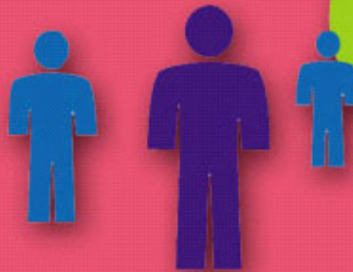


RADIATION PROTECTION



Medico-legal exposures,
exposures with ionising radiation
without medical indication

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Introduction

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In 1997, the Council Directive 97/43/Euratom on the health protection of individuals against the dangers of ionising radiation in relation to medical exposures (the Medical Exposure Directive (MED)) was issued. Medico-legal exposures were included in the list of medical exposures and defined as ‘*exposures performed for insurance or legal purposes without a medical indication*’. The Directive requires that special attention be given to justification and optimisation of these exposures. The Directive also states that a medical exposure that is not justifiable should not be allowed. Because of this, but also for ethical reasons, the justification of these exposures is very important.

Within the context of the Directive a medical exposure includes not only those exposures that are part of the normal diagnosis and treatment of patients but also exposures for occupational health surveillance, health screening programmes, research and medico legal procedures. This can lead to a degree of ambiguity when discussing medico-legal exposures and exposures which have a medical indication. Often, the latter are referred to simply as medical exposures – a term that is clearly imprecise within the context of the Directive.

Medico-legal exposures are difficult to define and it is not always easy to decide which exposures are 'real' medico-legal and which are not. Often certain exposures could also be interpreted as being occupational or medical. The definition mentioned above is not sufficient to solve this problem. The reason for this would seem to be that the range of exposures that could now be considered to medico-legal were simply not envisaged when the Directive was originally drafted. It may be that a more complete definition of medico-legal exposures is required.

Medico-legal exposures are indeed exposures without a (strict) medical indication, but they are not only performed for insurance or legal purposes. The term should also include other exposures where the aim is to expose people for reasons other than medical diagnosis or treatment, but not necessarily for insurance or legal reasons.

The term ‘*medical indication*’ is also difficult to define precisely. Investigations, using x-rays etc, are considered to be medically indicated if there are clinical symptoms, which indicate that something should be investigated in order for a correct diagnosis to be made, or to start or follow up some clinical treatment.

Some examples will show the ambiguity:

An X-ray to diagnose a recently broken arm, with all of the usual symptoms, has undoubtedly a medical indication. In contrast, the use of x-rays in the age determination of asylum seekers would not seem to be medically indicated.

Chest x-rays of immigrants might be regarded as medically indicated when the person comes from a country with a high incidence of tuberculosis and positive identification of the disease results in the person being given treatment. However, if the positive finding merely results in

refused entry to the country without offering medical care, it should be regarded as a medico-legal exposure.

There is a large range of reasons for non-medically indicated exposures and their justification has to be considered thoroughly.

Suppose a cargo is x-rayed to detect contraband, but illegal immigrants happen to be inside and are unintentionally exposed. There is clearly no medical indication, and the question can be asked, whether or not this is justifiable.

In some prisons, prisoners are X-rayed after the lunch break in order to detect knives etc. This can happen either routinely or because there are suspicious circumstances. There is normally no medical indication for this exposure and there would be some debate about whether or not it is justifiable.

There is an increasing interest at airports in being able to check every visitor or passenger not only with a metal detector but also with X-rays or backscatter techniques to detect weapons. This means that millions of people could get a (very small) radiation dose. There is no medical indication for this type of exposure and if it is to be used, proper justification is essential.

In the case of cocaine smuggling, it could be argued that an X-ray can save the life of the person who swallowed the condoms. However using x-rays in this way will inevitably lead also to the exposure of individuals who have not in fact swallowed drugs.



The follow up of stress fractures in sportsmen is medically indicated and probably justifiable, but people will perhaps argue about scans to detect overloading due to intensive training. The use of x-rays to predict fitness for forthcoming sporting events is another application where there may be division about both justification and medical indication.

Another instance where x-rays are used is in growth prediction of young dancers. There seems to be no medical indication for this type of exposure and the justification is not clear-cut.

A totally different issue is the use of medical exposures to prove child abuse in court (not for diagnostic or treatment purposes). Exposures are performed, not only in cases of recent abuse, but also to detect past abuse. This can sometimes involve not only the abused child but also siblings who do not display any clinical symptoms.

