Due to their relatively large surface they give a diffuse light compared to point sources e.g. HID, halogen or LED-lamps.

The fluorescent lamp system consists of a fluorescent tube, a starter and a ballast [30] (see Fig. III-1 in Annex III). A starter or glow-switch is needed to ignite the lamp. The originally developed starters contain small amounts of radioactive material (i.e. up to 500 Bq ^{3}H or ^{85}Kr) and the emitted electrons are used in the ignition process. The exposure risks during the life cycle of starters are negligible and will remain well below the dose criteria of exemption. This is in particular the case for starters containing ^{3}H since the activity 500 Bq per starter is minute compared to the exemption value of 1 GBq. The risk of exposure to starters containing up to 500 Bq 85Kr is also very minimal (see also Refs. [III-1, III-2, III-3]).

Around 1980 it became technically possible to make smaller tubes and to bend them into smaller, compact lamps. The first systems were equipped with a small glow-switch built into the cap of the lamp (see Fig. III-2 of Annex III) and a separate ballast (not shown). Glow switches may contain small amounts of radioactive material for the same reason as described above for starters. Also here either ^{3}H or ^{85}Kr is used in activities up to 500 Bq per glow switch[31].

In more recent years (around 2005) one manufacturer introduced starters and glow switches that are free from radioactive material and which became available on the market. Other

[30] An electrical ballast or control gear limits and regulates the amount of current in an electrical circuit.
[31] Integrated compact fluorescent lamps do not contain radioactive material.

manufacturers have been working or still are actively working towards radioactive-free solutions. Whereas some manufacturers have not yet been able to manufacture radioactive-free alternatives, the required activity per starter has been reduced substantially over the years.

Installed luminaires can have a life expectancy of 20–30 years or even longer. As is the case for HID-lamps, the replacement of fluorescent lamps accounts for a significant proportion of the volumes sold. During replacement of the lamp, starters are also replaced. For this reason radioactive starters are still commonly used in the low cost systems.

There are now also radioactive-free electronic versions available on the market. The latter technology is, however, more expensive compared to conventional starters. The electronic version cannot be used as an alternative for systems with conventional starters since the working mechanisms of the starters differ from each other.

In summary, radioactive starters are used next to non-radioactive alternatives. Starters are essential for the ignition of the energy saving fluorescent lamps. Whereas the dose consequences of the currently produced starters are very limited and remain well below the dose criteria for exemption, the ELC continuously makes efforts to eliminate radioactivity from starters. Reliable radioactive-free alternatives have, however, not yet been developed as an industrial standard.

