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(FSME-12-034, April, Other, IAEA Draft DS401)

April 11, 2012

ALL AGREEMENT AND NON-AGREEMENT STATES STATE LIAISON OFFICERS

**OPPORTUNITY TO REVIEW AND COMMENT ON INTERNATIONAL ATOMIC ENERGY AGENCY (IAEA) DRAFT SAFETY GUIDE DS401, "IAEA DRAFT SAFETY STANDARD – APPLICATION OF THE PRINCIPLE OF JUSTIFICATION TO PRACTICES, INCLUDING NON-MEDICAL HUMAN IMAGING" (FSME-12-034)**

**Purpose:** To provide States with opportunity to review and comment on the Draft Safety Guide DS401, "IAEA Draft Safety Standard – Application of the Principle of Justification to Practices, including Non-Medical Human Imaging." **We would appreciate receiving any comments<sup>1,2,3</sup> by April 30, 2012.**

**Background:** Draft Safety Guide DS401, "IAEA Draft Safety Standard – Application of the Principle of Justification to Practices, including Non-Medical Human Imaging."

**Discussion:** NRC has been provided the Draft Safety Guide DS401, "IAEA Draft Safety Standard – Application of the Principle of Justification to Practices, including Non-Medical Human Imaging" for Member State review and comment. A revised version was previously

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<sup>1</sup> This information request has been approved by OMB 3150-0029 expiration 11/30/2013. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and FOIA/Privacy Services Branch (T-5F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to [infocollects@nrc.gov](mailto:infocollects@nrc.gov), and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0029), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

<sup>2</sup> This information request has been approved by OMB 3150-0200, expiration 08/31/2012. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and FOIA/Privacy Services Branch (T-5F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to [infocollects@nrc.gov](mailto:infocollects@nrc.gov), and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0200), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

<sup>3</sup> This information request has been approved by OMB 3150-0163, expiration 01/31/2013. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and FOIA/Privacy Services Branch (T-5F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to [infocollects@nrc.gov](mailto:infocollects@nrc.gov), and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0163), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

re-submitted for Safety Committee review in October 2011. We are also providing a copy of the latest version of the IAEA comment resolution table for the October 2011 version of DS401. Please note, that all of NRC's editorial comments were accepted and most of the substantive comments as well.

We regret the short time frame for review. A blank template for comment preparation is enclosed for your use. If you have any questions regarding this correspondence, please contact me or the individual named below.

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Enclosures:

1. DS401
2. IAEA Comment Resolution Table
3. IAEA Comments Template

DS401

Date: January 2012

# IAEA SAFETY STANDARDS

for protecting people and the environment

Status: For Member State comment.

Closing date for comment: 7 June 2012.

## Application of the Principle of Justification to Practices, including Non-Medical Human Imaging

DRAFT SAFETY GUIDE

**DS401**

New Safety Guide



**IAEA**

International Atomic Energy Agency

## **FOREWORD**

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DRAFT

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# 1. INTRODUCTION

## BACKGROUND

1.1. The fundamental safety objective given in the Fundamental Safety Principles [1] is to protect people and the environment from harmful effects of ionizing radiation. Ten safety principles are stated and their intent and purpose are briefly explained. The fourth principle states “facilities and activities that give rise to radiation risks must yield an overall benefit”. The Safety Requirements: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (the BSS) [2], in elaborating requirements in order to implement this principle state “the government or regulatory body, as appropriate, shall ensure that provision is made for the justification of any type of practice and for review of the justification, as necessary, and shall ensure that only justified practices are authorized”.

1.2. A “practice” is 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 [2]. Justification is the process of comparing the benefits to individuals and to society from introducing or continuing a practice with the harm (including radiation detriment) resulting from the practice.

1.3. When the principle was first formally expressed, many types of practice were already in widespread use, especially in the medical and industrial fields, and, in general, their justification was implicit. Others, particularly the generation of electrical energy by nuclear fission, are matters of national policy and their justification involves many aspects other than just radiation safety. The justification for yet others was considered during the development of specific safety standards for those types of practice. The question, however, has been raised from time to time as to whether there is a need for generic guidance on the application of the principle during the authorization of practices, particularly those that may cause radiation exposure of members of the public.

1.4. In recent years, practices involving deliberate exposure of persons – both workers and members of the public – for non-medical purposes, such as security screening, have been proposed or introduced [3, 4]. Provisions relating to these exposure types – referred to as human imaging using radiation for purposes other than medical diagnosis, medical treatment or biomedical research – are given in the BSS [2], but decisions on their justification are left to national governments and regulatory bodies. A survey showed that human imaging for purposes other than medical diagnosis, medical treatment or biomedical research is being performed for many different purposes in many countries [5]. It also showed there was a lack of formal justification of some uses of radiation for these purposes.

1.5. While international consensus on the acceptability of all types of practice is unlikely to be achievable, it was felt that international guidance would be desirable on the process that governments and national authorities should use in determining whether a proposed new or an existing type of practice is justified. The present Safety Guide has therefore been prepared in response to this. It is particularly relevant to the application of the principle of justification to the approval of consumer products and of practices involving deliberate exposure of persons for non-medical purposes. The

approach may however also be relevant to a broader range of practices. The intention is that by applying the approach given in the Safety Guide, governments and national authorities will be better able to reach consistent and transparent decisions on the justification of types of practice.

## OBJECTIVE

1.6. The objective of this Safety Guide is to provide guidance to governments and regulatory bodies, on the approach that should be adopted when considering whether a particular type of practice is justified. It is intended to assist them in their decision-making process when they are confronted with the need or a request to authorize a novel type of practice or the need to review an already established type of practice. It also provides some guidance to those wishing to demonstrate to governments or regulatory bodies that a particular type of practice is justified. It should be seen as complementing the guidance given in the IAEA Safety Guide on the Regulatory Control of Radiation Sources [6].

## SCOPE

1.7. This Safety Guide covers the elements that should be considered and the process that should be applied in determining whether a particular type of practice is justified. It was developed to assist governments and regulatory bodies with particularly challenging proposals, primarily consumer products, the use of radioactive sources in lightning protection systems and tritium exit sign, and human imaging for purposes other than medical diagnosis, medical treatment or biomedical research, such as security screening at airports. It may also be used in reviewing an already established type of practice.

## STRUCTURE

1.8. Section 2 describes the principle of justification of practices given in the BSS, those types of practice already deemed not to be justified and the relationship between the justification principle and its sister principle of optimization of protection and safety. Section 3 defines the responsibilities of the relevant parties. Section 4 presents a structured approach for obtaining systematically all the relevant inputs needed to reach a decision on justification and shows how these inputs might be brought together to reach a decision regarding whether a particular proposed type of practice is justified. A separate section, Section 5, discusses the issues associated with the application of the justification principle to proposed uses of radiation for human imaging for non-medical purposes, such as security screening at airports. The Annexes give examples of decisions taken by governments or national authorities; however they are not part of this Safety Standard and should not be used to indicate any endorsement of these national decisions by IAEA Member States as a whole.



## 2. THE PRINCIPLE OF JUSTIFICATION OF PRACTICES

### GENERAL

2.1. The principle of justification is both simple and logical in concept: practices should produce a positive net benefit to the exposed individuals or to society. This principle 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 [2] however explicitly require a demonstration of a positive net benefit before a practice can be authorized by the regulatory body. This presents the regulatory body with some difficulty. While the regulatory body should be competent in assessing the radiological detriment associated with a given type of practice, it is unlikely to have any special competence in assessing other types of detriment or in determining benefit. A consequence may be that any judgements made will reflect the personal views of the individual decision maker rather than society as a whole. To avoid this, some mechanism should be set up within a country to ensure that an appropriate level of consultation takes place, commensurate with the radiological and social significance of the type of practice, before it can be considered as either justified or unjustified, see para. 3.18.

2.2. The justification requirement in the BSS [2] has its origins in the recommendations of the International Commission on Radiological Protection (ICRP), the latest version of which are given in ICRP Publication 103 [7]. From these recommendations, a number of indications as to the intent of ICRP can be extracted. The ICRP notes “the consequences [of activities involving an increased level of radiation exposure, or a risk of potential exposure] to be considered are not confined to those associated with the radiation – they include other risks and the costs and benefits of the activity. Sometimes, the radiation detriment will be a small part of the total harm. Justification thus goes far beyond the scope of radiological protection, and also involves the consideration of economic, societal and environmental factors. It is for these reasons that the Commission only recommends that justification requires that the net benefit be positive. To search for the best of all the available alternatives is a task beyond the responsibility of radiological protection authorities”.

2.3. The ICRP recommendations have a number of implications. First, those concerned with radiation protection should be satisfied that a given type of practice has benefits that exceed the radiological risk. Thus, it is not their responsibility to act as surrogates for the eventual user of the practice to decide whether the benefits outweigh all of the costs<sup>1</sup>. Second, in general, it is not their responsibility to make comparisons with non-radioactive or non-radiation emitting alternatives and to decide on behalf of the user which is the preferred alternative.

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<sup>1</sup> This point is well illustrated by reference to the use of radioactive sources in smoke detectors. Those concerned with radiation protection should focus on the radiation risks and the benefits from the use of the detectors for detecting fire. They do not need to concern themselves with, for example, the selling price of the detector.

2.4. The ICRP recommendations [7] go on to state “the responsibility for judging the justification usually falls on governments or national authorities to ensure an overall benefit in the broadest sense to society and thus not necessarily to each individual. However, input to the justification decision may include many aspects that could be informed by users or other organisations or persons outside of government. As such, justification decisions will often be informed by a process of public consultation, depending upon, among other things, the size of the source concerned. There are many aspects of justification, and different organisations may be involved and responsible. In this context, radiological protection considerations will serve as one input to the broader decision process”. Thus, the keys points here are that interested parties should be consulted during the process of determining the justification of a type of practice.

2.5. A further point is made in the Fundamental Safety Principles, which state: “For facilities and activities<sup>2</sup> to be considered justified, the benefits that they yield must outweigh the radiation risks to which they give rise. For the purposes of assessing benefit and risk, all significant consequences of the operation of facilities and the conduct of activities have to be taken into account” (Ref [1], para. 3.18). This means that in any assessment of radiological detriment associated with a type of practice, the exposures received from routine situations, reasonably foreseeable accidents, transport and waste disposal should be evaluated before a decision on the justification of the practice as a whole can be reached.

2.6. In the very broadest sense, a practice includes everything related to the use of a source, from manufacture to disposal. However, for the purposes of this Safety Guide, there is a need to delineate the areas of interest, particularly when considering consumer products.

2.7. The BSS [2] defines a ‘consumer product’ 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.” An explanatory note to the definition adds “this includes items such as smoke detectors and luminous dials into which radionuclides have deliberately been incorporated and ion generating tubes. It does not include ceramic tiles, spa waters, minerals and foodstuffs, and it excludes products and appliances installed in public places (e.g. exit signs)”. More generally, a consumer product is an item that is readily available to members of the public without any requirements being imposed in relation to any source of radiation therein. They may be available through commercial outlets where personal and household products are normally purchased, and there is a reasonably large market for such products, resulting in their wide scale distribution. The term ‘provider’ as used in relation to consumer products includes manufacturers, importers or other legal persons authorized by the regulatory body to provide consumer products to persons who have no regulatory obligations with respect to the product. The Safety Guide GS-G-1.5 states “There are some types of practice for which the associated risks are so small that a system of regulatory control is not required. In addition, there are some types of practice for which there is no effective

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<sup>2</sup> Practices are a subset of “facilities and activities”.

way of exercising regulatory control after large numbers of sources have been supplied to the public. Consumer products have the first characteristic, the second characteristic being an inevitable consequence of the availability of such consumer products. The only method of control is by means of the authorization of their supply. In authorizing the supply of such consumer products, the regulatory body should therefore ensure the appropriate protection of the public” (Ref. [6], paras 4.1, 4.2).

2.8. Thus, in the case of consumer products, the justification analysis should be carried out with respect to the provision of the products to the public. This should entail consideration of the benefits to the public and the radiological detriment to the public arising from the normal handling, transport and use, as well as mishandling, misuse, accident, recycling and disposal of the product. The benefits of employment to those involved in the manufacture, transport and provision of the products and the associated radiological detriment should not be part of the analysis. This approach avoids any distortion that might otherwise be caused, for example, where there is significant benefit to those who produce the products (i.e. employment) but relatively little benefit to those who use them.

2.9. In the case of human imaging for non-medical purposes, the justification analysis should be with respect to the detriment to the exposed individuals and the benefit to the individuals or society as a whole depending on the particular application. Again, it should not take account of the economic benefits and detriment to those involved in the manufacture and supply of equipment.

## JUSTIFICATION AND AUTHORIZATION

2.10. The government or regulatory body, as the case may be, should define clearly the type of practice that has been considered as justified. Once a type of practice has been recognized by government or regulatory body as being justified, there is still an obligation for a person or organization to seek an authorization for the specific practice or to be exempted from the need for an authorization.

2.11. In the case of a particular type of consumer product containing radioactive substances that is considered as being justified for use by members of the public, the authorization should relate to the provision of each variation or model of that type of product (Ref. [6], para. 4.2). Often, such authorization will be based on a demonstration of compliance with criteria that have been defined by the regulatory body. These criteria may eventually be expressed in radiation safety standards for that type of product.

2.12. In the case of other products, a further level of justification may be appropriate at the local level. For instance, if the government considers the use of X-rays for security screening of individuals at a major international airport to be justified, those responsible for security at another international airport should be required to demonstrate that their particular application of the practice is also justified. Application of X-ray screening of individuals for security purposes in other locations, such as government buildings or shops, should be regarded as a separate type of practice and subject to separate scrutiny. In addition, criteria should be established to indicate when any particular individual should be subject to screening (i.e. when it is

considered justified to apply the technique to an individual).

## PROHIBITIONS AND PRACTICES NORMALLY DEEMED TO BE NOT JUSTIFIED

2.13. The BSS state “The following practices are deemed to be not justified:

- (a) Practices, except for justified practices involving medical exposure, that result in an increase in activity, by the deliberate addition of radioactive substances or by activation, in food, beverages, cosmetics or any other commodity or product intended for ingestion or percutaneous intake by, or application to, a human person;
- (b) Practices involving the frivolous use of radiation or radioactive substances in commodities in or products such as toys and personal jewellery or adornments, which result in an increase in activity, by the deliberate addition of radioactive substances or by activation, and
- (c) Human imaging using radiation used as a form of art or for publicity purposes.” (Ref. [2], para. 3.17).

2.14. A footnote to the term “activation” in the BSS states that “this requirement is not intended to prohibit those practices that involve short-term activation of commodities or products, for which there is no increase in radioactivity in the commodity or product as supplied”. It is not the intention to prohibit commodities or products that are activated for a short time during security screening in ports.

2.15. The phrase “deliberate addition” should be taken to mean that the trace amounts of naturally occurring radioactive materials that are present in all materials need not be taken into account, when the concentrations are below the levels given in the Safety Guide [8]. “Toys” should be taken to mean any product or material designed or clearly intended for use in play by infants or children. Articles of “personal jewellery or adornment” should be taken to mean articles to be worn on the person where the radioactive substance has no function other than decoration. Thus, the deliberate use of uranium as a colouring material of items such as brooches should be regarded as an unjustified practice<sup>3</sup>.

