

INSAG-11

The Safe Management of Sources of Radiation: Principles and Strategies

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A REPORT BY THE
INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP

INSAG



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OF RADIATION:
PRINCIPLES AND STRATEGIES**

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**A report by the
International Nuclear Safety Advisory Group**

The International Nuclear Safety Advisory Group (INSAG) is an advisory group to the Director General of the International Atomic Energy Agency, whose main functions are:

- (1) To provide a forum for the exchange of information on generic nuclear safety issues of international significance;
- (2) To identify important current nuclear safety issues and to draw conclusions on the basis of the results of nuclear safety activities within the IAEA and of other information;
- (3) To give advice on nuclear safety issues in which an exchange of information and/or additional efforts may be required;
- (4) To formulate, where possible, commonly shared safety concepts.

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FOREWORD
by Mohamed ElBaradei
Director General

The International Atomic Energy Agency's activities relating to nuclear safety are based upon a number of premises. First and foremost, each Member State bears full responsibility for the safety of its nuclear facilities. States can be advised, but they cannot be relieved of this responsibility. Secondly, much can be gained by exchanging experience; lessons learned can prevent accidents. Finally, the image of nuclear safety is international; a serious accident anywhere affects the public's view of nuclear power everywhere.

With the intention of strengthening its contribution to ensuring the safety of nuclear power plants, the IAEA established the International Nuclear Safety Advisory Group (INSAG), whose duties include serving as a forum for the exchange of information on nuclear safety issues of international significance and formulating, where possible, commonly shared safety principles.

The present report by INSAG deals with the general principles governing the safety of all sources of radiation and with the application of these principles. In doing so, it builds upon the three Safety Fundamentals publications issued by the IAEA as Safety Series Nos 110, 111-F and 120. It intends to show that, at the conceptual level, the distinction traditionally made between nuclear safety and radiation protection is hardly justifiable.

The report is intended primarily for those non-specialists who need to take decisions about the safe management of sources of radiation and who wish to gain a better understanding of the approach followed in managing the safety of these sources.

I am pleased to have received this report and am happy to release it to a wider audience.

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1. INTRODUCTION

1. Radiation has always been present on Earth. Radiation exists predominantly in the form of natural or 'background' radiation to which all living organisms are exposed. Radiation also comes from a large number and variety of human made sources¹, such as industrial and medical sources, smoke detectors, radioactive illuminated signs, research equipment, uranium mining and milling, nuclear power plants and radioactive waste. The purpose of this report is to set out the common principles that have evolved for the safe management of peaceful applications of technologies that involve sources of radiation. The consistent application of these principles is necessary to achieve and maintain an adequate level of safety.

2. For historical reasons, radiation protection and nuclear safety have evolved largely independently. The former has dealt mainly with the assessment and control of radiation exposure, initially in medical uses, and subsequently in wider applications and with accidents and their consequences. The latter has been concerned with the safe operation of nuclear plants, including the prevention of accidents and the mitigation of their consequences. These differences are clearly apparent in the approaches to safety contained in the different Safety Series publications mentioned in para. 3. However, radiation protection and nuclear safety should be regarded as different parts of a common set of activities aimed at limiting the risks associated with technologies that involve ionizing radiation.

3. Between 1993 and 1996, the IAEA issued three Safety Fundamentals publications in its Safety Series. They present fundamental safety principles as applied, respectively, to nuclear installations [1], radioactive waste [2] and radiation sources [3].

4. In response to a request from the Director General of the IAEA, INSAG in 1997 began to prepare a report that would draw together the common principles underlying the three Safety Fundamentals publications.

5. The present report attempts to provide a coherent framework by placing objectives and principles of safety and radiation protection within the context of a general objective of safety and control of radiation risk, whatever its origin and nature. The report presents a logical, unifying approach to this particular aspect of

¹ Source of radiation is taken here to mean anything that may cause radiation exposure, such as by emitting ionizing radiation or releasing radioactive substances or materials.

risk management. It also presents examples to illustrate the importance of these principles and discusses how failing to apply them can result in serious consequences.

6. This report is aimed primarily at policy makers and those who need to take a higher level view of some of the practices involving sources of radiation. It is not written for specialists and does not assume any detailed knowledge of the nature of radiation or its effects. It is written in a rather informal style and is intended to provide general guidance. INSAG publications are not part of a series of 'standards' and hence are issued in a form which appears most appropriate to the topic at hand. They are not of a regulatory nature and do not need to follow the formal written style of the Safety Standards series.

7. Following this introduction, Section 2 discusses risk and risk management, starting from the premise that any technological activity involves risk of one kind or another. It discusses the nature of risk, its perception and its management, and proceeds to the particular nature of radiation hazards. Section 3 deals with the various elements that need to be considered for the effective control of radiation risk. Section 4 then discusses the safety of some typical sources of radiation, namely industrial sources, medical applications of radiation, radioactive waste disposal facilities and nuclear installations. The management of these diverse sources is based on the principles of radiation safety and protection, but each type of source requires a different emphasis in the application of specific strategies. In spite of an overall excellent safety record, several accidents involving sources of radiation have occurred and Section 4 reviews these briefly in terms of their root causes, i.e. a failure to apply effectively one or more of the principles. Section 5 presents conclusions.

2. RISK AND RISK MANAGEMENT

2.1. RISK AND RISK PERCEPTION

8. All human activities and, in particular, all technological activities involve risks of one type or another. They must be identified and appropriately managed, to ensure that the benefits of technological activities outweigh the risks.

