This publication has been superseded by GSR Part 4, GSG-12, GSG-13, SSG-8, SSG-11, SSG-45, SSG-49, SSG-55, SSG-57, SSG-58, SSG-87, Safety Reports Series No. 50, and IAEA Nuclear Energy Series Nos. NW-G-2.1 and NW-T-2.3.

IAEA Safety Standards

for protecting people and the environment

Safety of Radiation Generators and Sealed Radioactive Sources

Safety Guide

No. RS-G-1.10

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IAEA SAFETY RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

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SAFETY OF RADIATION GENERATORS AND SEALED RADIOACTIVE SOURCES

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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

IAEA SAFETY STANDARDS SERIES No. RS-G-1.10

SAFETY OF RADIATION GENERATORS AND SEALED RADIOACTIVE SOURCES

SAFETY GUIDE

INTERNATIONAL ATOMIC ENERGY AGENCY
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FOREWORD

by Mohamed ElBaradei
Director General

The IAEA's Statute authorizes the Agency to establish safety standards to protect health and minimize danger to life and property — standards which the IAEA must use in its own operations, and which a State can apply by means of its regulatory provisions for nuclear and radiation safety. A comprehensive body of safety standards under regular review, together with the IAEA's assistance in their application, has become a key element in a global safety regime.

In the mid-1990s, a major overhaul of the IAEA's safety standards programme was initiated, with a revised oversight committee structure and a systematic approach to updating the entire corpus of standards. The new standards that have resulted are of a high calibre and reflect best practices in Member States. With the assistance of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its safety standards.

Safety standards are only effective, however, if they are properly applied in practice. The IAEA's safety services — which range in scope from engineering safety, operational safety, and radiation, transport and waste safety to regulatory matters and safety culture in organizations — assist Member States in applying the standards and appraise their effectiveness. These safety services enable valuable insights to be shared and I continue to urge all Member States to make use of them.

Regulating nuclear and radiation safety is a national responsibility, and many Member States have decided to adopt the IAEA's safety standards for use in their national regulations. For the Contracting Parties to the various international safety conventions, IAEA standards provide a consistent, reliable means of ensuring the effective fulfilment of obligations under the conventions. The standards are also applied by designers, manufacturers and operators around the world to enhance nuclear and radiation safety in power generation, medicine, industry, agriculture, research and education.

The IAEA takes seriously the enduring challenge for users and regulators everywhere: that of ensuring a high level of safety in the use of nuclear materials and radiation sources around the world. Their continuing utilization for the benefit of humankind must be managed in a safe manner, and the IAEA safety standards are designed to facilitate the achievement of that goal.

CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. Radiation sources have wide application in medicine, industry, research, agriculture and education. Such sources must be managed safely and securely. Incorrectly used or unsecured radioactive sources can cause death, serious injury and economic loss, as experience in many parts of the world has shown. The IAEA has published a number of reports that review the human health consequences of accidents involving a loss of control over or misuse of sources [1–14]. Economic losses can also be high, especially following accidents that cause widespread radioactive contamination, such as those at Juarez, Mexico, in 1983 [15] and Goiânia, Brazil, in 1987 [1].

1.2. The IAEA Board of Governors has discussed the safety and security of radiation sources on a number of occasions. Furthermore, in resolution GC(42)/RES/12 on The Safety of Radiation Sources and the Security of Radioactive Materials, adopted on 25 September 1998, the General Conference, inter alia, encouraged all governments "to take steps to ensure the existence within their territories of effective national systems of control for ensuring the safety of radiation sources and the security of radioactive materials".

1.3. The IAEA has issued a number of publications emphasizing the necessity of national systems for ensuring the safety of sources in its Member States:

— The former Safety Fundamentals publication, Radiation Protection and the Safety of Radiation Sources[1], now superseded [16], sets out the principles for radiation protection, including the need for governments to establish a legal framework for regulatory control of activities involving radiation sources.

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and the Safety of Radiation Sources, Safety Series No. 120, IAEA, Vienna (1996).

— The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS) [17] place requirements on responsible parties, particularly registrants, licensees and employers, to put in place a system of control for radiation sources to ensure their safety.
— The Safety Requirements publication Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety (the Requirements for Legal and Governmental Infrastructure) [18] sets out legislative and governmental responsibilities for establishing a national regulatory infrastructure.
— The Code of Conduct on the Safety and Security of Radioactive Sources (the Code of Conduct) [19] additionally requires States that adopt it to take appropriate measures to ensure that sources are safely managed and securely protected. According to the Code of Conduct, every State should have in place an effective national regulatory system that, inter alia, minimizes the likelihood of loss of control over sources.

This Safety Guide supports the implementation of the requirements of the BSS and the Requirements for Legal and Governmental Infrastructure, and is consistent with the expectations for safety and security deriving from the Code of Conduct.

OBJECTIVE

1.4. The objective of this Safety Guide is to assist Member States in implementing regulatory requirements for radiation sources to ensure their safety. To that end, this Safety Guide provides guidance on responsibilities for safety within the legal and governmental infrastructure, on methodologies for performing safety assessments and on specific design and operational measures that should be taken to ensure safety throughout the lifetime of a radiation source.

SCOPE

1.5. This Safety Guide is intended for regulatory bodies[2] and for users[3], to provide them with guidance regarding the safety of radiation generators and sealed radioactive sources. It applies to all practices except those that qualify for exemption from the requirements of the BSS (Ref. [17], paras 2.17 and 2.18). The guidance generally applies to actions to be taken and issues to be considered by authorized legal persons[4] throughout the lifetime of a radiation source[5].

1.6. All facilities where radiation sources need to be safely managed are covered by this Safety Guide, including those containing the sources[6] shown in Table 1 in Section 3. The safety measures recommended are also applicable to radioactive sources in nuclear facilities or radioactive waste disposal facilities, while it is recognized that these facilities should in any case provide a high standard of source safety.

1.7. Guidance on security matters relating to the prevention and detection of, and response to, malicious acts is beyond the scope of this Safety Guide and is addressed in other IAEA publications (see, for example, Refs [19, 20][7]).

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[2] The term 'regulatory body' is used to cover all types of regulatory infrastructure, including systems having single or multiple authorities at the national level only and federal systems where authority is distributed across the relevant regional, provincial or State jurisdictions. 'Regulatory body' is synonymous with the term 'Regulatory Authority' that was used in some earlier IAEA publications, such as the BSS.

[3] In this Safety Guide, the term 'user' is sometimes used as an alternative to 'principal party' (see para. 2.6) to avoid awkwardness of expression. 'Principal party' is always used when it is the subject of a recommendation (a 'should' statement).

[4] A 'legal person' is an individual or organization recognized as an entity for legal purposes (see the BSS [17]).

[5] Where the word 'source' is used in this Safety Guide without qualification, or in the term 'radiation source', it is to be taken to mean either a radiation generator or a radioactive source, depending on the context.

[6] Radiation sources are often built into devices that direct, filter, scatter or otherwise affect the radiation emitted. Such devices are covered by this Safety Guide to the extent that the source is an integral part of a device; the safety of devices more generally is dealt with in other IAEA publications. In this sense, the word 'source' is used in this Safety Guide to mean 'source and device', as appropriate.

[7] Reference [20] contains interim guidance only. Further publications dealing with security matters are issued in the IAEA Nuclear Security Series.

However, the need to keep sources secure to ensure safety is vital, and this Safety Guide refers to requirements of the BSS for the security of sources in this context, in particular to prevent unauthorized access to and use of sources[8]. The safety and security of nuclear material[9], the control of medical exposures, the recovery of control over orphan sources[10] and procedures following an accident are also beyond the scope of this Safety Guide.

STRUCTURE

1.8. Guidance on national infrastructures and responsibilities is provided in Section 2 of this Safety Guide. Guidance on the performance of a safety assessment is provided in Section 3, followed by guidance on the design, manufacture and use of radiation sources and the design and operation of facilities in Section 4. Some of the recommendations in this Safety Guide apply to the safe and secure handling of radiation sources at several stages of their lifetime, and some additional discussion of issues that arise at the final stages of their lifetime is presented in Section 5. An example is provided in Annex I of factors that should be considered in establishing a system of source safety, and a description of some probabilistic safety assessment techniques is presented in Annex II.

[8] The phrase 'security for safety' is used in this Safety Guide to convey this limited meaning.

[9] The term 'nuclear material' is defined in the Convention on the Physical Protection of Nuclear Material [21] as "plutonium except that with isotopic concentration exceeding 80% in plutonium-238; uranium-233; uranium enriched in the isotope 235 or 233; uranium containing the mixture of isotopes as occurring in nature other than in the form of ore or ore-residue; any material containing one or more of the foregoing".

[10] The term 'orphan source' refers to a radioactive source that is not under regulatory control, either because it has never been so, or because it has been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorization.

2. REGULATORY INFRASTRUCTURE AND RESPONSIBILITIES

RADIATION SAFETY INFRASTRUCTURE

2.1. In the BSS [17] and the Requirements for Legal and Governmental Infrastructure [18] the elements of a national infrastructure are considered to be: legislation and regulations; a regulatory body empowered to authorize and inspect regulated activities and to enforce the legislation and regulations; and sufficient resources and an adequate number of trained personnel to implement the regulatory system. The regulatory body should be provided with the necessary powers and resources to fulfil these functions and should be effectively independent of any government departments and agencies that are responsible for the promotion and development of the practices being regulated. The regulatory body should also be independent of the registrants, licensees, designers and constructors of the radiation sources used in practices.

2.2. Legislation and regulations should cover the requirements set out in the BSS [17]. The BSS (in para. 2.13(c)) require any person applying for an authorization to make an assessment of the nature, magnitude and likelihood of the exposures attributed to the source and to take all necessary steps for the protection and safety of workers and the public. The BSS (in para. 2.13(d)) also require that if the potential for an exposure is greater than any level specified by the regulatory body, a safety assessment shall be made and submitted to the regulatory body as part of the application. The BSS (Ref. [17], para. 2.37) further require that safety assessments relating to protection and safety measures shall be performed at different stages in the lifetime of a source, including siting, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning. Detailed requirements relating to practical aspects of the safety of radiation sources can be found in Appendix IV of the BSS, and further guidance is given in supporting publications in the IAEA Safety Standards Series, for example in the Safety Guide on Regulatory Control of Radiation Sources [22].

