

IAEA Safety Standards

for protecting people and the environment

Regulatory Control of Radiation Sources

Jointly sponsored by
FAO, IAEA, ILO, PAHO and WHO



IAEA

Safety Guide

No. GS-G-1.5



IAEA

International Atomic Energy Agency

Copyright International Atomic Energy Agency
Provided by IHS Markit under license with IAEA

No reproduction or networking permitted without license from IHS

Full document details: IAEA GS-G-1.5 2004

Licensee=/, User=,
Not for Resale,



Documents

Document Sharing Hub

IAEA SAFETY RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

Under the terms of Article III of its Statute, the IAEA is authorized to establish or adopt standards of safety for protection of health and minimization of danger to life and property, and to provide for the application of these standards.

The publications by means of which the IAEA establishes standards are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety, and also general safety (i.e. all these areas of safety). The publication categories in the series are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

Safety standards are coded according to their coverage: nuclear safety (NS), radiation safety (RS), transport safety (TS), waste safety (WS) and general safety (GS).

Information on the IAEA's safety standards programme is available at the IAEA Internet site

<http://www-ns.iaea.org/standards/>

The site provides the texts in English of published and draft safety standards. The texts of safety standards issued in Arabic, Chinese, French, Russian and Spanish, the IAEA Safety Glossary and a status report for safety standards under development are also available. For further information, please contact the IAEA at P.O. Box 100, A-1400 Vienna, Austria.

All users of IAEA safety standards are invited to inform the IAEA of experience in their use (e.g. as a basis for national regulations, for safety reviews and for training courses) for the purpose of ensuring that they continue to meet users' needs. Information may be provided via the IAEA Internet site or by post, as above, or by e-mail to Official.Mail@iaea.org.

OTHER SAFETY RELATED PUBLICATIONS

The IAEA provides for the application of the standards and, under the terms of Articles III and VIII.C of its Statute, makes available and fosters the exchange of information relating to peaceful nuclear activities and serves as an intermediary among its Member States for this purpose.

Reports on safety and protection in nuclear activities are issued in other publications series, in particular the **Safety Reports Series**. Safety Reports provide practical examples and detailed methods that can be used in support of the safety standards. Other IAEA series of safety related publications are the **Provision for the Application of Safety Standards Series**, the **Radiological Assessment Reports Series** and the International Nuclear Safety Group's **INSAG Series**. The IAEA also issues reports on radiological accidents and other special publications.

Safety related publications are also issued in the **Technical Reports Series**, the **IAEA-TECDOC Series**, the **Training Course Series** and the **IAEA Services Series**, and as **Practical Radiation Safety Manuals** and **Practical Radiation Technical Manuals**. Security related publications are issued in the **IAEA Nuclear Security Series**.

REGULATORY CONTROL OF RADIATION SOURCES

© IAEA, 2004

Permission to reproduce or translate the information contained in this publication may be obtained by writing to the International Atomic Energy Agency, Wagramer Strasse 5, P.O. Box 100, A-1400 Vienna, Austria.

Printed by the IAEA in Austria
December 2004
STI/PUB/1192

SAFETY STANDARDS SERIES No. GS-G-1.5

REGULATORY CONTROL OF RADIATION SOURCES

SAFETY GUIDE

JOINTLY SPONSORED BY
THE FOOD AND AGRICULTURE ORGANIZATION
OF THE UNITED NATIONS,
INTERNATIONAL ATOMIC ENERGY AGENCY,
INTERNATIONAL LABOUR OFFICE,
PAN AMERICAN HEALTH ORGANIZATION
AND WORLD HEALTH ORGANIZATION

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2004

COPYRIGHT NOTICE

All IAEA scientific and technical publications are protected by the terms of the Universal Copyright Convention as adopted in 1952 (Berne) and as revised in 1972 (Paris). The copyright has since been extended by the World Intellectual Property Organization (Geneva) to include electronic and virtual intellectual property. Permission to use whole or parts of texts contained in IAEA publications in printed or electronic form must be obtained and is usually subject to royalty agreements. Proposals for non-commercial reproductions and translations are welcomed and will be considered on a case by case basis. Enquiries should be addressed by email to the Publishing Section, IAEA, at sales.publications@iaea.org or by post to:

Sales and Promotion Unit, Publishing Section
International Atomic Energy Agency
Wagramer Strasse 5
P.O. Box 100
A-1400 Vienna
Austria
fax: +43 1 2600 29302
tel.: +43 1 2600 22417
<http://www.iaea.org/Publications/index.html>

IAEA Library Cataloguing in Publication Data

Regulatory control of radiation sources : safety guide / jointly sponsored by the Food and Agriculture Organization of The United Nations ... [et al.]. — Vienna : International Atomic Energy Agency, 2004.
p. ; 24 cm. — (Safety standards series, ISSN 1020-525X ; no. GS-G-1.5)
STI/PUB/1192
ISBN 92-0-105004-6
Includes bibliographical references.

1. Radiation — Safety measures. I. International Atomic Energy Agency. II. Food and Agriculture Organization of the United Nations. III. Series.

IAEAL

04-00386

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.