9. To many people 'risk' is simply a threat, a hazard or a probability of occurrence. However, scientific, rigorous definitions of risk include reference to a specific consequence arising from a hazard (e.g. the death of an individual) and to the probability of occurrence. But, as stated in INSAG-9 [4], the concept of risk involves sets of event

probabilities whereby each event can give rise to a variety of consequences, not all of which are represented by a single number. Instead, the full range of potential events and their respective probabilities and consequences must be considered. Methods have been developed for carrying out such analyses.

10. Although an estimate of risk can often be obtained by means of such scientific techniques, members of the general public form their own views on the acceptability of various risks, and this issue of 'risk perception' needs to be addressed when dealing with the management of risk. Several factors that are thought to influence public perception have been identified. Among these are the following:

- The magnitude of potential accidents is important. The occurrence of rare accidents involving many fatalities is generally viewed as more serious than the occurrence of more common ones that cause fewer fatalities. Thus, most people are more concerned about an accident that could cause 10 000 fatalities once every 100 000 years than about accidents each of which causes one fatality every ten years, even though mathematically the average annual risk of fatality is the same in both cases (i.e. 0.1 per year).
- Many people are actually exposed to risks higher than those which they decline to accept when they are aware of them. They appear to be particularly averse to risks with which they are unfamiliar in everyday life and to those in the face of which they feel powerless and which are imposed upon them by others. There is also an aversion to risks that are associated with dreaded consequences such as cancer even if the risk is small.
- The acceptance of an industrial activity will also be influenced by the distribution of benefits and risks. For example, those living close to a potentially hazardous industrial plant may be at higher risk but may also receive significant benefits and, hence, may be more tolerant of that risk. Similarly, different societies may view the benefits and risks differently. Furthermore, some processes lead to risks that are present over substantial periods of time, and this means that the risks created by one generation sometimes have to be borne or managed by later generations. The management of radioactive waste and the effects of emissions from the burning of fossil fuels are both examples of issues for which intergenerational equity is an important consideration.

11. The fact that ionizing radiation is commonly poorly understood by the general public, that it can cause harm without being seen or felt, is capable of causing cancer and is associated in the public mind with atomic explosions and uncontrolled accidents, has the consequence that public aversion to technologies involving radiation tends to be particularly strong, and this has been reinforced in some cases by poor communication and by incorrect and biased information.

12. Given the factors discussed in para. 10, it is not possible to set simple quantitative guidelines for acceptability of risk that will cover all circumstances. Each case must be regarded on its own merits. It has been proposed, however, that when considering the actual levels of risk to which the public is exposed, two 'boundaries' be established. At one extreme, activities that expose individuals to a risk above some value are clearly unacceptable, except in extraordinary situations. At the other end of the spectrum, there is a level of risk associated with some activities that is considered to be broadly acceptable.

13. A major study by the Royal Society of London [5] noted some years ago that there is a view that very few people would commit their own resources to reduce further an annual risk of death of about one in a million. It could therefore be inferred that this level of risk is broadly acceptable. Given that in industries traditionally considered dangerous, such as quarrying, mining or construction, average levels of fatal accidents to workers were between 1 in 10 000 and 3 in 10 000, the same study concluded that this level may be close to the limit of acceptability and that an annual risk of death of 1 in 1000 would generally be unacceptable to most individuals except in special circumstances.

14. Although public perception is an important factor in managing risks, it is essential that the public and those concerned with the management of risks make judgements, to the degree possible, on the basis of the best available scientific information. This not only allows for informed decision making, but also provides the basis for setting priorities when allocating finite resources to improve safety and environmental protection. Allocating resources to reduce risks in one area may reduce the ability to reduce higher risks elsewhere. It is also important that the benefits as well as the risks of any activity be properly communicated to the public.

15. As stated in the introduction, all industrial activities involve some risk. Although risks vary considerably from one technology to another, three principles should be used in evaluating and controlling them.

16. Firstly, whenever risk considerations are part of the decision making process for an industrial activity, the balance between the potential benefits to be gained from the activity and the risks likely to be associated with it will be carefully examined. This applies particularly to new industrial activities. The activity will only proceed if it is judged that the benefits outweigh the risks that arise from its application or introduction. It is now widely recognized that the risks associated with the entire life-cycle, from construction (including acquisition of raw materials), to operation, to decommissioning and to wastes, are to be considered in the decision making process.

17. This principle not only includes the present geographical and social distribution of risks and benefits, but will, where possible, also take into account longer term effects and the quest for sustainability, so that:

- Present industrial activities should not impose undue burdens on future generations;
- Future generations should not be exposed to risks that are currently unacceptable;
- Wherever it is reasonable and possible to do so, decisions taken now should not prevent future generations from taking a different course of action, should new and important evidence emerge about the risks associated with the activity.

18. Secondly, once the benefits arising from a new industrial activity have been judged to outweigh the risk, the latter should, at all times, be kept as low as reasonably achievable (ALARA), economic and social factors being taken into account. This is the prime means by which risks are controlled in practice.

19. Thirdly, no individual should be exposed to an unacceptable level of individual risk as a consequence of an industrial activity. Adherence to this principle requires that pre-established limits and conditions be set, beyond which operation is not acceptable.

20. In rare situations it is possible that accidents occur that may cause the limits set for normal operation to be exceeded. Safety measures need to be put into place to reduce the probability of accidents and to ensure that workers and the public are adequately protected against such events. Safety considerations require that there be a safety objective to establish and maintain an effective defence against hazards, to reduce their probability of occurrence and to limit their consequences, should they occur.

21. Many factors enter into the decision of whether or not to proceed with an industrial activity. The importance of risk perception was mentioned in para. 10. The State, the news media, politicians, public interest groups and the proponents of a given technology often introduce other factors. Owners/operators must ultimately select a given option and gain the agreement of the regulator. They essentially base their selection upon costs and on the safety, reliability, performance record and ease of maintenance of the available choices, particularly as they relate to normal operating and anticipated transient conditions.