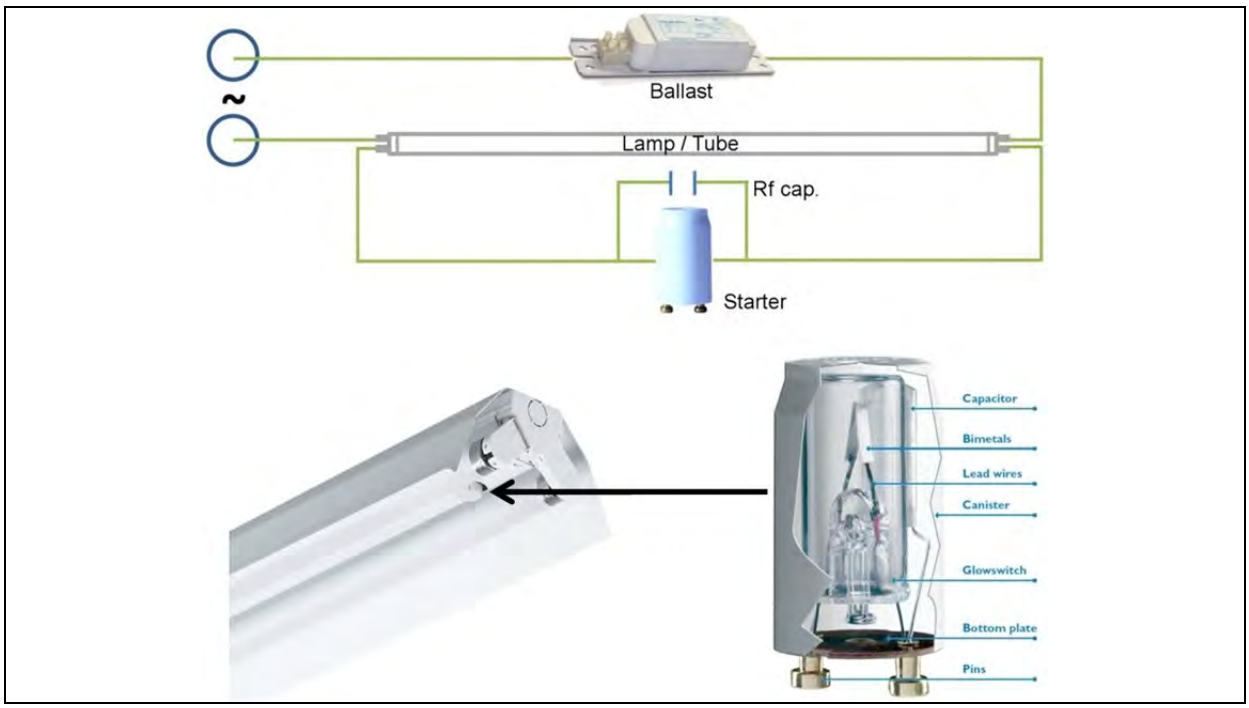

FIG. III-1. Fluorescent tube lamp system
The top picture shows the schematic diagram of the components and the working principle of the fluorescent lamp system. On the bottom left an image of a fluorescent lamp system is shown. The position of the starter in the system is indicated by the black arrow. The picture on the right shows a starter with a detail of the glow switch that is mounted inside and encapsulated by the plastic cover. (Images courtesy of Philips).

FIG. III-2. Non-integrated compact fluorescent lamp system.
The image shows a desk lamp containing a non-integrated compact fluorescent lamp. The lamp on the right hand side and the glow switch that is built into the base of the lamp is shown separately underneath the lamp. (Images courtesy of Philips)

REFERENCES TO ANNEX III

[III-1] EUROPEAN COMMISSION, A Review 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 Shaw, J., Dunderdale, J., Paynter, R.A. NRPB Occupational Services Department, Radiation Protection 146, Final report of the study contract for the European Commission B4-3040/2001/327150/MAR/C4, EC, Brussels (2007). http://ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/146.pdf

[III-2] EUROPEAN COMMISSION, Transport of Consumer Goods containing Small Quantities of Radioactive Material, Radiation Protection – Sealed Radioactive Sources – Leakage Test Method, NRPB-GRS-2001, EC Contract Number: 4.1020/D/99-006 (DG TREN), EC, Brussels (2001).

[III-3] ELEVELD, H., PRUPPERS, M.J.M., (Report in Dutch), Schattingen van de individuele en collectieve doses als gevolg van consumentenproducten waarin radioactieve stoffen zijn verwerkt, RIVM-rapport 610310 005, RIVM Rijksinstituut voor Volksgezondheid en Milieu, Bilthoven, NL (2000). http://www.rivm.nl/bibliotheek/rapporten/610310005.html

ANNEX IV.
QL-INDUCTION LAMPS CONTAINING SMALL AMOUNTS OF ^{85}Kr

In QL-induction lamp is a gas discharge lamp in which electrical energy is supplied to the mercury vapour by means of a high frequency electromagnetic field without any electrodes (see Fig. I-5 in Annex I). As for HID-lamps, ^{85}Kr is added as an ignition aid to the noble gas filling of these lamps. Since electrodes are absent, the life time can be up to 60 000 hours or about 15 years. The operational reliability during its relative extremely long life time and its energy efficient manner to produce light are benefits that justify the use of ^{85}Kr.