2.16. The BSS state:

“Human imaging using radiation that is performed for occupational, legal or health insurance purposes, and is undertaken without reference to clinical indication, shall normally be deemed to be not justified. If, in exceptional

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<sup>3</sup> This blanket prohibition on the use of radioactive substances is a matter of principle, the BSS being an approved safety standard and therefore reflecting consensus achieved amongst IAEA Member States. It is therefore independent of the dose that the wearer would receive. It could of course be argued that the use of a small quantity of uranium as a colouring material in articles of personal adornment would result in negligible doses to the wearer and others and that such a blanket prohibition is unnecessarily restrictive. The final decision is made according to the circumstances of each country.

circumstances, the government or the regulatory body decides that the justification of such imaging for specific practices is to be considered, the requirements of paras 3.61 to 3.64 and 3.66 [of the BSS] shall apply”.

“Human imaging using radiation for theft detection purposes shall be deemed to be not justified”.

“Human imaging using radiation for the detection of concealed objects for anti-smuggling purposes shall normally be deemed to be not justified”. It recognizes however that there may be exceptional circumstances in which the justification of such imaging is to be considered by the government or the regulatory body. In such exceptional circumstances, the requirements of paras 3.61 to 3.67 [of the BSS] shall apply”.

“Human imaging using radiation for the detection of concealed objects that can be used for criminal acts that pose a national security threat shall be justified only by the government. If the government decides that the justification of such human imaging is to be considered, the requirements of paras 3.61 to 3.67 [of the BSS] shall apply.” (Ref. [2], paras 3.18-3.21).

2.17. These requirements are considered further in Section 5. However, the overall conclusion that can be drawn from the above at this stage is that since irradiation of persons for non-medical purposes is not to be welcomed (and, indeed, is deemed to be not justified when used for theft detection purposes), any proposed practices involving such exposure should be extremely carefully considered by the government before they can be authorized.

## RELATION WITH THE OTHER RADIATION PROTECTION REQUIREMENTS

2.18. Justification is the process of deciding whether there is a net benefit from the practice, but demonstration of net benefit is not a sufficient precondition of radiation protection for the practice to be authorized or exempted from authorization<sup>4</sup>. All of the radiation protection requirements should be considered by the regulatory body during the process of determining whether to grant an authorization or an exemption for a proposed practice. In particular, the BSS [2] require the optimization of protection and safety, including the establishment of constraints, as appropriate, for dose and risk, and the application of dose limits for public and occupational exposure. Dose limits for the public should not be applied to practices involving the use of medical equipment for human imaging for non-medical purposes.

2.19. Optimization of protection and safety is the process of deciding on the method of protection so as 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

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<sup>4</sup> Safety Guide, RS-G-1.7 [8] states, in para. 2.6 “In essence, exemption 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”.

practice involve the weighing of radiological detriment against benefit; the former, however, simply requires there to be a net benefit; the latter requires the net benefit to be maximized.

2.20. Optimization of protection and safety involves the establishment or approval of dose and risk constraints, as appropriate, for dose and risk, for the type of practice being considered. This is a general requirement of the BSS (Ref. [2], para. 3.22 (c)). In the case of the use of human imaging procedures carried out for purposes other than medical diagnosis, medical treatment or biomedical research, conducted by medical staff using medical radiological equipment, the BSS [2] (see para. 3.64 (b)) require the establishment of dose constraints instead of diagnostic reference levels<sup>5</sup>.

2.21. Regarding the use of imaging devices for the purpose of detection of concealed weapons, contraband or other objects on the body, the BSS state that these procedures “shall be considered as giving rise to public exposure” and notes that “the licensees shall apply the requirements for public exposure in planned exposure situations” (Ref. [2], para. 3.65). In particular, this means that the dose limits for public exposure apply. Furthermore, the BSS state that “optimization of protection and safety is subject to any dose constraints for public exposure set by the government or the regulatory body” (Ref. [2], para. 3.65).

2.22. Thus, the justification decision is only the first stage in (or a prior stage to) the regulatory process. The other radiation safety issues – optimization of protection and safety, including ensuring the establishment of and compliance with dose (and risk) constraints and ensuring compliance with dose limits – should be addressed in individual authorizations. Any requirements resulting from these considerations should be expressed in the specific conditions attached to authorizations and any radiation safety standards for the particular type of practice.

## EXEMPTION

2.23. Exemption is important in the context of consumer goods, for the simple reason that once such products have been supplied to members of the public, it will no longer be practical to exercise regulatory control over them (Ref. [6], para. 4.3).

2.24. The BSS provide for exemption: “the government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of [the BSS] ...” (Ref. [2], Requirement 8). The criteria for exemption of practices or sources within practices are set out in the BSS:

- (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

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<sup>5</sup> In practice, those procedures that are carried out by medical staff using medical radiological equipment may lead to doses higher than the dose limit for public exposure, so the establishment of dose constraints in this situation is particularly important.

- (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” (Ref [2], para. I-1).

2.25. Schedule I of the BSS [2] provides individual dose criterion as well as activities and activity concentrations that may be used for the purpose of exempting practices and sources within practices. In addition, provision is made for the exemption of radiation generators and equipment containing sealed radioactive sources that are of a type approved by the regulatory body, subject to defined conditions. Thus, the activities given in the BSS are not limits on the activities that can be used in products that are exempt from authorization; however, those products that contain higher levels need to be of a type approved by the regulatory body. Arrangements for type approval should therefore be incorporated into the regulatory system.

2.26. Compliance with the provisions is a necessary prerequisite for the authorization to the provision of a particular type of consumer product to members of the public. This is supported by the Safety Guide GS-G-1.5 which states “Authorization [to provide] should be based on a prior assessment of the individual and collective doses<sup>6</sup> that may be received to determine whether the criteria for exemption are likely to be met. Account should be taken of normal use, misuse and accidents and of likely methods of disposal” (Ref. [6], para. 4.3). The application of these provisions for exemption is further developed in the Safety Guide RS-G-1.7 [8].

2.27. The provisions for exemption only apply to justified practices. Thus, demonstration that a particular type of product satisfies the provisions for exemption is not sufficient and does not remove the need for a demonstration that the product is justified.

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<sup>6</sup> The criteria for exemption given in the BSS [2] are now only given in terms of individual dose. Collective dose was generally found not to be limiting. Furthermore, there are good reasons for de-emphasizing the role of collective dose which is made up of very low doses in a large number of individuals (see para. 4.15 and Ref. [7])

### 3. RESPONSIBILITIES

#### GENERAL

3.1. “A properly established legal and governmental framework for safety provides for the regulation of facilities and activities that give rise to radiation risks. There is a hierarchy of responsibilities within this framework, from governments to regulatory bodies to the organizations responsible for and the people engaged in activities involving radiation exposure. The government is responsible for the adoption within its national legal system of such legislation, regulations, and standards and measures as may be necessary to fulfil all its national and international obligations effectively, and for the establishment of an independent regulatory body. In some cases, more than one governmental organization may have the functions of a regulatory body for activities within their jurisdiction relating to the control of radiation and radioactive material” (Ref. [2], para. 1.9).

3.2. “The government or the regulatory body shall ensure that only justified practices are authorized” (Ref [2], Requirement 10). Thus, irrespective of where the responsibility for ensuring that only justified practices are authorized resides – whether with the government or has been delegated to the regulatory body – the justification of a practice should be established before the process of determining whether the practice should be authorized.

3.3. Some types of practice have a significant international dimension. For example, consumer products may be traded internationally; use of human imaging for non-medical purposes in one country may result in the exposure of people from other countries. Furthermore, lack of consistency in approaches can lead to confusion and increased anxiety. The government or the regulatory body, as the case may be, should therefore seek to cooperate with other governments or regulatory bodies with the objective of achieving as much consistency in the acceptability of particular types of practice and the standards that should be applied to those that are considered as justified.

#### GOVERNMENT

3.4. The Safety Requirements document GSR Part 1 establishes requirements for a governmental, legal and regulatory framework for safety. It states “the government shall establish a national policy and strategy for safety, the execution of which shall be subject to a graded approach, in accordance with the national circumstances and with the radiation risks associated with the facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals” (Ref. [9], Requirement 1). The safety fundamentals are given in Ref. [1].

3.5. “The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated” (Ref. [9], Requirement 2).



3.6. “The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities” (Ref. [9], Requirement 3). “The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making” (Ref. [9], Requirement 4). It notes however that the independent regulatory body will not be entirely separate from other governmental bodies and that the government has the ultimate political responsibility for involving legitimate and recognized interests in its decision making. Even so, the regulatory body should make decisions within its statutory obligation for the regulation of facilities and activities and should exercise its regulatory functions without undue pressure or constraint.

3.7. The Fundamental Safety Principles state “In many cases, decisions relating to benefit and risk are taken at the highest levels of government, such as a decision by a State to embark on a nuclear power programme. In other cases, the regulatory body may determine whether proposed facilities and activities are justified” (Ref. [1], para. 3.19). The former are often when the radiological detriment to individuals is only a small part of the total cost and the overall justification of a type of practice goes far beyond the scope of radiation safety, decisions being largely influenced by broader political, economic and social concerns. This is the case, as, for example, with the use of X-rays for security screening of individuals at airports. The decision on whether this type of practice is justified is a matter of national policy and the responsibility for it should therefore fall on the national government. Proposals of this type of practice which are of a strategic nature would normally be considered at the governmental level, although the responsibility for managing the analysis would normally be allocated to governmental organizations.

3.8. The government should determine and clarify under what conditions the regulatory body has been assigned the task of considering the justification for a given type of practice as distinct from those types of practice for which it would wish to exercise that responsibility directly itself. In general, for those types of practice where the radiological detriment is relatively low and the benefit of no great strategic significance, it would be reasonable for governments to delegate to the regulatory body responsibility for decision making regarding justification. Proposals for the introduction of such types of practice would normally arise from industry and might be regarded as falling within the routine work of the regulatory body.

3.9. “The government shall establish mechanisms to ensure that:

- (a) The activities of the regulatory body are coordinated with those of other governmental authorities ... and with national or international organizations that have related responsibilities;
- (b) Interested parties are involved as appropriate in regulatory decision making processes or regulatory decision aiding processes” (Ref [2], para. 2.19).

The requirement to involve interested parties is an important one in the context of justification of a type of practice and is developed further in the next sections.

3.10. “The government shall ensure that appropriate arrangements are in place at the national level for making decisions relating to protection and safety that fall outside the authority of the regulatory body” (Ref. [2], para. 2.20). Thus, for those types of practice of a strategic nature, the government should establish a process for determining whether or not they are justified. This may take various forms according to the nature of the proposal. At one extreme, it may involve setting up a judicial review process or public inquiry. More commonly however, it is likely to involve the establishment of a consultative process overseen by government officials. Whatever approach is adopted, it should involve consultation with interested, including affected, parties. Thus, for example, a proposal to use human imaging for non-medical purposes should involve consultation with members of the public who may be affected by it. It is considered essential that there be a broad range of interests, experience and expertise for justification decisions.

3.11. The government should also involve the regulatory body in the process in view of the fact that it should have the appropriate competence regarding the assessment of radiological risk and would be involved in the authorization of a practice that is considered as being justified.

3.12. Where human imaging for security reasons is being considered, the government should ensure that officials and experts concerned with national security are also integrated into the consultative process. Other experts to include in the process would be in the areas of privacy and ethical concerns.

3.13. Where human imaging for non-medical purposes using medical radiological equipment is being considered, the government should ensure that the appropriate professional bodies (radiologists, medical physicists, etc.), together with other important stakeholders, are integrated into the consultative process.

## REGULATORY BODY

3.14. The objective of the regulatory functions is the verification and assessment of safety in compliance with the regulatory requirements [9]. GSR Part 1 states “the regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities” (Ref. [9], Requirement 20). It is stated that “the regulatory body may decide to give formal status to the processes by which the regulatory body is provided with expert opinion and advice” (Ref. [9], para. 4.18). It goes on to require that “arrangements shall be made to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services” (Ref. [9], para. 4.20).

3.15. “The regulatory body shall ensure that regulatory control is stable and consistent” Ref. [9], Requirement 22). GSR Part 1 requires that “the regulatory process shall be a formal process that is based on specified policies, principles and associated criteria and that follows specified procedures ...” (Ref. [9], para. 4.26). The use of a formal process, involving established policies, principles and criteria, in the justification of a type of practice is important as it will facilitate consistency in decision making by the regulatory body and defence of a decision in the event that it

is challenged. In particular, it will help in preventing subjectivity in decision making by individual staff members of the regulatory body. This is particularly important in the case of consumer products if responsibility for determining whether any particular proposal is justified or not has been assigned to the regulatory body. The process used in decision making, including the reasons for any particular decision, should be transparent.

3.16. GSR Part 1 requires “the regulatory body shall review and assess relevant information – whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere – to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization” (Ref. [9], Requirement 25). As part of this review and assessment, the regulatory body should assess all risks associated with normal operations, anticipated operational occurrences and accident conditions. This is necessary for the processes of justification and of determining whether radiation risks are as low as reasonably achievable (i.e. protection is optimized). In the case of consumer products, the regulatory body should review and assess the doses arising from normal handling, transport and use, as well as mishandling, misuse, accidents and disposal of the product. The regulatory body should record the results of its reviews and assessments and any consequential decisions.

3.17. The BSS also includes requirements on safety assessment: “the regulatory body shall establish and enforce requirements for safety assessment, and the person or organization responsible for a facility or activity that gives rise to radiation risks shall conduct an appropriate safety assessment of this facility or activity” (Ref. [2], Requirement 13).

3.18. For those practices for which responsibility for ensuring that they are justified has been delegated to the regulatory body, the regulatory body should set up an appropriate mechanism to avoid the personal preferences of individual members of staff dominating. This should normally involve the establishment of an advisory body to the regulatory body comprising individuals reflecting<sup>7</sup> various interests. For example, in the case of consumer products, such a group might comprise individuals from consumer interest groups, manufacturers or providers of such products, academics and government officials. As an input to the group, the regulatory body should provide its own assessment of the radiological risks associated with the proposed practice.

3.19. In consultation with its advisory body, the regulatory body should develop guidance for use by persons or organizations seeking to demonstrate the justification for a new type of practice. This should cover the development and presentation of safety assessments, any other required safety related information, and the criteria which will be used in determining the justification.

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<sup>7</sup> The word “reflecting” rather than “representing” is important and is intended to indicate that the process is consultative rather than consensual.

3.20. In the event that the regulatory body considers the type of practice to be unjustified and therefore decides not to issue an authorization or renew an authorization, the regulatory body should provide the applicant with a statement of the reasons for its position.

3.21. The regulatory body should recognize that there may be costs and risks associated with modifying decisions regarding the justification for established types of practice. Therefore, for example, any decision to revoke the authorization of the provision to the public of a particular type of consumer product should be subject to careful scrutiny to evaluate the impact. This should include consideration of the potential impact of such a decision on those who already own this type of consumer product. Again, transparency is important and the regulatory body should consult interested parties before such decisions are made.

## APPLICANT

3.22. The first principle given in the Safety Fundamentals document [1] states “the prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks”. This is then given as requirement 5 in the Safety Requirements document [9], which states “the government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated safety requirements, as well as to demonstrate such compliance”. The BSS [2] in para. 1.8 expands on this principle: “other parties also bear certain responsibilities. For instance, suppliers of radiation generators and radioactive sources have responsibilities in relation to the design and manufacture and operating instructions for their safe use”.

