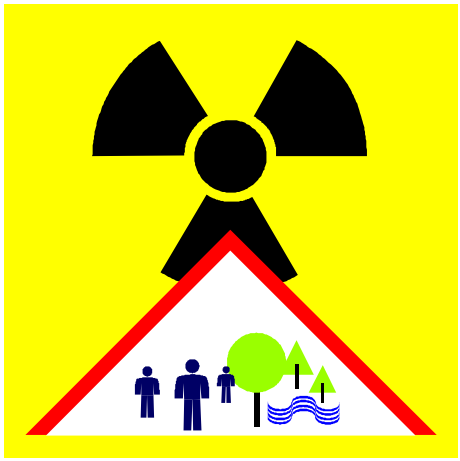
Radiation protection 102



Implementation of the "Medical Exposure Directive" (97/43/Euratom)

Proceedings of the international workshop held in

Madrid, on 27 April 1998

European Commission

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1998

Directorate-General
Environment, Nuclear Safety
and Civil Protection

Foreword

The Council of the European Union issued the Medical Exposure Directive (MED) 97/43/Euratom on 30 June 1997. Member States must implement the Directive in national legislation no later than 13 May 2000.

To assist Member States with transposing the Directive the European Commission developed a number of technical guidelines directly related to explain further parts of the Directive.

This conference was designed to promote knowledge on the MED and the related guidelines on the one hand and to bring about a discussion on practical ways of transposing the Directive on the other.

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D. TEUNEN	EC/DG XI.C.1 – Radiation Protection (scientific secretariat)

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Opening address

by Mr. José-Manuel ROMAY-BECCARIA
Spanish Minister of Health

Mr Kindelán (President of the Nuclear Safety Council), Mrs Frigren (Director of the Nuclear Safety Directorate, DG XI), Mr Juan José Francisco Polledo (Director-General for Public Health), Mr Kaiser (Head of the Radiation Protection Unit at the European Commission), Ladies and Gentlemen:

It is a great pleasure for me to take part in this opening session of the Workshop on the implementation of the Directive on health protection against the dangers of ionising radiation in relation to medical exposures. I wish you all a warm welcome to our hospitable city and would like to thank you for selecting the Ministry of Health and Consumer Affairs as the venue for this important meeting. I would also like to congratulate the European Commission's Directorate-General for the Environment, Nuclear Safety and Civil Protection on its initiative in calling this meeting. Finally, I would like to thank the Spanish Radiation Protection Society and, of course, all the other scientific bodies, industry representatives, public authorities and experts involved in the radiation protection of patients for their participation and collaboration.

During the Workshop we will have an opportunity to exchange views and experiences and thus become more familiar with the principles underlying Directive 97/43/Euratom. I am sure that the final results of this meeting will make it easier for the Member States to transpose the new directive into national legislation.

The Directive is basically intended to bring about improvements in patient safety and protection by extending the application of the principles of justification and optimisation of medical exposures already set out in earlier directives. This will bring undoubted health benefits and, above all, will improve the protection afforded to patients by reducing exposures.

Of special interest are the newly-introduced requirements concerning paediatric exposures, health screening programmes, practices involving high doses, preventing the exposure of pregnant and breastfeeding women, and the introduction of quality assurance programmes in radiological installations.

The radiation protection of patients and health professionals is one of the priority aims of the Ministry of Health and Consumer Affairs and is organised jointly with the Nuclear Safety Council and the Autonomous Communities. To do this, and ensure that radiation protection programmes are effectively implemented, a coordinating committee has been set up within the Interregional Health Council. Through this committee's efforts, there has been a national census of diagnostic radiology, nuclear medicine and radiotherapy installations, criteria have been drawn up to avoid the unnecessary proliferation of installations, and the inspection and monitoring programmes for these installations have been harmonised.

I would like to stress that the setting up of this committee within the Interregional Council, which is the highest coordinating body in the national health service, enables us to ensure in the most effective way possible that European and national legislation on protection against ionising radiation is applied uniformly throughout Spain.

I would also like to point out that many of the requirements in the new Directive have been transposed into Spanish legislation by Royal Decree 1841/1997, which lays down quality criteria in the nuclear medicine field. In addition, the Government will shortly be approving another royal decree on quality

criteria for radiotherapy. Finally, there is a royal decree on quality criteria for diagnostic radiology, which will be submitted to the European Commission within the next few weeks.

This legislation clearly demonstrates that the Ministry of Health and Consumer Affairs is determined to make the necessary arrangements by the time the new Directive enters into force in May 2000.

In this connection, I would like to express my thanks for the excellent advice given by officials from DG XI's Radiation Protection Unit, who collaborated with officials from the Ministry of Health's Directorate-General for Public Health.

To end, it is my view that this workshop, in which I hope you will all play an active part, will enable us to exchange ideas and information so as to arrive at a thorough understanding of the contents and purpose of Directive 97/43/Euratom. I have no doubt that this will make it easier to transpose the directive into national legislation throughout the European Union.

Thank you for your attention. I hope you have a happy stay in Madrid and trust that you will find time to enjoy the attractions of our city.

Opening address

by Mrs. Suzanne FRIGREN
European Commission

Ladies and Gentlemen,

It is my pleasure to welcome you in name of the European Commission to this workshop on the implementation of the Medical Exposure Directive which was approved by the Council of Ministers on 30 June 1997.

First of all, I would like to thank the Spanish co-organisers of this workshop, the Ministry of Health and Consumers affairs and the Spanish Association for Radiation Protection, for their invaluable contribution to ensure the success of the workshop.

The European Commission considers the Medical Exposure Directive a very important tool to consolidate the good level of radiation protection achieved under the 1984 Directive and, at the same time, to optimise protection where possible taking into account, among other factors, scientific and technical progress.

In its effort to create the best possible conditions for implementation, the European Commission has organised today's workshop as a first attempt to establish a positive environment for a more harmonised approach to implementation. An intensive exchange of views between administrators, professionals daily involved in the medical use of ionising radiation and the manufacturers of radiological equipment coming from all Member States as well as from outside the Union, should allow competent authorities to learn about practical aspects of implementing the Directive.

This workshop focuses on a number of key-issues, which may require special attention because they are new compared to the 1984 Directive or simply because experience has shown that problems can arise. Nine experts will give you a brief introduction to each issue highlighting essential questions.

The final success of this workshop, however, largely depends on your input to the discussion bearing in mind that bringing up proposals for solutions today may prevent difficulties in a later stage of the procedure.

For the European Commission this workshop is not the end but rather the beginning of a continuous effort of assisting the Member States and it is my conviction that similar multilateral and bilateral consultations will take place during the next two years.

Finally, I would like to thank you all for attending in such large number and I wish you a very successful meeting.

Opening address

by Mr. Juan Manuel KINDELAN
Consejo de Seguridad Nuclear

Minister, Mrs Frigren, Ladies and Gentlemen:

I would like to start by thanking the organisers of this Workshop – the European Commission, the Ministry of Health and the Spanish Radiation Protection Society – for their invitation to take part in this opening ceremony, which gives me an opportunity to share some thoughts on certain aspects associated with the implementation of Directive 97/43/Euratom.

Throughout this century, and particularly in the last 50 years, the use of ionising radiation had developed enormously in both the diagnostic and therapeutic fields. Medical imaging protocols, procedures for isotope-based function tests and the use of radiotherapy facilities embrace a range of techniques in which ionising radiation makes a fundamental contribution to the detection and treatment of particular diseases.

However, it is important to remember that all applications of ionising radiation must be carried out with a wide safety margin, by controlling the risks to individuals and preventing environmental contamination. Achieving this aim has been and will continue to be one of the main priorities of the health authorities and the regulatory organisations in every country, not to mention the professionals working in this field. As an illustration of this, an international conference was held in Seville last November, sponsored by the International Atomic Energy Agency (IAEA) and the World Health Organisation (WHO) and coordinated by the Nuclear Safety Council. It was attended by over 500 experts from 65 countries, who examined the biological, epidemiological and regulatory aspects of low radiation doses and reviewed the latest scientific knowledge on this subject.

As for Spain, my own organisation (the Nuclear Safety Council) and the Ministry of Health have set up a working group within the Interregional Health Council, which is the body that coordinates health policy in Spain and includes representatives from the Autonomous Communities and central government. The remit of this group is to look at all aspects of radiation protection in hospitals and clinics throughout the country.

The European Commission has always been extremely vigilant and active in this area, as shown by the approval in 1984 of an initial directive laying down basic measures for the radiation protection of persons undergoing medical examination or treatment. This has been replaced by Directive 97/43, which we are here to discuss and which regulates in a much more precise and exhaustive way the various aspects of protection for patients and medical staff against the risks associated with medical uses of ionising radiation.

The transposition of the Directive into the national legislation of the Member States will signal the incorporation into daily medical practice within the EU of the three principles recommended by the International Commission on Radiological Protection, namely justification, optimisation and limitation of individual doses. This will benefit the ever-increasing number of patients who are exposed to ionising radiation.

Today's workshop provides a valuable and timely opportunity to foster debate and encourage the competent authorities of the Member States, those responsible for health issues at the European Commission, general practitioners, prescribing physicians, radiation protection experts, professionals

involved in medical uses of radiation and industry representatives to exchange views on the best way of implementing the Directive in the area that concerns us.

As President of the Nuclear Safety Council, I would like to reiterate our commitment to collaborating with the Ministry of Health, as the law provides, in transposing the Directive into our domestic legislation and medical practice in the most effective way possible.

To end, I would like to congratulate you on taking this wonderful initiative. I am sure the workshop will be a great success.

Thank you very much.

Major changes in the Medical Exposure Directive

Diederik TEUNEN
European Commission

European legislation on radiation protection is governed by the EURATOM Treaty and the regulations, directives and other legislation developed in implementation of it. Directives are legal instruments that are binding on Member States as to their objectives but leave the freedom to the Member States to choose how to implement the directive into national law. The framework directive is the Basic Safety Standards directive (BSS) on the protection of the public and exposed workers against the dangers of ionising radiation. It covers practices, interventions and work activities. The directive actually in force dates back to 1980 and 1984 (80/836/Euratom and 84/467/Euratom). It was revised in 1996 (96/29/Euratom) to take into account the recommendations of the International Commission on Radiological Protection in ICRP 60. The scope of this directive covers all practices, including medical practices, but no specific requirements are present to protect the individual undergoing medical exposure. In fact, article 6 of the BSS confirms that a medical exposure is subject to the principles of justification and optimisation but excludes individuals who receive such exposure from the dose limitation principle. BSS are to be implemented in national law by Member States not later than 13 May 2000.

On 3 September 1984 the Council of Ministers issued a directive laying down basic measures for the radiation protection of persons undergoing medical examination or treatment (84/466/Euratom). This directive complemented the BSS as regards the protection of individuals undergoing medical exposures. The so-called “Patient directive” was the first specific attempt of the European Commission to define radiation protection concepts in medical application of ionising radiation.

The merit of the Patient directive is not only that it entailed legal initiatives to regulate medical radiation protection in all Member States but it also created the necessary platform for the further development of a “radiation protection culture” in this field. The directive was concise and had only 5 operational articles together with an annex with practical recommendations that were not binding on Member States.

The transposition of the directive in national law, which took place the following decade, showed that not all of the requirements present were clearly formulated and that in some cases improvement of the wording was required.

In 1994 the European Commission started the procedure for revising the Patient directive. The major objectives of this revision were to harmonise the directive with the new BSS, taking into account experience gained with the implementation of the Patient directive and taking account of scientific and technical evolution in medical practice.

The revised Medical Exposures Directive (MED) (97/43/Euratom), approved by the Council of Ministers on 30 June 1997, reaffirms the major objectives of the Patient directive i.e. to aim at optimum diagnostic efficacy at reasonable dose to the patient and to reduce the number of inadequate exposures. These objectives are pursued by 4 types of requirement:

- provisions relating to duties, responsibilities and qualifications of the staff of medical facilities
- provisions related to equipment
- provisions related to procedural requirements

– provisions related to ‘special practices’

The MED can be summarised as follows:

Article 1 entitled “Purpose and scope” is new. It links the MED directly to the BSS. According to this article not only ‘patients’ are covered by its requirements but other individuals, directly or indirectly exposed to a medical exposure, are covered as well. It gives a list of exposures such as in biomedical research, occupational health surveillance and medico-legal procedures.

Article 2 entitled “Definitions” is also new. It gives a list of definitions of terms used in the directive. The purpose of this article is to clarify further some requirements of the directive and to minimise possible misunderstandings. It also gives the directive a more updated look according to modern legal practice in the Union.

Article 3 “Justification” takes over the principles already present in the Patient directive and in the 1996 BSS. It makes the distinction between justification of practices which usually is a generic justification and justification of individual exposures. It also identifies those exposures where the justification requires special procedures or particular attention, such as exposure for medical or biomedical research, medico-legal exposure and the exposure of an individual assisting a patient.

Article 4 “Optimisation” also refers to a basic principle already present in the Patient directive but now makes a distinction between radiodiagnostic and radiotherapeutic procedures. It introduces the concept and use of diagnostic reference levels as a tool for optimisation and specifies particular requirements for exposures such as healthy individuals exposed during medical or biomedical research and individuals willingly and knowingly helping patients. These categories of people are not covered by the BSS as far as dose limitation is concerned. Therefore dose constraints to control exposures are required.

Article 5 “Responsibilities” is a new article stipulating the role of the practitioner, prescriber and the rest of the staff involved in a radiological procedure. It states clearly that the medical practitioner has the clinical responsibility for the exposure, but he may delegate parts of his responsibility to other, qualified and recognised, individuals. This article also requires Member States to lay down procedures to be observed in the case of medico-legal examinations. This means that the Member State must create a legal framework within which those exposures can take place, on condition that this type of exposure is considered justified by the Member State in the first place.

Article 6 “Procedures” identifies a number of requirements, some of which were already present in the Patient directive; others are new. It introduces three concepts of importance: the obligation to lay down a protocol per piece of equipment, the availability of referral criteria for prescribers and the introduction of clinical audit as part of the quality assurance programme. It also specifies that if the diagnostic reference levels as mentioned in article 4 are consistently exceeded, the practitioner should review his procedures and possibly take corrective action. Finally, it describes in greater detail the involvement of the expert in medical physics in radiological procedures. For this purpose different levels of involvement are given referring to the different types of exposures i.e. radiotherapy, diagnosis and nuclear medicine.

Article 7 “Training” refers back to article 2 of the Patient directive. It adds, however, the requirement to establish the necessary curricula and the recognition of corresponding diplomas, certificates or qualifications. It also insists on continuing professional education being available and Member States must encourage the introduction of radiation protection in the basic curriculum of medical and dental schools. It creates the possibility for those individuals still in training to participate in radiological procedures.

Article 8 "Equipment" groups requirements related to the duties of the holder of the installation and to the duties of competent authorities regarding equipment. Many of these requirements were present in the Patient directive such as the avoidance of unnecessary proliferation of equipment, strict surveillance, the availability of an inventory, steps to be taken in case of inadequate or defective equipment and the drawing up of criteria of acceptability (minimum criteria) for equipment. Some of the requirements of 1984, however, were strengthened, for example the prohibition of fluoroscopic examinations without image intensification. It also introduces the concept of quality assurance programmes and acceptance testing and performance testing of the equipment. For new diagnostic equipment a device informing the practitioner on the quantity of radiation produced during the exposure should be present with the aim to enhance his awareness as far as administered dose is concerned.

Article 9 "Special practices" identifies three categories of exposure that merit special attention from the radiation protection' point of view. The exposure of children, because of their greater sensitivity to radiation, health screening programmes because healthy individuals are exposed and those procedures involving exposure to high doses, particularly if deterministic effects may occur. The MED stresses the need to pay special attention in this case to quality assurance and quality control measures for equipment and to ensure adequate training of the staff.

Article 10 "Special protection during pregnancy and breastfeeding" lays down the framework to be respected in the case of radiological examinations of women of childbearing age or breastfeeding. In particular the justification (urgency) and the optimisation of the procedure are addressed.

Article 11 "Potential exposures" makes the link to the BSS's equivalent articles in specifying the particularities of accident prevention in medical applications, especially in radiotherapy. It also gives the tools to be used for this purpose i.e. application of quality assurance programmes and the correct use of the criteria of acceptability as mentioned in article 8.

Article 12 "Estimates of population doses" links up with article 14 of the BSS. It says that individual dose estimates from medical exposures should be made. There is also an indirect link with the establishment of diagnostic reference levels as mentioned in article 4.

Article 13 "Inspection" makes clear that Member States have a duty to control the provisions of the directive. This requirement was implicitly present in the Patient directive, but now distinction is made between quality control at the level of the holder (and user) of the installation and an external control performed by the Member State's competent authority or an equivalent recognised body.

Article 14 "Transposition into Member State law" gives, consistent with the BSS, 13 May 2000 as the latest date for complying with the MED. The Patient directive will then be repealed.

The European Commission, with the help of the scientific experts established according to article 31 of the EURATOM Treaty, is developing several technical guidelines to assist Member States with the implementation of the MED in national law. These documents are not binding on Member States but must be considered as practical examples. Guidelines on the development of criteria of acceptability of radiological and nuclear medicine installations were recently published in collaboration with Member States' competent authorities. Other topics covered are protection of family and friends of patients treated with I-131, protection of the unborn child, protection during medical and biomedical research and the establishment and use of diagnostic reference levels.

Conclusion

The Medical Exposures Directive (97/43/Euratom) strengthens the provisions of the old Patient directive (84/466/Euratom). It also expands the scope of application to individuals other than patients.

It introduces several new concepts such as quality assurance, clinical audit and acceptance and performance testing of equipment etc. This MED is to be implemented in national law before 13 May 2000 at which date the Patient directive will be repealed.

Radiation protection following Iodine-131 therapy

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The Hague – The Netherlands

This paper addresses the most important aspects of the publication " Radiation Protection following I-131 Therapy" from the regulatory point of view. The guidance given in this publication also applies to I-131 diagnosis in those (rare) cases where relatively high levels of I-131 (up to 400 MBq) are used, but does not apply to I-131-MIBG therapy or therapies with other radionuclides because the situations differ widely and require different guidance.

In his paper, Mr Teunen mentioned medical exposures as being radiological exposures relating to:

- patients
- occupational health surveillance
- health screening
- biomedical and medical research
- medico-legal procedures

For the present paper, it is important to note that the Medical Exposures Directive (MED) also applies to '*exposure of individuals knowingly and willingly helping (other than as part of their occupation) in the support and comfort of individuals undergoing medical exposure' (Article 1(3)).*

This paper deals with patient discharge levels, the justification and optimisation of these levels, the instructions to be given before discharging and the responsibility for discharging.

Aim of the guidance

For convenience the term 'discharge levels' is often used, even though out-patients cannot, strictly speaking, be discharged. The term covers the levels of discharge of in-patients as well as the level up to which out-patient treatment is allowed.

A working party of the Article 31 group recently tried to come up with harmonised discharge levels following iodine treatments. But it soon became apparent that this was for the time being not possible. The differences between Member States were too great.

One reason for this is the different outcome of the justification process as applied to discharge levels in the Member States: in some Member States there is a lack of specially protected rooms to hold patients for one or more days while in other countries the costs for an in-patient are considered too high for this particular purpose. Therefore, higher levels than elsewhere are justified in such cases. On the other hand, there are countries where doses received by other people should be very low before the patient can go home, resulting in discharge levels which are quite low.

As a result of the social and economic factors taken into account when justifying them, discharge levels in the Member States differ widely, ranging from 95 to 800 [sometimes even 1100] MBq I-131.

In the Netherlands the discharge level up to about 4 years ago was 200 MBq, but it is now 400 MBq as a result of a review of the justification. In Germany it is still 95, but will probably be raised to 250 MBq.

These different approaches made it impossible to agree harmonised discharge levels, but the article 31 group did succeed in recommending harmonised dose constraints and harmonised instructions for behaviour after leaving the hospital.

Justification and optimisation

Under Article 6(4) of the Basic Safety Standards (BSS), dose limits do not apply to the type of exposures being discussed. However, if there are no dose limits, the principles of justification and optimisation are even more important than for other (non-medical) sources. That was also made clear in the last presentation: in relative terms, much more attention is given to these principles in the MED than in the BSS.

The benefits of these exposures are different since they accrue to the same persons as the ones receiving the doses, resulting in the **justification** of doses higher than the dose limits. Moreover, a therapeutic or diagnostic procedure should not be interrupted or stopped half-way through because some dose level is exceeded.

The second important principle is **optimisation**. Within the optimisation process dose constraints are required. This is firstly strongly advised (*'dose constraints should be used'*) in Article 7 of the BSS, but subsequently Article 4(4)(a) of the MED (*Member States shall ensure that " dose constraints are established"*) specifically requires that, for the purpose of optimisation, dose constraints be set for doses received by others owing to treatment or diagnosis undergone by patients.

In addition, guidance should be given on dose optimisation. The published guidelines are designed to answer this need.

Dose constraints

According to a joint NEA/CEC report, dose constraints are:

- Tools for optimisation
- Ceiling values, not supposed to be exceeded
- Prospectively set
- Based on well-managed practices or expert judgement
- NOT dose limits!

The most important points are that dose constraints are prospectively set and they are not dose limits. Hence, exceeding a dose constraint may lead to a review or an investigation but does not represent a violation of a regulation.

The guidance also indicates the rationale behind the recommended dose constraints.

Firstly, the constraints are based on risk factors: average risk is not an appropriate measure because the risk does not continue over a life time, given that this type of exposure happens perhaps once or twice in a person's life. Therefore, 5 mSv can be seen as a useful reference value (according to the BSS, in special circumstances people are allowed to receive more than 1 mSv in a single year as long as the average over 5 years does not exceed 1 mSv). Moreover, the actual risk at the age of exposure and, hence, age-dependant risk factors should be applied, and not the average over a lifetime.

According to ICRP 60, these age-dependant risk factors are as follows: for adults the average, for unborn children and children up to 10 years old a 3 times higher risk than the average, and for elderly people a risk which is from 3 or 5 up to 10 times lower.

Secondly, dose limits are considered not as values to be adopted but as providing a frame of reference for the acceptability of certain exposures.

Exposed groups to be considered

Different exposed groups can be considered.

Let us begin with the group closest to the patient. This group is called ‘family and close friends’.

The exposure of this group can be justified because these people also derive some benefit from the fact that the patient is at home and no longer in the hospital. They have their father, mother or partner at home and don’t have to visit the patient in the hospital. (Such patients really need some visits because they normally stay in an isolated room and often have psychological problems owing to the nature of their illness.)

The second group is formed by so-called ‘third persons’. These are people who derive no benefit at all from the fact that the patient is not staying in the hospital, except perhaps when the patient is a colleague and they have to take over his/her work.

In general, third persons do not help knowingly and willingly. Accordingly, the MED does not apply for them but they are covered by dose limits.

In some countries, parents are not allowed to take decisions on behalf of children who are still too young to make an informed decision. These children cannot help knowingly and willingly, and should therefore be regarded as ‘third persons’.

If a family refuses to have a patient at home as long as he/she is a radioactive source, such a family also qualifies as ‘third persons’.

Recommended dose constraints

Based on the above considerations, the recommended dose constraints for the different groups are:

For family and close friends: 3 mSv

> (For adults, if no other sources of exposure at all were present, 5 mSv could be the reference value for acceptability. However, other sources are always present, so 3 mSv in a year is an appropriate value.)

For unborn children and children under 10 years old : 1 mSv

> (The risk factor is about 3 times higher, so the recommended level for adults 3 is divided by 3 = 1 mSv)

For adults aged 60 or over: 15 mSv

> (The risk factor is about 5 times lower, so 15 mSv seems an acceptable value.)

As mentioned before, for third persons dose constraints do not apply but the dose limit does. As there are also other sources exposing third persons, the level should be well below the cumulative dose limit of 1 mSv in a year. That is why a fractional value of 0.3 mSv has been chosen.

Instructions on behaviour

The instructions on behaviour are of course based on the ways in which other people may be irradiated or contaminated, so exposure pathways are important.

There are various conceivable pathways but some of them have little or no relevance.

The important pathways are the external irradiation of people in the immediate vicinity of the patient, including those present at autopsies, laying out, vigils or attendance and funeral services. In addition, internal contamination by inhalation of I-131 aerosols exhaled by the patient could cause a significant dose.

The last pathway is often not recognised and some people even doubt whether it exists. However, if you work in a laboratory with iodine, you know how quickly iodine aerosols can be formed. Furthermore, significant traces of iodine are found in the urine of small babies after treatment of the mother.

A simple general rule can be derived from this: **keep your distance**!

As for external irradiation, when a patient dies shortly after administration of I-131, it is the best to seek advice from a qualified expert and to consult the family etc. about their intentions.

In some countries such as the Netherlands, this consultation is compulsory but no further restrictions are applied to burial or cremation because dose calculations have shown that the doses are not relevant. However, if the family wants to take the ashes home, this is only allowed after some time has elapsed.

The instructions concerning **children** are the most restrictive.

There are two types of ‘sources’, namely those who work with children, and parents, grandparents etc.

It is important to keep children at a distance or, if this is not possible (e.g. when small children are around), let them stay somewhere else with friends or grandparents, for example, or stay away yourself (e.g. if working with small children).

There is, however, no harm in visiting the parent, but the patient should not change nappies or hug a young child too long or too frequently.

It should not be too difficult to explain to the parents that this is in the best interests of the child. It is astonishing, though, that the same people who happily give their babies to a neighbour or other members of their family when they want to go on holiday sometimes object to this.

If relevant, breastfeeding should be stopped totally. It is also recommended that pregnancy should be avoided for 4 months, in order to stay under the 1mSv limit for the unborn child.

An important additional recommendation is that the period for following instructions should be extended by one week when young children are involved, because the risk for this group is higher.

In the case of **partners** etc., it is worth noting that elderly partners need not follow strict instructions because of the high dose constraint of 15 mSv that applies to their age group.

As regards the **toilet, cutlery** and **crockery**, the aim is to avoid direct contamination, but otherwise there is no need for special instructions.

The instructions concerning **third persons** are more restrictive than for the family and close friends because the dose constraint is only 0.3 mSv. In general they are intended to minimise close contact over longer periods of time.

A question frequently asked is: Why are instructions needed given that the dose limits do not apply? (The fact that dose limits do not apply also gives the impression that doses are not important).

Indeed, dose limits do not apply but the ALARA principle still does, because doses (e.g. in children) may in certain cases be as high as 20 mSv (sleeping in the same bed as the patient). This dose cannot be called really 'dangerous' but it is unacceptably high.

An average dose of 2 mSv is already high compared to other sources, especially when the maximum dose for all sources together is only 1 mSv. Therefore the instructions based on the ALARA principle are not superfluous; on the contrary, they should be carefully followed.

Responsibilities (Article 4(4)(c))

The responsibilities are clearly stated in the Medical Exposures Directive:

"*The medical practitioner or the holder of the radiological installation provides the patient or legal guardian with written instructions, with a view to the restriction of doses to persons in contact with the patient as far as reasonably achievable and to provide information on the risks of ionising radiation.*

These instructions shall be handed out before leaving the hospital or clinic or a similar institution."

The Guidance specifies and expands on this requirement as follows:

The instructions should not only be given in written form. It is not enough to hand out a piece of paper just before the patient leaves the hospital and to say goodbye. The instructions should be explained orally to the patient (and his family, if present), who should also be given the opportunity to ask for further explanations. To be reasonably sure the instructions are given properly, these procedures must to be noted down.

The medical practitioner is also responsible for deciding, before the patient leaves the hospital, whether the condition of the patient is good enough to follow the instructions.

It is also important for the medical practitioner to make certain that the situation at home (or possibly elsewhere) is such that the instructions can be complied with. He should therefore ensure that the patient is asked about these conditions.

It is important to note that the medical practitioner takes the decision to discharge the patient or to treat the patient as an out-patient on the basis of the information given but that he cannot be held responsible if incorrect information is supplied.

It is the patient himself who is responsible for his own behaviour and for keeping the doses to other persons as low as reasonably achievable by applying the instructions, in the same way as it is the responsibility of a pregnant woman not to smoke or drink.

Questions (Q) / Answers (A) / Remarks (R)

relevant to the subject presented by Mrs. ZUUR

Q: There is a clear trend towards prescribing fractionated cancer treatment of I-131 to patients in order to avoid hospitalisation. Is this justified?

A: The guidance is very clear about that: it is not justified because you give the patient a higher total dose and, indirectly, people at home receive higher doses as well.

Q: How can you calculate doses to other persons?

A: 400 MBq activity in the patient gives a calculated maximum dose of 5 mSv to an individual who is continuously within 1 meter of the patient. This is the reasoning behind the instruction in the guide to keep 2 meters away at all times. However, measurements made in Sweden and the United Kingdom found values lower than 1 mSv.

Q: These days people are often treated abroad and this could present a problem when a patient dies suddenly shortly after receiving a therapeutic dose. Would it not be useful to draw up international regulations on the transport of corpses containing radionuclides ?

A: Yes, that would of course be useful, but unfortunately such regulations do not exist yet.

Q: How can you check that a treated patient does comply with the instructions? For example, when the patient goes to work, who should inform the employer?

A: That is the responsibility of the patient. I really think it is up to him to inform his colleagues and the employer of his condition. You cannot expect the practitioner to inform every individual who might be in contact with the patient.

Q: In a hospital you may have the situation where several treated patients are in the same room and they have additional doses due to each other. Is this a medical exposure and do we need to apply the ALARA-principal in this case or maybe set a dose constraint?

A: When we calculate the additional dose, it is low compared to the original dose due to the treatment. If you have 2 or 3 patients in a room it is not a big problem for the patients but it might create an occupational risk for the staff.

Radiation protection of the unborn child

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Introduction

Frequently this topic is referred to – incorrectly - as *Protection of pregnant women*. The concern is the protection of the unborn child and not possible health effects for the mother-to-be herself. There are many good reasons to address this topic in the context of the Medical exposure directive (MED97). First of all the MED requires that special attention shall be given to this issue. For other but medical exposures the basic safety standards (BSS96) are providing dose limits, both when the mother-to-be is a worker and when she can be regarded as a member of the public. For medical exposures the situation needs clarification. The unborn child is not a patient and will not direct benefit from the medical procedures and strict dose limits are not applicable. In addition, the unborn child and the infant are more sensitive to radiation and hence radiation protection should be given more attention than to adults.

A working group set up by the EURATOM Article 31 group is preparing a document giving guidance for this task. In this document information can be found on matters that had to be omitted in the present overview. Note that the term *unborn child* is used as to cover the entire time period of development, from conception to delivery.

Medical exposure directive (MED)

Article 10 in the MED states:

1. *(a) In the case of a female of childbearing age, the prescriber and the practitioner shall inquire as specified by the Member States whether she is pregnant, or breastfeeding, if relevant; and*

   (b) if pregnancy cannot be excluded, depending on the type of medical exposure, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimization of the medical exposure taking into account the exposure both to the expectant mother and the unborn child.

2. *In the case of breastfeeding females, in nuclear medicine depending on the type of medical examination or treatment, special attention shall be given to the justification, particularly the urgency, and to the optimization of the medical exposure, taking into account the exposure both for the mother and the child.*

3. *Without prejudice to Article 10 (1) and (2), any measure contributing to increasing the awareness of women subject to this Article, such as public notices in appropriate places, could be helpful.*

The strategies for dealing with the radiation risk of unborn children and infants from parental medical exposures in an effective way can be divided into four main categories:

- To avoid unintentional exposures.
- To minimise the exposure to the unborn child or infant when parental exposure is necessary
- To assess the radiation risk for the unborn child after the exposure.