The key issue in medico-legal exposures seems to be justification. Justification is the balancing of the advantages against the disadvantages, but both are difficult to quantify and are therefore often difficult to compare. The disadvantages could be the dose given, fear, public anxiety and the fact that some people are 'against' all of these kinds of things. The advantages could include safety, or the feeling of being safe, the avoidance of crime, reassurance, financial profit and a personal sense of well being.

Of all of the ionising radiation to which man is exposed, medical exposures are becoming one of the most important sources. In developed countries, the doses have doubled in the last 10 years.

In medicine, ionising radiation has important applications in both diagnostics and therapy. In most cases those applications are performed on the basis of medical indication. However this is not always the case and considering the relatively high doses that can be involved, all of these exposures should be justified.

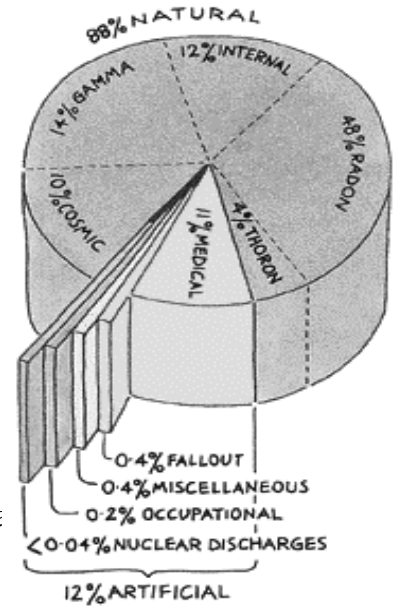


Figure 5 Eric J Hall, "Radiation &

Effects

As mentioned before, particles and electromagnetic waves have energy associated with them. When they interact with matter, some of this energy can be deposited as heat. This heat can damage cell material. Another possibility is that the interaction between radiation and matter can result in the production of free radicals. These free radicals are highly reactive and can interfere with the DNA present in cells.

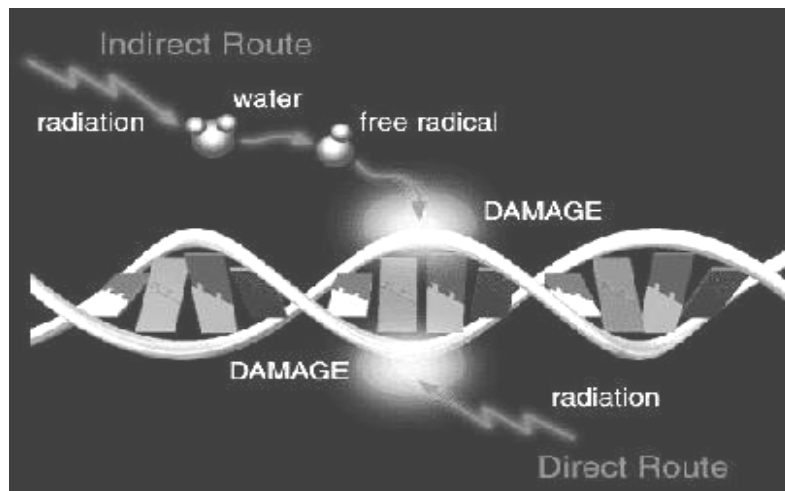
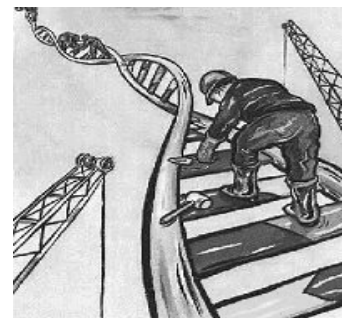


Figure 6 Direct and indirect DNA damage due to radiation

Some damage can be repaired. However, sometimes the damage is irreparable or incorrect repair can occur. When only a single strand in the DNA chain is affected, the damage can be repaired. However, when both strands are damaged close to each other, mistakes can occur in the repair.



Following DNA damage, there are three possibilities:

- a The DNA chain repairs correctly and there are no consequences.
- b The damage to the DNA (and other parts of the cell) is too severe and the cell dies directly. This happens only at relatively high doses. The consequences are dependant on the organ and the number of cells killed.
- c The DNA chain repairs incorrectly which can lead to the induction of tumour cells or to cell death during the next or later cell divisions.

DNA damage due to relatively low doses may cause so called stochastic effects. Stochastic effects can be either tumour induction or genetic effects.

In radiation protection genetic effects are taken into account despite the fact that based on the data from Hiroshima, Nagasaki, and Chernobyl, there is no convincing evidence in humans that these effects can be caused by ionising radiation. However, as it is statistically proven in animals, a cautious approach is adopted and it is assumed that the effect could also occur in humans.

