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Radiological Protection in Medicine

CONTENTS

1. Background

Publication 73 'Radiological Protection and Safety in Medicine' (ICRP, 1996) was published to expand on the application in medicine of the 1990 recommendations of the

Commission (ICRP, 1991). The Commission is currently preparing an updated set of recommendations, and requested Committee 3 to produce a document underpinning its recommendations for the medical exposure of patients, including their comforters and carers to assist in this process.

The Commission has over the last decade published a number of documents prepared by Committee 3 that provide detailed advice related to radiological protection and safety in the medical applications of ionising radiation. Each of these publications addresses a specific topic defined by the type of radiation source and the medical discipline in which the source is applied, and was written with the intent of communicating directly with the relevant medical practitioners and supporting medical staff. These publications (in chronological order) are:

- Publication 84. Pregnancy and Medical Radiation (ICRP, 2000a)
- Publication 85. Avoidance of Radiation Injuries from Medical Intervention Procedures (ICRP, 2000b)
- Publication 86. Prevention of Accidental Exposures to Patients Undergoing Radiation Therapy (ICRP, 2000c)
- Publication 87. Managing X-ray Dose in Computed Tomography (ICRP, 2000d)
- Supporting Guidance 2. Radiation and Your Patient: A Guide for Medical Practitioners (ICRP, 2001)
- Supporting Guidance 2. Diagnostic Reference Levels in Medical Imaging - Review and Additional Advice (ICRP, 2001)
- Publication 93. Managing Patient Dose in Digital Radiology (ICRP 2003a)
- Publication 94. Release of Patients after Therapy with Unsealed Radionuclides (ICRP, 2004)
- Publication 97. Prevention of High-Dose-Rate Brachytherapy Accidents (ICRP, 2005a)
- Publication 98. Radiation Safety Aspects of Brachytherapy for Prostate Cancer using Permanently Implanted Sources (ICRP, 2005b)

Also, in 1999, the Commission published Publication 80 ‘Radiation Dose to Patients from Radiopharmaceuticals’ (ICRP, 1999a), a joint document of Committees 2 and 3, that presented biokinetic and dosimetric data on ten new radiopharmaceuticals not previously published and updated the similar data presented in the series of earlier ICRP publications on this subject.

In preparation for the present document, Committee 3:

- Reviewed the main topics covered in Publication 73;
- Augmented that review with the additional advice provided in the documents (listed above) published since Publication 73; and
- Reviewed the Commission recommendations under development.

The Commission uses Task Groups and Working Parties to deal with specific areas. Task Groups are appointed by the Commission to perform a defined task, and usually contain a majority of specialists from outside the Commission's structure. Working Parties are set up by Committees with the approval of the Commission, to develop ideas for the Committee, sometimes leading to a Task Group. The membership is usually limited to Committee members. Currently, Committee 3 has a number of similar documents in preparation addressing the following topics:

- Managing patient dose in multi-detector computed tomography (Task Group)
- Radiological protection for cardiologists performing fluoroscopically guided procedures (Task Group)
- Radiological protection issues of modern radiation therapy techniques (Joint Task Group with International Commission on Radiation Units and Measurements)
- Radiation dose to patients from radiopharmaceuticals (Joint Task Group with Committee 2).
- Protecting children: Diagnostic techniques involving ionising radiation (Working Party)
- Doses to the hands of radiopharmacists (Working Party)
- Radiological protection training for diagnostic and fluoroscopically guided interventional procedures (Working Party)
- Medical examinations and follow-up of persons accidentally or occupationally exposed to ionising radiation (Working Party)

- Medical screening of asymptomatic persons using ionising radiation (Working Party)

Additional advice from Committee 3 concerning radiological protection in medicine will be forthcoming as these documents are completed.

In this Committee 3 document, the term ‘exposure’ is used to express the act of being exposed to ionising radiation. The terms ‘dose’ or ‘radiation dose’ are used when the context is not specific to a particular radiation dose quantity. When the context is specific, the name for the quantity is used (e.g., absorbed dose, equivalent dose, effective dose).

2. Scope of Ionising Radiation in Medicine

More people are exposed to ionising radiation from medical practice, and in many cases the individual doses are higher than from any other human activity. In countries with advanced health care systems, the annual number of radiological diagnostic procedures approaches or exceeds one for every member of the population. Furthermore, the doses to patients for the same type of examination differ widely between centres, suggesting that there is considerable scope for management of patient dose.

Radiation exposures in medicine are predominantly to individuals undergoing diagnostic, fluoroscopically guided interventional, or radiation therapy procedures. But staff and 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 also occurs, but it is almost always very small. Radiological protection in medicine refers to all these exposures. Other Commission documents cover radiological protection for workers in medicine (occupational exposure), and radiological protection for members of the public associated with medicine (public exposure). This document covers the following types of exposure in medicine and biomedical research (called in brief medical exposure):

- 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.

The use of radiation for medical diagnostic examinations contributes over 95 percent of man-made radiation exposure and is only exceeded by natural background as a source of exposure (UNSCEAR, 2000). In the next few years [particularly as a result of the rapidly spreading use of computed tomography (CT) in developed and developing countries], radiation uses of medicine may exceed natural background as a source of population exposure.

UNSCEAR (2000) compared estimates of the 1985-1990 and 1991-1996 periods and concluded that the worldwide annual per caput effective dose from medical exposure of patients increased by 35 percent and the collective dose by 50 percent, while the population increased by only 10 percent. It was also estimated that worldwide there were about 2,000 million x-ray studies, 32 million nuclear-medicine studies and over 6 million radiation therapy patients treated annually. These numbers are expected to increase in future years.

The estimated number of medical and dental radiographic machines is about 2 million worldwide. While it is difficult to estimate the number of occupationally exposed medical workers, UNSCEAR (2000) estimated that monitored medical-radiation workers exceed 2.3 million.

3. Brief Summary of Biological Basis for Radiological Protection

The biological effects of radiation can be grouped into two kinds: deterministic effects (tissue reactions) and stochastic effects (cancer and hereditary effects). These effects are briefly noted here; the biological basis for radiological protection is covered in depth in other Commission documents. The Commission recognises that the generic terms, deterministic and stochastic effects, have a firmly embedded use in its system of protection and will use the generic and directly descriptive terms synonymously, according to context.

3.1 Deterministic Effects (Tissue Reactions)

If the effect results only when many cells in an organ or tissue are killed, the effect will be clinically observable only if the radiation dose is above some threshold. The magnitude of this threshold will depend on the dose rate (i.e., dose per unit time) and LET (linear energy transfer) of the radiation, the organ irradiated, and the clinical effect of interest. With increasing doses above the threshold, the probability of occurrence will rise steeply to l00 percent (i.e., every exposed person will show the effect), and the severity of the effect will increase with dose. The Commission calls these effects deterministic (tissue reactions), and a detailed discussion and information on deterministic effects (tissue reactions) is found in ICRP (2006a). Such effects can occur in the application of ionising radiation in radiation therapy, and in interventional medical procedures that are fluoroscopically guided when the procedure times are lengthy.

3.2 Stochastic Effects (Cancer and Hereditary Effects)

There is good evidence from cellular and molecular biology that radiation damage to the DNA in a single cell can lead to a transformed cell that is still capable of reproduction. Despite the body's defenses, which are normally very effective, there is a small probability that this type of damage, promoted by the influence of other agents not necessarily associated with radiation, can lead to a malignant condition. Because the probability is low, this will occur in only a few of those exposed. If the initial damage is to the germ cells in the gonads, hereditary effects may occur.

The probability of a stochastic effect attributable to the radiation increases with dose and is probably proportional to dose at low doses. At higher doses and dose rates, the probability often increases with dose more markedly than simple proportion. At even higher doses, close to the thresholds of deterministic effects (tissue reactions), the probability increases more slowly, and may begin to decrease, because of the competing effect of cell killing. These effects, both somatic and hereditary, are called stochastic. The probability of such effects is increased when ionising radiation is used in medical procedures.