11/11/2004 10:11:11 AM

PREFACE

The basic requirements for the protection of persons against exposure to ionizing radiation and for the safety of radiation sources were established in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the Basic Safety Standards), jointly sponsored by the Food and Agriculture Organization of the United Nations (FAO), the International Atomic Energy Agency (IAEA), the International Labour Organization (ILO), the OECD Nuclear Energy Agency (OECD/NEA), the Pan American Health Organization (PAHO) and the World Health Organization (WHO) (the Sponsoring Organizations). The application of the Basic Safety Standards is based on the presumption that national infrastructures are in place to enable governments to discharge their responsibilities for radiation protection and safety. Requirements relating to the legal and governmental infrastructure for the safety of nuclear facilities and sources of ionizing radiation, radiation protection, the safe management of radioactive waste and the safe transport of radioactive material are established in the Safety Requirements on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, Safety Standards Series No. GS-R-1.

This Safety Guide, which is jointly sponsored by the FAO, the IAEA, the International Labour Office, the PAHO and the WHO, gives detailed guidance on the key elements for the organization and operation of a national regulatory infrastructure for radiation safety, with particular reference to the functions of the national regulatory body that are necessary to ensure the implementation of the Basic Safety Standards. The Safety Guide is based technically on material first published in IAEA-TECDOC-1067¹, which was jointly sponsored by the FAO, the IAEA, the OECD/NEA, the PAHO and the WHO. The requirements established in GS-R-1 have been taken into account.

The Safety Guide is oriented towards national regulatory infrastructures concerned with protection and safety for radiation sources used in medicine, industry, agriculture, research and education.

¹ INTERNATIONAL ATOMIC ENERGY AGENCY, Organization and Implementation of a National Regulatory Infrastructure Governing Protection against Ionizing Radiation and the Safety of Radiation Sources, IAEA-TECDOC-1067, Vienna (1999).