- To provide the mother-to-be with balanced information about the impact of the irradiation.

What is said about the unborn child is also valid, where applicable, for breast-fed children in connection with nuclear medicine examination or treatment of the mother.

In this paper possible measures will be given that may be taken by the member states, by the competent authorities, by the professional organisations and by the individuals involved in the medical care of patients. As will be shown, it is crucial for measures to be effective that the latter have the necessary knowledge and commitment.

Radiation risk

Different types of risk are associated with irradiation of the unborn child (see also Table 1). They are generally dependent on the time during the pregnancy where the exposure occurs. Carcinogenic effects are believed to be present during the entire period of pregnancy, with a risk factor as for children, 15 % per sievert for fatal cancer.

In the early phase, lasting from fertilisation to the settling of the embryo into the uterine mucosa, the number of cells is small. Failure of implantation or death of the conceptus would be the most likely radiation effects, even if carcinogenic effects cannot be dismissed.

During the period of organogenisis there is the potential of malformation of organs. However, there are indications that a threshold in the order of 100 mSv exists and hence malformations of organs are very unlikely to be caused by diagnostic exposures.

Exposures during the period of major formation of the central nerve system (8^{th} through 15^{th} week) have lead to a downward shift of the distribution of IQ with increasing dose. A figure of about 30 IQ points per sievert is reported. On this basis, a dose of 100 mSv would lead to a reduction of 3 IQ points for an individual, a figure not clinically observable.

How to avoid unintentional irradiation of the unborn child?

The following procedures are applicable to radiation treatment or examinations that might cause a considerable dose to the unborn child. They are not applicable if these doses would be rather low, say below 1 mSv, e.g. for x-ray examinations that don’t involve the uterus in the primary beam.

Whenever a female patient of childbearing age is subject for a medical examination or treatment involving ionising radiation the presence of pregnancy should be evaluated. The patient should be explicitly asked, orally or in writing, whether she might be pregnant or may have missed a period. According to national rules the prescriber and the practitioner should asked this at referral and at the time of the examination or treatment. The outcome of the questioning should be recorded. A notice requesting the patient to inform the staff about pregnancy should be displayed prominently.

If the patient is found not to be pregnant, without any doubt, the considered medical examination or treatment can be performed as planned. If there are doubts, e.g. because of a missed period or because the period is known to be irregular, pregnancy should be considered and the planned examination or treatment postponed until after the next period, if this is acceptable from a medical point of view.

If the planned examination or treatment would involve a high dose to the uterus, say more than 10 mSv, the evaluation of the presence of pregnancy is very crucial. This is a situation where the so-called ten-day-rule (exposure only during the first ten days after the beginning of the period where pregnancy is unlikely), which has been abandoned as a general routine application many years ago, still may be considered. Alternatively a pregnancy test may be performed.

How to proceed when pregnancy is ascertained?

When pregnancy is verified, or cannot be ruled out, the radiation risk for the unborn child must be taken into account in the decision about radiological procedures of the mother-to-be. One of the following alternatives may be appropriate:

- The examination is postponed until after delivery, if this is acceptable from a clinical point of view, balancing the risk and benefit for the mother and the child.
- Other methods of diagnosis are chosen, leading to a lower dose or no dose at all to the unborn child, taking into account their potential drawbacks.
- If delay is not considered medically acceptable, the examination/treatment is performed with special concern about the dose to the unborn child. Due attention is given to the possible consequences for the mother such as reduced efficacy of the examination/ treatment. The dose to the unborn child is estimated before the radiological procedure is carried out and reassessed, if relevant, afterwards.

Possible alternative procedures for x-ray or nuclear medicine examinations could be magnetic resonance imaging or ultrasound. When an x-ray examination is performed, a reduction of the dose to the unborn child could be achieved by reducing the number of images, limiting the fluoroscopy time to a minimum, careful selection of the projections and collimation of the radiation beam. A protocol should be available for various x-ray examinations of the abdomen to ensure that the radiation dose to the unborn child is as low as reasonably achievable, whilst taking due attention to the outcome for the patient herself.

All decisions concerning the selection of alternatives, especially if they may influence the medical care of the mother-to-be or involve high doses to the unborn child, must be done in consensus with the patient after she has been informed about the consequences of the various options.

What is to be done after the examination/treatment?

When pregnant women have undergone medical procedures involving ionising radiation, the dose to the unborn child should always be assessed and the risk associated discussed with the mother-to-be. It is extremely important that the facts are presented in a balanced way, not depreciating and, generally even more important, not exaggerating the risks. Normally the risk will be small compared with the "naturally" occurring risks, and reassurance of the mother-to-be not worry for the child because of her medical exposure may be the ultimate task of the physician responsible for the patient.

It must be emphasised that abortion is a very drastic decision that should not be taken without very serious reasons. Below 100 mSv abortion on the ground of radiation alone should not be considered. Above 100 mSv individual circumstances should be taken into account. However, even a dose to the unborn child as high as several hundreds of millisievert may not in all circumstances lead to advice for abortion.

Radiation protection of the breast-fed child

If the planned procedure for a female of fertile age is a nuclear medicine examination or treatment with radionuclides, the patient should be asked, orally or in writing, whether she is breast-feeding a child. A notice requesting the patient to inform the staff about breast-feeding should also be prominently displayed in the waiting area. If the answer is yes, advice about restriction of breast-feeding should be given to the patient. These recommendations are ranging, dependent on the diagnostic or therapeutic procedure, from continuing without interruption to a complete stop of breast-feeding.

Precautions after nuclear medicine procedures

Unlike after x-ray examinations the exposure continues after administration of radionuclides. In order to avoid undue radiation doses to the child to be born, advice should be given to the patient on not becoming pregnant after the nuclear medicine procedure within a specified time. This time varies, depending on the kind of procedure, between zero and 24 months.

Conclusions

One of the major strategies for the protection of the unborn child and of infants from parental medical exposure is the introduction of administrative procedures with the aim of avoiding unintentional exposures. A condition for this strategy to be successful is that all personnel involved is well informed and committed. Another important issue is the communication with the mother or mother-to-be concerning the risk to the offspring from the parental medical exposure. It is a difficult task to give a balanced view that is understood by the patient. Nevertheless, much effort should be undertaken in order to prevent unnecessary irradiation of unborn children and infants and to avoid psychical disturbances for the mother or mother-to-be.

References

BSS96 *Council directive 96/29/EURATOM of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.* Official Journal of the European Communities L 159, 1-28, 1996.

MED97 *Council directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/EURATOM.* Official Journal of the European Communities L 180, 22-27, 1997.

Table 1 Radiation risks associated with exposures of the unborn child

Period of pregnancy	Type of detriment	Risk figure
Pre-implantation phase	Failure to implant/ death of conceptus	?, relatively low risk
Organogenesis, 3^{rd} - 8^{th} week	Malformation of organs	Threshold 100 mSv?
Formation of CNS, 8^{th} - 15^{th} (25^{th}) week	Mental retardation, loss IQ	40%/Sv severe mental retardation loss of 3 IQ-points/ 100mSv
Whole pregnancy	Cancer	15%/Sv

Questions (Q) / Answers (A) / Remarks (R)
relevant to the subject presented by Mr. LEITZ

R: On the subject of making patients aware of the risks involved, and not only on this particular subject, it is very important that radiographers are well trained because very often they are the persons who are asked initially and they can overly worry patients or overly reassure them.

Q: In the medical exposure directive the term 'unborn child' is not defined and therefore it is not clear when we are talking about a foetus or a conceptus or an unborn child.

A: The Article 31 experts deliberately chose the term "unborn child" so as to include all stages from conception until delivery. In the guide, "unborn child" is defined in this way.

Q: At what dose level can we recommend an abortion to the pregnant women?

A: This is a difficult question to answer because it is not only a question of dose. Many other factors can be of importance: for example, if the pregnant woman has had difficulty in conceiving in the past, finally gets pregnant and absolutely wants to keep the baby. However, when the dose is sufficiently high, above deterministic threshold levels, then abortion could be recommended. But there are also cases of exposure of equivalent doses of several 100's of mSv where no abortion was performed and the children were perfectly normal.

Q: What do you recommend regarding the planning of a pregnancy just after a nuclear-medicine examination?

A: This is clearly explained in the guide. It contains a table where, depending on the type of examination or treatment, women are advised not to become pregnant for a given time period. For example, following treatment with I-131 for carcinoma of the thyroid we recommend avoiding pregnancy for 4 months.

Q: In the past, we used the 10-day rule to determine whether or not to perform an examination. Then we were told that in the first weeks of development it was an all or nothing event meaning that either the foetus is OK or it dies following exposure. Now I have the impression we are going back to the old system where each time we want to perform an X-ray or nuclear-medicine examination we should make a detailed evaluation. Is this correct?

A: It depends on the type of examination you perform. If there is direct exposure of the foetus because it is in the beam, or if the expected equivalent dose of a nuclear-medicine examination is above 10 mSv, the woman should always be asked if she is pregnant or has missed a period. If the foetus is not in the beam or the expected dose is low, for example 1mSv or less, I do not think this whole procedure is necessary.

Q: What do we do about the first two weeks of the menstruation? No woman can tell you whether or not she is pregnant during this period.

A: Again, it depends of the type of examination that you intend to perform but if there is doubt, for whatever reason, the woman must be assumed to be pregnant.

Acceptability criteria for radiological installations and quality assurance programmes

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INTRODUCTION

The Medical Exposure Directive (MED) (97/43/Euratom)[1] states that Member States shall ensure that appropriate quality assurance programmes including quality control measures and patient dose or administered activity assessments are implemented in practice by the holder of the radiological installation. Acceptance testing shall be carried out before the first use of the equipment for clinical purposes and thereafter performance testing on a regular basis, and after any major maintenance procedure. Furthermore, competent authorities shall adopt specific criteria of acceptability for equipment in order to indicate when remedial action is necessary.

Differing interpretations of quality assurance (QA) are possible. According to the International Organization for Standardization (ISO)[2], QA is defined as all those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service. Quality control is defined by the ISO[3] as the set of operations (programming, co-ordinating, carrying out) intended to maintain or improve quality. The World Health Organization (WHO)[4] definition of QA in diagnostic radiology implies the optimum quality of the entire diagnostic process, i.e., the consistent production of adequate diagnostic information with minimum exposure of patients and personnel. According to WHO[4] Quality Control (QC) as applied to a diagnostic procedure covers monitoring, evaluation and maintenance at optimum levels of all characteristics of performance that can be defined, measured, and controlled. The WHO[5] provides the following definition for QA in radiotherapy: all those procedures that ensure consistency of the medical prescription and the safe fulfilment of that prescription as regards dose to the target volume, together with minimal dose to normal tissue, minimal exposure of personnel, and adequate patient monitoring aimed at determining the end result of treatment. The definition of QC according to the WHO[5] is the measures taken to restore, maintain and/or improve the quality of treatment. The MED[1] defines QA and QC as a combination of that of ISO[2] and WHO[4].

The European Commission (EC) criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations[6] specify minimum standards of performance. The criteria are applicable to facilities in use for diagnostic radiology, radiotherapy and nuclear medicine.

In the present contribution various approaches of QA and QC are presented for medical applications of ionizing radiation, with emphasis on diagnostic radiology.

CRITERIA OF ACCEPTABILITY FOR RADIOLOGICAL (INCLUDING RADIOTHERAPY) AND NUCLEAR MEDICINE INSTALLATIONS

To assist the competent authorities of the European Union (EU) Member States in their task to establish or to review minimum criteria, the EC has prepared a document on criteria of acceptability for radiological and nuclear medicine installations[6]. The purpose of the document was to specify minimum standards of performance. The criteria are to be considered as “remedial levels”, i.e., levels of performance at which remedial action need to be initiated. It is stressed that the proposed criteria are not to be used as recommended values for QC purposes.

A summary of the types of equipment dealt with in the document is presented in Table 1. Criteria for digital radiography, except computed tomography (CT), were not included due to a lack of experience. For paediatric radiology only some general statements are made, mainly in relation to the small size of the patient.

As an example, the criteria for film processing are presented in Table 2. This example shows that criteria are either given in terms of absolute values (base and fog) or with reference to baseline values (speed index, contrast index). It can also be learned from the table that, e.g., test methods and frequencies are not included in the document.

QUALITY CONTROL OF EQUIPMENT USED IN DIAGNOSTIC RADIOLOGY

In general, the situation in Europe after the publication of the EC document on criteria of acceptability of equipment resembles that in The Netherlands after the amendment[7], dated May 25, 1997 to the Dutch Decree on Radiation Protection of September 10, 1986[8]. In an annex to this amendment technical criteria are included for equipment used in diagnostic radiology (radiotherapy and nuclear medicine). The criteria were to be considered as a first attempt to implement quality control. In general, no measurement methods are indicated or referred to. Furthermore, the limiting values presented can be fulfilled easily in practice. Finally, the number of parameters included was rather limited. Therefore, the Dutch Ministry of Health, Welfare and Sports (VWS) invited (professional) societies to participate in a working group on "Quality criteria for equipment used in diagnostic radiology" with the aim to formulate guidelines for QC. Each guideline should include criteria for technical parameters and accompanying measurement methods.

Four Netherlands Societies, i.e., for Radiology, of Radiographers and Radiological Technologists, for Radiological Protection and for Clinical Physics participated in the working group. Scientific and secretarial support to the working group was provided by the TNO Centre for Radiological Protection and Dosimetry. The working group restricted its activities to formulating guidelines including limiting values and measurement methods for conventional installations employed in diagnostic radiology. Based on information in the literature and the experience of the members of the working group, eleven technical parameters or parts of equipment having a major impact on image quality and patient dose were selected (Table 3). The structure of the guidelines was kept identical for each technical parameter or part of equipment. The limiting values included in the guidelines are based on values recommended in internationally accepted standards, for instance those from the International Electrotechnical Commission (IEC). The measurement methods, as described in international standards, were not always considered to be easily applicable to a clinical situation. Therefore, on various occasions alternative measurement methods were drafted by the working group with emphasis on simplicity of measurements and cost effectiveness. Drafts of the guidelines were tested in 20 departments of radiology at university and peripheral hospitals. The tests were performed by radiographers, instrumentation engineers and medical physicists. The results of these tests were implemented in the guidelines where appropriate. Further details on limiting values and principles of the measurement methods can be found elsewhere[9]. About 400 copies of the final version of the guidelines have been distributed among the boards of directors of health institutes having a diagnostic X-ray installation and among all diagnostic radiology departments in The Netherlands.

The professional societies and the Dutch Minister of Health consider these guidelines as a valuable instrument for QC of equipment used in diagnostic radiology. The Minister of Health recommends that holders of radiological installations gain experience with these guidelines to be able to meet future requirements[1]. Guidelines are lacking for computed tomography, fluoroscopy and digital imaging systems.

At present, Report 77 of the Institute of Physics and Engineering in Medicine (IPEM)[10] is the most comprehensive document within Europe for QC of diagnostic X-ray imaging systems. It covers

radiographic equipment; films, intensifying screens, processors and the darkroom; mammographic equipment, dental equipment; image intensifiers; digital fluorography systems and CT. The document includes or refers to test methods, contains test frequencies, level of expertise required, priority of tests, and remedial and suspension levels.

QUALITY CONTROL OF EQUIPMENT USED IN RADIOTHERAPY

The WHO[5] identifies the following areas for QC in radiotherapy: mechanical and geometrical aspects of external therapy machines and simulators; dosimetry; treatment planning system; brachytherapy; safety. It is further stated by the WHO[5] that the QA programme of the technical and physical aspects should include the specifications drawn up when the equipment is ordered, acceptance tests after the purchase of the equipment and the determination of a baseline standard, the initial calibration, periodic constancy checks and special tests after major repairs. The responsibility for the QC of equipment rests with the (clinical) physicist. Table 4 shows the recommendations for some tests on beam performance and light-field accuracy selected from WHO[5]. Mentioned are tolerance levels, test frequencies and on some occasions an indication of the test method.

Various publications[11-21] exist which provide more detailed information on QC of equipment used for radiotherapy. For example, The Netherlands Commission on Radiation Dosimetry (NCS) recently published a comprehensive report on methods for QC of medical linear accelerators[19]. NCS report 8[19] covers a large number of technical parameters, including an extensive description of test methods, test frequencies and tolerance levels and is meant to serve as a model for good clinical practice. The checks described in the report are not meant to be mandatory. A more differentiated set of regulations had to be set up for the following reasons. Firstly, NCS report 8 is rather extensive, i.e., describing checks for a large variety of circumstances. Secondly, the test frequencies and tolerance levels are to be considered as a suggestion and can therefore be adapted to the local situation by a responsible physicist. Thirdly, in order to test a certain parameter, more than one method can be suitable, making it difficult to impose one test method for all radiotherapy institutions. It was, therefore, considered to be desirable to draft guidelines that should be used in any institution in The Netherlands.

In NCS Report 9[20] such a minimum set of parameters to be checked regularly for medical linear accelerators has been formulated together with minimum test frequencies and action levels suitable for all radiotherapy institutions in the Netherlands. In formulating these, use was made of QC protocols and other reports on quality assurance for radiotherapy(5,11,12,14,15,16,17,18).

A comparison of the recommendations of the various QC protocols was made in NCS Report 9. In addition, the test frequencies among all (21) radiotherapy centres in The Netherlands were collected through a questionnaire. As an example, the frequency distribution of the field flatness check for photon beams is shown in Figure 1 and the recommended test frequencies and tolerance levels are presented in Table 5. It can be concluded that the tolerance levels are not too much different. The test frequencies show large variations.

It should be borne in mind that, contrary to the concept of (minimum) test frequency, different interpretations of tolerance levels exist. The stated tolerance level sometimes represents just a guideline for acceptable deviations. In other cases, a tolerance level has a stricter character in the sense that actions are (immediately) required if a tolerance level has been exceeded. The values of the tolerance levels in NCS Report 8[19] should be considered as desirable during normal clinical use of a medical linear accelerator. In the report of Brahme et al.[12] and Johansson et al.[14] the concept of tolerance level has a different meaning. According to their definitions, the equipment is suitable for high quality radiation therapy, if a parameter remains within the tolerance level. In these cases no actions are required unless a series of measured values stays close to one tolerance level. Beside this tolerance level, an action level is defined in such a way that whenever this is reached, it is essential that appropriate actions are taken. From this point of view, tolerance levels are appropriate limits for performance specification and for

acceptance testing procedures, while action levels might be regarded as more relevant values for use in ongoing quality control activities. As a consequence, "tolerance levels", e.g., those presented in Table 5, can have different interpretations, depending on the definitions used. The limits presented in NCS Report 9[20] should be regarded as action levels as defined by Brahme et al. (see also Figure 1).

However, some parameters are not easily and quickly corrected or repaired; it may sometimes be justified to use the radiation equipment clinically, even if an action level has been exceeded. Such a delicate decision can only be taken after careful consideration of the responsible clinical physicist, with the knowledge of the clinicians and radiographers. For example, curative treatments demand a high stability of the treatment table height, especially during lateral irradiation. If due to mechanical tolerances, the table height cannot be adjusted within 1 cm, it still may be justified to perform palliative posterior-anterior or anterior-posterior treatments if no alternatives are present at all. The decision to use a treatment unit clinically, in spite of the fact that an action level has been exceeded, has to be discussed thoroughly and documented for every treatment method. Under these special circumstances the action level can no longer be considered as restrictive; i.e., since the clinical relevance of a parameter can differ considerably from one treatment to another, it is impossible to implement an action level as a mandatory minimum demand.

Recommendations on QC of simulators and CT are made, e.g., by Brahme et al.[12], Kutcher et al.[11] and the NCS[21]. The situation is, in principle, similar to that for medical linear accelerators. For QC of treatment planning systems recommendations are less advanced.

The importance of QC of dosimetry has been recognized already much earlier than that of other parts or performances of equipment. In general, national protocols and/or codes of practice exist for dosimetry in radiotherapy. The NCS, e.g., has published protocols/codes of practice for the dosimetry of high-energy photon beams, dosimetry and quality control of radioactive sources used in brachy-therapy, dosimetry of high-energy electron beams, calibration of Iridium-192 high dose rate sources and dosimetry of low and medium energy X rays.

QUALITY CONTROL OF EQUIPMENT USED IN NUCLEAR MEDICINE

In principle, QC of equipment in nuclear medicine is not different from that in diagnostic radiology or radiotherapy. The types of equipment, however, generally differ. The Dutch recommendations[22] concern the types of equipment listed in Table 6. The recommendations include measurement methods, test frequencies, criteria, equipment required, archiving and references. Similar protocols for QC of equipment used in nuclear medicine are produced in various countries, e.g., in the UK by the IPEM, in the USA by the American Association of Physicists in Medicine (AAPM) and the National Electrical Manufacturers Association (NEMA) and by international bodies such as the International Atomic Energy Agency (IAEA) and IEC.

ALTERNATIVE APPROACH TO QUALITY CONTROL OF EQUIPMENT USED IN DIAGNOSTIC RADIOLOGY

QC in diagnostic radiology based on proper functioning of equipment has as a disadvantage that the number of parameters which has to be tested is quite large and still increasing. For instance in mammography, initially by TNO eight technical parameters were tested, whereas the European Guidelines on Quality Control in Mammography Screening[23] contain about 40 technical parameters, to be tested at various time intervals. Consequently, QC can become time consuming and thus expensive. Another approach, which might be less time consuming, is proposed by the EC[24,25]. This approach consists of three major elements, i.e., diagnostic requirements, criteria for radiation dose to the patient and examples of good radiographic techniques. Reference levels for entrance surface dose were proposed for examination of chest, lungs and heart (PA and lateral projection), skull (PA and lateral), lumbar spine (PA/AP, lateral and lateral of lumbo-sacral joint), pelvis (AP), urinary tract (AP before and after

administration of contrast medium) and breast (medio-lateral oblique and craniocaudal). The ICRP[26] adopted this approach and introduced the term diagnostic reference level, which applies to an easily measurable quantity, usually the absorbed dose in air or muscle tissue at the surface of a simple standard phantom or a representative patient.

The selection of the quantity entrance surface dose (in air or muscle tissue) for specification of diagnostic reference levels by the ICRP[26] has a number of disadvantages. First, entrance surface dose is not the most appropriate dosimetric quantity for risk assessment. Second, other basic dosimetric quantities such as dose area product (DAP) and computed tomography dose index (CTDI) which are often used for dose assessment are excluded. Third, both air and an unspecified tissue equivalent material are allowed for dose specification. Fourth, measurements are allowed on patients and on phantoms.

In The Netherlands, patient doses are usually specified in terms of effective dose, whereas DAP (or CTDI) is commonly the parameter measured. The possible restriction of the use of DAP in relation to risk assessment is illustrated by the following example. A study on dose in paediatric patients undergoing PA chest examinations, showed an approximately linear increase in measured DAP values with age from about 0.005 Gy cm^2 (at about 1 year of age) to over 0.020 Gy cm^2 (at about 11 years of age). Although an increase by a factor of approximately four was observed in DAP the effective dose remained approximately constant at 0.005 mSv. The use of entrance surface dose would have resulted in a similar dependence on age as DAP, although probably less pronounced.

Various methods are available for assessment of image quality including quality criteria for diagnostic radiographic images, use of specific test phantoms, use of contrast-detail (C-D) phantoms, more fundamental methods based on determination of modulation transfer functions, noise spectra and contrast transfer and application of so-called receiver operating characteristic (ROC) curves. Among these methods some are close to daily practice in a department of radiology, whereas others are most likely not readily interpreted by radiologists. In The Netherlands, the use of C-D phantoms and the image quality figure (IQF)[27] is the most widespread method for assessment of image quality. IQF has as a disadvantage that it is not the most sensitive parameter (especially in the case of mammography) which can be derived from images of a C-D phantom. Another disadvantage of the use of C-D phantoms for image quality assessment is the dependence of the results on the human observer. This disadvantage might be resolved by computer assisted scoring of digital images. It will be of great interest to compare the results from all mentioned methods for assessment of image quality for different types and techniques of examination employed in diagnostic radiology.

QUALITY ASSURANCE IN MAMMOGRAPHY

As stated in the introduction QA can be interpreted in different ways. Among the types of examination in diagnostic radiology, mammography deserved special attention with respect to QA and QC. This was most likely due to the fact that this type of examination involves large groups of healthy women who may not get a benefit, but will be at (some) risk due to exposure to ionizing radiation. Furthermore, it was recognized that the benefits of mammography screening can only be achieved when optimal image quality is attained.

In the first edition, the European Guidelines[29] were predominantly devoted to QC of technical aspects of mammographic equipment. It was, however, already indicated that organizational aspects including objectives, age group, population to be screened and call/recall systems and medical aspects, including recognition of pathology, epidemiology and treatment are also of great importance.

In the second edition of the European Guidelines[23] the number (and details) of QA aspects covered was considerably increased. In the general section, key organizational aspects (conditions and objectives), the QA programme (identification of target population, data-administrative system, screening age groups and intervals, the screening examination, professional communication, radiation protection, cost-

effectiveness and training), quality maintenance and assessment process are addressed. In addition, the roles of the radiographer and the radiologist are described.

Detailed protocols and guidelines are presented on QA in epidemiology, cytopathology, pathology and on QC of the physical and technical aspects of breast cancer screening. In addition, reference is made to the European protocol on Dosimetry in Mammography[30].

Although the European Guidelines were extended considerably there are still various aspects that are not covered (in detail), e.g., the role of the physicist, cost-effectiveness calculations and guidelines for treatment.

DISCUSSION AND CONCLUSIONS

The interpretation of QA for medical application of ionizing radiation can be quite different. Usually, implementation of QA programmes starts with QC of equipment, except in radiotherapy where accurate dosimetry deserved primary attention. Concerning QC of equipment, the first step is often the formulation of criteria of acceptability such as those published by the EC[6] for a restricted number of parameters. A next step is to add measurement (test) methods, test frequencies, registration of measurements, evaluation and interpretation (including criteria) and reporting, see, e.g., Dutch guidelines for QC of equipment used in diagnostic radiology[9]. A further step is to cover (almost) the whole field of e.g., diagnostic X-ray imaging, and add levels of expertise needed, priority of tests and to refine the criteria in terms of, e.g., remedial and suspension levels (IPEM)[10].

Although the types of equipment in radiotherapy and nuclear medicine are generally different from that used in diagnostic radiology, the general trends in QC are similar. Points of concern for QC of equipment used for medical application of ionizing radiation are the large diversity of protocols for the same purpose and the still increasing number of tests.

An example of the confusion that can be caused due to the large number of protocols is the term used for constraint, e.g., limiting value, tolerance, remedial level, action level, suspension level (see also Figure 2). Usually, the recommendations in different protocols are not too much different (see, e.g., Table 5) although the frequencies of tests might be quite different. A situation as described above also existed for dosimetry in mammography, where national protocols in Europe were available in Germany, France, the UK, The Netherlands, the Nordic countries, Spain and Italy. The national protocols dealt in varying extent with the evaluation of absorbed dose as a part of QA. For countries where protocols were available the European protocol aimed to serve comparability of the reported dose values. For other countries, the European protocol provides consistent methods of dosimetry. A similar approach might also be followed for QC of equipment used in diagnostic radiology (except mammography) within Europe with the aim to increase harmonization. For mammography European protocols exist.

QC of equipment can become too time consuming due to the increasing number of technical parameters to be tested. In diagnostic radiology, an alternative approach can be to evaluate the integral imaging system through assessment of patient dose and image quality. However, this approach requires still an appreciable research effort especially with respect to assessment of image quality. A similar approach has been used for WHO interlaboratory comparison studies in nuclear medicine imaging using total performance phantoms (see, e.g., Busemann Sokole[31]). For radiotherapy, the use of electronic portal imaging devices (EPIDs) allows the treatment beam alignment to be visualized with respect to patient anatomy. The use of EPIDs might reduce the number of tests on mechanical parameters.

The European guidelines for quality assurance in mammography contain detailed protocols/ guidelines. In addition, organizational aspects, QA programme, quality maintenance and assessment process are addressed. Still, extensions are possible, e.g., guidelines for treatment.

With regard to radiotherapy, e.g., comprehensive QA has been formulated in a report of the AAPM radiation therapy committee task group 40[11]. This report includes the comprehensive QA programme, which details the quality control tests and procedures, the action criteria, the records required and the personnel to perform them; QA of radiotherapy equipment (radiation sources, simulators, treatment planning) including test frequency and guidelines for tolerance values; brachytherapy; QA of clinical aspects; and the roles and responsibilities of the radiation oncologist, oncology physicist, medical radiation dosimetrist and radiation therapist (radiologic technologist).

For nuclear medicine, e.g., the Dutch guidelines[22] contain recommendations on diagnostic methods for various types of examination, including principles, reasons for examination, data available before examination, radiopharmaceutical substance (type and activity), patient preparation, ancillary equipment, performance of the examination, equipment used, record-keeping, interpretation of results and pitfalls, alternative diagnostic methods and references. Similarly, recommendations are given for therapeutic applications of nuclear medicine. A separate section is devoted to radiopharmaceuticals including preparation, QC, interactions, unwanted side effects and references. Recommendations for QC of equipment are already mentioned before. Appendices deal with radiation dosimetry, paediatric patients, and measures in case of radioactive contamination.

It can be concluded that QA in radiotherapy and nuclear medicine is, in general, more advanced than in diagnostic radiology, except mammography. Thus, a larger effort seems to be necessary for diagnostic radiology than for nuclear medicine and radiotherapy, although QC of treatment planning systems is still an area of research. In view of the complexity of QA in diagnostic radiology, radiotherapy and nuclear medicine it might be worthwhile to restrict the activities to the aspects most closely correlated with radiation protection.