Whereas a single radiological examination confers on a patient a small probability of cancer induction, of the order of 10^{-3} to 10^{-5} in a lifetime, the fact that in developed countries each member of the population undergoes on the average such an examination once in a year, the cumulative risk increases accordingly. Calculations performed on the assumption of a linear non-threshold model of radiation action estimate that the proportion of cancer deaths that could be attributed to exposure from radiological procedures may reach a level from a fraction of one to several percent of that cancer mortality. In addition, one has to remember that the risk is non-uniformly distributed in a population. There are some groups of patients who are much more frequently examined than the average numbers would suggest. Also, there are groups that show higher than average sensitivity for cancer induction due to age (children and adolescents). Moreover, cancers occurring early in life result in much higher lifetime loss than those that become manifest late in life. All these circumstances indicate that proper justification of radiation use in medicine is an indispensable principle of radiological protection.

A detailed discussion and information on somatic and hereditary effects is found in ICRP (2006a), and the Commission's view on cancer risk at low doses is presented in Publication 99 (ICRP, 2006b). It is generally impossible to determine on epidemiological grounds alone that there is, or is not, an increased risk of cancer associated with absorbed doses of the order of 10 mGy or below. The linear no-threshold (LNT) model remains a prudent basis for the practical purposes of radiological protection at low doses and low dose rates.

The Commission has also reviewed the topic of individuals with genetic susceptibility to cancer and expressed its preliminary views in Publication 79 (ICRP, 1999b), and will continue to monitor this subject in regard to its implications for radiological protection.

3.3 Effects of In Utero Irradiation

There are radiation-related risks to the embryo and fetus during pregnancy that are related to the stage of pregnancy and the absorbed dose to the embryo or fetus. These are noted below briefly under the topics of lethal effects, malformations, central nervous system effects, and leukemia and childhood cancer. The Commission has evaluated the effects of prenatal irradiation in detail in Publication 90 (ICRP, 2003b).

Lethal effects - There is embryonic sensitivity to the lethal effects of irradiation in the pre-implantation period of embryonic developments. At doses under 100 mGy, such lethal effects will be very infrequent and there is no reason to believe that there will be significant risks to health expressing after birth.

Malformations - During the periods of major organogenesis, conventionally taken to be from the third to the eighth week after conception, malformations may be caused especially in the organs under development at the time of exposure. These effects have a threshold of 100 to 200 mGy or higher.

Central nervous system - During the period of 8 to 25 weeks post conception, the central nervous system is particularly sensitive to radiation. A reduction in intelligence quotient (IQ) cannot be clinically identified at fetal doses of less than 100 mGy. During the same time period, fetal doses in the range of 1 Gy result in a high probability of severe mental retardation. The sensitivity is highest 8 to 15 weeks post conception, and less sensitive at 16 to 25 weeks of gestational age.

Leukemia and childhood cancer - Radiation has been shown to increase the probability of leukemia and many types of cancer in both adults and children. Throughout most of pregnancy, the embryo and fetus are assumed to be at about the same risk for potential carcinogenic effects as are children.

Consideration of the effects listed above is important when pregnant patients undergo diagnostic, fluoroscopically guided interventional and therapeutic procedures using ionising radiation. A balance must be attained between the health care of the patient and the potential for detrimental health effects to the fetus (or embryo) that accompanies the specific radiological procedure.

4. Dosimetric Quantities

The basic physical quantity used in radiological protection is the absorbed dose averaged over an organ or defined tissue (i.e., mean absorbed dose; the energy deposited in the organ divided by the mass of that organ). The SI unit for absorbed dose is J per kg and its special name is gray (Gy).

During medical imaging procedures using x rays, absorbed doses in tissues and organs of the patient undergoing diagnostic x-ray or fluoroscopically guided interventional procedures usually cannot be measured directly. Measurable quantities that characterize the external radiation field are used therefore to assist in managing the patient dose. These include simple quantities such as absorbed dose in a tissue equivalent material at the surface of a body or in a phantom, but also a number of other quantities of varying complexity, depending on the nature of the x-ray equipment. Significant progress has been achieved in recent years in providing methods to derive absorbed doses in tissues and organs from a number of practical measurements, and a considerable body of data is available, in particular, ICRU Report 74 ‘Patient Dosimetry for X Rays used in Medical Imaging’ (ICRU, 2005).

Some radiations are more effective than others in causing stochastic effects. To allow for this, a quantity equivalent dose (the average absorbed dose in an organ or tissue multiplied by a dimensionless radiation weighting factor) has been introduced. For almost all the radiations used in medicine, the radiation weighting factor is unity, so the absorbed dose and the equivalent dose are numerically equal. The exceptions are alpha particles, for which the current radiation weighting factor is 20, and neutrons, for which the current radiation weighting factors are between 5 and 20, depending on the energy of the neutrons incident on the body. The special name for the unit of equivalent dose is the sievert (Sv). A detailed discussion on radiation weighting factors is provided in Publication 92 (ICRP, 2003c).

Radiation exposure of the different organs and tissues in the body results in different probabilities of harm and different severities. The Commission calls the combination of probability and severity of harm 'detriment', meaning health detriment. To reflect the combined detriment from stochastic effects due to the equivalent doses in all the organs and tissues of the body, the equivalent dose in each organ and tissue is multiplied by a tissue weighting factor, and the results are summed over the whole body to give the effective dose. The special name for the unit of effective dose is also the sievert (Sv). The tissue weighting factors proposed in the most current draft recommendations are those in (ICRP, 2006c).

The Commission intended effective dose for use as a principal protection quantity for the establishment of radiological protection guidance. It should not be used to assess risks of stochastic effects in retrospective situations for exposures in identified individuals, nor should it be used in epidemiological evaluations of human exposure, because the Commission has made judgements on the relative severity of various components of the radiation risks in the derivation of ‘detriment’ for the purpose of defining tissue weighting factors. Such risks for stochastic effects are dependent on age. 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.

5. Unique Aspects of Radiological Protection in Medicine

Several features of radiation exposure in medicine require an approach to radiological protection that is somewhat different from that for other types of radiation exposure.

5.1 Deliberate Exposure

The exposure of patients is deliberate. Except in radiation therapy, 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.

5.2 Voluntary Exposure

Medical uses of radiation are voluntary in nature, combined with the expectation of direct individual health benefit to the patient. The voluntary 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, and also on cultural or societal factors. Usually little informed consent is given for low risk procedures (such as a chest x-ray procedure), more informed consent is given for fluoroscopically guided interventional procedures and a high level (typically written) consent is often obtained before most radiation therapy procedures.

The exception to the concept of a voluntary exposure leading to a direct individual medical benefit is the use of radiation in biomedical research. In these circumstances, the voluntary exposure usually accrues to a societal benefit rather than an individual benefit.

5.3 Medical Screening of Asymptomatic Patients

Screening is performed to try and identify a disease process that has not become manifest clinically. The aim is that earlier diagnosis will lead to earlier and more effective treatment and a better outcome in terms of quality of life and survival. For example, current screening practices using ionising radiation (e.g., mammography) appear to be valid and are recommended for certain populations. On the other hand, there is increasing use of computed tomography (CT) (including self-referral) and positron emission tomography (PET) in screening for disease in asymptomatic individuals, and these applications have not been justified on the basis of current scientific literature.

Patients undergoing these scans should be fully informed of the potential benefits and risks, including the radiation risks. Each application of ionising-radiation for screening of asymptomatic individuals should be evaluated and justified in regard to its clinical merit.

5.4 Radiation Therapy

In radiation therapy, the aim is to eradicate the neoplastic target tissue. Some deterministic damage (tissue reactions) to surrounding tissue and some risk of stochastic effects in remote non-target tissues are inevitable, but the goal of all radiation therapy is to optimise the relationship between tumor control probability and normal tissue complications.

5.5 Management of Radiation Dose

In medicine, the requirement is to manage the radiation dose to the patient to be commensurate with the medical purpose. The goal is to use the appropriate dose to obtain the desired image or desired therapy. In this regard, the Commission introduced the use of diagnostic reference levels for imaging procedures, which will be discussed in more detail later in this document.

5.6 Demographics of the Patient Population

Risk estimates developed by the Commission apply to either the working population or the whole population, and were derived for age- and sex-averaged populations for the purpose of establishing radiological protection guidance (see Section 4). The risks for various age groups are different by amounts that depend on the age at exposure and the organs and tissues exposed. For the exposure of young children, the attributable lifetime risk of death (total cancers) would be higher, perhaps by a factor of 2 or 3 (Annex C of Publication 60) (ICRP, 1991a). For many common types of diagnostic examination, the higher risk per unit dose may be offset by the reduction in dose relative to that to an adult. For an age at exposure of about 60 years, the risk would be lower, perhaps by a factor of three. At higher ages at exposure, the risks are even less (Annex C of Publication 60) (ICRP, 1991a).