12345678910111213141516171819202122232425262728293031323334353637383940414243444546474849505152535455565758596061626364656667686970717273747576777879808182838485868788899091929394959697989910010110210310410510610710810911011111211311411511611711811912012112212312412512612712812913013113213313413513613713813914014114214314414514614714814915015115215315415515615715815916016116216316416516616716816917017117217317417517617717817918018118218318418518618718818919019119219319419519619719819920020120220320420520620720820921021121221321421521621721821922022122222322422522622722822923023123223323423523623723823924024124224324424524624724824925025125225325425525625725825926026126226326426526626726826927027127227327427527627727827928028128228328428528628728828929029129229329429529629729829930030130230330430530630730830931031131231331431531631731831932032132232332432532632732832933033133233333433533633733833934034134234334434534634734834935035135235335435535635735835936036136236336436536636736836937037137237337437537637737837938038138238338438538638738838939039139239339439539639739839940040140240340440540640740840941041141241341441541641741841942042142242342442542642742842943043143243343443543643743843944044144244344444544644744844945045145245345445545645745845946046146246346446546646746846947047147247347447547647747847948048148248348448548648748848949049149249349449549649749849950050150250350450550650750850951051151251351451551651751851952052152252352452552652752852953053153253353453553653753853954054154254354454554654754854955055155255355455555655755855956056156256356456556656756856957057157257357457557657757857958058158258358458558658758858959059159259359459559659759859960060160260360460560660760860961061161261361461561661761861962062162262362462562662762862963063163263363463563663763863964064164264364464564664764864965065165265365465565665765865966066166266366466566666766866967067167267367467567667767867968068168268368468568668768868969069169269369469569669769869970070170270370470570670770870971071171271371471571671771871972072172272372472572672772872973073173273373473573673773873974074174274374474574674774874975075175275375475575675775875976076176276376476576676776876977077177277377477577677777877978078178278378478578678778878979079179279379479579679779879980080180280380480580680780880981081181281381481581681781881982082182282382482582682782882983083183283383483583683783883984084184284384484584684784884985085185285385485585685785885986086186286386486586686786886987087187287387487587687787887988088188288388488588688788888989089189289389489589689789889990090190290390490590690790890991091191291391491591691791891992092192292392492592692792892993093193293393493593693793893994094194294394494594694794894995095195295395495595695795895996096196296396496596696796896997097197297397497597697797897998098198298398498598698798898999099199299399499599699799899910001001100210031004100510061007100810091010101110121013101410151016101710181019102010211022102310241025102610271028102910301031103210331034103510361037103810391040104110421043104410451046104710481049105010511052105310541055105610571058105910601061106210631064106510661067106810691070107110721073107410751076107710781079108010811082108310841085108610871088108910901091109210931094109510961097109810991100110111021103110411051106110711081109111011111112111311141115111611171118111911201121112211231124112511261127112811291130113111321133113411351136113711381139114011411142114311441145114611471148114911501151115211531154115511561157115811591160116111621163116411651166116711681169117011711172117311741175117611771178117911801181118211831184118511861187118811891190119111921193119411951196119711981199120012011202120312041205120612071208120912101211121212131214121512161217121812191220122112221223122412251226122712281229123012311232123312341235123612371238123912401241124212431244124512461247124812491250125112521253125412551256125712581259126012611262126312641265126612671268126912701271127212731274127512761277127812791280128112821283128412851286128712881289129012911292129312941295129612971298129913001301130213031304130513061307130813091310131113121313131413151316131713181319132013211322132313241325132613271328132913301331133213331334133513361337133813391340134113421343134413451346134713481349135013511352135313541355135613571358135913601361136213631364136513661367136813691370137113721373137413751376137713781379138013811382138313841385138613871388138913901391139213931394139513961397139813991400140114021403140414051406140714081409141014111412141314141415141614171418141914201421142214231424142514261427142814291430143114321433143414351436143714381439144014411442144314441445144614471448144914501451145214531454145514561457145814591460146114621463146414651466146714681469147014711472147314741475147614771478147914801481148214831484148514861487148814891490149114921493149414951496149714981499150015011502150315041505150615071508150915101511151215131514151515161517151815191520152115221523152415251526152715281529153015311532153315341535153615371538153915401541154215431544154515461547154815491550155115521553155415551556155715581559156015611562156315641565156615671568156915701571157215731574157515761577157815791580158115821583158415851586158715881589159015911592159315941595159615971598159916001601160216031604160516061607160816091610161116121613161416151616161716181619162016211622162316241625162616271628162916301631163216331634163516361637163816391640164116421643164416451646164716481649165016511652165316541655165616571658165916601661166216631664166516661667166816691670167116721673167416751676167716781679168016811682168316841685168616871688168916901691169216931694169516961697169816991700170117021703170417051706170717081709171017111712171317141715171617171718171917201721172217231724172517261727172817291730173117321733173417351736173717381739174017411742174317441745174617471748174917501751175217531754175517561757175817591760176117621763176417651766176717681769177017711772177317741775177617771778177917801781178217831784178517861787178817891790179117921793179417951796179717981799180018011802180318041805180618071808180918101811181218131814181518161817181818191820182118221823182418251826182718281829183018311832183318341835183618371838183918401841184218431844184518461847184818491850185118521853185418551856185718581859186018611862186318641865186618671868186918701871187218731874187518761877187818791880188118821883188418851886188718881889189018911892189318941895189618971898189919001901190219031904190519061907190819091910191119121913191419151916191719181919192019211922192319241925192619271928192919301931193219331934193519361937193819391940194119421943194419451946194719481949195019511952195319541955195619571958195919601961196219631964196519661967196819691970197119721973197419751976197719781979198019811982198319841985198619871988198919901991199219931994199519961997199819992000200120022003200420052006200720082009201020112012201320142015201620172018201920202021202220232024202520262027202820292030203120322033203420352036203720382039204020412042204320442045204620472048204920502051205220532054205520562057205820592060206120622063206420652066206720682069207020712072207320742075207620772078207920802081208220832084208520862087208820892090209120922093209420952096209720982099210021012102210321042105210621072108210921102111211221132114211521162117211821192120212121222123212421252126212721282129213021312132213321342135213621372138213921402141214221432144214521462147214821492150215121522153215421552156215721582159216021612162216321642165216621672168216921702171217221732174217521762177217821792180218121822183218421852186218721882189219021912192219321942195219621972198219922002201220222032204220522062207220822092210221122122213221422152216221722182219222022212222222322242225222622272228222922302231223222332234223522362237223822392240224122422243224422452246224722482249225022512252225322542255225622572258225922602261226222632264226522662267226822692270227122722273227422752276227722782279228022812282228322842285228622872288228922902291229222932294229522962297229822992300230123022303230423052306230723082309231023112312231323142315231623172318231923202321232223232324232523262327232823292330233123322333233423352336233723382339234023412342234323442345234623472348234923502351235223532354235523562357235823592360236123622363236423652366236723682369237023712372237323742375237623772378237923802381238223832384238523862387238823892390239123922393239423952396239723982399240024012402240324042405240624072408240924102411241224132414241524162417241824192420242124222423242424252426242724282429243024312432243324342435243624372438243924402441244224432444244524462447244824492450245124522453245424552456245724582459246024612462246324642465246624672468246924702471247224732474247524762477247824792480248124822483248424852486248724882489249024912492249324942495249624972498249925002501250225032504250525062507250825092510251125122513251425152516251725182519252025212522252325242525252625272528252925302531253225332534253525362537253825392540254125422543254425452546254725482549255025512552255325542555255625572558255925602561256225632564256525662567256825692570257125722573257425752576257725782579258025812582258325842585258625872588258925902591259225932594259525962597259825992600260126022603260426052606260726082609261026112612261326142615261626172618261926202621262226232624262526262627262826292630263126322633263426352636263726382639264026412642264326442645264626472648264926502651265226532654265526562657265826592660266126622663266426652666266726682669267026712672267326742675267626772678267926802681268226832684268526862687268826892690269126922693269426952696269726982699270027012702270327042705270627072708270927102711271227132714271527162717271827192720272127222723272427252726272727282729273027312732273327342735273627372738273927402741274227432744274527462747274827492750275127522753275427552756275727582759276027612762276327642765276627672768276927702771277227732774277527762777277827792780278127822783278427852786278727882789279027912792279327942795279627972798279928002801280228032804280528062807280828092810281128122813281428152816281728182819282028212822282328242825282628272828282928302831283228332834283528362837283828392840284128422843284428452846284728482849285028512852285328542855285628572858285928602861286228632864286528662867286828692870287128722873287428752876287728782879288028812882288328842885288628872888288928902891289228932894289528962897289828992900290129022903290429052906290729082909291029112912291329142915291629172918291929202921292229232924292529262927292829292930293129322933293429352936293729382939294029412942294329442945294629472948294929502951295229532954295529562957295829592960296129622963296429652966296729682969297029712972297329742975297629772978297929802981298229832984298529862987298829892990299129922993299429952996299729982999300030013002300330043005300630073008300930103011301230133014301530163017301830193020302130223023302430253026302730283029303030313032303330343035303630373038303930403041304230433044304530463047304830493050305130523053305430553056305730583059306030613062306330643065306630673068306930703071307230733074307530763077307830793080308130823083308430853086308730883089309030913092309330943095309630973098309931003101310231033104310531063107310831093110311131123113311431153116311731183119312031213122312331243125312631273128312931303131313231333134313531363137313831393140314131423143314431453146314731483149315031513152315331543155315631573158315931603161316231633164316531663167316831693170317131723173317431753176317731783179318031813182318331843185318631873188318931903191319231933194319531963197319831993200320132023203320432053206320732083209321032113212321332143215321632173218321932203221322232233223432253226322732283229323032313232323332343235323632373238323932403241324232433244324532463247324832493250325132523253325432553256325732583259326032613262326332643265326632673268326932703271327232733274327532763277327832793280328132823283328432853286328732883289329032913292329332943295329632973298329933003301330233033304330533063307330833093310331133123313331433153316331733183319332033213322332333243325332633273328332933303331333233333334333533363337333833393340334133423343334433453346334733483349335033513352335333543355335633573358335933603361336233633364336533

