2. FRAMEWORK FOR RADIATION PROTECTION IN PAEDIATRIC RADIOLOGY

2.1. BASIS FOR RADIATION PROTECTION IN PAEDIATRIC RADIOLOGY

The basis for radiation protection in pediatric radiology is well recognized.It includes the requirement that there be a clear delineation of responsibility extending from the level of the board of governors of the facility (e.g. a hospital or clinic) involved, to the operational level. The requirement for involvement of the hospital management and the need for a good operational structure which can deliver both the required technical and scientific advice and its effective implementation in the clinical environment is also well recognized [2, 3, 12].

It is key to successful development, in this regard, that the head of department be aware of and accept and discharge his or her responsibilities with respect to radiation protection.

The licensee of the pediatric radiology facility, through theauthorization issued by the regulatory body, has the prime responsibility for applying the relevant national regulations and meeting the conditions of the license. The licensee retains overall responsibility, but may appoint other people to carry out actions and tasks related to these responsibilities. In particular, the radiological medical practitioner[1], the medical physicist[2], themedical radiation technologist[3] and the radiation protection officer[4] (RPO) all have key roles and responsibilities in radiation protection in the pediatric radiology facility.

A medical physicist needs to be available to fulfil, oversee or advise on radiation protection requirements for imaging, calibration, dosimetry and quality

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[1] The term 'radiological medical practitioner' is defined in the BSS [2] (see Appendix III), and is used to cover the range of health professionals that include radiologists, nuclear medicine physicians, radiation oncologists, cardiologists, dentists and other specialists that might use radiation. In this publication, the term 'radiological medical practitioner' is used when the more general sense is appropriate and, at other times, the names of specific health professionals are used when this gives better clarity.

[2] The term 'medical physicist' is defined in the BSS [2] (see Appendix III).

[3] The term 'medical radiation technologist' is defined in the BSS [2] (see Appendix III), and is used to cover the range of health professionals that are known by various terms in different parts of the world, and include radiographers, radiation technologists and nuclear medicine technicians.

[4] The term 'radiation protection officer' is defined in the BSS [2] (see Appendix III).

assurance in pediatric radiology, and an RPO has to be available for radiation protection matters with respect to staff and members of the public and to advise on general regulatory requirements for radiation protection. In many cases, these two roles may be carried out by one person, where that person is recognized as having the requisite specialist competence for both roles. The medical physicist and the RPO also have to be closely involved in the development of the department's operational arrangements and its safety policies, and in monitoring, reviewing and revising these arrangements.

In practice, a radiation protection committee is normally required, with the various stakeholders, including management, represented. A member of the department is usually appointed as RPO. The RPO's responsibilities include monitoring the implementation of the committee's policies. When a department is sufficiently large to allow roles to be differentiated, the RPO may not hold key departmental line management roles, such as head of department or chief medical radiation technologist.

In practice, radiation protection relies on meeting requirements [2] that apply three principles adopted in most regulatory systems throughout the world [13, 14]. These requirements concern:

— Justification of the activities or practices involved;
— Optimization of protection and safety in the activities or practices involved in terms of risks, costs, benefits, etc.;
— Limitation of the doses received by various groups, including workers and the general public.

Discussions of various aspects of these arrangements are available from many sources [2–4, 12–14].

2.2. JUSTIFICATION

2.2.1. General considerations

The benefits of many procedures that utilize ionizing radiation are well established and well accepted both by the medical profession and society at large. When a procedure involving radiation is medically justifiable, the anticipated benefits are almost always identifiable and are sometimes quantifiable. On the other hand, the risk of adverse consequences is often difficult to estimate and quantify. In its 1990 and 2007 recommendations, the International Commission on Radiological Protection (ICRP) stated as a principle of justification that "Any decision that alters the radiation exposure situation should do more good than

harm" [12–14]. A stronger position on justification of medical exposures is often taken to the effect that the 'good' (i.e. the benefit) has to substantially outweigh any risks that may be incurred, in part because of the uncertainty of the risks [15].