The maximal ^{85}Kr-activity added to QL-lamps depends on the size of the spherical bulb and does not exceed 5 000 Bq. The dose consequences, due to external exposure to gamma-radiation during normal conditions and submersion following an accident, will not differ from those described for HID-lamps containing up to 10 000 Bq ^{85}Kr in this study.

In contrast to HID-lamps, the bulb of QL-lamps is made of glass with a minimal thickness of 0.4 mm. This thickness of less than 1 mm will, therefore, not completely attenuate the emitted beta-radiation emitted within the lamp bulb [IV-1]. The skin dose resulting from manual handling of QL-lamps may be more elevated compared to HID-lamps. For the reasons described in the paragraphs on the radiological assessment for professional use and on comparison to exemption levels in [IV-2], the resulting increase of the skin equivalent dose will be rather limited. Again, the critical exposure pathway determining the exemption level for total activity of 10 000 Bq ^{85}Kr is based on external exposure of the skin to the emitted beta-radiation during handling of a source [IV-2]. Although the total activity within a practice may exceed the exemption level, a person will at any time only handle lamps with an activity of no more than 5 000 Bq. Even if beta-particle attenuation by the 0.4 mm of glass bulb is not taken into account, the beta-particle fluence rate per cm^2 is, due to the area of the bulb surface of at least 230 cm^2, substantially smaller compared to the area of 0.5 cm^2 described for the 10 000 Bq ^{85}Kr-source used for the skin exposure model described in [IV-2]. For these reasons, the dose limit for the skin will not be exceeded for any 1 cm^2 area of skin.

In conclusion, the justification and optimization requirements for using ^{85}Kr in QL-lamps are similar to those described for HID-lamps. The radiological consequences due to exposure to QL-lamps will not differ from those described for HID-lamps.

REFERENCES TO ANNEX IV

[IV-1] DELACROIX, D., GUERRE, J.P., LEBLANC, P., HICKMAN, C., Radionuclide and Radiation Protection Data Handbook 2002, Radiation Protection Dosimetry Vol. 98, No. 1, (2002).

[IV-2] EUROPEAN COMMISSION, Principles and Methods for Establishing Concentrations and Quantities (Exemption Values) Below which Reporting is not Required in the European Directive, Doc. XI-028/93 Radiation Protection 65, EC, Brussels (1993).

ANNEX V.
THE USE OF FUNCTIONALITY TESTS IN DEMONSTRATING LEAK TIGHTNESS OF ARC TUBES

V-1. EXCERPT FROM THE NUREG-1556 PUBLICATION ON CONSOLIDATED GUIDANCE ABOUT MATERIAL LICENSES [V-1]

Chapter 9 Information required for specific types of distribution licenses

Paragraph 9.3 10 CFR 32.14: CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

Under 10 CFR 30.15, persons who apply or incorporate by-product material into or who initially transfer or distribute products such as electron tubes, watches with luminous paint, or ionizing radiation measuring instruments containing calibration sources to persons exempt from licensing, must have a license pursuant to §32.14, 'Certain items containing by-product material; requirements for license to apply or initially transfer.' The product information as outlined in §§ 32.14, 32.15, and 32.16 must be provided for review in order to obtain an exempt distribution license.

For electron tubes, lamps, etc., applicants can use mathematical calculations or functionality tests to demonstrate and verify that each product contains no more than the quantity of by-product material specified for that product, pursuant to §32.14(c). The functionality tests may involve testing each tube or lamp to confirm that it works and that the light output is within the range known for that tube or lamp for which the specific activity has been determined. *Non-working product or below par output are considered indicative of leaking tubes.*

V-2. EXAMPLE OF A SAFETY TESTING PROGRAMME FOR THE TRANSPORT OF PACKAGES OF LAMPS

A number of standard tests are used to ensure that packages of lamps are protected during transport until the end-user. A programme of tests is executed for every new lamp type or new package design and includes conditioning, drop, rolling, toppling, vibration, stacking and impact tests. The following test programme is an example of that used by one of the members of the European Lamp Company Federation (ELC) and is derived from ISO-norm requirements. Other ELC-members use similar test programmes.