22. Because the hazards from radiation have long been recognized, the above mentioned principles have become part of a well established and strongly enforced

framework of control for technologies that involve ionizing radiation. Indeed, if the same rigour were used in dealing with some other sources of risk, it is likely that the number of fatalities and injuries and the extent of environmental damage would be significantly reduced. The following sections of this report describe how such principles have been applied in practice to control radiation hazards.

2.2. RADIATION HAZARDS

23. The discovery of ionizing radiation, specifically X rays, over a century ago was followed by its use in the medical field for diagnostic purposes and not long thereafter for therapeutic purposes. Because of this, some of the harmful effects of human made radiation were also rapidly recognized, as was the need to control exposure to radiation while reaping the benefits that could be derived from the use of X rays. Moreover, by 1911 the occurrence of radiation induced cancer had already been recognized.

24. Radiation sources emit energy in the form of ionizing radiation. The amount of energy absorbed per unit mass in the materials exposed is called the absorbed dose. Different types of radiation affect living organisms to varying degrees, depending on the organism and the specific organs or tissues that are irradiated. To take account of this, an effective dose can be calculated which takes account of the type of radiation, its intensity, the organ and tissue being exposed, etc., so that for protection purposes all exposures can be expressed in terms of a single comparable quantity. This quantity, the effective dose, is expressed in units of sieverts (Sv) or millisieverts (mSv), as defined in the International System of Units.

25. As a global average, humans receive a dose of about 2.4 mSv per year from natural background radiation. This figure typically varies from place to place. For example, it may be higher by a few millisieverts a year in many places and may be up to as much as tens of millisieverts a year in extreme cases. Harmful effects such as an excess of cancer induction arising from exposure to such higher than average background radiation, if they occur, are too small to be statistically distinguished in epidemiological studies from variations in cancer rates arising from other causes such as diet and lifestyle. Exposure to human made radiation mainly arises as medical exposure. In countries with advanced health care, this amounts to about 1.1 mSv per year. By contrast, the contribution from all routine nuclear power activities is estimated to give an annual average dose to the population of less than one thousandth of this figure. Typically, people living close to a nuclear power plant receive an annual dose from this source of less than about 0.02 mSv. For comparison, the maximum annual exposure from all human made sources recommended by the International

Commission on Radiological Protection (ICRP) for members of the general population is 1.0 mSv per year (averaged over five consecutive years under special circumstances). In a number of jurisdictions, activities involving sources of radiation that could give rise to doses of the order of 0.01 mSv per year are exempted from regulatory control.

26. The harmful effects of radiation are of two types, deterministic and stochastic. Deterministic effects are those which occur above some threshold of exposure of the order of 1000 mSv and where the severity of the induced effects is proportional to the dose. They are the result of cell destruction in a tissue which, if severe enough, may impair the functioning of an organ or even cause death. Stochastic effects are those which are not certain to occur, but for which the probability of occurrence increases with the dose. The most important stochastic effect is cell modification, which can lead to the occurrence of cancer, usually many years after the exposure.

27. Radiation effects have been thoroughly studied and a large volume of information on experimental and epidemiological studies is available. This information is summarized in the reports of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). These reports represent the fundamental and authoritative scientific basis for evaluating the relationship between exposure to radiation and risk, which forms an important element of the basis for the recommendations of the ICRP.

28. Epidemiological studies on populations exposed to significant doses of radiation following the atomic bombing of Hiroshima and Nagasaki in Japan in 1945 have provided an indication of the dose–effect relationship at relatively high doses and dose rates but, for those arising from the normal use of radiation sources in the range appropriate to the protection of the public and workers, the studies are generally not sensitive enough to conclusively establish a dose–effect relationship. Therefore, for protection purposes, the dose–response relationship for stochastic effects is assumed to be linear, without threshold. As a consequence of this precautionary, simplifying assumption, and for protection purposes only, each increment of dose is assumed to carry a corresponding increment of risk. For protection purposes, risk coefficients have been derived by the ICRP to estimate the risk to an individual exposed to a given dose of radiation. It is also possible to assess the collective impact of doses over a population exposed to varying levels of individual doses arising over defined time periods. This is termed ‘collective dose’ and is the product of the number of individuals exposed to a source and their time averaged radiation dose.

29. The concept of collective dose can be useful in risk management, but the uncertainties inherent in such calculations mean that the concept should be used with great

care. In particular, for very low doses to large populations occurring over long periods of time, calculated collective doses can lead to predictions of potential harm that are unlikely to be realized. Great care should be taken to make the uncertainties inherent in such calculations very clear. Furthermore, the presentation of collective dose distributed over very wide ranges of individual doses and time should best be separated into blocks, each comprising limited ranges of dose and time. This should make it easier for the decision maker to take account of the levels of individual dose and the distribution of collective dose with time. It should also be noted that the concept of collective dose is not generally applied in calculating the potential long term effects arising from other industrial hazards with the potential for causing long term health effects (e.g. chemical discharges).

30. Human activities that involve ionizing radiation can be divided into two types. First, those where the source of radiation is used because of the specific properties of the radiation or of the radionuclide chosen, for instance in medical and some industrial uses. Second, those where radiation is inevitably generated in a given process and has to be controlled, for example in nuclear power plants. To a greater or lesser extent, most of these activities generate radioactive waste, just as other technologies generate their particular forms of waste.

31. Protection against radiation must address a range of types of exposure and exposure situations. It will thus be necessary, for example, to distinguish between situations of exposure due to normal operation, and those caused by possible accidents, i.e. potential exposure. There will also be a need to consider exposure of workers separately from that of the public, and to address the issue of exposure in the short term compared with exposure that may occur in the future.