The ICRP has recommended a multi-step approach to the justification of patient exposures, and this is further discussed in Section 2.2.3 [12–14]. In the case of the individual patient, justification normally involves both the referring medical practitioner (who refers the patient, and may, for example, be the patient's physician and/or surgeon) and the radiological medical practitioner (under whose responsibility the examination is conducted) (see Appendix III).

Since 2007, there has been a heightened sensitivity to justification in pediatric radiology. This has become more visible due to both concerns emerging in scientific publications and events reported in the media [16–19]. More recently, the IAEA and the Alliance for Radiation Safety in Pediatric Imaging (the Image Gently Campaign) have articulated these concerns and have provided both a structured approach to solutions and a forum for development inthe area [10, 20].

Justification for radiation exposure almost inevitably involves a physician familiar with the patient and the medical history. Normally, an appropriately qualified medical or dental practitioner (e.g. a radiologist, cardiologist or dentist) takes overall responsibility for the conduct of an examination and needs to work in close cooperation with the referring physician(s) in order to establish the most appropriate procedure for the management of the patient.

It is particularly important with infants and children that the feasibility of alternative techniques that do not use ionizing radiation (e.g. ultrasound and magnetic resonance imaging (MRI)) be considered. This is even more important in children with chronic diseases. Some jurisdictions, for example, in the European Union (EU), add a requirement that where an examination cannot be justified it should be prohibited [5]. An effective way of improving good justification practice is to include it as part of a program of clinical audit [17, 21].

2.2.2. The physician's and radiologist's knowledge

Education and training of both referring physicians and radiologists play a crucial role in ensuring that justification works well in practice. Effective justification requires that these physicians possess knowledge of the particular case and its circumstances. Current experience and the published literature suggest that, in many clinical settings, the referring practitioner may have limited awareness of the radiation doses and risks involved [15–18]. As advocated by the Image Gently Campaign and many individual workers, it is essential that those actually performing the procedures be well informed [10, 20–24].

In practice, knowledge of the situation always has to be viewed in the context of what can reasonably be expected. New knowledge can and needs to be acquired as developments occur. The knowledge required for justification includes:

— The clinical history, including examinations already performed;
— Potential benefits of the action;
— Awareness of short term and long term consequences, including the risks;
— Up to date knowledge of any available alternative actions;
— Knowledge of the consequences of not taking any action;
— Knowledge of referral guidelines and/or acceptability criteria where they are available.

2.2.3. Justification, the ICRP and the procedure

The ICRP identifies three levels at which justification operates [12, 14]. Level 1 deals with the use of radiation in medicine in general. In practice, such use is accepted as doing more good than harm to the patient, and its justification is taken for granted. Level 2 deals with specified procedures with a specified objective (e.g. chest radiographs for patients showing relevant symptoms). The aim at this level is to judge whether the procedure will improve diagnosis or provide necessary information about those exposed. Finally, Level 3 deals with the application of the procedure to an individual (i.e. whether the particular application is judged to do more good than harm to the individual patient). In practice, all individual medical exposures need to be justified in advance, by taking into account the specific objectives of the exposure and the characteristics of the individual patient.

2.2.4. Justification and the patient

Each person, including children and adolescents, has dignity, and is entitled to a reasonable expectation of health. Respect for the dignity of each individual is grounded in contemporary philosophical, social and legal thinking on the nature of the person [15, 17, 18]. It has implications for the level of involvement of the individual and/or their guardian or legal proxy in deciding whether a radiological examination is required or appropriate. Thus, the individual is entitled to know what is to happen [15, 22]. Parents of some children may desire to have information about radiation risk, in particular for high dose examinations such as CT or fluoroscopy guided interventions. Responsibility for providing this information could lie with both the clinician requesting the study and the radiologist. In some situations, the patient may be referred to a medical physicist for dose estimation.

In spite of concern, some patients may misinterpret radiation risk and may refuse a useful or potentially life saving examination for fear of radiation. There is evidence that explaining the risk will not dissuade patients from undergoing the examination, even when the risk is explained to parents of children in theradiation sensitive age group [23, 24]. However, this may not be universally trueand will depend upon the local conditions of societal and individual perception ofradiation risk. A brief information handout can improve parental understanding of the risk related to exposure to ionizing radiation, without causing parents to refuse studies recommended by the referring physician [10, 24]. Information on risk to children undergoing high dose examinations may not interfere with appropriate care and may improve parental understanding.