IAEA SAFETY STANDARDS

SAFETY THROUGH INTERNATIONAL STANDARDS

While safety is a national responsibility, international standards and approaches to safety promote consistency, help to provide assurance that nuclear and radiation related technologies are used safely, and facilitate international technical cooperation and trade.

The standards also provide support for States in meeting their international obligations. One general international obligation is that a State must not pursue activities that cause damage in another State. More specific obligations on Contracting States are set out in international safety related conventions. The internationally agreed IAEA safety standards provide the basis for States to demonstrate that they are meeting these obligations.

THE IAEA STANDARDS

The IAEA safety standards have a status derived from the IAEA's Statute, which authorizes the Agency to establish standards of safety for nuclear and radiation related facilities and activities and to provide for their application.

The safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment.

They are issued in the IAEA Safety Standards Series, which has three categories:

Safety Fundamentals

- Presenting the objectives, concepts and principles of protection and safety and providing the basis for the safety requirements.

Safety Requirements

- Establishing the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements, which are expressed as 'shall' statements, are governed by the objectives, concepts and principles of the Safety Fundamentals. If they are not met, measures must be taken to reach or restore the required level of safety. The Safety Requirements use regulatory language to enable them to be incorporated into national laws and regulations.

Safety Guides

- Providing recommendations and guidance on how to comply with the Safety Requirements. Recommendations in the Safety Guides are expressed as 'should' statements. It is recommended to take the measures stated or equivalent alternative measures. The Safety Guides present international good practices and increasingly they reflect best practices to

help users striving to achieve high levels of safety. Each Safety Requirements publication is supplemented by a number of Safety Guides, which can be used in developing national regulatory guides.

The IAEA safety standards need to be complemented by industry standards and must be implemented within appropriate national regulatory infrastructures to be fully effective. The IAEA produces a wide range of technical publications to help States in developing these national standards and infrastructures.

MAIN USERS OF THE STANDARDS

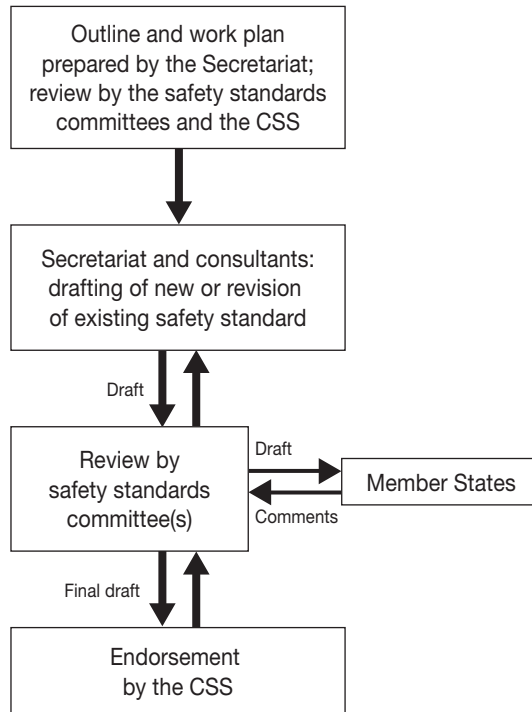
As well as by regulatory bodies and governmental departments, authorities and agencies, the standards are used by authorities and operating organizations in the nuclear industry; by organizations that design, manufacture for and apply nuclear and radiation related technologies, including operating organizations of facilities of various types; by users and others involved with radiation and radioactive material in medicine, industry, agriculture, research and education; and by engineers, scientists, technicians and other specialists. The standards are used by the IAEA itself in its safety reviews and for developing education and training courses.

DEVELOPMENT PROCESS FOR THE STANDARDS

The preparation and review of safety standards involves the IAEA Secretariat and four safety standards committees for safety in the areas of nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), and a Commission on Safety Standards (CSS), which oversees the entire safety standards programme. All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of the CSS is appointed by the Director General and includes senior government officials having responsibility for establishing national standards.