3.23. The Safety Guide RS-G-1.5 notes “consumer products constitute a special category of source ... in that persons possessing them, and the public at large, may well not know that the product contains a radioactive substance and, in general, they will not be able to evaluate the significance of any radiation exposure incurred” (Ref. [6], para. 4.2). Thus, in this case, the prime responsibility for safety should reside with the manufacturer or provider of the product and it is for this reason that the only method of ensuring safety is by means of authorization of provision of consumer products to the public.

3.24. “The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization ...” (Ref. [9], Requirement 24). GSR Part 1 requires that “prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures” (Ref. [9], para. 4.33). This is further developed in the BSS which requires that “any person or organization applying for authorization ... shall submit to the regulatory body the relevant information necessary to support the application” (Ref. [2], para. 3.9). Although the information should include the “nature, likelihood and magnitude of the expected exposures due to the source”, it need not be limited to this. Indeed, applicants should also be required to submit information on the benefits associated with a type of

practice when a judgment on the justification for that type of practice is required.

3.25. The Safety Guide GS-G-1.5 states “The responsibility for conducting a generic safety assessment for a given type of practice in relation to a consumer product should rest with the manufacturer which, on the basis of the assessment, should apply to the regulatory body for an authorization to provide to the public the consumer product. The regulatory body should establish criteria for the approval of consumer products and should compare the findings of the generic safety assessment with these approval criteria. It should verify any safety assessment provided by the manufacturer” (Ref. [6], para 4.7). This means that the manufacturer or provider of the product is responsible for:

- (a) Conducting a safety assessment;
- (b) Preparing the case to demonstrate the justification of the product;
- (c) Ensuring that as far as it is within its powers protection is optimized.

3.26. In the case of those types of practice of a strategic nature that have been analyzed by the government, and considered by it as being justified, responsibility for the safety of any related equipment lies with the manufacturer or supplier. In addition, unless the practice has been exempted by the regulatory body, the user of the equipment will need to be authorized and comply with any safety requirements specified in the regulations or conditions of the authorization.

## 4. APPROACH TO JUSTIFICATION DECISIONS

### A STRUCTURED APPROACH

4.1. The government or the regulatory body, as the case may be, should use a structured and transparent approach when considering the justification for a proposed type of practice or reviewing an existing type of practice in the light of new information about its efficacy or consequences.

4.2. The approach, including the mechanism for consultation and decision making, should be established *a priori*. At the governmental level, this is likely to vary according to the type of practice to be considered. With the more routine proposals falling under the responsibility of the regulatory body, the approach will normally follow a standard procedure. Both situations should involve consultation with interested parties. In the case of decisions taken at the governmental level, the consultation should include the regulatory body, which should provide information on the radiological risks, as well as those who will be affected by the type of practice.

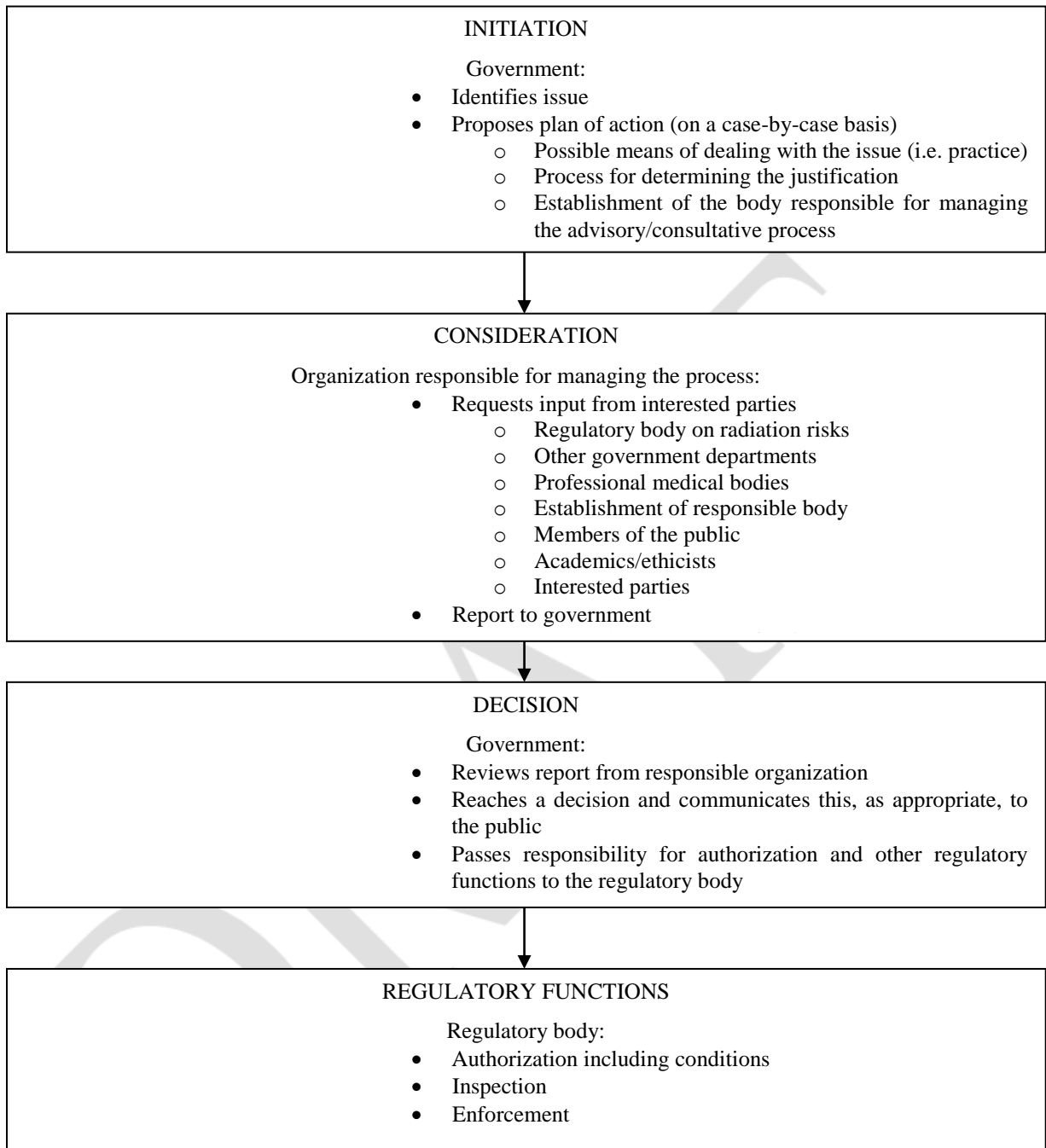
### TYPES OF PRACTICE OF A STRATEGIC NATURE

4.3. In the case of decisions that are to be taken at the governmental level, the terms of reference of committees, advisory groups, judicial inquiries, etc. and responsibility for the final decision should be clearly defined. The process should be transparent and the reasons for the final decision be clearly stated. The government should follow the steps broadly outlined in Figure 1. Application of the approach is discussed further in Section 5 with reference to the use of human imaging for non-medical purposes.

4.4. When the government has decided that a particular type of practice is justified, the regulatory body should then exercise its normal regulatory functions, which include the authorization of specific applications of the justified type of practice. The objective of these regulatory functions should be the verification and assessment of safety in compliance with regulatory requirements. The performance of these functions should provide a high degree of confidence that safety is optimized and any relevant radiological criteria that have been established, e.g. dose constraints for members of the public, are met. In particular, the regulatory body should ensure that:

- (a) Equipment is designed and constructed to meet the relevant safety requirements;
- (b) Facilities are operated within the limits and conditions specified in the safety assessment and established in the authorization and operations are carried out safely under a proper management system;
- (c) The authorized party has the human, organizational, financial and technical resources to operate the facility or equipment safely.

FIG. 1. The process to be used by the government for determining the justification of a type of practice.



## TYPES OF PRACTICE OF A ROUTINE NATURE

4.5. In the case where the regulatory body is responsible for deciding on the justification of a type of practice, the approach should be based on consultation with a formally constituted advisory body to avoid the imposition of their own personal preferences when deciding on the justification for a particular type of consumer product (see para. 3.18). The regulatory body should ensure that sufficient information is given to those being consulted to permit them to understand the risks associated with radiation exposure and to be able to place those risks in perspective with other everyday risks.

4.6. All relevant factors should be taken into account and the approach should make clear the relative importance that has been attached to any particular factor. The regulatory body should follow the process that is shown in Figure 2.

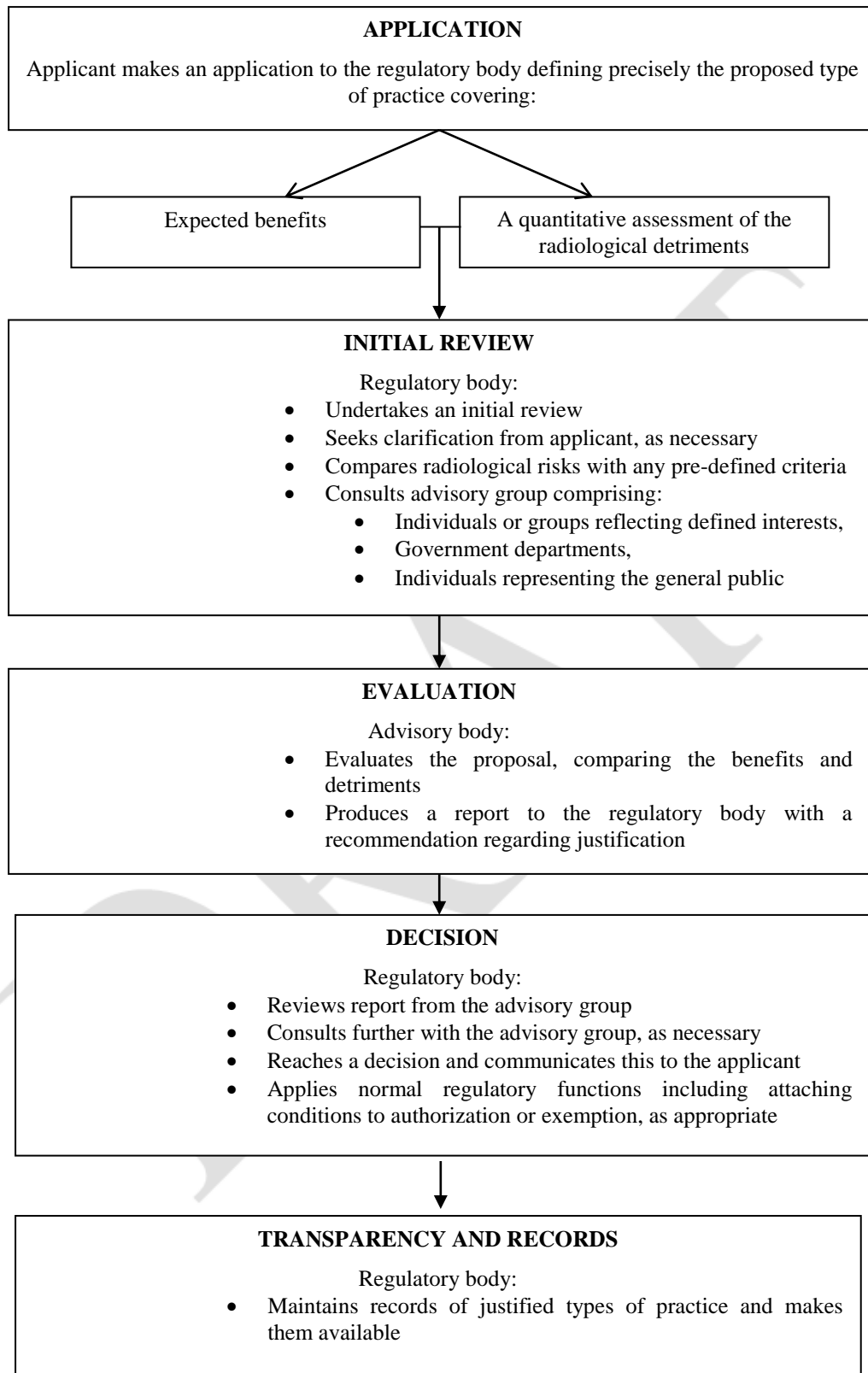
4.7. When the regulatory body has decided that a particular type of practice is justified, the regulatory body should then exercise its normal regulatory functions.

4.8. In the case of consumer products, the regulatory body should only authorize the provision of those products that comply with any criteria that it has established or defined in relevant safety standards e.g. criteria for exemption. Furthermore, the use of those products for which provision to the public has been authorized should also be exempt from authorization (see paras 2.23-2.27).

4.9. In the case of other products, such as those that are used in places to which the public have access, the regulatory body should consider whether it is necessary to authorize or exempt particular applications. Such authorizations or exemptions should define the necessary conditions to be met – the requirements for design and the conditions of use.



FIG. 2. The process to be used by the regulatory body for determining the justification of a type of practice.



## **Application**

4.10. Where the regulatory body has responsibility for ensuring that a type of practice is justified, the information that the applicant should provide to the regulatory body should include:

- (a) The applicant's name and contact details;
- (b) A description of the type of practice with drawings and diagrams, where appropriate;
- (c) A full explanation of the radiation sources that will be used and the measures that will be taken to ensure safety and reduce the radiological consequences;
- (d) An appraisal of the benefits and radiological detriments of the type of practice. This appraisal should include the economic, social, health and safety, waste management, recycling and decommissioning aspects. The assessment of the radiological detriment should cover both magnitude and likelihood of expected exposures and an assessment of the potential exposures;
- (e) An indication of the expected extent of use of the type of practice.

4.11. Applicants may find it useful to obtain the assistance of a consultant in preparing their applications to the regulatory body.

## **Initial review**

4.12. The regulatory body should initially focus on the information provided by the applicant and determine whether the applicant has provided all the necessary information. Where necessary, the regulatory body should seek clarification on particular points of issue. It should also make an initial comparison with any pre-established criteria. For instance, if the application concerns a type of consumer product, the regulatory body should determine whether the criteria for exemption given in paras 2.23-2.27 and Refs [2, 8] are likely to be met. Following this, the regulatory body should seek the advice of the advisory group.

## **Evaluation**

4.13. The advisory body should:

- (a) Review and examine the benefits claimed for the type of practice and, if necessary, consult with interested parties;
- (b) Review and examine the stated radiological detriments that are expected to arise from the type of practice and again, where necessary, seek further information and/or advice on the adequacy of the assessment of radiological detriments;
- (c) Consider the balance of the benefits and radiological detriments and the relevant evidence;
- (d) Produce a report to the regulatory body with recommendations regarding the justification for the type of practice.

### *Radiological assessment*

4.14. All relevant radiological aspects of the type of practice should be considered in the evaluation of a proposed type of practice. These include the radiation doses from normal use, accidents and other incidents, misuse, recycling and waste management. In assessing the doses from accidents, account should be taken of their probability. The focus of the radiological assessment should be on the doses to the most exposed individuals.