It is difficult to apply the concept of effective dose to compare doses from medical exposure of patients to other sources of exposure to humans as the effective dose values are for an age and sex-averaged population. Effective dose can be of value for comparing 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. As noted in Section 4, for planning the exposure of patients and risk-benefit assessments, the equivalent dose or the absorbed dose to irradiated tissues is the relevant quantity.

5.7 Range of Detriments from Radiation Uses in Medicine

There is a wide range of potential radiation detriment to an individual patient that occurs in medical practice. The detriments range from most commonly minimal to rarely lethal.

An example of minimal detriment would be a chest x-ray procedure on a very elderly patient. There would be no chance of deterministic effects (tissue reactions) and essentially no risk of stochastic effects.

An example of more significant detriment is computed tomography (CT) examinations, which can involve relatively high doses to patients. The absorbed doses to tissues from a whole-body CT examination are typically in the range of 10 to 100 mGy. Therefore, a 45-year old adult who beginning at that age undergoes an annual whole-body CT examination for 30 years could accrue a significant lifetime cumulative absorbed dose to tissues [i.e., 300 to 3,000 mGy (0.3 to 3 Gy)]. This cumulative absorbed dose is of a magnitude at which an increase in the probability of cancer has been observed in human epidemiological studies.

There are also a growing number of deterministic injuries (tissue reactions) resulting from unnecessarily high doses from the use of fluoroscopy during interventional procedures. In radiation oncology, the tolerance for deviation from the treatment regimen is very small. Usually overdosage in excess of 10 percent will result in an unacceptably high risk of severe or fatal complications. Underdosage will result in not curing the cancer and will cause more than expected deaths from cancer.

6. The Framework of Radiological Protection in the 2007 Recommendations

The primary aim of radiological protection is to provide an appropriate standard of protection for people and the environment without unduly limiting the beneficial practices giving rise to radiation exposure. As noted before, in most situations arising from the medical uses of radiation, the radiation sources are deliberately used and are under control.

In the 1990 Recommendations, the Commission gave principles of protection for practices separately from intervention situations. The Commission continues to regard these principles as fundamental for the system of protection, and has now formulated a set of principles that apply equally to planned, emergency and existing controllable situations. In the 2007 Recommendations, the Commission also clarifies how the fundamental principles apply to radiation sources and to the individual, as well as that the source-related principles apply to all controllable situations.

Source Related

- The principle of justification: Any decision that alters the existing radiation exposure situation (e.g., by introducing a new radiation source or by reducing existing exposure) should do more good than harm.
- The principle of optimisation of protection: Optimisation of protection should ensure the selection of the best protection option under the prevailing circumstances (e.g., maximising the margin of good over harm). This procedure should be constrained by restrictions on the doses or risks to individuals (dose or risk constraints). Optimisation involves keeping exposures as low as reasonably achievable (ALARA), taking into account economic and societal factors, as well as any inequity in the distribution of doses and benefits amongst those exposed.

Individual Related

- The principle of dose limits in planned situations: The total dose to any individual from all the regulated sources should not exceed the appropriate limits specified by the Commission.

Provided that the doses have been properly justified and that they are commensurate with the medical purpose, it is not appropriate to apply dose limits or constraints to the medical exposure of patients, because such limits or constraints would often do more harm than good (see Sections 9.2 and 10).

In its system of radiation of protection in the next Recommendations, the Commission is continuing to use the term ’dose constraint’ in planned situations but is introducing the term ‘reference level’ for existing and emergency situations. However, although the medical exposure of patients is a planned situation, the term ‘dose constraint’ is not applicable (as stated previously) and the ‘diagnostic reference level’ (Section 13) will still be used as the tool for the optimisation of protection in medical exposure of patients.

The term ‘practices’ requires some attention in the context of medical exposures, and will be discussed in a Section 7 of this document.

In most situations in medicine, other than radiation therapy, it is not necessary to approach the thresholds for deterministic effects (tissue reactions), even for the most part in fluoroscopically guided interventional procedures if the staff is properly educated and trained. The Commission's policy is therefore to limit exposures so as to keep doses below these thresholds. The possibility of stochastic effects cannot be totally eliminated, so the policy is to avoid unnecessary sources of exposure and to take all reasonable steps to reduce the doses from those sources of exposure that are necessary or cannot be avoided.

In using these principles to develop a practical system of protection that fits smoothly into the conduct of the activity, the Commission uses a division into three types of exposure: medical exposure, which is principally the exposure of persons as part of their diagnosis or treatment and their non-professional comforters and carers, but also includes volunteers in biomedical research; occupational exposure, which is the exposure incurred at work, and principally as a result of work; and public exposure, which comprises all other exposures. In some respects, the system of protection is applied differently to these types of exposure, so it is important to clarify the distinctions. The subject of this document is the distinctions concerning medical exposure to patients, non-professional comforters and carers, and volunteers in biomedical research (as described in Section 2).

7. Discussion of the Term ‘Practice’

The Commission previously distinguished between ‘practices’ that added doses and ‘interventions’ that reduced doses (Publication 60) (ICRP, 1991a). Different principles of protection were applied in the two situations. That distinction has caused difficulties and is seen as artificial. The Commission therefore now recommends one set of principles for all the situations to which its recommendations apply namely planned situations, emergency situations and existing situations.

The term practice has, however, become widely used in radiological protection. The Commission will continue to use this concept, and now defines practice as an endeavor that causes an increase in exposure to radiation or in the risk of exposure to radiation. An endeavor can be a business, trade, industry or any other productive enterprise; it can also be a government undertaking, a charity or some other act of enterprising. It is implicit in the concept of a practice that the radiation sources that it introduces or maintains can be controlled directly by action on the source. The Commission will use the term ‘intervention’ only to describe actions to reduce exposure and not any longer to describe a radiological situation.

7.1 The Term ‘Practice’ in the Field of Medicine

In the field of medicine, the term practice typically refers to the medical care that a practitioner provides to patients. In radiation oncology, the term refers to initial consultation with the patient, accurate diagnosis and staging of the cancer, treatment planning, administering a course of treatment and subsequent follow-up.

Treatment for cancers varies and therefore each type of treatment can be referred to as a practice. For example, palliative treatment for lung cancer would be a practice and treatment of prostate cancer with permanent implants would be another practice. In this way each type of treatment for a specific cancer could be evaluated for efficacy and risks (referred to as justification). Each type of treatment would be adjusted (such as the field size or dose) to the specific patient (referred to as optimisation). This logic is familiar to medical staff and is the way they normally practice.

7.2 Introduction and Elimination of 'Practices' in the Field of Medicine

It is instructive to examine how medical practices are introduced or eliminated, because there are some significant differences compared to how most other practices are introduced (e.g., commercial nuclear power).

Introduction of a practice in medicine - Articles in professional journals are a common way for physicians and other members of the medical staff to learn about new uses of established procedures or new techniques (typically new equipment). Usually the initial claims are associated with case reports and tend to be over-optimistic, but as the medical community uses a technique and additional articles of larger randomised studies appear the appropriate place of that technique in the medical armamentarium becomes clearer. Another issue driving implementation of a new technique or use is the medical practitioner's desire to offer the latest or best technique to the patient with hopes of improving outcomes.

Although it is rare, a specific use of a procedure may occur as a result of administrative fiat or regulation. Examples of this usually occur as a result of public health measures (e.g., screening chest x-ray procedures for tuberculosis), for compensation or medical monitoring (e.g., assessment after asbestos or silica exposure to identify asbestosis and mesothelioma, or pneumoconiosis), or for insurance purposes.

Benefit versus risk has clear implications for introduction of a medical practice. Death and other severe complications for a potential new practice are obviously taken into account. Radiation risks are considered but usually in a secondary way. For example, if a practice is being introduced (e.g., specific applications of spiral CT), dose reduction (or management) is usually a secondary matter and is usually treated as 'optimisation' rather than during an initial justification phase.