For Safety Fundamentals and Safety Requirements, the drafts endorsed by the Commission are submitted to the IAEA Board of Governors for approval for publication. Safety Guides are published on the approval of the Director General.

Through this process the standards come to represent a consensus view of the IAEA's Member States. The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international expert bodies, notably the International Commission on Radiological Protection (ICRP), are taken into account in developing the standards. Some standards are developed in cooperation with other bodies in the United Nations system or other specialized agencies, including the Food and Agriculture Organization of the United Nations, the International



The process for developing a new safety standard or revising an existing one.

Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

The safety standards are kept up to date: five years after publication they are reviewed to determine whether revision is necessary.

APPLICATION AND SCOPE OF THE STANDARDS

The IAEA Statute makes the safety standards binding on the IAEA in relation to its own operations and on States in relation to operations assisted by the IAEA. Any State wishing to enter into an agreement with the IAEA concerning any form of Agency assistance is required to comply with the requirements of the safety standards that pertain to the activities covered by the agreement.

International conventions also contain similar requirements to those in the safety standards, and make them binding on contracting parties. The Safety Fundamentals were used as the basis for the development of the Convention on Nuclear Safety and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. The Safety

Requirements on Preparedness and Response for a Nuclear or Radiological Emergency reflect the obligations on States under the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

The safety standards, incorporated into national legislation and regulations and supplemented by international conventions and detailed national requirements, establish a basis for protecting people and the environment. However, there will also be special aspects of safety that need to be assessed case by case at the national level. For example, many of the safety standards, particularly those addressing planning or design aspects of safety, are intended to apply primarily to new facilities and activities. The requirements and recommendations specified in the IAEA safety standards might not be fully met at some facilities built to earlier standards. The way in which the safety standards are to be applied to such facilities is a decision for individual States.

INTERPRETATION OF THE TEXT

The safety standards use the form 'shall' in establishing international consensus requirements, responsibilities and obligations. Many requirements are not addressed to a specific party, the implication being that the appropriate party or parties should be responsible for fulfilling them. Recommendations are expressed as 'should' statements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures) for complying with the requirements.

Safety related terms are to be interpreted as stated in the IAEA Safety Glossary (<http://www-ns.iaea.org/standards/safety-glossary.htm>). Otherwise, words are used with the spellings and meanings assigned to them in the latest edition of The Concise Oxford Dictionary. For Safety Guides, the English version of the text is the authoritative version.

The background and context of each standard within the Safety Standards Series and its objective, scope and structure are explained in Section 1, Introduction, of each publication.

Material for which there is no appropriate place in the body text (e.g. material that is subsidiary to or separate from the body text, is included in support of statements in the main text, or describes methods of calculation, experimental procedures or limits and conditions) may be presented in appendices or annexes.

An appendix, if included, is considered to form an integral part of the standard. Material in an appendix has the same status as the main text and the IAEA assumes authorship of it. Annexes and footnotes to the main text, if included, are used to provide practical examples or additional information or explanation. An annex is not an integral part of the main text. Annex material published by the IAEA is not necessarily issued under its authorship; material published in standards that is under other authorship may be presented in annexes. Extraneous material presented in annexes is excerpted and adapted as necessary to be generally useful.

CONTENTS

1.	INTRODUCTION	1
	Background (1.1–1.4)	1
	Objective (1.5–1.6)	1
	Scope (1.7–1.9)	2
	Structure (1.10)	3
2.	LEGAL FRAMEWORK FOR A REGULATORY INFRASTRUCTURE	3
	Scope of the basic legal framework (2.1–2.3)	3
	Prime responsibility for safety (2.4)	4
	Legislative basis for a regulatory body (2.5–2.9)	5
	Regulatory independence (2.10–2.18)	7
	Legislation for funding (2.19)	10
	Legislative focus on interagency co-operation (2.20–2.21)	10
3.	PRINCIPAL FUNCTIONS AND ACTIVITIES OF THE REGULATORY BODY (3.1).....	11
	Establishing regulations and guides (3.2–3.20)	11
	Notification and authorization (by registration or licence) (3.21–3.52)	18
	Inspection (3.53–3.68)	28
	Investigation of accidents (3.69–3.74)	33
	Enforcement (3.75–3.89)	35
	Dissemination of information (3.90–3.91)	38
4.	REGULATORY CONTROL OF THE SUPPLY OF CONSUMER PRODUCTS	39
	Regulatory approach to the generic approval of consumer products (4.1–4.14)	39
	Authorization for the supply of consumer products (4.15–4.20)	43
	Inspection for the supply of consumer products (4.21).....	46

5. FUNCTIONS OF THE REGULATORY BODY SHARED WITH OTHER GOVERNMENTAL AGENCIES 46

Intervention in emergencies (5.2–5.4) 47

Intervention in chronic exposure situations (5.5) 48

Transport safety (5.6–5.7) 48

Waste safety (5.8–5.9) 49

Co-ordination and co-operation (5.10) 49

6. ORGANIZATION AND STAFFING OF THE REGULATORY BODY (6.1–6.25) 50

7. DOCUMENTATION OF THE FUNCTIONS AND ACTIVITIES OF THE REGULATORY BODY (7.1–7.4) 56

8. SUPPORT SERVICES (8.1–8.4) 58

9. QUALITY MANAGEMENT FOR THE REGULATORY SYSTEM (9.1–9.6) 59

REFERENCES 62

CONTRIBUTORS TO DRAFTING AND REVIEW 64

BODIES FOR THE ENDORSEMENT OF SAFETY STANDARDS .. 65

IAEA Document No. GSG-1.5

1. INTRODUCTION

BACKGROUND

1.1. The achievement and maintenance of a high level of safety in the use of radiation sources depend on there being a sound legal and governmental infrastructure, including a national regulatory body with well-defined responsibilities and functions. An appropriately organized and staffed regulatory body with access to adequate resources is a key element of such an infrastructure.