4.15. The collective dose to all those exposed as a consequence of the introduction of a type of practice should not be a determinant. The integral of low individual exposures over large populations, large geographic areas and over long periods of time is generally not a useful tool for decision making because this aggregates information excessively and the estimated health consequence has significant uncertainties [7]. Furthermore, both collective dose and collective benefit will increase in proportion to the extent to which the type of practice is used and therefore the radiological assessment should focus on the doses and benefits to the affected individuals.

4.16. All radiological assessments should be as realistic as possible to avoid distortion in the subsequent comparison of radiological detriment and benefit. The assessments should be made by persons who have the appropriate competence in radiation safety.

### *Assessment of benefit*

4.17. The benefits from a practice could be of many different types, including possible saving of life, prevention of injury or illness, technical benefits, prevention of property damage or security improvements. They should be quantified to the extent possible.

4.18. Where both benefits and radiological detriments can be expressed in commensurate terms, such as lives or money, the decision should be relatively straightforward. However, in general, this will not be the case and therefore subjectivity cannot be altogether avoided, but it should be reduced to the extent possible.

4.19. It should be noted that whereas the assessment of radiological consequences is technical in nature and only necessitates the appropriate competence for it to be carried out, the assessment of benefit is often very subjective. To limit bias by the advisory body in the assessment of benefit, the advisory body should, wherever feasible, establish criteria *a priori*, to assist in making its recommendations to the regulatory body.

### *Report to the regulatory body*

4.20. The advisory body should review and evaluate all the inputs taking into account any criteria that have been established. The process of evaluation should be thoroughly documented. The report should set out the key evidence, the uncertainty in the evaluation, and the basis and rationale for the advisory body's recommendation, whether positive or negative. It should also indicate clearly the importance attached to each input.

4.21. In making its recommendation, the advisory body need not take account of any non-radioactive or non-radiation-emitting alternative methods of achieving the same or similar objectives (see para. 2.3). Indeed, the mere existence of an alternative should not be used as a reason for deciding that the type of practice is not justified. Nevertheless, if such comparisons with non-radioactive or non-radiation-emitting alternatives are seen as necessary, they should be undertaken with appropriate caution. Alternatives are unlikely to be without detriment and, furthermore, may not achieve entirely the same benefit. In particular, in situations where the radiological detriment from a type of practice can be shown to be trivial (which should be the case if the type of product is a candidate for exemption), the prohibition of the radioactive or radiation-emitting method may unduly restrict consumer choice and thereby militate against consumer sovereignty.

### **Decision**

4.22. The regulatory body should review the report of the advisory group. Following any further necessary consultations with the advisory group, the regulatory body should make a decision on the justification of the type of practice. Once a decision has been made, it should be communicated to the applicant. Where a type of practice is regarded as justified, the regulatory body should then follow the normal process of considering applications for authorization. This should involve clarification of the conditions that are applicable based on considerations of optimization of protection. These conditions should cover such things as the type and activity of the radionuclide that can be used.

### **Transparency and records**

4.23. Having completed its consideration, the regulatory body should take steps to bring the proposed decision to the attention of those likely to be affected by it. The regulatory body should also maintain an up-to-date list of the types of practice that are considered to be justified and make this list available in order to assist those who may wish to apply for an authorization or exemption from authorization for a particular application of the type of practice.

4.24. The regulatory body should include within the list of the types of practice that are considered to be justified, those types of practice that are already authorized or for which an exemption has been granted. The existence of an authorization or exemption should be considered as sufficient to demonstrate that the type of practice is justified. However, the fact that a type of practice has been the subject of an authorization or exemption does not preclude the regulatory body from reviewing the justification for the type of practice at some stage.

4.25. The Safety Guide GS-G-1.5 states “Important factors that are relevant to justification in relation to safety and which may lead to optimized protection, as required in the Basic Safety Standards ..., include the following:

- (a) Selection of the most appropriate radionuclides with respect to the half-life, radiation type, energy and amount of radioactive material 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) Construction of the product;
- (d) Prevention of access to the radioactive substance without the use of special tools;
- (e) Experience with other products, particularly similar products, that have previously been assessed;
- (f) Verification of quality” (Ref. [6], para. 4.6).

DRAFT

## 5. APPLICATION TO NON-MEDICAL HUMAN IMAGING

5.1. In view of the current significant interest in the use of human imaging for non-medical purposes, this section gives specific consideration to the matter. Unlike the medical uses of radiation, these practices are not motivated primarily by the health benefit of the exposed individual.

### INTERNATIONAL GUIDANCE

5.2. In 1969, the ICRP made the following statement: “the irradiation of persons for non-medical purposes, such as “anti-crime” fluoroscopy and in customs examinations, is generally deprecated. If in exceptional circumstances that are permitted by the competent authority, such examinations are decided to be essential, they shall be carried out under the supervision of a qualified medical radiologist” [10]. There was no elaboration on how or on what grounds the competent authority might grant permission and it was not clear who would decide whether the examinations were essential.

5.3. Subsequently, as a consequence of international events at the time, namely a spate of aircraft hijackings, the ICRP was asked to provide its views on an international proposal to use radiography as part of a system for security-screening of airline passengers. In its response, it envisaged that a small proportion of passengers might be examined radiographically, using specially developed techniques that would restrict the individual exposure to 10  $\mu$ Sv or less of any part of the body, to be used only when other methods had indicated the presence of unexplained objects on the passenger [11]. The passenger would be given the choice between X-ray examination and a body search. The ICRP concluded that, “in view of the grave risks involved in the seizure of aircraft, the proposal ... could be justified in the light of the benefits that might be expected”. But again, there was no elaboration with respect to responsibilities and processes.

5.4. In its 1977 recommendations, the ICRP considered the justification for examinations for occupational, medico-legal or insurance purposes [12]. It stated: “examinations carried out to assess the fitness of an individual for work, to provide information for medico-legal purposes, or to assess the health of a subscriber to, or beneficiary of, an insurance may carry some direct or indirect advantages for the individual examined, but they also carry advantages for the employer, third parties and the insurer. All these aspects should be considered in assessing the justification of such examinations”.

5.5. The latest recommendations of ICRP state [7]: “the Commission considers that certain exposures should be deemed to be unjustified without further analysis, unless there are exceptional circumstances. These include the following: radiological examination for occupational, health insurance, or legal purposes undertaken without reference to clinical indications, unless the examination is expected to provide useful information on the health of the individual examined or in support of important

criminal investigations. This almost always means that a clinical evaluation of the image acquired must be carried out, otherwise the exposure is not justified”.

5.6. The World Health Organization (WHO), in 1977, considered many non-medical situations, including medico-legal, occupational, immigration, irradiations as a routine administrative procedure, weapon detection and the detection of smugglers [13]. It concluded that irradiation for purposes unrelated to health should be done only when no satisfactory alternative methods exist.

5.7. Medico-legal procedures may be defined as procedures performed for insurance or legal purposes without a medical indication [14]. The term “human imaging using radiation for purposes other than medical diagnosis, medical treatment or biomedical research” as used in the BSS [2] covers a range of procedures that is both broad and diverse, extending beyond those performed for insurance or as a result of legal proceedings. A distinguishing feature of these exposures is that, in most cases, they are not medically indicated and the main reason for performing them does not directly relate to the health of the individual being exposed. The population being scanned may not be the population deriving the benefit and, in fact, the individual exposed may be disadvantaged by the radiological consequences of the exposure<sup>8</sup>. This contrasts sharply with practices within diagnostic radiology which are predicated on a risk-benefit paradigm that assumes that the benefit accrues to the person subjected to the risk. Where this is not the case, the framework of radiation protection, including the justification process, must be constructed so that it adequately protects the exposed individual. Such practices should be subject to regulatory control and appropriate systems put in place to ensure that this is achieved.

## APPLICATION OF THE REQUIREMENTS OF THE BSS

5.8. The BSS [2] have been developed on the basis of two categories of human imaging using radiation for purposes other than medical diagnosis, medical treatment or biomedical research, defined by common attributes – where the imaging is performed, what sort of radiation equipment is used, who operates that equipment and who reports on the images.

5.9. The first category, referred to here as category 1, takes place in a medical radiation facility, involves the use of radiological equipment, is performed by radiology personnel and produces images reported by a radiologist or other doctor. The purposes include obtaining legal evidence, insurance, employment, immigration, age determination, assessment of physiology, and detection of drugs within a person.

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<sup>8</sup> Benefit to the exposed individuals may also be relevant. For instance, (1) the radiographing of containers that may be hiding illegal immigrants could be of benefit to the immigrants themselves as there have been cases where such people have suffocated to death (see, for example, CBC News, “*Three illegal migrants die in shipping container*”, November 11, 2000. Retrieved on 2007-10-03); (2) the early detection of concealed drugs within an individual may prevent injury or death to the individual as a consequence of the rupture of the package containing the drugs.

5.10. The second category, referred to here as category 2, takes place in a non-medical facility (often a public place), involves the use of a specialized inspection imaging device, is performed by non-radiology personnel and produces images viewed by a non-medically qualified person. The purposes include detection of concealed weapons, for example, on airline passengers, theft detection and screening cargo containers and vehicles.

5.11. In keeping with the ICRP recommendations, the BSS requires human imaging using radiation for theft detection purposes shall be deemed to be not justified. In addition, human imaging using radiation for the following purposes shall normally be deemed to be not justified:

- (a) Occupational, legal or health insurance purposes, and undertaken without reference to clinical indication, and
- (b) The detection of concealed objects for anti-smuggling purposes (Ref. [2], paras 3.18-3.20).

Thus, the default position is that human imaging using radiation is deemed to be not justified. However, the BSS recognize that, in the case of the procedures in (a) or (b), there may be exceptional circumstances where the justification of imaging is to be considered and other requirements of the BSS apply. The BSS requires that using radiation for “the detection of concealed objects that can be used for criminal acts that pose a national security threat” is to be justified only by the government (Ref. [2], para. 3.21).

5.12. The phrase “exceptional circumstances” is taken to mean that the human imaging procedure is only carried out for an exceptional “category” of people, and not for exceptional individuals. For example, the use of the technique of X-raying children for age determination could be carried out exceptionally for children that do not have documents to support their date of birth e.g. asylum seekers. In some countries, the number of such children may be large.

5.13. A characteristic of these types of practice is that there is no general agreement on an overarching statement regarding their justification. There may be cases where there is a strong public health, legal or security/safety reason which may result in the type of practice being justified. Each type of practice results in different benefits and detriments and therefore should be considered on a case by case basis, i.e., decisions should be made with respect to a particular type of use, such as X-ray screening at airports. There may also be regional or local differences in the benefits and detriments for a particular type of practice.

5.14. The BSS places the responsibility for considering the justification for these exceptional circumstances on the government (Ref. [2], para 3.61). Governments are required to consider, inter alia,

- (a) The benefits and detriments of implementing the type of human imaging procedure;
- (b) The benefits and detriments of not implementing the type of human imaging procedure;



- (c) Any legal or ethical issues associated with the introduction of the type of human imaging procedure;
- (d) The effectiveness and suitability of the type of human imaging procedure, including the appropriateness of the radiation equipment for the intended use;
- (e) The availability of sufficient resources to conduct the human imaging procedure safely during the intended period of the practice.

5.15 The BSS require that if a type of practice involving human imaging using radiation for purposes other than medical diagnosis, medical treatment or biomedical research is determined to be justified, then that practice should be subject to regulatory control (Ref. [2], para. 3.62). This should entail authorization for particular applications of the type of practice under defined conditions, inspection of facilities and enforcement of regulatory requirements. It is for the regulatory body, in cooperation with other relevant authorities, agencies and professional bodies as appropriate, to establish the requirements for regulatory control of the practice, including the establishment of dose constraints, and the periodic review of the justification. It may be necessary to review the justification decision as new information or technology becomes available.

5.16. If a particular type of practice involving human imaging using radiation for purposes other than medical diagnosis, medical treatment or biomedical research is considered to be justified, separate levels of justification should be applied in respect of particular applications of the technique. For example, the use of X-ray screening for the detection of concealed objects that can be used for criminal acts that pose a national security threat in principle is the first level of justification. Its application in specific airports is a second, although often, these two levels will be considered together. The application of the technique in other situations, such as access controls to buildings should necessitate a separate consideration, care being taken to avoid undue proliferation of the use of the technique.

5.17. A further level of justification relates to the selection of particular individuals to whom the technique is to be applied. Criteria for the selection of individuals should be established before the type of practice is accepted and reviewed as part of the overall justification process. In the particular example of the use of X-ray screening for the detection of concealed objects that can be used for criminal acts that pose a national security threat at airports, they should specify whether the technique is to be applied to all passengers, or only a selection made on a random or other basis. Particular consideration should be given to the application of the technique to children, pregnant women and other sensitive population groups. In addition, they should, as necessary, cover whether the procedure should be made mandatory or subject to informed consent, particularly, if alternative techniques not involving radiation are available.

### **Category 1 practices**

5.18. For those types of practice falling within category 1, the government is required to ensure, as a result of consultation between relevant authorities, professional bodies

and the regulatory body, the establishment of dose constraints<sup>9</sup> for the procedures (Ref. [2], para. 3.64 (a)). Such dose constraints should be established prior to a decision on the justification of the type of practice so that they can be taken into account in the review process. They should be constructed so that they adequately protect the exposed individual.

5.19. In view of the significant doses that may be obtained from some procedures involving medical radiological equipment, there should be substantial justification for using the procedure in individual cases.

#### *Detection of illicit trafficking in drugs*

5.20. This relates to the use of X-ray techniques to image packages of drugs inside a person's body and is considered to fall into category 1 i.e. takes place in a medical facility. Packages may have been swallowed or otherwise concealed internally by a courier transporting them.

5.21. The examination can be carried out using conventional diagnostic X-ray techniques or a CT scan. The procedure should only be used on an individual when there is a high degree of suspicion that the individual has swallowed a package containing drugs, particularly when there are concerns for the health of the individual. It should be noted that alternative techniques not involving the use of radiation are available. These include the administration of emetics or taking the person into custody for a period of time.

5.22. The benefit is the reduction in the illicit trafficking in drugs. There may also be some benefit to the person being examined in that swallowed drug packages may split and release the content into the intestines, resulting in serious injury or death. In that sense, the exposure could be regarded as medical, but since the primary purpose is to detect illicit trafficking in drugs, the exposure should not normally be regarded as medical unless the person concerned has clinical indications.

5.23. For practices that are deemed to be justified, individual exposures should be justified in advance taking into account the objectives of the exposure and the individual concerned. Information relating to the radiological risk should be given to the individual in advance, even if the examination is mandatory.

5.24. This type of practice uses the same equipment as used for medical exposures. However, given that there is no medical indication for the examination, dose constraints are to be established and used in place of diagnostic reference levels

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<sup>9</sup> See footnote 5. Dose constraints should play an important role with category 1 practices. Since the procedures make use of medical radiological equipment, it would not be appropriate to limit doses to the dose limit for members of the public. It should also be noted that diagnostic reference levels (DRLs) apply to medical procedures. These are levels used in medical imaging to indicate whether, in routine conditions, the dose to the patient in a given radiological procedure is usually high or low for that procedure [2]. The dose constraints established for category 1 practices may well be lower than the DRLs for the same procedures used in human imaging for non-medical purposes. For example, the dose from a CT of the abdomen performed to detect swallowed drugs should be significantly lower than a medically-indicated CT of the abdomen looking for anatomical detail.