ISO 2206 (1986)	Packaging - Complete, filled transport packages - Part I: Identification of parts when testing.
ISO 2233 (1986)	Packaging - Complete, filled transport packages - Conditioning for testing.
ISO 2248 (1985)	Packaging - Complete, filled transport packages – Vertical impact test by dropping.
ISO 2876 (1985)	Packaging - Complete, filled transport packages – Rolling test.
ISO 8768 (1986)	Packaging - Complete, filled transport packages - Toppling test.

ISO 2247 (1985)	Packaging - Complete, filled transport packages - Vibration test at fixed low frequency.
ISO 2234 (1985)	Packaging - Complete, filled transport packages - Stacking tests using static load.
ISO 2874 (1985)	Packaging - Complete, filled transport packages - Stacking test using compression tester.
ISO 2244 (1985)	Packaging - Complete filled transport packages - Horizontal impact test (horizontal or inclined plane test).
ISO/TC122/ SC3N444 (1986)	Packing - Complete, filled transport packages - Stability testing of unitized loads; rotational drop test.

REFERENCES TO ANNEX V

[V-1] NUCLEAR REGULATORY COMMISSION, Consolidated Guidance about Materials Licenses, Program-Specific Guidance about Exempt Distribution Licenses, NUREG-1556, Vol. 8, NRC-1556, Office of Nuclear Material Safety and Safeguards, Washington DC (1998).

ANNEX VI.
DOSE CALCULATIONS FOR SCENARIOS OF EXPOSURE TO LAMPS CONTAINING SMALL AMOUNTS OF ^{85}Kr

VI-1. INCREASE OF THE EFFECTIVE DOSE DURING NORMAL OCCUPATIONAL EXPOSURE TO INTACT LAMPS CONTAINING SMALL AMOUNTS OF ^{85}Kr

The radionuclide ^{85}Kr is contained in the arc tube of the lamp. The arc tube and the glass envelope provide effective shielding against the emitted beta-radiation [VI-1]. The stopping of beta-particles generates, however, bremsstrahlung and this production is relatively important since the beta-particle emission probability (100%) is relatively high compared to the emitted gamma-radiation (0.4%). The bremsstrahlung contribution is considered equal to that of gamma-emission [VI-2]. In summary, when lamps are intact only photon radiation contributes to the dose in the surrounding environment.

The codes of the programme Microshield Version 8.01 (Grove Software Inc., Lynchburg, USA 2008) were used to calculate contribution of the emitted gamma-radiation to the ambient dose equivalent rate at 10 mm depth and the directional dose equivalent rate at 0.07 mm depth as defined in [VI-3][32]. The calculated values are multiplied with a factor 2 in order to take the bremsstrahlung contribution into account. At a distance of 10 cm from surface of the pallet, both operational radiation protection quantities increase with a value of 50 nSv per hour. At a distance of 1 meter from the surface of the pallet both dose rates increase with a value of 8 nSv per hour.

The maximum activity that can be loaded is described in paragraph 2.d 'Operational Dose Rates Close to Pallet Stacked with lamps'. For a conservative approach a pallet of 1 m^3 is assumed to contain 20 MBq ^{85}Kr.

Annual occupational exposure at 1 meter distance from one pallet containing 20 MBq ^{85}Kr during 400h:

Annual increase of effective dose due to occupational exposure to lamps containing ^{85}Kr

$$= 8 \text{ nSv/h} \times 400 \text{ h/a} = 3.2 \text{ µSv per year}$$

VI-2. INCREASE OF THE EQUIVALENT DOSE IN SKIN DUE TO OCCUPATIONAL EXPOSURE TO INTACT LAMPS CONTAINING SMALL AMOUNTS OF ^{85}Kr

During manual handling any surface of the skin can only be exposed to the radiation emitted by a single lamp. As a consequence, any surface of the skin will not be in close contact to an ^{85}Kr activity exceeding the exemption level of 10,000 Bq defined in Schedule I of the BSS [VI-5]. The skin is, due to the lamp design and configuration, effectively protected against the emitted beta-radiation that would otherwise dominantly contribute to the equivalent skin dose.