In addition, to quantify the benefit from a medical practice (often referred to as evidence-based medicine) is an extremely difficult task, especially for diagnostic procedures. Even for simple practices such as the use of a chest x-ray procedure for a patient with suspected pneumonia, the benefit may be more in terms of confidence of the practitioner in their diagnosis than actual changes in outcome, but still of benefit to the patient. Mammography is one of the few areas of diagnostic radiology in which careful studies have been done to allow reasonable cost-benefit analysis. For radiation therapy protocols, randomised trials can provide a measure of benefit (usually in terms of one or five year survival).

Elimination of a 'practice' in medicine - Ineffective or dangerous practices in medicine are rarely eliminated by government or regulatory authorities. Practices that result in an unexpectedly high morbidity or mortality are usually discontinued by the practitioners as a result of experience, information they have received or lawsuits.

For some less dangerous outcomes, the practitioners themselves discover that one procedure is not as convenient or accurate as another. One example of a non-ionising radiation procedure being replaced by a radiation procedure is the now infrequent use of ultrasound for the diagnosis of appendicitis having been replaced by CT. The CT results are less dependent on the CT operator and much easier to interpret and consequently more accurate.

Other practices are eliminated as they are replaced by newer and better technology. An example of this is replacement of the radiographic oral cholecystograms by ultrasound for the diagnosis of cholecystitis (an example of evidence-based radiology).

Finally, some practices are replaced as a result of changes in professional approaches or training. An example of this has been the replacement of nuclear medicine procedures by radiographic procedures or when radiographic procedures are added to formerly single nuclear medicine procedures. For example, traditional ventilation perfusion nuclear medicine lung scans for the diagnosis of pulmonary embolism have been largely replaced by CT pulmonary angiography, which is now technically feasible with ultra-fast CT scanners. As another example, PET/CT scanners have made the positron emission scans much easier to interpret because anatomic localisation of pathological foci by positron emission scan has become more precise.

Radiological protection issues or patient dose play a minor role in the introduction and elimination of medical practices as understood by the medical profession. The term practice, when the Commission is communicating with the medical community regarding the utilisation of ionising radiation in medicine, needs to be presented in a way that is readily understood by the medical community. One option is to use the term ‘radiological practice in medicine’ to differentiate between the usual meaning of the term practice in medicine. This should help the medical profession to better understand the radiological protection concepts of the Commission.

8. Justification of a Radiological Practice in Medicine

In principle, the decision to adopt or continue any human activity involves a review of the benefits and disadvantages of the possible options. This review usually provides a number of alternative procedures that will do more good than harm. The more elaborate process of judging which of these options is the ‘best’ (e.g., choosing between the use of x rays or ultrasound) is still necessary and is more complex. The harm, more strictly the detriment, to be considered is not confined to that associated with the radiation; it includes other detriments and the economic and social costs of the practice. Often, the radiation detriment will be only a small part of the total. For these reasons, the Commission limits its use of the term ‘justification’ to the first of the above stages (i.e., it requires only that the net benefit be positive). To search for the best of all the available options is usually a task beyond the responsibility of radiological protection organizations.

Depending on the system of health care in a country, there may be an influence of commercial interests on referral of patients to radiological examinations, since such examinations may be a major source of income to hospitals, academic medical institutions and clinics with modern radiological departments. Such a situation may create referral incentives for frequent radiological examinations of patients that could exceed the needs of good medical practice. Committee 3 disapproves of such a practice that confers unjustifiable risk on patients, being inconsistent with medical ethics and principles of radiological protection.

Most of the assessments needed for the justification of a radiological practice in medicine are made on the basis of experience, professional judgment, and common sense, but quantitative decision-aiding techniques are available and, if the necessary data are accessible, they should be considered.

There are three levels of justification of a radiological practice in medicine.

- At the first and most general level, the use of radiation in medicine is accepted as doing more good than harm. Its justification is now taken for granted, and is not discussed here further.
- 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 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 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.

8.1. The Justification of a Defined Radiological Procedure (Level 2)

The justification of the radiological procedure is a matter for national professional bodies, in conjunction with national health authorities and with national radiological protection regulatory authorities. 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.

It should be noted that the justification of a medical procedure does not necessarily lead to the same choice of the best procedure in all situations. For example, chest fluoroscopy for the diagnosis of serious pulmonary conditions may do more good than harm, but chest radiography is likely to be the procedure of choice in a country with substantial resources, because the ratio of good to harm would be larger. However, fluoroscopy might be the procedure chosen in countries with fewer resources, if it would still produce a net benefit and if no better alternatives were available.

In a similar manner, the justification for routine radiological screening for some types of cancer will depend on the national incidence and on the availability of effective treatment for detected cases. National variations are to be expected.

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. The possibility of accidental 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.

The justification of diagnostic investigations for which the benefit to the patient is not the primary objective needs special consideration. In the use of radiography for insurance purposes, the primary benefit usually accrues to the insurer, but there may be some economic benefit for the individual examined. Examinations ordered by physicians as a defense against malpractice claims may have only marginal advantages for the individual patient.

8.2 The Justification of a Procedure for an Individual Patient (Level 3)

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 neurological 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.

9. Optimisation of Protection for Patient Doses in Medical Exposures

9.1 General Approach

The optimisation of protection in medicine is usually applied at two levels: (1) the design and construction of equipment and installations, and (2) the day-to-day methods of working (i.e., the working procedures). The basic aim of the optimisation of protection is to adjust the protection measures relating to the application of a source of radiation within a practice in such a way that the net benefit is maximised.

The concepts involved can be set out in simple terms, but their practical application can range from simple common sense to complex quantitative processes. In selecting the provision for protection in relation to a source, there is always a choice of options. The choice of the protection option directly alters the level of exposure of the patient, the staff, and sometimes the public. But the choice also alters the scale of resources applied to protection. These resources may be reflected directly in financial costs, but they may also involve less easily quantified social costs such as other health risks to staff.

The optimisation of protection means the same as keeping the doses ‘as low as reasonably achievable, economic and societal factors being taken into account,’ and is best described in medical practice as: management of the radiation dose to the patient to be commensurate with the medical purpose.

9.2. The Use of Constraints

In the protection of the patient, the detriments and the 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, management of patient dose is important and often can be achieved by use of a reference level (named the diagnostic reference level) that has no regulatory implications, but rather is a method of evaluating whether the patient dose is commensurate with the medical task.

In other medical exposures, such as the exposure of families and friends, and in the exposure of volunteers in biomedical research programmes that provide no direct benefit to the volunteers, dose constraints are applicable to limit inequity and because there is no further protection in the form of a dose limit.

9.3 Management of Medical Exposure

There is considerable scope for dose reductions in diagnostic radiology. Simple, low-cost measures are available for reducing doses without loss of diagnostic information, but the extent to which these measures are used varies widely.

The optimisation of protection in medical exposures (as implemented through management of patient dose) does not necessarily mean the reduction of doses to the patient. For example, diagnostic radiographic equipment often uses antiscatter grids to improve the image quality, yet removing the grid would allow a reduction in dose by a factor of 2 to 4. For radiography of the abdomen of adults, where the scattered radiation is important, the net benefit would be reduced by removing the grid because the benefit of the dose reduction would be more than offset by the loss of quality of the image. The optimisation of protection would not call for the removal of the grid. In the radiography of small children, however, the amount of scattered radiation is less and the benefit of the dose reduction resulting from the removal of the grid is not fully offset by the small deterioration of the image. The optimisation of protection then calls for the reduction in dose allowed by the removal of the grid.

In radiation therapy, it is necessary to differentiate between the dose to the target tissue and the dose to other parts of the body. If the dose to the target tissue is too low, the therapy will be ineffective. The exposures will not have been justified and the optimisation of protection does not arise. However, the protection of tissues outside the target volume is an integral part of dose planning, which can be regarded as including the same aims as the optimisation of protection.

The exposure (other than occupational) of individuals helping to support and comfort patients also is considered medical exposure. This definition includes the exposures of families and friends of patients discharged from hospital after therapeutic nuclear medicine procedures using unsealed radionuclides or permanently implanted sealed sources. The procedure of optimisation of protection for these groups is no different from that for public exposure, except that the exposures need not be restricted by dose limits, but would include the use of dose constraints.

10. Individual Dose Limits

It is not appropriate to apply dose limits to medical exposures, because such limits would often do more harm than good. Often, there are concurrent chronic, severe or even life-threatening medical conditions that are more critical than the radiation exposure. The emphasis is then on justification of the medical procedures and on the optimization of protection.

