(318) An important task for a regulatory authority is to provide operating organisations with information aimed at the prevention of emergencies. An accident and incident reporting routine with feedback to users is an indispensable part of such a system. In order for such a system to work and achieve its goals, mutual trust is required. Licensing constitutes the formal confirmation of a regulatory authority's trust in a user. However, operating organisations also need to be able to trust the regulatory authority. A primary requirement is that all users are treated in a fair and equal manner. For an incident reporting system to work properly, users must also trust authorities to regard safety improvements as more important than punishments. Realising this, some regulatory authorities use an approach where legal actions are reduced or removed altogether in response to honest reporting of a problem and immediate action to rectify the situation, but any attempt at hiding a problem is an offence in itself and will lead to legal actions.

6.6.4. Management requirements

(319) The first, and in many ways the most important, of the practical steps in implementing the Commission's recommendations is the establishment of a safety-based attitude in everyone concerned with all the operations from design to decommissioning. This can only be achieved by a substantial commitment to training and recognition that safety is a personal responsibility and is of major concern to the top management.

(320) The explicit commitment of an organisation to safety should be made manifest by written policy statements from the highest level of management, by the establishment of formal management structures for dealing with radiological protection, by issuing clear operating instructions, and by clear and demonstrable support for those persons with direct responsibility for radiological protection in the workplace and the environment (*Publication 75,* ICRP 1997). To translate this commitment into effective action, senior management should identify appropriate design and operational criteria, determine organisational arrangements, assign clear responsibilities to put these policies into effect, and establish a culture within which all those in the organisation recognise the importance of restricting both normal and potential exposures to ionising radiation. The aims of the management requirements should be to set out the practical basis for protecting all concerned. The detailed techniques cover such aspects as the choice of radiation source or radioactive material, the use of shielding and distance to reduce radiation fields, the restriction of the time spent in the proximity of sources, and the use of containment, usually in several stages, to limit the spread of radioactive materials into workplaces and the public environment.

(321) There should be plans for dealing with accidents. These plans should be subject to periodic review and result in written management requirements. Planning for the event of emergencies should be an integral part of normal operating procedures. Any changes in responsibility, e.g. from the usual line of command to an emergency controller, should be planned in advance.

(322) The organisational approach should include involvement and participation of all workers. It is sustained by effective communications and the promotion of competence that enables all employees to make a responsible and informed contribution to the health and safety effort. The visible and active leadership of senior managers is necessary to develop and maintain a culture supportive of health and safety management. The aim is not simply to avoid accidents, but to motivate

and empower people to work safely. It is important that management ensures that mechanisms are in place by which workers may provide feedback on radiological protection issues, and workers should be fully involved in developing methods to ensure that doses are as low as reasonably achievable.

(323) Another common responsibility of the operating management is to provide access to occupational services dealing with protection and health. The protection service should provide specialist advice and arrange any necessary monitoring provisions commensurate with the complexity of the operation and its potential hazards. The head of the protection service should have direct access to the senior operating management. The principal role of the occupational health service is the same as it is in any occupation.

6.6.5. Compliance with the intended standard of protection

(324) The measurement or assessment of radiation doses is fundamental to the practice of radiological protection. Neither the equivalent dose in an organ nor the effective dose can be measured directly. Values of these quantities must be inferred with the aid of models, usually involving environmental, metabolic, and dosimetric components. Ideally, these models and the values chosen for their parameters should be realistic, so that the results they give can be described as 'best estimates'. Where practicable, estimates and discussion should be made of the uncertainties inherent in these results.

(325) All the organisations concerned with radiological protection should have a duty to verify their compliance with their own objectives and procedures. The operating management should establish a system for reviewing its organisational structure and its procedures, a function analogous to financial auditing. National authorities should conduct similar internal audits and should have the added duty of, and authority for, assessing both the level of protection achieved by operating managements and the degree of compliance with the regulatory provisions. All these verification procedures should include consideration of potential exposures by a verification of the safety provisions. Verification procedures should include a review of quality assurance programmes and some form of inspection. However, inspection is a form of sampling - it cannot cover all eventualities. It is best seen as a mechanism for persuading those inspected to put, and keep, their own houses in order.

7. MEDICAL EXPOSURE OF PATIENTS

(326) Medical exposures are predominantly to individuals undergoing diagnostic, fluoroscopically guided interventional, or radiation therapy procedures. But other individuals helping to support and comfort patients are also open to exposure. These individuals include parents holding children during diagnostic procedures, and others, normally family or close friends, who may come close to patients following the administration of radiopharmaceuticals or during brachytherapy. Exposure to members of the general public from released patients also occurs, but it is almost always very small. In addition, volunteers in biomedical research often undergo medical procedures that are similar to procedures performed on patients. Medical exposure refers to all these types of exposures and the present Chapter, in particular, covers the following:

- The exposure of individuals for diagnostic, fluoroscopically guided interventional, and therapeutic purposes;
- Exposures (other than occupational) incurred knowingly and willingly by individuals such as family and close friends helping either in hospital or at home in the support and comfort of patients undergoing diagnosis or treatment;
- Exposures incurred by volunteers as part of a program of biomedical research that provides no direct benefit to the volunteers.