RESPONSIBILITIES OF THE REGULATORY BODY

2.3. The Requirements for Legal and Governmental Infrastructure [18] set out the requirements for governmental responsibilities in establishing a national regulatory framework for the control of radiation sources.

Responsibilities of the regulatory body are detailed in the BSS [17] and in Ref. [22]. The regulatory body should establish a graded approach to the regulation of safety to ensure the efficient and effective utilization of resources: the higher the risk associated with a source, the more stringent should be the regulatory requirements that apply to it. Some sources and equipment may be exempted from the requirements of the BSS (including the requirements for notification, registration and licensing) if they meet the exemption criteria in Schedule I of the BSS.

2.4. The regulatory body should require that those who intend to possess and use radiation sources seek an authorization, and should, as appropriate, require a safety assessment from the person seeking the authorization. Section 3 provides further guidance on safety assessment.

2.5. The regulatory body:

(a) Should maintain appropriate records of holders of authorizations to possess or use radiation sources, with a clear indication of the types of source that they have been authorized to own or use.
(b) Should maintain an up to date register of individual sources — as a minimum for radioactive sources in Categories 1 and 2 (see Table 1) — including appropriate records of the transfer and disposal of sources on termination of an authorization.
(c) Should establish systems for ensuring that, where practicable, radioactive sources are identifiable and traceable. Where continued identification is not practicable, as may be the case, for example, for some separable or segmentable sources, such as sources in wire form used in brachytherapy, the regulatory body should ensure that processes for identifying and tracing the history of use and status of the sources are in place.
(d) Should ensure that the regulatory principles and criteria remain adequate and valid and that operating experience and internationally endorsed standards and recommendations, as applicable, are taken into account.
(e) Should implement an inspection programme to verify that facilities and programmes are maintained so as to manage the radiation sources adequately.

RESPONSIBILITIES OF THE PRINCIPAL PARTIES

2.6. Registrants and licensees are the principal parties[11] who bear the responsibility for setting up and implementing the technical and organizational measures that are needed for ensuring the safety of the sources for which they are authorized. These arrangements for safety and protection should be documented. Registrants and licensees may appoint other people to carry out actions and tasks relating to these responsibilities, but they retain the responsibility for the actions and tasks themselves. They should specify the individuals responsible for ensuring that sources are used in accordance with the recommendations in this Safety Guide and the requirements of the BSS, or with national regulations.

2.7. The principal parties should ensure that:

(a) Sources are used in accordance with the authorizations held for them.
(b) Access to sources is controlled by means of administrative and engineering measures appropriate for the category of source. Such measures include physical barriers and locks and releases to which only authorized persons have the keys.
(c) When sources are not in use they are stored promptly in an approved manner. In particular, temporary arrangements should be avoided when a source will not be used for some time. Storage should be in accordance with the requirements for the category of the source.
(d) Any transfer of sources to another person is documented and that person is authorized in accordance with the applicable regulatory requirements to receive the transferred source.
(e) Financial provisions in accordance with the regulatory requirements for the safe management of disused sources are in place.
(f) Sources are shipped and received in accordance with regulatory requirements.

2.8. The principal parties and the authorized persons identified by the principal parties should be prepared to assist State authorities or local law enforcement authorities in recovering any lost or stolen source belonging to the registrant or licensee.

[11] The BSS [17] state (para. 1.6) that: "The principal parties having the main responsibilities for the application of the Standards shall be: (a) registrants or licensees; and (b) employers."

Individuals with assigned responsibilities for sources

2.9. An individual who has been assigned responsibilities by the principal party should have the expertise and authority to ensure that the measures for the safety of sources recommended in this Safety Guide are implemented.

2.10. The responsible individual should ensure that all personnel who use or have access to the sources are authorized and have the proper training consistent with their duties in handling those sources.

Security for safety

2.11. The BSS (Ref. [17], para. 2.34) specifically require that measures be taken to prevent damage to or unauthorized possession of radiation sources by ensuring that control over them is not relinquished or improperly transferred and that periodic inventories are made of movable sources:

> "Sources shall be kept secure so as to prevent theft or damage and to prevent any unauthorized legal person from carrying out any of the actions specified in the General Obligations for practices of the Standards (see paras 2.7–2.9), by ensuring that:
>
> (a) control of a source not be relinquished without compliance with all relevant requirements specified in the registration or licence and without immediate communication to the [regulatory body], and when applicable to the relevant Sponsoring Organization, of information regarding any decontrolled, lost, stolen or missing source;
> (b) a source not be transferred unless the receiver possesses a valid authorization; and
> (c) a periodic inventory of movable sources be conducted at appropriate intervals to confirm that they are in their assigned locations and are secure."

2.12. 'Security for safety' measures should, as a minimum, provide control for protection against damage, loss or theft. Advice should be sought from security experts in implementing measures that are appropriate for each source and are in conformance with the requirements of authorities having responsibility for security. Further guidance is provided in other IAEA publications (e.g. Refs [19, 20]).

Accountability for sources — inventories and records

2.13. Records should be kept of all sources. Inventories should be updated on a regular basis consistent with the source categorization or in accordance with other applicable regulatory requirements. The records should be kept safe.

2.14. In addition to regular maintenance and updating, source records should be updated whenever a change (e.g. of location) occurs and, in particular, when sources are transferred. The records for radioactive sources should include the following particulars:

(a) Serial number or unique identifier;
(b) Manufacturer's type number and reference to where construction details can be found;
(c) Radionuclide (elemental symbol and isotopic number);
(d) Activity on a specified date;
(e) Physical form;
(f) Physical and chemical properties, including the principal emissions (α, β, γ, n);
(g) Location of the source;
(h) Where not otherwise evident from the foregoing records, details of the device or equipment with which the source is used, if essential for safety;
(i) When appropriate, a source use history (e.g. a log of source handling operations);
(j) Details of receipt or transfer or disposal of the source.

For X ray generators, the source descriptors (c), (d), (e) and (f) above should be replaced with details of the peak tube potential (in kVp) and maximum rated beam current (in mA). For particle accelerators, all parameters important for safety should be recorded, as required by the regulatory body.

Status and event reporting system

2.15. The principal party should ensure that there is a procedure for communicating routinely to the regulatory body details of the source status and the reporting information required.

2.16. In addition to normal reporting requirements relating to safety issues, reports of unusual events that may affect safety should be made promptly, and the events should be investigated. National legislation should require such investigations to be carried out and reported on, with the regulatory body

having authority to conduct an investigation into significant events having safety implications. Unusual events to be reported to the regulatory body and, as appropriate, to security authorities may include:

(a) Loss of control over a radiation source, including theft;
(b) Unplanned exposures from a source;
(c) Unauthorized access to, or unauthorized use of, a source;
(d) Failures of equipment containing sources that may have safety or security implications;
(e) Discovery of an unaccounted for source.

2.17. These reports should enable the regulatory body to keep track of sources and should aid in the identification and recovery of lost sources.

3. SAFETY ASSESSMENT

SAFETY ASSESSMENTS

3.1. Registrants or licensees should carry out safety assessments for the sources for which they are responsible. The initial safety assessment is the primary tool for determining the protection measures that should be put in place, and all the parameters that have a bearing on radiation protection and source safety should be considered. Subsequent safety assessments are undertaken to confirm that safety measures continue to meet the standards set and to indicate the need for improvement where necessary. The BSS (Ref. [17], para. 2.37) state that:

> "Safety assessments related to protection and safety measures for sources within practices shall be made at different stages, including siting, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning, as appropriate, in order:
>
> (a) to identify the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment;
> (b) to determine the expected magnitudes of normal exposures and, to the extent reasonable and practicable, to estimate the probabilities and the magnitudes of potential exposures; and

(c) to assess the quality and extent of the protection and safety provisions."

3.2. The primary objective of the assessment is to assess the adequacy of planned or existing measures for protection and safety and to identify any additional measures that should be put in place. As such, both routine use of the source and the probability and magnitude of potential exposures arising from accidents or incidents should be considered. Where the assessment indicates that there is a realistic possibility of an accident affecting workers or members of the public or having consequences for the environment, the registrant or licensee should prepare a suitable emergency plan.

3.3. The BSS (Ref. [17], para. 2.13 (c)) require the legal person (principal party) applying for authorization from a regulatory body to "make an assessment of the nature, magnitude and likelihood of the exposures attributed to the source and take all necessary steps for the protection and safety of both workers and the public". Such an assessment should always be made by the principal party, even when considering the safety of sources in the lower risk categories and in commonplace applications. Safety assessments may be specific or generic. Generic safety assessments are not specific to a particular facility but cover all sources and/or devices of a particular design. They may be used for types of sources with a high degree of uniformity in design and may be available to the registrant or licensee from the manufacturer or supplier (further guidance on manufacture is given in Section 4). Such an assessment is likely to be available, for example, for a particular design of industrial gauge. However, the generic safety assessment may need to be supplemented by a site specific safety assessment covering, for example, the location of the source and the suitability of local shielding. In circumstances where no generic safety assessment is available, a full specific safety assessment should be carried out.

3.4. The principal party may also perform a generic assessment, making use of prior experience with the use of similar sources. Such an approach would be appropriate when the principal party already has authorization for several similar sources on the site, but it may still need to be supplemented by additional information on specific issues relating to the location.

3.5. The BSS (Ref. [17], para. 2.13(d)) also require that "if the potential for an exposure is greater than any level specified by the [regulatory body],… [a safety assessment shall be] made and submitted to the [regulatory body] as part of the application [for an authorization]". This requirement allows the regulatory body to specify the situations in which a documented safety

assessment will be required as part of the process for review of an application for authorization. In such a case, the principal party should carry out a specific assessment for the particular circumstances that apply. Applications for authorization that are likely to require the submission of a safety assessment to the regulatory body include those for industrial irradiation facilities, industrial radiography facilities and radiation oncology facilities.

3.6. A safety assessment should be carried out before the source is first received at the site or brought into routine use, to give sufficient time for the necessary protection and safety measures to be put into place. A new safety assessment is not necessary for the replacement or replenishment of a source, but the replacement process may need to be assessed.