Dose limits do apply to occupational and public exposures from medical procedures, although, in most situations, the use of the optimisation of protection now makes them of limited relevance.

11. Radiological Protection in Emergency Medical Situations with Radioactive Materials

In medicine, medical intervention is the term applied to the remedial actions taken to reduce doses, or their consequences, resulting from an accident or from the misuse of a radioactive material.

Accidents and errors may occur with x-ray generators and accelerators, but the termination of the exposures is easy and does not constitute medical intervention. In fractionated radiation therapy, an error in an early fraction can be partly corrected by adjusting further fractions, but this is best thought of as part of dose planning rather than as medical intervention.

The misadministration of radiopharmaceuticals in diagnostic nuclear medicine does not usually cause a serious health problem but does need to be explained fully to the patient.

Several examples of medical intervention in emergency situations associated with the use of radioactive materials in medicine are:

- The dose from an excessive or erroneous administration of radioiodine in therapy may be reduced by the early administration of stable iodine as potassium iodide or iodate to reduce the uptake of radioiodine by the thyroid.

- The dose from a missing brachytherapy source can be reduced by measures to locate the source and warnings to those who may be exposed.
- The dose from a major spill of radioactive materials in nuclear medicine may be reduced by the early isolation of the contaminated area and by the controlled evacuation of staff and patients.
- The doses resulting from the improper disposal and subsequent damage or mishandling of a teletherapy source may be both serious and widespread. Major countermeasures in the public domain may have to include evacuation, destruction of property, and decontamination of substantial areas. A widespread monitoring program will be indispensable. Guidance on the levels of averted dose that would justify such intervention is given in Publication 63 (ICRP, 1993).

12. Practical Methods of Protection

12.1 Occupational Exposure

The principles for the protection of workers from ionising radiation, including in medicine, are fully discussed in Publication 75 (ICRP, 1997) and these principles apply to staff in x-ray, nuclear medicine and radiation therapy facilities.

The control of occupational exposure can be simplified and made more effective by the designation of workplaces into two types: controlled areas and supervised areas. In a controlled area, normal working conditions, including the possible occurrence of minor mishaps, require workers to follow well-established procedures and practices aimed specifically at controlling radiation exposures. A supervised area is one in which the working conditions are kept under review, but special procedures are not normally needed. The definitions are best based on operational experience and judgment. In areas where there is no problem of contamination by unsealed radioactive materials, designated areas may sometimes be defined in terms of the dose rate at the boundary.

Individual monitoring for external radiation is fairly simple and does not require a heavy commitment of resources. In medicine, it should be used for all those who work in controlled areas.

In several areas of medicine the control of occupational exposures is of particular importance. One of these is the nursing of brachytherapy patients when the sources have been implanted, rather than inserted by after-loading techniques. A second is palpation of patients during diagnostic fluoroscopy. A third is in fluoroscopically guided interventional procedures, as in heart catheterisation. In all these procedures, careful shielding and limitation of time are needed. Individual monitoring with careful scrutiny of the results is also important. In brachytherapy, the frequent and careful accounting for sources is essential.

The system of protecting the staff from the source (e.g., shielding) should be designed to minimise any sense of isolation experienced by the patient. This is particularly relevant in nuclear medicine and brachytherapy, where the source is within the patient.

Concerning radiological protection for the embryo and fetus of a pregnant woman who is occupationally exposed, the early part of a pregnancy is covered by the normal protection of workers, which is essentially the same for males and females.

The Commission recommends that the working conditions of a pregnant worker, after the declaration of pregnancy, should be such as to make it unlikely that the additional equivalent dose to the embryo and fetus will exceed about 1 mSv during the remainder of the pregnancy. In the interpretation of this recommendation, it is important not to create unnecessary discrimination against pregnant women.

12.2. Public Exposure

Public access to hospitals and to radiology rooms is not unrestricted, but it is more open than is common in industrial operations. There are no radiological protection grounds for imposing restrictions on the public access to non-designated areas. Because of the limited duration of public access, an access policy can be adopted for supervised areas if this is of benefit to patients or visitors and there are appropriate radiological protection safeguards. Public access to controlled areas, especially to brachytherapy and nuclear medicine areas, should be limited to patients' visitors, who should be advised of any restrictions on their behaviour.

12.3 Exposure of Volunteers in Biomedical Research

The use 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 these volunteers as if it were medical exposure.

The ethical and procedural aspects of the use of volunteers in biomedical research have been addressed by the Commission in Publication 62 (ICRP, 1991b). 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.

In many countries, radiation exposure of pregnant females 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 fetus.

12.4 Exposure of Comforters and Carers of Patients

Friends and relations helping in the support and comfort of patients are also volunteers, but there is a direct benefit both to the patients and to those who care for them. Their exposures are defined as medical exposure, but dose constraints should be established for use in defining the protection policy both for visitors to patients and for families at home when nuclear medicine patients are discharged from hospital. Such groups may include children. The Commission has not previously recommended values for such constraints, but a value of 5 mSv per episode (i.e., for the duration of a given release of a patient after therapy) is likely to be reasonable. This constraint is not to be used rigidly. For example, higher doses may well be appropriate for the parents of very sick children. This topic is covered in further detail in Section 17.7.

13. Diagnostic Reference Levels

13.1 Diagnostic Reference Levels (Publications 60 and 73)

In Publication 60 (ICRP, 1991a), reference levels were described as values of measured quantities above which some specified action or decision should be taken. They include recording levels, above which a result should be recorded, lower values being ignored; investigation levels, above which the cause or the implications of the result should be examined; intervention levels, above which some remedial action should be considered; and, more generally, action levels, above which some specified action should be taken. The use of these levels can avoid unnecessary or unproductive work and can help in the effective deployment of resources. They can also be helpful in radiological protection by drawing attention to situations of potentially high risk.

One particular form of reference level applies to diagnostic radiography and diagnostic nuclear medicine. In Publication 60 (ICRP, 1991a), the Commission recommended that consideration should be given to the use of dose constraints, or investigation levels, selected by the appropriate professional organization or regulatory authority, for application in some common diagnostic procedures. They should be applied with flexibility, to allow higher doses where indicated by sound clinical judgment.

In Publication 73 (ICRP, 1996), the Commission decoupled the concept of diagnostic reference level from that of a dose constraint, and discussed the concept in more detail, as noted below.

The Commission now uses the same conceptual approach in the 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. More discussion of its implementation is given in this section. 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.

The Commission now recommends the use of diagnostic reference levels for patients. These levels, which are a form of investigation level, apply to an easily measured quantity, usually the absorbed dose in air, or in a tissue-equivalent material at the surface of a simple standard phantom or representative patient. In nuclear medicine, the quantity will usually be the administered activity. In both cases, the diagnostic reference level will be intended for use as a simple test for identifying situations where the levels of patient dose or administered activity are unusually high.

If it is found that procedures are consistently causing the relevant diagnostic reference level to be exceeded, there should be a local review of the procedures and the equipment in order to determine whether the protection has been adequately optimised. If not, measures aimed at reduction of the doses should be taken.

Diagnostic reference levels are supplements to professional judgment and do not provide a dividing line between good and bad medicine. They contribute to good radiological practice in medicine. The numerical values of diagnostic reference levels are advisory, however, implementation of the diagnostic reference level concept may be required by an authorised body (ICRP, 2001). It is inappropriate to use the numerical values for diagnostic reference levels as regulatory limits or for commercial purposes.

Diagnostic reference levels apply to radiation exposure of patients resulting from procedures performed for medical diagnostic purposes. They are difficult to apply to fluoroscopically guided interventional procedures. They do not apply to radiation therapy, and also do not apply to occupational and 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. The values should be selected by professional medical bodies 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.

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

Diagnostic reference levels should be related only to common types of diagnostic examinations and to broadly defined types of equipment. The levels are not intended to be used in a precise manner and a multiplicity of levels will reduce their usefulness.

13.2 Diagnostic Reference Levels (Supporting Guidance 2)

More recently, in Supporting Guidance 2 (ICRP, 2001), additional advice was provided, as noted below.

The objective of a diagnostic reference level is to help avoid radiation dose to the patient that does not contribute to the clinical purpose of a medical imaging task. This is accomplished by comparison between the numerical value of the diagnostic reference level (derived from relevant regional, national or local data) and the mean or other appropriate value observed in practice for a suitable reference group of patients or a suitable reference phantom. A reference group of patients is usually defined within a certain range of physical parameters (e.g., height, weight). If an unselected sample of patients were used as a reference group, it would be difficult to interpret whether the observed value for the sample is higher or lower than the diagnostic reference level. A diagnostic reference level is used for a given medical imaging task or protocol, and is not applied to individual patients.