(327) The Commission has used the term 'practice' since *Publication 26* (ICRP, 1977) to refer to human activities. However, for the medical profession, the term 'practice' typically refers to the medical care that a practitioner provides to patients. For example, for a radiation oncologist, the term refers to initial consultation with the patient, accurate diagnosis and staging of the cancer, treatment planning, administering treatment and subsequent follow-up. Introduction of a practice in medicine typically derives from the peer-reviewed literature, where physicians learn about new uses of established procedures or new techniques. Elimination of a practice in medicine typically occurs when the practice results in an unexpectedly high morbidity or mortality (i.e., discontinued by the practitioners as a result of experience). Other practices are eliminated as they are replaced by newer and better technology or medical treatments. It is necessary to improve the understanding of the concept 'practice' as defined by the Commission and present radiological protection in medicine in a way that is readily understood by the medical community. To more clearly communicate the concept, the term '*radiological practice in medicine*' is used for medical situations in order to differentiate it from the usual meaning of 'practice' in medicine.

(328) Radiation exposures of patients can occur in diagnostic, fluoroscopically guided interventional, or therapeutic procedures. There are several features of *radiological practice in medicine* that require an approach that differs from the radiological protection in other planned exposure situations. The exposure is intentional and for the direct benefit of the patient. In radiotherapy, the biological effects of high-dose radiation (e.g., cell killing) are used for the benefit of the patient to treat cancer and other diseases. The application of the Commission's recommendations to the medical uses of radiation therefore requires separate guidance, and medical exposure of patients is therefore dealt with in the present Chapter.

(329) The objective is the management of doses to patients to be commensurate with the medical purposes. In diagnostic and fluoroscopically guided interventional procedures, this means avoiding unnecessary exposures and unproductive doses, while in radiotherapy it requires delivery of the required dose to the volume to be treated, avoiding unnecessary exposure of healthy tissues.

(330) The Commission's recommendations for radiological protection and safety in medicine are given in *Publication 73* (ICRP, 1996a), which remains valid. These recommendations note important differences between the implementation of the system of protection in medicine and implementation in the other two categories of exposure (occupational and public). These differences include:

- The principle of justification applies at three levels in medicine as described in Section 7.1.1.
- In applying the principle of optimisation of protection of the patient, the detriments and benefits are received by the same individual, the patient, and the dose to the patient is determined principally by the medical needs. Dose constraints for patients are therefore inappropriate, in contrast to their importance in occupational and public exposure. Nevertheless, some management of patient exposure is needed and the use of diagnostic reference levels is recommended in *Publication 73* (ICRP, 1996a) with further guidance in *Supporting Guidance 2* (ICRP, 2001b).
- The limitation of the dose to the individual patient is not recommended because it may, by reducing the effectiveness of the patient's diagnosis or treatment, do more harm than good. The emphasis is then on the justification of the medical procedures and on the optimisation of protection.

(331) The basic framework for protection established in *Publication 73* (ICRP, 1996a) has been further elaborated upon in a series of publications described below. The recommendations, guidance, and advice in these publications remain valid, forming part of an increasing library of information on medical exposure by the Commission [see also *Radiological protection in medicine* (ICRP, 2007)].

(332) The exposure of patients is deliberate. Except in radiotherapy, it is not the aim to deliver radiation dose as a therapy, but rather to use the radiation to provide diagnostic information or to conduct a fluoroscopically guided interventional procedure. Nevertheless, the dose is given deliberately and cannot be reduced indefinitely without prejudicing the intended outcome. Medical uses of radiation are also voluntary in nature, combined with the expectation of direct individual health benefit to the patient. The decision is made with varying degrees of informed consent that includes not only the expected benefit but also the potential risks (including radiation). The degree of informed consent varies based on the exposure level and the possible emergent medical circumstances.

(333) The physicians and other health professionals involved in the procedures that irradiate patients (e.g., radiographers and technicians) should always be trained in the principles of radiological protection, including the basic principles of physics and biology. The final responsibility for the radiation exposure lies with the physician, who therefore should be aware of the risks and benefits of the procedures involved.

(334) Medical exposures of patients to external radiation are commonly concerned with limited parts of the body only, and it is important that medical staff are fully aware of the doses to normal tissue in the irradiated fields. With low tissue weighting factors for skin and relatively low values for a number of other tissues, very localised partial body exposures can result in appreciable equivalent doses to local tissues even though the corresponding effective dose may be small. Similar considerations apply to doses from intakes of radionuclides if there is markedly preferential uptake of the radioactive material to a particular tissue or organ. Care has to be taken in such situations so that no undesirable tissue reactions occur.

7.1. Justification for medical exposure of patients

(335) Medical exposure of patients calls for a different and more detailed approach to the process of justification. The medical use of radiation should be justified, as is any other planned exposure situation, although that justification lies more often with the profession than with government. The principal aim of medical exposures is to do more good than harm to the patient, subsidiary account being taken of the radiation detriment from the exposure of the radiological staff and of other individuals. The responsibility for the justification of the use of a particular procedure falls on the relevant medical practitioners. Justification of medical procedures therefore remains a principal part of the Commission's Recommendations.