32. Human activities that increase the overall exposure to radiation, for example by introducing new sources of exposure or new pathways, by exposing more individuals or by modifying the exposure pathways from existing sources to humans and that result in an increase in exposure, are, for historical reasons, referred to as '*practices*'². Other human activities that decrease the overall exposure by removing existing sources, by modifying exposure pathways or by reducing the number of people exposed are referred to as '*interventions*'².

² When used in this sense, these words appear in italics in this report.

33. A *practice* is distinguished from an *intervention* in that the former leads to a benefit, often economic, at the cost of an increase in radiation exposure (use of medical or industrial sources, nuclear power generation, etc.), while the latter leads to a benefit from reducing a radiation exposure at an economic cost (cleanup of a contaminated site, for instance).

34. *Practices* are also distinguished from *interventions* in that, for a practice, society can decide whether or not to undertake the activity. For an *intervention*, society is faced with an existing situation involving exposure to radiation. It can only decide whether or not to intervene, i.e. by undertaking a remedial activity or not carrying out such an activity.

3. THE CONTROL OF RADIATION RISK

3.1. GENERAL CONSIDERATIONS FOR SAFETY AND PROTECTION

35. The general objective of controlling radiation risk is to protect individuals, society as a whole and the environment against the harmful effects of ionizing radiation. A unifying principle underpinning the management of sources of radiation is that a fundamentally conservative approach should be taken. This does not mean that resources should be employed to continuously drive down the levels of risks when they are judged to be already extremely low, but it does mean that where doubt exists, it is appropriate to err on the side of safety.

36. In applying this unifying principle, radiation exposures are controlled in normal circumstances. Abnormal circumstances are prevented and mitigated so that the radiological consequences of accident situations remain generally minor, with an extremely small likelihood of severe accidents with serious radiological consequences. The general principles of radiation protection and safety discussed below are implemented to control radiation exposures in normal and abnormal circumstances.

37. Protection for *practices* is based on three general principles equivalent to those discussed in Section 2.1:

- No *practice* involving exposure to radiation should be adopted unless it produces at least sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes;

- In relation to any particular source of radiation within a *practice*, all reasonable steps should be taken to adjust the protection so as to maximize the net benefit, economic and social factors being taken into account;
- A limit should be applied to the dose received by an individual as a result of all the *practices* (other than from medical exposures) to which this individual is exposed.

38. Dose limits do not apply to medical exposure because such exposure, if given on the basis of proper indications, is intended to lead to a very substantial net benefit to the patient and has been accepted voluntarily for this reason.

39. Implementation of an *intervention* is based on two general principles:

- The proposed *intervention* should do more good than harm, i.e. the benefits resulting from the reduction in dose should be sufficient to justify the harm and the costs, including social costs, of the *intervention*;
- The form, scale and duration of the *intervention* should be chosen so that the net benefit of the reduction in dose less the costs of the intervention is maximized.

40. In this context, it should be noted that the disposal of waste should not be regarded as a free standing *practice*. For new *practices*, disposal of the waste should be included as part of the justification of the *practice* that will give rise to the waste. For waste resulting from past *practices*, and from some ongoing *practices*, for which disposal was not originally considered to be part of the *practice*, the situation is different. Disposal could be viewed as an *intervention* subject to regulatory approval. Such an *intervention* would normally take place if improvements thus attained in terms of radiation protection were greater than the harm and the costs incurred, including the social costs.

41. To satisfy the objectives set out in para. 36 and the general principles of radiation protection, safety measures are applied to the design, implementation and operation of *practices*, and to the implementation of *interventions*. Thus, design, operation and management measures must meet defined standards and provide sufficient safety margins for normal circumstances and for unusual, but anticipated, abnormal events. Those measures are maintained, reviewed and where necessary improved over the life of the installation. While steps are taken to prevent accidents with a high degree of confidence, it is recognized that, nonetheless, accidents may occur — even those of low probability. Hence provisions are made to mitigate the consequences of accidents — in particular to minimize the radiological consequences — and to ensure that the likelihood of accidents with severe radiological

consequences is extremely small. To accomplish this, specific safety criteria have been developed and are described in the following.

42. Radiation protection and safety principles, if they are to be satisfied, require the full commitment of the management and the entire staff concerned with the design, operation and support of the specific source of radiation.

3.2. SAFETY FRAMEWORK

43. The prime responsibility for safety and protection rests with the owner/operator. The responsibilities of operators include ensuring that contractors or others who carry out tasks on their behalf conform to acceptably high quality and safety standards. Designers, manufacturers and constructors have a responsibility to provide a sound design and sound equipment.

44. The operator must also implement a safety management system that is appropriate for the potential risk arising from the source. As a minimum it must define the organization, the main responsibilities and the principal requirements to ensure safety. For complex sources of radiation (e.g. nuclear power plants), highly sophisticated and extensive management systems are implemented (see Section 4.4).

45. Governments are responsible for establishing a legal framework that provides for the clear assignment of responsibilities for safety and protection and for the regulation of practices and interventions, and that meets commitments set out in international agreements such as the Convention on Nuclear Safety. This responsibility includes establishing regulatory organizations which, through application of the legal and regulatory framework, provide independent and competent control of the activities of organizations that conduct or promote activities involving radiation.

46. As safety and protection matters can have long term implications, governments are also responsible for ensuring continuity of responsibilities and funding. This applies particularly to the fields of decommissioning and radioactive waste management, but is relevant to the control of any *practice*.