(DRLs). Such a dose constraint may be lower than the DRL for the equivalent “diagnostic procedure”.

5.25. The exposure, if considered justified, should be done under the supervision of radiology personnel. The images produced should be reported by a radiologist or other doctor. Medical professional societies should be consulted during the process of making the justification decision for such practices.

#### *Use of imaging in sport*

5.26. Imaging is used in both professional and recreational athletes. Imaging in sports medicine can be used for acute or chronic overuse injuries or for screening purposes. Imaging for acute sports injuries are, on the whole, medically justified and therefore out of the scope of this Safety Guide. With chronic overuse injuries, the need for imaging may either be for diagnosis or prognosis. While the former is clearly a medical exposure, the latter may have financial implications and the motivation to perform such imaging may not be for medical care. Such imaging falls into a grey area which may involve non-medical exposures [15].

5.27. Imaging is also used to aid selection for competition, to support decisions on training and nutrition and as a preventive tool. The preventive use of imaging is important but requires guidance to avoid misuse.

5.28. Imaging is also used for screening purposes in certain contact sports as a precautionary tool to rule out certain conditions which if present would lead to heightened risk for the individual involved [15].

5.29. Imaging for screening purposes is also used where X-rays are requested without any specific clinical indication, for example, to assess an individual’s potential before a transfer or appointment, as part of professional or contractual obligations or, with young persons, to assess their potential growth.

5.30. Each of these examples should be treated as a separate type of practice requiring explicit consideration of justification by the government. All of the practices described are in Category 1.

5.31. As part of the justification process it is useful to consider the motivation for the practice. In some cases the benefit would be primarily to the requestor of the examination in case there is some unknown factor affecting the fitness or development and hence value of the person. There may however be some potential benefit to the person being examined, for example, detection of a previously undetected but treatable condition that could impair the person’s progression in the profession or an unknown condition which resulted in them being at serious risk.

5.32. Guidance should be developed on when such imaging is justified to avoid misuse, including consideration of alternative imaging using non-ionising radiation. Development of such guidance might take the form of referral criteria. These criteria should be evidence based and be acceptable to athletes, referrers, radiological medical practitioners and other relevant individuals or bodies.

5.33. Justification on an individual level remains the provenance of the radiological medical practitioner following discussion with the referrer, subject to informed consent from the individual to be exposed.

#### *Age determination*

5.34. The reason for such examinations usually originates from some legal circumstance where there is no valid proof of date of birth. This may be for adoption, for refugees seeking asylum, for illegal immigrants or when the police need to decide whether to apply the adult penal law. Two types of examination are carried out, dental and skeletal. The skeletal examination is normally of a selected part of the body such as the hand and wrist, iliac crest or clavicle.

5.35. The main rationale and hence benefit is to the authorities to provide a sound basis for a decision. There may or may not be a direct benefit to the person being examined.

5.36. However, the technique has significant limitations in accuracy. It is likely that such techniques would only be useful where there is a large difference between the age claimed by the individual and the true chronological age. For many methods, accuracy falls with chronological age, becoming less accurate in adolescents than in children, and even less accurate in adults than in adolescents. This factor is, in addition to the uncertainties, inherent in the technique itself and any inter- and intra-observer variability. The techniques available may not be sufficiently accurate for use in confirming or otherwise whether an individual is above 18 years (or other threshold of majority) [16].

5.37. Given the fact that radiological methods of age estimation have significant limitations in accuracy, the use of such techniques not only requires justification in general but individual justification should be applied. As racial, sexual and possibly socio-economic differences exist in dental and skeletal development, the correct reference data should be available and the validity of the method established for each individual case [16].

#### *Immigration and emigration checks*

5.38. Chest radiographs can be used to determine whether immigrants or emigrants have active or past tuberculosis (TB). This type of practice involves the examination of individuals and is similar to the pre-employment examination of asymptomatic persons. As such, automatic examination is normally deemed not to be justified [2]. However, issues in relation to the protection of public health and vulnerable individuals within society may result in the consideration of such practices as a necessary public health safeguard.

5.39. The justification process should review the proposed referral or selection criteria to be applied as part of the practice. For practices that are deemed to be justified, individual justification in advance of the exposure should also take place. This should be the responsibility of the medical practitioner following discussion with the referrer and should be subject to informed consent from the individual to be exposed.

5.40. The consequences of a positive identification of disease should also be considered. For example, a proposal where all immigrants from countries where TB is endemic are X-rayed to determine if they have active or past tuberculosis (TB), and are treated should a positive diagnosis be made, is quite different to one where a positive identification of disease is regarded as a barrier to entry and acts as a trigger for deportation.

5.41. For exposures that are required for the purposes of emigration, the justification process will have to consider how the justification and requirements of the country of destination are met.

5.42. Those exposures that are directed at diagnosis and treatment, may be considered to be medical exposures and as such are not covered by this Safety Guide

### **Category 2 practices**

5.43. The benefits from some of these types of practice (inspection procedures) could be substantial, for example, improved security of aircraft passengers. In general, they will be to the authorities and hence society at large, rather than to the exposed individuals<sup>8</sup>. Nevertheless, for those types of practice where a large number of people might be affected, such as the screening of aircraft passengers, the government should carefully consider the need for extensive public consultation.

#### *Detection of contraband on persons*

5.44. Security screening involves the use of X-ray scanning to detect weapons or other objects concealed on the body. Two known uses are to screen aircraft passengers and visitors to prisons or other buildings where security considerations apply. Each of these uses should be regarded as a separate type of practice. In these types of practices, the benefit is in the reduced threat from the use of weapons and improved security, which, in the case of aircraft passengers, could result in great loss of life.

5.45. A dose assessment should include the individual dose per examination as well as the potential doses to those who are likely to be exposed frequently e.g. frequent air travellers, frequent visitors to prisons.

5.46. Privacy, communication, selection criteria for individuals to be screened and informed consent issues should be considered during the justification process. This may result in particular requirements being applied to these practices.

5.47. The benefits from these types of practice could clearly be substantial. Nevertheless, proposals to introduce them into a country should also be very carefully scrutinized by the government. In the particular case of the screening of aircraft passengers, the government should carefully consider the need for extensive public consultation. In addition, the government should also consider liaising with counterparts in other countries in view of the international dimension of air travel.

#### *Detection of contraband in containers*

5.48. The primary objective of irradiating containers at border crossings, either using X-rays or radioactive sources, is usually to detect items that are not supposed to be

present. These may be cigarettes or alcohol, drugs, explosives or weapons or even people being smuggled into a country. Such irradiation could therefore give a radiation dose to illegal immigrants whose presence is not known in advance.

5.49. The benefit is clearly to the authorities and hence to society at large. There is also a potential benefit to persons within the container who may be detected and released from circumstances that have been known to claim lives, e.g. through suffocation.

## CONDITIONS

5.50. For those types of practice that the government considers as justified, the regulatory body should give careful consideration to the conditions that might be incorporated into the authorization and other aspects of regulatory control, including those relating to optimization of protection and safety (including dose and risk constraints) and, where appropriate, compliance with dose limitation. These should be based on the outcome of the justification process as well as the normal regulatory requirements.

5.51. Those types of practice considered as justified and falling within category 1 should be carried out in a medical facility by radiology personnel using medical radiological equipment. The imaged persons should be afforded the same level of protection as if they were patients undergoing a medical exposure, with the exception that specific dose constraints replace diagnostic reference levels. The images should be reported on by a radiologist or another medical doctor.

5.52. The imaged person who is to be exposed to radiation in inspection procedures (category 2) should be afforded the same level of protection as a member of the public, again with purpose-specific dose constraints. Furthermore, the BSS requires that “all persons who are to undergo procedures with inspection imaging devices in which ionizing radiation is used are informed of the possibility of requesting the use of an alternative inspection technique that does not use ionizing radiation, where available” (Ref. [2], para. 3.66).

5.53. For both categories of practice, the conditions should define such things as the extent of use of the practice and the individual selection criteria that will be applied. These conditions should make it clear that the decision only applies to a clearly defined situation of use. In addition, information relating to the radiological risk should be given to the affected individual in advance.

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## ANNEX I: CASE STUDY ON WEAPONS DETECTION FOR AIRCRAFT PASSENGERS BOARDING FLIGHTS

### INTRODUCTION

I-1. The use of X-ray scanning of aircraft passengers is carried out in some countries and prohibited in others [I-1]. However, there are no published regulatory decisions on formal justification of this type of practice. The matter was however discussed at the Dublin Symposium [I-2] and the information presented at that symposium forms the basis of the discussion here.

I-2. The purpose of X-ray scanning is to detect a concealed weapon that might otherwise be carried on board an airplane. The X-ray scanners are seen as a complement to the use of walk-through metal detectors and pat-down searches. They also are an alternative to the more intrusive strip-search. The equipment uses backscatter X-ray imaging to quickly acquire high-resolution images. To perform a scan, the subject is asked to stand relatively still on an external stage for several seconds while the system acquires two-dimensional raster-scanned image data. The electronic image of the subject is formed using the intensity of X-rays scattered from each location on the body via Compton-scattering interactions. The X-ray scatter intensity is a function of both the atomic number and density of the material probed by the primary X-ray beam, in this case either the body itself or items worn on the body. Denser objects such as metals, explosives, plastics, and packed drugs interact more strongly and therefore appear on the image along with the body itself. Two scans (front and back) are typically required for a routine inspection. However, the technique only images materials on the surface of the body and is not effective for detecting materials that are concealed within body cavities.

I-3. The failed attempt to blow up a plane from Amsterdam to Detroit on 25 December 2009 by the use of explosive powder sewn into the person's underwear has sparked new calls to step up security at airports. Much of the attention has focused on the use of body scanners that can reveal objects concealed beneath a passenger's clothing.

I-4. The global airport traffic statistics indicate that the total number of air passengers is over 4.8 billion annually and that international passenger traffic accounts for 42% of this (Airport Council International Annual World Airport Traffic Reports).

### BENEFITS

I-5. There are obvious social and individual benefits of this practice, which include the following:

- (a) *Social benefit - improved flight security.* The scan for concealed weapons, in addition to actually finding weapons, has a deterrent effect on terrorists; this will obviously improve flight security and should result in fewer hijacks of airplanes with a possible disastrous outcome.

(b) *Individual benefit - passenger confidence.* Passengers are clearly influenced by terrorist actions as was clearly experienced with a significant drop in airline passengers after the terrorist attacks in the US on the 11 September 2001. With an effective screening for concealed weapons, the passenger confidence will increase resulting in an increased number of airline passengers.

I-6. These benefits will also have a positive effect on national and international economics.

## DETRIMENTS

I-7. The subject being scanned is exposed to an effective dose of 0.05  $\mu\text{Sv}$  per scan, i.e. 0.1  $\mu\text{Sv}$  in total per person per examination from a backscatter X-ray scan (it is about 5  $\mu\text{Sv}$  from a transmission X-ray scan). The total dose to an individual in a year would, of course, depend on the number of times the individual was subjected to an examination. If, for example an individual were subjected to 200 such examinations in a year, the total effective dose would be of the order of 20  $\mu\text{Sv}$ .

I-8. An additional aspect to take into account is the fact that such scans of the whole body would invade privacy.

## EVALUATION

I-9. The dose to an individual from a single examination is very low, substantially lower than the individual would receive from cosmic rays even during a short-haul flight. Even if individuals were subjected to many examinations in a year, the total effective dose would still be very low.

I-10. The consequences of failure to detect a hidden weapon could well be considerable. Nevertheless, balancing the various beneficial and detrimental factors is not straightforward, the main issues being ethical in nature, including intrusion into a person's privacy.

## DECISION

I-11 There do not appear to be any published decisions on the justification for the introduction of this practice. Nonetheless, it is being tried out at several airports.

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## ANNEX II: CASE STUDY ON DETECTION OF DRUGS SMUGGLED ON PERSONS

### INTRODUCTION

II-1. One way of smuggling drugs is to transport them inside the body of human carriers. The use of X-ray scanning of persons at borders and elsewhere is therefore carried out in some countries to check for this. Any packages in the gastrointestinal tract are usually easily visible on radiographs. However, as with the previous case study, there are no published regulatory decisions on formal justification of this type of practice. The matter was however discussed at the Dublin Symposium [II-1].

II-2. In the UK, the Drugs Act 2005 gives the police powers to order an X-ray or ultrasound scan of suspected drug swallows. Under this Act, an X-ray must not be carried out unless the appropriate consent has been given in writing and the X-ray may only be carried out by a suitably qualified person at a hospital or other medical establishment.

### BENEFITS

II-3. The checking and examination of selected individuals to uncover smuggling of drugs is considered to have several benefits including:

- (a) *Individual benefit - less intrusive than an extensive full body examination.* The only alternative to a full body examination including all cavities is the X-ray examination. Innocent suspects would probably find the X-ray examination more tolerable than the full body examination.
- (b) *Individual benefit - increased chance for a smuggler to survive.* If a smuggler has swallowed a package with drugs, there is a risk of serious damage to the smugglers health if the wrapping of the drugs starts to leak. Being discovered by a body examination and placed under intensive surveillance at a hospital increases the chance for the smuggler to survive a broken wrapping in the gastrointestinal tract.

### DETRIMENTS

II-4. The subject being examined by X-rays is exposed to an effective dose which is probably in the region of 1-2 mSv.

### EVALUATION

II-5. The individual risk to people being selected for an X-ray examination with the purpose of detecting swallowed drug packages is relatively low, being of the same order as the dose from an X-ray of the spinal cord. However, the dose limit for public exposure is likely to be exceeded. The benefits however are substantial, both for the smuggler, in terms of increased

chance of surviving a broken package, and to society as a whole, in terms of prevention of illicit drugs reaching the market. Nevertheless, as with other case studies, there are ethical issues which would need to be considered. These would be somewhat offset by a requirement for informed consent before the procedure is used.

## DECISION

II-6. Clearly, the UK considers the benefit sufficient for it to be included within its own national legislation. It is also understood that it is in use at some borders. However, there does not appear to be any published decision on the justification for this type of practice.

## REFERENCES TO ANNEX II

- [II-1] EUROPEAN COMMISSION, Medico-legal exposures, exposures with ionising radiation without medical indication, Proceedings of the International Symposium Dublin, Ireland, 4-6 September 2002, RP-130, CEC, Luxembourg (2003).

**ANNEX III:  
CASE STUDY ON JUSTIFICATION FOR THE USE OF X/GAMMA RADIATION  
SCANNERS FOR DETECTING PEOPLE SEEKING TO ENTER A COUNTRY  
ILLEGALLY IN VEHICLES AND/OR FREIGHT, BY CLANDESTINE MEANS**

## INTRODUCTION

III-1. This summary describes the main elements of the justification case for this type of practice as published by the UK Home Office [III-1]. In the UK, the rate of clandestine entry by people concealed in vehicles or freight at ferry ports and the Channel Tunnel is very high. People attempting to enter illegally that have been detected in East Kent alone, including the Port of Dover, numbered over 17,000 in 1999 and 19,700 in the year 2000. The detection measures in use include carbon dioxide (CO<sub>2</sub>) sensors, which give a quick and generally reliable indication of concealed human presence, and dog search teams. Both these measures, however, have fairly significant limitations. For example, certain types of freight emit CO<sub>2</sub> thus masking detection. Also, the construction of some containers prevents examination by CO<sub>2</sub> sensors. Alternative measures are sometimes employed, such as physically unloading full freight loads. This is a very costly and time-consuming process, which can only be used in a limited number of cases. As a consequence, the Immigration Service planned to deploy X/gamma radiation scanners at UK ports and control zones to detect people seeking to circumvent UK immigration controls. This practice would be integrated with other search techniques to provide a balanced and effective search regime. In most cases, scanners would be used as a second phase of checking, as a form of confirmation where the first phase of checking (e.g. CO<sub>2</sub> sensors) has provided inconclusive results.