1.2. The Safety Requirements publication entitled Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety [1] establishes the requirements for such an infrastructure. The term ‘infrastructure’ refers to the underlying structure of systems and organizations. This includes requirements concerning the establishment of a regulatory body for radiation sources and the responsibilities and functions to be assigned to it.

1.3. The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the Basic Safety Standards) [2] establish basic requirements for protection against the risks associated with exposure to ionizing radiation and for the safety of radiation sources that may give rise to such exposure (hereinafter the term ‘radiation safety’ is used to cover both these aspects). The Basic Safety Standards are not intended to be applied as they stand in all States and regions, but should be adapted to take account of local conditions. The ways in which States apply the Basic Safety Standards will vary depending on their legal systems, their technical resources, the scale of the installations concerned and related factors.

1.4. The Basic Safety Standards [2] can be applied only by means of an effective infrastructure for radiation safety, which includes adequate legislation and regulations, an efficient regulatory system, supporting experts and services, and a commitment to safety shared by all those with responsibilities for protection and safety, including both management and workers.

OBJECTIVE

1.5. This Safety Guide is intended mainly to assist States to implement the requirements established in Ref. [1] for a national regulatory infrastructure to

regulate any practice involving radiation sources in medicine, industry, agriculture, research and education.

1.6. Member States receiving assistance from the IAEA in the application of nuclear energy or radiation technology are expected to implement the Basic Safety Standards [2] or equivalent standards for radiation protection and safety as may be appropriate for the conditions. This can only be ensured by means of an adequate regulatory system, which is a key element of the national infrastructure for radiation safety. The other sponsors of the Basic Safety Standards — the Food and Agriculture Organization of the United Nations (FAO), the International Labour Organization (ILO), the Pan American Health Organization (PAHO), the World Health Organization (WHO) and the OECD Nuclear Energy Agency (OECD/NEA) — apply them in their respective spheres of activity.

SCOPE

1.7. This Safety Guide covers the elements of a national regulatory infrastructure necessary to achieve an appropriate level of protection and safety for radiation sources used in medicine, industry, agriculture, research and education. It also provides guidance on the organization and implementation of a system for the regulatory control of radiation sources.

1.8. The guidance given in this Safety Guide is not oriented towards nuclear facilities. Although it is relevant to these facilities, they require a more elaborate and technically advanced safety infrastructure, as set out in four interrelated Safety Guides [3–6]. In using this Safety Guide, regulatory bodies should be aware of the current IAEA safety standards (and relevant national documents) concerning nuclear safety, radiation protection, the transport of radioactive material and the management of radioactive waste. This Safety Guide does not cover the safety infrastructures at the operator¹ level. These

¹ An operator is defined as any organization or person applying for authorization or authorized and/or responsible for nuclear, radiation, radioactive waste or transport safety when undertaking activities or in relation to any nuclear facilities or sources of ionizing radiation. This includes, inter alia, private individuals, governmental bodies, consignors or carriers, licensees, hospitals, self-employed persons, etc. It is synonymous with operating organization. This Safety Guide uses the term operator in the same sense as it is used in GS-R-1, and with the same meaning as for the term legal person as used in the Basic Safety Standards [2].

will be considered by the IAEA in practice specific publications on radiation safety. However, the present Safety Guide does cover the interactions between the government and those operators subject to its control.

1.9. While the guidance is intended primarily to assist in establishing a national regulatory infrastructure for regulating the safety of radiation practices and sources, it is also generally applicable for a regulatory infrastructure appropriate for regulating intervention. The latter type of infrastructure is different in some respects, however, and those aspects of the regulatory infrastructure that are unique to intervention are covered elsewhere.

STRUCTURE

1.10. Section 2 provides general information about the legal framework necessary to establish and maintain a regulatory infrastructure for radiation safety. The principal functions and activities of the regulatory body are identified in Section 3. Section 4 provides advice on the regulatory control of consumer product supply. Section 5 examines those functions of the regulatory body that are shared with other governmental organizations. The requirements applicable to the staffing of the regulatory body are reviewed in Section 6. Section 7 discusses the documentation of the regulatory body's functions and activities. Section 8 addresses the support services and the procedures to be established for ensuring that the regulatory body maintains an effective regulatory system. Section 9 outlines the content of a quality management system for the regulatory body.