47. Regulatory activities include developing regulations and requirements, issuing licences to authorize particular activities, after appropriate assessment, and ensuring surveillance of safety performance. Regulatory bodies have the legal power to require corrective actions from operators and to take any necessary enforcement actions including, in the extreme, withdrawal of a licence. Regulatory authorities need to be independent from organizations that conduct or promote activities involving

radiation, to ensure that they are protected from any undue pressure which might compete with the requirement to achieve safety and protection.

3.3. SPECIFIC STRATEGIES

48. Because of the many types of radiation sources, the general principles of safety and radiation protection must be translated into specific strategies. Each application thus requires a particular 'mix' of strategies appropriate to the source under consideration.

49. Fostering a strong safety culture and providing systematic defence in depth are two of the most important strategies that are employed. Other elements include the use of proven engineering practices and quality assurance, the deployment of competent and qualified staff, and the use of research and feedback from experience in the design, construction, operation and maintenance of sources of radiation. For the sake of simplicity, these have been separated and are discussed as specific topics below, but it should be noted that they are strongly interlinked. Thus, the provision of competent staff is an important element for a strong safety culture, and the use of proven engineering practice underpins defence in depth.

3.3.1. Safety culture

50. Safety culture is defined in INSAG-4 [6] as that assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, safety and protection issues receive the attention warranted by their significance.

51. Safety culture has two general components. The first is the management system or safety framework within the organization, as discussed in para. 43. The second is the attitude of staff at all levels in responding to and benefiting from the framework.

52. In any important activity, the manner in which people act is conditioned by requirements set at the highest level. Policies promoted at that level create the working environment and condition the behaviour of individuals. The achievement of a strong safety culture starts, therefore, with the approach and attitudes of the senior management in all organizations. Managers ensure not only that their staff understand the significance of their duties and that they are continuously motivated towards high levels of personal performance, but they are themselves fully aware of their own responsibility towards safety.

53. Each member of the organization has a responsibility for safety and it is important that staff and contractors at all levels respond to and benefit from the framework set by management. They should strive for excellence in matters affecting safety, displaying a questioning attitude and a prudent approach to their work. They should be willing and encouraged to communicate concerns about safety to managers and their other colleagues.

3.3.2. Defence in depth

54. To compensate for potential human and mechanical failures, a defence in depth concept is implemented with, as far as is necessary and practicable, several successive levels of protection to contain radioactive material and to prevent exposure.

55. Generally speaking, the defence in depth strategy consists of a hierarchical deployment of different levels of equipment and procedures in order to maintain the adequate effectiveness of several successive barriers placed between radioactive materials and workers, the public and the environment. Defence in depth is implemented through design and operation to compensate for human and mechanical failures. It provides protection against a wide variety of situations, from normal operation to accidents, to the extent warranted by their significance. It further includes measures to adequately protect workers, the public and the environment in cases where the barriers are not fully effective.

56. The first priority of defence in depth is to put in place provisions to prevent deviations from safe operating conditions. The next requirement is to have in place systems which return the source to a safe state should such deviations occur. Measures aimed at mitigating the consequences of an accident are also part of the strategy. Where necessary, emergency plans are prepared and maintained before and during the period during which the source of radiation is allowed to operate. Such plans are tested periodically.

57. The number of 'layers' in the defence in depth approach and the reliability required from them depends upon the type of source to which the strategy is to be applied. It needs to take account of several factors:

- The amount and type of radioactive material present in the radiation source,
- The potential for dispersion of the radioactive material due to its physical and chemical nature,
- The possibility of nuclear, chemical or thermal reactions that could occur under abnormal conditions,
- The possible loss of cooling capability for fuel in nuclear installations.

3.3.3. Other requirements

58. In addition, and in some cases as part of a good safety culture and adequate defence in depth, it is important to pay attention to other complementary requirements. They include the following.

Proven engineering practices

59. The design and construction of any facility involving radiation or any source of radiation is based upon engineering practices that have been sufficiently proven by testing and experience and that are supported, as far as necessary, by codes, standards or other appropriate documents. New technologies are only incorporated in a design if they have been proven or qualified by sufficient testing. The design of equipment takes into account the capabilities and limitations of human performance at the human-machine interface in establishing operational requirements.

Quality assurance

60. Quality assurance practices include planned and systematic actions to provide adequate confidence that requirements are correctly specified and that they are fully satisfied. They are applied to all activities, processes, services and equipment important to safety and protection.

61. In particular, the potential impact on safety of any change, be it a physical modification or an organizational change, needs to be properly assessed before the change is made. For large, complex sources such as nuclear installations, systems should be in place to ensure that safety implications of proposed changes are formally and independently reviewed before any modification is approved. Assessing and controlling change is an important component of safety management.

62. Successful implementation of quality assurance programmes requires the commitment of all those who manage and perform tasks as well as of those who are responsible for verification and monitoring effectiveness. In particular, managers have a responsibility to ensure that quality assurance practices are integrated with daily work activities.

Competent and qualified staff

63. Staff engaged in activities involving sources of radiation should be adequately trained and qualified to perform their duties. Organizations engaged in activities important to safety and protection need to ensure that there are sufficient numbers of

adequately trained and authorized staff who work in accordance with validated and approved procedures.

64. One of the most important lessons learned in the field of radiation protection and safety is that most near misses and incidents result from incorrect human action. To reduce human error, improvements have been made to both sides of the human-machine interface. On the 'machine' side, design has become more tolerant of human error, equipment is now more automated and easier to operate, and computer systems provide greater reliability. On the human side, staff are periodically exposed to retraining aimed at updating their technical and other skills, and work instructions and procedures are regularly reviewed for accuracy and clarity.

Research and feedback from experience

65. Research can provide a better understanding of safety and protection margins and can improve the control of radiation risks in both design and operation. Research ensures that knowledge and competence are maintained within organizations that operate, support or regulate activities associated with sources of radiation.