It is estimated that there is a probability of about 5 % per sievert that a tumour will be induced. This can be interpreted as meaning that if 20 million people receive a dose of 1 μ Sv, tumour induction will result in only one individual, as a result of the ionising radiation.

Cell killing / deterministic effects

Deterministic effects in medical exposures are rare and should not occur at all at the exposure levels, which are typical of those, used for medico-legal exposures. At these latter levels cell killing will not occur.

Cell killing due to ionising radiation can cause deterministic effects. If there are only a few cells killed in an organ, there are no clinical consequences. Other cells will divide and the cells killed will be replaced in due time. When somewhat more cells are killed, dysfunction of the organ can occur and permanent damage can arise. If many cells are killed the organ may no longer function, which could be lethal depending on the organ.

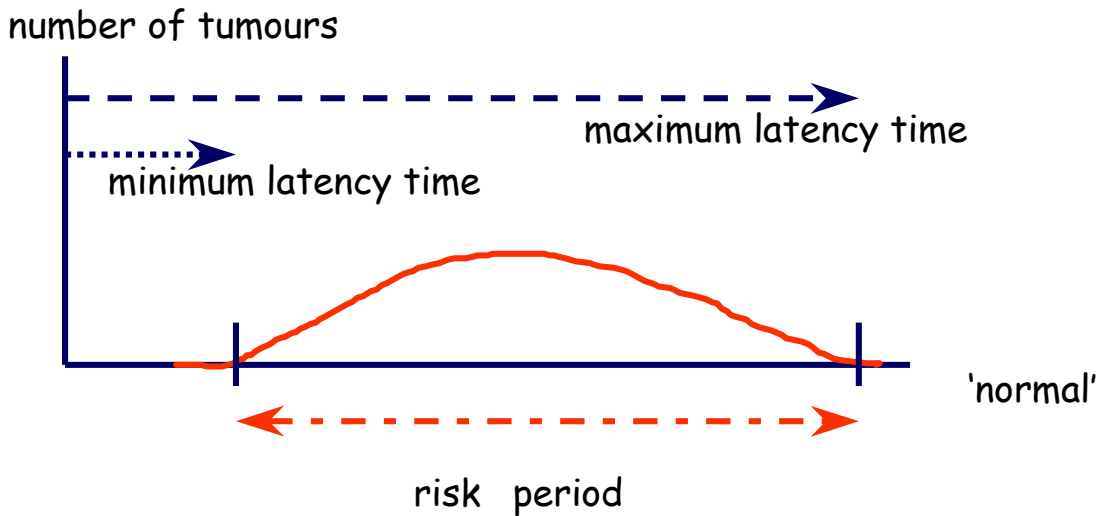
Deterministic effects only occur when the dose is above a certain (relatively high) level. The exact level or threshold depends on the organ involved. Adult brain tissues are relatively insensitive to ionising radiation compared to kidneys, which are more radiosensitive. However in both organs, doses of several sieverts are required for effects to be seen. Dose levels of this magnitude would only be likely to be seen in radiotherapy or following a severe accident. If a deterministic effect occurs, the effect will be more severe at higher doses: e.g. in the case of irradiation of the skin, after a few sieverts, there is only redness; at higher levels, firstly there are dry blisters, then wet blisters and finally at high doses, necrosis (death of deep cell layers).

The difference with tumour induction (a stochastic effect) is that while deterministic effects always occur above a certain level, there is only a probability that a tumour occurs at any level of radiation. The probability is dose dependant and is believed to increase with increasing dose.

Latency period

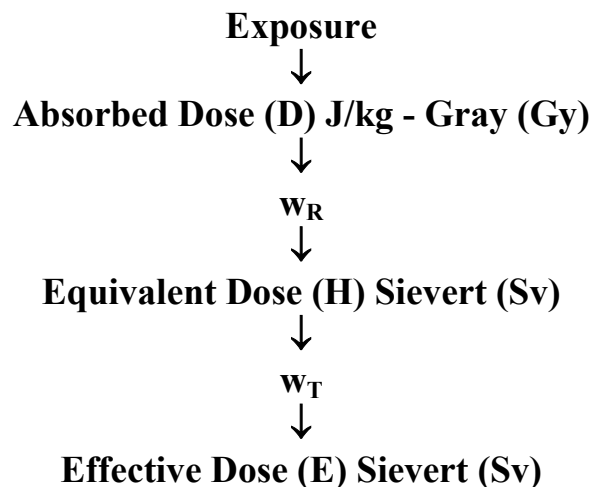
Induced tumours don't appear immediately after the irradiation. Often even tens of years will pass before a clinical tumour may develop. This period is called the latency time and this time is also dependent on the type of organ. e.g. for leukaemia in children the minimum latency

time is 2 years and the average 5 years. For bladder cancer the corresponding periods are 15 and 25 years. This is illustrated in the diagram below for the case of leukaemia.



Doses

The terminology and the system of doses are somewhat complicated but are shown schematically below:



When tissue is exposed to ionising radiation, the quantity of radiation absorbed is expressed as the absorbed dose, which has units of J/kg or Gray. In order to take account of the fact that different types of radiation can cause different levels of harm, a radiation weighting factor is used.

◆ gamma radiation	1
◆ x-rays	1
◆ beta (electron)	1
◆ alpha (2 protons + 2 neutrons)	20

The absorbed dose multiplied by the weighting factor, w_R is equal to the equivalent dose. The unit of effective dose is the sievert (Sv).

Not all tissues and organs are equally radiosensitive. In some organs there is a higher chance of introducing tumours than in others. For example, cells that are undergoing rapid division are more sensitive for tumour induction. This makes it complicated to use the equivalent dose as an indicator for damage. There are not only differences between the rate of tumour induction, but also in the lethality of the organ tumours and the years lost due to an induced tumour (e.g. childhood leukaemia versus bladder cancer in 65+ years old). The consequence of all those differences is such that a 100 mSv equivalent dose to the skin has a much lower potential effect than 100 mSv to the lungs.

Therefore another weighting factor is required: the tissue weighting factor. The equivalent dose is multiplied by the tissue weighting factor to give the effective dose. The unit of effective dose is the sievert (Sv). Most dose limits are expressed in effective dose.

One should recognise that an effective dose of 1 Sv is a very large dose and that such a dose will not be received easily. The doses given in some specific circumstances are:

Sievert (Sv)

- ♦ very severe accidents (fire fighters at Chernobyl)
- ♦ radiotherapy (patient)

milliSievert (mSv) = 1 thousandth of a Sievert

- ♦ dose limits workers (20 mSv) and public (1 mSv)
- ♦ medical exposures, mostly below or around 1 mSv per X-ray or nuclear medicine procedure
- ♦ CT scan of the abdomen about 30 mSv

microSievert (μ Sv) = one millionth of a Sievert

- ♦ doses due to normal discharges NPP, hospitals etc. $< 1 \mu$ Sv
- ♦ effects of Chernobyl in the Netherlands $< 80 \mu$ Sv
- ♦ chest x-ray 50-150 μ Sv

Low dose effects

As mentioned before, even at low doses there is a probability of tumour induction. Moreover it is not certain that there is a linear relationship between the dose received and the probability of an effect. There could be linearity down to zero dose, but it is also possible that at lower doses the effect is relatively smaller or perhaps even beneficial (hormesis theory). None of these theories can be proven because underlying incidence of tumour induction (unrelated to radiation) is of the order of 25-30% during life time. So the additional tumours caused by low doses of ionising radiation cannot be definitively identified.

In radiation protection, a cautious approach is adopted. The recommendations of the International Commission on Radiological Protection (ICRP) are followed and linearity without a threshold dose (LNT) is assumed. However, this LNT curve should never be used to calculate effects after high doses in accidents or radiotherapy. In these cases individual approaches are essential.

This LNT approach gives rise to a specific problem. If many people are exposed as a result of medico-legal exposures, can it be said that the effect of 1000 persons receiving a dose of 1 millisievert is the same as 10 persons receiving 100 mSv? As this question has not been conclusively answered, radiation protection errs on the side of caution and assumes that the answer is yes.

Assuming LNT, one could argue that if 20 million people are irradiated (or 4 million people 5 times) in the airport, assuming a dose of 1 μ Sv, with a 5% probability of lethal tumour induction per sievert, then theoretically 1 person will die in the coming 10-50 years due to a cancer induced by the X-ray. However the so called collective dose (doses multiplied by number of people exposed) should not be used to calculate risks for very low doses in very large groups, because of the uncertainties about the LNT approach at this dose level.

The question then is: is this justifiable, taking into account the assumed advantages of these controls and taking into account that assuming LNT at this dose level is probably an overestimation.

This brings us back to the central theme of this symposium: the whole issue of medical and medico-legal exposures circles around JUSTIFICATION.