Calculations were done for a typical lamp described having a diameter of 2 cm. The arc tube containing ^{85}Kr is centered in the middle of the lamp, is 1 cm long and has a diameter

[32] Where applicable in this study, this programme was also used to calculate the effective dose and the equivalent skin dose as defined in [VI-4].

of 0.7 cm and contains an activity of up to 300 Bq. For a conservative assumption, the dose rate is calculated at 1 cm distance from a point source having an ^{85}Kr activity of 10 000 Bq. The codes of the programme Microshield Version 8.01 (Grove Software Inc., Lynchburg, USA 2008) were used to calculate the contribution of the emitted gamma-radiation to the directional dose equivalent rate at 0.07 mm depth. The dose rate increases with a value of 40 nSv per hour. This value was doubled to 80 nSv per hour in order to take the bremsstrahlung contribution into account.

An annual exposure time of 10 hours for direct contact during manual handling is assumed according to EU-RP-65.

Annual occupational skin exposure to lamps, each containing 10 000 Bq ^{85}Kr during 10 hours of direct contact per year:

$$= 80 \text{ nSv/h} \times 10 \text{ h/a} = 800 \text{ nSv per year}$$

$$= 0.8 \text{ µSv per year}$$

VI-3. SUBMERSION TO ^{85}Kr UNDER INCIDENT CONDITIONS DUE TO LOSS OF CONTAINMENT.

The radiological consequences of loss of containment of ^{85}Kr were evaluated according to the Q-system described in the advisory material published by the IAEA for the safe transport of radioactive material [VI-6].

- The instantaneous release of a consignment of 20 pallets of lamps products equaling to an activity of 400 MBq ^{85}Kr;
- Krypton-85 is released and uniformly distributed into a storeroom of dimensions 3 m × 10 × 10 m^3;
- The storeroom is ventilated with four air changes per hour; i.e. the ^{85}Kr-air concentrations fall exponentially with a decay constant of 4 h^{-1};
- A person is exposed during 0.5 h. For a conservative approach, full decay of the concentration is assumed.
- The dose coefficients to estimate the increase of the effective dose due to submersion to ^{85}Kr = 2.40 E-16 $Sv.Bq^{-1}.s^{-1}.m^3$;
- The dose coefficients to estimate the increase of the skin equivalent dose due to submersion to ^{85}Kr = 1.32 E-14 $Sv.Bq^{-1}.s^{-1}.m^3$;
- Increase of the effective dose due to submersion to ^{85}Kr under incident conditions:

$$= \quad 2.40 \text{ E-16 } Sv.Bq^{-1}.s^{-1}.m^3 \times 60 \text{ sec/min} \times 60 \text{ min/h} \times 1/4 \text{ } 1/h^{-1} \times 400 \text{ MBq} / 300 \text{ } m^3$$

$$= \quad 0.3 \text{ µSv per incident}$$

VI-4. INCREASE OF THE SKIN EQUIVALENT DOSE DUE TO SUBMERSION TO ^{85}Kr UNDER INCIDENT CONDITIONS

The increase of the skin equivalent dose due to submersion to ^{85}Kr under incident conditions is given by:

$$\text{Increase} = 1.32\ \text{E-14 Sv.Bq}^{-1}.\text{s}^{-1}.\text{m}^3 \times 60\ \text{sec/min} \times 60\ \text{min/h} \times 1/4\ 1/\text{h}^{-1} \times 400\ \text{MBq} / 300\ \text{m}^3$$

$$= \quad 16\ \mu\text{Sv per incident}$$

REFERENCES TO ANNEX VI

[VI-1] DELACROIX, D., GUERRE, J.P., Radionuclide and Radiation Protection Data Handbook 2002, Radiation Protection Dosimetry Vol. 98, No. 1, (2002).