2. LEGAL FRAMEWORK FOR A REGULATORY INFRASTRUCTURE

SCOPE OF THE BASIC LEGAL FRAMEWORK

2.1. A legislative and statutory framework (e.g. an act, law or decree; hereinafter termed 'the legislation') which allows for the beneficial use of ionizing radiation and regulates the safety of facilities and activities is required to be established by the legislative and governmental mechanisms of States

(Ref. [1], para. 2.2(1)). The enabling legislation should be as straightforward as feasible, consistent with the national situation, so that the need for its subsequent amendment is minimized. This is important because the process of amending the legislation is usually a slow and resource intensive one. In contrast, regulations, which contain administrative and technical requirements, can be amended as knowledge is gained from scientific and technical developments and experience is gained from regulated practices and in intervention situations.

2.2. The legislation “shall specify facilities, activities and materials that are included in the scope of the legislation” (Ref. [1], para. 2.4(2)). The legislation should be applicable to occupational, public and medical exposure, and to all sources of ionizing radiation (in use or disused). Thus, it should apply both to radiation sources containing radionuclides and to radiation generating machines (e.g. X ray equipment, particle accelerators), even those not in use. The legislation should also make reference to the radiation protection requirements established in the Basic Safety Standards [2] (i.e. requirements for the justification of practices, the limitation of doses, the optimization of protection and safety, dose constraints and guidance levels for medical exposure).

2.3. While it is required that the legislation specify facilities, activities and materials that are included in its scope, and this may be done by specifying exclusions from its requirements, it should also confer on the regulatory body authority to exclude certain exposures on the grounds of their being considered unamenable (not amenable) to regulatory control by any practicable means [2]. The regulatory body should also be granted authority to exempt certain practices from the requirements of the regulations when the imposition of such requirements is unnecessary. Such provisions for exemption should be in line with the provisions in Schedule I of the Basic Safety Standards [2].

PRIME RESPONSIBILITY FOR SAFETY

2.4. A fundamental concept that is required to be made clear in the legislation is that prime responsibility for radiation safety resides with those authorized to possess and to use, manufacture, supply or install radiation sources. “The prime responsibility for safety shall be assigned to the operator” (Ref. [1], para. 2.3). In relation to medical exposures, the final responsibility is placed on the medical practitioner. “Registrants and licensees shall ensure that (a) no patient is administered a diagnostic or therapeutic medical exposure unless the

exposure is prescribed by a medical practitioner; (b) medical practitioners are assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure” (Ref. [2], para. II.1(a), (b)).

LEGISLATIVE BASIS FOR A REGULATORY BODY

2.5. Government is required to establish through legislation a national regulatory body to regulate the introduction and conduct of any practice involving sources of radiation (Ref. [1], para. 2.2(4)). The term ‘regulatory body’² means an authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating nuclear, radiation, radioactive waste and transport safety. Although it is preferable for a single body to have regulatory responsibilities for radiation safety, especially in States with no nuclear power programme, such responsibilities are often divided among several bodies already having responsibilities for protection and safety in general, e.g. a ministry of health regulating medical practices, a ministry of labour regulating industrial and research practices, and a ministry of transport regulating the transport of hazardous materials. In legislating to establish the governmental infrastructure, it should be ensured that the regulation of all aspects of radiation safety is covered and that the responsibilities of the governmental bodies involved are clearly specified and allocated. Where regulatory responsibilities for radiation safety are divided, the legislation should establish clear lines of authority and responsibility so as to avoid gaps or overlaps, and so that those operators that use or possess sources know which parts of their activities are within the remit of the various governmental bodies. For these purposes, the legislation should require that the regulatory bodies formally establish a system of liaison and working procedures so as to ensure an appropriate degree of co-ordination and co-operation between regulatory bodies sharing responsibilities.

2.6. The regulatory body is required (Ref. [1], para. 2.6) to have the authority to:

- (a) Develop safety principles and criteria;

² The term regulatory body and the term Regulatory Authority as used in Ref. [2] are equivalent.

- (b) Establish regulations and issue guidance;
- (c) Require any operator to conduct a safety assessment;
- (d) Require that any operator provide it with any necessary information, including information from its suppliers, even if this information is proprietary;
- (e) Issue, amend, suspend or revoke authorizations and to set conditions;
- (f) Require an operator to perform a systematic safety reassessment or a periodic safety review over the lifetime of facilities;
- (g) Enter a site or facility at any time to carry out an inspection;
- (h) Enforce regulatory requirements;
- (i) Communicate directly with governmental authorities at higher levels when such communication is considered to be necessary for exercising effectively the functions of the body;
- (j) Obtain such documents and opinions from private or public organizations or persons as may be necessary and appropriate;
- (k) Communicate independently its regulatory requirements, decisions and opinions and their basis to the public;
- (l) Make available to other governmental bodies, national and international organizations, and to the public, information on incidents and abnormal occurrences, and other information, as appropriate;
- (m) Liaise and co-ordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security and transport of dangerous goods;
- (n) Liaise with regulatory bodies of other States and with international organizations to promote co-operation and the exchange of regulatory information.

2.7. The regulations and guidance that the regulatory body is required to establish should cover such matters as:

- (a) Technical, administrative and competence requirements governing radiation safety;
- (b) Administrative requirements governing notification and authorization;
- (c) Criteria for exemption from regulatory requirements;
- (d) Management of radioactive waste;
- (e) Transport of radioactive material;
- (f) Supporting codes of practice and guides, as appropriate, to assist in implementing the regulatory body's regulations and in enhancing radiation safety.