A diagnostic reference level can be used:

- To improve a regional, national or local distribution of observed results for a general medical imaging task, by reducing the frequency of unjustified high or low values;
- To promote attainment of a narrower range of values that represent good practice for a more specific medical imaging task; or
- To promote attainment of an optimum range of values for a specified medical imaging protocol.

These uses are differentiated by the degree of specification for the clinical and technical conditions selected by the authorised body for a given medical imaging task. Definitions and examples associated with the uses are given in Supporting Guidance 2 (ICRP, 2001).

Appropriate local review and action is taken when the value observed in practice is consistently outside the selected upper or lower level. This process helps avoid unnecessary tissue doses being received by patients in general and, therefore, helps avoid unnecessary risk for the associated radiation health effects.

For fluoroscopically guided interventional procedures, diagnostic reference levels, in principle, could be used to promote the management of patient doses with regard to avoiding unnecessary stochastic radiation risks. However, the observed distribution of patient doses is very wide, even for a specified protocol, because the duration and complexity of the fluoroscopic exposure for each conduct of a procedure is strongly dependent on the individual clinical circumstances. A potential approach is to take into consideration not only the usual clinical and technical factors, but also the relative 'complexity' of the procedure. More than one quantity (i.e., multiple diagnostic reference levels) may be needed to evaluate patient dose and stochastic risk adequately.

Diagnostic reference levels are not applicable to the management of deterministic effects (tissue reactions) (i.e., radiation-induced skin injuries) from fluoroscopically guided interventional procedures. In this case, the objective is to avoid deterministic effects (tissue reactions) in individual patients undergoing justified, but long and complex procedures. The need here is to monitor in real time whether the threshold doses for deterministic effects (tissue reactions) are being approached or exceeded for the actual procedure as conducted on a particular patient. The relevant risk quantity is absorbed dose in the skin at the site of maximum cumulative skin dose. A helpful approach is to select values for maximum cumulative absorbed dose in the skin at which various clinical actions regarding the patient's record or care (related to potential radiation-induced skin injuries) are taken (Publication 85) (ICRP, 2000b). Then, during actual procedures, appropriate quantities that can help indicate the maximum cumulative absorbed dose in the skin are monitored.

Diagnostic reference levels should be used by authorised bodies to help manage the radiation dose to patients so that the dose is commensurate with the clinical purpose.

The concept of a diagnostic reference level permits flexibility in the choice of quantities, numerical values, and technical or clinical specifications, in order to allow authorised bodies to meet the objectives relevant to their circumstances. The guiding principles for setting a diagnostic reference level are:

- The regional, national or local objective is clearly defined, including the degree of specification of clinical and technical conditions for the medical imaging task;

- The selected value of the diagnostic reference level is based on relevant regional, national or local data;
- The quantity used for the diagnostic reference level can be obtained in a practical way;
- The quantity used for the diagnostic reference level is a suitable measure of the relative change in patient tissue doses and, therefore, of the relative change in patient risk for the given medical imaging task; and
- The manner in which the diagnostic reference level is to be applied in practice is clearly illustrated.

Authorised bodies are encouraged to set diagnostic reference levels that best meet their specific needs and that are consistent for the regional, national or local area to which they apply.

14. Preventing Accidents and Emergencies in Medicine

Accident prevention should be an integral part of the design of equipment and premises and of the working procedures. A key feature of accident prevention has long been the use of multiple safeguards against the consequences of failures. This approach, now often called 'defense in depth' is aimed at preventing a single failure from having serious consequences. Some defenses are provided by the design of equipment, others by the working procedures.

Although the main emphasis in accident prevention should be on the equipment and procedures in radiation therapy (Publications 86 and 97) (ICRP, 2000c; 2005a), some attention should be paid to accidents with diagnostic equipment.

Radiation therapy equipment should be designed to reduce operator errors by automatically rejecting demands outside the design specification or by questioning the validity of the instruction. Enclosures should be designed to exclude staff during exposures, without unduly isolating the patient.

Radiation therapy equipment should be calibrated after installation and after any modification and should be routinely checked by a standard test procedure that will detect significant changes in performance.

Working procedures should require key decisions, especially in radiation therapy, to be subject to independent confirmation. The patient's identity and the correct link to the prescribed treatment should be double-checked. In therapeutic nuclear medicine, dual checks should be made on the correctness of the pharmaceutical and its activity. Effective communication between all the staff involved is a vital part of the process.

Radioactive sources used for therapy can cause very serious exposures if they are mislaid or misused. Brachytherapy sources should be subject to frequent and thorough accounting checks and provision should be made for their eventual disposal. The possible presence of implanted sources or therapeutic activities of radiopharmaceuticals should be taken into account in the handling of deceased patients.

15. Education and Training

There should be radiological protection training requirements for physicians and other health professionals who order, conduct or assist in medical procedures that utilise ionising radiation in diagnostic and fluoroscopically guided interventional procedures, nuclear medicine and radiation therapy. 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.

Education and training should be given at the medical schools, during the residency and in focused specific courses. There should be an evaluation of the training, and appropriate recognition that the individual has successfully completed the training. In addition, there should be corresponding radiological protection training requirements for clinical support personnel that assist physicians in the conduct of procedures utilizing ionizing radiation.

16. Institutional Arrangements

In particular, it is important to clarify the separate responsibilities of the referring physicians who request radiological procedures, the radiologists who undertake the procedures, and the administrators who provide the resources.

One important need is to provide adequate resources for the education and training in radiological protection for future professional and technical staff who request or partake in radiological practices in medicine. The training program should include initial training for all incoming staff and regular updating and retraining.

Quality assurance programs are essential for maintaining the intended standards in all the functions of the undertaking. Their scope should specifically include radiological protection and safety.

Any system of verification includes record-keeping. The requirements for recording occupational exposures will usually be determined by the regulatory authorities. Diagnostic exposures rarely need to be measured, but if they are, records should be kept of any comparisons with diagnostic reference levels. In radiation therapy, the data from dose planning, administered activity (in nuclear medicine), and, for radiation therapy patients, the activity at the time of discharge should be included in the patients' records.

17. Focused Evaluations of Radiological Protection in Medicine

Committee 3 has produced a number of documents that provide detailed advice related to radiological protection and safety in the medical applications of ionising radiation. Each document focuses on a particular radiation source as applied in a given medical discipline or to a given type of patient. Each document is a compendium of the application of the extant Commission recommendations, as applicable to medical radiation. For the most part, Committee 3 has found no hindrance to these efforts because of the existing recommendations. In brief, the following observations appear to be the predominant ones in regard to radiological protection and safety in medicine.

- Communications must be directed to the relevant medical practitioners, in a format in which they are conversant, and channeled to them by an appropriate authoritative or professional body.
- In diagnostic and fluoroscopically guided interventional procedures, management of the patient dose commensurate with the medical task is the appropriate mechanism to avoid unproductive radiation exposure. Equipment features that allow that to be accomplished, and diagnostic reference levels derived at the appropriate national, regional or local level are likely to be the most effective approaches.

In radiation therapy, the avoidance of accidents is the predominate issue. A review of such accidents and advice for preventing them is found in Publication 86 (for external beam and solid brachytherapy sources) (ICRP, 2000c), Publication 97 (additional advice for high-dose-rate brachytherapy sources) (ICRP, 2005a) and Publication 98 (additional advice for permanently implanted sources used in brachytherapy for prostate cancer) (ICRP, 2005b). Brief synopses of these publications are provided below. Each illustrates the aspects of the Commission's radiological protection framework that are most relevant.

17.1 Pregnancy and Medical Radiation (Publication 84)

Thousands of pregnant patients and radiation workers are exposed to ionising radiation each year. Lack of knowledge is responsible for great anxiety and probably unnecessary termination of pregnancies. For many patients, the exposure is appropriate, while for others the exposure may be inappropriate, placing the unborn child at increased risk.

Before any exposure using ionising radiation, it is important to determine whether a female is, or could be, pregnant. Medical exposures during pregnancy require specific consideration due to the radiation sensitivity of the developing fetus. The manner in which an examination is performed depends on whether the fetus will be in the direct beam and whether the procedure requires a relatively higher dose.