[VI-2] HER MAJESTY'S STATIONARY OFFICE, Handbook of Radiological Protection Part 1: Data prepared by a panel of the Radioactive Substances Advisory Committee, London (1971).

[VI-3] INTERATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Data for Use in Protection against External Radiation, ICRP Publication 51**,** Annals of the ICRP, Vol. 17 No. 2/3, Pergamon Press, .Oxford and New York (1987).

[VI-4] INTERATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Conversion Coefficients for use in Radiological Protection against External Radiation, ICRP Publication 74, Annals of the ICRP, Vol. 26, No. 3/4, Pergamon, (1996).

[VI-5] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards – Interim Edition, IAEA Safety Standards Series GSR Part 3 (Interim), IAEA, Vienna (2011).

[VI-6] INTERNATIONAL ATOMIC ENERGY AGENCY, Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, IAEA Safety Standards Series No. TS-G-1.1 (Rev. 1), IAEA, Vienna (2008).

ANNEX VII.
THORIUM-232 DECAY SERIES

	Half-life	Mode of decay[a]	Gamma energy (keV)[b]
^{232}Th	1.405×10^{10} a	Alpha	
^{228}Ra	5.75 a	Beta	
^{228}Ac	6.15 h	Beta	911.204 (25.8%), 968.971 (15.8%)
^{228}Th	1.912 a	Alpha	
^{224}Ra	3.66 d	Alpha	240.986 (4.10%)
^{220}Rn	55.6 s	Alpha	
^{216}Po	0.145 s	Alpha	
^{212}Pb	10.64 h	Beta	238.632 (43.6%)
^{212}Bi	60.55 min	Beta 64.06% Alpha 35.94%	727.330 (6.67%)
^{212}Po	0.299 µs	Alpha	
^{208}Tl	3.053 min	Beta	583.191 (84.5%), 2614.533 (99.16%)
^{208}Pb	Stable	–	

[a] Only major modes of decay are shown.

[b] Only major gamma emissions of interest are shown.

ANNEX VIII.
DOSE CALCULATIONS FOR SCENARIOS OF EXPOSURE TO LAMPS CONTAINING ^{232}Th

In addition to the dose results in the aforementioned independent studies, dose calculations were made according to the conditions of the EC Directive Doc. XI-028/93-Radiation Protection 65 [VIII-1] and sophisticated codes of computer modelling Microshield V. 8.03. For the calculations ^{232}Th was assumed in the equilibrium with the progenies (= Th-nat) as a conservative approach.

VIII-1. EXAMPLE 1 - TRANSPORT ACCIDENT: BROKEN LAMPS

Parameters:

Twenty pallets with altogether 2 000 lamps (2 000 × 1 000 Bq/lamp) are involved in an accident and all the lamps are fully destroyed. The radioactive parts are fixed inside the Tungsten matrix and can therefore be collected and put into a box were they can be disposed afterwards. The exposure is caused by the gamma- and beta radiation of the electrodes. The dose contribution of the alpha radiation is not relevant due to the low reach in air (few centimeters).

The time for collecting the lamp parts is assumed to 2 hours/employee. This example over estimates the dose because the employees who handle the metal and glass parts will wear gloves to protect the skin from injuries.