(336) The principle of justification applies at three levels in the use of radiation in medicine:

- At the first level, the use of radiation in medicine is accepted as doing more good than harm to the patient.
- At the second level, a specified procedure with a specified objective is defined and justified (e.g., chest radiographs for patients showing relevant symptoms, or a group of individuals at risk to a condition that can be detected and treated). The aim of the second level of justification is to judge whether the radiological procedure will usually improve the diagnosis or treatment or will provide necessary information about the exposed individuals.
- At the third level, the application of the procedure to an individual patient should be justified (i.e., the particular application should be judged to do more good than harm to the individual patient). Hence all individual medical exposures should be justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.

The second and third levels of justification are discussed below.

7.1.1. The justification of a defined radiological procedure (level 2)

(337) The justification of the radiological procedure is a matter for national and international professional bodies, in conjunction with national health and radiological protection authorities and the corresponding international organisations. The total benefits from a medical procedure include not only the direct health benefits to the patient, but also the benefits to the patient's family and to society. Although the main exposures in medicine are to patients, the exposures to staff and to members of the

public who are not connected with the procedures should be considered. This falls into the category of occupational exposure. The possibility of emergency or unintended exposures should also be considered. The decisions should be reviewed from time to time, as more information becomes available about the risks and effectiveness of the existing procedure and about new procedures.

7.1.2. The justification of a procedure for an individual patient (level 3)

(338) Beyond checking that the required information is not already available, no additional justification is needed for the application of a simple diagnostic procedure to an individual patient with the symptoms or indications for which the procedure has already been justified in general. For complex diagnostic and fluoroscopically guided interventional procedures (e.g., some cardiac and neuroradiological procedures), the second level of justification may not be sufficient. Individual justification by the practitioner and the referring physician (the third level) is then important and should take account of all the available information. This includes the details of the proposed procedure and of alternative procedures, the characteristics of the individual patient, the expected dose to the patient, and the availability of information on previous or expected examinations or treatment. It will often be possible to speed up the procedure by defining referral criteria and patient categories in advance.

7.2. Optimisation of protection for patient doses in medical exposures

(339) The Commission now uses the same conceptual approach in source-related protection, irrespective of the type of source. In the case of exposure from diagnostic and fluoroscopically guided medical procedures, the *diagnostic reference level* has as its objective the optimisation of protection, but it is not implemented by constraints on individual patient doses. It is a mechanism to manage patient dose to be commensurate with the medical purpose (see Section 7.2.1).

(340) The important message from the Commission is that the goal of optimisation of protection is applicable, regardless of the type of source or the terminology used.

7.2.1. Diagnostic reference levels

(341) Diagnostic reference levels apply to radiation exposure of patients resulting from procedures performed for medical diagnostic purposes. They do not apply to radiation therapy, and also do not apply to occupational or public exposure. Diagnostic reference levels have no direct linkage to the numerical values of the Commission's dose limits or dose constraints. Ideally, they should be the result of a generic optimisation of protection. In practice, this is unrealistically difficult and it is simpler to choose the initial values as a percentile point on the observed distribution of doses to patients or to a reference patient. The values should be selected by professional medical bodies (in conjunction with national health and radiological protection authorities) and reviewed at intervals that represent a compromise between the necessary stability and the long-term changes in the observed dose distributions. The selected values will be specific to a country or region.

(342) Diagnostic reference levels are used in medical diagnosis to indicate whether, in routine conditions, the levels of patient dose or administered activity from a specified imaging procedure are unusually high or low for that procedure. If so, a local review should be initiated to determine whether protection has been adequately optimised or whether corrective action is required (ICRP, 1996a). The diagnostic reference level should be expressed as a readily measurable patient dose - related quantity for the specified procedure. Additional guidance is given in *Radiological Protection in Medicine* (ICRP, 2007) and in *Supporting Guidance 2* (ICRP, 2001b).

(343) In principle, it might be possible to choose a lower diagnostic reference level below which the doses would be too low to provide a sufficiently good image quality. However, such diagnostic reference levels are difficult to set, because factors other than dose also influence image quality. Nevertheless, if the observed doses or administered activities are consistently far below the diagnostic reference level, there should be a local review of the quality of the images obtained.

(344) Extensive information on the management of patient dose in fluoroscopically guided interventional procedures, computed tomography and digital radiology is provided in *Publications 85*, *87*, and *93*, respectively (ICRP 2000e; 2000f; 2003d).

7.2.2. Radiotherapy

(345) In radiotherapy, optimisation involves not only delivering the prescribed dose to the tumour, but also planning the protection of tissues outside the target volume. For radiotherapy considerations, including planning the protection of tissues outside the target volume, *Publication 44* (ICRP, 1985) should be consulted.

7.3. Effective dose in medical exposure

(346) The age distributions for workers and the general population (for which the effective dose is derived) can be quite different from that of the overall age distribution for the population undergoing medical procedures using ionising radiation, and will also differ from one type of medical procedure to another, depending on the age- and sex-prevalence of the individuals for the medical condition being evaluated. For these reasons, risk assessment for medical uses of ionising radiation is best evaluated using appropriate risk values for the individual tissues at risk and for the age and sex distribution of the individuals undergoing the medical procedures. Effective dose can be of value for comparing the relative doses from different diagnostic procedures and for comparing the use of similar technologies and procedures in different hospitals and countries as well as the use of different technologies for the same medical examination, provided the reference patient or patient populations are similar with regard to age and sex.

(347) The assessment and interpretation of effective dose from medical exposure of patients is very problematic when organs and tissues receive only partial exposure or a very heterogeneous exposure, which is the case especially with diagnostic and fluoroscopically guided interventional procedures.

7.4. Exposure of patients who are or may be pregnant

(348) Before any procedure using ionising radiation, it is important to determine whether a female patient is, or could be, pregnant. The feasibility and carrying through of medical exposures during pregnancy require specific consideration due to the radiation sensitivity of the developing embryo/fetus. The manner in which an examination is performed depends on the radiation dose to the embryo/fetus.

(349) Prenatal doses from most correctly performed diagnostic procedures present no measurably increased risk of prenatal or postnatal death, developmental damage including malformation, or impairment of mental development over the background incidence of these entities. Life-time cancer risk following in-utero exposure is assumed to be similar to that following irradiation in early childhood. Higher doses such as those involved in therapeutic procedures have the potential to result in developmental harm.

(350) The pregnant patient has a right to know the magnitude and type of potential radiation effects that might result from in-utero exposure. Almost always, if a diagnostic radiology examination is medically indicated, the risk to the mother of not doing the procedure is greater than the risk of potential harm to the embryo/fetus. However, some procedures and some radiopharmaceuticals that are used in nuclear medicine (e.g., radioiodides) can pose increased risks to the fetus. The Commission has given detailed guidance in *Publication 84* (1CRP, 2000c).

(351) It is essential to ascertain whether a female patient is pregnant prior to radiotherapy. In pregnant patients, cancers that are remote from the pelvis usually can be treated with radiotherapy. This however requires particular attention in treatment planning. The expected radiation dose to the fetus, including the scattering component, must be estimated. Cancers in the pelvis can rarely be adequately treated during pregnancy without severe or lethal consequences for the fetus.

(352) Termination of pregnancy is an individual decision affected by many factors. Absorbed doses below 100 mGy to the developing organism should not be considered a reason for terminating a pregnancy. At embryonic/fetal doses above this level, informed decisions should be made based upon individual circumstances, including the magnitude of the estimated embryonic/fetal dose and the consequent risks of serious harm to the developing organism and risks of cancer in later life.

(353) Radiation risks after prenatal radiation exposure are discussed in detail in *Publication 90* (ICRP, 2003). The exposure of patients who are or may be pregnant is dealt with in detail in *Publication 84* (ICRP, 2000c) and in the ICRP Committee 3 Report *Radiological Protection in Medicine* (ICRP, 2007), which also discuss the considerations to be taken into account regarding termination of pregnancy after radiation exposure. Radiation exposure of pregnant females in biomedical research is discussed in Section 7.7.

7.5. Medical exposure: Accident prevention in external beam therapy and brachytherapy

(354) Accident prevention in external beam therapy and brachytherapy should be an integral part of the design of equipment and premises and of the working procedures. A key focus of accident prevention has long been the use of multiple

safeguards against the consequences of failures. This approach, now often called 'defence in depth', is aimed at preventing a single failure from having serious consequences. Some defences are provided by the design of equipment, others by the working procedures. The Commission has given extensive advice on reducing the probability of potential exposure and preventing accidents in *Publications 76, 86, 97* and *98* (ICRP, 1997, 2000d, 2005b, 2005c).

7.6. Medical exposure: Release of patients after therapy and the protection of their carers and comforters

(355) Unsealed radionuclides are used in the diagnosis and treatment of various diseases in the form of radiopharmaceuticals that are given to the patient by injection, ingestion or inhalation. These may localise in body tissues until they decay or they may be eliminated through various pathways (e.g., urine).

(356) Precautions for the public are rarely required after diagnostic nuclear medicine procedures but some therapeutic nuclear medicine procedures, particularly those involving iodine-131, can result in significant exposure to other people, especially those involved in the care and support of patients. Hence, members of the public caring for such patients in hospital or at home require individual consideration.

(357) *Publication 94* (ICRP 2004a) provides recommendations for the release of patients after therapy with unsealed radionuclides. These recommendations include that young children and infants, as well as visitors not engaged in direct care or comforting, should be treated as members of the public for radiological protection purposes (i.e., be subject to the public dose limits of 1 mSv/year). For individuals directly involved in comforting and caring, other than young children and infants, a dose constraint of 5 mSv per episode (i.e., for the duration of a given release after therapy) is likely to be reasonable. This constraint is not to be used rigidly. For example, higher doses may well be appropriate for parents of very sick children.

(358) The Commission's recommendations regarding dose limits and dose constraints related to the release of patients following unsealed radionuclide therapy have been interpreted in different ways in various countries. Although these recommendations advise that a dose constraint of 5 mSv per episode would be reasonable for carers and comforters, who should not be subject to the public dose limit, this dose constraint has often been inappropriately interpreted as a rigid annual dose limit.

(359) The risk of cancer induction for adult carers and comforters from exposure to patients treated with radioiodine is low. However, the thyroid gland of persons under the age of 15 is more radiosensitive, so that particular care should be taken to avoid the contamination of infants, children, and pregnant women (i.e., the embryo or fetus).

(360) The recommendations do not explicitly state that urine should be stored or that patients should be hospitalised after therapy with high activities of radiopharmaceuticals. The decision to hospitalise or release a patient after therapy should be made on an individual basis considering several factors including residual activity in the patient, patient's wishes, family consideration (particularly the presence of children), environmental factors, and national or local regulations.