66. The systematic review of research results, design and operational experience and the communication of lessons learned from such reviews are essential features of a 'learning organization'. Such organizations place a high value on evaluating their performance through exchange, review and analysis of experience and thus ensure that lessons are learned and improvement actions pursued.

3.4. CRITERIA FOR STRATEGY SELECTION

67. This report has so far described the principles applied to control any human activity involving radiation risks. Four broadly defined criteria guide the application of the strategies to control the risks arising from a particular activity. These criteria are:

- the size and activity of the source of radiation,
- the complexity involved in the application,
- the capacity for effective control,
- the overall potential for harm.

68. A description of the size and activity of a source includes characteristics such as the inventory of radioactive material, the type of radionuclides and their decay

properties, and the chemical and physical state of the material and its specific activity. This is important because it defines the limit of the maximum amount of radioactive material that could be released and relates to the need for defence in depth. For small portable sources that may, nonetheless, be highly active, the degree to which defence in depth can be applied is limited. For these, safety culture and the presence of competent and qualified staff are therefore of prime importance.

69. Complexity involves both technical and managerial factors. Depending upon the type of source, technical factors include the potential for uncontrolled nuclear reactions, the stored energy, the need for maintaining active cooling and the possibility of chemical reactions occurring. Managerial factors include the number and variety of systems to be controlled, the range of expertise required to achieve this and the number of individuals needed to manage and operate the application. The more complex the system, the more comprehensive the management system needs to be to identify and control risks. On the other hand, low complexity is a positive safety factor. It allows for some freedom of choice in the combination of strategies to be used. Where complexity is high, however, all strategies need to be carefully applied to ensure the safety of a source.

70. The capacity for effective control is determined by a variety of factors such as the existence of an adequate infrastructure, effective regulatory oversight and continued institutional control. It is also important to retain knowledge about the location of sources, since large numbers of distributed sources operated by small organizations with little or no safety infrastructure can lead to practical difficulties, both in regulating and in managing the safety of these sources. Industrial and medical sources have been lost or stolen on a number of occasions due, in part, to inadequate institutional control.

71. Concern has also been expressed about the ability to maintain institutional control over long lived radioactive waste over the long time-scales during which the waste remains hazardous. To minimize requirements for such control, a defence in depth approach based on the use of multi-barriers that aims at achieving passive long lasting safety becomes that much more important.

72. The potential for harm involves the number of individuals who might be affected by an incident, and also, in the case of a release of radioactive material, the propensity and the pathways for release, the magnitude of any consequent individual doses, the nature of the exposure (internal or external), the spread and form of potential contamination and the resultant economic and social consequences. This is important because it ultimately determines the risk that could be imposed on individuals and on members of the public.

4. THE MANAGEMENT OF SPECIFIC SOURCES OF RADIATION

73. Section 4 discusses some of the major sources of radiation and the application of specific strategies to the safe management of these sources based on the criteria discussed above. Sources have been categorized as industrial, medical, radioactive waste and nuclear installations. This order broadly reflects the increasing variety and number of factors that have to be taken into account to ensure safety.

4.1. SOURCES OF RADIATION IN INDUSTRY

74. A large number of small sources such as smoke detectors or exit signs are in use. They will not be discussed further here because the very small inventory of radioactive material they contain means that the risk they pose is negligible. For this reason, they are usually exempt from regulatory controls.

75. Other industrial radiation sources range from instruments to measure density, thickness or level, to detectors for chemicals and explosives or for gas leak measurements, to sources used in well logging and in mobile radiography units (for quality control of welds, for instance), to fixed installations such as X ray radiography units and installations for the irradiation of food or equipment. Other equipment such as accelerators and research and analytical equipment are also included in this category.

76. Portable industrial sources are commonly small and their activity, although variable, is low in comparison with some other sources considered in this paper. They display a limited complexity but, because of their nature, effective control over them is difficult to achieve. Unless they are properly registered, such sources are difficult to track. At the end of their useful life it is therefore particularly important to ensure their safe management and, ultimately, their disposal. Their potential for harm is very real but limited in that incidents will commonly affect one or two people only, though the effects on these individuals may be severe.

77. The design and manufacture of such sources has reached an advanced level and quality assurance and proven engineering practice are adequate in almost all cases. An analysis of feedback from experience gained in using this equipment and of the relative importance of the criteria mentioned above shows clearly that the strategy most needed for the safe management of such sources is a well developed safety culture. In this case, the safety culture will manifest itself through the presence of competent, qualified and motivated staff and a management system to keep track of the sources. Defence in depth is a difficult strategy to apply because the nature of the

equipment leaves little room for the presence of successive barriers, although it is important that those which are in place are effective and properly used.

78. Larger industrial sources include installations for food or equipment irradiation, X ray radiography units as well as accelerators and research or analytical equipment. In contrast to smaller portable sources, they can have considerably higher activity and their complexity is greater. This generally means that the capacity for effective control is good. Their overall potential for harm can be generally restricted to a few individuals in any particular accident, but in these circumstances accidents have often been fatal.

79. Defence in depth plays a more important role through the presence of fail-safe interlocking mechanisms and alarm systems. None of these strategies, however, can substitute for a well established safety culture among the management and staff of the organization.

4.2. SOURCES OF RADIATION IN MEDICINE

80. Three categories of people are concerned and may be affected by the use of radiation sources in medicine: patients, staff and the public. The strategies applied to protect the staff and the public are basically the same as those that apply to handling industrial sources, and involve rigorous application of radiation protection and safety principles. Patients fall into two categories: those exposed to radiation for diagnostic purposes (X rays, radioactive tracers, etc.) and those exposed for therapeutic purposes (treatment of tumours and other diseases).