External exposure by handling

E = $H_{Skin} \times W_{Skin} \times$ (contact/body);

H_{Skin} = $A_S \times T \times (R_7 + R_{24})$ = equivalent dose of skin;

A_S = $C \times U$ = activity of contaminated area;

C = Activity concentration of the radiation source max. 72 Bq/g;

U = Relation mass/surface (17.1) g/cm²;

R_7 = Equivalent dose rate by gamma for skin = 1.65 × E-7 (Sv/h)/(Bq/cm²);

T = 2 h;

R_{24} = Equivalent dose rate by beta radiation = 1.94 × E-6 (Sv/h)/(Bq/cm²);

contact = 100 cm² area; body = 1E+4 cm² area;

W_{Skin} = Tissue weight factor skin = 1E-2;

E = <u>0.52 µSv/accident</u>

VIII-2. EXAMPLE 2 - WAREHOUSE ACCIDENT FIRE SCENARIOS

Fire: Contamination of the skin

This pathway considers a warehouse fire in which the radioactive source is ignited. The fraction of the source which is combustible into ash is assumed to be 0.1% for solid waste forms. For skin contamination it is assumed that the ash is deposited over a large area of the

workplace, to a thickness of 0.1 mm. The skin dose was calculated assuming that a skin area of 100 cm^2 was exposed to the deposit for 10 minutes. This is likely to be the parts of the face or the back of the hands, where the skin thickness is only 40 μm.

Parameters

The total amount of burned sources will be 24 palettes and therefore about 144 Mercury Short Arc Lamps each with 4 500 Bq = 648 kBq ^{232}Th (max. value)

The ash will be spread over the workplace up to a deposit thickness of 0.1 mm.

Exposure time T = 10 Minutes = 0.16h

Skin dose via skin contamination:

H_{Skin} =	$As \times T \times (R_7 + R_8) \times s$
R_7 =	Equivalent dose rate for the basal cell layer by gamma radiation ^{232}Th: 1.65E-07 (Sv/h) / (Bq/cm²)
R_8 =	Equivalent dose rate for the basal cell layer by beta radiation ^{232}Th: 9.46E-06 (Sv/h) / (Bq/cm²)
s =	Incident probability of an event during a year (1E-2/a)
A =	Activity of source before ignition (144 × 4 500 Bq)
c =	Fraction of source which is combusted into ash (= 1E-3)
As =	(A × c) / AREA= 648 000 × 1E-3 / 86 400 = 7.5E-3 Bq/cm²

The ash covered area will be determined as follow:

AREA =	(M × c) / (ρ × t) = 86 400 cm²
M =	Mass of the source at the beginning of the fire (144 × 3 000 g)
c =	Fraction of source which is combusted into ash (= 1E-3)
P =	Density of deposit on surface (= 0.5 g/cm^3)
T =	Thickness of deposit (1E-2 cm)

Effective dose by skin contamination:

E =	$H_{Skin} \times w_{Skin} \times$ (CONTACT / BODY)
w_{Skin}=	Weighting factor for the skin (0.01)
CONTACT =	Area of the skin contamination (100 cm²)
BODY =	Total skin area (1E+4 cm²)
H_{Skin} =	7.5E-3 × 0.16 × (1.65E-7+ 9.46E-6) × 0.01 = 1.16 E-10 Sv
E =	0.116 nSv × 0.01 × (100/1E+4)
E =	0.01 pSv

Fire: Inhalation of dust or volatiles

This pathway considers the same fire as previously described, in which a person inhales the combustion products for 10 minutes. This could occur even after the fire is extinguished, if the air remains burdened with combustion products. It is assumed that 100% of the combusted fraction (according to NUREG 1717 [VIII-2] = 0.1% for all other waste forms) fills a room of 32 m^3 and remains at the same air concentration for at least 10 minutes.

Effective dose for inhalation of aerosols and ash in case of fire:

E =	$X \times T \times INH \times R_{10} \times s$
E=	Annual effective dose
X =	Activity per unit volume of air (Bq/m^3) due to fire
T =	Exposure time 10 min.
INH =	Breathing rate (1 m^3/h)
R_{10} =	Effective dose coefficient ^{232}Th: 1.53E-04 Sv/Bq
s =	Probability of exposure during one year = 1E-2/a

Calculation of activity per unit volume:

X =	$(A \times c) / VOL$
A =	Activity of the radiation source prior combustion
c =	Fraction of the radiation source, combusted to ash (= 10^{-3})
VOL=	Volume of the location wherein combustion takes place (proposal = 32 m^3, e.g. warehouse)

Therefore:

E =	$(A \times c \times T \times INH \times R_{10} \times s) / VOL$
E =	<u>5.0 µSv</u>

Fire: External dose from combustion products

In this scenario it is assumed that the fire in the previous scenario forms a cloud which persists for at least 10 minutes, in which time an individual will be exposed by an external dose from the gamma- and beta-radiation within the cloud. It is assumed that 100% of the combustible fraction fills a room of 32 m^3, with the same air concentration for 10 minutes.