2.8. The legislation is required to establish a procedure for the review of, and appeal against, regulatory decisions (Ref. [1], para. 2.4(7)). The lodging of such an appeal, however, should not absolve operators from complying with safety requirements and conditions as specified by the regulatory body pending the result of the appeal.

2.9. In order to ensure the effective discharge of its responsibilities and performance of its functions, the legislation should also empower the regulatory body, within its sphere of responsibility, as appropriate:

- (a) To establish arrangements with other governmental and non-governmental bodies, when it is necessary to discharge regulatory responsibilities, for performing essential activities and providing services (e.g. individual monitoring, training in radiation safety, calibration of radiation measuring equipment) that are beyond the capabilities required of operators and which are not otherwise available;
- (b) To make arrangements for the approval of dosimetry services to undertake the assessment of and/or make and keep records of individual doses for the types of practice authorized;
- (c) To co-ordinate its emergency preparedness and response arrangements with national and local plans and to fulfil its related international agreements and obligations, and to participate in the development and implementation of the more generic plans, to the extent that they concern aspects of radiation safety.

REGULATORY INDEPENDENCE

2.10. The importance of regulatory independence is reflected in the Safety Requirements (Ref. [1], para. 2.2(2)), which require the establishment of a regulatory body and its separation and independence from any governmental departments or agencies and other organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. The primary reason for this independence is that it should be ensured that regulatory judgements can be made, and regulatory enforcement actions taken, without pressure from interests that may conflict with safety. Furthermore, the credibility of the regulatory body will depend in large part upon whether it is considered to be independent of the organizations that it regulates, as well as independent of the governmental agencies and industry groups that develop and promote the practices being regulated.

2.11. It is recognized that a regulatory body cannot in every respect be absolutely independent of other areas of government; it must function within a national system of legislation and policies, just as other governmental bodies and private organizations do. Nevertheless, for the credibility and effectiveness of the regulatory body, it should have effective independence so as to be able to take the necessary decisions with regard to the protection of workers, patients, the public and the environment.

2.12. The need for the independence of the regulatory body should not be interpreted to mean that it ought to have an adversarial relationship with operators or with any other party.

Aspects of regulatory independence

2.13. *Political aspects.* The political system is required to ensure the clear and effective separation of responsibilities and duties between the regulatory body and the organizations promoting or furthering the development of the practices being regulated. In this regard, the distinction between independence and accountability should be made. The regulatory body should not be subject to political influence or pressure in taking decisions relating to safety. The regulatory body should, however, be accountable in respect of fulfilling its mission to protect workers, patients, the public and the environment from undue radiation exposure. One way of providing this accountability is by establishing a direct reporting line from the regulatory body to the highest levels of government. Where a regulatory body reports to a government agency that has responsibility for utilizing or promoting the practices being regulated, there should be channels for reporting to higher authorities so as to be able to resolve any conflicts of interest that may arise. This accountability should not compromise the independence of the regulatory body in taking decisions relating to safety with neutrality and objectivity.

2.14. *Legislative aspects.* The functions, competence and independence of the regulatory body in respect of safety should be defined in the legislative framework of a national regulatory system (that is, in legislation relating to radiation protection). The regulatory body is required to have the authority and responsibility to adopt or to develop regulations relating to safety to effect the legislation enacted by the legislature. The regulatory body is also required to have the authority to take decisions, including decisions on enforcement actions. There should be a formal mechanism for appeal against regulatory decisions, with predefined conditions that must be met for an appeal to be considered.

2.15. *Financial aspects.* “The regulatory body shall be provided with adequate authority and power, and it shall be ensured that it has adequate staffing and financial resources to discharge its assigned responsibilities” (Ref. [1], para. 2.2(4)). While it is recognized that the regulatory body is in principle subject, as is the rest of government, to financial controls, the budget of the regulatory body should not be subject to review and approval by the government departments or agencies and other organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities.

2.16. *Competence aspects.* The regulatory body should have independent technical expertise available to it in the areas relevant to its responsibilities for safety. The management of the regulatory body should therefore have the authority and responsibility to recruit staff with the skills and technical expertise it considers necessary to enable the regulatory body to perform its functions. In addition, the regulatory body should maintain an awareness of the ‘state of the art’ in safety related technology. In order to have access to external technical expertise and advice that is independent of any funding or support from operators, in support of its decision making on regulatory matters, the regulatory body is required to be able to set up and fund independent advisory bodies to provide expert opinion and advice (Ref. [1], para. 2.4(9)) and to award contracts for research and development projects. In particular, the regulatory body is required to be able “to obtain such documents and opinions from private or public organizations or persons as may be necessary and appropriate” (Ref. [1], para. 2.6(10)).

2.17. *Public information aspects.* One of the responsibilities of the regulatory body is to inform the public. “The regulatory body shall have the authority to communicate independently its regulatory requirements, decisions and opinions and their basis to the public” (Ref. [1], para. 2.6(11)). The public will have greater confidence in the safe use of nuclear and radiation related technologies if regulatory processes are open and decisions are made public. The governmental authorities should set up a system to allow independent experts and experts from major interested parties (e.g. operators, the workforce and the public) to give their views. The experts’ findings should be made public.

2.18. *International aspects.* “The regulatory body shall have the authority to liaise with regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information” (Ref. [1], para. 2.6(14)).