III-2. The scanners use X or gamma radiation to produce an image of the freight, via a highly sensitive detector array system. The scanner moves from one end of the vehicle over the whole length to obtain a complete image. It typically takes less than a few minutes to complete a scan and produce an image by detecting transmission or backscattered radiation.

## BENEFIT

III-3. The use of X/gamma radiation equipment was considered to represent a very significant deterrent because:

- (a) For individuals who aim to breach immigration controls, the likelihood of discovery will be greatly increased;
- (b) For hauliers, ferry operators and the Channel Tunnel operator, the increased prospect of having heavy civil penalties applied to them should encourage them to take far better security precautions than they do at present; and
- (c) For those engaged in human trafficking, the prospect of disruption to their activities will have a significant effect, particularly where detection results in successful prosecution.

III-4. The social benefits were considered to include prevention of death or serious injury or illness because of the very poor physical condition in which many illegal entrants have been detected in vehicles. Some had in fact died. The deployment of scanning equipment would

significantly increase the likelihood of the Immigration Service detecting people in freight and thereby relieving potential suffering and possible death, especially where detection takes place early on in the transit history.

III-5. Furthermore, it was considered to provide an ability to mount a rapid mobile response to new trends and routes of attempted illegal entry by individuals and to be a more effective technique than CO<sub>2</sub> checking, which can only be used on certain types of cargo.

III-6. The economic benefits were considered to include:

- (a) Detecting people hidden in vehicles and/or freight without the need for the physical offloading of freight in the search process, which is both labour intensive and costly.
- (b) X/gamma radiation scanners can be used on a wide variety of vehicles including curtain (soft) sided, refrigerated and container trucks, tankers, lutons, vans and where necessary coaches. (CO<sub>2</sub> sensors are limited to curtain sided vehicles).
- (c) A reduction in the overall cost to the government of asylum processing and support by encouraging improved security precautions by hauliers and ferry operators by enforcing the Civil Penalty and Carrier Liability Scheme.
- (d) A capacity to search a greater proportion of vehicles destined for, or arriving in, the UK.
- (e) The more productive use of Immigration Service resources in searching vehicles and in the deployment of other control staff to better effect on an intelligence-led basis.
- (f) Reduction in support costs; in 2000, support costs of £142 per week for single claimants and £307 per week for families were paid to those entitled to receive such support.

## DETRIMENT

III-7. The annual effective dose to an employee operating the equipment (including the driver) was considered to be less than 0.5mSv. The maximum annual effective dose to a member of the public outside the exclusion zone was estimated to be 100 µSv. The average effective dose to a person inside the vehicle or freight was estimated to be 1 µSv per scan and should not exceed 2 µSv per scan under the most pessimistic conditions.

## EVALUATION

III-8. A single scanner was used in a cost-benefit analysis to compare the costs and benefits of the equipment. Based on a maximum dose to a worker of 0.5 mSv in a year and assuming up to 36 workers would be deployed on a scanner, the resulting annual collective effective dose was calculated to be 18 man mSv.

III-9. The scanners would be located in restricted areas in a secure port environment where members of the public would have very limited access. In addition, it is extremely unlikely that they would loiter at the perimeter of the boundary of the exclusion zone, which would be monitored by scanner team members. The Immigration Service estimated that, in a worst

case, 10 members of the public per day (365 days per year) could potentially be exposed to the X-ray beam. This would result in an annual collective effective dose of 3.6 man Sv.

III-10. The evaluation assumed that 1000 illegal immigrants hidden inside a vehicle or freight are detected in a year by each scanner and each received an effective dose of 2  $\mu$ Sv per scan. The resultant annual collective effective dose would be 2 man mSv.

III-11. These collective doses were evaluated using the relevant NRPB reference values of £50,000 per man Sv for workers and £20,000 per man Sv for members of the public. On this basis, the annual health related cost of operating the proposed equipment is £1,012 per scanner. To the extent that the proposed practice may result in saving several lives, a cost benefit can be attached to this of £1,600,000 per life.

## DECISION

III-12. The use of X/gamma radiation scanners to detect people seeking to enter the UK illegally was considered justified because:

- (a) Lives will be saved and suffering and injury will be prevented when people hidden in vehicles and/or freight are detected prior to lengthy channel crossings and/or road journeys;
- (b) The radiological detriment cost of £1,012 is very small compared to the value assigned to a human life of £1,600,000;
- (c) The current detection measures in use (involving CO<sub>2</sub> sensors, dog search teams and unloading of vehicle and/or freight) have limitations. The likelihood of detecting people concealed in vehicles and/or freight will be greatly enhanced by the use of X/gamma radiation scanners;
- (d) Any radiation doses received by people hidden in vehicles and/or freight will be extremely small and do not pose a significant health risk. For example, the doses are much less than the average dose received in the UK every day by a member of the public from natural background radiation and are similar to the dose received by aircraft passengers undertaking a short, UK domestic flight.

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## **ANNEX IV: CASE STUDY ON AGE DETERMINATION**

### **INTRODUCTION**

IV-1. The information presented on the use of X-rays for the determination of age to young persons was discussed at the Dublin Symposium [IV-1] and forms the basis of the discussion here. The assessment of age can be carried out on the basis of either dental or skeletal examination. The latter would involve taking X-rays of ossification centres, studying the fusion of metaphysis in long bones, e.g. by taking X-rays of the hand, wrist, elbow or the iliac crest, or by examining the clavicle with CT. As with the earlier examples, there are no published regulatory decisions on formal justification of this type of practice.

IV-2. The objectives were considered to be:

- (a) To check the age of older children seeking adoption who have no or poor quality documentary information as to their age;
- (b) To assess the age of asylum seekers, who would obtain significant advantage if they were declared as ‘minors’;
- (c) To assess the age of young offenders, in order to decide whether or not adult laws are applicable.

IV-3. The procedure is recognised as a relevant “scientific procedure” in a document containing guidelines for the protection and care of refugee children issued by the UNHCR in 1994 [IV-2].

### **BENEFITS**

#### **Legal benefits**

IV-4. There is in many countries a major difference between the legal punishments of children or adult offenders. Furthermore, in some countries, child asylum seekers are accepted, whereas adults are sent back immediately if there is not a good reason to accept them.

#### **Psychological benefits**

IV-5. Sometimes the approximate age of a child may not be obvious, especially if that child had suffered from malnutrition. It can harm a child psychologically if he/she is placed among the wrong age group at school or in society. The uncertainties involved in the age determination vary from 6 months to 1 year. Guidance on this topic from the UNHCR however states that “when the exact age is uncertain, the child should be given the benefit of the doubt”.

### **DETRIMENT**

IV-6. The dose to the wrist or elbow from a single X-ray is about 0.15 mGy, resulting in a very low effective dose. The dose from an orthopantomogram is about 0.5 mGy to the neck and 0.05 mGy to the thyroid, giving an effective dose of about 2.5  $\mu$ Sv. As this is an individual examination the collective dose is not relevant.

## EVALUATION

IV-7. The fact that the procedure is recognized as relevant by the UNHCR provides some evidence that there may well be important benefits for young refugees. Furthermore, the detriment due to the radiation exposure is low. Nevertheless, this type of procedure poses ethical questions that clearly should be considered carefully by the relevant national authority.

## DECISION

IV-8. There do not appear to be any published decisions on the justification for the introduction of this practice.

## REFERENCES TO ANNEX IV

- [IV-1] EUROPEAN COMMISSION, Medico-legal exposures, exposures with ionising radiation without medical indication, Proceedings of the International Symposium Dublin, Ireland, 4-6 September 2002, RP-130, CEC, Luxembourg (2003).
- [IV-2] UNITED NATIONS. Refugee Children: Guidelines for Protection and Care (Endorsed by the UNHCR Executive Committee in October 1993). UNHCR (1994).

## **ANNEX V: CASE STUDY ON LIGHTNING PROTECTION SYSTEMS WITH RADIOACTIVE SOURCES**

### **INTRODUCTION**

V-1. Lightning conductors using radioactive sources provide an example of a product that has been used for many decades without an adequate demonstration of benefit and where the radioactive source has subsequently been shown to provide no benefit.

### **BENEFITS**

V-2. The idea that a radioactive source in the vicinity of a Franklin rod could improve the rod's efficacy dates from the early part of the 20<sup>th</sup> century [V-1]. The basis for this was the fact that the radioactive sources ionize the air around the rod and this ionization would be sufficient to increase the zone of protection of the lightning rod. This in turn would reduce the number of rods required or the need for a Faraday cage to protect a building. As a consequence, they were cheaper and easier to install than the conventional lightning protection systems. Beginning in the 1930s, such rods were installed in many countries [V-2]. Initially, radium-226 was used but with the advent of artificially produced radionuclides, americium-241, krypton-85, cobalt-60 amongst others, were introduced. The activity of the americium-241 on one lightning rod was typically of the order of 3.7 GBq.

V-3. Doubts over the efficacy of these radioactive lightning rods go back at least to the 1960s when they were used to protect very high structures, e.g. churches, television towers, skyscrapers [V-1]. However, they continued to be installed throughout the world and although it is now widely accepted that the radioactive sources are not effective in increasing the zone of protection, many are still installed on buildings [V-3, V-5].

### **DETRIMENTS**

V-4. Because of they are generally installed at quite some distance from places to which the public have access, the doses received from normal use are likely to be very low [V-4]. However, once the system has been dismantled, the disused sources need to be managed as radioactive waste. Since 1970, many countries have operated programmes to remove radioactive lightning conductor rods from service [V-4, V-6].

### **EVALUATION**

V-5. It is considered that there no benefit from the presence of the radioactive source. Because of the misconceptions regarding the efficacy of the devices, it is likely that those places where they are currently in use are under protected against lightning strikes. As a consequence, their use could lead to economic losses and put lives at risk [VI-1]. This is a

particular problem in tropical countries where lightning strikes are much more frequent than in temperate countries.

## DECISION

VI-6. There do not appear to be any published decisions on the justification for the introduction of this practice.

## REFERENCES TO ANNEX V

- [V-1] Baatz H., Radioactive isotopes do not improve lightning protection. *Elektrotechnische Zeitschrift A*, vol. 93, pp. 101-104, Feb. 1972.
- [V-2] Chrzan K.L. and Hartono Z.A., Inefficacy of radioactive terminals and early streamer emission terminals, XIIIth International Symposium on High Voltage Engineering, Millpress, Netherlands (2003).
- [V-3] Hartono Zainal Abidin, Robiah Ibrahim, Conventional and Un-conventional Lightning Air Terminals: An Overview, Forum on lightning protection, Hilton Petaling Jaya, 8th January 2004.
- [V-4] Shaw J., Dunderdale J. and Paynter R. A., A Review of Consumer Products Containing Radioactive Substances in the European Union, Radiation Protection 146, European Commission, Luxembourg (2007).
- [V-5] Darveniza, M., Mackerras, D., and Liew, A. C., Standard and Non-standard Lightning Protection Methods, *Journal of Electrical and Electronics Engineering*, Australia, 1987.
- [V-6] INTERNATIONAL ATOMIC ENERGY AGENCY, Identification of Radioactive Sources and Devices, IAEA Nuclear Security Series No. 5, IAEA, Vienna (2007).

## **ANNEX VI: TRITIUM EXIT SIGNS**

### **INTRODUCTION**

VI-1. The tritium EXIT sign is a self-luminous product illuminated by gaseous tritium light sources (GTLS). Each GTLS is a glass tube capsule filled with the radioactive gas tritium. The inner surface of the glass tubes is coated with luminous phosphor. The beta radiation from the disintegration of tritium causes the emission of light from the phosphor. The intensity of light diminishes as the tritium in the tube decays. The useful life of a GTLS tube is typically 10-12 years.

### **BENEFITS**

VI-2. Tritium EXIT signs are self-illuminating and do not need any connection to an electrical source. They require no maintenance, and they remain self-luminescent for 10-12 years. They can save lives during fires, power outages and other emergencies.

### **DETRIMENTS**

VI-3. Tritium emits a weak beta particle that cannot penetrate the glass tube of an EXIT sign. The beta particle also cannot penetrate a sheet of paper or the outer dead layer of skin. It therefore poses no radiation hazard if outside the body.

VI-4. There is internal exposure to individuals when tritium is taken into the body through inhalation, absorption or ingestion. Inhalation is primarily a concern in close proximity to a point of release, or in a confined or poorly ventilated situation. This situation could arise from close contact with a damaged sign. Tritium has a biological half-life of about 10 days. The potential for adverse health effects from a broken tritium sign is relatively low.

VI-5. The potential clean-up costs and liabilities that can result from a tritium sign being broken can be significant. The US EPA has prepared training material on the responsible management of tritium EXIT signs, which includes summaries of a number of incidents that resulted in significant clean-up costs [VI-1]. The US Health Physics Society has prepared an information sheet on the proper clean-up of a broken tritium exit sign, and on how to dispose of a broken sign [VI-2].

VI-6. Proper disposal of tritium EXIT signs is required after they are no longer used. They should never be disposed of as trash. Proper disposal is achieved by return to the manufacturer or supplier. Elevated levels of tritium have been found in the landfill leachate, the liquids that percolate down through landfill, in California, Pennsylvania and Scotland [VI-3, VI-4], with the potential for tritium to move into groundwater.

### **EVALUATION**

VI-7. The use of such signs in some countries indicates that there is a benefit of saving lives during emergencies that outweigh the detriment from the use in normal situations and from damaged signs, and from incorrect disposal. Some countries limit their use to situations where it is not practical or feasible to use alternative signs.

## DECISION

VI-8. There does not appear to be any published decisions on the justification for the introduction of this practice.

VI-9. Regulatory requirements for such devices are published by some regulatory bodies, indicating that their use is considered justified in some countries. This includes the requirements on their use such as: limiting their use to situations where alternatives are not practical or feasible, requiring licensing when the total amount on premises exceeds a particular level, that the tritium EXIT signs must not be disposed of as normal trash, and the owner of the sign is required to file a report regarding the disposal of the sign.

## REFERENCES TO ANNEX VI

- [VI-1] U.S. EPA, Responsible management of tritium EXIT sign, published on the following web page:  
[http://www.trainex.org/web\\_courses/tritium/index.htm](http://www.trainex.org/web_courses/tritium/index.htm)
- [VI-2] Health Physics Society, <http://www.hps.org/publicinformation/ate/q3753.html>
- [VI-3] Mutch, R.D., Mahoney J.D., Paquin, P.R. Cleary, J., A study of tritium in municipal solid waste leachate and gas, published on the following web page:  
[http://www.hydroqual.com/publications/rdm\\_07\\_01\\_p.pdf](http://www.hydroqual.com/publications/rdm_07_01_p.pdf)
- [VI-4] Hicks, T.W., Wilmot, R.D., Bennett, D.G., Tritium in Scottish Landfill Sites, published on the following web page: [www.sepa.org.uk](http://www.sepa.org.uk)

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## CONSULTANTS MEETINGS

Vienna 21-23 June 2004;

Vienna 6-10 December 2004;

Vienna 7-11 March 2010.