Effective dose caused by external beta- and gamma radiation exposure:

E =	$(X \times T ((R_1 \times CF1) + (R_2 \times CF2 \times w_{Skin}))s/h$
T =	Exposure time (= 0.16h)
R_1 =	Average photon energy per nuclear transformation ^{232}Th: 2.52E+00 MeV
CF1=	Effective dose rate within a cloud of 1 Bq/m^3 per MeV gamma energy (1.6E-6 (Sv/h) / (MeV(Bq/m^3)))

R_2 = Average beta energy per nuclear transformation
^{232}Th: 1.37E+00 MeV

CF2 = Dose equivalent rate on the skin within a cloud of 1 Bq/m³ per MeV beta energy (2E-6 (Sv/h)/(MeV(Bq/m³)))

w_{skin} = Weighting factor for the skin (0.01)

s = Probability of exposure during one year (0.01)

h = Number of hours (8 760 h/a)

Calculation of activity per unit volume:

X = (A × c) / VOL

A = Activity (= 6.5E+5Bq)

c = Fraction of radiation source, combusted to ash (= 1E-3)

VOL= Volume of the location where combustion takes place (= 32 m^3)

X = 20.25 Bq/m³

E = <u>0.025 nSv</u>

VIII-3. EXAMPLE 3 — END OF LIFE — TREATMENT AND DISPOSAL

Ingestion of Thoriated Electrode (child swallows an electrode on a landfill)

E = C × M_1 × f × R_9 × decay × s

C = Activity concentration of electrode material 72 Bq/g max.

M_1 = Mass of electrode = 100E-3 g, only small electrodes can be swallowed

f = Swallowed part of electrode = 100%

R9 = Effective dose coefficient for incorporation by ingestion
^{232}Th sec = 4.93 × E- 6 Sv/Bq

including follow up dose

decay = Factor 1

s = Probability of exposure during one year (0.01)

E = <u>0.36 µSv</u>

Ingestion of a thoriated electrode is considered an exceptional case because the initial sharp glass scratches would probably prevent intake. Additionally, the resorption of the ^{232}Th in such form (bounded in the tungsten matrix) will not be complete in the body.

VIII-4. EXAMPLE 4 – ASSEMBLEY OF LAMPS INTO LUMINARIES

The quartz glass completely shields alpha and beta radiation from the encapsulated ^{232}Th. However, some exposure from gamma radiation can be expected. The thickness of the quartz glass is typically 4mm and the tungsten matrix has the dimensions 20 mm ×18 mm.

Parameters:

A = ^{232}Th activity/lamp (= 4 500 Bq max.)

t = Exposure time (= 200 h/a)

d = Handling distance (0.2 m)

Dr = Effective dose rate calculated by Software Microshield 8.0
= 0.0288 µSv/h

E = Annual effective dose = 0.0288 µSv/h × 200

= 5.76 µSv/a

D_{skin} = Effective skin dose rate calculated by Software Micro Shield 8.0
= 0.0246 µSv/h

E_{skin} = Annual skin dose = 0.0246 µSv/h × 200

= 4.9 µSv/a

REFERENCES TO ANNEX VIII

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[VIII-2] NUCLEAR REGULATORY COMMISSION, Systematic Radiological Assessment of Exemptions for Source and By-product Materials, NUREG-1717, Office of Nuclear Regulatory Research, Washington, DC. (2001) http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1717/nureg-1717.pdf

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