Methodology for safety assessment

3.7. The BSS (Ref. [17], Appendix IV, paras IV.3–IV.7) require the following for carrying out a safety assessment:

> "IV.4. The safety assessment shall include, as appropriate, a systematic critical review of:
>
> (a) the nature and magnitude of potential exposures and the likelihood of their occurrence;
> (b) the limits and technical conditions for operation of the source;
> (c) the ways in which structures, systems, components and procedures related to protection or safety might fail, singly or in combination, or otherwise lead to potential exposures, and the consequences of such failures;
> (d) the ways in which changes in the environment could affect protection or safety;
> (e) the ways in which operating procedures related to protection or safety might be erroneous, and the consequences of such errors; and
> (f) the protection and safety implications of any proposed modifications.
>
> "IV.5. The registrant or licensee shall, as appropriate, take into account in the safety assessment:
>
> (a) factors which could precipitate a substantial release of any radioactive substance and the measures available to prevent or control such a release, and the maximum activity of any radioactive

substance which, in the event of a major failure of the containment, might be released to the atmosphere;
(b) factors which could precipitate a smaller but continuing release of any radioactive substance and the measures available to prevent or control such a release;
(c) factors which could give rise to the unintended operation of any radiation beam and the measures available to prevent, identify and control such occurrences;
(d) the extent to which redundant and diverse safety features, being independent of each other so that failure of one does not result in failure of any other, are appropriate in order to restrict the probability and magnitude of potential exposures.

"IV.6. The safety assessment shall be documented and, if appropriate, independently reviewed within the relevant quality assurance programme. Additional reviews shall be performed as necessary for ensuring that the technical specifications or conditions of use continue to be met whenever:

(a) significant modifications to a source or its associated plant or its operating or maintenance procedures are envisaged;
(b) operating experience, or other information about accidents, failures, errors or other events that could lead to potential exposures indicates that the current assessment might be invalid; and
(c) any significant changes in activities, or any relevant changes in guidelines or standards, are envisaged or have been made.

"IV.7. If as a result of a safety assessment, or for any other reason, opportunities for improving the protection or safety measures associated with a source within a practice seem to be available and desirable, any consequential modifications shall be made cautiously and only after a favourable assessment of all the implications for protection and safety; and if such improvements cannot all be implemented, or not all at once, they shall be prioritized so as to result in optimum improvements in protection or safety."

3.8. It should be emphasized that human factors such as lack of training and failure to follow operating rules and licence conditions have been found in practice to be major contributors to the occurrence of accidents and overexposure events. Particular attention should therefore be paid in safety assessments to the possibility of human error and its consequences.

Graded approach

3.9. The depth and level of detail required in a safety assessment is very much dependent on the practice under consideration. The scale of the task will depend on the safety significance of the activities assessed and on the maturity and complexity of the technology involved and its safety history. The prime consideration is that a safety assessment should be suitable and sufficient to identify adequately the protection and safety measures required for a particular practice[12].

3.10. The IAEA has developed a categorization system for radioactive sources used in common practices [23], as shown in Table 1. According to this scheme, sources should be allocated to one of five categories, depending on the scale of the hazard associated with them. Sources in Category 1 are potentially the most dangerous and sources in Category 5 the most unlikely to be dangerous. Sources in Categories 1–3 are generally capable, if not properly controlled, of giving rise to exposure sufficient to cause severe deterministic effects[13].

3.11. For radioactive sources, this categorization system may be used as a starting point for determining the scale of the safety assessment required for a particular practice. The safety assessment for commonly used radioactive sources in Category 4 or 5 will generally be relatively straightforward and may incorporate generic information from the supplier on doses and safety systems. Consideration of local features (e.g. access, shielding, frequency of use) should also be incorporated into the assessment.

3.12. For X ray generators and particle accelerators, there is no formal international system of categorization in relation to hazard. X ray generators have an inherent protection against misuse to the extent that they do not produce X rays when switched off (see, however, footnote 15). The principal misuse that may need to be addressed in a safety assessment is likely to be unauthorized activation of a generator that is left unattended by the operator. Adherence to the use of approved generator designs and safety procedures that include locks and key codes for access and activation should minimize the possibility of harm. However, there is a wide variation in generator power and

[12] An IAEA Safety Requirements publication covering safety assessment and verification is in preparation.

[13] A severe deterministic effect is one that is fatal or life threatening or results in a permanent injury that decreases quality of life [23].

TABLE 1. RECOMMENDED CATEGORIES FOR RADIOACTIVE SOURCES USED IN COMMON PRACTICES

Category	Source and practice	Activity ratio (A/D)[a]
1	Radioisotope thermoelectric generators Irradiators Teletherapy sources Fixed multibeam teletherapy (gamma knife) sources	$A/D \geq 1000$
2	Industrial gamma radiography sources High/medium dose rate brachytherapy sources	$1000 > A/D \geq 10$
3	Fixed industrial gauges that incorporate high activity sources Well logging gauges	$10 > A/D \geq 1$
4	Low dose rate brachytherapy sources (except eye plaques and permanent implants) Industrial gauges that do not incorporate high activity sources Bone densitometers Static eliminators	$1 > A/D \geq 0.01$
5	Low dose rate brachytherapy eye plaques and permanent implants X ray fluorescence (XRF) devices Electron capture devices Mossbauer spectrometry sources Positron emission tomography (PET) check sources	$0.01 > A/D$ and $A >$ exempt[b]

[a] The categorization system is based on the 'dangerous source' concept, which is quantified in terms of D values. The D value is the radionuclide specific activity of a source that, if not under control, can cause severe deterministic effects for a range of scenarios. For further information on determining A/D values, see Ref. [23].

[b] Exempt quantities are given in Schedule I of the BSS [17].

control systems, and the scale of hazard appropriate to the circumstances should be taken into account in the safety assessment.

3.13. Information on all the administrative and technical measures that are planned or are built into the installation to keep individual doses low should be considered in the safety assessment for normal operation. In particular, it should be shown that the protective measures taken, such as shielding or necessary maintenance procedures, satisfy the requirements for optimization of protection.

3.14. A comprehensive safety assessment should be carried out for sources that produce high radiation fields, such as industrial radiography sources, other Category 1, 2 and 3 sources and particle accelerators, as these sources have a high potential for high exposures with severe or fatal consequences. The assessment should include an examination of postulated scenarios for exposure in order to ensure that safety features such as barriers and interlocks are adequate. The approach and the tools used to perform a safety assessment can range from straightforward qualitative assessments to the use of deterministic and probabilistic assessments. The level of detail and rigour applied to a safety assessment for a source should be commensurate with the potential hazard posed by the source. Probabilistic or other assessments of the likelihood of equipment failures should be supplemented with appropriate assessment of the likelihood of human error.

3.15. Some guidance is given in Annex II on methods of probabilistic safety assessment. This type of assessment may need to be performed if the potential radiological consequences of equipment failure are high. Such assessments should be designed to reveal the level of safety achievable for the installation and the possible need for improvements. A probabilistic safety assessment should be able to answer three questions:

(a) What could go wrong?
(b) How likely is it?
(c) What would be the consequences for safety?

From the answers, the assessment should be able to provide the information needed to aid in the design and use of an effective safety system for the source.

Reviews of the safety assessment

3.16. The safety assessment should be documented and should be reviewed whenever:

(a) Safety may be compromised or affected as a result of modifications to the facilities or to the procedures;
(b) Operational experience or the investigation of accidents or errors indicates that a review is necessary; or
(c) Any significant changes to relevant guidelines or standards have been made or are envisaged.

Any consequential modifications should be made cautiously and only after a proper assessment of all the implications for protection and safety.

3.17. Periodic audits of the arrangements for radiation protection and source safety should also be made, preferably as part of the quality management programme in place at the facility. The findings of these audits may also lead to amendment of the arrangements for safety assessment and radiation protection.

3.18. The regulatory body may call for an independent audit of a safety assessment if this is considered necessary, or the regulatory body may conduct its own review.

Use of generic safety assessments by the regulatory body

3.19. Regulatory bodies should have a good understanding of the potential exposures associated with different practices, both to determine those areas that require the greatest attention and to review applications for authorizations. This understanding can be obtained in several ways. The regulatory body should, for specific applications, require applicants to submit a safety assessment with their application for authorization. This process provides useful information for the review by the regulatory body. Another approach is for the regulatory body to carry out generic safety assessments for its own purposes. This approach will enable the regulatory body to build up a good knowledge base in a wide range of practices. A further possibility is for the regulatory body to make a judgement as to the suitability of the application on the basis of a safety assessment made by another party, such as another regulatory body or the manufacturer of the source. However, for each specific practice, the responsibility for carrying out a safety assessment remains with the registrant or licensee, rather than with the regulatory body. Furthermore, only the registrant or licensee is in a position to incorporate site specific information into an assessment.

3.20. To make the best use of resources, the regulatory body should establish priorities for its activities to ensure that the greatest effort is focused on those radiation sources that present the greatest radiation hazards. Generic safety assessments of the radiation hazards resulting from various practices will provide the necessary information to determine those practices that should be given the greatest attention. The source categorization of Table 1 provides a useful initial ranking for this purpose.

3.21. A generic radiation safety assessment should cover issues of safety and interactions with security that may arise during each stage of the lifetime of the source, including distribution, installation, commissioning, use, maintenance and disposal. The review should identify the potential for accidents to cause serious injury or radioactive contamination, and the probability of such accidents occurring and their consequences. Past performance in compliance and information on any past accidents should be reviewed as part of the prioritization process.

3.22. Items that should be considered when performing an initial evaluation of radiation sources for the purposes of ranking their relative radiation hazards include:

(a) In the case of a sealed source, factors intrinsic to the source, such as the amount of radioactive material and the radiation emitted, the radioactive half-life, the dispersibility of the radioactive material, the physical and chemical properties of the sealed source;
(b) For radiation generators, the intensity of the radiation emitted;
(c) Practice related issues, such as shielding, devices and conditions of use (e.g. whether the radiation source remains within a shielded container or is removed from a shielded container when in use), and site characteristics (e.g. field use or use in a fixed facility).

Authorization

3.23. The IAEA has issued several publications that provide practice specific information regarding the use of radiation sources in a safe and secure manner [19, 20, 24–32]. These publications should be consulted when preparing a safety assessment or establishing a radiation protection system. Other IAEA publications provide practice specific checklists with items to be considered in the authorization of applications and in the performance of inspections by the regulatory body [33, 34].

3.24. An authorization issued by the regulatory body should be based on the outcome of the safety assessment performed for a source, whether it is a generic one provided by the applicant or carried out by the regulatory body or a specific one provided by the applicant. The authorization should, as appropriate, be applicable to each stage of the lifetime of the source, to ensure that adequate radiation protection is in place throughout. In all cases, the regulatory body should be mindful of end of life issues where there may be the potential for a loss of regulatory control of sources if accountability is not

maintained. In particular, options for the management of disused sources should be identified prior to the granting of any authorization.

3.25. Practices for which a generic safety assessment can be performed may be suitable for authorization by registration. Other practices should be authorized through licensing (Ref. [17], paras 2.11 and 2.12).

INTERACTIONS BETWEEN SAFETY AND SECURITY

3.26. Attention should be paid to both safety and security in safety assessments. Some measures designed to provide safety, such as the use of interlocks and radiation detectors, will also provide a degree of security against the loss of a source or attempts to gain control over a source. Similarly, measures designed to prevent unauthorized access to sources will contribute to their safety by reducing the likelihood of misuse. Conversely, there could be situations in which, for example, measures intended to restrict access might adversely affect the safe use of a source. These aspects of safety and security should be considered together to avoid the possibility of one detracting from the other.

3.27. Security assessments are needed to implement measures for preventing access by people deliberately and maliciously seeking to cause exposure or harm. This aspect of source security is beyond the scope of this Safety Guide; further guidance is provided in other IAEA publications (e.g. Refs [19, 20]).

4. DESIGN, MANUFACTURE AND USE OF RADIATION SOURCES AND DESIGN AND OPERATION OF FACILITIES

4.1. Issues of radiation safety and security for radiation sources may arise during each stage of the lifetime of a source, including its distribution, installation, use, maintenance and disposal. Figure 1 illustrates the key stages throughout this lifetime. The extent of safety measures should be commensurate with the specific practice for which the source is used and the potential hazards, as determined by safety assessments.

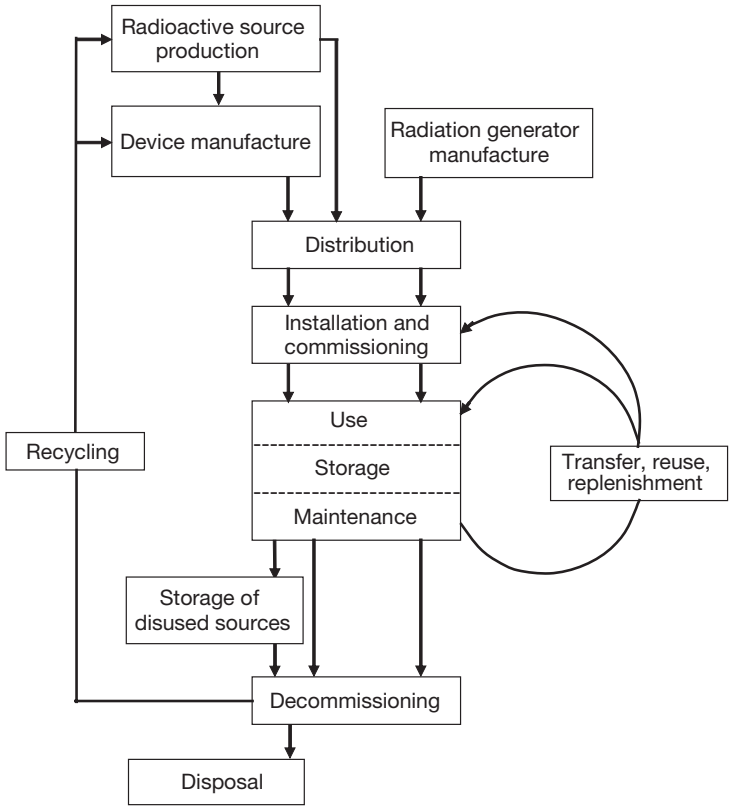

FIG. 1. Lifetime of a radiation source. Distribution may involve import and export.

4.2. Transport of a radiation source may occur between or during any of the phases of the lifetime and, although this is not shown specifically in the diagram, the recommendations given in paras 4.27–4.34 should be followed.

SOURCE DESIGN AND MANUFACTURE

4.3. Good design and a high manufacturing quality of radiation sources are essential for optimum safety. The BSS [17] state the following in Appendix IV:

> "IV.8. Registrants and licensees, in specific co-operation with suppliers, shall ensure that the following responsibilities be discharged, if applicable:

(a) to provide a well designed and constructed source that:
  (i) provides for protection and safety in compliance with the Standards [i.e. the BSS];
  (ii) meets engineering, performance and functional specifications; and
  (iii) meets quality norms commensurate with the protection and safety significance of components and systems;
(b) to ensure that sources be tested to demonstrate compliance with the appropriate specifications; and
(c) to make available information in a major world language acceptable to the user concerning the proper installation and use of the source and its associated risks.

"IV.9. In addition, and where applicable, registrants and licensees shall make suitable arrangements with suppliers of sources:

(a) to establish and maintain mechanisms for suppliers to obtain information from the registrants and licensees or other users on the use, maintenance, operating experience, dismantling and disposal of sources, and any particular normal or abnormal operating conditions that may be important for the protection of individuals or the safety of the source;
(b) to establish and maintain a mechanism to feed back to registrants and licensees information that may have implications for protection or safety affecting other registrants or licensees, or that may have implications for future improvements in protection or safety in the design of their products.

"IV.10. Systems and components of sources that are related to protection or safety shall be designed, constructed, operated and maintained so as to prevent accidents, as far as possible, and in general to restrict to levels which are as low as reasonably achievable, social and economic considerations being taken into account, the magnitude and likelihood of exposure of workers and members of the public."

Manufacture and production — general

4.4. The producers and suppliers of radiation generators and radioactive sources have responsibilities relating to their safe use, in particular responsibilities in the design and manufacture of the sources. Control measures should be taken during manufacture to ensure that the sources remain

physically secure and to ensure their safe production and shipment. For radioactive sources, the production process commonly consists of irradiation of the target material and subsequent processing and shipment to the source manufacturer. Radiation generators generally do not pose a radiation hazard until power is applied to the unit. Suppliers should initiate the documentation chain that leads to the effective identification of sources and devices throughout their lifetimes. Manufacturers should also provide appropriate documentation for the safe use of the source by the end user.

4.5. Sealed sources and containment devices and radiation sources are normally designed and manufactured in accordance with national or international standards that specify, among other things, the nature of the encapsulation and the required performance characteristics [35, 36]. These standards include performance and safety requirements that are designed to ensure safe and effective operation.

4.6. The manufacture of sealed sources, devices and radiation generators should also be subject to the requirements of quality management systems such as ISO 9001 [37–39]. Effective implementation of quality management procedures ensures that the designed safety features are consistently reproduced during production.

4.7. Some sources are designed and manufactured so that the source container also serves as a container (package) for transport. Special form sources of this type are designed to be non-dispersible in situations arising from possible transport accidents, and their containers are subjected to rigorous thermal and shock tests. For practices that require frequent transport of sources, such as field radiography, the requirements for special form sources should be met to ensure consistency with the IAEA Regulations for the Safe Transport of Radioactive Material (the Transport Regulations) [40].

4.8. Some manufacturers also specify a recommended working life for sources, which is the period of time over which the source is expected to maintain its integrity. In specifying the recommended working life, account is taken of the nature of the radioactive material, its half-life and the encapsulation of the source. A source that has exceeded its recommended working life should be inspected by the manufacturer or other appropriate body to ensure that the integrity of the source has been maintained. The regulatory body may permit sources that have exceeded their recommended working lives to continue in service subject to confirmation of continuing integrity.

Manufacture and production of radioactive sources

4.9. Provision for the safe manufacture of sealed sources and for ensuring that they remain physically secure should, as a minimum, include the following elements, as appropriate:

(a) Systems that provide shielding to allow for the safe processing of the radioactive material and that include measures to prevent unintended access to the material. The integrity of the barriers should be commensurate with the category of the sealed source. In the manufacture of high activity sources, the application of defence in depth, including the use of redundant systems, should be considered, and will generally be required for the manufacturing process.
(b) Measures to identify the presence of radioactive material. Typically these include signs and warning signals external to the area or room in which the source is to be used [41].
(c) Measures to store material that is being processed and finished products that ensure that they are accessed only by persons authorized to do so.
(d) Periodic verification of the inventory of material.

4.10. The unique identification of sealed sources is essential for source tracking. Finished sealed sources should be permanently marked. This may be difficult for small sources, where space may not allow for much information to be included, but markings or labels should include at least a unique serial number. The information provided should follow recognized international standards. For example, ISO 2919 [35] specifies a hierarchy of labelling requirements beginning with the word 'radioactive' or the trefoil symbol, followed by the identity of the manufacturer, the serial number of the source, the mass number and chemical symbol of the radionuclide and, for neutron sources, the target element.

4.11. The manufacturer should verify that the radioactive source is leak free and contamination free using tests in accordance with international standards such as ISO 9978 [36]. Certification of source activity and leak free status and dates of determination should be provided to the source purchaser and should be traceable to the source.

4.12. The manufacturer should establish and maintain procedures to ensure that the sealed source is correctly contained or packaged and that its transport conforms to requirements governing the transport of radioactive material. This

should include controls to ensure that the contents match the information provided in the shipping documents.

4.13. The supplier should establish and maintain procedures for the control of records relating to source contents, identification and the original purchaser. These procedures should include a description of the applicable records and procedures for indexing, storage, maintenance and disposition.

Manufacture and production of devices incorporating radioactive sources

4.14. Devices that contain sealed sources normally include shielding to limit radiation exposure. Design features for the safe use and security of these devices should, as a minimum[14], include the following elements, as appropriate:

(a) Measures to control access to the source within it. Examples of such measures include locks, interlocks and shutter mechanisms. Particular attention should be paid to ensuring the secure retention of the source within its containment.
(b) Measures to identify properly the presence of radioactive material, typically by means of labels, signs and warning signals [41].
(c) Measures to identify properly and control access to an empty device incorporating shielding made of depleted uranium.
(d) Periodic verification of the inventory of material.
(e) Periodic leak tests.