(361) The unintentional exposure of members of the public in waiting rooms and on public transport is not high enough to require special restrictions on nuclear medicine patients, except for those being treated with radioiodine (*Publications 73* and *94*; ICRP, 1996a; 2004a).

(362) In principle, similar reasoning applies when patients are treated with permanently implanted sealed sources. However, the available data show that, in the vast majority of cases, the dose to comforters and carers remains well below the recommended limit of 1 mSv/year. Only the (rare) case where the patient's partner is pregnant at the time of implantation may need specific precautions (*Publication 98,* ICRP, 2005).

(363) When performed in the first few months after implantation of a sealed source, cremation of bodies (frequent in some countries) raises several issues related to: (1) the activity that remains in the patient's ashes; and (2) the airborne dose, potentially inhaled by crematorium staff or members of the public. Available data shows that cremation can be allowed if 12 months have elapsed since implantation with ^{125}I (3 months for ^{103}Pd). If the patient dies before this delay has elapsed, specific measures must be undertaken (ICRP, 2005).

7.7. Volunteers for biomedical research

(364) The participation of volunteers in biomedical research makes a substantial contribution to medicine and to human radiobiology. Some of the research studies are of direct value in the investigation of disease; others provide information on the metabolism of pharmaceuticals and of radionuclides that may be absorbed from contamination of the workplace or the environment. Not all these studies take place in medical institutions, but the Commission treats the exposure of all volunteers in biomedical research as if it were medical exposure.

(365) The ethical and procedural aspects of the use of volunteers in biomedical research have been addressed by the Commission in *Publication 62* (ICRP, 1991c). The key aspects include the need to guarantee a free and informed choice by the volunteers, the adoption of dose constraints linked to the societal worth of the studies, and the use of an ethics committee that can influence the design and conduct of the studies. It is important that the ethics committee should have easy access to radiological protection advice.

(366) In many countries, radiation exposure of pregnant females as subjects in biomedical research is not specifically prohibited. However, their involvement in such research is very rare and should be discouraged unless pregnancy is an integral part of the research. In these cases, strict controls should be placed on the use of radiation for the protection of the embryo/fetus.

8. PROTECTION OF THE ENVIRONMENT

(367) Interest in the protection of the environment has greatly increased in recent years, in relation to all aspects of human activity. Such interest has been accompanied by the development and application of various means of assessing and managing the many forms of human impact upon it. The Commission is thus aware of the growing need for policy advice and guidance on such matters in relation to radiological protection, even though such needs have not arisen from any new or specific concerns about the effects of radiation on the environment. The Commission also recognises that there is a current lack of consistency at international level with respect to addressing such issues in relation to radioactivity, and therefore believes that a more proactive approach is now necessary.

8.1. The objectives of radiological protection of the environment

(368) The Commission acknowledges that, in contrast to human radiological protection, the objectives of environmental protection are both complex and difficult to articulate. The Commission does however subscribe to the global needs and efforts required to maintain biological diversity, to ensure the conservation of species, and to protect the health and status of natural habitats and communities. It also recognises that these objectives may be met in different ways, that ionising radiation may be only a minor consideration - depending on the environmental exposure situation - and that a sense of proportion is necessary in trying to achieve them.

(369) The Commission has previously concerned itself with mankind's environment only with regard to the transfer of radionuclides through it, primarily in relation to planned exposure situations, because this directly affects the radiological protection of human beings. In such situations, it has been considered that the standards of environmental control needed to protect the general public would ensure that other species are not put at risk, and the Commission continues to believe that this is likely to be the case.

(370) However, the Commission considers that it is now necessary to provide advice with regard to all exposure situations, including those that may arise as a result of accidents and emergencies, and those that exist but were not planned. It also believes that it is necessary to consider a wider range of environmental situations, irrespective of any human connection with them. The Commission is also aware of the needs of some national authorities to demonstrate, directly and explicitly, that the environment is being protected, even under planned situations.

(371) The Commission therefore believes that the development of a clearer framework is required in order to assess the relationships between exposure and dose, and between dose and effect, and the consequences of such effects, for non-human species, on a common scientific basis. This issue was first discussed in *Publication 91* (ICRP, 2003b), and it was concluded that it was necessary to draw upon the lessons learned from the development of the systematic framework for the protection of human beings. This framework is based on an enormous range of knowledge that the Commission attempts to convert into pragmatic advice that will

be of value in managing different exposure situations, bearing in mind the wide range of errors, uncertainties, and knowledge gaps of the various data bases.

(372) The advantage of such a comprehensive and systematic approach is that, as the needs for change to any component of the system arise (as in the acquisition of new scientific data, or changes in societal attitudes, or simply from experience gained in its practical application) it is then possible to consider what the consequences of such a change may have elsewhere within the system, and upon the system as a whole. Such an approach would not work unless it was based on a numerical framework that contained some key points of reference.

8.2. Reference Animals and Plants

(373) In the case of human radiological protection, the Commission's approach to such issues has been greatly assisted by the creation of an entity called Reference Man (now called Reference Person). It has therefore concluded that a similar approach would be of value as a basis for developing further recommendations for the protection of other species. The Commission is therefore developing a small set of Reference Animals and Plants (Pentreath, 2005), plus their relevant data bases, for a few types of organisms that are typical of the major environments. Such entities will form the basis of a more structured approach to understanding the relationships between exposures and dose, dose and effects, and the potential consequences of such effects.

(374) The Reference Animals and Plants can be considered as hypothetical entities with certain assumed basic biological characteristics of a particular type of animal or plant, as described to the generality of the taxonomic level of Family, with defined anatomical, physiological, and life-history properties. They are not, therefore, necessarily the *direct* objects of protection themselves but, by serving as points of reference, they should provide a basis upon which some management decisions could be made. Simple dosimetric models, plus relevant data sets, are currently being developed for different stages of the life cycle of each type. Available data on radiation effects for each type are also being reviewed.

(375) Some form of practical means is obviously required in order to make judgements, based on our current level of knowledge of the effects of radiation on different types of animals and plants, in order to meet the Commission's objectives. With the exception of mammals, however, there is a general paucity of information upon which dose response curves can be established that would enable sensible conclusions to be drawn, particularly with respect to the relatively low dose rates likely to obtain in most exposure situations. Indeed, in general, the data bases on radiation effects for the majority of animals and plants are not dissimilar from those relating to 'chemical toxicity' studies, where the levels required to produce a given effect are many orders of magnitude greater than those expected in the majority of environmental situations.

(376) With radiation there is another source of reference, and that is the natural background radiation to which such animals and plants are continuously and 'typically' exposed. Thus additional radiation doses to animals and plants can be compared with those dose rates known or expected to have certain biological effects

in those types of animals and plants, and with the dose rates normally experienced by them in their natural environments.

(377) The Commission does not therefore propose to set any form of 'dose limits' with respect to environmental protection. By setting out data for some Reference Animals and Plants, in a transparently derived way, and upon which further managerial action may be considered, the Commission intends to offer more practical advice than in the past. The Commission will use this framework to gather and interpret data in order to provide more comprehensive advice in the future, particularly with regard to those aspects or features of different environments that are likely to be of concern under different radiation exposure situations.

GLOSSARY OF KEY TERMS AND CONCEPTS

Absorbed Dose, D: the fundamental dose quantity given by

$$D = \frac{\mathrm{d}\bar{\varepsilon}}{\mathrm{d}m}$$

where $\mathrm{d}\bar{\varepsilon}$ is the mean energy imparted by ionising radiation to the matter in a volume element and dm is the mass of the matter in this volume element. The SI unit for absorbed dose is joule per kilogram ($J\ kg^{-1}$) and its special name is gray (Gy).

Activity, A: The expectation value of the number of nuclear transformations occurring in a given quantity of material per unit time. The special unit of activity is the becquerel (Bq).

Adaptive Response: A post-irradiation cellular response which, typically, serves to increase the resistance of the cell to a subsequent radiation exposure.

Averted dose: The dose prevented or avoided by the application of a countermeasure or set of countermeasures, i.e. the difference between the projected dose if the countermeasure(s) had not been applied and the actual projected dose.

Becquerel (Bq): The special name for the SI unit of activity, $1\ Bq = 1\ s^{-1}$ ($\approx 2.7 \times 10^{-11}$ Ci).

Bioassay: Any procedure used to determine the nature, activity, location or retention of radionuclides in the body by in vivo measurement or by in vitro analysis of material excreted or otherwise removed from the body.

Bystander effect: A response in unirradiated cells that is triggered by signals received from irradiated neighbouring cells.

Categories of exposure; The Commission distinguishes between three categories of radiation exposure; occupational, public and medical exposures of patients.

Collective Dose: See collective effective dose.

Collective Effective Dose, S: The sum of individual effective doses of persons with effective dose values between E_1 and E_2 from a specified source and for a specified time period Δ T is

$$S(E_1, E_2, \Delta T) = \int_{E_1}^{E_2} E \frac{\mathrm{d}N}{\mathrm{d}E}\,\mathrm{d}E$$

where $\frac{\mathrm{d}N}{\mathrm{d}E}$ denotes the number of individuals who experience an effective dose between E and E + dE and Δ T specifies the time period within which the effective doses are summed. The unit of the collective effective dose is man sievert (man Sv).

Committed Effective Dose, $E(\tau)$: The sum of the products of the committed organ or tissue equivalent doses and the appropriate organ or tissue weighting factors (w_T), where τ is the integration time in years following the intake. The commitment period is taken to be 50 years for adults, and to 70 years for children.

Committed Equivalent Dose, $H_T(\tau)$: The time integral of the equivalent dose rate in a particular tissue or organ that will be received by an individual following intake of radioactive material into the body by a reference person, where τ is the integration time in years

Constraint: The most fundamental level of protection for the most highly exposed individuals from a source within a type of exposure to be used prospectively in the optimisation process in order.

Controlled area: A defined area in which specific protection measures and safety provisions are or could be required for controlling normal exposures or preventing the spread of contamination during normal working conditions, and preventing or limiting the extent of potential exposures. A controlled area is often within a supervised area, but need not be.

Detriment: A measure of the total harm to health experienced by an exposed group and its descendants as a result of the group's exposure to a radiation source. Detriment is a

multi-dimensional concepts; its principal components are the stochastic quantities probability of attributable fatal cancer, weighted probability of attributable non-fatal cancer, weighted probability of severe hereditary effects, and length of life lost if the harm occurs.

Deterministic effect: A health effect of radiation for which generally a threshold level of dose exists above which the severity of the effect is greater for a higher dose. Such an effect is described as a 'severe deterministic effect' if it is fatal or life threatening or results in a permanent injury that reduces quality of life. Deterministic effects are also called 'tissue reactions'.