**DRAFT IAEA SAFETY GUIDE (DS-401)**

**JUSTIFICATION OF PRACTICES CAUSING EXPOSURE DUE TO CONSUMER PRODUCTS & NON-MEDICAL HUMAN IMAGING**

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: COLLATED COMMENTS. Country/Organization:				Date: 30-November-2011			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
Japan	General	RASSC28 in June 2010 has already discussed DS401 with some comments from RASSC members. The reflection for these comments should be explained with this new version of DS401.	Some comments from Japan were accepted in RASSC28, but these comments were not reflected to new version.	A	These are dealt with later in this document.		
Japan	General	According to the title, this document should focus on justification of consumer products and non-medical human imaging and discuss the process and specific application.	The title of this document explicitly specifies consumer products and non-medical human imaging. However Section 4 mentions a generalized process of justification. On the other hand Section 5 addresses non-medical human imaging, but the description is mainly relevant to BSS so, specific approaches for Section 4 are not mentioned. In addition there is no example of consumer products (corresponding to Section 5), hence it is imbalanced.	A	This was discussed in RASSC in Dec 2011. The title has been changed to: Application of the Principle of Justification to Practices, including Non-Medical Imaging		
Japan	General	Non-radioactive and non-radiation emitting alternative methods should be mentioned in Section 1 and 2.	Para.2.3 and 4.20 say that it is not necessary to take non-radioactive and non-radiation emitting alternative methods into account. This would be true from the view point of justification in radiation protection, but a comparison with alternative methods is needed in the national decision making				Non-radioactive and non-radiation emitting alternative methods are mentioned in Para 2.2 and 2.3. The comment is unclear as to whether this text needs to be



			process.				altered.
Japan	Title	The title should be "Justification of Practices Causing Exposure Due to Non-Medical Human Imaging and Consumer Products".	Consumer products are not described very much in the text, but mainly in the ANNEX only.	A	See earlier comment from Japan.		
Pakistan	All document	General comments	<u>The comments regarding consumer products are as follows:</u> The applicant for consumer product is most likely the Industry which has the prime responsibility for the safety from radiation risk. The benefit and detriment arising from an individual consumer product to an individual user are so small that justification of introduction of practice cannot be determined. The justification of the practice by the regulatory body may also consider the bulk use of material in the industry to produce consumer products.			R	Para. 2.8 of DS401 explains why only benefits and detriments for the user are to be considered in the justification process..
Pakistan	All document	General comments	<u>Comments regarding non-medical imaging of humans:</u> - The non-medical imaging of humans involves international issues e.g., security screening at airport for narcotics or weapons may involve international passengers. The rules/regulations in one country may be different from the other resulting in anxiety or legal issues may arise. Therefore a consistent international policy may be developed to deal with this issue and IAEA play the main role in			R	During the drafting of the revised BSS, Member States said that decisions regarding the justification of security screening are for national governments to make. The IAEA could develop guidance on the use of such equipment.

			this regard.				
Japan	Page 22	General comments	The process of justification by Regulatory Authority involves the general public. This should describe level of general public and to be more appropriately replaced by “representatives of general public”	A	The text in the Table has been modified to read: “individuals representing the general public”.		
Germany	1.2	Add new sentence: “... number of people exposed [3]. <u>Justification is the process of weighing the benefits to individuals and to society from introducing or continuing a practice against the harm (including radiation detriment) resulting from that practice.</u> The principle of justification means that any practice giving rise to radiation exposure <u>must yield an overall benefit, i.e.</u> should do more good than harm.”	Clarification to emphasize that justification is a process. Compare with definition in the glossary of the revised BSS: “Justification is the process of determining whether in a planned exposure situation ... the benefits to individuals and to society from introducing or continuing a practice outweigh the harm (including radiation detriment) resulting from that practice.”	A	The text has been modified.		
Germany	1.7	last sentence: “It may also be used in reviewing an already established type of practice.”	Editorial.	A	The text has been modified.		
Germany	1.9	1 <sup>st</sup> sentence: “... the relationship between the justification principle and its sister principle of optimization of protection <u>and safety.</u> ”	Consistency with the terminology used in paras 2.21 and 2.22 as well as in the revised BSS, Requirement 11 (Optimization of protection and safety).	A	The text has been modified.		
Germany	2.2	4 <sup>th</sup> sentence: “Sometimes, the radiation detriment will be a small part of the total <u>harm.</u> Justification thus goes far beyond the scope of radiological protection <u>and also involves the consideration</u>	Clarification and completion. Proposed wording is adopted from para 1.13 of the revised BSS.	A	The text has been modified.		

		<u>of economic, societal and environmental factors.”</u>					
Germany	2.2	5 <sup>th</sup> sentence: “... the Commission only recommends that justification requires that the net benefit be positive.”	Editorial.	A	The text has been modified.		
Germany	2.3	last sentence: “... it is not their responsibility to make comparisons with <u>non-radio-active</u> or non-radiation emitting alternatives and decide on behalf of the user which is the preferred alternative.”	Completion. Consistency with wording in para. 4.20 of the draft.	A	The text has been modified.		
Germany	2.7	7 <sup>th</sup> sentence: “The Safety Guide <u>GS-G-1.5</u> [7] states <u>in para 4.1</u> ...”	Completion.	A	The text has been modified, but the final decision rests with the IAEA editors.		
Germany	2.8	1 <sup>st</sup> sentence: “Thus, in <del>this</del> <u>the</u> case of consumer products containing radioactive material, the justification analysis should be <u>carried out</u> with respect to ...”	Wording.	A	The text has been modified.		
Germany	2.8	2 <sup>nd</sup> sentence: “... radiological detriment to the public arising from the use and <del>eventual</del> <u>uncontrolled</u> disposal of the product.”	Consumer products are made available to members of the public without regulatory control after sale. Compare with wording in para 3.16 of the draft: “In the case of consumer products containing radioactive material, the regulatory body should review and assess the doses arising from normal use, reasonably foreseeable accidents and uncontrolled disposal, the latter since effective	A	The text of paragraphs 2.8 and 3.16 has been made consistent each other, and with the BSS.		

			control over any waste products cannot be guaranteed.”				
Germany	2.13	b) ... by the deliberate addition of radioactive substances or by activation;” c) ... as a form of art or for publicity purposes.”	Editorial (replace quotation mark by semicolon).  Editorial (add quotation mark at the end of para).	A	The text has been modified.		
Japan	Footnote 4	Add “The final decision might be made according to the circumstance of each country.” at the last of this footnote.	Para.2.15 states “the deliberate use of uranium as a colouring material ... should be regarded as an unjustified practice”. But, this footnote is ambiguous expression.	A	The text has been modified.		
Germany	2.19	1 <sup>st</sup> sentence: “... Human imaging using radiation for the detection of concealed objects ...”	Editorial.	A	The text has been modified.		
Germany	2.20	2 <sup>nd</sup> sentence: “However, the overall conclusion that can be drawn from the above at this stage is that <del>although</del> <u>since</u> irradiation of persons for non-medical purposes is not to be welcomed (and, indeed, is deemed to be not justified when used for theft detection purposes), any proposed practices involving such exposure should be extremely carefully considered by the government before they can be authorized.”	In the context of this sentence, the preposition “since” seems to be more appropriate than “although”.	A	The text has been modified.		
Germany	2.23	1 <sup>st</sup> sentence: “Optimization of protection <u>and</u> <u>safety</u> involves the establishment or approval of dose and risk constraints, ...”	Consistency with the terminology used in paras 2.21 and 2.22 as well as in the revised BSS, Requirement 11.	A	The text has been modified.		
Germany	2.27	b) “Regulatory control of the practice or the source ...	Editorial (delete quotation mark).	A	The text has been modified.		

Germany	2.28	1 <sup>st</sup> sentence: “ <u>Schedule I of t</u> The BSS [2] provides an individual dose criterion as well as <u>activityies</u> and activity concentrations that may be used ...”	Wording.	A	The text has been modified.		
Germany	2.29	2 <sup>nd</sup> sentence: “This is supported by the Safety Guide <u>GS-G-1.5</u> [7] which states in <u>para 4.3</u> ...”	Completion.	A	The text has been modified.		
Germany	2.29, 2.30	Combine both paras: “... and of likely methods of disposal. The application of these provisions for exemption is further developed in a <u>the Safety Guide RS-G-1.7</u> [9].”	Text in para 2.30 is direct continuation of the text in para 2.29 and can't be understood in an isolated manner.	A	The text has been modified.		
Japan	3.7/8	Delete “the introduction of a nuclear power programme or” from “This is the case, as, for example, with <u>the introduction of a nuclear power programme or</u> the use of X-rays for security screening of individuals at airports.”	As examples of the practice that needs decisions influenced by not only radiation safety but also political concerns, a nuclear power programme and a use of X-rays for security. But, the nuclear power programme is out of scope of this document.	A	The text has been modified.		
Japan	3.9	The BSS state, in para. 2.19, ... → Para 2.19 of the BSS[2] states ...	The same expression with 3.1 and 3.10.	A	The text has been modified. All three paragraphs have been modified.		
Germany	3.9	a) “The activities of the regulatory body ... b) “Interested parties are involved ...  last sentence: “The requirement to involve interested parties is an important one in the context of justification of a type of practice and <del>it</del> <u>is</u> developed further in the next sections.”	Editorial (delete quotation mark).  Editorial.	A	The text has been modified.		

Germany	3.16	5 <sup>th</sup> sentence: “In the case of consumer products containing radioactive material, the regulatory body should review and assess the doses arising from normal use, reasonably foreseeable accidents, <u>misuse</u> , <u>recycling</u> and uncontrolled disposal, ...”	Consistency with wording in paras 2.29 (“Account should be taken of normal use, misuse and accidents and of likely methods of disposal.”) and 4.13 (“All relevant radiological aspects of the type of practice should be considered in the evaluation ... These include the radiation doses from normal use, reasonably foreseeable accidents, credible abuse and waste disposal.”). Recycling may also be part of the life cycle of a consumer product. See DPP for the IAEA Draft Safety Guide DS458 “Radiation safety and regulatory control of consumer products”.	A	The text of paragraphs 2.8 and 3.16 has been made consistent each other, and with the revised BSS.  Para 2.29 is a direct quote from an existing Safety Guide.		
Germany	3.16	3 <sup>rd</sup> sentence: “... all risks associated with normal operations, anticipated operational occurrences and accident conditions.”	Editorial.	A	The text has been modified.		
Germany	3.23	1 <sup>st</sup> sentence: “As noted in <u>para 4.2 of the Safety Guide GS-G-1.5 Ref. [7]</u> , ...”	Completion.	A	The text has been modified.		
Germany	3.24	3 <sup>rd</sup> sentence: “This is further developed in para. 3.9 of the BSS [2] which requires <del>the</del> <u>that ...</u> ”	Editorial.	A	The text has been modified.		
Germany	3.25, 3.26	Combine both paras: “... any safety assessment provided by the manufacturer. This means that the manufacturer or supplier of the product is responsible for: ...”	Text in para 3.26 is direct continuation of the text in para 3.25 and can't be understood in an isolated manner.	A	The text has been modified.		
Germany	Section 4	Check the numbering of paras in Section 4: Multiple existence of para	Editorial.	A	The text has been modified.		

		4.7.					
Germany	4.2	last sentence: “Both situations should involve consultation with interested parties; <del>which, in</del> <u>In</u> the case of decisions taken at the governmental level, <u>the consultation</u> should include the regulatory body, which should provide information on the radiological risks, as well as those who will be affected by the type of practice.”	Wording to improve understanding.	A	The text has been modified.		
Germany	4.4	c) The authorized party has the human, organizational, financial and technical <del>capabilities</del> <u>resources</u> to operate the facility or equipment safely.	Wording. The IAEA Safety Requirements GS-R-3 “The Management System for Facilities and Activities” utilize the term “resources” instead of “capabilities”.	A	The text has been modified.		
Japan	4.4/6 (p.21) 4.8/2 (p.23)	Add examples of “relevant radiological criteria” or “criteria that it has established or defined”. para.4.4 ...The performance of these functions should provide a high degree of confidence that safety is optimized and <u>any relevant radiological criteria that have been established</u> are met.... para.4.8 In the case of consumer products containing radioactive material, the regulatory body should only authorize the supply of those products that comply with <u>any criteria that it has established or defined in relevant safety</u>	These criteria are important and make this document user-friendly.	A	The text has been modified.		

		standards....					
Japan	Fig.1	In the frame of “consideration”, what does “body” mean? Maybe “organization” or “party” should be appropriate.	In the text, “organization” or “party” is used.	A	The text has been modified.		
Japan	4.7 (after 4.8)	This paragraph number should be changed to 4.9. And the number should be changed from page 25 to 27.	Miss numbering.	A	The text has been modified.		
Japan	4.9,(c)/3 (p.25)	... minimize the radiological impact <b><u>in normal use as well as in reasonably foreseeable accidents</u></b>	It should be explicitly stated that the safety must be ensured in normal use as well as in reasonably foreseeable accidents. This comment was judged as "generally accept" in 28th RASSC meeting. Despite of this judgment, it is overlooked.	A	The text has been modified. Note that (d) covers “potential exposure”.		
Germany	4.9	c) ... to ensure safety and <u>to minimize the radiological impact on people and the environment;</u>	Proposed amendment is adopted from the revised BSS as well as from the Safety Fundamentals SF-1.	A	The text has been modified.		
Germany	4.9	d) ... The <u>assessment of radiological detriment should cover both expected exposures from normal use and potential exposures from reasonably foreseeable accidents, misuse, recycling and waste disposal, including magnitude and likely consequences of exposures;</u>	Clarification and completion. Consistency with wording in paras 2.29, 3.16 and 4.13 (“All relevant radiological aspects of the type of practice should be considered in the evaluation ... These include the radiation doses from normal use, reasonably foreseeable accidents, credible abuse and waste disposal.”). Recycling may also be part of the life cycle of a consumer product. See DPP for the IAEA Draft Safety Guide DS458 “Radiation safety and regulatory control of consumer products”.	A	The text has been modified.		