4.15. Devices should be designed in accordance with national and international standards such as ISO 3999 for industrial gamma radiography [42]. These generally include requirements for the prevention of unintended exposure to the source by means of locks, interlocks and tamper proof fasteners. Further guidance on devices used in particular practices is given in other IAEA and ISO publications, such as ISO 7205 for radionuclide gauges [43].

4.16. Finished devices should be permanently marked in accordance with national and international standards. This includes a requirement to mark the device with a unique serial number and to provide identification of the contained radionuclide and its activity and the date of determination.

[14] Further guidance on the safety of devices is to be provided in other IAEA publications at present under development, and separate guidance on the design and manufacture of sources to address security objectives is planned.

Examples include identification plates that are permanently affixed to the device and source identification labels that are exchanged during replenishment of the source. Labels should be adequate to enable the user to track the device and the sources contained in it during its use and maintenance.

Manufacture and production of radiation generators

4.17. Radiation generators normally include shielding to limit radiation exposure and do not present a radiation hazard until they are assembled to a point where power can be connected. Once the unit is able to generate radiation[15], provisions for safe use should include, as appropriate:

(a) Measures to control access to the generator and controls, such as a key system, to ensure that the device cannot be operated unintentionally or by an unauthorized person;
(b) Measures to identify the presence of a radiation source, typically by means of signs;
(c) Warning signals (visual and audible) to indicate when the device is activated;
(d) Periodic verification of the inventory of generators.

4.18. The manufacturer of radiation generators should establish a system that ensures the positive identification of the generator. Generators should be permanently marked with a unique model and serial number and should be designed in accordance with national and international standards.

USE OF SOURCES AND DESIGN AND OPERATION OF FACILITIES

4.19. In accordance with the management requirements and technical requirements of the BSS [17] (in particular paras 2.36 and 2.37) and the specific requirements relating to Potential Exposure: Safety of Sources (Appendix IV), registrants and licensees should ensure that facilities are designed and sources are used in a manner that results in protection being optimized. As part of the safety assessment, registrants and licensees should assess the potential for sources to give rise to exposures greater than designed or to exceed levels

[15] Attention should also be paid to the possibility of a 'dark current' (when the power to the electron source is off but a high voltage remains on the anode) and of activation of accelerator components in the case of very high energy particle accelerators.

specified by the regulatory body, and they should assess the magnitude and consequences of such exposures. They should be prepared to take any necessary action for responding to and correcting any foreseeable operating mishap or accident involving a source. Types of accident and an evaluation of the situations that gave rise to them have been described in several IAEA Safety Reports. References [2–4] relate to industrial irradiation facilities, Refs [8, 9] to industrial radiography and Refs [1, 6] to radiotherapy sources. Accidents involving radiotherapy sources and the administration of incorrect radiation doses to patients can arise from either equipment failure or human error. Such accidents differ in kind from those that have resulted from a loss of control over sources.

4.20. Persons working with or near radiation sources should be appropriately trained concerning the radiation safety and source security requirements of the radiation source or facility. The level of training should be commensurate with the category of radiation source and the person's associated duties and activities. Users should be trained to a level that satisfies the requirements of the regulatory body for training in radiation safety for the practice or the area of use [44, 45].

Engineering controls

4.21. Access controls should be employed to prevent inadvertent or unauthorized access to sources. Access controls may include a combination of physical measures and administrative procedures[16]. In many cases (especially with Category 1 or 2 radiation sources) it is not possible or practicable to employ only one of these methods. In providing for the safety of radiation sources, preference should be given, where practicable, to engineering controls over administrative controls and personal protective equipment (Ref. [17], para. I.29).

4.22. Measures to ensure that sources remain physically secure should include, as a minimum, access controls that pose a physical barrier to the sealed source or device (e.g. doors, fences, walls, cages, locks and interlocks and shielded containers). Systems should be fail-safe; for example, faults in warning devices such as lamps should cause the device to remain in or to return to its shielded or inactive state, resulting in an inability to expose the source.

[16] Guidance on engineering controls for the security of sources will be provided in other IAEA publications.

4.23. The design and integrity of physical barriers such as shielding walls should be commensurate with the category of the radiation source, and the principles of defence in depth should be taken into account. Category 1 radioactive sources should generally have multiple physical barriers that are of high integrity with robust access mechanisms (adequate shielding and barriers). Conversely, Category 4 and 5 sources may need only a single physical barrier, or access may be controlled entirely by administrative measures. Devices are typically constructed with inherent physical barriers to the radioactive source they contain (e.g. shielding, shutters, on/off mechanisms) that can be defeated only by dismantling the device. For such devices, additional physical barriers may be needed to control access to the device for the prevention of inadvertent or unauthorized removal.

Administrative controls and record keeping

4.24. Administrative controls may supplement engineering controls; these should be commensurate with the category of the radiation source. Examples of administrative controls include:

(a) Procedures for providing authorized access, such as distribution of keys or access codes;
(b) Procedures for the authorized use of the source, including prohibitions on improper actions such as unauthorized modification of the source;
(c) Promulgation of the local rules that are to be followed in controlled areas;
(d) Maintenance of records of authorized users.

Administrative controls form part of the radiation protection system for a facility. Examples of factors relevant to establishing a radiation safety system for an industrial irradiation facility are given in Annex I.

4.25. Administrative controls should include the user maintaining a written record of all material and devices held. The inventory should include:

(a) The unique identification of each radiation source (typically model number and serial number);
(b) The location of the source (installed location or location of authorized use);
(c) The type and activity of radioactive material contained in each sealed source or device;
(d) The peak tube potential (in kVp) and maximum rated beam current (in mA) for each generator;

(e) The dates the material or device is received into and removed from the inventory;
(f) A record of where the source was received from or transferred to.

4.26. Means for controlling and tracking the use of sources should be utilized. For individual radiation sources used in mobile operations, a written use log should be maintained. The log should be kept consistent with the inventory record and should contain the following information for each occasion the sealed source or device is removed from storage for use:

(a) Identification of the radiation source by its unique identifier.
(b) Date and times of use (when the source is removed and returned); the expected time of return of the source may also be indicated.
(c) Identification of any person removing and using the radiation source.
(d) The location of use of the source.

TRANSPORT OF RADIOACTIVE SOURCES

4.27. Safety measures during the transport of radioactive material by all modes on land (road, rail and inland waterways), on the sea or in the air must be consistent with the requirements of the IAEA Transport Regulations [40]. The Transport Regulations cover all operations and conditions associated with and involved in the movement of radioactive material, including preparation, consigning, packaging, loading, carriage including in-transit storage, unloading and receipt at the final destination. The Transport Regulations have been fully incorporated into regulatory documents of the international organizations concerned with transport and serve as the basis for the domestic transport regulations of States.

Consignor

4.28. Under the Transport Regulations, the consignor (shipper) is required to ensure that the requirements relating to the preparation of packages specified therein are followed. This includes the correct identification of packages, the proper use of labels and markings on the packages, and the provision of proper shipping documents.

4.29. Similarly, as part of the preparation for transport, the consignor is required to ensure that packaging of the appropriate type is used. A system of accountability should be used to ensure, as far as practicable, that the quantity

and nature of the radioactive material and its associated transport packaging are appropriately matched with the consignee. The consignor should also verify that the radioactive material has been loaded into the correct package, that the appropriate transport documents accompany the consignment and that any relevant documentation relating to safety is sent to the consignee.

4.30. Physical controls for packages in a consignment should be maintained throughout the transport cycle. The consignor should ensure that the areas where the packages are prepared for transport and stored prior to pick-up by the carrier are properly controlled. Sealed sources or packages of radioactive material should not be left unattended unless adequate physical barriers are in place to prevent unauthorized access to them or their removal.

4.31. The shipping documents that accompany the package should provide information on the consignor, the consignee, and the type and quantity of radioactive material, as well as other information as specified in the Transport Regulations. The information given in the shipping documents should be sufficient for the consignee to identify positively the radioactive material received.

Carrier

4.32. The carrier (transport company) should have a system of accountability for the packages in the consignment during transport. This should include a means of confirming the dispatch of the package at the consignor's location, a method of identifying, to the extent practicable, the location of the package along the shipping route both while in transit on a carrier's conveyance and during in-transit storage, and a means of confirming receipt by the consignee. The carrier should not deliver a consignment to the consignee or leave a consignment at a consignee's location unless proper receipt of the package can be confirmed. If the consignment cannot be properly delivered, the carrier should retain the package and should continue to be responsible for it. If the consignee cannot be contacted, the consignor and/or the regulatory body should be contacted as soon as practicable to determine where the consignment should be taken.

Consignee

4.33. The consignee should ensure that incoming packages are properly stored and received. The area where the packages are delivered should be controlled. In all situations, procedures should be established for the receipt and storage of

the packages. These procedures should include arrangements for receipt during working and non-working hours and a means to check for external radiation levels of the packages and for leaks from the packages or damaged packages.

Local transport

4.34. During the use and local transport of sources, a system of accountability should be maintained for portable devices such as industrial radiography sources and oil well logging sources, and for level gauges, thickness gauges and moisture density gauges. Their locations should always be known, and they should not be shipped or transferred to another user without authorization. The user should ensure that portable devices are signed out from the storage location and that the operator is identified. The system of accountability may be a field log, which covers all aspects of use, including location, temporary storage and removal from use for maintenance. For local transport, portable devices should be kept physically secure by such means as placing them in locked storage locations on the vehicle. When not in use at a job site, portable devices should be stored in a secure area.

5. DECOMMISSIONING OF FACILITIES AND MANAGEMENT OF DISUSED SOURCES

5.1. There are several factors that may lead to radiation sources becoming disused. For sealed sources, these include radioactive decay to activity levels at which the source is no longer useful and concern about the integrity of a source due to its age, leading to use of the source being discontinued. The sale or closure of a facility, the replacement of a source or facility with new technology and the bankruptcy of the enterprise owning or using a source or facility are other factors that can lead to the disuse of a radiation source.

5.2. There have been many instances in recent years of serious accidents, injuries and loss of life occurring as a result of failure to organize the prompt and formal decommissioning and disposal of devices containing sealed sources. The Code of Conduct on the Safety and Security of Radioactive Sources expects that every State should ensure that sealed sources are not stored for extended periods of time in facilities that have not been designed for the purpose of such storage [19]. The Code of Conduct also expects each State to ensure that, before the regulatory body authorizes receipt of a sealed source,

arrangements, including financial provisions, have been made for its safe management once it becomes a disused source. The IAEA has developed guidance on measures to be taken to reduce the risk of accidents associated with disused sealed sources [46] and on methods of identifying and locating disused and lost sources [47].

5.3. The following management options for disused sources may be available to the principal party:

(a) Storage prior to disposal;
(b) Transfer to another authorized user;
(c) Return to the manufacturer and/or supplier;
(d) Decommissioning and disposal.

Storage of sources prior to disposal

5.4. Sources may be stored prior to disposal specifically to allow the radioactive decay of short lived radionuclides, thus simplifying the disposal arrangements, or may be stored while disposal arrangements are being made. However, the protracted storage of disused sources for reasons other than radioactive decay is not encouraged. The choice of how best to manage the period of storage while awaiting final decommissioning and disposal should be made by the principal party, with the approval of the regulatory body, with account taken of the particular circumstances in the facility. For example, if the facility contains a large number of sources on a disused production line, the option of gathering these sources into a secure location should be considered. Such action should in any case be taken if retaining control of the sources cannot be guaranteed within the disused premises. Although the Transport Regulations do not apply to the movement of sources within a facility, the principles of these regulations as they affect source safety should be taken into consideration when planning internal movement of radioactive material. IAEA guidance regarding the handling, conditioning and storage of spent sealed sources should be taken into account [48].

5.5. Records should be kept of the number, type, activity and location of sources in storage awaiting disposal. This inventory should identify separately sources in use and disused sources in storage. If sources are being stored to reduce their activity by radioactive decay, the date and activity level at which they will be disposed of should be specified.

5.6. Disused sources, prior to their disposal, should ideally be kept physically separate from sources in use. This helps to prevent an active source from being mistakenly handled or disposed of as a used source; it also avoids clutter around active sources. If this segregation is not practicable, disused sources should be labelled to indicate that they are not for use, and should preferably be locked or sealed to ensure that they cannot be used.

Transfer of a source to another authorized user

5.7. Transfer of sources to other users offers both economic and environmental benefits. However, the transfer should be carried out in a controlled manner and the recipient of the source should be made aware of the relevant regulatory requirements. If planning to transfer a source to another user, the principal party should be aware that this involves taking on responsibilities for safety and accountability that are equivalent to those of the original source manufacturer. This includes the obligation to verify the consignee's status as a holder of a valid authorization to use the source. Many principal parties may not be sufficiently familiar with all the relevant regulations, particularly if the source is to be transferred to a user in another State. Hence, any principal party considering this option should seek advice from the source manufacturer and the regulatory body, as necessary, to ensure that all safety issues relating to the transfer are correctly addressed, including ensuring appropriate documentation and the updating of source inventories.

5.8. Special attention should be paid by the principal party to ensuring that the sealed sources and devices are in a serviceable condition and are suitable for the intended new application. Copies of all relevant information on the history of use of the source (such as conditions of use and maintenance logs) should be provided to the new owner. At a minimum, this should include the source's serial number, radionuclide content and activity. For high activity sources, it is likely that the relevant serviceability checks could only be carried out in a specialist facility. Therefore, direct transfer to another user may not be appropriate for such sources; transfer should be done through a source manufacturer or supplier, or other competent body.

Return of a source to the manufacturer or supplier

5.9. The manufacturer or supplier of a source should provide guidance to the user at the time of supply on the arrangements for return of the source. These arrangements may change over the lifetime of the source. The principal party should therefore contact the manufacturer or supplier immediately prior to a

planned return of the source to confirm the availability of the disposal route and to obtain details of current procedure. However, the supplier may not be fully familiar with the user's national regulations concerning source disposal, or with all the alternative options that may be available within the user's State. This is likely to be the case if the source is being purchased from a supplier in another State. The principal party will therefore need to ensure that the proposed disposal route complies with the national regulations. In the event that a manufacturer or supplier does not keep to an agreement to take back a source — for example, owing to bankruptcy — the principal party should consult the regulatory body for advice.

5.10. The leasing of sources is becoming increasingly common. In some respects, leasing improves the safety of sources as the manufacturer retains ownership of the source and, with it, responsibility to recover the source for disposal. However, continuing responsibility for day to day safety remains with the principal party.

Decommissioning

5.11. Decommissioning refers to the removal of licensed radiation sources from a facility and the administrative and technical actions undertaken to remove some or all of the regulatory controls. Some facilities may have only one installed radiation device, such as a teletherapy machine. Other facilities may include licensed premises in which many individual devices are installed (such as a production line containing industrial gauges) or stored (such as a store for mobile devices). Decommissioning may involve the removal of a large number of sources prior to the termination of a facility's licence. Decommissioning may also involve the removal of part of a facility's inventory of devices prior to the issuing of a new licence and the installation of replacement devices for future work. Source replacement within an existing device is not considered to be decommissioning. IAEA guidance on the safe management of decommissioning activities for medical, industrial and research facilities [49] should be followed in the planning and execution of decommissioning activities.

5.12. For facilities using sealed sources, decommissioning may involve only the authorized removal of all sources from the facility. In more complex situations where on-site dismantling of equipment containing sources is to be undertaken, decommissioning activities should be carried out by suitably qualified and experienced staff, in areas that are suitable for the types of procedure to be undertaken. Many users of equipment containing sources will not have the staff

or authorization for the full dismantling of equipment involving removal of the sealed source. The principal party should therefore ensure that suitably qualified persons are employed or contracted. If it is necessary to employ an external organization to carry out decommissioning, the principal party should confirm that the company holds the necessary authorization and expertise to carry out the proposed activities.

5.13. As decommissioning involves the removal of regulatory controls, the principal party should advise the regulatory body of when decommissioning operations are to be undertaken.

5.14. The facility in which a radiation source has been used may not be suitable for the safe and secure handling and storage of unshielded sources. The extent of the decommissioning activities at the user's premises should therefore be minimized. In many cases, the source holder forms an integral part of the approved transport container and removal of the source from the holder should not be necessary. As the source holder is likely to have details of the contents engraved on it, including the radionuclide content, activity, reference date and serial number, removal of the source from the holder would introduce the potential for loss of accountability. The small size of many sources can introduce the possibility of a source being dropped or mislaid without this being noticed. Instances have also occurred in which sealed sources have been inadvertently damaged while being removed from a housing, resulting in significant contamination. Consequently, if it is not necessary to remove the source from the equipment at the point of use, such removal should be avoided.

5.15. On the completion of decommissioning (i.e. after the removal of all licensed radiation sources from a premises with the purpose of removing regulatory controls), the principal party should carry out a final check to ensure that all radioactive material has been removed.

5.16. Following decommissioning and termination of a licence to use sources, records of sources that have been transferred should be retained for a suitable period as agreed by the regulatory body.

5.17. The regulatory body should ensure that disposal and decommissioning have been carried out by the principal party in accordance with regulatory requirements.

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Annex I

FACTORS RELEVANT TO ESTABLISHING A RADIATION SAFETY SYSTEM: EXAMPLE OF A LARGE INDUSTRIAL IRRADIATION UNIT

In this annex, the word 'should' is used in its usual dictionary sense only.[1]

ORGANIZATION AND MANAGEMENT

I–1. The following material illustrates some of the factors that should be addressed when designing and implementing a radiation safety system. It is not intended to be prescriptive or exhaustive, but to provide an overview for guidance. Detailed guidance for practices of various types is presented in other IAEA publications[2].

I–2. Industrial irradiation units present a large potential gamma radiation hazard, since the amount of activity in a large irradiator is typically about 10^{16}–10^{17} Bq, with some facilities exceeding 10^{18} Bq. The organizational structure of such units should reflect a significant commitment to safety and a continuous awareness of radiation safety on the part of senior management.

I–3. A radiation protection officer should be designated by senior management and should be recognized as competent and authorized by the regulatory body. The radiation protection officer and radiation protection staff (if any) should have an adequate amount of time available for safety duties. For larger facilities, a full time radiation protection officer should be appointed. The responsibilities of the radiation protection officer should include all aspects of radiation safety: policy, safety procedures, appointment and training of staff, quality assurance for the installation of safety systems, surveillance and

[1] This annex provides an illustrative example compiled from expert advice and multiple sources. 'Should' statements in the body text and appendices of a Safety Guide express recommendations, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures) for complying with the requirements. However, an annex is not an integral part of the standard, and where the word 'should' is used in this annex, it does not have this special meaning. In this annex the word 'should' is used in its usual dictionary sense only.

[2] Publications under development include Safety Reports on industrial radiography, radioactive gauges and well logging using radioactive sources.

record keeping. Irradiator operators authorized to operate the irradiator without supervision should be designated in writing by the radiation protection officer. The irradiator should be kept in a safe shutdown state unless an authorized operator is present. The licensee should also consult with an appropriate qualified expert on radiation protection issues and on any design modifications or changes that may have a bearing on radiation protection and source safety.

I–4. All staff should be provided with written procedures in their own language for any assignments that require adherence to safety requirements or procedures. Senior management should monitor the safety status of the facility frequently, and should include safety in their performance ratings of the management and staff of the irradiation facility.

SELECTION AND TRAINING OF PERSONNEL

Radiation protection staff

I–5. Personnel should demonstrate a capability to follow safety procedures both in routine operations and in emergencies. All employees should therefore demonstrate maturity and emotional stability. The radiation protection officer should have formal and certificated training in radiation safety to a level appropriate to his or her position, as well as experience working at an irradiation facility or a facility presenting similar radiation safety considerations. Other radiation safety staff should receive formal radiation safety training to an appropriate level. Formal training should be supplemented with on the job training at the irradiation facility to acquaint the staff with the safety requirements specific to the facility itself. Periodic refresher training should be provided at least annually to remind the staff of safety requirements and to review changes in requirements.

Operators

I–6. Irradiator operators need not have any special qualifications beyond those appropriate for normal industrial operational jobs. Placing special emphasis on the psychological stability of irradiator operators should be considered, however, owing to the importance of adhering to safety procedures. A training programme should be documented and completed by each member of staff prior to starting work at an irradiation facility.

I–7. A formal training programme should include training in basic radiation protection, the use of radiation detection instruments, the design and safety features of irradiation facilities, and operating procedures and emergency procedures. Emphasis should be placed on the hazards of acute radiation exposure and excessive chronic exposure. Personnel should have adequate on the job training prior to working without supervision. Refresher training (see para. I–5) should include a review of safety procedures, of any changes in requirements or technology, and of the safety record of the facility and any problems experienced.

OCCUPATIONAL RADIATION CONTROL

Control of external doses

I–8. Owing to the large amount of radioactive material involved, irradiation facilities contain elaborate shielding and other safety features. A summary of the basic design features is given below.

Source design

I–9. The radiation sources in the irradiation facility should be properly designed, manufactured and prototype tested to maintain their integrity under normal and, to the extent practicable, accident conditions. The supplier should provide documentation to demonstrate the quality performance of the sources.

Shielding

I–10. Shielding for an irradiator usually consists of walls constructed of concrete with a substantial thickness. Shielding should be provided for both the storage and the use of the source assembly. Most irradiation facilities use a water pool for storage of the source assembly when not in use, while some use dry storage involving substantial concrete barriers. The entrance to the irradiation room is usually designed with a maze or staggered shielding to obviate the need for a heavily shielded door. In the design and construction stages of the facility, care must be taken to avoid creating any unshielded access channels in the structure that would allow radiation beams to escape from the shielded area.

Interlocks and alarms

I–11. Unshielded irradiation sources can deliver a fatal dose in a few seconds. Automatic interlocks and alarms are therefore necessary to prevent accidental access to the irradiation area when the sources are not shielded. Interlock systems may consist of a series of electronic locks, motion detectors and pressure switches that automatically lock the shielded area when the sources are exposed, automatically move the source assembly to a shielded position if a person tries to enter the irradiation area and prevent the sources from being exposed until the area has been cleared and no one is present. The locks should be designed so that a person caught in the irradiation area can leave quickly without using a key or having to follow special procedures. An emergency stop device should also be provided inside the irradiation area. Visible and audible alarms should be provided to warn persons when sources are about to be moved to the unshielded position, when radiation levels are high or if someone has violated an interlock. Safety systems should incorporate principles of defence in depth; that is, they should include levels of redundancy so that a single failure will not result in access to areas of high dose rate. Interlock systems should also be designed and installed so that they operate in a fail-safe manner. The provision of safety systems at the product entry point should permit the passage of the product carrier but should prevent the entry of persons. The method by which this is achieved is very much dependent on the design of the facility, but may entail the use of heat sensors, automatic hatches and local barriers.

Water quality

I–12. Water filtering systems should be provided to prevent the accumulation of corrosive substances in the water pool for the source assembly that may damage the containment of the radioactive sources. The filter systems should be monitored regularly for radiation levels that would indicate a failure of source integrity. An automatic water level monitor should be provided to warn of low water levels. An emergency water supply should be available.

Protection of the facility

I–13. The design of an irradiation facility should be appropriate for the risk of external hazards, particularly earthquakes or tornadoes. A fire protection system should be provided to extinguish any fires in the irradiation room. The system for handling the irradiated material should be designed to avoid interference with the source assemblies and their transport mechanism.

Ventilation and monitoring should be provided to prevent the accumulation of ozone at hazardous levels.

Administrative controls

I–14. Written procedures should be established to ensure that no attempt is made to move the source to its unshielded position when anyone is present in the irradiation room. Administrative controls should be established to prevent unauthorized persons from being in the vicinity of entrances to the irradiation room, including the product carrier entrance. Local rules specifying the procedures to be followed and the precautions to be taken during the operation of the facility should be drawn up and should be provided to all the operators. A combination of engineering and administrative controls should be used to ensure that the desired level of occupational radiation protection is achieved [I–1].

Surveillance programme

I–15. Periodic surveillance should be conducted to check that there are no unexpected levels of radiation and to ensure the proper maintenance of all equipment in the facility. A surveillance checklist should be maintained.

Source position

I–16. Radiation monitors should be provided to indicate radiation levels in the irradiation room both when the source is shielded and when it is unshielded. These radiation monitors should be supplemented by electronic source position indicators that inform the operators whether the source is in a shielded, partially shielded or unshielded position. Since very high radiation levels will damage most detectors, some partial shielding of the detectors is usually advisable. Anyone entering the irradiation room should check the radiation levels with a portable monitor.

Shielding

I–17. Direct radiation surveys should be conducted periodically to check the integrity and adequacy of shielding, particularly whenever new sources are loaded.

Occupational monitoring

I–18. Provided that the operators follow the established procedures and the facility is provided with sufficient shielding, it is unlikely that personnel will receive significant radiation exposures. However, it is good practice that at least a representative sample of the personnel should wear personal dosimeters. In addition, all personnel who engage in non-routine service operations should wear alarming dosimeters.

Radiation sources

I–19. Sources should be checked periodically for leaks either directly or by water sampling and monitoring of water filter systems.

Safety systems

I–20. All equipment, interlock systems and monitoring equipment at an irradiation facility should be checked periodically for proper operation and should be serviced and maintained in accordance with the suppliers' instructions. Equipment in the irradiation room is susceptible to long term radiation damage. Crucial safety systems such as radiation monitors, interlocks and alarms should be checked daily.

PUBLIC EXPOSURE CONTROL

I–21. No special provisions are normally necessary for the control of public exposure, as the facility shielding will ensure that exposures outside the premises are below the reference levels specified by the regulatory body and members of the public are not expected to have access to the facility. Control measures for occupational exposure will usually be adequate to ensure that exposure rates at locations accessible to the public are sufficiently low, but this should be confirmed. Access control should be maintained to protect against unauthorized access to the irradiation facility. Irradiation sources should be disposed of by returning them to the manufacturer, supplier or similar authorized recipient. In most circumstances the manufacturer or supplier will be involved directly in source replacement and loading, and will also take away the used sources.

EMERGENCY PLANNING

I–22. Most incidents at irradiation facilities will merely necessitate the source assembly being remotely set to the safe storage position until the problem is resolved. Written emergency procedures should be prepared for foreseeable incidents, such as jamming of the source in the unshielded position, interlock failure, loss of water, leaking of the source, fire and excessive ozone levels. In the unlikely event of a ruptured source, a breach of shielding or an overexposure to radiation, the emergency could have serious consequences and could even be life threatening, and it should be ensured that arrangements have been made to deal with such emergencies [I–2–I–4]. The facility's emergency plan should ensure that:

(a) The facility is shut down immediately and the sources returned to the storage position (if practicable);
(b) No one enters the irradiation room until the emergency has been evaluated by the radiation protection officer and such authorization has been granted;
(c) If shielding is breached, a restricted area is established and monitored;
(d) Outside expert assistance is obtained as appropriate;
(e) The competent authority is notified immediately;
(f) Employees involved in the emergency do not leave the facility until the possible needs for decontamination and medical attention have been evaluated.

I–23. The procedures in the emergency plan should be rehearsed at periodic intervals so that all operators are aware of, and familiar with, the actions to be taken in the event of an emergency.

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Annex II

PROBABILISTIC SAFETY ASSESSMENT

II–1. To conduct a safety assessment of a radiation source, both the intended operation of the source and the ways in which the process may deviate from the intended operation should be understood. Particularly important are those deviations that could lead to unwanted consequences, such as a release of radioactive material due to damage to the source, with possible consequential exposure to radiation at high levels.

II–2. A safety assessment for normal operation addresses all the conditions under which the radiation source operates as expected, including all phases of the lifetime of the source. Due account needs to be taken of the different factors and conditions that will apply during non-operational phases, such as installation, commissioning and maintenance.

II–3. Possible abnormal conditions and their causes, such as failures of protection systems or human errors, need to be identified in safety assessments for incorrect operation. The likelihood, significance and consequences of such abnormal conditions are then assessed by means of an appropriate methodology for risk analysis; some examples are given below. Probabilistic safety analysis (PSA) is an established technique in risk evaluation for nuclear power plants [II–1], and much of the experience gained from it is adaptable in simplified form to complex applications involving radiation sources. As noted in para. 3.8, the inability of analyses to account adequately for human factors imposes some limitation on the value of these assessments.

SAFETY ANALYSIS METHODS

II–4. There are several established methods that may be used to perform a systematic evaluation of risk. These were developed in various industries, but they are adaptable for use in analysing the safety of practices using radiation sources. In some cases, a combination of techniques may be needed. The following brief descriptions provide only an introduction to the subject. There is a vast literature on safety assessment and risk analysis; a good starting point for further reading in the context of radiation safety is Publication 76 of the International Commission on Radiological Protection (ICRP) [II–2].

Event tree analysis

II–5. Event trees provide a graphical means of representing a sequence of individual events that may culminate in a failure of protection. Event trees begin with an initiating event that causes a sequence of demands on the components of the safety system, and set out possible consequent events and paths, branching at each node or event in the tree. The nodes correspond to the demands made on each component of the safety system, and the branches indicate success or failure of the component. A logical structure is thereby built up that can link the initiating event to any of the resulting events. Furthermore, if probabilities can be assigned to each event, the likelihood of a resulting event may be computed mathematically.

II–6. To illustrate the technique, consider the following example, adapted from Ref. [II–2]. A radiation source is used to irradiate an object or material inside an enclosure or exposure room (Fig. II–1). The source may be an X ray set that can be switched off or a radioactive source in a source container having a shutter that can be closed. In this simplified and hypothetical example, the protection system consists of an arrangement of interlocks that is designed to place the source in a safe condition if someone enters the exposure room during operation. The first interlock monitors the door to the exposure room by means of a sensor. If the sensor detects that the door has been opened, it

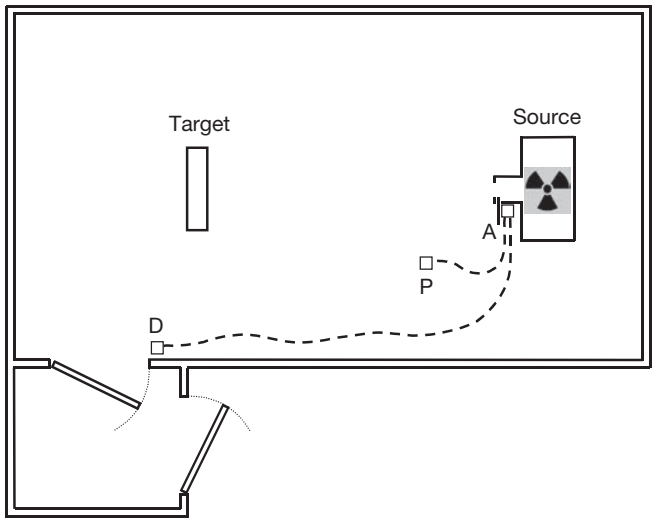

FIG. II–1. Exposure room with door sensor (D), proximity sensor (P) and shutter actuator (A).

sends a signal to an actuator to close the shutter or switch off the X ray beam. The second interlock is a proximity sensor mounted close to the source itself. If it detects a person nearby, it sends a signal to the actuator on the shutter or the power supply.

II–7. The initiating event in this example occurs when a person enters the exposure room during operation. In practice, of course, there would be procedures in place to ensure that this would not happen, but here we are concerned with only a small part of the overall safety system. If either sensor works, the actuator receives a signal to close off the source. If both fail, however, the actuator will not receive a signal and the exposure will continue, leading to a failure of the safety system and exposure of the person. Similarly, if the actuator fails to work when it receives a signal from one of the sensors, the protection system will fail. An event tree describing this situation is shown in Fig. II–2.

II–8. Note that not all permutations are shown in Fig. II–2. For example, if both sensors fail the actuator does not receive a demand, so the test 'actuator works?' is redundant in this case. Similarly, if the door sensor works, the test 'proximity sensor works?' is redundant. To quantify the overall likelihood of failure, it is necessary to identify and remove redundant paths, leaving what are known as 'minimal cut sets'. A complete discussion of this topic is beyond the scope of this annex, but the following explanation will suffice here.

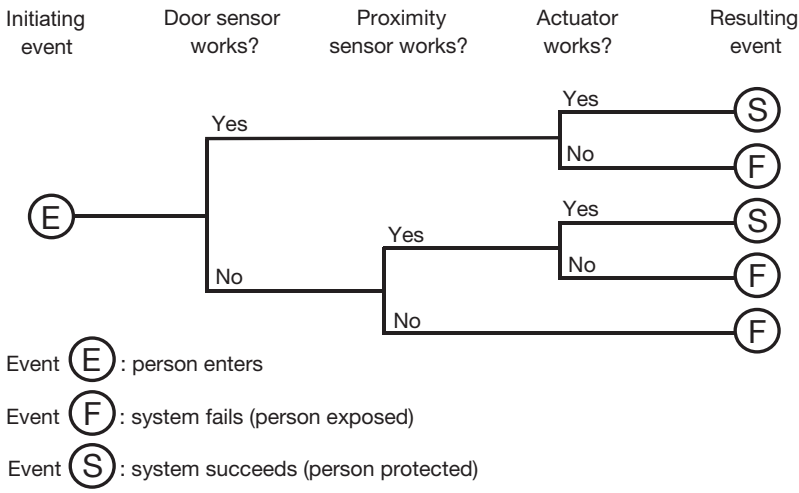

FIG. II–2. Event tree for simplified interlock safety system.

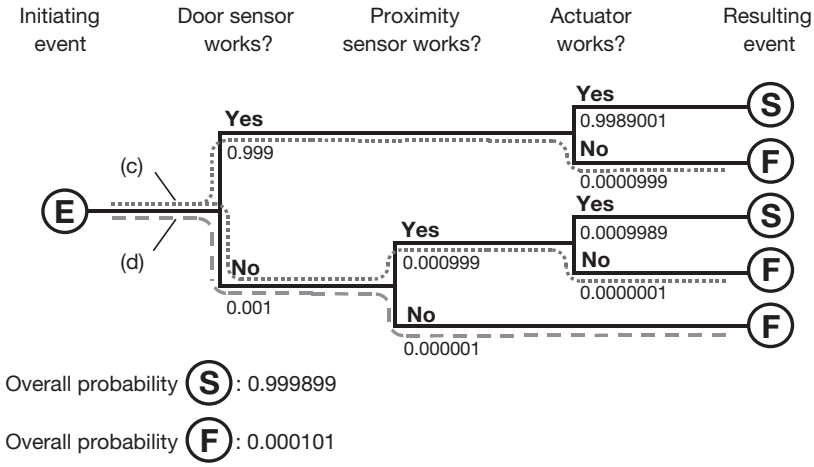

FIG. II–3. Event tree showing minimal cut sets.

A component failure is called a 'cut', and a sequence (called a 'set') of component failures is called a 'cut set' if it leads to failure of the overall system. A minimal cut set may be defined as a minimum combination of failure events that leads to failure of the system. To illustrate this, consider the complete set of possible component failures for the example above:

(a) The door sensor fails;
(b) The proximity sensor fails;
(c) The actuator fails;
(d) Both sensors fail;
(e) The door sensor and the actuator fail;
(f) The proximity sensor and the actuator fail; or
(g) Both sensors and the actuator fail.

Of these possible outcomes, (a) and (b) do not lead to a system failure, so they are not cut sets. Furthermore, (e), (f) and (g) are each duplicative because if the actuator fails it does not matter whether the sensors work, so these are not minimal cut sets. On the other hand, (c) and (d) are minimal cut sets because they each define a minimum set of failures leading to failure of the overall system.

II–9. These failure sequences are illustrated in Fig. II–3 by the broken lines (c) and (d). If the probabilities of failure of each component can be estimated, it is possible to assign probabilities to the branch points in the tree, as shown. If the probability of failure of each sensor is 10^{-3} per demand (i.e. on one occasion in

every 1000 times the room is entered) and the probability of failure of the actuator is 10^{-4}, the overall likelihood[1] of failure is 1.01×10^{-4}.

II–10. One result of this analysis that is immediately apparent is that the weakest link in the chain is the actuator. This risk of failure is one hundred times greater than the risk of both sensors failing. To improve safety, either a more reliable actuator could be used or a duplicate actuator could be installed in parallel. This illustrates the value of this approach in terms of sensitivity analysis: it provides a means of identifying the crucial components in the system that dominate the overall risk of failure.

Fault tree analysis

II–11. A fault tree analyses a safety system from the perspective of the final outcome or failure, called the 'top event'. Developing a fault tree is like analysing an event tree in reverse, in that the components of the safety system are assessed working backwards to find out what could have caused the top event. Fault trees also expressly include Boolean logic symbols, which can make their evaluation, especially numerical risk analysis, easier to carry out than for event trees. Another difference is that fault trees may be multinodal (i.e. one node or logic symbol may be connected to several preceding events), whereas event trees have only binary branches.

II–12. A simple fault tree illustrating the above interlock system is shown in Fig. II–4. Boxes are used to represent events, and the logic tree connects the top event with the initiating event at the bottom. The utility of the logic gates is evident: AND gates correspond to multiplicative probabilities, while OR gates correspond to additive probabilities.

Identification of fault sequences

II–13. While event trees and fault trees provide valuable graphical representations of event sequences, the events themselves, and the scenarios in which they occur, would be analysed by examining each element of the safety system and its interdependences and assessing what could go wrong. There are

[1] Note that figures are given to an unrealistic degree of precision in these illustrative calculations in order to show the working. In practice, a single significant figure is likely to be appropriate.

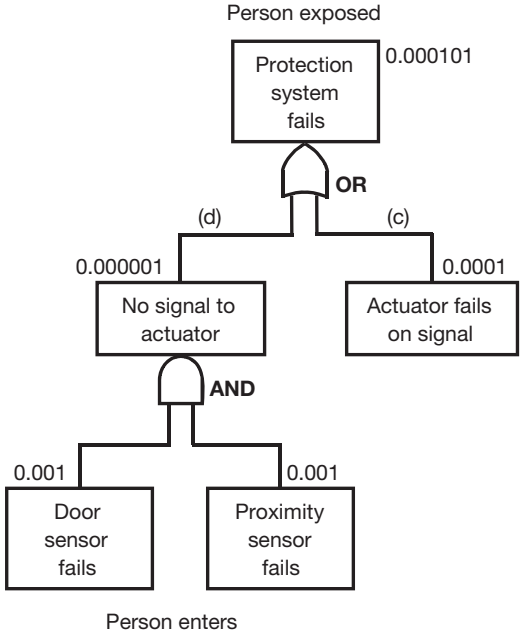

FIG. II–4. Fault tree for simplified interlock safety system.

several established methods for carrying out these analyses, such as hazard and operability studies and failure modes and effects analysis. Hazard and operability studies (Hazop) analyse each component of a system from the perspective of deviations from their intended operation. Deviations are categorized by keywords such as 'none of', 'more of', 'part of' and 'less than'; possible causes of a deviation are investigated and its effects are listed. Failure modes and effects analysis (FMEA) is a similar method, focusing on identifying the modes of failure and their consequences. Components are tabulated and each table entry includes the component failure mode, its possible causes and the effects of failure on adjacent or subsequent components.

Human reliability analysis

II–14. Experience has shown that human action (or failure to act) is frequently a dominant contributor to accidental exposure to radiation. Consequently, human behaviour — particularly at times of stress — needs special attention. Although the methods discussed above were originally developed to evaluate devices or mechanical systems and processes, they can also accommodate the human factors that affect safety. Human reliability analysis (HRA) is a method

that was developed to address those factors that are related to human performance in an activity, using human error analysis and task analysis, both qualitative and quantitative, to identify the effects of possible human errors on a system.

II–15. The failure of humans to act adequately when so demanded can be taken account of by introducing the human as one component of the safety system. Quantification of human error is difficult and involves several factors, such as previous training, working conditions and stress, which provide the context for the occurrence of an error. While a figure of 10^{-3} per demand is considered to be a reasonable choice for a human error rate in many complex situations, it can be 10^{-2} per demand or higher, depending on the factors mentioned above [II–2]. It is also possible that the probability of an error being repeated increases if earlier occurrences do not lead to undesirable outcomes that are identified as such. Human reliability analysis is used extensively in probabilistic safety assessments for nuclear power plants [II–3], and much of the experience from that is adaptable to circumstances involving radiation sources. However, it cannot properly account for actions that are in flagrant contravention of operating procedures, such as the deliberate circumvention of safety features.

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