Alternative approaches that induce confidence are likely to be very powerful. These include assurance that the CT facility is certified by an appropriate body that oversees radiation doses to patients, that there is a system in place for regular monitoring of radiation doses to patients and comparing with national or international standards, and maintaining doses within the reference levels. Patients and parents are likely to be satisfied more by the availability of quality control and dose management mechanisms being in place rather than by information on radiation doses that the patient may not understand. A programof informing parents about the radiation risks associated with relatively high dose procedures and the benefits of the procedure is a good practice.

2.2.5. Justification of medical exposures and dose limits

The ICRP has recommended that dose limits not be applied to medical exposures and, even with the higher radiation sensitivity of children, this recommendation is also applied to pediatric radiology. It is based on the fact that the exposed individual will derive benefit from the procedure, provided it has been properly justified. The BSS state that dose limits are not to be applied to medical exposures [2]. This approach has been adopted in all countries and, thus,dose limits are not applied to patients for justified procedures [12].

2.2.6. Non-medical procedures

Procedures involving exposure to ionizing radiation that may not yield direct health benefits for the exposed individual may be permitted or required by law in some jurisdictions [25–27]. Examples include, but are not limited to, imaging required for security purposes, purposes of crime detection or prevention, or medico-legal purposes of insurance companies or the courts.Examples of areas where exposures of this type may arise in pediatric radiology

include surveys of siblings in cases of suspected non-accidental injury, or age determination in court cases or migration tribunals.

The justification for such practices sometimes involves consideration of the public interest or the common good. Such practices are outside the scope of this Safety Report, but it is noted that the BSS set out requirements for justification and optimization for these practices [2].

2.2.7. Referral and/or appropriateness guidelines and clinical audit

A number of tools are available to facilitate identification of the correct radiological examination for a particular patient presentation. The most widely known involve "appropriateness or referral criteria and/or guidelines". Referral guidelines provide advice on the appropriateness of imaging modalities and specific examinations for many common clinical presentations. They also help exclude inappropriate examinations. In addition, the radiation dose and the strength of the evidence base for the advice offered are indicated. These guidelines need to be available to all clinicians who request imaging studies on children and adolescents.

An updated version of the referral guidelines for pediatric radiology published by the EC is reproduced in Appendix II [28, 29]. These guidelines and/or criteria and their application in practice are under revision and are further discussed in the justification sections of Sections 4–7. Further examples of guidance include the appropriateness criteria developed by the American College of Radiology in the United States of America, and the guidelines produced in the United Kingdom [30, 31]. There is much variability in the extent to which these tools are implemented in practice.

Tools of this type, or similar systems, are essential. In application, they provide an effective 'technology' that has recently been reviewed and has been shown to prevent inappropriate examinations and, thereby, reduce unnecessary radiation doses in adults [17]. They also show promise with younger patients, even though there is a dearth of studies in pediatric radiology [32]. Due to the value of such tools, the BSS require that relevant national or international referralguidelines be taken into account in the justification of a given radiological procedure for a given patient [2].

These tools have limitations in that they could be considered as advice and need not be given the status of a legal or required standard of practice. They need to be used with discretion in light of concrete situations, such as the immediately accessible technology and the condition, age and social circumstances of the patient. Regardless of the quality of the publicly available guidelines, there is a need for special consideration in pediatric radiology because of the different patterns of presentation and distribution of diseases.

There is widespread pressure to use radiological imaging techniques to screen for many diseases. In many cases, this form of health screening cannot be justified for unselected populations based on the overall risks and benefits involved. However, there may be considerable pressure from individual professionals and the public to undertake programs of radiological imaging for health screening purposes.