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Table 1 Types of equipment included in the EC Acceptability Criteria Document[6]

- Diagnostic radiographic installations in general
- Film processors, image receptors and viewing boxes
- Fluoroscopic equipment
- Conventional and computed tomography units
- Equipment for dental radiography
- Mammographic installations
- Radiotherapy equipment
- Nuclear medicine installations

Table 2 Criteria for film processing for diagnostic radiology applications in the EC Acceptability Criteria Document[6]

- Base and fog
  Base and fog should be less than 0.30 OD
- Speed index
  Deviation of the speed index from the baseline value should be less than 0.20 OD
- Contrast index
  Deviation of the contrast index from the baseline value should be less than 0.20 OD

Table 3 Technical parameters included in the Dutch guidelines for QC of equipment used in diagnostic radiology[9]

- Tube voltage
- Automatic exposure control
- Film processing
- Film screen combination
- Light tightness and illumination of the darkroom
- Half value layer and filtration
- Light beam alignment
- Grid
- Focal spot size
- Viewing boxes
- Geometrical indicators of the X-ray unit

Table 4 Some tests on beam performance and light-field accuracy for radiotherapy selected from WHO[5]

Performance characteristic or item of equipment tested	*Remarks*	*Tolerance level*	*Frequency*
Light field indication	Visual inspection for the four main gantry positions	--	Monthly
	Density measurements	± 2 mm	Every 6 months
Central axis dose calibration	At a reference point in a phantom for each set of conditions	--	Yearly
Constancy checks:			
accelerators	Dose per monitor unit for the most usual energies from 0.1 to 10 Gy	± 2%	Daily or at least twice a week
Linearity of monitor	--	± 1%	Yearly or after repair
X-ray beam:			
beam flatness	--	± 3%	Twice a month
beam symmetry	--	± 3%	or after repair
Electron beams:			
flatness and symmetry	For each energy used	± 3%	Twice a month or after repair
Transmission factor of wedges and compensators	Any variation is, in general, an indication of a misalignment	± 2%	Yearly
Transmission factor of trays	--	± 3%	Yearly or after repair

Table 5 Intercomparison of recommended test frequencies and tolerance levels for the photon field flatness and symmetry of linear accelerators(20)

Report	*Frequency*[3]	*Tolerance level*	
		flatness	*symmetry*
Ref. 12	M	±2%	±3%
Ref. 13	M	±4% (±2.5)%	--
	W	--	±3% (±1.5%)
Ref. 14	A[1]	--	--
Ref. 17	W[2]	±3% (≤30 cmx30cm)	±3%
		±5% (>30cmx30cm)	
Ref.18	W	±1.5%	±3%
Ref. 20	W/M	±3% (±2%)	--
Ref. 21	A	±3%	--
	M	--	±3%
Ref. 19	M	±3%	±3%

[1] Eight measurements of the "5-point" test and four measurements of the scan test

[2] One energy each week with alternating four gantry angles with four collimator angles

[3] W = weekly; M = monthly; A = annually

Table 6 Equipment subjected to QC in nuclear medicine in the Netherlands(22)

- Gamma camera planar
- Gamma camera whole body scanning
- Gamma camera SPECT
- Imaging equipment
- Scintillation counter (thyroid probe)
- Surgical detector/probe
- Dose calibrator
- Semi-conductor detector
- Flood source

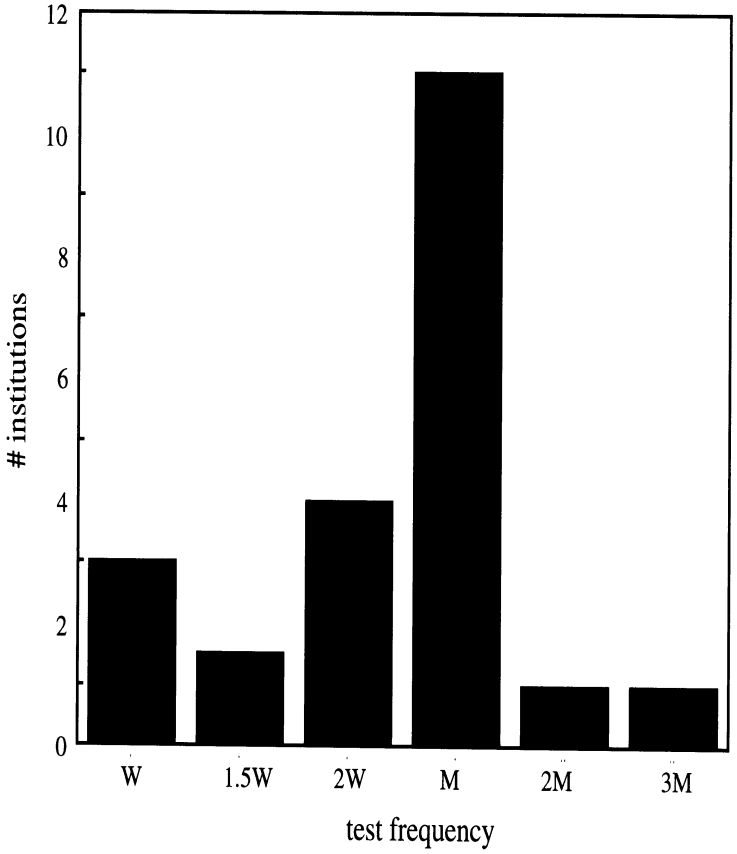

Figure 1: Frequency distribution of the field flatness check for photon beams according to NCS[20] (W = weekly, M = monthly).

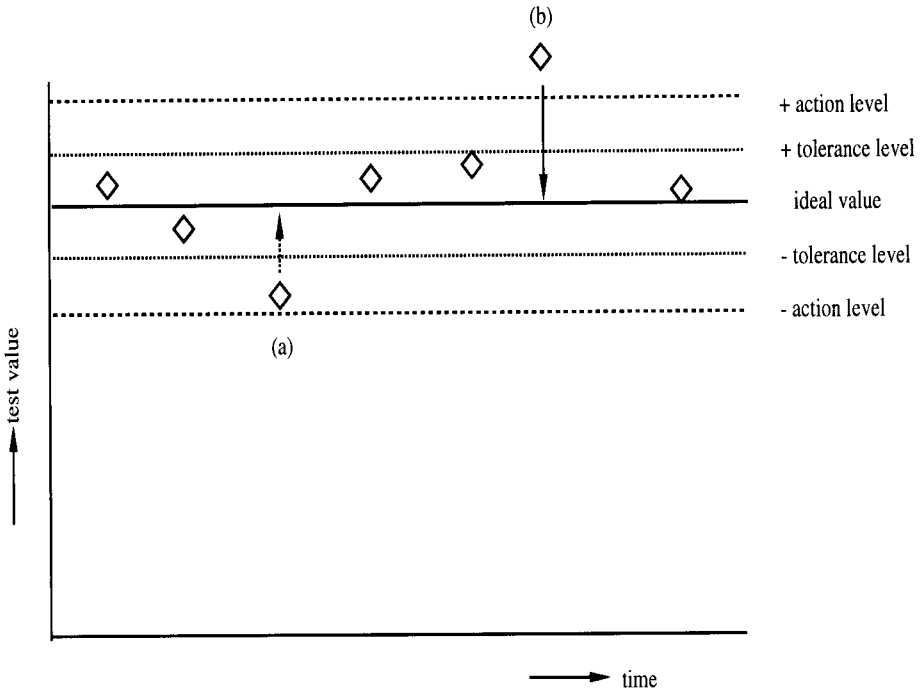

Figure 2: Definitions of tolerance and action level for an arbitrary parameter. The results of QC tests are shown in course of time. At point (a), adjustments are recommended. At (b), immediate corrective actions need to be taken, unless due to special circumstances the clinical physicist decides that treatment can proceed. This delicate decision has to be discussed extensively in the centre and documented for every treatment method[20].

Questions (Q) / Answers (A) / Remarks (R)
relevant to the subject presented by Mr. ZOETELIEF

Q: Would it be useful to harmonise quality control programs in Europe?

A: Yes, I am totally in favour of harmonization of quality control programs in Europe, especially if no such programs are available at national level.

Q: No European guide on quality control for radiotherapy equipment exists for the moment. Would it not be a good idea to use the AAPM Report 46 entitled 'Comprehensive quality assurance for radiation oncology'?

A: The AAPM report is a very good document and can be used as reference document. However, in some Member States protocols on radiotherapy exist already and it also seems useful to develop European guidelines in addition to that.

Q: Referring to Article 8.6 of the MED, what is exactly the device informing the practitioner of the quantity of radiation produced? Could an mAs-meter be used for this purpose?

A: What a practitioner ideally should be informed of is the cumulated effective dose or, in case of interventional radiology, also the maximum dose to the patient's body. An mAs-meter does not indicate these quantities but, by calculating the conversion between the two measurements, it might in practice be possible to use an mAs-meter.

Q: What is the suggested policy for the future use of single-phase fully-rectified generators?

A: I do not think it is to be expected that this type of generators will fulfil the national requirements, if available, or the European criteria for acceptability of equipment.

Q: Does all medical equipment in use have to comply with the Medical Devices Directive and should it bear the CE mark?

A: The Medical Devices Directive refers to new equipment whilst the Medical Exposure Directive refers to equipment in use. The answer to the question is no.

Q: Don't you think that too stringent quality control programs might impair the access to certain examinations or treatments in radiology or nuclear medicine which could provoke a setback for patient's health?

A: That could theoretically be possible. Therefore, as I said before, we should be careful with our definitions of suspension level or of an acceptability criterion. For example, some radiotherapy installations, no longer accepted for curative use, may be used under specified conditions to give palliative treatment.

Q: Large quality control programs can put a heavy workload on the staff of a department. Do you think this can be a restriction on introducing such programs?

A: Hospitals often are subject to budget restrictions. A large radiology department doing about 100,000 examinations per year needs 1 full-time person to perform control checks. There is some reluctance to spend this money on someone who only checks the performance of equipment. Moreover, many radiologists do not like to have somebody in the department who is 'always looking over their shoulder when they are doing their job'. If there is no legal obligation, quality control is clearly not a priority.

Q: You said image quality and dose are the two relevant parameters to be taken into account. Do you agree that phantoms can be sufficiently relevant to evaluate image quality in diagnostic radiology?

A: Useful phantoms exist but what still needs to be achieved is to relate image quality as determined by radiologists with the physical methods behind this image to convince the radiologist that a better physical ‘performance’ also results in better diagnostic images.

Radiation Protection in medical and biomedical research

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The principle of medical and surgical morality consists in never performing on man an experiment which might be harmful to him to any extent, even though the result might be highly advantageous to science, i.e., to the health of others.
Claude Bernard, 1865

Keywords

Radiation medicine, biomedical ethics, biomedical research, health policy

Summary

This paper situates the 'Medical Exposures' Directive within the framework of biomedical ethics. It stresses the importance of ethical conduct in biomedical research in order to respect and maintain individual and public trust in the use of radiation in biomedical research. After locating the research referred to in the Directive within the broader field of biomedical research in general, the paper examines the importance of the principles of respect, beneficence, and justice for biomedical research involving exposure to radiation. Following a consideration of the ethical importance of risk in the research setting involving radiation exposure, there is a discussion of the importance of informed consent and ethical review in protecting research subjects. The importance of the 'Medical Exposures' Directive is situated within the framework of an evolving European Community public health policy is discussed in the conclusion. Finally, a recommendation is made for the establishment of an expert group to draft guidelines on informed consent and ethical review for research projects involving the exposure of persons to ionising radiation.

Introduction

Medical and biomedical research on human subjects involving ionising radiation poses specific ethical challenges requiring scientific, procedural, and legal approaches to their resolution. Council Directive 97/43/EURATOM of 30 June 1997 (the 'Medical Exposures' Directive)[1, 2] imposes for the first time in European Union law specific protection for healthy individuals and patients participating in medical and biomedical research involving radiation. While the scope of the Directive is much broader, giving particular attention to increased protection to patients, health workers, and other individuals[3] exposed to radiation in standard medical and medico-legal procedures, the specific concern with medical and biomedical research has special significance.

1 The author wishes to thank Diederik Teunen of the European Commission, DG XI.C.1 Radiation Protection for his guidance and support in the preparation of this paper. Additionally, Professor Joseph J. Hoet of the WHO Collaborating Centre, Faculty of Medicine, Université Catholique de Louvain, provided valuable advice regarding issues of science and ethics discussed below. Any remaining errors or shortcomings of the paper are attributable solely to the author.

2 Council Directive 97/43/EURATOM of 30 June 1997on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom. (OJ L-180 of 9 July 1997).

3 The more direct coverage of health workers and the general public is covered in Council Directive 96/29/EURATOM of 13 May 1996 laying down basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation. (OJ L-159 of 05/10/84 page 1).

The exposure of individuals to radiation in research settings requires a legal framework that promotes high scientific standards and establishes rigorous ethical guidelines. The Directive provides a fundamental basis on which to build and maintain public trust in medical experimental procedures where participants are exposed to radiation. The implementation of this Directive requires reflection on the ethical conduct of medical and biomedical research, while at the same time it engages a further development of high ethical and scientific standards in the interest of public health.

Trust and Human Radiation Experiments

The primary purpose of the Directive is stated in Article 1.1. as follows:

> This Directive supplements Directive 96/29/Euratom and lays down the general principles of radiation protection of individuals in relation to . . . exposure.

The development and implementation of well considered legal principles for the protection of European citizens in biomedical research is important in order to foster trust in research. At the heart of biomedical research, involving radiation or any other form of medical intervention, is a relationship of confidence between a patient and her physician (or other health care professional). This is a relationship in which an individual entrusts not just bodily health to a caring professional, but indeed one's general sense of well-being. The patient trusts that, in this very private and confidential relationship, her well-being will be the predominant, if not sole, concern of the health care provider. Biomedical research introduces a peculiar challenge to this relationship because it requires that the physician's interest also be directed, in part, towards the general concerns of science. By bringing explicitly under its scope the protection of individuals 'in medical or biomedical, diagnostic or therapeutic, research programmes', the Directive reinforces the primacy of the physician-patient relationship over the researcher-subject relationship.

One of the most decisive factors for patients entering biomedical research is the fact that they have confidence in the advice of their physicians. In the article 'Trust: The Fragile Foundation of Contemporary Biomedical Research' the authors document the force of trust in the physician-patient relationship with anecdotes of the following sort:

> 'My doctor told me if I do not take the drug, in a couple of months I [will] die. So, I had no choice. Who wants to die? Nobody.'
> 'Well, he [the oncologist] said he'd already 'been through everything he knew what to do. He would try to keep me as comfortable as he could. That's when he told me about this new treatment. I told him we would try it.'
> 'There's not a lot that you can control when you're sick, so you have to trust your doctors . . . if he suggests that you should go into a research project, I think you should really take his advice or her advice . . . because if you take the time to get yourself a good doctor and they're involved in research, they would never steer you wrong.'
> '[T]o me, they are the doctors, and once I trusted them . . . it was pretty much up to them.'[4]

Patients are in an essentially vulnerable, dependent relationship with their physician. Their readiness to trust is understandable, given the weakness of their condition and the power of the physician to treat that condition. It is essential that in the process of discussion and decision-making with the patient that the physician respond with integrity regarding a proposed treatment's potential benefits and potential risks. In the case of research, the physician-researcher may encounter extraordinary moral challenges in maintaining the integrity of their interactions with the patient (potential subject). This challenge may arise because of the physician-investigator's interest in science and the possibilities for benefiting future patients. However, it may also arise out of the physician-investigator's interest in the patient and the potentially bleak outlook on a specific health problem. Respecting the trust of the relationship depends on maintaining an integrity that is responsive to the patient's trust.

4 Nancy E. Kass, Jeremy Sugarman, Ruth Faden, and Monica Schoch-Spana, "Trust, The Fragile Foundation of Contemporary Biomedical Research," *Hastings Center Report* 26.5: September-October 1996. Pp. 5-10

Additionally, trust is at the heart of the public's confidence in government health policy and the medical profession in general. The effective implementation and development of (public) health policies and medical practices requires an open dialogue with all the different sectors of society involved in health care, including the patients. Helen Carter of the Research Trust for Metabolic Diseases in Children, United Kingdom, recently expressed this concern at a meeting in the European Parliament as follows:

> We live in exciting times. We have unprecedented opportunities for industry, patient groups and governments to work together to develop our economies, strengthen industry and promote and enable our health and well being.[5]

The dialogue between the different sectors of society in health care should be based on a concern to promote medical and biomedical practices that are safe and efficacious, permitting only a minimal level of risk. As is indicated in the draft document entitled 'Guidance on Medical and Biomedical Research for the Working Party on Medical Exposures'[6], radiation experiments are of specific concern in the area of public trust in health policy:

> A comprehensive culture of radiation protection and safety in medicine has been progressively developing throughout the European Union with regard to the medical use of ionising radiation and has been integrated into the various branches of diagnosis and treatment.
>
> The European Commission has contributed to this evolution with the establishment of legal requirements to be implemented by Member States for the radiation protection of persons undergoing medical examinations or treatment. (p. 1)

The 'Medical Exposures' Directive makes a particularly important contribution to this protection both including medical and biomedical research within its scope and by providing guidance for radiation research similar to the guidance legislated at the European level for clinical trials involving pharmaceuticals and for research involving medical devices. A 'comprehensive culture of radiation protection and safety' needs to be situated within, and co-ordinated with, the wider culture of medical and biomedical research concerned with public health.

There is a recent and disturbing historical memory of experimentation on human beings involving radiation that has been extensively documented in the United States by the Advisory Committee on Human Radiation Experiments[7]. The Committee's *Final Report* shows in exhausting detail repeated abuses of human subjects in radiation experiments, largely by the government, military, academic, and hospital communities between 1944 and 1974. The experiments were carried out during the period of the Cold War usually under a veil of secrecy (often understood as 'national security') with the rationale that the national interest and the general public welfare were at stake. Testifying before the Committee on Governmental Affairs of the US Senate in the Hearing on Radiation and Other Experimentation on Human Beings in 1994, an expert methodologist in the design and conduct of clinical trials, Curtis Meinert, stated the following:

> The recent flurry of events, and accompanying publicity, regarding radiation studies done in the past has created a crisis of confidence that extends far beyond the specifics of radiation research. It is a crisis that concerns us all whatever our perspective – that of a research subject, a researcher, citizen, or human being. Hence, it is appropriate to have a public airing of the specifics, and of the general issues involved, to restore the trust of the public in the collective research enterprise where indicated, and to correct deficiencies where noted. We will not help anyone, starting with those we treat, if this debate leads the public to believe that they are likely to be unwitting guinea pigs every time they enter a health care facility. We have a crisis of confidence that, unless dealt with forthrightly and resolutely, will affect us all, to the extent that we depend on mutual trust and respect

5 Helen Carter, "Rare Diseases: The Availability of Cures and the 5th Framework Programme," *Biomedical Research and Orphan Medicinal Products*, Hessel Dijkstra, Erica Poot, and Ilse Wilczek, eds. (Baarn, The Netherlands: European Platform for Patients' Organisations, Science and Industry, 1998).

6 Working Group – Article 31, 'Guidance on Medical and Biomedical Research for the Working Party on Medical Exposures,' Draft document, DGXI-1, 10 April 1998.

7 Advisory Committee on Human Radiation Experiments, *Final Report* (US Government Printing Office, October 1995).

> in carrying out any research on human beings. The ability to do such work is, itself, a form of public trust and violations of that trust have the potential of pushing us back to the era [of] nonexperimental empiricism in choosing the treatments in use.[8]

The 'crisis of confidence' Meinert refers to is perhaps considerably less in Europe than in the United States.[9] However, the potential for abuses to occur in medical research – while actual occurrences today are perhaps few in number – demands a high level of public responsibility in reviewing, authorising, and monitoring biomedical research.

Defining Biomedical Research

Certainly many of the standard practices today involving radiation medicine can be improved upon, and it is likely that as our understanding of human biology and nuclear medicine increases new practices will be proposed using radiation in diagnostic and therapeutic health interventions. The revision of standards or the introduction of new practices in biomedicine requires research on persons for their justification.

Biomedical research may be broadly defined as any systematic investigation in the field of health intended to develop or contribute to medical understanding and practices. This includes all testing, evaluation, and development of medical products (pharmaceuticals), medical devices, surgical techniques, and radiation exposure. Falling clearly within the scope of this definition are all experimental interventions involving persons.

> This definition includes all research done on or relating to people or their body fluids or tissues, as well as that done on records or data on human beings, even if the specific project in question does not involve any contact with persons to whom the records or data pertain.[10]

Thus, biomedical research involving persons has a broad scope, and we need to be aware of this when we consider the application of ethical principles. Neither the World Medical Associations' (WMA) *Declaration of Helsinki*[11], the Council for International Organizations of Medical Sciences' (CIOMS) *International Ethical Guidelines for Biomedical Research Involving Human Subjects*[12], nor the European *Convention on Human Rights and Biomedicine*[13] provides a definition of biomedical (or medical) research, although all of these internationally accepted ethical guidelines are to be applied to biomedical research.

However, within the definition of biomedical research lies a complex dilemma: the inherent freedom of the inquiring mind versus the privilege of carrying out research on persons. Most often we see one side or another of this dilemma put forward, which then bears directly on the scope of what biomedical

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8 Reprinted in Advisory Committee on Human Radiation Experiments, *Final Report*, Supplementary Volume 1, p. 822.

9 Yet there is good reason to believe that human radiation experiments were also widely undertaken in European countries. For one example, see Campaign for Nuclear Disarmament, "British Nuclear Guinea-Pigs: Human Radiation Experiments in Britain from 1957 to the Current Day" (London: CND Information Office, November 1996). Also available on the World Wide Web at http://www.mcb.net/cnd/radexpts/report.htm.

10 Curtis L. Meinert, "Hearing on Radiation and Other Experimentation on Human Being[s]," 20 January 1994, Testimony, reprinted in Advisory Committee on Human Radiation Experiments, *Final Report*, Supplementary Volume 1, p. 824. See also United States Department of Health and Human Services, 45 CRF §46.102(d); 18 June 1991.

11 World Medical Association, *World Medical Association Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects*. Adopted by the 18th World Medical Assembly Helsinki, Finland, June 1964. Amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; 35th World Medical Assembly, Venice, Italy, October 1983; 41st World Medical Assembly, Hong Kong; and the 48th General Assembly, September 1989. Somerset West, Republic of South Africa, October 1996.

12 Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO). *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Geneva 1993.

13 Council of Europe (Directorate of Legal Affairs). *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*. European Treaty Series – No. 164. Oviedo, 4 November 1997.

research may be. The European *Convention on Human Rights and Biomedicine* comes squarely down on the side of freedom, never referring to the privilege of research. Article 15 reads as follows:

> Scientific research should be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.

Although the freedom of research is not absolute, its limitations are strictly legal in nature. The justification for this 'General Rule' is provided by the supporting *Explanatory Report*:

> Freedom of scientific research in the field of biology and medicine is justified not only by humanity's right to knowledge, but also by the considerable progress its results may bring in terms of the health and well-being of patients.[14]

The 'right to knowledge' guarantees the researcher broad freedom in the design and execution of biomedical research projects. Further, this right needs to be upheld in order to prophylactic, diagnostic, and therapeutic treatment at the disposal of standard medicine for addressing the health needs of the population.

On the other hand, it is becoming increasingly common today for ethicists and experts in biomedical research to emphasise the privilege of biomedical research on human subjects. Curtis Meinert writes the following:

> I argue that being able to carry out research on human beings is a privilege, not a right . . . .[15]

Those emphasising the privilege of biomedical research stress the importance of the consideration of the safety and well-being of the research subject over the interests of science. At times linked to this claim is the suggestion that biomedical researchers be certified or that their institutions be accredited.[16] However, the dilemma of the freedom versus the privilege of biomedical research involving human subjects need not lead to an impasse. One of the great challenges to biomedical ethics today is to ensure that the freedom of research and the privilege of research compliment one another in practice.

The 'Medical Exposures' Directive regulates biomedical research in the European Union insofar as it involves the exposure of persons to ionising radiation. It does not attempt to define biomedical research, nor does it address the freedom or the privilege of biomedical research. However, the Directive's concern is clearly with a limited scope of biomedical research that can be termed 'clinical research': biomedical research on persons within the setting of a medical clinic, or co-ordinated or directed by a medical clinic, and aimed at testing the safety and/or efficacy of an intervention. The

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14 Directorate of Legal Affairs, Council of Europe, *Explanatory Report to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.* DIR/JUR 5. Strasbourg, May 1997, p. 23.

15 Curtis L. Meinert, Letter to Ruth R. Faden, Chair of the United States Advisory Committee on Human Radiation Experiments, 24 February 1995, published in Advisory Committee on Human Radiation Experiments, *Final Report*, Supplementary Volume 1, p. 820. This argument finds support in the *Principles for Those in Research and Experimentation* of the World Medical Association (adopted by the Eighth General Assembly of the World Medical Association, 1954) which states in its first principle:

> 1. Scientific and Moral Aspects of Experimentation
>
> The word experimentation applies not only to experimentation itself but also to the experimenter. An individual cannot and should not attempt any kind of experimentation. Scientific qualities are indisputable and must always be respected. Likewise, there must be strict adherence to the general rules of respect of the individual.

Here the very definition of a valid (bio)medical experiment infers the privilege of the undertaking.

16 On the same subject, Ernest Prentice points to the following situation in the United States:

> It is ironic to think that the American Association for the Accreditation of Laboratory Animal Care (AAALAC) has accredited 550+ institutions and this accreditation requires submission of a detailed self-study and AAALAC site visit [sic] every 3 years. We do not, however, have a comparable system for accreditation of institutions involved in human subject research.

See Ernest D. Prentice, Letter to Ruth R. Faden, Chair of the United States Advisory Committee on Human Radiation Experiments, 24 February 1995, published in Advisory Committee on Human Radiation Experiments, *Final Report*, Supplementary Volume 1, p. 832.

Good Clinical Practice Guideline of the International Conference on Harmonization (ICH) defines a clinical trial/study as follows:

> Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s) and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.[17]

While this definition was written in the context of biomedical research involving pharmaceuticals, it seems that it would be largely applicable to biomedical research involving exposure to radiation.

The 'Medical Exposures' Directive applies to all biomedical research in which persons are exposed to ionising radiation. Article 1.2 establishes this in broad lines:

> This Directive shall apply to the following medical exposure:
> . . . .
> (d) the exposure of healthy individuals or patients voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes.

The requirements of the Directive thus apply to all instances of research where there is exposure to ionising radiation, whether or not the safety or efficacy of the exposure is to be a measured result of the research. These would also apply to research involving dosage studies, whether studying experimental dose quantities or comparing standard dose quantities. They apply equally to biomedical research involving either external radiation or radiopharmaceuticals. The Directive also applies to research involving the testing of medical or biomedical equipment where there is exposure to (or the potential for exposure to) radiation, e.g., radiographic equipment, mammographic equipment, image intensifiers, digital fluoroscopy systems, or computed tomography installations. In addition, the Directive applies to a wide range of studies where evaluating the efficacy of a pharmaceutical, device, or surgical intervention requires radiation exposure.

The Purpose of Biomedical Research Involving Exposure to Radiation

Biomedical research is generally understood to have as its purpose the improvement of knowledge regarding the health of individuals or groups in society. The *Declaration of Helsinki* provides the following guidance:

> The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

The *Declaration* insists that biomedical research on persons may only be carried out with the aim of developing or contributing to current biomedical knowledge. This imposes a strong responsibility on the researcher to be informed of the current state of understanding in her field, and to ensure that repetitive, redundant, or in some other way ill-informed or ill-advised research proposals regarding the scientific community's current state of knowledge are not undertaken. Biomedical research on human subjects that is not expected to advance current scientific knowledge is considered to be unethical, no matter how benign. Poorly designed (or poorly conducted) research is without scientific or ethical merit. Even where minimum risk is present it should not be permitted.

The 'Medical Exposures' Directive provides for clear guidance regarding the situations in which biomedical research exposing persons to radiation is acceptable. Article 3.1 (a) states the following:

> — all new types of practices involving medical exposure shall be justified in advance before being generally adopted,

17 International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH). *Guideline for Guidance on Good Clinical Practice* (CPMP/ICH/135/95) 1 May 1996.

— existing types of practices involving medical exposure may be reviewed whenever new, important evidence about their efficacy or consequences is acquired.

Research is required in order to justify either new types of interventions, or to review or modify existing practices. The Directive places a strong emphasis on the need to justify new or modified practices, and this seems to require research. It continues in paragraph 3. of the same article by insisting

> If an exposure can not be justified, it should be prohibited.

The justification for the introduction of new interventions or modification of existing ones would require biomedical research, which, in all cases, would require exposure to persons. However, as is implied by the same article's insistence on ethical review, the research that would justify standard practices needs to be justified itself in advance of its being performed.

The *Declaration of Helsinki* provides a clear statement on this:

> The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provide that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

The essential justification for a biomedical research project needs to be clearly defined and motivated in a protocol. The protocol should be designed according to current scientific standards and it should demonstrate

1. a thorough understanding of the current level of scientific knowledge in the field,
2. a need for the research (including a need to carry out the research on persons),
3. the identity and qualifications of the researchers,
4. a statement of the objective of the research,
5. a statement of the hypothesis to be examined,
6. a well defined methodology for examining the hypothesis,
7. a well defined method for radiation dose calculation (for radiation research),
8. a statement of the potential risks,
9. a well considered ethical appreciation of the risks and inconveniences for the participants, a means for evaluating the data,
10. the inclusion/exclusion criteria for potential research subjects,
11. procedures for the ongoing monitoring of the research,
12. criteria for the discontinuation of individual subject participation,
13. criteria for the discontinuation of the study as a whole,
14. a plan for the communication of the results of the research.

Responsible biomedical research is never a freewheeling, unstructured activity. No matter how innovative or seemingly promising, the departure from standard or accepted practice by a medical practitioner does not by itself constitute biomedical research.[18] Research requires a critical evaluation

18 The 'Medical Exposures' Directive leaves open to practitioners the possibility to deviate from standard or accepted practices in individual cases. Article 3.1 (b), in the second paragraph, reads as follows:

> If a type of practice involving a medical exposure is not justified in general, a specific individual exposure of this type could be justified in specific circumstances, to be evaluated on a case-by-case basis.

Certainly no single case of a deviation from standard medical practice could be considered research. The example of a specific case could not by itself contribute to general knowledge. More importantly, while such a deviation might be envisaged (for example, in an effort to provide the best care to a terminally ill patient) it could not be justified in any scientific sense beyond the judgement, however professional or expert, of those taking the decision. How the proposed evaluation is to be made in such specific cases, the Directive does not address. Even if this sort of deviation from

of the problem to be addressed and a well prepared plan for assessing a proposed intervention. Already in 1979 the *Belmont Report* stated in summary fashion:

> [T]he term research designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.[19]

New practices or modifications of standard practices in radiation medicine require justification through research, i.e., clear demonstrations that the practices to be introduced are safe and efficacious. At the same time, the research itself needs to be justified in advance in order to show that it is ethically responsible and scientifically sound.

Applying Ethical Principles to Biomedical Research Involving Radiation

Today it is becoming increasingly clear that good science is always essentially ethical. Scientific research that is sound and well considered takes into account, not only the interests of building upon the general body of knowledge shared by the international community of scientists, but also the interests and welfare of those involved in the research and those for whom the research will have a direct benefit. High scientific thought and conduct is not distinguishable from high ethical thought and conduct. In recent years ethical principles have been introduced as part of accepted biomedical research. These principles are firmly rooted in Western moral philosophy, and they are considered to be universal in their application:

- The principle of respect for persons
- The principle of beneficence
- The principle of justice

These principles were first described in relation to the ethics of research in the *Belmont Report* and they were later articulated in much the same fashion in the CIOMS' *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. While the European *Convention on Human Rights and Biomedicine* does not enunciate these principles, they clearly form the underlying ethical structure of the document.

In the context of biomedical research, these principles function as a guide to the conscience of the researcher in the preparation of a research protocol and in the activity of carrying out the research. In addition, through the demonstration of their application, they serve as a justification for the ethical integrity of a biomedical research project. The principles can be explained in their relationship to biomedical research as follows:

RESPECT FOR PERSONS

The principle of respect for persons derives from the fundamental recognition of the dignity of each and every person. Each individual deserves to be treated with respect because of the dignity of their person. Perhaps best formulated and described in the philosophy of Immanual Kant, the dignity of a person refers to the capacity for independent and autonomous decision making. The respect due every person, in biomedical research as well as in all other activities of human life, is a fundamental recognition of their freedom in thought and self-determination, whether or not they enjoy the

standard practice would be highly exceptional, which one would expect, there remains the real problem of establishing in advance an appropriate mechanism for evaluating such types of practice.

19 Department of Health, Education, and Welfare, Office of the Secretary, Protection of Human Subjects. *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Report of the National Committee for the Protection of Human Subjects of Biomedical and Behavioural Research*. DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014. 18 April 1979. p. 3.

capacities or the circumstances to exercise that freedom. Respect for the dignity of the human person is the unquestionable foundation for ethical conduct in biomedical research.