Diagnostic reference level: used in medical diagnosis to indicate whether, in routine conditions, the patient dose or administered activity from a specified procedure are unusually high or low for that procedure.

Dose and dose-rate effectiveness factor (DDREF: A judged factor that generalises the usually lower biological effectiveness (per unit of dose) of radiation exposures at low doses and low dose rates as compared with exposures at high doses and high dose rates.

Dose coefficient: Used as a synonym for dose per unit intake, but sometimes also used to describe other coefficients linking quantities or concentrations of activity to doses or dose rates, such as the external dose rate a specified distance above a surface with a deposit of a specified activity per unit area of a specified radionuclide.

Dose constraint: A prospective and source related restriction on the individual dose from a source, which serves as an upper bound on the dose in optimisation of protection for that source. For occupational exposures, the dose constraint is a value of individual dose used to limit the range of options considered in the process of optimisation. For public exposure, the dose constraint is an upper bound on the annual doses that members of the public should receive from the planned operation of any controlled source.

Dose Equivalent, *H*: The product of D and Q at a point in tissue, where D is the absorbed dose and Q is the quality factor for the specific radiation at this point, thus

$H = D\,Q$.

The unit of dose equivalent is joule per kilogram (J kg^{-1}) or sievert (Sv).

Dose conversion convention: The assumed relationship between potential alpha energy exposure and effective dose. Used to estimate doses from measured or estimated exposure to radon (units: mSv per J·h/m^3).

Dose limit: The value of the effective dose or the equivalent dose to individuals from planned exposure situations that shall not be exceeded.

Doubling dose (DD): The dose of radiation (Gy) that is required to produce as many heritable mutations as those arising spontaneously in a generation.

Effective Dose, E: The sum of the equivalent doses in all specified tissues and organs of the body, given by the expression:

$$\text{or} \qquad E = \sum_{T} w_T \sum_{R} w_R D_{T,R}$$

where H_T or $w_R D_{T,R}$ is the equivalent dose in a tissue or organ, T, and w_T is the tissue weighting factor.

Emergency: A non-routine situation or event that necessitates prompt action primarily to mitigate a hazard or adverse consequences for human health and safety, quality of life, property or the environment. This includes situations for which prompt action is warranted to mitigate the effects of a perceived hazard.

Emergency exposure situations: Unexpected situations that occur during the operation of a practice, requiring urgent action. Emergency situations may arise from practices.

Equivalent Dose, H_T: The radiation-weighted dose, H_T, in a tissue or organ T is given by:

$$H_T = \sum_{R} w_R D_{T,R}$$

where $D_{T,R}$ is the mean absorbed dose from radiation R in a tissue or organ T and w_R is the radiation weighting factor. Since w_R is dimensionless, the unit for the equivalent dose is the same as for absorbed dose, J kg^{-1}, and its special name is sievert (Sv).

Exclusion: The deliberate exclusion of a particular category of exposure from the scope of an instrument of regulatory control on the grounds that it is not considered amenable to control through the regulatory instrument in question.

Exemption: The determination by a regulatory body that a source or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure (including potential exposure) due to the source or practice is too small to warrant the application of those aspects or that this is the optimum option for protection irrespective of the actual level of the doses or risks.

Existing exposure situations: Situations that already exist when a decision on control has to be taken, including natural background radiation and residues from past practices that were operated outside the Commission's recommendations.

Exposed individuals: The Commission distinguishes between three categories of exposed individuals; workers (informed individuals), the public (general individuals), and patients, including their comforters and carers.

Gray (Gy): The special name for the SI unit of absorbed dose: 1 Gy = 1 J kg^{-1}.

Incidence: The rate of occurrence of a disease within a specified period of time, often expressed as a number of cases with a disease per 100,000 individuals per year (or per 10,000 person-years).

Induced genomic instability: The induction of an altered cellular state characterised by a persistent increase over many generations in the spontaneous rate of mutation or other genome-related changes.

Intake, *I*: Activity that enters the body through the respiratory tract or gastrointestinal tract from the environment.

Justification:

Legal person: Any organisation, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with national legislation, who or which has responsibility and authority for any action having implications for protection and safety.

Life Span Study (LSS): The long-term cohort study of health effects in the Japanese atomic bomb survivors in Hiroshima and Nagasaki.

Linear energy transfer (LET): A measure of the ability of material to absorb ionising radiation; the radiation energy lost per unit length of path through a material.

Linear-non-threshold model (LNT): A hypothesis which is based on the concept that, in the low dose range, above background, radiation doses greater than zero will increase the risk of excess cancer and/or heritable disease in a simple proportionate manner

Linear quadratic dose response: A statistical model that expresses the risk of an effect (e.g. disease, death or abnormality) as the sum of two components, one proportional to dose (linear term) and the other one proportional to the square of dose (quadratic term).

Multifactorial diseases: Diseases that are attributable to multiple genetic and environmental factors.

Nominal risk coefficient: Sex and age at exposure averaged lifetime risk estimates for a representative population.

Non-cancer diseases: Diseases other than cancer eg. cardiovascular disease, and cataracts.