While, to date, such pressures are not a feature of pediatric radiology, it is conceivable, given developments in the area, that they may arise in the future. If this is the case, then such a proposed health screening program for pediatrics would need to be justified by the relevant health authority in conjunction with appropriate professional bodies [2]. This approach is similar to those already established for selected groups (e.g. mammography for women in certain age groups).

A neglected aspect of justification of medical exposures is the audit of its effectiveness. Recent developments in clinical audit of radiology have included approaches to audit of justification [17, 21, 33]. Referral and/or appropriateness guidelines can provide a useful benchmark for audit. Some audit studies with adults have demonstrated the potential for significant sustainable dose savings in the range of 20–50%. There is every reason to believe that such savings could also be achieved in pediatric radiology. Considerable future activity is anticipated in this area [17]. In a similar focus but strictly for radiation protectionpurposes, the BSS have a requirement that a radiological review be performed periodically, and this would include a critical review of the practical application of justification in the given facility [2].

2.3. OPTIMIZATION OF PROTECTION AND SAFETY

Once examinations are justified, they are required to be optimized (i.e. performed at a lower dose while maintaining efficacy and accuracy). Optimization of the examination has to be generic for the examination type and all of the equipment and procedures involved. It will also be specific for the individual, and include a review of whether or not it can be effectively done in a way that reduces the dose for the particular patient. For example, can a lower dose be used because less contrast or resolution is required, or because the patientis small, or can the irradiated volume be reduced?

Much of the material in Sections 4–7 can be viewed as contributing to the optimization process, including diagnostic reference levels (DRLs), dose constraints, good technique, good practice and optimized equipment subject to a regular quality assurance program. Most of these areas need additional

attention in pediatric radiology as the available literature is, for the most part, based on radiology studies in adults.

Regulatory systems generally recognize that patients benefit from medical exposures. They essentially strike a bargain on behalf of society that dose limits will not be applied to justified medical exposures. This bargain places the burden of justification on the radiological medical practitioner and the referring practitioner [2, 5].

Medical exposure also includes exposures of individuals, such as members of the patient's family, who comfort or care for the patient during a medicalexposure [12, 25]. This includes family members who help restrain a child during aprocedure. The definition of medical exposure is also extended to include exposuresthat are incurred as part of a program of authorized biomedical research.

2.3.1. Diagnostic reference levels

In the absence of dose limits, radiologists and other practitioners are often concerned to establish whether their practice is reasonable and whether they are achieving satisfactory examinations at reasonable dose levels. The adoption and use of pediatric protocols is paramount to achieving this goal in facilities in which children are imaged.

A tool for optimization is the concept of DRLs. These act as a trigger for review and are not intended to function as surrogate dose limits [12]. The BSS mandate their use [2]. In practice, they tend to be set so that if the values involved are exceeded, the radiological procedure involved needs to be investigated. This does not mean that there is necessarily anything wrong occurring, rather that there is something unusual which requires explanation, review and, possibly, a new approach. The DRL for an examination is generally derived from a regionalor national survey of the doses for that examination. It is usually taken as the third quartile dose value for the dose distribution obtained in the survey, i.e. the dose value below which 75% of doses lie [34].

This may be illustrated by examining the EC's DRLs for 5 year old children in Table 2 [35]. These were established by surveying the doses received for a number of the more common projections in a range of institutions throughout the EU in the early to mid-1990s. For general radiography, various projections of chest, skull, abdomen, spine and pelvis are included. In practice, doses that were easy to measure, usually entrance surface dose (ESD), were taken. The terminology currently employed, with updated approaches to dosimetry, is slightly different but the numerical values are little changed [36].

As the DRL is taken as the third quartile dose value, there is a reasonable expectation that measurements averaged over a number of patients in any institution will lie below it. If the dose is systematically above the DRL, it is

relatively easy to identify problems, if any, and to correct them without loss of clinical information. For example, it might be the unnecessary use of a grid. It is also possible that the dose may be too low, and corrective action in this regard, in pursuit of necessary improvements in image quality, may also be warranted.