In the European *Convention on Human Rights and Biomedicine*, this principle underlies Article 1:

> Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

The principle of the respect for the dignity of the human person has led directly in the last fifty years to the central role of the informed consent and ethical review in biomedical research. These important structures for the protection of the (potential) research participant are discussed later in this paper. The principle of respect for the dignity of each and every person applies to all activities of biomedical research. Its application supersedes all other considerations. There is no goal or achievement, in science, politics, business, or any other activity, whose value or esteem exceeds the recognition of the fundamental dignity of the individual person. Even the lofty and praiseworthy pursuit of knowledge in the service of humanity loses its force and is blasphemous to science when respect for the dignity of an individual is shunned. The principle of respect gives force and honour to the activities of biomedical research. It also underlies its two companion principles.

BENEFICENCE

The principle of beneficence derives from the obligation that persons be addressed in the interest of their well-being in each and every circumstance. This principle asserts that the aim of every medical or biomedical intervention, whether in standard practice or in research, be aimed at promoting the health (the good) of the patient or recipient of the intervention. The first sentences of the *Declaration of Helsinki* reinforce the importance of this principle in biomedical research:

> It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

Essentially, this principle asserts the obligation to maximise benefits and minimise risk. The Hippocratic maxim ‘do no harm’ applied to the situation of biomedical research requires the researcher to ensure that the risks of the research are reasonable in respect of the expected benefits.

However, it is the very nature of research that there is an area of the intervention where no current knowledge exists regarding potential risks and benefits. In all medical and biomedical research there are inherent risks, most of which – and the most threatening of which – will hopefully be seen in advance of the undertaking of the research. Still the risks (foreseen and hidden) can only be properly evaluated by well designed and executed research projects.

> Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.[20]

Biomedical research is continually challenged by the principle of beneficence. Concern with the health and well-being of the individual research subject may appear at odds with the interest of science and the need to advance biomedical understanding. Evaluating and balancing potential risks with potential benefits forms an essential task in the design and approval of biomedical research proposals.

In many biomedical situations, and certainly in the field of nuclear medicine, research and treatment can be very well joined. This is very often the case in attempts to find an improved diagnosis or

20 Department of Health, Education, and Welfare, Office of the Secretary, Protection of Human Subjects. *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Report of the National Committee for the Protection of Human Subjects of Biomedical and Behavioural Research*. DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014. 18 April 1979. p. 4.

treatment for a patient's condition or for attempting to diagnosis or treat cases for which there is no standard of care. In such cases the potential benefits justify the potential risks. However, in a great deal of biomedical research (for example, phase I radiopharmaceutical trials) healthy volunteers are the subject of investigation, and this principle appears difficult, if not impossible, to apply. There are only potential risks, no potential health benefits for the research subject. Jay Katz posed the dilemma in the following manner:

> When, if ever, should conflicts between advancing medical knowledge for our benefit and protecting the inviolability of citizen-subjects of research be resolved in favour of the former?[21]

The *Declaration of Helsinki* tries to ensure that the interests of the physician-research, qua physician, will always take precedence over the interests of the physician-research, qua researcher. However, Katz indicates rightly that the ethical challenge is not so easily removed. Instead, he concludes with the following response to the dilemma:

> 1. that any exception to the principle of individual autonomy, since it tampers with fundamental democratic freedoms, must be rigorously justified by clear and sufficient reasons; and
> 2. that such exceptions cannot be made by investigators or IRBs [ethics committees] alone, but only by an authoritative and highly visible body.[22]

Katz's proposal that the dilemma can be addressed by justifying exceptions to the ethical principle in an open and publicly acceptable manner reinforces the importance of trust in biomedical research. However, it does not resolve the dilemma. It remains difficult, if not impossible, to find 'clear and sufficient reasons' for violating ethical principles in biomedical research. With respect to the principle of beneficence, where this violation appears most threatening in research involving radiation exposure, perhaps the best researchers and society can do at the present time is to remain aware of the dilemma and vigilant in ensuring that it does not become an instrument for abuse.

JUSTICE

The principle of justice requires that biomedical researcher projects engage potential and actual research subjects equally and fairly according to the health needs of the subjects, not according to their economic means, race, creed, class, or some other form of societal entitlement. The *Declaration of Lisbon on the Rights of the Patient*[23] demonstrates a strong concern that the principle of justice is applied, not only in standard medical care, but also in biomedical research. In the Preamble it makes the following statement:

> In the context of biomedical research involving human subjects – including non therapeutic biomedical research – the subject is entitled to the same rights and consideration as any patient in a normal therapeutic situation.[24]

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21 Jay Katz, "Statement by Committee Member Jay Katz," in Advisory Committee on Human Radiation Experiments, *Final Report* (US Government Printing Office, October 1995). p. 849. Katz seems to limit the dilemma only to cases where full and satisfying informed consent has not been obtained from the citizen-subject. However, it is our contention here that the dilemma is broader, that it appears in many standard practices where informed consent is duly obtained. Having obtained informed consent (and/or favourable ethical review by an appropriate committee) does not release an investigator from any of the obligations of the ethical principles of biomedical research.

22 Jay Katz, "Statement by Committee Member Jay Katz," in Advisory Committee on Human Radiation Experiments, *Final Report* (US Government Printing Office, October 1995). p. 853.

23 World Medical Association, *World Medical Association Declaration of Lisbon on the Rights of the Patient*. Adopted by the 34th World Medical Assembly, Lisbon, Portugal, September/October 1981 and amended by the 47th General Assembly, Bali, Indonesia, September 1995.

24 This is an important statement in the consideration of research subjects. Indeed the idea may be better stated more forcefully: All potential subjects in biomedical research, including healthy volunteers, are to be considered as patients once enrolled in biomedical research, entitled to the same rights and considerations as any other patient in a research or standard care situation. It would be irresponsible for a physician or other health care professional to expose individuals to risks for the sake of research without at the same time admitting them into their care.

The *Declaration of Lisbon* continues with the following principles:

> 1. Right to medical care of good quality
>   a. Every person is entitled without discrimination to appropriate medical care.
>   c. The patient shall always be treated in accordance with his/her best interests. The treatment applied shall be in accordance with generally approved medical principles.
>   e. In circumstances where a choice must be made between potential patients for a particular treatment which is in limited supply, all such patients are entitled to a fair selection procedure for that treatment. That choice must be based on medical criteria and made without discrimination.

One of the concerns for the principle of justice in biomedical research has to do with the fair selection of research subjects. On the one hand, this concerns the equal possibility for persons to be included in biomedical research projects, particularly with respect to their health conditions. In recent years patients have become better informed regarding the potential for participating in clinical research and they have become increasingly more proactive in asserting their 'right' to participate. This has been most forcefully illustrated among communities of persons living with HIV/AIDS around the world. Biomedical research has also been faulted for its demographic make-up. Women and minority cultures have felt themselves discriminated against in the designs of protocols and the recruitment of subjects. The principle of justice, thus, concerns the fair distribution of the opportunity to participate in research among individuals and across society.

On the other hand, the principle of justice concerns the maintenance of a vigilant guard against the inclusion of persons because of a vulnerable situation in which they find themselves. Vulnerability here refers to situations of an institutionalised hierarchy (e.g., persons in prisons, the military, hospital or academic settings), of a compromised position (e.g., persons who are poor, who belong to minority cultures, or who are institutionalised), or of a physical, intellectual, or emotional impairment (e.g., persons who are unconscious, who are mentally or emotionally handicapped, or children and adolescents). With respect to vulnerability we need also to take into account persons who are in a situation that is easily manipulated or persons who are simply available. In these last two groups, we should not forget, we find patients:

> Patients have always been the most vulnerable group for purposes of research.[25]

Patients are usually the most readily available and most easily manipulated group for the recruiting biomedical researcher. Patients are notably not only interested in participating in research because of the hope for the amelioration of their own conditions, but they are very often anxious to contribute to preventing future patients/persons from suffering the same illnesses and pains they themselves experienced.

The principle of justice is also concerned with the distribution of biomedical research within societies and across societies. There is a growing awareness that biomedical research is often motivated by economic or political interests. This leads to the situation where, on the one hand, adverse health conditions that are widely prevalent or affect a well represented group within a society receive an undue proportion of biomedical research and are even subject to redundant research. On the other hand, while diseases affecting a small part of a population or weaker groups within society are largely ignored in the distribution of research. This has led to the situation in Europe (as in other developed parts of the world) where there is an increasing polarisation between 'mainstream medicine' and 'orphan medicine'. At a meeting held at the European Parliament in September 1997, P. Peters of the European Commission expressed the problem as follows:

> Public health is by definition addressed to the health needs of the entire population. This means that available health services and resources . . . should be used for the benefit of as many people as possible. This principle applies just as much to those affected by rare diseases as it does to those affected by the "major health scourges".

25 Jay Katz, "Statement by Committee Member Jay Katz," in Advisory Committee on Human Radiation Experiments, *Final Report* (US Government Printing Office, October 1995). p. 851.

> However, the very fact of the rareness of the low-prevalence diseases and conditions and the consequent lack of information about them can lead to many affected by these conditions not receiving the health resources and services they need.[26]

It can be well understood that the biomedical research community focuses its efforts on diseases that affect the larger part of the population. After all, research in these areas is usually best financed and advances in these areas lead to the largest recognition. However, a patient that suffers wants in the first place to have his or her suffering ended, regardless of the condition that causes the suffering. The principle of justice imposes upon the biomedical research community and society as a whole that a balance be developed in research investments across the entire range of health afflictions.[27]

In addition, a growing ethical concern in the biomedical research is focused on research in developing countries, as well as research in Central and Eastern Europe. There is a growing tendency, very often well founded, to export biomedical research on persons either for reasons of economics, of required study populations, or of regulatory restrictions. Three general ethical concerns arise here. First, the ethical and/or scientific standards in the community hosting the research may be unacceptably low from a European point of view. Second, the communities from which the research subjects are drawn may not benefit from the outcome of the research once the investigations are completed. Third, the infrastructure of the host community may not be able to support the research in an acceptable manner.[28] The principle of justice requires researchers to consider the situation in which the research is to be conducted and the community from which the research subjects are to be drawn. Further, the European Community has a responsibility to ensure that biomedical research sponsored by instances within the Community and carried out in other regions of the world meet the same ethical and scientific standards that are imposed on research conducted within the Community.[29]

The principle of justice also applies to considerations of compensation for subjects who are injured due to their participation in a biomedical research. The Guideline 13 of the CIOMS *International Ethical Guidelines* reads as follows:

> Research subjects who suffer physical injury as a result of their participation are entitled to such financial or other assistance as would compensate them equitably for any temporary or permanent impairment or disability. In the case of death, their dependants are entitled to material compensation. The right to compensation may not be waived.

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26 R. Peters, 'The European Commission's Views on Rare Diseases,' *Biomedical Research and Orphan Medicinal Products*, proceedings of A Roundtable Conference Organized by European Platform for Patients' Organisations, Science and Industry, Brussels, 23 September 1997. Baarn, The Netherlands: European Platform for Patients' Organisations, Science and Industry, 1998.

27 Not discussed here is the increasingly dramatic global distinction between the investment in biomedical research for diseases that are prevalent in the 'developed world' and the investment in biomedical research in the 'undeveloped world'. While the economic and political reasons are clear for this distinction, the principle of justice leaves us feeling more than a little ill at ease with the current investment and distribution of biomedical research in different regions of the world.

28 For a summary of the current discussion, see Vassilike Leontis, "Ethical Challenges Posed by Trials of Biomedical Intervention on Human Subjects Conducted in Developing Countries," [manuscript] Information paper for the preparation of the European Conference of National Ethics Committees in Porto on 9-10 November 1998. The paper was prepared under the auspices of the Bioethics Section, Directorate of Legal Affairs, Council of Europe. It was presented to the Working Party on Biomedical Research in the Spring of 1998. See also Dale Guenter, Rapporteur, "Final Report: UNAIDS-Sponsored Regional Workshops to Discuss Ethical Issues in Preventive HIV Vaccine Trials (Geneva, UNAIDS, 3 June 1998 [draft]).
It should be pointed out that currently an important amount of biomedical research on persons is being 'exported' out of the European Union because of improved efficiency and quality in the research process in other countries. This is especially the case with many clinical trials in Central and Eastern Europe. See Suzanne Pozsonyi, "Update on GCP in Central and Eastern Europe," *Applied Clinical Trials* 7.8 (1998): 32-34; and Danielle M. Jacobs, "GCP Compliance in Central and Eastern Europe," *Applied Clinical Trials* 7.8 (1998): 36-37.

29 It is expected that the Protocol on Biomedical Research currently being drafted by the Council of Europe as an addendum to the European *Convention on Human Rights and Biomedicine*.

There is general agreement among Member States in Europe today that the right to compensation for research subjects in the case of injury needs to be taken into account in all biomedical research[30]. The obligation to provide compensation remains whether the injury is due to malpractice (negligence) or product liability. Although there is no European legislation addressing this issue[31], in all Member States researchers are now required by law to provide for insurance coverage where there is risk of injury to the subject.[32]

Finally, the principle of justice plays an important role in considerations of the copyrighting and patenting of products of biomedical research. This includes considerations of intellectual property regarding scientific results and publications, as well as the manufacturing and marketing of products.

The application of the principle of justice to biomedical research requires the careful design of research protocols with regard to the recruitment, inclusion, and compensation of subjects. It also requires the development of a public health policy that address the distribution of biomedical research and the licensing of the products of the research.. Such a policy must take into account both the rights of patient (citizen) to participate in research and the need for society to protect the vulnerability of persons participating in research.

SUMMARY OF THE PRINCIPLES OF RESPECT, BENEFICENCE, AND JUSTICE

These principles provide guidance to biomedical research. They all derive from a fundamental reverence for the dignity of each and every person in all situations. A mere reference to, or enunciation of, these principles is never a guarantee that they have been applied and adhered to in preparing and carrying out biomedical research. Rather, they serve as valuable touchstones, both for the researcher engaged in clinical trials and for those outside who may demand justification of the research. These principles apply to both individual researchers and their institutions in carrying out particular research projects, and to society at large in its concern with biomedical progress and the care for public health.

Risk

The central ethical concern in biomedical research on human subjects is with the kinds and extents of the risks to which subjects will be exposed. In biomedical research risk refers to all potential adverse events arising from a subject's participation in a research project. Any potential untoward health condition that may be causally linked to a subject's participation in an investigation must be considered a risk. This is the case whether the undesired condition is a result of the agent or instrument being tested, or whether it is a result of an intervention in support of the testing of the agent or instrument. For example, a patient enrolled in a cancer trial involving the testing of a registered pharmaceutical for a new indication may be exposed to additional risks other than those that belong to the drug, e.g., the risks of radiation exposure used to measure the progression of a tumour during the course of the trial. Indeed, in some instances, the risks associated with the procedures may be greater than the risks associated with the agent or instrument being tested.

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30 See Francis P. Crawley, "The Role of Insurance Coverage in the Ethical Review System," Special Edition: The Present Position and Outlook for Clinical Trials of Medicines in Europe: The Legal Stature in the European Union and the Problems of International Harmonisation. Peter Bennett, ed. *European Pharmaceuticals Law Notebook*. forthcoming in 1998. See also Y. Lambert-Faivre, "La responsibilité médicale confrontée á l'évolution du droit et de la science," *Journal de Médecine Légale Droit Médical* 39.2 (1996): 83-86; Robert Saury, "Le contrat médical: Les aspects juridiques du 'colloque singulier' entre le médecin et le malade," *Revue française. dommage corp*. 2 (1996): 117-132; P.A.W. Edgar, "Insurance against Injury in Clinical Trials," *BMJ* 308 (1994): 1638-1639; and Denis Lacombe, "Insuring International Clinical Trials: An Academic Viewpoint," *Applied Clinical Trials* 7.3 (1998): 24-29

31 However, the Directive on product liability would be applicable to many products used in biomedical research, including some studies involving radiation exposure. See 'The Council of the European Commission, EC Product Liability Directive, Council Directive of 25 July 1985, no. 85/374/EEC.

32 The one exception to this is the United Kingdom which, while requiring insurance for biomedical research privately sponsored, does not require insurance for research sponsored by the government.

The design of each research project should take into account an assessment of the predictable risks to subjects. The risks then need to be weighed against any foreseeable or expected benefits. The fifth basic principle of the *Declaration of Helsinki* is specifically concerned with the evaluation of risk:

> Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

While the *Declaration* reinforces the dignity of the individual over the over the interests of science and society, it does not insist that persons may be subjected to risk in biomedical research only when their own prospects for benefits outweigh the risks. Article 16 of the European *Convention on Human Rights and Biomedicine* makes a similar statement:

> Research on a person may only be undertaken if all the following conditions are met:
> . . . .
> ii the risks which may be incurred by that person [the research subject] are not disproportionate to the potential benefits of the research.

It is generally agreed that for patients (with some exceptions) the benefits must outweigh the risks. However, in cases where biomedical research needs to be performed in healthy volunteers, it is generally accepted that, if the risks to the individual are kept to a minimum and there is a real prospect that the research will advance knowledge and benefit future persons, then the research may be justified.

The 'Medical Exposures' Directive follows these guidelines in its concern with risk in biomedical research involving the exposure to radiation. Article 4.2 (b) states the following:

> [Member States shall] ensure that for each biomedical and medical research project . . .
> . . . .
> — a does constraint is established for individuals for whom no direct medical benefit is expected from this exposure,
> — in the case of patients, who voluntarily accept to undergo an experimental diagnostic or therapeutic practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the target levels of doses shall be planned on an individual basis by the practitioner and/or prescriber.

Risk in procedures involving ionising radiation is evaluated in terms of the expected effects of specific radiation doses on the health of subjects. The extent of the risk depends on the amount of radiation absorbed by a subject, the dose rate of exposure, the length of the exposure, and the particular organ(s) exposed. The extent of risk is usually evaluated according to the concept of 'whole body effective dose equivalent'. Because radiation affects cellular structure, the predominant risks in radiation exposure are (1) the risk of cancer and (2) the risk of genetic mutations.

In 1977 the International Commission on Radialogical Protection published recommendations in which it identified two types of radiation effects for which protection is required:

> "Stochastic" [random] effects are those for which the probability of an effect occurring, rather than its severity, is regarded as a function of dose without threshold, whereas "non-stochastic" effects are those for which the severity varies with the dose and for which a threshold may occur.[33]

The potential for stochastic and non-stochastic effects of the projected radiation exposure need to be evaluated in terms of risk in the course of design a research project. Within the framework of the Directive, it is important to bear in mind that radiation risk in terms of biomedical research may need to be assessed in other ways than when considering other circumstances of exposure. M. C. Thorne expresses this as follows:

33 MC Thorne, "Principles of the International Commission on Radiological Protection System of Dose Limitation," *Br J Radiol* 60.709 (1987): p. 32.

> In the case of patients deliberately exposed to ionising radiations, the objectives of radiation protection differ somewhat from those applying to radiation workers and members of the public. For patients, risks and benefits relate to the same person and upper limits on acceptable risks may differ grossly from those appropriate to normal individuals.[34]

Thus, for the cases of patients and healthy volunteers in biomedical research involving exposure to research, the risk levels need to take into consideration the objectives of the intervention and the potential diagnostic or therapeutic benefit for the research subject. At the same time, it is essential that the exposure be limited to the smallest dose required to effectively carry out the investigation.

One of the most difficult challenges in biomedical research involving exposure to radiation lies in communicating the risks to the potential subjects. Robert Levine makes the following point:

> There is one important continuing problem in the field of "radiation research." That is, it is difficult to convey meaningful information to prospective research subjects about the risks of radiation exposure.[35]

While the biomedical community's knowledge and appreciation of the use of ionising radiation has increased in the last fifty years leading to refined and considerably safe practices, the general public continues to be thwarted in its attempts to come to terms with the use of radiation in medicine.

> [T]he lack of public understanding of radiation and the misleading treatment of issues of radiation safety in the popular press can confound the best efforts of physicians and researchers to explain these matters.[36]

The communication of risk to potential research subjects with terms and references that are readily understandable is one of the most important challenges to biomedical research involving radiation exposure. A carefully assessed risk-benefit ratio needs to be included in the informed consent process.

Informed Consent

The most important single safeguard to the subject in biomedical research is informed consent. The essential focus of informed consent is the subject's informed and considered decision to either participate or not to participate in a proposed research project. Informed consent is a process in which a physician (or other health care professional) proposes to a subject that she participate in a research process and explains the aim(s) of the project, the nature of the intervention, the procedures, the foreseeable risks and benefits, and other information relevant to the subject's decision to participate or not. The informed consent process is primarily concerned with extending the trust of the physician-patient relationship into the context of the investigator-subject relationship. Although the informed consent process, and especially the written informed consent procedures, has come to have legal implications, informed consent is essentially an ethical engagement.[37] The motivation behind the informed consent procedure is the ethical principle of autonomy: an individual can only freely decide

34 MC Thorne, "Principles of the International Commission on Radiological Protection System of Dose Limitation," *Br J Radiol* 60.709 (1987): p. 32.

35 Robert J. Levine, Letter to Ruth R. Faden, Chair of the United States Advisory Committee on Human Radiation Experiments, 24 February 1995, published in Advisory Committee on Human Radiation Experiments, *Final Report*, Supplementary Volume 1, p. 816.

36 James W. Ryan, Letter to Ruth R. Faden, Chair of the United States Advisory Committee on Human Radiation Experiments, 24 February 1995, published in Advisory Committee on Human Radiation Experiments, *Final Report*, Supplementary Volume 1, p. 816.

37 See D.D. Kerrigan, et al., 'Who's afraid of informed consent? *BMJ* 306(1993): 298-300; J.P. Demarez, 'Consentements', *La Lettre du Pharmacologue*, 6.9 (1992): 215-218; J.P. Gérard, et al. 'Evaluation des conséquences de la signature d'un consentement écrit sur la relation médecin-malade. A propos de la loi Huriet', *Bull Cancer* 80 (1993): 903-904; Y. Lambert-Faivre, "La responsibilité médicale confrontée á l'évolution du droit et de la science," *Journal de Médecine Légale Droit Médical* 39.2 (1996): 83-86; See also Robert Saury, "Le contrat médical: Les aspects juridiques du 'colloque singulier' entre le médecin et le malade," *Revue française. dommage corp*. 2 (1996): 117-132.

to engage in an activity if she is informed by an understanding of the potential consequences of that activity.[38]

Informed consent became the core pillar of (bio)medical in 1946 as a result of an American Tribunal decision during the trials held in Nuernberg for German's accuse of war crimes.[39] The Nuremberg Military Tribunal's decision in the case of the United States v. Karl Brandt, et al. the Nuremberg Military Tribunal issued a ten-point statement on human experimentation as part of its decision. The first point of that statement reads as follows:

> 1. The voluntary consent of the human subject is absolutely essential.
>
> This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
>
> The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.[40]

While the *Nuremberg Code* has a strong foundation for the requirement of informed consent in biomedical research, it also left a trace on the ethics of human experimentation that has been difficult to overcome. On the one hand, the emphasis on the 'legal capacity' of the subject to consent has tended toward an implementation of the informed consent process in a purely procedural manner. Indeed, even today very often the focus is on 'securing the signature' of the prospective subject, perhaps at the expense of ensuring the autonomy of the decision. On the other hand, the historical background to the *Code*, the fact that it arose in the confrontation of war criminals with heinous crimes that were clearly beyond the pale of science, led to a complacent attitude among researchers: 'Oh, our experiments are of an entirely different nature. They are sound and intended to benefit individuals or society.' In a certain sense, many researchers rejected the import of the *Code* on their work, quite logically, because they also sought to reject any importance to the 'science' carried out by Nazi doctors in the shadow of the war.[41]

The *Declaration of Helsinki* reinforced the requirement of informed consent in 1964. It brought the concept more securely into the realm of professional responsibilities in biomedical research. Basic Principle 9 of the *Declaration* states the following:

> In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and that he or she is at liberty to abstain from participation

38 See Francis P. Crawley. "The Role of Insurance Coverage in the Ethical Review System." Special Edition: The Present Position and Outlook for Clinical Trials of Medicines in Europe: The Legal Stature in the European Union and the Problems of International Harmonisation. Peter Bennett, ed. *European Pharmaceuticals Law Notebook*. forthcoming in 1998.

39 For a history of informed consent see Tom L. Beauchamp and Ruth L. Faden, "History of Informed Consent," *Encyclopedia of Bioethics*, rev. ed., Warren T. Reich, ed. (New York: Macmillan, 1995).

40 Nuremberg Code. "Permissible Medical Experiments." Trials of War Criminals Before the Nuernberg Military Tribunals Under Control Council Law No. 10: Nuernberg, October 1946-April 1949. Washington, D.C.: U.S. Government Printing Office (n.d.), vol. 2, pp. 181-182.

41 See Evelyne Shuster, 'Fifty Years Later: The Significance of the Nuremberg Code," *New England Journal of Medicine* 338 (1997): 1436-40. See also Jay Katz, "The Consent Principle of the Nuremberg Code: Its Significance Then and Now," in G.J. Annas and M.A. Grodin, eds. *The Nazi Doctors and the Nuremberg Code Human Rights in Human Experimentation* (New York: Oxford University Press, 1992).

> in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.

While informed consent is an integral part of biomedical research, informing the prospective subject of nature of her participation and allowing her to freely decide whether or not to participate, it needs to be firmly situated within the more global relationship of that between a patient and her physician. Indeed, only when viewed within this wider context is it possible to appreciate the importance of informed consent in biomedical research. The *Declaration of Lisbon on the Rights of the Patient* insists importance of the patient's right to free decision in all therapeutic (or diagnostic) situations. Principle 3.a. states the following:

> The patient has the right to self-determination, to make free decisions regarding himself/herself. The physician will inform the patient of the consequences of his/her decisions.

Similarly the European *Convention on Human Rights and Biomedicine* establishes informed consent as the General Rule for interventions in the field of health. Article 5 sets forth the following requirement:

> An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.
> This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.
> The person concerned may freely withdraw consent at any time.

The patient's 'right' to informed consent goes beyond the research situation. It is the very basis of the physician's expression of respect for her patient. In paragraph 37 of the *Explanatory Report* accompanying the European *Convention*, the different forms of consent are set forth, generally divided into express or implied, with express consent being either verbal or written. Express consent may not be required in many standard medical interventions, but this only so long as the patient is 'sufficiently informed'.

At the same time, research introduces a specific kind of situation outside of the standard physician-patient relationship. This calls for more attention to the informed consent process, ensuring that the patient (prospective subject) is aware that the intervention lies outside that of standard treatment and may involve more risk. One of the more important instruments used to address this exceptional situation is to request the individual's informed consent in writing. Neither the *Declaration of Helsinki*, the *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, nor the European *Convention on Human Rights and Biomedicine* require that informed consent in a biomedical research setting at all times be provided in writing. The lack of emphasis of, and even reference to in the latter two documents, written informed consent can be understood as a move toward a more ethical, rather than legalistic interpretation of the informed consent procedure and its value. More recently, the ICH GCP Guideline has insisted, without exception, that biomedical research involving pharmaceuticals does require the potential subject's signature on an informed consent form.

The 'Medical Exposures' Directive does not invoke the term 'informed consent'. However, with respect to biomedical research involving exposure to radiation, the Directive is clear that potential subjects need to be informed and participate voluntarily in the research project. Article 4.2 (a) requires that Member States

> ensure for each biomedical and medical research project . . .
> — the individuals concerned shall participate voluntarily,
> — these individuals shall be informed about the risks of this exposure,
> . . . .

These two points taken together would appear to require that informed consent be a part of the procedures for medical and biomedical research projects involving exposure to radiation. The Directive's requirement that individuals 'participate voluntarily' would seem to require their consent.

Similarly, the requirement that they be 'informed about the risks of this exposure' could be understood as an additional requirement for the informed consent process with research involving radiation exposure.

However, at the same time, the Directive would have been stronger on this subject if some reference had been given to the complete process of informed consent. This could have been done, for example, by reiterating (in legislation) the requirement for physicians (and other health care professionals) to abide by the *Declaration of Helsinki*. For the purposes of the ethics of biomedical research, there is perhaps a too strong concentration in the Directive on the specific science being addressed, the use of ionising radiation in medicine. Thus, the ethics of the Directive is largely limited to concerns regarding the safety of the use of radiation, and tends to ignore the wider concerns regarding the respect of the dignity of the individual in the biomedical research setting.

Ethical Review

While the requirement for informed consent in biomedical research involving human subjects addresses the core of the ethical concern with regard to respecting the dignity of the individual, the complexity of decision-making in biomedical research and the stringent need to safeguard the interest of the patient have led to the development of ethics committees. Ethics Committees are now established in all European countries. They provide a valuable resource for the investigator in her decision to engage a research project. From the point of view of the research subject, the ethics committee provides additional assurance that the engagement of her physician (health care professional) is sound and in keeping with the scientific and ethical requirements of high quality biomedical research.[42] The primary role of an ethics committee in biomedical research is to serve as an independent and competent body for examining the possible effects of proposed research on the dignity and rights of the patient-subject.[43] In this sense, an ethics committee provides an open and reliable field for the extension of the investigator's conscience.

Neither did the *Nuremberg Code* or the first version of the *Declaration of Helsinki* in 1964 make any reference to ethical review as a requirement for biomedical research.[44] It was not until the first revision of the *Declaration of Helsinki* in 1975 that the first international guideline for biomedical research included ethical review as a requirement. This was subsequently refined further in the 1989 revision.[45] The current statement on ethical review in the *Declaration of Helsinki* reads as follows:

> The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

As this statement indicates, the role of an ethics committee is not simply to approve or to disapprove a proposed research project. Rather, as an independent body, the ethics committee should reflect on the project proposed, provide comments where appropriate, and assist the investigator through guidance. It is the fact of the independence (and competence) of such a committee that it can assist an investigator in the appreciation of the bearing the proposed intervention may have on perspective subjects.

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42 See Francis P. Crawley, Guest Editor. Special Edition: Ethics and Quality Assurance in Clinical Trials. *The Quality Assurance Journal*. Forthcoming.

43 See Francis P. Crawley, "Ethics Committees and Informed Consent: Locating Responsibility in Clinical Trials." *Human Rights and Dignity in the Practice of Medicine*. Japan: Tokai University Press, 1997: 19-30. Republished in *Tokai J Exp Clin Med.* 22.6 (1997): 259-265.

44 For a history of the ethical review process, see Robert J. Levine, "Research Ethics Committees," *Encyclopedia of Bioethics*, rev. ed., Warren T. Reich, ed. (New York: Macmillan, 1995); and Robert J. Levine, *Ethics and Regulation of Clinical Research*, 2d ed. (Baltimore: Urban and Schwarzenberg, 1986).

45 See World Medical Association, "Summary History of The World Medical Association Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects," Manuscript, n.d.

The 'Medical Exposures' Directive has recognised the importance of the role of the ethics committee with respect to biomedical research involving exposure to radiation. Article 3.1 (c) states the following:

> [M]edical exposure for biomedical and medical research shall be examined by an ethics committee, set up in accordance with national procedures and/or by the competent authorities.

The advantage legislated by this Directive is, firstly, to reinforce the requirement of ethical review in the biomedical research setting where there is exposure to radiation and, secondly, to require that the exposure itself makes up part of the evaluation by the ethics committee. Thus, the implementation of this Directive should strengthen both the legal and the ethical protections for European citizens participating in biomedical research where there is exposure to radiation. The specific risks associated with exposure to radiation require that the investigator seek the advise of a multi-disciplinary and pluralistic body whose reflection can provide assurance that the foreseeable risks of the exposure have been clearly defined and that they are justifiable.