81. The sources of radiation used for diagnostic purposes include a variety of radioactive isotopes as well as different kinds of X ray equipment for various parts of the body (teeth, chest, etc.). The size of such diagnostic sources is small and their activity is generally low. Applications are rarely complex and the capacity for effective control is good, both in nuclear medicine and in radiography installations. As a consequence, the potential for harm is nowadays relatively minor.

82. In spite of the positive aspects noted in the evaluation criteria, accidents have occurred because of inadequate safety culture and poorly trained or unqualified staff. As in the case of large industrial sources, human error rather than material and equipment shortcomings has been the main cause of accidents.

83. Therapeutic medical applications of radiation aim to destroy some cells while affecting others to the minimum extent possible. The deterministic effects that

radiation protection is normally meant to avoid are thus used here in a very deliberate way. Some healthy tissue close to the target may, in the process, be subjected to doses that would otherwise be unacceptable because they do not satisfy the basic objectives of radiological protection. This exposure is justified, however, because the benefit to the patient is greater than the harm suffered locally.

84. The size of such sources is small, but the intensity of radiation is high. Sources are not complex and the capacity to control them effectively is good. The potential for harm is considerable, however. While they are normally limited to one or two individuals, accidents have occurred where, because of a particularly unfortunate sequence of events, several tens of patients have suffered major adverse effects. In one case (in Goiânia, Brazil) for instance, a radiotherapy institute moved to new premises without informing the regulatory authority that a teletherapy unit had been left behind. The source was subsequently stolen and dismantled. This led to large scale contamination of the environment and to the death of four people and contamination of 245. In another case (in Costa Rica), a new cobalt radiation therapy source was installed in a hospital and an error was made in calibration. As a result, eight patients died from overexposure, 20 suffered major adverse effects and 26 were found to be at some risk of suffering adverse radiation related effects in the future.

85. A strong quality assurance system supported by a good safety culture is the most important strategy for the successful application of radiation for therapeutic purposes. These should be applied by all staff members, from senior management to assistants and medical students. This requirement also extends to non-medical staff, technicians and engineers who may interact with the equipment. Defence in depth is commonly built into the equipment, but simple human errors in calculating or measuring doses may cause accidents. Indeed, an exposure of 10% above the correct dose can have unacceptable consequences.

86. The fact that a large number of therapeutic sources of radiation are in safe daily use throughout the world shows that the importance of a strong safety culture, quality assurance and proven engineering practice is well recognized. The remarkable progress achieved in this field since the first radiograph of a human hand and the first case of overexposure more than a century ago has only been made possible by systematic and rigorous improvements in all aspects of safety.

4.3. RADIOACTIVE WASTE

87. This section deals exclusively with waste committed for disposal. (Waste in storage only differs from waste committed for disposal in that the time component

associated with disposal and the specific problems that accompany it need not be considered.)

88. Industrial activities generate wastes of different toxicities. Toxic wastes need to be disposed of in such a way that hazardous substances will not re-enter the biosphere in such quantities as to have a detrimental effect on humans and/or the environment. Measures for long term isolation depend on the toxicity of the material to be disposed. This holds for applications of nuclear technology in medicine, industry, research and development and in the generation of electricity, all of which lead to the production of waste. The diversity of applications results in a variety of such wastes in gaseous, liquid and solid form. These represent a range of potential hazards depending on the concentrations and half-lives of the radionuclides and on the physical and chemical nature of the waste. For new practices, as discussed in para. 16, the requirement for and the means of waste disposal need to be considered when the practice that produces the waste is justified. The generation of waste should be reduced to a reasonably practicable minimum.

89. The activity of such wastes at the time of generation may range from very low levels, as in wastes resulting from the use of radioisotopes in medical diagnostic procedures, to very high levels, such as wastes arising from the reprocessing of spent nuclear fuel or radiation sources used in radiography, radiotherapy and sterilization. Wastes may be very small in volume, e.g. spent radiation sources, or very large and diffuse, e.g. tailings from the mining and milling of uranium.

90. Given the variety of types of waste, each has to be considered on its own merits in establishing strategies for protection. Waste is thus commonly divided into short lived waste, long lived waste of low activity and long lived waste of high activity. Some low activity liquid waste may be disposed of in the environment, but short lived waste and long lived waste of very low activity may be stored in near surface repositories having a design life of a few hundred years. By contrast, long lived waste of intermediate and high activity needs to be isolated from the environment for thousands of years. The fact that the half-lives of the radionuclides comprising such waste ranges over several orders of magnitude is an important factor in the design of repositories for long lived, high activity waste. The capacity for control is good in the short term but is hard to evaluate in the long term.

91. For waste disposal the objective is to achieve an ultimately passive solution with, as far as possible, no long term requirement for intervention by humans or for continuing institutional control. Disposal thus seeks to isolate the waste from the environment for sufficiently long periods of time so that the risks to humans from such disposal, including any risk from inadvertent human intrusion, would be very small.

92. For geological disposal, the principal concern is that groundwater could become contaminated and make its way to the surface where it would pose a risk to human health and the environment. Several countries have carried out quantitative estimates of the risk potentially associated with such a facility. These show that for a well designed disposal facility with good defence in depth, the risk is small. No facility for deep geological disposal of high level waste is yet in operation, however.

93. The most important strategy for solid waste disposal is a defence in depth based on a multi-barrier approach. This implies that sound engineering practice and quality assurance accompany the defence in depth strategy. An effective safety culture applied by a competent and qualified staff will contribute to the development of a successful disposal policy. By contrast, feedback from experience can only play a minor role because experience with disposal sites so far only extends over a few decades.