Prenatal doses from most correctly performed diagnostic procedures present no measurably increased risk of prenatal death, developmental damage including malformation, or impairment of mental development over the background incidence of these entities. Higher doses, such as those involved in using therapeutic procedures Have the potential to result in developmental harm.

The pregnant patient or worker 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 is the risk of potential harm to the embryo or fetus. Most nuclear medicine procedures do not result in high doses to the embryo and fetus. However, some radiopharmaceuticals that are used in nuclear medicine (e.g., radioiodides) can pose increased fetal risks.

It is essential to ascertain whether a female patient is pregnant prior to radiation therapy. In pregnant patients, cancers that are remote from the pelvis usually can be treated with radiation therapy. This however requires careful planning. Cancers in the pelvis cannot be adequately treated during pregnancy without severe or lethal consequences for the embryo and fetus.

The basis for the control of the occupational exposure of women who are not pregnant is the same as that for men. However, if a woman is, or may be, pregnant, additional controls have to be considered to protect the unborn child.

In many countries, radiation exposure of pregnant females 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 fetus.

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 fetal doses above this level, informed decisions should be made based upon individual circumstances, including the magnitude of the estimated embryonic or fetal dose and the consequent risks of harm to the developing fetus and risks of cancer in later life.

17.2 Medical Interventional Procedures (Fluoroscopically Guided) (Publication 85)

Fluoroscopically guided interventional procedures are being used by an increasing number of clinicians not adequately trained in radiation safety or radiobiology. Many of these interventionists are not aware of the potential for injury from these procedures or the simple methods for decreasing their incidence. Many patients are not being counselled on the radiation risks, nor followed up when radiation doses from difficult procedures may lead to injury. Some patients are suffering radiation-induced skin injuries and younger patients may face an increased risk of future cancer. Interventionists are having their practice limited or suffering injury, and are exposing their staff to high doses.

In some of these interventional procedures, skin doses to patients approach those experienced in radiation therapy fractions in the treatment of cancer. Radiation-induced skin injuries are occurring in patients due to the use of inappropriate equipment and, more often, poor operational technique. Injuries to physicians and staff performing these interventional procedures have also been observed. Acute radiation doses (to patients) may cause erythema at 2 Gy, cataract at 2 Gy, permanent epilation at 7 Gy, and delayed skin necrosis at 12 Gy. Protracted (occupational) exposures to the eye may cause cataracts at 4 Gy if the dose is received in less than 3 months, at 5.5 Gy if received over a period exceeding 3 months.

Practical actions to control dose to the patient and to the staff are available. The absorbed dose to the patient in the area of skin that receives the maximum dose is of priority concern. Each local clinical protocol should include, for each type of fluoroscopically guided interventional procedure, a statement on the cumulative skin doses and skin sites associated with the various parts of the procedure. Interventionists should be trained to use information on skin dose and on practical techniques to control dose. Maximum cumulative absorbed doses that appear to approach or exceed 1 Gy (for procedures that may be repeated) or 3 Gy (for any procedure) should be recorded in the patient record, and there should be a patient follow-up procedure for such cases. Patients should be counselled if there is a significant risk of radiation-induced injury, and the patient's personal physician should be informed of the possibility of radiation effects. Training in radiological protection for patients and staff should be an integral part of the education for those using these interventional procedures. All interventionists should audit and review the outcomes of their procedures for radiation injury. Risks and benefits, including radiation risks, should be taken into account when new fluoroscopically guided interventional techniques are introduced.

17.3 Accidental Exposures in Radiation Therapy (Publication 86)

From the viewpoint of radiation safety, radiation therapy is a very special application of radiation because:

- Human beings are directly placed in a very intense radiation beam (external beam therapy), or radiation sources are placed in direct contact with tissue (brachytherapy), to deliver intentionally very high doses (20 to 80 Gy), and
- Overdosage as well as under dosage may have severe consequences.

This publication aims to assist in the prevention of accidental exposures involving patients undergoing treatment from external beam or solid brachytherapy sources. It does not directly deal with radiation therapy involving unsealed sources. The document is addressed to a diverse audience of professionals directly involved in radiation therapy procedures, hospital administrators, and health and regulatory authorities. The approach adopted is to describe illustrative severe accidents, discuss the causes of these events and contributory factors, summarise the sometimes devastating consequences of these events, and provide recommendations on the prevention of such events. The measures discussed include institutional arrangements, staff training, quality assurance programs, adequate supervision, clear definition of responsibilities, and prompt reporting.

In many of the accidental exposures described in this report, a single cause cannot be identified. Usually, there was a combination of factors contributing to the accident, e.g., deficient staff training, lack of independent checks, lack of quality control procedures, and absence of overall supervision. Such combinations often point to an overall deficiency in management, allowing patient treatment in the absence of a comprehensive quality assurance program. Factors common to many accidents are identified and discussed in detail, and explicit recommendations on measures to prevent radiation therapy accidents are given with respect to regulations, education, and quality assurance.

Doses received during radiation therapy are on the upper edge of tolerable doses to normal tissues. As a result, accidental over dosages have often had devastating and sometimes fatal consequences. Accidental exposures involving a 10 percent or more over dosage should be detectable by a well-trained clinician, based upon an unusually high incidence of adverse patient reactions. Under dosage accidents are difficult to detect clinically and may only be manifest as poor tumor control.

Radiation therapy is increasing worldwide and accidents may be expected to increase in frequency, if measures for prevention are not taken. While a number of serious and fatal radiation therapy accidents are reported, it is likely that many more have occurred but were either not recognised or reported to regulatory authorities or published in the literature.

The complex equipment and techniques used in radiation therapy mandate that for accident prevention, there must be sound and risk-informed regulations, managerial commitment at the hospital level, an adequate number of trained staff, adequate resources, a functional implemented quality assurance program, good communication, and continuing education.

There is a danger in not fully appreciating that modern equipment and new technologies require more quality assurance and highly qualified maintenance. Persons in charge of radiation therapy facilities should ensure that there is proper commissioning of new equipment and proper decommissioning of old equipment and sources.

17.4 Computed Tomography (Publication 87)

Computed tomography (CT) examinations can involve relatively high doses to patients. The absorbed doses to tissues from computed tomography (10 to 100 mGy) can often approach or exceed the levels known from epidemiological studies to increase the probability of cancer. The frequency of CT examinations is increasing worldwide and the types of examinations using CT are also becoming more numerous. However, in contrast to the common trend in diagnostic radiology, the rapid developments in CT have not led in general to a reduction of patient doses for a given type of application.

Therefore, management of patient dose is crucial. The referring physician should evaluate whether the result of each examination will affect patient management. The radiologist should concur that the procedure is justified. The operator should be aware of the possibilities to reduce patient doses by adapting technical parameters to each patient and the examination at hand, with special attention being paid to pediatric and young patients. More than a 50 percent reduction in patient dose is possible by an appropriate choice of technical parameters, attention to quality control, and the application of diagnostic reference levels in co-operation with a medical physicist. Further improvements in CT equipment could help the operator to reduce unnecessary patient doses substantially. The most important of these features will be anatomically based on-line adjustment of exposure factors and new image reconstruction approaches associated with multi-slice computed tomography.

17.5 Guide for General Practitioners (Supporting Guidance 2)

This didactic text is devoted to the protection of patients against unnecessary exposure to ionising radiation. It is organised in a questions-and-answers format.

There are obvious benefits to health from medical uses of radiation, in x-ray diagnostics, fluoroscopically guided interventional procedures, nuclear medicine, and radiation therapy. However, there are well-established risks from high doses of radiation (radiation therapy, fluoroscopically guided interventional procedures), particularly if improperly applied, and possible deleterious effects from small radiation doses (such as those used in diagnostics). Appropriate use of large doses in radiation therapy prevents serious harm, but even low doses carry a risk that cannot be eliminated entirely. Diagnostic use of radiation requires therefore such methodology that would secure high diagnostic gains while minimising the possible harm.

The text provides ample information on opportunities to minimise doses, and therefore the risk from diagnostic uses of radiation. This objective may be reached by avoiding unnecessary (unjustified) examinations, and by optimising the procedures applied both from the standpoint of diagnostic quality and in terms of reduction of the excessive doses to patients.

Optimisation of patient protection in radiation therapy must depend on maintaining sufficiently high doses to irradiated tumors, securing a high cure rate, while protecting the healthy tissues to the largest extent possible.

Problems related to special protection of the embryo and fetus in the course of diagnostic and therapeutic uses of radiation are presented and practical solutions are recommended.

17.6 Digital Radiology (Publication 93)

Digital techniques have the potential to improve the practice of radiology but they also risk the overuse of radiation. The main advantages of digital imaging (i.e., wide dynamic range, post processing, multiple viewing options, and electronic transfer and archiving possibilities) are clear but overexposures can occur without an adverse impact on image quality. In conventional radiography, excessive exposure produces a ‘black’ film. In digital systems, good images are obtained for a large range of doses. It is very easy to obtain (and delete) images with digital fluoroscopy systems, and there may be a tendency to obtain more images than necessary.

In digital radiology, higher patient dose usually means improved image quality, so a tendency to use higher patient doses than necessary could occur. Different medical imaging tasks require different levels of image quality, and doses that have no additional benefit for the clinical purpose should be avoided.

Image quality can be compromised by inappropriate levels of data compression and/or post processing techniques. All these new challenges should be part of the optimisation process and should be included in clinical and technical protocols.

Local diagnostic reference levels should be re-evaluated for digital imaging, and patient dose parameters should be displayed at the operator console. Frequent patient dose audits should occur when digital techniques are introduced. Training in the management of image quality and patient dose in digital radiology is necessary. Digital radiology will involve new regulations and invoke new challenges for practitioners. As digital images are easier to obtain and transmit, the justification criteria should be reinforced.

Commissioning of digital systems should involve clinical specialists, medical physicists, and radiographers to ensure that imaging capability and radiation dose management are integrated. Quality control requires new procedures and protocols (visualisation, transmission, and archiving of the images).

Industry should promote tools to inform radiologists, radiographers, and medical physicists about the exposure parameters and the resultant patient doses associated with digital systems. The exposure parameters and the resultant patient doses should be standardised, displayed, and recorded.

17.7 Unsealed Radionuclides (Release after Therapy) (Publication 94)

After some therapeutic nuclear medicine procedures with unsealed radionuclides, precautions may be needed to limit doses to other people, but this is rarely the case after diagnostic procedures. Iodine-131 results in the largest dose to medical staff, the public, caregivers, and relatives. Other radionuclides used in therapy are usually simple beta emitters (e.g., phosphorus-32, strontiuin-89, and yttrium-90) that pose much less risk. Dose limits apply to exposure of the public and medical staff from patients.

Previously, the Commission recommended that a source-related dose constraint of a few mSv per episode applies to relatives, visitors, and caregivers at home, rather than a dose limit (Publication 73) (ICRP, 1996). A dose constraint of 5 mSv per episode (i.e., for the duration of a given release of a patient after therapy) is likely to be reasonable (see Section 12.4).

Publication 94 (ICRP, 2004) recommends that young children and infants, as well as visitors not engaged in direct care or comforting, should be treated as members of the public (i.e., be subject to the public dose limit of 1 mSv/year).

The modes of exposure to other people are: external exposure; internal exposure due to contamination; and environmental pathways. Dose to adults from patients is mainly due to external exposure. Contamination of infants and children with saliva from a patient could result in significant doses to the child’s thyroid. It is important to avoid contamination of children and pregnant women. After radioiodine therapy, mothers must cease breastfeeding immediately. Many types of therapy with unsealed radionuclides are contraindicated in pregnant females. Women should not become pregnant for some time after radionuclide therapy.

Technetium-99m dominates discharges to the environment from excreta of nuclear medicine patients, but its short half-life limits its importance. The second largest discharges, iodine-131, can be detected in the environment after medical uses but with no measurable environmental impact. Storing patients' urine after radionuclide therapy appears to have minimal benefit. Radionuclides released into modern sewage systems are likely to result in doses to sewer workers and the public that are well below public dose limits.

The decision to hospitalise or release a patient should be determined on an individual basis. In addition to residual activity in the patient, the decision should take many other factors into account. Hospitalisation will reduce exposure to the public and relatives, but will increase exposure to hospital staff. Hospitalisation often involves a significant psychological burden as well as monetary and other costs that should be analyzed and justified. Patients traveling after radioiodine therapy rarely present a hazard to other passengers if travel times are limited to a few hours.

Environmental or other radiation-detection devices are able to detect patients who have had radioiodine therapy for several weeks after treatment. Personnel operating such detectors should be specifically trained to identify and deal with nuclear medicine patients. Records of the specifics of therapy with unsealed radionuclides should be maintained at the hospital and given to the patient along with written precautionary instructions. In the case of death of a patient who has had therapy with unsealed radionuclides in the last few months, special precautions may be required.

17.8 High-Dose-Rate Brachytherapy (Accidents) (Publication 97)

High-dose-rate (HDR) brachytherapy is a rapidly growing technique that has been replacing low-dose-rate (LDR) procedures over the last few years in both industrialised and developing countries. It is estimated that about 500,000 procedures (administrations of treatment) are performed by HDR units annually. LDR equipment has been discontinued by many manufacturers, leaving HDR brachytherapy as the major alternative.

HDR brachytherapy techniques deliver a very high dose, of the order of 1.6 to 5.0 Gy per minute, so mistakes can lead to under- or overdosage with the potential for clinical adverse effects. More than 500 HDR accidents (including one death) have been reported along the entire chain of procedures from source packing to delivery of dose. Human error has been the prime cause of radiation events. In the present report, the International Commission on Radiological Protection concludes that many accidents could have been prevented if staff had had functional monitoring equipment and paid attention to the results.

Since iridium has a relatively short half-life, the HDR sources need to be replaced approximately every 4 months. Over 10,000 HDR sources are transported annually, with the resultant potential for accidents; therefore, appropriate procedures and regulations must be observed.

A number of specific recommendations on procedures and equipment are given in this report. The need for an emergency plan and for practicing emergency procedures is stressed. The possibility of loss or theft of sources must be kept in mind.

A collaborating team of specifically trained personnel following quality assurance (QA) procedures is necessary to prevent accidents. Maintenance is an indispensable component of QA; external audits of procedures reinforce good and safe practice, and identify potential causes of accidents. QA should include peer review of cases. Accidents and incidents should be reported and the lessons learned should be shared with other users to prevent similar mistakes.

17.9 Brachytherapy for Prostate Cancer with Permanent Sources (Radiation Safety) (Publication 98)

The use of permanent radioactive implants (^{125}I or ^{103}Pd seeds) to treat selected localised prostate cancer patients has been increasing rapidly all over the world for the last 15 years. It is estimated that more than 50,000 patients receive this treatment annually worldwide, and this number is anticipated to increase in the near future.

Although no accidents or adverse effects involving medical staff and members of the patient's family have been reported to date, this brachytherapy technique raises a number of radiation safety issues.

All data concerning the dose received by people approaching patients after implantation have been reviewed. Those doses have been either measured directly or calculated. The available data show that, in the vast majority of cases, the dose to comforters and carers is well below a value of 1 mSv/year. Only the (rare) case where the patient's partner is pregnant at the time of implantation may need specific precautions.

Expulsion of sources through urine, semen, or the gastrointestinal tract is rare. Specific recommendations should be given to patients to allow them to deal adequately with this event. Of note, due to the low activity of an isolated seed and its low photon energy, no incident or accident linked to seed loss has ever been recorded.

The cremation of bodies (frequent in some countries) in the first few months after implantation 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. Review of 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.

Specific recommendations have to be given to the patient to warn his surgeon in case of subsequent pelvic or abdominal surgery. A 'wallet card' with all relevant information about the implant is useful.

In most cases, brachytherapy does make the patient infertile. However, although the therapy-related modifications of the semen reduce fertility, patients must be aware of the possibility of fathering children after such a permanent implantation, with a limited risk of genetic effects for the child.

Patients with permanent implants must be aware of the possibility of triggering certain types of security radiation monitors. The 'wallet card' including the main information about the implant (see above) may prove to be helpful in such a case.

Considering the available experience after brachytherapy and external irradiation of prostate cancer, the risk of radio-induced secondary tumors appears to be extremely low. The demonstrated benefit of brachytherapy clearly outweighs, by far, the very limited (mainly theoretical) increase in the radiation-induced cancer risk.

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