The values shown in Table 2 are from surveys conducted in 1996 and for 5 year olds. Different values might be obtained with newer technology, better techniques or newer dosimetry protocols, and with infants or 10 year olds. The values and units used in this publication are those employed in the publications cited. Some more up to date data for individual countries, involving newer equipment, and with older and younger age groups, are available (see Section 4.2.2 and Appendix III). Some of these are used as local departmental, regional or national reference values. However, more up to date EC or other international DRLs have not been adopted. This is a significant deficit in the support system necessary for optimization of protection and safety in pediatric radiology. Reference doses for other techniques are presented in the appropriate parts of Sections 4–7.

Finally, it is necessary to be aware that achieving dose levels below the DRL does not guarantee that optimization of protection and safety has been achieved. For example, one hospital in the United Kingdom has achieved local reference doses that are routinely 5–25 times less than the national DRLs. The hospital attributes this to careful optimization of all of the equipment and

TABLE 2. THE EUROPEAN COMMISSION'S DIAGNOSTIC REFERENCE LEVELS (STANDARD 5 YEAR OLDS) [35]

Radiograph	Entrance surface dose per image (μGy)
Chest PA	100
Chest AP (for non-cooperative patients)	100
Chest lateral	200
Chest AP (newborn)	80
Skull PA/AP	1500
Skull lateral	1000
Pelvis AP	900
Pelvis AP (infants)	200
Abdomen AP/PA (with vertical/horizontal beam)	1000

Note: AP: antero-posterior; PA: postero-anterior.

technique steps in the imaging process [37]. Thus, while DRLs are useful, they are not the only tool in the 'optimization toolbox' and the use of parallel approaches to implementing optimization needs to continue.

2.4. DOSE LIMITS AND DOSE CONSTRAINTS FOR OCCUPATIONALLY EXPOSED WORKERS, CARERS AND COMFORTERS, AND MEMBERS OF THE PUBLIC

Occupational exposure of radiation workers in hospitals or dental practices is treated in depth elsewhere and will not be addressed in detail here [2, 38]. Nevertheless, the dose limits for occupationally exposed workers and the dose limits for members of the public are provided in Table 3 [2]. In general, with good practice and good facilities, there will be no difficulty meeting the limits for workers, even for interventional procedures and special procedures (Section 5). However, in the absence of good practice or good facilities, there is some risk in these areas. Advice is provided that will help workers deal with these situations.

With regard to exposure of members of the public, this will not normally happen during pediatric radiology. Relatives or friends of the child will be classified as carers and comforters when they willingly and necessarily accompany, comfort, restrain or care for a child during a diagnostic procedure. Exposures received by them in these circumstances are classified as medical exposures and are not subject to the dose limits for public exposure [2, 5, 12, 39]. This arises because there is a direct benefit, both to the patients and to those who care for them.

Carers and comforters have to be provided with adequate information on how to protect themselves and, where necessary, with appropriate protective clothing and/or devices. Pregnant women are not to be allowed to assist in this

TABLE 3. DOSE LIMITS FOR OCCUPATIONALLY EXPOSED WORKERS AND FOR MEMBERS OF THE PUBLIC [2]

Type of limit	Occupational exposure	Public exposure
Effective dose	20 mSv per year	1 mSv per year
Annual equivalent dose to:		
Lens of the eye	20 mSv	15 mSv
Skin	500 mSv	50 mSv
Hands and feet	500 mSv	—

Note: Some flexibility with regard to averaging over longer periods is allowed [2].

way. The BSS [2] treat the selection of constraints for carers and comforters as a complex process in which it is required to take a number of factors into account, including the possibility that the individual carer or comforter is pregnant.

Dose constraints are a valuable planning tool in this context. They are used as an upper bound on the doses that individuals might expect to receive from a planned procedure, such as comforting, caring for or assisting with immobilization of a patient. An international consensus has not fully evolved on appropriate values, but those in Table 4 have been recommended by both the IAEA and the EC for those involved in a single episode of radio-iodine therapy [40–42]. These values are not to be rigidly applied as a dose limit. They may be exceeded where circumstances warrant it, for example, in the case of a particularly serious illness or difficult intervention [12, 41].

2.5. UNNECESSARY EXPOSURES

Unnecessary radiation exposures of patients can arise from failures of optimization or from errors. In pediatric radiology, these would include a radiological procedure performed on the wrong person, the wrong body part being subject to the exposure, the exposure being substantially greater than was intended, or, in the case of an adolescent girl, the inadvertent exposure of an embryo or fetus. Such events need to be investigated to determine the doses received and to determine and implement the corrective actions that are needed to prevent recurrence of the event. In some cases, such as for significant doses and as required under the law, the event would have to be reported to the regulatory body [43]. In all cases, the patient and the referring medical practitioner have to be informed [2].

TABLE 4. PROPOSED DOSE CONSTRAINTS FOR EXPOSURE FOR FAMILY AND CLOSE FRIENDS AS CARERS AND COMFORTERS [40, 41]

Age	Dose constraint (mSv)
Children (including unborn children)	1
Adults up to about 60 years old	3
Adults over 60 years old	15

2.6. SPECIAL CONSIDERATIONS ASSOCIATED WITH PREGNANCY

The general provisions of the BSS [2] and/or national legislation and professional codes of practice are required to be observed with respect to pregnant or potentially pregnant, occupationally exposed workers, and exposure of carers and comforters, and members of the public. These will not be repeated here and the reader is referred to the standard literature in this area [44–46].

Pregnancy can occur in adolescent girls. Precautions for this group have to be taken for exposures that may involve a foetus, and such exposures need to be avoided where possible. In female adolescents who are menstruating, the ten day rule needs to be considered when procedures with high exposures are involved, such as examinations or interventions involving the abdomen, pelvis or uterus, and in particular CT [45].

With this group, care and sensitivity have to be exercised with regard to the circumstances in which they are asked the relevant questions, so as both to respect their privacy and to increase the likelihood of being told the truth. With respect to pregnancy tests, many are of little value in excluding early pregnancy.In the EU, pregnancy is assumed in females of childbearing age in whompregnancy cannot be explicitly excluded. If the requested examination is considered urgent, the referring clinician may override these concerns [45].

2.7. RESEARCH INVOLVING IRRADIATION OF CHILDREN

Biomedical research involving the use of ionizing radiation in children has to be performed within the well established framework provided by national and international recommendations [2, 5, 14]. This generally includes the provision that the research be approved by an ethics committee or institutional review board. The ethics committee or equivalent will generally include representatives of both institutional and public interests, who will consider the radiation benefitsand risks associated with the use of radiation in the proposed research as just onepart of their approval process. It is, therefore, essential that correct information ondoses, risks and benefits, with respect to the proposed exposures, be presented tothe ethics committee as part of the research proposal.

The use of repeated radiographs or CT scans to monitor progress in, for example, drug trials can only be undertaken after much deliberation. The examinations, where possible, have to be limited to essential scans or views. For example, yearly full skeletal survey examinations may not be necessary tomonitor progress of therapies for Gaucher’s disease. The use of dose constraints for exposures incurred as part of biomedical research is a practical means for radiation protection, and ethics committees need to specify such constraints in

granting their approval [2]. The detailed requirements are not addressed here but attention is drawn to the special issues involved in irradiation of children. Research is generally severely proscribed and is to be undertaken only when there is no alternative.

2.8. EDUCATION AND TRAINING

The need for medical practitioners providing radiological services, and for other professions, including medical physicists and medical radiation technologists, to undertake additional special education and training is well recognized and has been extensively discussed elsewhere [2–4, 12, 47, 48]. Formally recognized training in the radiological techniques involved and in radiation protection is required. Radiologists, medical physicists and medical radiation technologists working with children need to have specific training in the special issues that arise in pediatric radiology, over and above their general radiological training.

There is value in emphasizing the team approach to operational aspects of radiation protection and dose reduction programs. Once such practitioners are trained, the need for continuing professional development in new techniques and technologies has to be recognized. The special needs for information and training of carers and comforters also have to be attended to in departmental training programs.

Training material in support of the above areas and many of the objectives mentioned are available with free downloads of related presentations from the IAEA's Radiation Protection of Patients web site [20] and the Image Gently web site [10].