The Directive also recognises the great diversity in the ethical review process between different Member States. Largely due to historical circumstances, as well as the difference of culture in medical practice, each Member State has developed a system of ethics committees that addresses the need for ethical review in a significantly different manner.[46] There is no European system for ethical review and neither is there a recognised authoritative body for harmonising the varying procedures.[47] In order to ensure the legitimacy and quality in ethical review, the 'Medical Exposures' Directive requires that the ethics committee reviewing the exposure is in conformity with the laws or procedures already in practice in a particular country, or that the ethics committee has been established by 'the competent authorities', usually referring to a department of a member states' government having responsibility for biomedical research. In order to guarantee the required needs to protecting the safeguards to the research subject, an ethics committee must be duly established and follow well defined and sufficiently comprehensive review procedures.[48]

Ethics committees have the potential to play an important role in assisting the implementation of the 'Medical Exposures' Directive with regard to protecting the individual in the biomedical research setting involving exposure to radiation[49]. Ethics committees are not purely perfunctory instruments for analysing proposed research protocols. Today they play a tremendously important role in European society by providing a forum for education regarding both ethics and science. Established outside of

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46 See Francis P. Crawley and Joseph J. Hoet, eds., *An International and Comparative Study of Ethical Review Mechanisms for Clinical Trials and Biomedical Research in General*. London: Chapman & Hall, forthcoming. See also Eigill F. Hvidberg, 'Continuous Improvement of Ethics Committees', *Drug Information Journal* 28 (1994): 1125-1128; M.E. Redshaw, and others, "Research Ethics Committee Audit: Differences between Committees," *Journal of Medical Ethics* 22 (1996): 78-82; and C. Legrand, and others, "Clinical Trial Initiation Procedures in Europe: The Legal Framework and Practical Aspects," *Drug Information Journal* 29 (1995): 201-259.

47 See Francis P. Crawley and Robert N. Smith. 'Facilitating transnational clinical and epidemiological research.' Editorial in the Special Edition: Co-ordinating and Harmonising Clinical Research in Europe. *International Journal of Pharmaceutical Medicine*. 12.3 (1998): 125-26.

48 See European Forum for Good Clinical Practice, *Guidelines and Recommendations for European Ethics Committees*, Revised ed. (Brussels: EFGCP, 1997 [1st ed. 1995]).

49 It should be pointed out in this context that the majority of ethics committees in Europe today provide only an initial review of proposed biomedical research projects. However, there is a need for ongoing monitoring of research in order to ensure 'a sustained state of equipoise'. This requires regular intervals of data analysis and project evaluation.

> '[O]ne is obliged to stop enrolling or treating and to modify the design or stop the trial when the data from the trial or elsewhere indicate that the state [of equipoise] no longer prevails.'
>
> Curtis L. Meinert, Letter to Ruth R. Faden, Chair of the United States Advisory Committee on Human Radiation Experiments, 24 February 1995, published in Advisory Committee on Human Radiation Experiments, *Final Report*, Supplementary Volume 1, p. 820.

While the concern with 'a sustained state of equipoise' would seem to be of essential concern in biomedical research involving exposure to ionising radiation, the 'Medical Exposures' Directive makes no reference to the need for ongoing monitoring of biomedical research involving exposure.

other traditional institutional structures, such as the government or university, they provide a place for a multidisciplinary, pluralistic education.[50] Recently, the European *Convention on Human Rights and Biomedicine* stressed the importance of open discussion regarding the biology and technology of new advancements in biomedical science. Article 28 is entitled 'Public Debate':

> Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

While certainly the 'public debate' envisioned here includes such forums as the media, parliamentary debate, and traditional institutions of education, ethics committees need to play a key role in providing significant focus and continuity to the debates. Marie-Hélène Parizeau described this special role as follows:

> [T]he ethics committee engenders a place for discussion where the fundamental problems touching the patient can finally be approached outside the usual inter-professional rivalry and the role of professional authority. The ethics committee is seen as the means by which the attitudes and norms can be put into question, can be modified in the long term by an ethical sensitisation of the hospital atmosphere centred on the patient and not on the medical technique.[51]

With the growing complexity of medical and biomedical science, and the increasing specialisation of biomedical research, it is essential that European society promote forums for mutual education between scientists, as well as education between the scientific community and the general public.

So much depends today on an analysis of, not only procedures and methodologies in biomedical research, but also perspectives and values. The fact that ethics committees are composed, not only of scientists and medical professional, but also individuals drawn from other walks of live, normally having other interests in their daily concerns, ensures a richness of exchange between biomedical science and society in general. The beneficiary of this pluralistic, multidisciplinary dialogue is certainly the individual patient/research subject. At the same time, the biomedical community gains the advantage of a critical appreciation of its projects as well as perhaps the opening up of new dimensions for future investigation.

Conclusion: Radiation Research and Health Policy

As the European Commission proceeds further in supporting and advising on the implementation of the Directive, it is of essential importance that further mechanisms are devised in order to ensure that the dignity and interests of the research participant will always be advanced ahead of the interests of science and society. While in the comfort of an armchair discussion or meeting room this principle appears obvious, it may not always take precedence in actual research situations where so often many other forces try to gain the upper hand over our moral commitments. Informed consent and ethical review today provide the very best safeguards for ensuring that the dignity of the person supersedes all other interests.

With respect to the ethics of biomedical research in the European Union, the implementation of the 'Medical Exposures' Directive is in some important ways redundant. First, there is a general

50 See Francis P. Crawley, "Culture and Community in Bioethics: The Case for an International Education Programme." *Bioethics in Asia*. Norio Fujiki and Darryl R.J. Macer, eds. Christchurch, NZ: Eubios Ethics Institute, 1998.

51 '[L]e comité d'éthique apporte un lieu de discussion où des problèmes fondamentaux touchant le patient peuvent enfin être abordé hors des rivalités interprofessionelles usuelles et des rôles d'autorité professionnelle. Le comité d'éthique est alors perçue comme le moyen par lequel l'éthique peut remettre en question des attitudes et des normes, voire les modifier à long terme par une sensibilisation éthique du milieu hospitalier centrée sur le patient et non sur la technique médicale'. Marie-Hélène Parizeau, 'Comité d'éthique', *Les mots de la bioéthique: Un vocabulaire encyclopédique* (Brussels: De Boeck Université, 1993): 75.

confidence in Europe today regarding the quality of biomedical research, including research involving exposure to radiation. Second, the *Declaration of Helsinki* is a binding document for all physicians and most health care workers in all Member States, and at the Community level adherence to the *Declaration* is require for all EU funded research on persons. Third, the European *Convention on Human Rights and Bioethics*, although still in the process of ratification, is applicable to all biomedical research on persons, including research involving exposure to radiation. Expected shortly from the Council of Europe is also an additional Protocol on Biomedical Research to be appended to the *Convention*. Finally, there is a large battery of legislation at the Member State and Community levels guiding biomedical research in other fields, which would provide sufficient guidance for carrying out biomedical research involving radiation exposure.

And yet, however redundant in a general sense, the ethical requirements of the 'Medical Exposures' Directive do have the advantage of reinforcing the protection of the individual citizen-subject in biomedical research involving. The Directive helps to tie together the general ethical requirements of biomedical research with the specific risks of exposure to radiation. Additionally, as a Directive, as opposed to a Regulation, it requires the legislative bodies of the Member States to reflect on the current status of their laws governing biomedical research and radiation exposure. The law educates, Plato insisted, not only legislatures, but also practitioners and the general public.

We cannot substitute law for ethics. The most important guarantee we have for the ethical conduct of biomedical research is conscientious reflection by researchers, patients, institutions, and citizens. The *Declaration of Helsinki's* first principle clearly puts forward conscious as the fundamental guide to ethical conduct. However, the *Declaration of Helsinki* cannot stand alone. States and institutions have a responsibility to ensure that when conscience fails, or is arrested, instruments are in place to safeguard the health and integrity of persons. The 'Medical Exposures' Directive, as legal instrument, contributes to the protection of persons in biomedical research involving exposure to radiation.[52]

As the European Union moves toward the development of a European health policy, under the mandate of the *Maastricht Treaty* and the proposed *Treaty of Amsterdam*, it is necessary that we consider the role of medical and biomedical research in the health and well-being of the European citizen. A high standard for every type of clinical research – be it research involving pharmaceuticals, medical devices, surgical techniques, or radiation – needs to be included in a comprehensive policy for the conduct of human experimentation. The recent Commission communication 'On the Development of Public Health Policy in the European Community'[53] points to three strands of action for a possible new Community public health policy:

- Improving information for the development of public health,
- Reacting rapidly to threats to public health,
- Tackling health determinants through health promotion and disease prevention.

The intention of this communication is to foster discussion on how a Community policy can be designed and implemented that provides for a 'health watch' across Member States. Although the Communication includes no discussion of the role of medical and biomedical research in health policy, certainly a key area will have to be the development of an overall approach to the conduct of human experimentation. The implementation of the 'Medical Exposures' Directive will be of significant value in generating a co-ordinated and harmonised policy across the Member States with respect to human radiation experiments.

52 See Francis P. Crawley and Joseph J. Hoet. "Ethics and Law: The *Declaration of Helsinki* under Discussion." Guest Editorial. *Applied Clinical Trials* 7.4 (1998): 36-40.

53 Commission of the European Communities, "Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the Development of Public Health Policy in the European Community," Brussels, April 15, 1998, COM (1998) 230 final.

At the same time, in the field of research on human subjects involving radiation exposure, as in other fields of medical and biomedical experiments on human subjects, there is a need to appreciate the limits of governmental laws and regulations when considering the ethics of the research. If we are to move forward in the protection of individuals (citizens) in medical experimentation, then it is essential that an ongoing and open discussion be pursued within Europe concerning ethical conduct in research. Ruth Faden, Chair of the US Advisory Committee on Human Radiation Experiments, has emphasised this point, adding:

> Our report also called for the establishment of a mechanism to provide for the continuing interpretation and application of ethics rules and principles for the conduct of human subject research in an open and public forum, an essential process if research involving human subjects is to have an ethical framework responsive to changing scientific and social times.[54]

Ultimately, good ethical practice, like Good Clinical Practice, cannot be enforced from outside the research community. While vigilance and circumspect is always required, our best guarantees for ethical conduct in medical and biomedical research lie in the development of high moral values within our research institutions and among the researchers themselves. These values, focused on the unimpeachable dignity of the human person, need to be continually responsive to the changing culture of research. The patient's trust in her physician and the public's trust in its government and health institutions need to be supported in medical and biomedical research involving radiation by law, public health policy, and the integrity of researchers and their institutions.

Already today much of what we accept as standard medical interventions depends on justified and controlled exposure to ionising radiation. As our understanding of the genetic structure of human biology increases alongside our growing understanding of nuclear physics we can well expect that the exposure to radiation will become an increasingly important instrument in biomedicine. Presently, there are many afflictions to the health of persons in our societies for which the advancement of the knowledge and use of radiation medicine may provide healing and/or comforting solutions. In the interests of the well-being of the individual citizen and public health, sound ethical and scientific research in radiation medicine need to be pursued by responsible researchers and institutions. This requires the development of appropriate legislation that ensures the protection of the citizen-subject and supporting guidance for the researcher. The 'Medical Exposures' Directive makes an important contribution in ensuring that the trust European citizens are largely apt to freely confide in their research institutions is neither misappropriated nor abused.

Recommendation

While the ethics of biomedical research remains an area of broad discussion today, the ethical requirements for biomedical research are generally well defined and readily applicable to all research. However, legislation on biomedical research at the Member State and EU levels is less co-ordinated. No connection is made between biomedical research involving exposure to ionising radiation and other forms of research, e.g., research involving pharmaceuticals, medical devices, or surgical techniques. Certainly while each of these forms of research have their own specific considerations, the larger part of the ethical and legal concerns are shared. A framework needs to be developed in European legislation that takes into account all forms of biomedical research. Patients require this. Ethics Committees require this. The research community and the general population would also benefit. Such a framework should be clearly and securely tied to general health policy. This is lacking at the present moment at the level of the European Union. One hopes that recent developments will move us closer to this goal.

54 Ruth Faden, "The Advisory Committee on Human Radiation Experiments: Reflections on a Presidential Commission," *Hastings Center Report* 26.5: September-October 1996.

Currently, an ethics committee or regulatory office reviewing a protocol for testing a radiopharmaceutical would need to consider legislation in the areas of pharmaceuticals, medical devices, and radiation exposure. For the experts working in a particular field there is normally a limitation to the number of legislative acts with which they need comply. However, ethics committees and patients, as well as the general public, should not be expected to weigh through volumes of legislation in order to ensure that a single protocol is, not only in conformity with the present law, but also adheres to generally accepted ethical practice in biomedical research. There is a need, perhaps urgent, to harmonise this legislation.[55]

A step in improving the situation could be taken alongside the implementation of the 'Medical Exposures' Directive. It would be useful to consider establishing a European expert group that would draft guidelines for informed consent and ethical review in medical and biomedical research on persons involving ionising radiation. These guidelines could be tied to other existing guidelines on ethics and good research practice, while providing specific guidance for research where there is exposure to radiation.

55 See Francis P. Crawley and Joseph J. Hoet. "Clinical research ethics and the proposed directive on the implementation of GCP III/5778/96, final. Cuadernos de Derecho Europeo Farmacéutico 3.7 (1997): 177-185.

Questions (Q) / Answers (A) / Remarks (R)
relevant to the subject presented by Mr. CRAWLEY

Q: In your opinion, do we need special rules for research on women in childbearing age, i.e. different from those for men, or are ethics committees sufficient also in this case?

A: In the case of pregnancy there must be particular justification. Pregnant women should only be involved in research if the subject is relevant to pregnancy. The normal considerations for women that might be pregnant by chance still apply.

Q: How should one treat exposed workers who want to participate as healthy volunteers for research involving ionising radiation?

A: This category of people is particularly vulnerable and therefore it seems advisable to make special provision for them within a trial protocol.

Potential exposures and accident prevention in medical application

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1. INTRODUCTION

Radiation exposure is divided into two broad categories: normal exposure and potential exposure (ICRP, 1991, 1993, 1997). "Normal exposure will occur with certainty while potential exposure is not certain to occur. Normal exposure includes both exposure from operations conducted as planned and exposure from events which are unintended but have a *high probability and low consequences"*. Normal exposure is thus certain (or almost certain with *low consequences*) as opposed to potential exposure, which is not certain and *may have significant consequences*. Once the potential exposure occurs it becomes real, i.e. an accident.

The term accident is defined in (IAEA, 1996) as: "any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety". Also in this definition, the *consequences or potential consequences* is the feature, which determines if an event is considered an accident.

Medical exposure is administered in three major disciplines: diagnostic radiology, nuclear medicine and radiotherapy. In diagnostic radiology, the most relevant situations from the point of view of potential exposure are interventional procedures. Nevertheless, diagnostic radiology is discussed under another topic of this workshop. In nuclear medicine, the most important consequences arise from therapeutic procedures with unsealed sources, in which the wrong patient is treated, or the wrong radiopharmaceuticals or a nursing mother is administered a radiopharmaceuticals without measures to avoid an accidental exposure to the child (IAEA, 1998). Measures to prevent those accidents are similar to those applicable in radiotherapy. Therefore this presentation will be focused on accidents in radiotherapy.

Modern radiotherapy has three major concerns: efficacy, quality of life, and safety (WHO, 1995). From the point of view of safety, radiotherapy is a very special application of radiation: humans are directly placed in a very intense radiation beam during 25 or 30 sessions, or sources are placed in direct contact with tissue; very high doses are intentionally delivered. No physical barriers can be placed between the radiation beam and the patient. Moreover, a radiotherapy treatment involves many professionals participating in a large number of steps between treatment prescription and treatment delivery, and a large number of treatment sessions where many parameters have to be adjusted. Not only overdosage but also underdosage may have severe consequences in radiotherapy, and constitutes an accidental exposure. The potential for an accident in radiotherapy is therefore very significant and deserves special measures for prevention.

Accidents are triggered by an initiating event that, if it passes undetected, it can progress until it becomes an accidental exposure. Accidents can be then prevented by placing safety barriers (both physical and procedural) to intercept the progression from an initiating event towards an accidental exposure. For the radiation safety specialist the method of placing layers of safety is called defence-in-depth. For the radiation oncologist and the medical physicist, accident prevention is an integral part of the overall quality assurance programme that is tailored "to obtain the best possible results from radiotherapy" and that "aims to ensure consistency of the medical prescription, as regards dose to the

target volume, together with minimal dose to normal tissue and minimal exposure of personnel" (WHO, 1988).

The combination of both approaches, i.e., use defence-in-depth methodology as a test for a quality assurance programme, can bring a substantial benefit to radiotherapy. In order to identify layers of safety needed, it is necessary to first identify accident scenarios. For this purpose prospective and retrospective methods can be used. Retrospective methods (the use of experience to learn about accident scenarios) has led to improvements of equipment and procedures in industrial applications and reduced the probability of fatal accidents by as much as three orders of magnitude (ICRP, 1997). However, retrospective methods may overlook potential accidents that never occurred and therefore no information of experience can be used. This remaining potential for accidents, not detected by retrospective methods needs to be identified by prospective methods (the most important approaches are event and fault tree analysis).

In an IAEA document on "Lessons learned from accidents in radiotherapy" (IAEA, 1998), retrospective methods, i.e., lessons from experience have been used to identify accident scenarios and to provide a comprehensive list of initiating events and contributing factors. The following presentation highlights the main lessons from (IAEA, 1998) and proposes measures for defence-in-depth. For a more comprehensive review the reader is referred to the original document that will be published this year. Details on prospective methods can be found in (ICRP, 1997).

2. ACCIDENTS IN EXTERNAL BEAM

2.1. Accidents related to design, manufacture, testing and maintenance of radiotherapy equipment.

a) *Design, manufacture and testing*

An operator of an accelerator changed too quickly from x-ray mode to electron mode before the machine was able to complete the previous demand to operate in x-ray mode and it operated with hybrid instructions. The accident repeated in six different hospitals before the problem was identified and two patients died from overdosage in the order of 160-180 Gy.

The following contributing factors were identified:

- The computer controlled accelerator did not seem to have been tested under extreme conditions that occurred afterwards in real practice in six different hospitals
- The problem was handled inefficiently and before the cause was identified, the same accident had occurred in six different hospitals and caused the death of two patients

Once the initiating event and the contributing factors are identified the following measures for prevention can be drawn: an authorization by the Regulatory Authority should be mandatory, not only for users of radiotherapy equipment, but also for manufacturers and suppliers of radiotherapy equipment. As part of the authorization process, the Regulatory Authority needs to require a formal safety assessment, which should include prospective (event and fault tree) analysis for a comprehensive identification of accident scenarios, as well as testing of the radiotherapy equipment in clinical conditions, i.e., challenging the equipment to all possible operating conditions by clinical personnel.

In addition, as precondition for authorization, the Regulatory Authority should require manufacturers and suppliers to:

1. establish a maintenance network and methodology for central compilation, analysis and close follow up of unusual equipment behaviour that may affect safety;
2. train and certify maintenance personnel, including identification of safety critical behaviour and accurately report to the manufacturer event circumstances through formally established procedures;
3. promptly disseminate information on any detected safety problem, together with preventive and corrective measures and a report to Regulatory Authorities;
4. incorporate knowledge on unusual events into the training of users and maintenance personnel.

b) Maintenance

There were two major accidents related to maintenance problems: in one of them, the initiating event was the misadjustment of energy in an accelerator (27 patients involved). The other accident was due to intermittent failures, followed by frequent interruption of the treatment and several unsuccessful attempts to repair the machine which finally led to the decision to disable interlocks, thus to treat patients in "physical mode", thus disabling interlocks. Both accidents had lethal consequences.

The following factors contributed to the accidents:

- insufficient understanding on the machine circuitry and of the consequences of the mis-adjustment of physical beam parameters,
- informal transfer of the accelerator for maintenance and return for clinical use without notification to the medical physicist, which resulted in resumed treatment without dosimetric check of the beam
- it was possible for the accelerator to operate with the energy selector disabled (which is equivalent to non-clinical mode): the selected energy was not the actual energy
- conflicting display and signals (one from a key indicating the selected electron energy and another from an instrument indicating the actual energy) were not correctly interpreted by the staff, who decided to accept the wrong one. Remark: staff, which has not been trained to deal with unusual situations, tends to accept the signal which allows resuming the work, thus becoming a contributing factor to accidents.
- tools for quick constancy checks were not available at that time; therefore, frequent (daily) quick checks of the beam were not possible
- in the second accident, repeated, intermittent, unresolved equipment faults caused interruption of treatments several times; this led the radiation oncologist to decide to operate in physical mode thus eliminating defence-in-depth (safety interlocks).

From these contributing factors it follows that the requirements by the Regulatory Authority on the manufacturers and suppliers, as described above, should be complemented with additional defence-in-depth measures, such as:

1. training of maintenance personnel on the consequences of mis-adjustment of beam parameters and on dealing with and accurate reporting of intermittent equipment faults;
2. formal procedures for transferring the equipment for repair and return through the medical physicist;

3. the formal procedures should include the decision to check the beam before resuming treatment depending on the maintenance done;
4. training of the radiotherapy staff on identifying and dealing with unusual and conflicting signals;
5. availability of quality control instrument for quick (daily) check of accelerator beams

2.2. Accidents related to calibration of beams

The most important events were those resulting in an error in the dose rate, and therefore in wrong irradiation times for all patients treated in these conditions. In one case (115 patients involved) an error in the beam calibration exposure time was made, that led an underestimation of the dose rate and thus to overdosage of patients. In the second case (207 patients), the dose at 5 cm depth was confused with the dose at the depth of maximum (25% overdosage). In the third case (426 patients) the decay curves for a new Co-60 source were wrongly drawn, which led to an overdosage that increased with time because the wrong curve was departing from the correct decay; the problem remained undetected for 22 months in which the physicist was devoting his time to a new accelerator.

In addition, there were also other cases of misinterpretations of calibration certificates and errors in correction factors for atmospheric pressure, as data reported by the weather station, which were corrected to sea level, were taken as the pressure at the weather station level. In one reported case, a Co-60 beam was used without calibration (the exposure value in Roentgen from the radiation source certificate was simply taken as cGy). In another case, a plane-parallel chamber was used incorrectly (upside down), as the label was misplaced and a new physicist was not acquainted with the chamber.

The following contributing factors can be identified from this group of accidents:

- staff had insufficient overall training on beam calibration, which resulted in misunderstanding of calibration certificates (absorbed dose to water was taken for dose to air) of the use of dosimetry equipment (the orientation of the plane-parallel ionization chamber was reversed);
- there was no redundant and independent absorbed dose determination (a simple calculation mistake after a source change was not detected before treating patients);
- in one of the cases, there was a lack of periodic measurements of absorbed dose during 22 months (dedication of the physicist to a new accelerator resulted in neglecting the Co-60 unit);
- there were no clear procedures and protocols and of overall supervision of compliance with procedures;
- there was a change of physicist with poor communication and transfer of information

From the above information the following general measures can be inferred: a) formal education, training and certification of medical physicists; it should include accident case histories to increase awareness of potential mistakes in the calibration of beams; b) formal commissioning of equipment and new beams (including source change) following approved protocols and c) a comprehensive quality assurance programme, including external audits. In addition, the following, more specific defence-in-depth measures and cross-checks can be implemented:

1. comparison of the obtained dose rate of the beam with the manufacturer’s source certificate (diversification of methods)
2. redundant calibration by an independent person with an independent instrument before initiating treatments (redundancy)

3. participation in postal dose check services (redundancy and diversification)
4. periodic re-measurement of the beam as part of the quality assurance programme (monthly for Co-60 beam)
5. “in vivo” dosimetry of the first fraction of a patient (redundancy and diversification)

It seems that any radiotherapy department can easily afford at least three of these layers that could have prevented all of the reported accidents.

2.3. Accidents related to treatment planning

The most important accident occurred when a manual distance correction was made, not knowing that the computer algorithm of the treatment planning system (TPS) already included the correction, thus the correction was applied twice. As a result, an underdosage of more than 1,000 patients, by as much as 30%, depending of the target volume depth. This led to a much lower tumour control probability than expected from the prescription.

In addition to this accident, there were several cases with entering wrong tables with basic data to be used by the computerized TPS. In another case, wedge factors were introduced twice and finally, a manufacturer provided inaccurate data that were used without acceptance test.

The following contributing factors were identified:

- an insufficient understanding of the TPS lead to a mistaken use of the correction factor;
- the absence of a formal commissioning of the TPS, following accepted protocols, made it possible for the mistake to be used in actual planning
- the lack of an independent check of the planning (either by manual calculations to selected points or by measurement on a phantom, or by “in vivo” dosimetry) resulted in wrong doses to patients and that remained undetected for several years.

The following measures would have prevented the accidents under this group:

1. training of staff on the specific type of TPS (more generally, training on any new equipment)
2. formal procedures for commissioning of TPS using approved testing protocols;
3. redundant test of a the TPS by a second independent person;
4. manual dose calculation of doses to reference points;

In addition, the following provisions would avoid accidents with individual patients:

1. in vivo” dosimetry for the first fraction of individual patients
2. formally approved protocols to transfer the prescription into the treatment planning to avoid miscommunication

2.4. Accidents related to treatment simulation

In one reported case, the wrong side of the patient was treated (laterality accident) due to incorrect labelling of the simulator film. Factors contributing to this accident were that the simulation was made in an unusual position and that there was no check of the anatomical site relative to the film.

2.5. Accident related to the treatment set-up and delivery

In one case, a patient responded when another patient was called by his name and a fraction of 2.5Gy was given to the wrong site; in several cases the use of the wrong patient's chart led to treating the wrong site (in one of them the accident was prevented by the presence of a second technologist who detected the wrong site and terminated the session); in another case, a tattoo from a previous treatment was confused with the correct one; in another case, the oncologist relied just on asking the patient to identify the site and the patient received a treatment with a strontium plaque to the eye instead of the prescribed 10 Gy external beam treatment; a technologist continued six more sessions than prescribed.

The factors contributed to the accidents:

- the procedure for identification of patients against the chart was not followed,
- the procedure for identification of the treatment site against anatomical marks on the patient were not followed or were ambiguous and patient objections about being treated on the wrong site were not thoroughly verified (looking at both patient and chart), or
- in the opposite case, the oncologist relied only on the answer of the patients with regard to the treatment site
- irradiation was initiated with the settings for rotational therapy from a previous patient

Provisions for accident prevention based on defence-in-depth philosophy are:

1. a picture of the patient should be on the chart (picture)
2. additionally, the patient should be requested to identify him/herself and verified against the chart, rather than the staff saying the patient's name and relying only on the answer "yes" or "I am", which is more likely to fail
3. anatomical marks should be unambiguously recognizable following accepted and documented procedures
4. involvement of two technologists in identifying the patient and site as well as in the whole set-up and delivery

3. ACCIDENTS IN BRACHYTHERAPY

3.1. Equipment design, manufacture, testing and maintenance

The most important case, related to equipment design and manufacture was an accident with fatal consequences in which sources were dislodged from the drive mechanism of an HDR remote afterloading machine; the warning signal from an area radiation monitor was ignored and the patient and clothes were not monitored before leaving the room. In another case, a treatment to the wrong site was given because a kink in the catheter prevented the sources from reaching the treatment site. The following were thought to contribute to the accidents:

- equipment seemed not sufficiently tested for extreme conditions such as stuck source train in the catheter or kink catheter
- conflicting signals were misinterpreted (the equipment signal was showing "source shielded" while an area monitor was indicating that there was radiation) and the wrong one was accepted
- there was a history of malfunctions of the radiation monitor that favored the misinterpretation, since the staff did not trust the monitor and believed in a false alarm

- the patient, clothes and room were not checked with a portable radiation monitor for the presence of a radiation source.

The same measures proposed in 2.1 for external beam are applicable to brachytherapy equipment. Additional special measures are required for HDR brachytherapy: since the contingency plan has to be applied within a few seconds and there is no time to wait for the person in charge of safely returning the sources, his/her presence is permanently needed (during all treatments).

3.2. Accidents related to source order and delivery, source calibration and acceptance

Different units were used by the hospital (mCi) and the manufacturer (mg-Ra-equivalent); the use of different units led to an overdosage of 74% of one patient. In three cases there was an underdosage due to the use of the sources without checking the source activity. In one of them the sources were used over years thus involving many patients, and the deviation in dose ranged from -5 to -29%. The factors that contributed to these accidents were:

- in one case the supplier delivered "wrong" sources;
- the delivery documents and source certificate were not sufficiently checked against the purchase order (only the number was checked but not the unit) and
- sources were used without acceptance test and without source calibration;
- sources were used as interchangeable without check for consistency;
- in one case, a wrong conversion factor was used when the hospital switched from Ra-226 to Cs-137;
- sources no longer in use were not withdrawn and physically separated from the others.

This group of accidents shows that accidents generally occur when more than one contributing factor are present, that is to say when more than one protective "barriers" fail (in these cases, a mistake by the manufacturer and lack of check by the user). Defence-in-depth measures would need a regulatory requirement to use the same units in all documents and a quality assurance programme in both the manufacturer's and user's procedures to cover the contributing factors listed above.

3.3. Accidents related to treatment planning

The errors under this group resulted in a wrong time calculation, the deviation from the prescribed dose ranging from -59% to +49%. Contributing factors were:

- copies of an obsolete form were still available for clinical use;
- miscommunication between radiation oncologist, physicist and dosimetrist (a treatment plan was modified but the unmodified protocol was used for treatment);
- lack of independent time calculations;
- in one case the records did not include the treating distance for the time calculation of the brachytherapy treatment.

The same defence-in-depth measures listed under 2.3 for external beam are applicable to brachytherapy.

3.4. Source preparation for the treatment

Wrong sources were used in some of the cases (-50% of the prescribed dose in one case, and doses lower than intended during three months in another case), in one case the manufacturer had delivered a

source with essentially no activity; two Ir-192 sources were lost (they were separated from the ribbon and left unsecured); a leaking I-125 source was re-used; sources withdrawn from clinical use were used with incompatible applicator. Contributing factors were:

- personnel handling sources and applicators lacked proper training;
- sources withdrawn from clinical use were not removed and were re-used by mistake;
- source activity was not verified;
- leakage of a source was not detected during preparation, and a similar incident that had occurred in another hospital had not triggered a check action;
- a source ribbon end was not correctly identified;
- survey of all radiation sources before implanting was not performed.

3.5. Accidents related to the treatment delivery

Events of this group were: a resident physician did not implant all prescribed sources; the wrong patient was treated; a source ribbon was dislodged from the catheter and was taped by a nurse on the face of the patient; sources became displaced; sources were removed by the patient; and a source that did not match the applicator was loose and fell out of the applicator.

The following factors contributed to these events:

- an untrained physician worked without supervision; general nurses were caring for brachytherapy patients with no specific training, no procedures and poor communication of instructions, that were not understood;
- a prescription was misunderstood;
- procedures for accountability of the sources were not in place;
- the wrong chart was left on the console of the remote afterloading machine and there was a lack of verification;
- errors were made with unusual treatments.

Defence-in-depth for prevention this group of accidents should include the measures to identify the patient, site and type of treatment similar to those listed under 2.5 for external beam. In addition, since the lack of specific training of nurses was a contributing factor to some of the accidents, safety provisions should include:

1. regulatory requirement of training for nurses of brachytherapy on caring for patients with sources inside;
2. formal procedures for caring for brachytherapy patients;
3. formal procedures to inform new staff including change of duty of nurses for brachytherapy patients);
4. rehearsal of brachytherapy procedures.