Germany	4.13	2 <sup>nd</sup> sentence: “... radiation doses from normal use, reasonably foreseeable accidents, <del>credible abuse</del> misuse, recycling and waste disposal.”	Consistency with wording in para 2.29 (“Account should be taken of normal use, misuse and accidents and of likely methods of disposal.”) and completion with regard to recycling. Recycling may also be part of the life cycle of a consumer product. See DPP for the IAEA Draft Safety Guide DS458 “Radiation safety and regulatory control of consumer products” (published in August 2011).	A	The text has been modified.		
Japan	4.19/3	The report should set out the key evidence, <b><u>uncertainty in the evaluation</u></b> , and the basis and rationale...	The report should include uncertainties in the dose assessment and in the prediction of future use. This comment was judged as “generally accept” in 28th RASSC meeting. Despite of this judgment, it is overlooked.	A	The text has been modified.		
Germany	4.20	3 <sup>rd</sup> sentence: “Nevertheless, if such comparisons with non-radioactive or <u>non-radiation-emitting</u> alternatives are seen as necessary, ...”	Clarification.	A	The text has been modified.		
Germany	5.3	2 <sup>nd</sup> sentence: “... specially developed techniques that would restrict the <u>individual</u> exposure to 10 µSv or less of any part of the body ...”	Wording.	A	The text has been modified.		
Japan	Title of section 5	The name of section 5 should be “Application to Non-Medical Human Imaging”.	“Radiographing of persons” includes medical use also. The word “Non-Medical Human Imaging” is used in the title and 4.3.	A	The text has been modified.		
Germany	5.7	4 <sup>th</sup> sentence: “... in fact, the individual exposed	Completion.	A	The text has been modified.		

		may be disadvantaged by the <u>radiological</u> consequences of the exposure.”					
Germany	5.11	2 <sup>nd</sup> sentence: “In addition, human imaging <u>using radiation</u> for the following <u>objectives shall <del>are required</del></u> normally to be deemed to be not justified: ...”  last sentence: “The BSS requires in <u>para 3.21</u> that <u>human imaging using radiation for</u> ”	Consistency with wording in paras 3.18 to 3.20 of the revised BSS.  Completion.	A	The text has been modified.		
Japan	5.13	The following sentence should be added at the end of the paragraph. “There may also be regional/local differences in the balance of benefits and risks even for the same type of practice.”	The risk of terror and alien smuggling varies by country/region. So does the prevalence of tuberculosis. Those variations could result in regional/local differences in the balance of benefits and risks even for the same type of practice. This comment was judged as "generally accept" in 28th RASSC meeting. Despite of this judgment, it is overlooked.	A	The text has been modified.		
Germany	5.14	(d) ... radiation equipment for the intended use;-	Editorial (replace punctuation mark by semicolon).	A	The text has been modified.		
Pakistan	Para 5.14	General comments	The periodic review of justification may be elaborated	A	The text has been modified – para 5.15.		
Pakistan	Para 5.14	General comments	The selection of passengers for x-ray screening made on random basis does not seems to be justified. There should be a criteria for x-ray screening of passengers			R	This is discussed in para 5.17.
Germany	5.16	last sentence: “... in other situations, such as access controls to buildings, should ...”	Editorial (add comma).	A	The text has been modified.		

Germany	5.17	last sentence: “... if alternative techniques not involving radiation <del>is</del> <u>are</u> available.”	Editorial.				
Japan	5.18/1 (p.33)	“dose constraints” should be changed to other expression, for example “any relevant radiological criteria”.	Dose constraints are used in optimization after justification.			R	The establishment of the dose constraints is not part of the optimization process, although they are to be used by the licensee in applying the requirements for optimization (see para 3.64 of the revised BSS (GSR Part 3)).
Germany	5.21	2 <sup>nd</sup> sentence: “... there is a high degree of suspicion that <del>that</del> <u>the</u> individual has swallowed a package containing drugs, ...”	Editorial.	A	The text has been modified.		
Japan	5.23/4	The following phrase should be added at the end of the paragraph. “even if the examination is mandatory.”	When there is a high degree of suspicion that an individual has swallowed a package containing drugs, the examination will be mandatory and the individual will not be allowed to refuse it. In this situation, even if information relating to radiological risk is provided, informed consent is not the priority. This comment was judged as "generally accept" in 28th RASSC meeting. Despite of this judgment, it is overlooked.	A	The text has been modified.		

Germany	5.26	2 <sup>nd</sup> sentence: “Imaging in sports medicine can be <u>used</u> for acute or chronic overuse injuries or for screening purposes.”	Missing word.	A	The text has been modified.		
Germany	5.27	2 <sup>nd</sup> sentence: “... guidance to avoid <u>misuse</u> .”	Editorial.	A	The text has been modified.		
Germany	5.29	1 <sup>st</sup> sentence: “... is also used where <del>x</del> X-rays are requested ...”	Editorial.	A	The text has been modified.		
Germany	5.36	4 <sup>th</sup> sentence: “This factor is <sub>2</sub> in addition to the uncertainties <sub>2</sub> inherent in the technique itself and any inter- and intra-observer variability.”	Editorial.	A	The text has been modified.		
Germany	5.37	last sentence: replace reference [17] by [16]	Cited Ref. [17] does not exist; text refers to Ref. [16].	A	The text has been modified.		
Germany	5.40	2 <sup>nd</sup> sentence: “... all immigrants from countries where TB is endemic ...”	Editorial.	A	The text has been modified.		
Germany	5.43	last sentence: “Nevertheless, <u>for</u> those types of practice where a large number of people might be affected, ...”	Missing word.	A	The text has been modified.		
Germany	5.45	1 <sup>st</sup> sentence: “An <u>dose</u> assessment <del>of the dose</del> should include <u>the individual</u> dose per examination <del>and should also be made of</del> <u>as well as</u> the potential doses to those who are likely to be exposed frequently ...”  2 <sup>nd</sup> sentence: “ <u>Millimeter wave</u> <del>s</del> Scanners which rely on technology ( <del>mm-wave</del> ) that does not use ionising radiation are now available and can provide an	Wording.  Wording.	A	The text has been modified.	R	Sentence has been deleted in line with next comment.

		alternative approach.”					
USA	5.45	Delete last sentence “Scanners which rely on technology (mm wave) that does not use ionizing radiation are now available and can provide an alternative approach.”	Para 4.20 “”In making it recommendation, the advisory body need not take account of any non-radioactive or non-radiation-emitting alternative methods of achieving the same or similar objectives.”	A	The text has been modified.		
Germany	5.48	2 <sup>nd</sup> sentence: “These may be cigarettes or alcohol, drugs, explosives or <del>other</del> weapons or even people being smuggled into a country.”	Wording.	A	The text has been modified.		
Germany	5.51	2 <sup>nd</sup> sentence: “The imaged persons should be afforded the same level of protection as if they were a patients undergoing a medical exposure, ...”	Editorial.	A	The text has been modified.		
Germany	5.52	2 <sup>nd</sup> sentence: “Furthermore, <u>para 3.66 of the BSS [2] requires that “all persons that who are about to be exposed to radiation for inspection procedures, to undergo procedures with <u>inspection imaging devices in which ionizing radiation is used</u> are informed <u>about</u> of the possibility of <del>choosing</del> <u>requesting the use of an alternative <u>inspection</u> technique that does not use ionizing radiation, where available”.</u>”</u>	Correct citation taken from BSS draft version 5.0 as of March 2011.	A	The text has been modified.		

Japan	ANNEX	Practical examples should be mentioned as far as possible.	Although DPP of DS401 says “Annexes will provide examples of decisions that have been taken in particular countries,” annexes in this document do not show practical examples. In addition some annexes do not adequately mention decisions (para,V-8, VI-8 and VII-10)		This issue is recognised by the Secretariat. Members of RASSC have been asked to provide examples where national justification studies have been made.		
Japan	ANNEX	Structure of Annexes should be arranged into consumer products part and non-medical human imaging part.	Clarification.	A	Structure of Annexes has been modified, in line with decision of RASSC/WASSC in December 2011.		
Germany	I-1	3 <sup>rd</sup> sentence: “The foreward to the group’s recommendations state ...”	Editorial.		Annex I has been deleted following decision at RASSC/WASSC meeting in December 2011. It is to be included in DS458.		
USA	I-4/line 6	Which is the annual effective dose? 1 µSv or 10 µrad	1 µSv ≠ 10 µrad		Annex I has been deleted following decision at RASSC/WASSC meeting in December 2011. It is to be included in DS458.		
Germany	I-4	4 <sup>th</sup> sentence: Please specify the correct annual effective dose to an individual householder as a result of normal use.	Note: 1 µSv ≠ 10 µrad		Annex I has been deleted following decision at RASSC/WASSC meeting in December 2011. It		

					is to be included in DS458.		
Germany	I-4, I-5	Add new para in subsection DETRIMENTS: <u>“Some older ICSDs may contain krypton-85, plutonium-238 or plutonium-239 sources. With these radionuclides the effective doses from normal use and waste disposal can be significantly higher [I-2].”</u>	Essential amendment taken from EC document Radiation Protection 146. Add this publication to the list of references to Annex I.		Annex I has been deleted following decision at RASSC/WASSC meeting in December 2011. It is to be included in DS458.		
Japan	I-4	1µSv(10µrad) → 1µSv (100µrem)	1µSv is not equal to 10µrad but to 100µrem.		Annex I has been deleted following decision at RASSC/WASSC meeting in December 2011. It is to be included in DS458.		
Germany	Ref. [I-2]	Shaw J., Dunderdale J. and Paynter R. A., A Review of Consumer Products Containing Radioactive Substances in the European Union, Radiation Protection 146, European Commission, Luxembourg (2007).	See comment to paras I-4 and I-5.		Annex I has been deleted following decision at RASSC/WASSC meeting in December 2011. It is to be included in DS458.		
Germany	II-3	1 <sup>st</sup> sentence: “... on 25 <sup>th</sup> December 2009 ...”	Editorial.	A	The text has been modified.		
Germany	II-5	b) “... terrorist attacks in the US on the 11 September 2001 <del>0</del> .”	Editorial.	A	The text has been modified.		
USA	II-11/b	Delete	See comment 1 above	A	The text has been modified.		

USA	II-12	Delete	See comment 1 above. The BfS decision was to select an alternative technology that doesn't use x-rays. The decision process used is counter to the advice given in this document. Delete or reconcile the inclusion of this example with the guidance provided.	A	The text has been modified.		
Germany	III-1	3 <sup>rd</sup> sentence: "Any packages in the <u>gastrointestinal GI</u> -tract are usually easily visible ..."	Wording.	A	The text has been modified.		
Germany	III-3	e) "... to survive a broken wrapping in the <u>gastrointestinal GI</u> -tract."	Wording.	A	The text has been modified.		
USA	III-3a, b and c	Delete	Highly speculative. Leave these issues to the social scientists, not the radiation protection community.	A	The text has been deleted.		
USA	III-4	Social detriment - A reduced amount of drugs on the market will drive the street price for the drugs higher.				R	See above comment.
USA	III-4	Social detriment - Higher prices for drugs may increase non-violent crime in order to pay for more expensive drugs.				R	See above comment.
Germany	IV-1	last sentence: "... where the first phase of checking; (e.g. CO <sub>2</sub> sensors); has provided inconclusive results."	Editorial (delete commas).	A	The text has been modified.		
USA	IV-6(f)		Unclear what the support costs are and how they relate to the justification of radiation scanners			R	This paragraph is taken directly from the study prepared by the UK Home Office. It is assumed that the support costs are provided to



							people who have illegally entered the UK, while they wait for the legal processes regarding their future are followed.
USA	IV-10	Is the number of illegal immigrants underestimated with 1,000?	Illegal entries into East Kent in 2000 was approximately 20,000 (para IV-1) Wouldn't the annual collective dose be considerably greater than 2 man mSv?			R	The number of 1000 is taken from the study prepared by the UK Home Office. The UK Home Office did not provide information on how the number of 1000 was derived. It is assumed that not all illegal entries to East Kent would be subject to radiation from the scanners (e.g. not all vehicles are to be scanned).
USA	IV	Revise Annex IV	A more relevant case study might be the use of radiation scanners to detect weapons of mass destruction transiting borders and the inadvertent exposure of illegal immigrants in these scanned containers.			R	The case study in Annex IV was derived from a justification study carried out in the UK and published by the UK Home Office. The USA is welcome to provide a case study on the use of radiation scanners to detect weapons of mass destruction transiting borders to

							include this Safety Guide.
Germany	VI-2	Move the whole para into the subsection BENEFITS.	In fact, para VI-2 describes some reasons why lightning rods were utilized in past decades. In contrast to this, para VI-3 does not address any benefits of such devices.	A	The text has been modified.		
Germany	VI-2	last but one sentence: “... <u>krypton-85</u> , ...”	Editorial.	A	The text has been modified.		
Germany	VI-3	1 <sup>st</sup> sentence: “Doubts over the efficacy of these radioactive lightning rods go back at least to the 1960s <u>when lightning rods were used to protect very high structures, e.g. churches, television towers, skyscrapers</u> [VI-1].”	Additional information taken from Ref. [VI-1].	A	The text has been modified.		
Germany	VI-4	2 <sup>nd</sup> sentence: “... the <u>disused</u> sources need to be treated as radioactive waste, <u>appropriately conditioned, and appropriately managed stored and disposed of.</u> ”  Add new last sentence: “ <u>Since 1970, many countries have operated programmes to remove radioactive lightning conductor rods from service</u> [VI-4, VI-6].”	Clarification and completion.  Additional information taken from EC document Radiation Protection 146 and from the IAEA Nuclear Security Series No. 5 (see chapter 5.20). Add this publication to the list of references to Annex VI.	A	The text has been modified.  “the disused sources need to be managed as radioactive waste.”  New sentence added.		
Germany	VI-6	“There <u>do not</u> appear to be any published decisions on the justification for the introduction of this practice.”	Clarification.	A	The text has been modified.		
Germany	Ref. [VI-6]	INTERNATIONAL ATOMIC ENERGY AGENCY, Identification of Radioactive Sources and Devices, IAEA Nuclear Security Series No. 5, IAEA, Vienna (2007).	See comment to para VI-4.	A	The text has been modified.		

Germany	VII-1	1 <sup>st</sup> sentence: “High intensity discharge lamps (HID) lamps produce bright white light ...”	Editorial.		Annex VII has been deleted following decision at RASSC/WASSC meeting in December 2011. It is to be included in DS458.		
Germany	Annex VIII	General note: The scope of this Annex should be limited to the justification for the use of those products that can be purchased without restriction by the public.	The definition of the term “consumer product” in the glossary of the revised BSS excludes products and appliances installed in public places that may give rise to radiation exposure of the public, e.g. exit signs containing gaseous tritium light sources (GLTS). Such devices are used quite extensively in public buildings and aircraft.			R	RASSC decided that Annexes on consumer products are to be included in the Safety Guide DS458: “Radiation Protection and Regulatory Control of Consumer Products”, and that the Annexes on “tritium exit signs” and “lightning protection systems” be retained in DS401.
Germany	VIII-4	1 <sup>st</sup> sentence: “There are internal <u>exposure</u> hazards when tritium is taken into the body ...”	Wording.	A	The text has been modified.		
Germany	after Annex VIII	Please add another two Annexes, provided that any studies on justification for the use of those items are available:  Annes IX “Case Study on Items containing Thorium such as Gas Mantles, Camera Lenses and Ophthalmic Lenses”	Items addressed here are available for the public in several EU Member States. An overview of national practices is given in the EC document Radiation Protection 146. Furthermore, the DPP for the IAEA Draft Safety Guide DS458 “Radiation safety and regulatory control of consumer products” (published in August 2011) will contain a section dealing with such			R	RASSC decided that Annexes on consumer products are to be included in the Safety Guide DS458: “Radiation Protection and Regulatory Control of Consumer Products”

		Annex X "Case Study on Items incorporating Uranium such as Ceramic Tiles, Glassware and Tableware"	items. Proposed Annex IX relates to consumer products to which small amounts of radioactive material have been deliberately added to improve their physical or chemical properties.				
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**TITLE**

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Country/Organization:				Page.... of.... Date:			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection