

IAEA Safety Standards

for protecting people and the environment

Safety of Radiation Generators and Sealed Radioactive Sources

Safety Guide

No. RS-G-1.10



IAEA

International Atomic Energy Agency

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SAFETY OF RADIATION GENERATORS AND SEALED RADIOACTIVE SOURCES

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IAEA SAFETY STANDARDS SERIES No. RS-G-1.10

SAFETY OF RADIATION GENERATORS AND SEALED RADIOACTIVE SOURCES

SAFETY GUIDE

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2006

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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.

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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 Sources¹, 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 bodies² and for users³, 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 persons⁴ throughout the lifetime of a radiation source⁵.

1.6. All facilities where radiation sources need to be safely managed are covered by this Safety Guide, including those containing the sources⁶ 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).

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 sources⁸. The safety and security of nuclear material⁹, the control of medical exposures, the recovery of control over orphan sources¹⁰ 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 parties¹¹ 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