3.6. Accident related to source removal

In addition to the case described under equipment design (HDR sources left inside the patient), there were several cases in which sources were lost due to lack of check after removal.

Contributing factors were:

- sources were not accounted for after removal;
- the patient, clothes and room and/or waste from the treatment room were not monitored;
- in one case, the sources were checked after removal against the total number of sources implanted, but not against the total number of sources that were sent to the room (more sources were sent than needed);

The preventive measures to remove the above contributing factors are obvious.

4. MITIGATION OF ACCIDENTS

The above overview of accidents shows that, often, staff was unable to recognize an accidental situation (although there was some evidence through signals and displays) and made the wrong decision or chose to ignore a warning signal. In most cases people engaged in such behaviour because of frequent prior false alarms, time or work pressure, or a feeling that the "rules don't match the job" (ICRP, 1997). Training on recognizing unusual events, and procedures and rehearsal to deal with them are essential for early detection and mitigation. An important element is the frequent clinical observation of patients' reaction and side effects: since a certain degree of side effects is expected under normal conditions, too little or too much side effects and complications may be an indicator of an under or overdosage, i.e., a significant deviation from the prescribed treatment.

5. SUMMARY OF CONCLUSIONS AND MEASURES FOR ACCIDENT PREVENTION

A formal safety assessment should be mandatory, not only to the radiotherapy department but also to manufacturers, suppliers and maintenance companies. The distribution of equipment in a country should only be authorized if there is a comprehensive strategy for maintenance.

Safety culture should permeate the use of radiotherapy and awareness should be promoted by training not only radiation oncologists, medical physicists, and technologist but also brachytherapy nurses maintenance engineers. The training should not only cover normal situation but should also be focused on detecting and effectively dealing with unusual events. Hospital managers and health authorities should undergo a training focused on raising awareness on the potential for accidents in medical exposures, their consequences and measures for prevention.

A comprehensive quality assurance programme, incorporating defence-in-depth commensurate to the potential for accidents and to the consequences, should be precondition to any authorization and be present in all steps of radiotherapy. Examples of defence-in-depth are given in the preceding sections. The programme should include external audits to detect incipient degradation of safety before it results in an accident.

Procedures for mitigation should be in place in order to effectively deal with detected unusual events. Close observation of patient's side effects and complications (frequency and severity) may detect under or overdosage.

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Questions (Q) / Answers (A) / Remarks (R)
relevant to the subject presented by Mr. ORTIZ

Q: What are the most common accidents in nuclear medicine?

A: In diagnostic applications, most of the 'accidents' are due to human failure, for example confusing examinations, isotopes or patients. Fortunately the consequences are not dramatic in most cases.

Q: Don't you think it would be useful if information on incidents and accidents in medical applications could be published more widely so that we all could learn from them?

A: Yes, I agree. In some countries it is obligatory to inform the authorities of accidents. Sometimes such events are also published in journals, for example journals of radiation protection associations. The Medical Device Directive contains a requirement that users of equipment should inform producers if the equipment is found to have failed.

Diagnostic Reference levels (including patient dosimetry)

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1. INTRODUCTION

Article 4 of the new Medical Exposure Directive (MED97)[1] deals with the optimisation of medical exposures. As an aid to keeping doses *As Low As Reasonably Achievable* (ALARA) it requires Member States to promote the establishment and use of *diagnostic reference levels (DRLs)* and for national regulations implementing this requirement to be in place by May 2000.

Article 2 of MED97 defines DRLs as:- "dose levels in medical radiodiagnostic practices or, in the case of radiopharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied." Article 6 furthermore requires "that appropriate local reviews are undertaken whenever *diagnostic reference levels* are consistently exceeded and that corrective actions are taken where appropriate".

The definition and promotion of DRLs in MED97 were preceded by remarkably similar recommendations from ICRP in its publication 73 in 1996[2]. In ICRP's recommendations DRLs - "are a form of investigation level and (for x-ray examinations) 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. DRLs should be related only to common types of diagnostic examination and to broadly defined types of equipment. They will be intended for use as a simple test for identifying situations where the levels of patient dose or administered activity are unusually high".

It is clear from both MED97 and ICRP Publication 73 that with their primary function as the initial standards in a local radiology (or nuclear medicine) audit process, *diagnostic reference levels* need to be expressed in terms of quantities that are readily known or can be easily measured in all medical imaging departments. Moreover, the values at which they are set by Member States should be at the borderline between good and bad current national practice rather than at some "optimum" level based on the latest and best technology.

2. APPROPRIATE DOSE QUANTITIES AND MEASUREMENT TECHNIQUES

2.1. X-ray examinations

To achieve widespread use, diagnostic reference levels need to be expressed in terms of dose quantities that are clearly defined and that can be easily measured with readily available dosemeters of sufficient precision and accuracy. They should provide a measurement of the typical dose received by patients examined in a particular facility from either a particular type of individual radiograph or a particular type of complete x-ray examination.

European experience in national, regional and local surveys of patient doses has been extensive over the past decade or so. Two dose quantities have become established for practical routine monitoring of

patient doses in conventional radiology (i.e. excluding CT). They are Entrance Surface Dose (ESD) for individual radiographs and the Dose-Area Product (DAP) for complete examinations.

The ESD can be directly measured with small dosemeters (usually TLDs) attached to the skin where the centre of the x-ray beam enters the patient. It is defined to include the radiation backscattered from the patient. Alternatively, ESD can be estimated from x-ray tube output measurements made in free air with an ionisation chamber dosemeter during routine quality assurance tests. In this case an appropriate backscatter factor should be applied and the measurement corrected for any difference between the measuring point and the position of the entrance surface of the patient. Backscatter factors are significant for the x-ray spectra and beam sizes used in diagnostic radiology and are likely to range between 1.2 and 1.4.

DAP is conveniently measured with a specially designed ionisation chamber DAP meter which can be attached to the x-ray tube diaphragm housing. The total DAP from a complete examination even when it involves fluoroscopy as well as radiography can be accumulated by the DAP meter and compared with the appropriate reference level. This provides a measure of the degree of patient protection afforded both by the imaging equipment and the examination procedures (e.g. collimation, number of images taken, duration of fluoroscopy, etc.) that are adopted in a particular facility.

DRLs are not intended to be used as investigation levels for individual patients but are to be compared with measured or assessed mean values for a representative sample of patients. Since doses are critically dependent on patient size, it is recommended that measurements be made on a representative sample of about 10 adult patients with mean weight close to 70 kg. The average dose to such a sample for each particular type of radiograph or examination should provide a good indication of typical clinical practice in each room of an x-ray department. The average doses can then be compared with national DRLs to assess local performance.

Different dose quantities are needed for CT where the exposure conditions are quite different from those in conventional radiology. Patient doses from CT examinations are relatively high, making the establishment of diagnostic reference levels for CT particularly important. A recently published EC Working Document on *Quality Criteria for Computed Tomography*[3] provides guidelines on DRLs for CT and recommends two dose quantities somewhat analogous to ESD per radiograph and DAP per examination for conventional x-rays. These are a weighted CT Dose Index ($CTDI_W$) per CT slice and a Dose-Length Product (DLP) per CT examination. Unlike the case for conventional x-rays, these quantities can only be derived from measurements on phantoms. The phantoms however are widely available and represent the head and trunk of average-sized adult patients.

2.2. Nuclear Medicine

Both ICRP Publication 73 and the EC Medical Exposure Directive recommend that diagnostic reference levels in nuclear medicine be expressed in terms of the quantity - administered activity. The activity administered to patients for diagnostic nuclear medicine procedures should be known and checked before every procedure, so this is readily available information that requires no additional measurements.

3. PHILOSOPHY BEHIND THE SELECTION OF REFERENCE VALUES

3.1. X-ray examinations

The method for selecting DRL values depends critically on a clear understanding of their intended purpose. Both MED97 and the ICRP recommendations state that DRLs are intended to act as **investigation levels** triggering a local investigation if the typical dose for a specific type of diagnostic

procedure is found consistently to exceed the relevant reference level. Unless such relatively high doses can be justified by sound clinical judgement, appropriate corrective action should be taken to improve practice. Appropriate action will involve changes in procedures or equipment to reduce doses to below the DRL without compromising the quality of the diagnostic information.

Essentially, diagnostic reference levels act as a simple test for identifying situations where patient doses are **becoming unusually high and action is most urgently required**. With this function in mind, they should not be set at an "optimum" or "minimum achievable" level but more at the borderline between acceptable and unacceptable practice.

A pragmatic way of setting this level, and one which has been adopted in earlier UK[4] and European[5] protocols, is to use the third quartile values observed in wide scale surveys of typical doses for common procedures. It was argued that if 75% of x-ray departments can operate satisfactorily below this dose level, then the remaining 25% should be made aware of their considerably less than optimum performance and should be encouraged to alter their imaging equipment or examination techniques to bring their doses in line with the majority. Indeed, ICRP Publication 73 recommends that - "...initial DRL values be chosen as a percentile point on the observed distribution of dose to patients." A report on *Nordic Guidance Levels for Patient Dose in Diagnostic Radiology* published in 1996[6] uses values closer to the mean rather than the third quartile. However, the survey was spread over 10 years in Norway and most Nordic hospitals are now expected to be able to meet the DRLs derived from the mean of measurements going back over such a long period.

Tables 1 and 2 show the DRLs currently quoted in the above UK, European and Nordic guidelines. The UK national reference dose values of ESD per radiograph and DAP per examination for standard adult patients are based on rounded values of the third quartile of the distributions of the mean doses seen on representative samples of patients from each hospital in the NRPB national survey of 1984. The same ESD reference dose values appear in the *European Guidelines on Quality Criteria for Diagnostic Radiographic Images*[5] since a 1991 European trial[7] showed similar mean dose distributions to the 1984 UK survey. More recent UK patient dose data (up to 1995)[8] show a clear trend towards lower doses for common conventional x-ray examinations. However, although the distributions of typical doses have shifted downwards, the variability between hospitals remains as high as before, indicating a continuing need for (perhaps lower) reference doses to help identify and bring more into line those hospitals at the top end of the dose range. Some UK x-ray departments are already using the more recent survey data to set lower reference doses for local use. The national levels have, so far, remained unchanged but are under review by NRPB and representatives of the professional bodies in radiology in the UK.

Table 3 shows the proposed DRLs for routine CT examinations as quoted in the EC Working Document on *Quality Criteria for Computed Tomography*[3]. They are also based on the third quartile values of the distributions of mean doses observed for representative samples of patients at each CT centre in a national survey. The most comprehensive national CT survey for which results were available at the time the document was published was an UK survey performed in 1989.

Article 9 of MED97 requires that special attention be given to patient dose assessment for children undergoing medical exposures. If DRLs are to be established for paediatric radiology they will undoubtedly have to be different from those for adult patients due to the large differences in patient size between children and adults (and indeed amongst children ranging from neonates to adolescents). So far within Europe only the most rudimentary DRLs have been developed for a few common paediatric radiology examinations and appear as dose criteria in the *European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics*[9]. Further studies are continuing supported by the EC Radiation Protection Research Programme.

3.2. Nuclear Medicine

The only published reference levels for common nuclear medicine procedures at the present time appear in the IAEA et al Basic Safety Standards[10] as *Guidance Levels,* based largely on the "maximum usual activities" (MUAs) quoted by the UK Administration of Radioactive Substances Advisory Committee (ARSAC)[11]. However, the derivation and purpose of these MUAs has not been formally established and they have not yet been officially recognised as diagnostic reference levels in the UK.

4. WHO IS RESPONSIBLE FOR SETTING DRLS?

ICRP Publication 73 recommends that - "the (DRL) 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." In MED97, the appropriate regulatory authorities within each Member State are required to ensure that guidance on the establishment and use of DRLs is available, but there is no indication of where this guidance should come from apart from a reference to - "having regard to European DRLs where available".

Whereas it is known that many aspects of radiodiagnostic and nuclear medicine practice differ between Member States, the impact that these differences might have on patient dose distributions within each country is not clear. It would seem to be most appropriate for individual Member States, in the first instance, to establish their own DRLs based on national dose distributions for a few common procedures. The regulatory authority should consult the professional bodies involved in medical radiology and radiological protection to develop national guidance on these matters. However, the resources required to determine national dose distributions are considerable and if they are not available in a particular Member State in time for implementation of this MED97 requirement by May 2000, then the levels published by the EC[3.5] could possibly be used.

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Table 1. Diagnostic Reference Levels in terms of ESD per radiograph

Radiograph		ESD per radiograph (mGy)	
		UK[4] & Europe[5]	Nordic[6]
Lumbar spine	AP	10	6
	Lat	30	
	LSJ	40	
Abdomen	AP	10	
Pelvis	AP	10	5
Chest	PA	0,3	0,2
	Lat	1,5	0,5
Skull	AP	5	
	PA	5	
	Lat	3	

Table 2. Diagnostic Reference Levels in terms of dose-area product per examination

Examination	DAP per examination ($Gycm^2$)	
	UK[4]	Nordic[6]
Lumbar spine	15	10
Barium enema	60	50
Barium meal	25	25
Intravenous urography	40	20
Abdomen	8	
Pelvis	5	4

Table 3 Proposed Diagnostic Reference Levels for CT examinations [3]

Examination	$CTDI_w$ per slice (mGy)	DLP per exam (mGy cm)
Routine head	58	1050
Routine chest	27	650
Routine abdomen	33	770
Routine pelvis	33	570

Questions (Q) / Answers (A) / Remarks (R)

relevant to the subject presented by Mr. WALL

Q: Diagnostic reference levels are set at the 75 percentile, as you illustrated. Why are they set only on the upper side of the distribution whilst examinations with low exposures usually do not provide the practitioner with useful diagnostic information?

A: Diagnostic reference levels form part of a quality assurance programme. The nature of such a programme is that it combines several criteria including image quality and diagnostic efficacy. So we should consider all aspects at the same time.

Q: What is the exact meaning of a reference level? It is not a level which your are aiming at, is it? And if you apply the system of revising these levels towards the lower part of the dose distribution on a continuous basis, where do you stop?

A: As I said before, reference levels are based on today's practice. They are used as a first step in the optimisation process to identify the 'bad guys' who are well away from the optimum. Corrective measures will have a maximum impact in this case. Reference levels are certainly not target values. If you are below them, it does not mean that you should not continue the optimisation effort. As far as the downward trend is concerned I do not see any problem in setting tighter goals when techniques improve and doses come down. Any way, we are still far away from the lower limit therefore this question is not quite relevant for the moment.

Justification of medical exposures and medico-legal exposures

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Introduction

I have the task of addressing the subject of justification of medical exposures, in particular medico-legal exposures. The Medical Exposure Directive gives prominence to the argument of justification. In doing so it requires us to be conscious of the broader philosophical, ethical and social contexts in which the question of justification of medical exposures is to be resolved. No scientific calibration, however sophisticated, can give us answers to this question. The matter is particularly difficult when, as m the case of medico-legal exposures, there is no way of balancing a direct health benefit to a particular person against the individual detriment that the exposure may cause him or her. Where there is such a direct health benefit, the calculus has the aura of the exercise of a conventional medical decision; without that benefit, the decision clearly has to be made by reference to other important non-medical criteria.

Justification for medical exposure under Article 3

Article 3(1) sets out the general principle for justification, requiring a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits the medical exposure produces against the individual detriment that it may cause. Article 3 (3) provides that, if an exposure can not be justified, "it should be prohibited." The concept of prohibition is worthy of reflection. It implies some edict or law which specifically provides, not merely the delimitation of what should be done, but also the specific banning of any activity falling outside the scope of that determination. I am not sufficiently familiar with the civil law systems to know whether the terminology of Article 3 (3) implies in those systems that there must be a legal sanction against exposures that can not be justified. Certainly, in the common law system of Britain and Ireland, Article 3 (3) would suggest that there has to be such a sanction. Indeed one normally speaks of prohibitions in the context of criminal sanctions.

I will now discuss in detail some of the other aspects of Article 3. Clearly it is significant that Article 3 (1) (a) requires that *new* types of practices must be justified in advance before being generally adopted and that *existing* types of practices *may* (not *must*) be reviewed whenever new important evidence about their efficacy and consequences is acquired. Article 3 (1) (b) requires all individual medical exposures to be justified in advance. If a type of practice involving a medical exposure is not justified in general, a specific individual exposure of this type "could be justified in special circumstances, to be evaluated on a case-by-case basis." The tentative use of "could be" and the emphasis on special circumstances and case-by-case evaluation make it clear that this exception is not envisaged as a particularly wide one. Article 3 (1) (c) requires that medical exposure for biomedical and medical research be examined by an ethics committee. This is in line with the general developments in regard to such research in most member states. Article 3 (2) deals with "helpers." It requires that the exposure show a sufficient net benefit, taking into account also the direct health benefits for the patient, the benefit to the helper and the detriment that it might cause. Some complicated ethical issues arise in this context, which I will merely adumbrate here, since they are reflected in the context of medico-legal exposures, which I discuss below. What is at stake is the practical conflict between the benefit to the patient and the detriment to the helper. In contrast to the person subjected to medico-legal exposures, the helper is not merely suffering detriment. His or her altruism is part of the tapestry of human

solidarity on which society is founded. Those called on to make decisions relating to justification in this context have the difficult task of determining the point at which paternalistic principles should override or limit the helper's exercise of altruistic autonomy.

Medico-legal procedures

I now turn to medico-legal procedures. It may be the useful, first, to mention the provisions of the Directive which refer explicitly to medico-legal procedures. Article 1(2)(e) makes it clear that the Directive applies to the exposure of individuals as part of medical procedures. Article 2 defines medico-legal procedures as "procedures performed for insurance or legal purposes without a medical indication". Article 3(1), which sets out the requirement that medical exposures referred to in Article 1(2) must be justified, provides in paragraph (d) that:

> "special attention shall be given to the justification of those medical exposures where there is no direct health benefit for the person undergoing the exposure and especially for those exposures on medico-legal grounds".

Article 4(2)(c), expanding on the optimization principle, requires Member States to "ensure that special attention be given, to keep the dose arising from the medico-legal exposure referred to in Article 1(2) (e) as low as reasonably achievable". Finally, we may note Article 4(4), which requires Member States to "ensure the laying down of procedures to be observed in case of medico-legal examinations".

What are medico-legal procedures?

As we have noted, Article 2 of the Directive defines medico-legal procedures as "procedures performed for insurance or legal purposes without a medical indication". This definition is understandably broad. It would have been unwise for the Directive to have attempted to provide an exhaustive list. Clearly, a procedure performed for insurance purposes falls within the scope of the definition. A person who wants life insurance cover, for example, may be required to submit to a medical examination, with the extra requirement of being subjected to a medical exposure. It might be considered that exposures of this kind are elective in the sense that the person need not apply for the insurance cover if he or she objects to the fact that it involves a medical exposure. In the real world, however, the insurance cover may in practice be compulsory, since it may be tied to an important aspect of the person's life -such as employment or a financial commitment (a mortgage, for example) which cannot be shaken off.

Article 2 speaks of procedures "for.... legal purposes". These can range widely. The legal process may require a person to subject himself or herself to a medical exposure. Legal systems throughout Europe vary widely but there would appear nothing in principle which is contrary to the European Convention in Human Rights for legislation or a court to require that a person can be subjected to a medical exposure where due regard is taken of that person's entitlements to life, health, bodily integrity, privacy and autonomy. I do not here wish to address in detail this aspect of the law other than to note that, in criminal law proceedings, concern for the presumption of innocence and principle against self-incrimination must be taken into account in determining the limits of the scope of the requirement to subject oneself to any medical or other intervention which impacts on one's bodily integrity and privacy. It is interesting to note that in the recent Irish decision of J. v C. (otherwise C.T.), High Court, 14 October 1996, Budd J. held that the Master of the High Court had competence to appoint a psychiatrist as medical inspector of both parties to a suit of nullity of marriage. He specifically rejected the argument that the appointment of such an inspector infringed the respondents' rights to bodily integrity and privacy.

In civil litigation, it may be necessary, or at all events highly desirable, that a litigant be subjected to a medical exposure. In some instances, the authenticity of a plaintiffs complaint of a medical condition can be tested effectively only by means of such an exposure. In other cases, where it is necessary to check a plaintiff's medical progress, a medical exposure may also be essential.

The Justification Principle

I now turn to consider exposures on medico-legal grounds in the context of Article 3, which sets out the justification principle. Article 3(1) requires that medical exposure referred to in Article 1(2) must show "a sufficient net benefit", weighing the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefit to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation.

Thus, on the one side are all the total diagnostic or therapeutic benefits, including (but clearly not limited to) the direct health benefits to an individual and the benefits to society. In the case of medico-legal exposures, as the Directive acknowledges in Article 2, there are no medical indications. One can envisage some relatively rare cases where beneficial medical results may follow from such exposures but these are not the reason for their occurrence and cannot seriously be considered under the justification principle.

If medico-legal exposures are to be justified as showing "a sufficient net benefit", therefore, the justification must be based on some other ground. What precisely is this ground? Article 3 would appear to be limited to "the benefits to society". It is hard to identify any other "potential diagnostic or therapeutic benefits". Undoubtedly society benefits from the phenomenon of medico-legal procedures involving medical exposures. The administration of justice, the litigation process, the delivery of insurance services and other areas of life would all be compromised, to a greater or a lesser extent, if these procedures were not available. But the fact that there are social benefits associated with any particular practice does not mean that it is necessarily justified. One must weigh the benefits against the damage that can result. In the present context, human individuals will suffer the damage in the interests of society.

The question of the extent to which an individual must risk injury or death for the benefit of society is of profound philosophical and ethical proportions. Much of the history of philosophical debate over the past two and a half millennia has been concerned with this question.

Some philosophers have argued in favour of broad utilitarian principles which allow for a "felicific calculus" in which individual welfare is subsumed into a social calculation and in which the language of individual rights that are capable of withstanding social convenience is anathema. Philosophers who adopt a materialist understanding of humanity do not necessarily give priority to social benefits (though many do), but they sometimes reject the concept of individual rights, either in its totality or in particular contexts. Other philosophers give centrality to human dignity, capacity, freedom and autonomy. Some of them seek to integrate that understanding with the vision of human beings as essentially "social animals", owing duties to their society and being entitled to its protection. Others adopt a more individualistic approach, some going so far as to assert that society has no legitimate claim to intrude upon individual autonomy.

The Directive makes no attempt to adopt any particular philosophy in this context. What is noteworthy is that its terminology nowhere seeks to answer in any specific way that is capable of empirical translation the question of what practical outcome should follow from the fact that a particular medical exposure is one that is part of a medico-legal procedure.

Article 3(1)(d)'s approach

In this context the language of Article 3(1)(d) is of interest. As has been mentioned, it requires that "special attention" be given to the justification for those medical exposures where there is no direct health benefit for the person undergoing the exposure and "especially" for those exposures on medico-legal grounds. A requirement to give special attention to the justification issue is not the same as a requirement to desist from authorising an exposure in any particular instance. What Article 3 (1)(d) does is to call the decision-maker to a state of particular solemnity when reaching a decision as to justification in this particular context. It does not seek to guide the decision-maker in any way as to the particular outcome of that decision.

I point this out not in criticism of the Directive but merely to show what might not otherwise have been obvious, which is that the Directive, having highlighted the issue of exposures on medico-legal grounds, is neutral on the question of which philosophical approach should be taken to resolve the justification question. If I had a criticism of the language of the Directive, it would be that Article 3(1) in its references to exposures on medico-legal grounds, uses language which makes no overt reference to the concepts of human dignity, autonomy and bodily integrity. I can fully understand why there should be some reticence about doing so, but it would seem possible to have given some acknowledgement of the true complexity of the problem and of the fact that there is a profound difference between balancing benefits against detriment in respect of one particular person and balancing social benefits against one particular person's detriment. These two questions raise quite different issues.

The existing legal framework

I cannot speak with any authority about the position in civil law systems. It may, however, be worth mentioning that courts in common law systems are well used to addressing in specific contexts precisely the balancing process which Article 3 requires. This arises most frequently in negligence litigation. Negligence is the all-pervasive tort (or delict) of the late twentieth century. Negligence litigation is used, not merely to respond to such manifest wrongdoing as careless driving, sub-standard medical treatment and ill-considered financial advice, but also to address and resolve in a judicial form complex issues of social policy.

Thus, for example, in the English decision of Knight v Home Office [1990] 3 All E.R. 237, the court had to determine whether a prison hospital should be required to come up to the same standards in monitoring the condition of a disturbed prisoner with suicidal tendencies as would be expected in a specialist psychiatric hospital. In Watt v Hertfordshire County Council [1954] 1 W.L.R. 835 and in Heeney v Dublin County Council (Irish High Court 1988) the courts had to consider the extent to which the emergency nature of a fire-fighter's occupation might affect the scope of an employer's duty of care to the fire-fighter. The courts have accepted that they have to balance the risk of injury to the plaintiff against the social benefits that result from the risky activity and the costs of removing or mitigating the risk. In addressing this balancing process, the courts are not guided by any overt philosophy since, as with Article 3, they operate on an analytic formula which allows them fill in the particular philosophy to which they subscribe. That philosophy changes over time and differs from country to country, yet the skeletal formula remains unchanged, it is capable of accommodating such diverse approaches in the "law and economics" school of Chicago with a more humane, person-centred approach favoured in some other jurisdictions. As McHugh J.A observed in the Australian decision of Western Suburbs Hospital v Currie, 9 N.S.W. L.R. 511, at 523 (1987),

> "negligence is not an economic cost/benefit equation. Immeasurable 'soft' values such as community concepts of justice, health, life and freedom of conduct have to be taken into account".

Future approaches

Perhaps the best way for the law at a Community level to deal further with the issue of medical exposures in the context of medico-legal procedures is to address specific areas and deal with them directly in relation to those areas. It would have been folly for the Medical Exposure Directive to have attempted this task. What is necessary is for these particular areas to be identified and for policies regarding medical exposures to be developed in the light of the corpus of law associated with these areas. Thus, for example, criminal law contains its own unique limitations which have no direct parallel in other legal contexts. In criminal law, an issue may arise as to the circumstances (if any) in which it is legally permissible to obtain evidence by means of a medical exposure against the wishes of the accused person. Over and above any questions of bodily integrity, privacy and autonomy, the criminal law has its own reasons for restraint, concentrating on the principle of the presumption of innocence and what in the common law system is identified as "the right to silence". In civil law, it is worth noting that circumstances can differ radically. It might possibly be thought fair to take the view that a plaintiff in personal injury litigation who refused to subject himself or herself to a necessary medical exposure should suffer the consequences in having the action dismissed or at least having serious inferences drawn against him or her. There are, however, other types of civil litigation where the party who is reluctant to subject himself or herself to a medical exposure is not such a free agent. A person who claims that he or she has been wrongfully committed to a mental hospital is placed in a dilemma rather than having a free choice, since the only option here may be between undergoing the exposure or remaining in the hospital. Somewhat similar considerations could arise in relation to refugees and asylum-seekers, who may not be truly free to decline the option of subjecting themselves to undesired exposures.

In this context, Article 4 rather than Article 3 may in practice offer the best protection. The obligation it sets down in paragraph (c) of Section (1) to ensure that special attention be given to keeping the dose as low as reasonably achievable requires that explicit consideration be given to the purpose for which the exposure is required.

Concluding Observations

The framers of the Directive are to be commended for their inclusion of medico-legal exposures within its terms. The principle of justification set out in Article 3 has the flexibility to render it capable of easy implementation throughout the Community.

Questions (Q) / Answers (A) / Remarks (R)
relevant to the subject presented by Mr. BINCHY

Q: Would it be of interest to define a European list of prohibited radiological practices?

A: In the first place the MED does not require such a list. I do not think that it would be feasible to develop such a list within the transposition period of only 2 years. It might be envisaged at national level, but I do not think that MS are keen on this.

Q: Does the EC plan a uniform approach towards medical-legal exposures, for example the radiological examination of drug smugglers?

A: I do not think so. There is not enough specificity and detail available to produce something realistic within such a short period of time. Also at the national level I do not see it happening. The question of calculating ratios of individual detriment versus social benefits is a difficult one. As regard the particular case of drug smuggling, criminal law not only considers the violation of the integrity of the individual but also the presumption of innocence and the entitlement of the suspect not to incriminate himself. Both principles have a bearing on a compulsory intervention such as an X-ray examination.

Q: What is your attitude towards consenting children?

A: I cannot give you a bold and clear answer to this question. The traditional view in law practice was to seek consent from the parents. Now there is a trend towards a greater autonomy for the child and the age of consent is clearly coming down - 10 to 15 years old, for example. But it remains a grey area where no absolute prohibitions exist and where courts are reluctant to go beyond general phrases such as: '…special attention shall be given … ' which you also find in the MED.

Q: In your opinion, does the MED contain requirements that could lead to court cases claiming money from practitioners for malpractice as we often see in the USA?

A: In Europe, no tradition of medical legal litigation exists. In the USA, the situation is different because they have the jury system which is not applied to such cases in Europe. Here medical legal negligence actions are not easily won because courts are reluctant to sanction practitioners for malpractice. Secondly, the level of damages awarded for malpractice in Europe is lower than in the USA. Therefore, I do not think the same situation will develop in Europe.

Training for medical application of ionizing radiation

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Introduction

Article 7 of Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure (1), establishes requirements concerning education and training. Member States may find that certain aspects of this Article require some clarification and guidance and this paper could provide an initial platform for discussion of a future EC Guideline containing some specific recommendations for the application of the Directive.

We assume that "adequate theoretical and practical training for the purpose of radiological practices" already exists in accordance with national requirements and that there are in existence national mechanisms to control this level of training. Nevertheless, some specific cases may need to be reviewed. One such instance concerns radiology technicians: there are very major differences between Member States in the content and length of their training (especially in the case of Spain).

For those aspects related to "relevant competence in radiation protection", harmonization at European level would be desirable. Great differences may exist between the Member States. Work along these lines was carried out in 1991-1993, as part of the European Commission (EC) VALUE programme for Radiologists and Radiographers. Draft documents concerning "Specific Educational Objectives in Radiological Protection and Quality Assurance for Diagnostic Radiology Installation Personnel" were produced (2). Within the framework of the ongoing European Concerted Action DIMOND (Digital Imaging: measures for optimisation of radiological information content and dose), a similar document for Interventional Radiology has also been drafted (3).

Some indication of the required level of training in radiation protection (RP) would be convenient to ensure appropriate curricula in the different Member States, establishing differences between:

- radiologists, nuclear medicine and radiotherapy specialists
- cardiologists
- other medical doctors using x-ray systems (specially fluoroscopy systems), such as urologists, vascular surgeons, traumatologists, etc.
- dentists
- orthopedists
- radiographers, nuclear medicine and radiotherapy technicians (if they have different previous training in a particular country)
- medical physicists
- maintenance engineers and maintenance technicians

Training for nurses, radiographers and other radiology technicians is required under Article 5.3 of the Directive. Medical physics experts are included in Article 6.3. Maintenance Engineers and other auxiliaries involved in medical exposures are not specifically mentioned, but obviously they need training in RP.

The World Health Organisation (WHO) recommendations for Interventional Radiology, produced during a Workshop held in Munich, in October 1996 (4), could be a good example of the training and credentialing requirements for people involved in interventional radiology practice.

During the workshop held in Grado (Italy) in September 1993, sponsored by the EC, some relevant conclusions about training in radiation protection were stated (5). One of the conclusions was that "a general and strong impression which came up was the need and demand to improve training in radiation protection and in quality assurance. Common training programmes at European level must be continued. A practical way to make progress in the harmonisation of training could be the elaboration of specific educational objectives, as made within the EC VALUE Programme for radiologists and radiographers".

The introduction of topics on quality assurance (QA) as part of the training programmes in radiation protection would contribute to the promotion of the safety culture. The routine application of QA programmes requires the participation of radiology technicians and a good training of this group of professionals is essential.

ERPET (European Radiation Protection Education and Training) courses are also a source of good training material. EC departments will publish the proceedings of the last course, held in Madrid in May 1997, on radiation protection in interventional radiology (6).

The experience of the American College of Radiology (ACR) could be valuable in this field. The ACR has established a Commission on Education, including specific Committees on Accreditation for Continuing Medical Education, Systematised Refresher Courses, Residency Training, Professional Self-evaluation Committee, etc.

Guidelines for the basic aspects of continuing education programmes are needed in Europe and ACR standards can be a relevant source of information.

It seems that in some European countries, national regulations do not deal very effectively with aspects concerning training. PHS Smith has recently published a paper in The British Journal of Radiology (8) stating that "some aspects of the POPUMET regulations (Protection of Persons Undergoing Medical Examinations or Treatment, UK regulation 1988), have caused considerable difficulties and have been ineffective, particularly with regard to training".

Other British authors (AD Quinn et al.) stress that the UK regulations state that a person clinically or physically directing a medical exposure shall have received adequate training to obtain a core of knowledge. Clinical directing is defined as having clinical responsibility for the decision to effect a medical exposure. In some fluoroscopy examinations this responsibility may lie with non-radiologists. The "core of knowledge" is defined in the statutory instrument and includes:

- knowledge of the nature of ionising radiation;
- risk of ionising radiation;
- range of dose associated with a particular procedure;
- principles of dose reduction.

These authors think that the introduction of a compulsory core of knowledge in medical school courses may be a more appropriate way to achieve the principles of POPUMET.

The International Commission on Radiological Protection also stresses the importance of training for good protection in medical exposures in its recent recommendations about "Radiological Protection and Safety in Medicine" (10).

General recommendations for Training Programmes in Radiation Protection

A list of topics to be included in the training programmes in RP for the different groups of professionals should be established. Good examples are the VALUE documents mentioned above (2),

agreed during a number of meetings attended by radiologists, radiographers and medical physicists from various European Countries. The following training areas have been agreed as being relevant to radiation protection:

- Atomic structure and the interaction of radiation
- Radiological quantities and units
- Physical characteristics of x-ray machines
- Fundamentals of radiation detection
- Detectors used in diagnostic installations
- Fundamentals of radiobiology: cell, systemic and whole body responses
- Radiation protection. General criteria
- Operational radiological protection
- General RP aspects in diagnostic radiology
- Particular aspects of patient and staff RP
- Quality control and quality assurance
- National and European regulations and standards
- Practical training

The WHO recommendations for interventional radiology (IR) requires a specific second level of training in RP for these specialists (11), defined for the following areas:

- X-ray systems for IR.
- Dosimetric quantities specific for IR.
- Radiobiology: risks in IR.
- Radiological protection of the staff in IR.
- Radiological protection of the patients in IR.
- Quality assurance in IR.
- Local and international rules concerned with IR.
- Procedures optimisation in IR.

There are also British recommendations for topics to be included in RP training for nuclear medicine (12):

- Nature of ionising radiation and its interaction with tissue.
- Genetic and somatic effects and how to assess their risks.
- Patient Doses
- Quality assurance and quality control
- Dose limitation
- Pregnancy
- Unsealed sources
- Organisation of radiation protection
- Statutory responsibilities

German regulations include special radiation-protection courses with the following content (13):

- Radiation physics, dose, and dosimetry
- Radiobiology and radiation risk
- Radiation protection of personnel and patients
- Radiation protection law
- And a second part about practical continuing training (physicians perform this training during the residency period)

Additionally, it is obvious that the topics to be included in the training courses, and the level of knowledge of the topics, should be different and adapted to the various specialities (diagnostic radiology, radiotherapy, cardiology, dentistry, etc.) and the different kind of work and responsibility (medical doctors, medical physicists, maintenance engineers, radiographers, etc.). During the WHO Munich meeting (11), different levels of training were proposed for interventional radiology. A list of topics and a level of knowledge were drawn up where relevant, for medical doctors, radiographers, nurses and maintenance engineers (medical physicists should know all the listed topics).

Table 1 presents a proposal of training topics and level of knowledge for the different groups of health professionals involved in medical exposures.

A formal recommendation about the number of hours for the training programmes (theory and practical work) should be established. This training period will depend on the prior knowledge of radiation physics, radiobiology, etc., possessed by the various groups of professionals in the different countries. A good tool for defining the number of hours need for training could be the use of guidelines containing the specific educational objectives (2, 3), whereby the length of the training period would depend on the objective to be achieved.

It is easier to agree a list of topics to be taught and a catalogue of specific educational objectives, than a set number of hours of training. Training is not just a matter of courses. Self-training and good training material should be promoted. A common level of knowledge in RP throughout Europe for the different groups of health workers would be desirable.

The range of recommended training time varies very widely, from half a day in the UK for practising nurses and doctors in Nuclear Medicine (12) to several weeks in Spain (14).

Practical exercises and practical sessions should be included in these programmes. As a minimum, a practical demonstration, lasting between one and two hours, in a clinical installation should be included even in the most simple training programmes. Practical sessions should make up 25-50% of the total time scheduled in more extensive courses.

TABLE 1									
TRAINING TOPIC	DR MD	RT MD	NM MD	CD MD	DT	MD	TE	NU	ME
Atomic structure and interaction of radiation	m	h	M	L	l	l	l	l	m
Nuclear structure and radioactivity	--	h	H	--	--	--	l	l	m
Radiological quantities and units	m	h	M	M	l	l	m	l	m
Physical characteristics of x-ray or therapy machines	m	h	l	M	l	m	m	l	h
Fundamentals of radiation detection	l	m	h	L	l	l	m	l	h
Fundamentals of radiobiology	m	h	h	M	l	m	l	l	l
Radiation protection. General criteria	h	h	h	H	m	m	m	l	m
Operational radiological protection	h	h	h	H	m	m	m	m	m
Particular RP aspects of patient	h	h	h	H	m	h	m	m	m
Particular RP aspects of staff	h	h	h	H	m	h	m	m	m
Quality control and quality assurance	m	h	m	M	l	l	m	l	m
National and European regulations and standards	m	m	m	M	m	m	m	l	h
Recommended training hours	20-30	40-60	30-50	20-30	10-15	15-20	15-50	10-15	40-60

DR/MD = Diagnostic Radiology Specialists (Medical Doctors)
RT/MD = Radiotherapy Specialists (Medical Doctors)
NM/MD = Nuclear Medicine Specialists (Medical Doctors)
CD/MD = Cardiology Specialists (Medical Doctors)
DT = Dentists
MD = Other Medical Doctors using X-ray systems
TE = Technicians
NU = Nurses
ME = Maintenance Engineers

Level of knowledge:

l = Low level of knowledge
m = Medium level of knowledge
h = High level of knowledge

The lecturers for these kinds of training programmes should be carefully selected. They should have previous experience in radiation protection in medical installations and in practical work in a clinical environment. Installations conducting practical training should be medical installations and not only laboratory or simulation exercises.

An important element in the outcome of these training activities is the availability of training material. Specific material in the form of books, slide collections, videos, interactive CD ROMs etc., is scarce and not always at the right level for the various courses. The EC should encourage the publication of the proceedings of the different ERPET courses and promote the drafting of specific training material

for a set of basic courses (e.g. basic training in radiation protection for cardiologists). Exploiting the experience gained in the various European countries in this field could also prove very useful.

Some specialities such as interventional radiology require, according to WHO (11) recommendations, a second level of specific training in radiation protection, over and above the general level received by diagnostic radiology specialists.

Special consideration should be given to the case of medical doctors (non radiologists) using fluoroscopy x-ray systems on a regular basis (urologists, vascular surgeons, traumatologists, etc.). In the USA, these doctors require a specific credentialing process in radiation protection (15): in Europe a similar system should be established.

Paediatric Radiology also requires some specific topics in RP for radiologists and radiographers involved in these examinations.

Recommendations concerning the credentialing process in radiation protection

A system for credentialing the training programmes in RP should be established at national or regional level. This responsibility should be assumed by the regulatory authority or by academic institutions (such as universities). A register of accredited bodies should be established.

The minimum requirements for credentialing a training programme should take account of all the aspects involved: enough administrative support, guarantees for the archiving of files, diplomas, etc., for a minimum number of years, enough didactic support (classroom, audiovisual support, etc.), teachers qualified in the topics to be taught and with experience in hospital medical physics work, instrumentation for practical exercises, availability of clinical installations for practical sessions, etc.

In the case of accreditation programmes for radiology technicians, it seems logical to require that training be conducted in hospital radiology departments with radiologists, medical physicists and senior radiology technicians as teachers.

Various alternatives should be proposed for credentialing different professionals with different duties and responsibilities (examination at the end of the course, residency, continuous evaluation, etc.).

The basic information cited in the diplomas or certificates received by people attending a training programme in RP should include: the centre conducting the training, number of accredited training hours, process of credentialing (examination or other form of assessment), date of the training, name of the tutor with responsibility for the training programme, etc.

The second level of training in RP for Interventional Radiology, recommended by the WHO (11) would also require a specific accreditation. The same applies in the special case of medical doctors using fluoroscopy on a regular basis.

Recommendations concerning radiation protection of the patient in relation to individuals undergoing training programmes in health centres

The RP of the patient during the training of residents and other health workers (radiographers, technicians, etc.) requires special consideration. The criteria of justification and optimisation should be applied carefully and all the procedures should be performed under the responsibility of a senior specialist.

Some specific recommendations could also be given for planning practical RP training in medical installations (e.g. X-ray systems must remain operational after the training sessions; if patients are

involved, simple procedures (low doses) must be selected; training must not involve any additional irradiation of the patients, etc.).

In the case of high patient dose procedures (interventional and some vascular diagnostic procedures), a strict patient dose control should be performed to guarantee that no significant additional doses are imparted.

Recommendations on continuing education and training after qualification and when new techniques are implemented

The ACR Continuing Medical Education (CME) Standard (for physicians and medical physicists) requires a minimum of 150 hours of approved education in category 1 and 2 every three years (this will be renewed in a three-year cycle) (7).

Category 1 (designated by ACR or other recognised organisations). The minimum number of hours is 60. Accredited residencies and fellowships up to 50 hours per year can be included.

Category 2. The maximum number of hours allowed is 90. Activities accepted: medical meetings, lectures, course syllabi, study of authoritative medical literature, teaching radiology-related services to medical students, preparation and publication of scientific papers, presentation of papers, courses, or scientific exhibits, clinical consultations, use of computer-assisted learning materials designed to enhance patient care, review of manuscripts for peer-reviewed journals and review of abstracts for scientific meetings.

If we consider this figure as a realistic recommendation, percentages between 2 and 6% (1 - 3 hours/year) of training devoted to continuing education in RP could be considered, depending on the kind of work. A radiotherapist or a medical physicist could need more time than a dentist.

Such continuing education in RP should be promoted by the Regulatory and Health Authorities and some basic courses, when necessary, should be organised by health centres, academic institutions or professional and scientific societies.

When a new radiation system is introduced in a Health Centre (e.g. a new CT or interventional radiology X ray system), staff should receive specific training before any clinical use of the system and the participation of the engineers of the firm supplying the system should be required. This training should be part of the commissioning process of the new radiation system. It is important to consider the responsibility of the supplier concerning the availability of full and understandable instructions in the local language.

Also, when a new technique is implemented in a centre (e.g. intravascular brachytherapy or some new interventional procedures) prior training for staff should be required. In this case the training should be carried out in another centre with previous experience in the technique to be implemented and the considerations stated in the previous section about “Recommendations concerning radiation protection of the patient in relation with individuals undergoing training programmes in health centres”, should be taken into account. A certain number of examinations and/or procedures, which should be performed under the control of an experienced physician could be considered in some cases.

Recommendations regarding the course on radiation protection in the basic curriculum of medical and dental schools

The EC Directive states that “Member States shall encourage the introduction of a course on radiation protection in the basic curriculum of medical and dental schools”.

Assuming that a basic knowledge of radiation physics exists as part of the content of the disciplines taught during the preclinical period (basic Medical Physics or equivalent), the recommended RP course could concentrate on topics which focus on patient protection. A possible outline could be the content of ICRP 73, Radiological Protection and Safety in Medicine (10).

1. Introduction
2. The Quantification of Radiation Dose and Risks
3. The Framework of Radiological Protection
4. The Justification of a Practice
5. The Optimisation of Protection
6. Individual Dose Limits
8. Practical Methods of Protection
9. Operational Guides and Reference Levels
10. Accidents and Emergencies
11. Institutional Arrangements

Obviously, differences between Medical and Dental Faculties should be considered where appropriate. Also a RP course should be introduced in nurses and orthopedic schools.

The duration of these courses should be between 15 and 30 hours, assuming some prior knowledge of radiation physics. Approximately 20-30% should consist of practical sessions analysing typical cases presented in clinical practice (pregnant patient who needs a radiological examination, paediatric exposures, dose and risk comparison between conventional and CT examinations, etc.).

This course should be mandatory and taught at the end of the preclinical or during the clinical period.

Outline for specific training in Radiation Protection for Interventional Radiology

As example of the usefulness of formulating specific educational objectives when preparing training activities, we present some items defined by a group of DIMOND experts (3), in line with the topics proposed during the WHO meeting in Munich:

1. X-ray systems for interventional radiology.

- To explain the effect of high additional filtration (e.g., copper filters) on conventional x-ray beams.
- To explain the operation of continuous and pulsed X-ray emission modes.
- To explain the benefits of the grid controlled X-ray tube when using pulsed beams.
- To explain road mapping.
- To explain temporal integration and its benefits in terms of image quality.
- To analyse the changes on the dose rate when varying the distance from intensifier to patient.

2. Dosimetric quantities specific for interventional radiology.

- To define the dose-area product (DAP) and the units it is usually measured in.
- To discuss the correlation between surface dose and DAP.
- To discuss the relationship between DAP and effective dose.
- To correlate the dose at the entry point in the patient with the dose at the exit surface and the dose at the intensifier input surface.

3. Radiobiology: risks in interventional radiology.

- To describe deterministic effects which may be observed in IR.
- To analyse the risks of deterministic effect induction as a function of the surface doses received by the patients.
- To analyse the relationship between received doses and deterministic effects in the lens of the eye.
- To be aware of the likely time intervals between irradiation and occurrence of the different deterministic effects, the required follow up and control of patients.

4. Radiological protection of the staff in interventional radiology.

- To comment on the most important factors which influence dose levels to staff in IR laboratories.
- To analyse the influence of X-ray C-arm positioning on occupational doses.
- To analyse the effects of using different fluoroscopy modes on occupational doses.
- To analyse the effects of using personal protection (e.g. leaded aprons, gloves, eyeglasses, thyroid protectors, etc.).
- To analyse the benefits and drawbacks of using articulated screens suspended from the ceiling.
- To understand the importance of choosing a suitable location for personal dosimeters.

5. Radiological protection of the patients in interventional radiology.

- To analyse the correlation between image number taken in a procedure and dose received by patients.
- To discuss the effects of the focus to skin distance and patient image intensifier input distance.
- To analyse the dose reductions attainable by modifying the image rate in cine or in digital acquisition.
- To give typical examples of patient entrance dose value per image in different procedures.
- To analyse the effect on the patient dose of using different magnifications.
- To discuss the parameters which should be recorded in the patient's history related to (or with reference to data concerning) the received doses.

6. Quality assurance in interventional radiology.

- To discuss the difference between parameters that usually do not downgrade over time and those which could do so and require regular checks.
- To discuss the importance of establishing simple criteria to compare doses at the patient or at the intensifier entrance, in different controls.
- To note the importance in QA programs of regular checks of patient dose and its comparison with reference dose levels.

7. Local and international rules concerned with interventional radiology.

- To discuss the different national regulations which apply in IR installations.
- To describe the international recommendations on IR (WHO, IAEA, ICRP, EC, etc.).
- To provide information about the international recommendations concerning to limitation of high-dose modes.

8. Procedure optimisation in interventional radiology.

- To note the value of optimisation in IR radiation procedures.
- To discuss the importance of reference levels related to the patient dose, at the local, national and international levels.
- To analyse the importance of regular patient dose checks in each room.
- To discuss the possibility of using different C-arm orientations addressing long procedures in which the threshold of deterministic effects may be attained.
- To analyse the importance of recording the dose values imparted to every patient.

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Questions (Q) / Answers (A) / Remarks (R)
relevant to the subject presented by Mr. VAÑO

Q: In medical physics, a shortage of trained physicists in diagnostic radiology is imminent. Does the EC envisage doing something about this?

A: Training is in the first place a national matter. However, in the past EC training schemes in collaboration with EFOMP have tried to give physicists access to the latest knowledge in the various application fields. For example, last summer we had a summer-school in Nice on radiology physics which was quite successful. The EC is planning to continue this effort to set an example and to help Member States to achieve a good level of education.

Q: Do predefined training programs for medical physicist in patient dosimetry, quality assurance, etc. exist?

A: For the moment I don't think such training programs exist. It would be a good suggestion for the EC to organise such courses in collaboration with EFOMP.

Q: Do you think that minimum levels of education for radiographers and radiology technicians can be set at European level together with an accreditation system.

A: The EC has no legal basis for doing this. It is, however, currently preparing a general guide, non-binding on Member States, where proposals for minimum knowledge for all the relevant professionals will be suggested. This guide could help to harmonise the approach of Member States in this respect.

Q: Which countries in the Union have regulations on continuing training?

A: No data are yet available but the European guide in preparation will suggest ways of realising continuous education together with a defined level of knowledge and an accreditation system.

R: The professional associations of radiologists and nuclear medicine specialists have developed curricula for practitioners on a European level. They are available to the Member State authorities who can use them as the basis for drafting legislation.

Q: In the undergraduate curriculum of a medical school, students in some countries receive training courses of about 10 hours on radiation protection aspects. In which year of the 6 years' basic curriculum do you think this training should take place?

A: The MED recommends providing such training in medical and dental schools. There is no recommendation yet to what extent such training should be given but I think it is important that the radiation protection training should be given at a level where the students are aware of what radiology means, what its purpose is, etc. Therefore I would say that the last two years, when clinical training is given, seems the correct moment to do so.

Special exposures: Paediatrics

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Introduction

There are basic differences in anatomy, physiology, distribution of radiosensitive tissue and age related diseases of paediatric patients as compared to adults. The most important points are listed in **Tab.1**. These differences greatly affect radiographic and fluoroscopic imaging. Furthermore, the susceptibility of paediatric patients to ionizing radiation is assumed to be higher than that of adult patients.

The MEDICAL EXPOSURE DIRECTIVE (Council Directive 97/43/Euratom) stresses many factors relevant for the of use of ionizing radiation in relation to medical exposures. According to **Article 9** exposures of paediatric patients have been defined as special exposures which have relevance in respect to education and training of radiographers/radiologists, appropriate equipment as well as effective optimization procedures. Optimization of diagnostic imaging (**Article 4**) depends on many factors: education and continual training and regular quality control measures organized by state authorities, medical physicists and the radiology departments itself.

SPECIFIC IMAGING PROBLEMS IN PAEDIATRIC PATIENTS

Holding persons

Ideally, no holding persons should be involved in radiography and fluoroscopy of patients. But in reality, severely ill patients require assisting persons to monitor the patient's condition. Furthermore, partially cooperating paediatric patients, especially after trauma or with severe pain, need holding persons to stabilize the patient's position for exact exposure.

If at all possible, the helping person should be a technician or a nurse. But, practically, often the parents present can and often will hold the child. If they hold the patient, they should be clearly informed as to the details of the radiologic examination so that they could properly fixate their child during the whole examination. If female persons assist the radiographer or the radiologist, they should be asked about a possible pregnancy.

According to a recent European survey on paediatric fluoroscopy in children's hospitals holding persons are present in frequently performed examinations, e.g. micturition cysturethrography, barium meal, in about 50% **Fig.1**.

X-ray equipment

X-ray tables and stands must be equipped with special paediatric holding systems and fixation devices to allow safe and quick examinations of paediatric patients of all ages **(Articles 8 and 9)**. These supporting devices for uncooperative patients in different sizes must be available for radiography, fluoroscopy and computed tomography. Correct positioning of the infant and toddler is a key point to obtain high quality radiographs. This can only be reached with fixation techniques (taping), specific restraining devices and tubes. As a consequence, radiology departments and private practices which are not appropriately equipped should not be allowed to x-ray paediatric patients.

The use of automatic exposure control (AEC) for radiography in young paediatric patients is often of limited value, even for such simple examinations as chest X-ray, pelvis etc. Currently, available measuring systems are oversized, and even special designs of AEC do not function properly because young patients will frequently move of out of the measuring area. Very often, these systems are combined with non-removable grids which are not needed in young infants and children. As the use of grids will often unnecessarily increase the dose to the patient these systems should be appropriately modified (removable grid) for use on paediatric patients **Fig.2**.

For this reason, most paediatric radiology departments use free hand settings based on age and weight of the patient for radiography. However, weight is not an ideal parameter to calculate the optimal exposure parameters of paediatric patients. In the future modern X-ray systems will use the diameter of the patient, e.g. by measuring the focus film distance and also the entrance site of the patient with ultrasound. Thereby, the optimal mAs-product can be calculated.

Blurring of spot films caused by rapid, unforeseeable movements in uncooperative young children occur frequently if the exposure time is too long. However, short exposure times are only possible with modern converter generators with high power (50 - 80 kW). Even mobile generators should be able to switch a minimum exposure time of at least 2 ms and very small mAs products. This problem is especially important since the number of X-rays in intensive care units (ICUs) of ventilated patients has enormously increased over the last 10 years.

It is well known that the kV pulse curve and the switching behaviour is highly dependent on the type and the performance of the generator. Regular constancy tests in defined intervals should be done, especially in equipment which are used exclusively or mainly in paediatric patients **(Article 8)**. For these tests special paediatric phantoms should be used. The test intervals should not be too long, e.g. 4 weeks would be sufficient. It is important to include all equipment, especially mobile equipments and C-arm systems, e.g. used in orthopaedic surgery into the quality assurance programmes.

OPTIMIZATION IN RADIOGRAPHY

Recommendations for good radiographic technique and image quality criteria for the most frequent X-ray examination of paediatric patients were officially published in the *European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics* EUR 16261 EN, Luxembourg. The practicability of the image criteria were evaluated in several Europe-wide dosimetric trials in four different age groups — newborns, infants, the 5 year old and the 10 year old patient. A relationship between the reduction of the entrance surface dose (ESD) with increasing compliance to the guidelines without deteriorating effect on the image quality score was found in almost all examinations and age groups tested by the European trials. **Fig.3** shows this for the chest X-rays of the five year old patients. However, these graphs also show that only 30% of the radiology departments participating in these surveys had implemented the criteria for good radiographic technique.

The reasons for the lack of introduction of the radiographic criteria of the European guidelines were: technical factors, e.g. old-fashioned equipment, insufficient knowledge of the radiographers and radiologists on radiation physics, but also, adherance to traditional procedures and strict protocols, e.g. routine use of grids, use of only one low speed screen-film system.

Simple optimization procedures in radiography are the use of the recommended voltage, addit-ional filtration, reasonable use of grids and high speed screen-film-systems/ digital image receptor systems

Following these guidelines the dose to patient can be reduced by a factor of 10 to 20. The only objective against this introduction is the adverse effect on the image contrast and the increase in noise. In most cases, this contrast degradation is acceptable for chest and abdominal films because most questions of the clinicians, e.g. catheter control, tube positioning, bowel obstruction etc., can still be

answered. Occasionally, bone radiographs for special questions, e.g. battered child syndrome, hyperparathyroidism etc., must be of high contrast and high resolution. In these cases, no additional filtration and a screen-film combination equivalent to a 200 system should be used. However, the maximal dose saving effect is only reached when all components — screen, film and cassette material (carbon fibre material, Kevlar®), and the film developing system— fit together.

Digital radiography, mostly storage phosphor plates, is now increasingly used as an image producing system especially in intensive care radiography. The resolution of newer systems is comparable to the standard screen-film combinations with a speed of 200 to 400. The advantage over conventional screen-film combination is the wider range of exposure with no significant loss or even enhancement of information and the possibility of image storage, transfer and postprocessing. Because the dose in digital radiography can inadvertently increase **Fig.4**, periodical or continual dose measurements are indicated. The paradoxical increase in dose is caused by unnecessary high mAs-product values set by the technician under the conditions in an ICU which are often highly variable and not beneficial for dose saving methods. Because the film blackening in digital computed radiography is to be kept constant internally, there is no proof of the increase of dose if no such controls were performed.

SPECIAL PROBLEMS IN PAEDIATRIC FLUOROSCOPY

In fluoroscopy five basic factors determine the dose to the patient:

- the specific design of the equipment,
- special adaption to paediatric fluoroscopy technique,
- irradiated area (volume) of the patient,
- the screening time and the number of spot films taken by the radiologist.
- The entrance dose to the patients is higher with the under couch systems compared to the over couch equipment. On the other hand, the dose to the radiologist and other people close to the patient (technician, nurse, parents) is higher with the over couch equipment. Training of all people working at the equipment is very important to use it safely and with the minimum occupational dose **(Articles 7, 9 and 11)**. In order to keep the X-ray field small a format limiting device (tubus) for under couch equipment and strict collimation for over couch systems should routinely be used. However, extreme coning using under couch systems can paradoxically increase the dose to patient. Therefore, practical teaching of young radiologist by an experienced teacher who knows the performance of the individual fluoroscopy unit is of great importance (see also training and education). The collimating system must regularly be inspected during quality control checks **(Article 8)**. All edges of the X-ray-field should be constantly visible on the viewing screen.The image intensifier size must not be larger than the television image.

As in plain film radiography, additional filtration and the selective use of a grid which must be easily removable can considerably save fluoroscopy dose to patients. Of great importance is the general recording of the whole fluoroscopic procedure, e.g. video tape recording, storage of digital images, cine-loops.

Schumacher showed in a phantom study that with simple changes of the equipment (grid, additional filtration) and digital fluoroscopy the dose can be diminished to as low as 10% of the original value **Fig.5**. In addition, pulsed digital fluoroscopy (grid controlled or generator controlled) lowers the effective screening time and therefore diminishes the dose to the paediatric patient enormously. For example, using the 3 pulse mode the screening dose can be decreased to 10% compared with

continuous fluoroscopy **Fig.6**. Digital fluoroscopy can be combined with pulsed fluoroscopy yielding an optimal imaging process. and a dramatically reduction of dose to the patients.

With the introduction of digital technology the fluoroscopy equipment has also been considerably changed, but also the behaviour of the radiologist. As the images can be stored and reevaluated during the examination, the "last image hold" function can be used for radiation-free collimation and the frame grabbing function can replace extra spot films. Thereby, the total fluoroscopy dose can theoretically be significantly decreased. However, also the opposite can happen, if the screening time will be increased because some investigators will produce a "perfect fluoroscopy study". Therefore, guidelines for fluoroscopy in pediatric patients for the most frequent examination are urgently needed. They are now under progress.

Further developments of an optimized paediatric fluoro equipment are necessary. The design of the measuring chambers is too large for most of the small paediatric patients. Smaller measuring devices, variable positioning and different shape could optimize the fluoroscopic investigation in very young patients. Furthermore, the dose rate controlling curves should be adapted to smaller diameters of paediatric patients and the fact, that very rarely a high contrast situation is needed. Extreme dose reduction is possible, e.g. if only tube positioning is done.

DOSE MEASURING SYSTEMS

Specific problems in dose measurement

Dosimetric surveys in European children's hospitals have shown a wide variation in radiographic technique and entrance surface dose (TLD-measurements) **Fig.7**. TLDs can be used for large surveys, but they are impractical in busy radiology departments. In addition, TLD measurements do not provide immediate feedback. In contrast, dose area product (DAP) measurement are more convenient and provide immediate feedback. DAP measurements have advantages: No direct application of the measuring device on the patient is needed, no shadow on the radiograph, and inclusion of the irradiated area. Ideally not only the DAP, but also the irradiated field and the dose should be measured separately. It is important to perform these measurements for all paediatric examinations, in order not to overlook deviations caused by the equipment or to detect systematic faults **(Articles 2, 4,6 and 8)**. When DAP in fluoroscopy is measured separately for screening and spot films it can help to improve the education of young technicians and radiologists, e.g. reduce unnecessary screening.

However, the sensitivity of the measuring device in small patients must be adapted to very small doses and small fields. The minimum field in newborn babies can be as small es 6 x 6 cm. Additional display of dose at the entrance side of the patient and the mean irradiated area would be very desirable. All equipment, also mobile X-ray machines, should have DAP-meters. All measured doses, should be stored together with the individual exposure data (kV, mA, s, grid use; image receptor system and the generator).

REFERENCE DOSES OR DOSE CONSTRAINTS

Diagnostic reference dose levels have been defined according to **article 2** for standardized patients or phantoms. This concept is impractical for paediatric patients because a "standard sized paediatric patient" does not exist. The variation in size (height, length), weight and diameter of paediatric patients in the same age group can be extreme. Dose constraints for 3 or 4 different age groups and for the most frequent examinations would be a more reasonable way to give guidance and information to the responsible radiographers and radiologist on the dose to the patients (**Tab.2 and Tab.3**).

EDUCATION AND TRAINING OF RADIOGRAPHERS AND RADIOLOGISTS

The aim of quality assurance programmes is to optimize the imaging process in order to avoid unnecessary exposures or overexposures to the patients. If paediatric patients are x-rayed, particular age-specific facts must be considered, i.e. specific knowledge of the anatomy in all age groups, the awareness of rapid movements of uncooperative patients, tight coning down to the area of interest, selection of the appropriate radiographic technique and application of specific radiation protection measures.

Optimal coning is extremely important in neonatal radiography and in most cases a matter of education. But, some radiographers were not able to change their careless attitude and inaccurate technique **Fig.8**. Therefore, regular quality control measures and education/ training programmes should be organized in the departments by the chief technicians and/or the responsible radiologists. In fluoroscopy the most important factor to save or increase dose is the radiologist (in some members states physicians with no license are allowed to screen), who performs the examination. Before an fluoroscopy examination is started, all information on the patients must be available, e.g. patient history, protocols of previous operations, all previous radiographs should be of course available and read by the radiologist, finally a definitive clinical questions to the radiologist has to be clearly formulated **(Articles 3 and 4)**.

Specific training programmes in radiation protection in paediatric radiology for radiographers and radiologists must be introduced during their curriculum. In the future, national radiological societies and the European scientific organizations must put all efforts to insure that radiography and fluoroscopic examinations in paediatric patients are only allowed to be performed either by radiographers or paediatric radiologists who have passed a special training, confirmed by a special diploma. Finally, postgraduate training and education in Europe should be accomplished by the introduction of a credit point system established and controlled by the scientific societies and national as well as European authorities.

Tables

Anatomy	body proportions size and shape of organs skeletal development bone marrow distribution shift during growth
Pathology	specific age dependant diseases (congenital heart disease, meconium ileus; battered child)
Biochemistry	total body water (newborns 90%, adult 60%) low fat mass different handling and metabolism of contrast media
Physiology	higher respiratory rate (newborns 80 – 120 breaths/ min.) higher heart rate (newborns 160 – 200 beats/ min.) fast body movements

Tab.1 Basic differences between paediatric and adult patients with impact on radiographic imaging

	Entrance Surface Dose values (µGy)							
	un-optimized technique				**optimized technique**			
	n	mini-mum	3rd quartile	maxi-mum	n	mini-mum	3rd quartile	maxi-mum
Chest ap premature	122	9	99	386	41	11	37	83
Chest ap 10 month	124	20	140	1373	32	21	67	115
Chest ap 10 month with mobile units	140	31	151	718	17	32	123	194

Tab.2 Reference dose values (shaded) for various chest ap X-rays in infants

	Entrance Surface Dose values (µGy)							
	un-optimized technique				**optimized technique**			
	n	mini-mum	3rd quartile	maxi-mum	n	mini-mum	3rd quartile	maxi-mum
Chest pa/ap	74	26	115	1347	24	19	63	120
Chest lateral	83	40	251	554	15	37	125	145
Chest ap with mobile units	83	29	126	333	15	30	68	94

Tab.3 Reference dose (shaded) for various chest ap X-rays in the five year old child

FIGURES

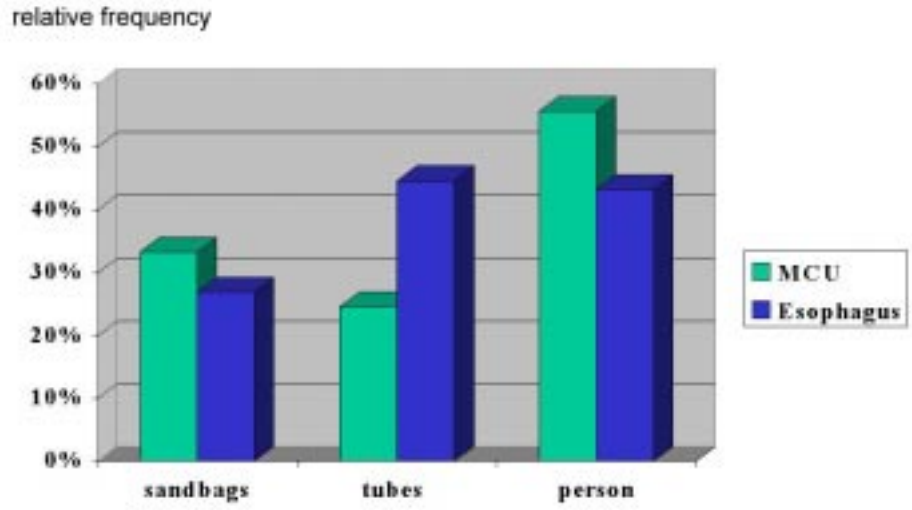

Fig.1 Patient fixation in micturition cysturethrography and esophagram - results of a European wide survey

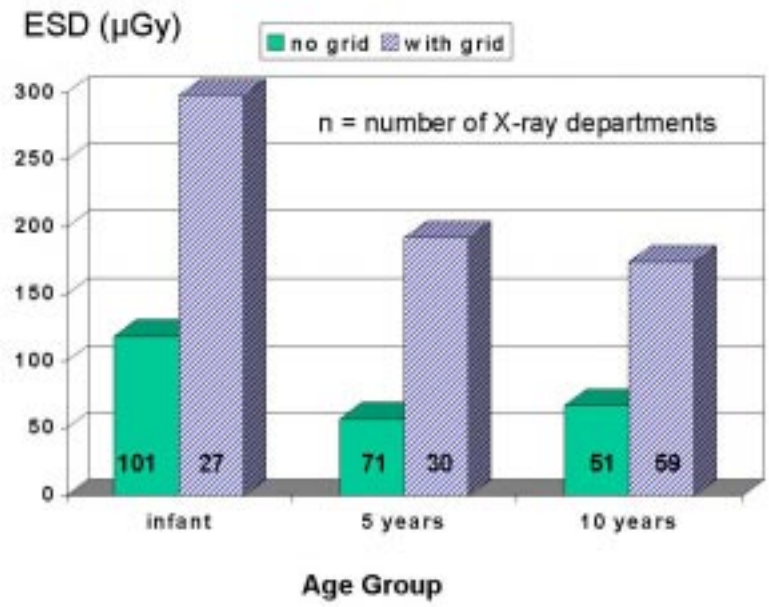

Fig.2 Relationship between mean entrance surface dose and the use of a grid in chest ap/pa radiography in paediatric patients of different age

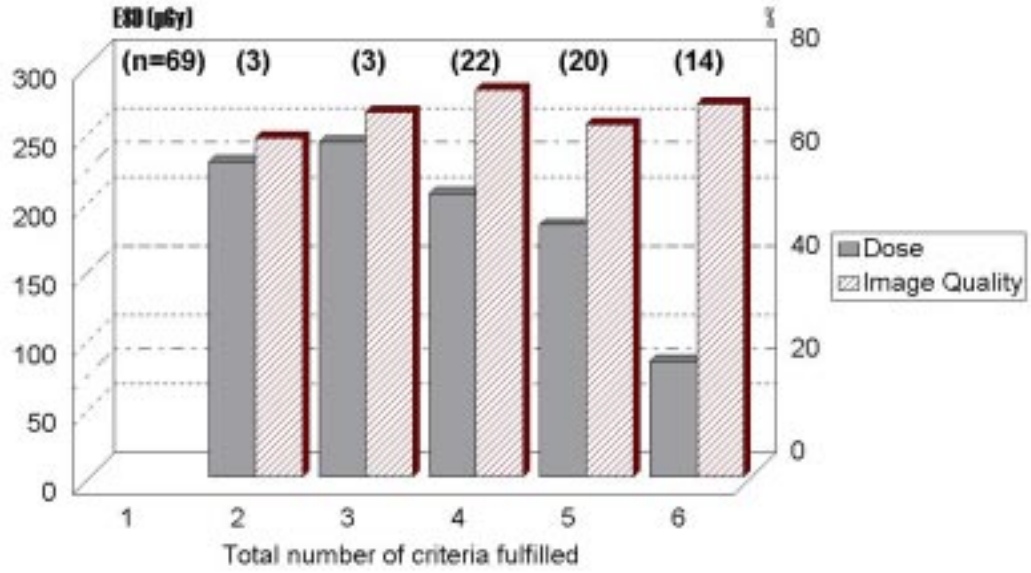

Fig.3 Impact of radiographic technique on the entrance surface dose and image quality in chest ap/pa radiography in 5 year old patients

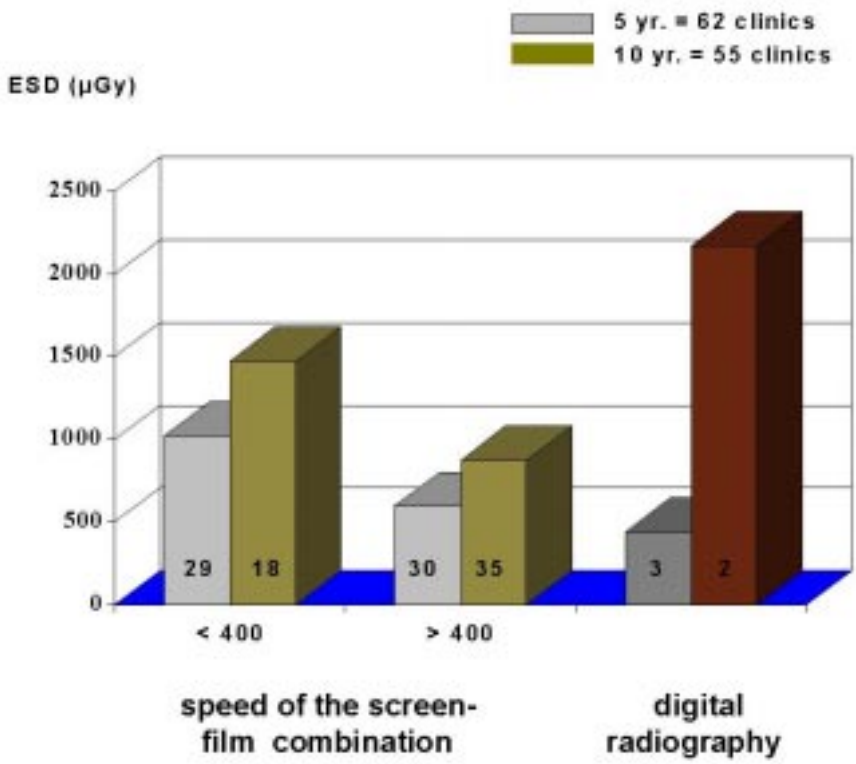

Fig.4 Relationship between image receptor system and mean entrance surface for abdomen ap in the 5 and 10 year old patient - results of European wide surveys

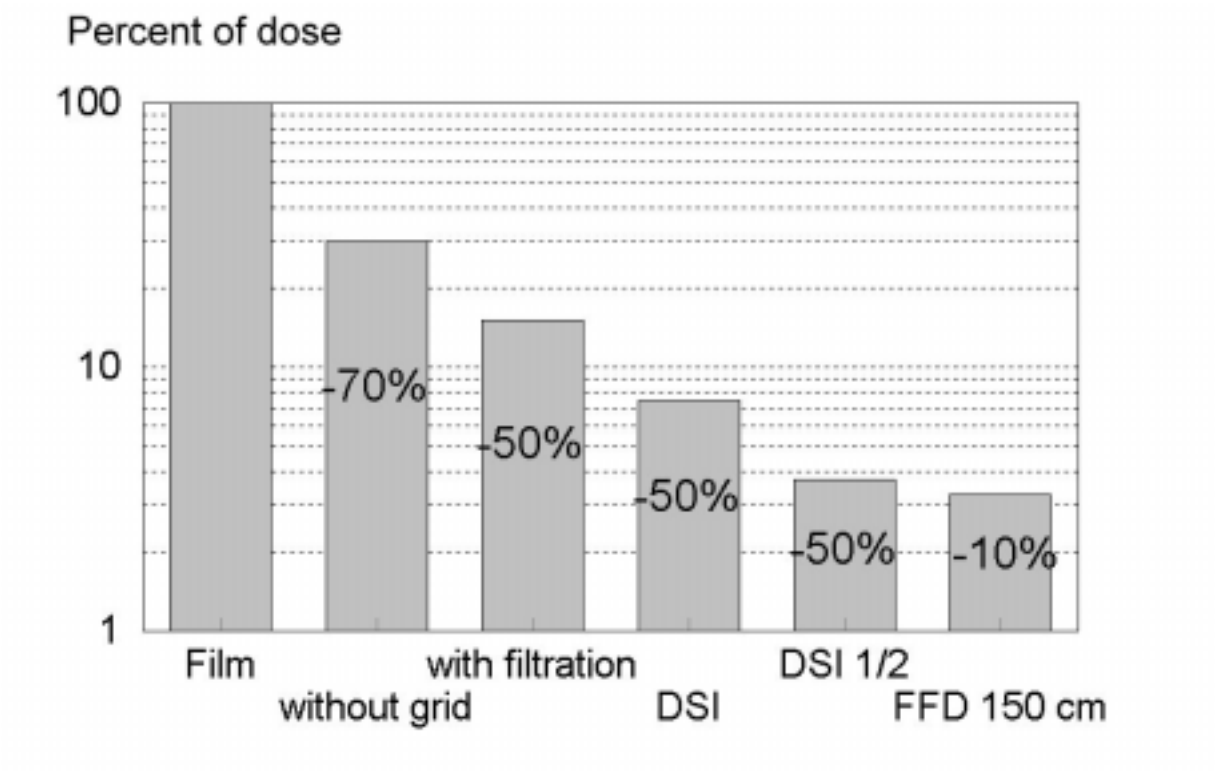

Fig.5 Dose reduction in fluoroscopy by simple changes of the equipment - phantom studies ref. Schuhmacher (1994)

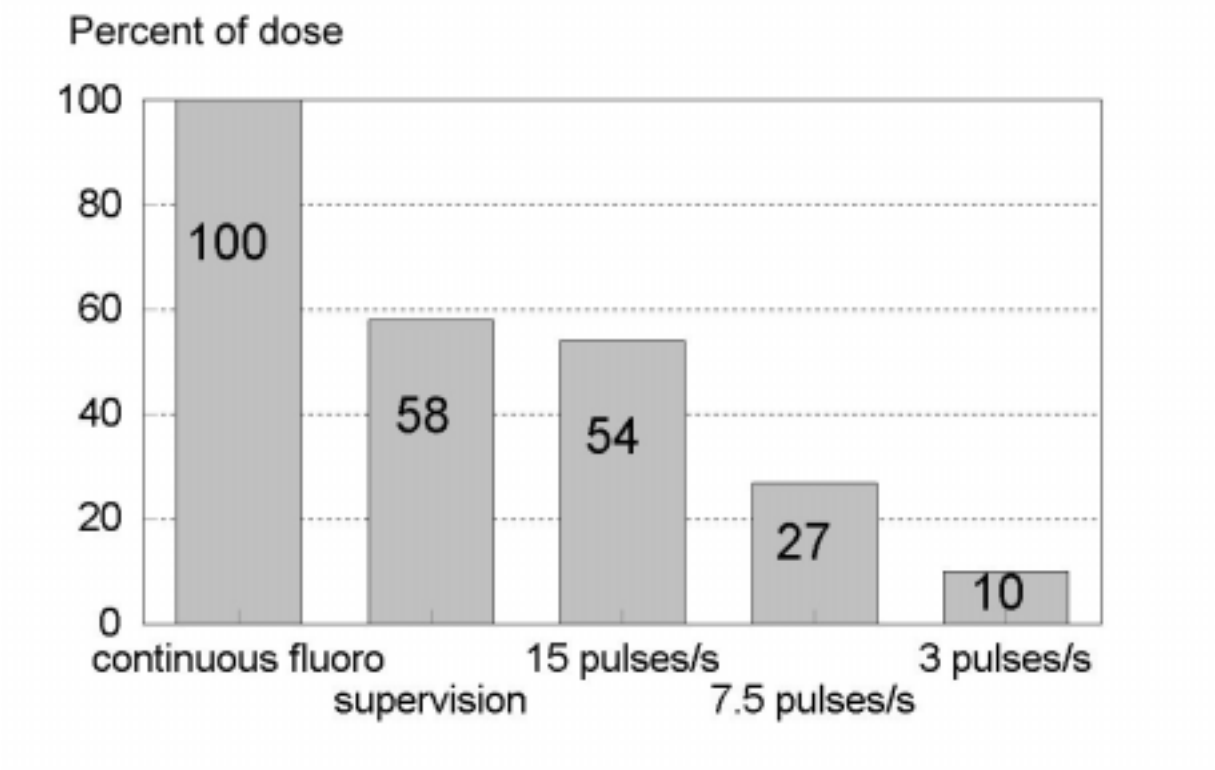

Fig.6 Dose reduction with digital pulsed fluoroscopy ref. Hermann et al. (1994)

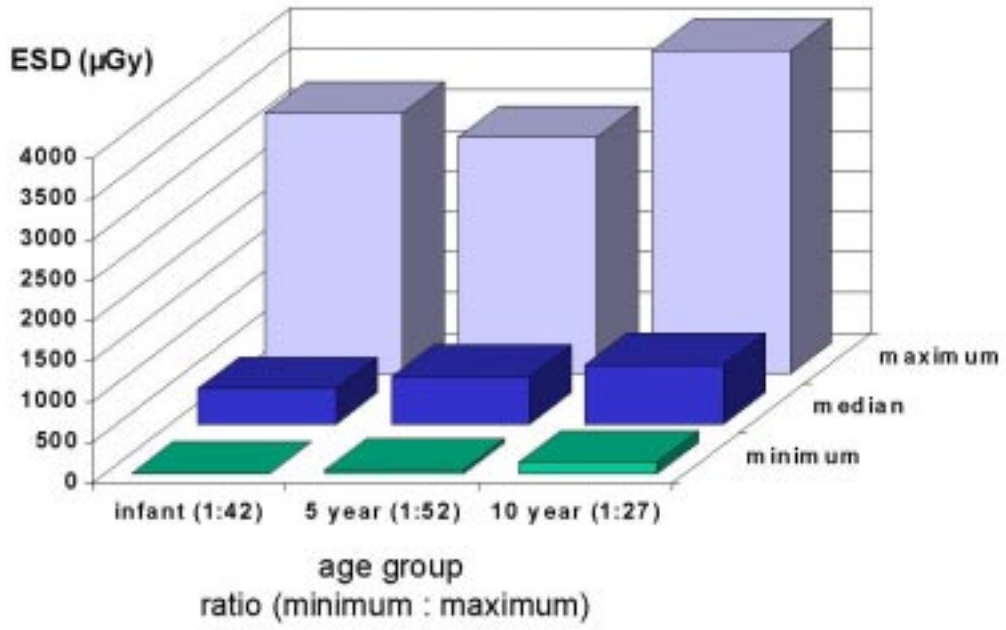

Fig.7 Variation of entrance surface dose for the abdomen ap in paediatric patients - results of European wide surveys

Fig.8 Variation of coning in neonatal chest radiography for 7 different radiographers from a paediatric radiology department

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Questions (Q) / Answers (A) / Remarks (R)
relevant to the subject presented by Mr. SCHNEIDER

Q: Dose reduction and improvement of image quality in paediatric radiology do not always go hand in hand. Sometimes, it is a long and slow learning process, don't you agree?

A: Yes, recent technological progress, and I am thinking in particular of digital radiography and digital fluoroscopy, dramatically improves image quality but also entails higher doses.

Q: How can one regulate the justification of paediatric exposures in a more restrictive way than for adults?

A: I do not think regulating this question will solve the problem. I think you must start in your own department to investigate where improvement is possible and this is the only practical way forward. I can recommend for this purpose WHO-report 757 entitled 'Rational use of imaging in paediatric patients'.

GENERAL DISCUSSION

The general discussion was grouped into two major themes, presented as question (Q), answer (A) or remark (R). The answers were given by an expert-panel of the invited speakers and CE officials.

1. Transposition of the Medical Exposure Directive (MED) and its harmonisation

Q: European Directives are general requirements, whereas national legislation is an interpretation of these general requirements. In view of the free market with free movement of persons and goods, what does the European Commission (EC) envisage doing as regards harmonisation of implementation of the MED?

A: The MED is an umbrella document and is quite general. Member States (MS), however, are required under Chapter III of the Euratom Treaty to send proposals for transposition to the EC. The EC can try to harmonise legal provisions at that level. The EC also intends to continue discussion with the MS through meetings like this one and bilateral meetings to share experiences. Finally, specific guidance on technical issues is being drawn up by the EC with the help of the Article 31 experts group. The EC has also started an information campaign targeted at the candidate MS and bilateral discussions on legislation will be initiated soon.

R: Nuclear medicine specialists consider the MED a good piece of legislation. It is now important that it is well transposed into national law. This transposition should not be too restrictive because, in that case, it could be counterproductive for the health benefit that the patient can obtain from ionising radiation in general and from some specific techniques in particular.

R: European radiologists accept the MED since it is in line with ICRP 73. However, they are quite disappointed in the lack of transparency of the procedure used to draw up the MED. Radiologists were not consulted sufficiently and this is a negative point. Furthermore, European legislation should not try to dilute achievements in some countries by bringing the general standard down to the lowest common level. Radiologists also fear bureaucracy, for example regarding informed consent which, if too strictly applied, could hamper medical procedures. Finally, giving the prescriber who has 1 week of training in radiation protection just as much responsibility in the justification procedure to as the practitioner who has a much longer training is an unbalanced approach and therefore not acceptable. For all these reasons, radiologists want to be closely involved in the transposition of the MED into national legislation in all MS. They could, for example, play a major role in developing referral criteria for prescribers.

Q: Clinical responsibility is a much broader concept as defined in the MED and goes beyond radiation protection aspects alone. In this context, what is meant by “informed consent”?

A: The concept of informed consent varies from MS to MS. Generally speaking, there are two views: the first is that the profession should set standards of disclosure, the second is a patient-centred test where the practitioner should look at the patient to determine which material risks he prefers to be disclosed. In practice, the outcome is often similar and debate is still going on as to the degree of liberality and as to whether the patient or on the profession should be the focus of the question of informed consent.

Q: Regarding informed consent, it is clear that the practitioner should never forget that the health of the patient is his major objective and to preserve this health the application of ionising radiation may be indicated. The patient, for his part, must have confidence in the knowledge and professionalism of the practitioner, don't you agree?

A: The situation is not quite that clear cut. Not every medical exposure is for the benefit of the patient. Some of them are not justified at all. Often a thorough clinical examination may reveal the necessary diagnostic information so that a radiological examination becomes irrelevant. To ask for a radiological examination in this situation, just to be sure, is not justified. It is also the duty of the prescriber to check whether the diagnostic information provided by previous radiological examinations can be used again. Once the request for a radiological examination is made, it is the practitioner who should make an evaluation of this request to see whether it is the best way to obtain the required information. Of course, this supposes that he has access to all relevant background information concerning the patient.

Q: To avoid repeated examinations, particularly in interventional radiology, would it not be a good idea to develop on a European level a document which informs the practitioner (and the prescriber) of previous examinations?

A: In some MS, the radiation-passport system was tested. It was not a success for several reasons, one of them being the bureaucratic burden. The EC therefore has no intention of initiating such a measure and MS are not keen on it either. The MED clearly puts assigns to the practitioner the responsibility for defining clinical responsibility. He must seek co-operation with other specialists, must actively look for previous information and must provide other colleagues with such information. And do not forget that the patient himself can also be an important source of information if the relevant questions are asked.

R: The MED allows flexibility regarding the responsibilities attributed to the prescriber and the practitioner. This is positive because it takes account of the different health care systems in place in the MS. In the UK, the prescriber will never have the same level of training as the practitioner and therefore it is the latter who will be fully responsible for the justification of an exposure. The role of the prescriber is to adequately inform the practitioner of what information is required so that he can make his decision in an informed way. In other words, the prescriber prescribes an investigation but not a technique and the practitioner is responsible to make a choice on the adequate technique.

R: It is an illusion to think that the prescriber can take real responsibility as far as radiation protection is concerned. Moreover, the direct risk due to a diagnostic examination is minimal. The risk of ionising radiation in medicine usually forms part of a general risk such as an invasive procedure which is performed under radiological control or it presents an indirect risk, that is, if the diagnostic information is inadequate the patient will be badly treated. It is the role of the practitioner to obtain the best benefit/risk ratio.

2. Protection of the unborn child

R: The Article 31 expert group's point of view on the protection of the unborn child is that for diagnostic examinations the 10 day rule is no longer applicable. The prescriber/practitioner must ask the woman if she is pregnant or has missed a period. If the answer is yes, special justification should be applied and in the case where the pelvic region might be exposed to high doses the examination should be postponed, if possible. If the answer is not clear, the woman should be treated as if she was pregnant. The philosophy behind this system is based on the presumption of an all-or-nothing effect of ionising radiation on foetal cells in the early stages of

development, although some studies on animals show that a small risk for genetic effects may exist.

Q: Two problems may arise: the first is that adolescent females (10-16years) accompanied by a parent often do not admit that they might be pregnant. The radiographer, the person who is in closest contact with the girl during the procedure, plays a very important role in finding out if there might be a possibility of pregnancy. The second problem is that if we apply the proposed system, the number of female patients that cannot exclude a possibility of pregnancy might become quite large. Performing a pregnancy test on all of them might considerably disturb the good functioning of a (large) radiological department.

A: Women usually know when a possibility of pregnancy is present. The important thing for the practitioner is not to forget to ask the relevant question. Moreover, except for trauma situations, very few examinations with high risk to the fetus are performed on 10-16 year old females. Obviously, no such questioning is necessary for an examination of the wrist.

R: Awareness on the part of the woman is an important issue. In Spain, the Association of Radiation Protection, together with the Ministries concerned, developed an informative poster for women which urges them to inform the practitioner if they might be pregnant. It is displayed in all radiological practices and hospitals.

Conclusions

Dr. Patrick SMEESTERS
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An international seminar on the transposition and implementation in the Member States of the new Directive on health protection in relation to medical exposure (Directive 97/43/Euratom), organised by the European Commission in conjunction with the Spanish Ministry of Health and Consumer Affairs and the Spanish Radioprotection Society, was held in Madrid on 27 April 1998. Its aim was to promote discussion and the exchange of views between all concerned, not only the competent authorities in the Member States but also, and perhaps above all, the representatives of the medical services, a group not traditionally open to new legislation in its field. This aim can certainly be said to have been achieved.

The seminar opened with a general presentation by a Commission representative explaining the changes which the new Directive has introduced, the main ones being as follows:

Firstly, it builds on the previous «patients» Directive:

- the *scope* has been extended (all exposure relating to medical practice, rather than just patient exposure);
- more detailed information is provided on the application of the principles of justification - (henceforth the *prescriber* is also involved) and optimisation (introduction of the concept of *quality assurance*);
- more detailed provisions are laid down for certain problem types of exposure (*high risk*, *high dose* or involving persons who are *not ill,* including embryos or foetuses);
- more stringent training requirements are introduced (it is now necessary to have undergone training and to have a *recognised* diploma or qualifications);
- the *responsibilities* of the parties involved are more clearly defined.

The Commission also drew attention to the various new concepts introduced: diagnostic reference levels, potential medical exposure, the requirement to carry out audits and the principle of radioprotection training as part of basic medical training (again the responsibility of the prescriber).

Nine specific topics were then presented by different speakers before the floor was opened for general discussion.

Of the subjects examined, several actually related to a set of draft *Recommendations* drawn up by the Commission (or its experts), and were thus not always directly connected with the new Directive's provisions:

- The first was «*Radioprotection during treatment using iodine 131*». This document was drawn up by the Article 31 experts' «Working Group on medical exposure». One important point which emerged was that the European experts have abandoned the idea of achieving agreement on harmonising the criteria for discharging patients after treatment with radioiodine, which was clearly disappointing for some of the participants. One debatable (and debated!) point was whether young children should be regarded as part of the «helping family» (with flexible «dose constraint») or treated as third parties (subject to the exposure limits).

– The document entitled «*Recommendations for the protection of unborn and breastfeeding children against irradiation as a result of medical exposure of the parents*» is in the advanced *draft* stage. It too was drawn up by the Article 31 experts' «Working Group on medical exposure».

  The main problem with this document was that the basic scientific information it contained was sometimes incomplete or *qualified.* Some of the participants called for full information (not concealing the existence of *uncertainties,* such as the risk threshold values, but putting them into perspective). Others felt it was more important to find *pragmatic* solutions and provide reassurance for the physicians involved. The fundamental question, therefore, was whether it was right for a high-profile document of this kind to leave out or to present in a veiled manner certain observations or analyses which might encourage greater caution, and what the ethical and legal implications of such an approach would be. This led to a discussion on the question of maintaining the 10-day rule (possibly only in certain circumstances), because it is the very beginning of pregnancy which is the most uncertain, not only in terms of ascertaining that there is a pregnancy or establishing the date of conception but also in terms of the nature of any risk or the threshold at which it occurs.

  Another important point raised was the precise meaning of the term «unborn child». The authors intended this phrase to cover all phases of pregnancy, from the egg to the baby immediately before birth. However, it appeared that in some quarters it had been interpreted as meaning the human being at the advanced or final stage of the pregnancy, which might suggest, for example, that the death of a very young egg or embryo (a risk inevitably carried by irradiation during the first days of pregnancy) was of no importance in terms of radioprotection.

– The «*Recommendations on medical and biomedical research*», another draft document drawn up by the above Working Group. This issue seemed to create few difficulties in itself, but the discussion showed the need to look more closely at a series of specific practical questions and to «create a culture» in this field.

– The «*Recommendations on diagnostic reference levels for medical exposure*», again drawn up by the above Group and at the advanced draft stage, are one of the main new concepts introduced by the Directive. The main problem was of a semantic nature: many people did not really understand the significance of these levels, so that discussion was fairly pointless. It should be remembered that, in the field of radiodiagnostics at least, this term has nothing to do with optimum levels or objectives to be achieved in terms of patient dose. It actually refers to «examination» levels, indicating the upper level of what is acceptable when «good practice» is applied.

– The «C*riteria for acceptability of radiology (including radiotherapy) and nuclear medicine equipment*», which has been the subject of lengthy discussion, were published in 1997 by the Commission (Radioprotection 91 collection) and have the status of a technical guide. There was no discussion on this document. A talk on quality assurance programmes, given by the same speaker, did give rise to discussion, the main conclusions of which were that recommendations should be drawn up to specify – and harmonise – the *scale* of the programmes and the *methods to be used* and that these programmes, which were costly in time and money, should not be overdeveloped.

The other topics discussed are not the subject of specific draft recommendations as yet. They concerned:

  – potential exposure in medical applications: the emphasis was on the need for wide dissemination of information about accidents (databases) and the need for procedures to facilitate or ensure their disclosure;

  – the justification of exposure from the legal angle: the main feeling was that the application of the Directive should not create difficulties on this level;

- the harmonisation of training for medical and paramedical staff: this was a good idea, but not easily achievable, judging from past experience in comparable fields; this point might be examined by the Working Group mentioned above;

- radioprotection in paediatric medicine: this was a very technical talk given by a German paediatric radiologist, which might provide a good source of inspiration for many.

The general discussion covered three «key issues» raised in oral and written questions: the conflict between harmonisation and subsidiarity, the responsibility of the prescriber in justification (a surprisingly sensitive issue) and the possible return to the «10-day rule» in radiology (examining women during the first 10 days of the cycle).

One notable aspect of the workshop was that, after initial hostility on the part of the physicians, who felt that they had not been consulted adequately or at all, they were ultimately positive about the Directive's provisions.

In conclusion, we could say that the power of discussion has once again been confirmed: it is essential to specify «what we are talking about» (semantics and definitions), to «talk about it together» (consultation), to «talk about it in the right place» (training and information of all involved) and to «say little but to say it properly» (teaching and strategy of disseminating methods outside the expert circles).

Mr. Stephen KAISER

European Commission
Luxembourg

Ladies and Gentlemen,

On behalf of the European Commission I have the honour to close this workshop on the implementation of the Medical Exposure Directive.

This workshop, designed to discuss important aspects of transposition of the Medical Exposure Directive into national legislation with Member States' competent authorities and with all interested professional societies, was extremely well attended and the debates were of great interest and conducted with great enthusiasm. It resulted in a number of practical recommendations and suggestions to the Commission that I consider very useful and that certainly will help us in our future work.

Today's experience will also stimulate the European Commission to continue its efforts in supporting the Member States in the transposition of the Directive. Therefore a second meeting in the spring of next year to evaluate the status of transposition seems to be the logical continuation.

Finally, let me congratulate the Spanish organizers for their firm commitment to bring this workshop to a successful conclusion and all of you for your invaluable contribution to the meeting.

Thank you very much and goodbye.

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ABSTRACT

The objective of the workshop was to promote discussion between competent authorities of the Member States, medical practitioners, pre-scribers, radiation protection experts and representatives of the industry on the transposition of the Medical Exposure Directive (MED) (97/43/Euratom). Nine relevant topics, on many of which the EC is preparing technical guidance, were introduced by key-note speakers, each followed by a discussion. In particular, the question of the usefulness of a return of the 10-day rule for women in child bearing age, the significance of diagnostic dose reference levels, the harmonisation of method and scale of quality assurance programmes, the responsibility of the pre-scriber in the justification process and the possibilities of harmonising training were discussed in depth. It was agreed that a second meeting on the transposition of the MED early 1999 should take place to evaluate transposition in a further stage.