Operating management: The person or group of persons that directs, controls, and assesses an organisation at the highest level. Many different terms are used, including, e.g., chief executive officer (CEO), director general (DG), managing director (MD), and executive group.

Operational Quantities: Are used in monitoring and are practical applications for investigating the situations involving external exposure and intakes of radionuclides. They are defined for measurements and assessment of doses in the body.

Optimisation of protection (and safety): The process of determining what level of protection and safety makes exposures, and the probability and magnitude of potential exposures, as low as reasonably achievable, economic and societal factors being taken into account.

Personal dose equivalent, $H_p(d)$: The dose equivalent in ICRU tissue at an appropriate depth, d, below a specified point on the human body. The unit of personal dose equivalent is joule per kilogram (J kg^{-1}) and its special name is sievert (Sv). The specified point is usually given by the position where the individual dosemeter is worn.

Planned exposure situations: Everyday situations involving the planned operation of sources including decommissioning, disposal of radioactive waste and rehabilitation of the previously occupied land. Practices in operation are planned exposure situations.

Pooled analysis: An analysis of epidemiologic data from several studies based on original data from those studies that are analysed in parallel.

Potential exposure: Exposure that is not expected to be delivered with certainty but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.

Principles of protection: A set of principles that apply equally to all controllable exposure situations; the principle of justification, the principle of optimisation of protection, and the principle of application of limits on of maximum doses in planned situations.

Protection Quantities: Dose quantities that ICRP has developed for radiological protection that allow quantification of the extent of exposure to ionising radiation from both whole and partial body external irradiation and from intakes of radionuclides.

Radiation detriment: Radiation detriment is a concept used to quantify the harmful health effects of radiation exposure in different parts of the body. It is defined by ICRP as a function of several factors, including incidence of radiation-related cancer or hereditary defects, lethality of these conditions, quality of life, and years of life lost due to these conditions.

Radiation Weighting Factor (w_R): A dimensionless factor by which the organ or tissue absorbed dose is multiplied to reflect the higher biological effectiveness of high LET radiations compared with low LET radiations. It is used to derive the equivalent dose from the absorbed dose averaged over a tissue or organ.

Radiation worker: Any person who is employed, whether full time, part time or temporarily, by an employer and who has recognised rights and duties in relation to occupational radiological protection.

Reference animals and plants: A hypothetical entity, with the assumed basic biological characteristics of a particular type of animal or plant, as described to the generality of the taxonomic level of Family, with defined characteristics defined by the Commission for the purpose of radiological protection.

Reference person: An idealised human with characteristics defined by the Commission for the purpose of radiological protection, and with the anatomical and physiological characteristics defined in the report of the ICRP Task Group on Reference Man (*Publication 89*; ICRP, 2002).

Reference Value: The value of a parameter recommended by ICRP for use in a biokinetic model in the absence of more specific information, ie. the exact value used to calculate the dose coefficients presented in the report. Reference values may be specified to a greater degree of precision than that which would be chosen to reflect the certainty with which the value is known, in order to avoid the accumulation of rounding errors in a calculation.

Relative Biological Effectiveness (RBE): The ratio of a dose of a low-LET reference radiation to a dose of the radiation considered that gives an identical biological effect. RBE values vary with the dose, dose rate and biological endpoint considered. In radiological protection the RBE at very low doses (RBE_M) is especially of interest.

Relative life lost: The ratio of the proportion of observed years of life lost among people dying of a disease in an exposed population and the corresponding proportion in a similar population without the exposure.

Relative survival: The ratio of proportion of cancer patients who survive for a specified number of years (eg 5 years) following diagnosis to the corresponding proportion in a comparable set of cancer-free individuals.

Residual dose: In a chronic exposure situation, the dose expected to be incurred in the future after intervention has been terminated (or a decision has been taken not to intervene).

Sievert (Sv): The special name for the SI unit of radiation-weighted dose, former term equivalent dose, of effective dose and of operational dose quantities. The unit is joule per kilogram ($J\ kg^{-1}$).

Source: An entity for which radiological protection can be optimised as an integral whole, such as the x-ray equipment in a hospital, or the releases of radioactive materials from an

installation. Sources of radiation, such as radiation generators and sealed radioactive materials, and, more generally, the cause of exposure to radiation or to radionuclides.

.**Stochastic effects:** Effects resulting from damage in a single cell, such as cancer and hereditary effects. The frequency of the event, but not its severity, increases with an increase in the dose. For protection purposes it is assumed that there is no threshold dose.

Supervised area: A defined area not designated a controlled area but for which occupational exposure conditions are kept under review, even though no specific protection measures or safety provisions are normally needed.

Target Region: Region within the body in which radiation is absorbed. The region may be an organ, a tissue, the contents of the gastrointestinal tract or urinary bladder, or the surfaces of tissues as in the skeleton and the respiratory tract.

Threshold dose for tissue reactions: Dose estimated to result in only 1% incidence of tissue reactions.

Tissue reactions: Injury in populations of cells, in some cases modifiable by post-irradiation procedures including biological response modifiers. Characterised by a threshold dose, and an increase in the severity of the reaction as the dose is increased further. Also termed deterministic effects.

Tissue weighting factors: Tissue weighting factors allow the quantification of the relative sensitivity of different organs or tissues in the body for developing cancer, or to a lesser extent hereditary effects.

Track Structure: Spatial patterns of energy deposition in matter from the passage of a radiation track.

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