94. Examples exist of the improper disposal of radioactive waste leading to contamination of the environment and irradiation of workers or of the public. In most cases, these situations arose during earlier mining and milling operations of radioactive ores (e.g. Port Radium, Canada, and Wismuth, Germany) and some of them go back several hundred years (e.g. Joachimstal, now in the Czech Republic). Groundwater contamination due to improper disposal of radioactive waste has occasionally been reported and cases are known of radioactive laboratory waste which was inappropriately discharged rather than being disposed of in special facilities.

4.4. NUCLEAR INSTALLATIONS

95. In addition to nuclear power plants, this section deals with research reactors, fuel enrichment, manufacturing and reprocessing facilities and certain facilities for radioactive waste treatment and storage. The discussion which follows applies primarily to nuclear power and reprocessing plants, but the same general approach is applicable to the other installations.

96. For these nuclear installations, the quantity of radioactive materials involved is high and the activity is considerable. They are complex systems with a potential for chemical and for uncontrolled nuclear reactions. Because of the energy stored in the radioactive material, there is also a need for continuous cooling, even after shutdown of nuclear power plants. The overall potential for harm is very large, as shown for instance by the Chernobyl accident in the former USSR in 1986, but the capacity for effective control is also considerable.

97. Given the nature of nuclear installations, all available strategies need to be fully applied to their operations. In fact, the concept of safety culture and the defence in depth approach were initially developed in the context of ensuring the safety of nuclear power plants. The application of the various strategies has been discussed in detail in previous INSAG documents [6–8]. As one example of the stringent approach to ensuring safety in nuclear power plants, the methodology of probabilistic safety assessment (PSA) was developed to help identify, quantify and manage risks in such installations. Its main values are the identification of accident vulnerabilities which might be overlooked in a very complex system and its ability to identify those elements most important to safety and to focus attention upon them.

98. It has been pointed out (para. 44) that any source of radiation needs to be managed within a ‘management system’ appropriate for the potential risk arising from the source. It follows that the most comprehensive management system will be applied to the design, construction and installation, operation, maintenance and decommissioning of nuclear power plants. The management system defines the organization, the main responsibilities and the principal requirements to ensure safety and reliability. It includes planning, control and support to ascertain that the required activities are implemented appropriately. It also ascertains that the involved individuals carry out their assigned tasks successfully and safely and it includes audit, review and feedback functions to improve performance and to learn from experience. The management system is the responsibility of the owners, operators, designers and contractors and it is documented with particular emphasis on the potential radiation risks, their control and their minimization. Details of the more important aspects of the system are submitted to the regulator for approval.

99. The accidents at Three Mile Island in the USA in 1979 and at Chernobyl in 1986 arose from a failure to understand and implement important aspects of the strategies described above.

100. The accident at Three Mile Island was attributable to many factors. These included a weak safety culture, manifested by the lack of a questioning attitude among staff whose training and competence were not at the levels required. INSAG-10 [8] summarized the lessons to be learned as follows:

“The accident illustrated the importance of human factors, of the human–machine interface and long term effective containment. Moreover, it demonstrated the importance of effective analysis and feedback of operating experience to identify and eliminate possible weaknesses in defence in depth, including weaknesses in design, operating procedures and training”.

The Three Mile Island accident demonstrated the importance of learning the lessons from PSAs and the effectiveness of defence in depth, particularly of the containment, in limiting the release of radioactive material to the environment.

101. The major causes of the Chernobyl accident were the design of a reactor which was intolerant of operator error and a general lack of safety culture, compounded by inadequate regulatory control. A number of specific weaknesses contributed to the accident. These included:

- A poor engineering design with inadequate defence in depth,
- Inadequate quality assurance practices and operating procedures not founded satisfactorily in safety analysis,
- Weakness in the competence of staff such that safety provisions were not understood and requirements for operational and testing procedures were not recognized,
- Inadequate feedback from experience at other plants and little exchange of safety information between operators and between operators and designers.

In this case, INSAG-10 pointed out the main lessons as follows:

“The accident at Chernobyl demonstrated the possible consequences of inadequate defence in depth and the importance of organizational issues such as the need for an effective regulatory regime and for a safety culture. It also focused attention on medium and long term contamination due to radioactive releases and the role of off-site emergency planning.”

102. Following each of these accidents, major reviews have been undertaken to understand their root causes and to find ways to avoid such accidents in the future. This has led to reinforcing the fundamental requirements of a strong safety culture. Apart from a small number of accidents, of which Three Mile Island and Chernobyl are the most notable, nuclear power plants have accumulated more than 8700 reactor-years of satisfactory operation. This is due to the consistent and thorough application of the principles and strategies described above.

5. SUMMARY AND CONCLUSIONS

103. The number of sources of radiation in use today is very large and their uses range from simple to highly complex. This INSAG report sets out the overall safety framework within which the control of all radiation risks from such sources is

accommodated. The report draws together the general principles at the highest level and thus provides an umbrella for the Safety Fundamentals as embodied in the publications 'The Safety of Nuclear Installations' [1], 'The Principles of Radioactive Waste Management' [2] and 'Radiation Protection and Safety of Radiation Sources' [3]. The systematic application of the principles and of the appropriate strategies discussed in this report will ensure the safe management of technologies involving radiation and enable society to benefit from them.

104. In the area of radiation risk, it is important that lessons learned from managing the safety of one type of source of radiation be shared with those responsible for managing other types of sources, so that good practices are used as widely as possible. More broadly, experience with the management of all technological risks should be shared widely so that all can benefit from best practices followed in different industrial sectors — commercial aviation, nuclear technologies, shipping, chemical processing and mining. In this way, the safety of individual industries and society in general can be enhanced for the common good.

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