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Review paper

X-rays for medical imaging: Radiation protection, governance and ethics over 125 years

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ABSTRACT

Starting from Röntgen's discovery and the first radiograph of his wife's hand, the curtain was raised on a new technique with remarkable possibilities for contributing to human health. While growth in applications proceeded rapidly, it was accompanied by significant harms to those involved and by inappropriate opportunistic application. This paper places the attempts to deal with the harms and inappropriate activities side by side with the positive developments. It attempts a narrative on the development of medical radiation protection over the 125-year period and places it in the context of a commentary on governance and ethics. The substance of the narrative is based on the recommendations of ICRP as they developed and altered over time. The governance commentary is based on assessing the independence of ICRP and its attention to medical exposures. In terms of ethics, the recommendations at each stage are reviewed in the light of values that are deemed appropriate to both medical ethics and radiation protection. The paper, while celebrating Röntgen-125, also hopefully provides a perspective for discussion as ICRP's centenary in 2028 approaches. This is an important part of ensuring continued acceptance and confident use of X-Rays, and helps underwrite the possibility of further developments in the area.

'Radiological protection relies on scientific knowledge, ethical considerations, and practical experience.' (ICRP 138)
'All professions are conspiracies against the laity' (George Bernard Shaw in The Doctor's Dilemma)

1. Introduction and background

1.1. Introduction

Roentgen's 1895 discovery brought great new possibilities to medicine. Like most innovation, the good was accompanied by significant harms that were not immediately recognised. This paper is an initial critical look at the history of the international initiatives to control and mitigate the harms. These initiatives were often foreshadowed in progress achieved nationally in, for example, the UK, US, and Germany. In due course, the international initiatives influenced development in most countries throughout the world, following a pattern in which respected international bodies often greatly assist local experts in progressing initiatives in their own countries. The International Commission for Radiological Protection (ICRP) is a highly respected body in radiation protection dating from circa 1928 [1]. Its formal *recommendations* describe the system of radiological protection, provide firm statements on what must be achieved to be effective, and are widely used by governments, the EC, and the UN, among others. The ICRP website states that the *system of radiological protection is based on the current understanding of the science of radiation exposures and effects, and value judgements. These value judgements take into account societal expectations, ethics, and experience gained in application of the system. As the understanding of the science and societal expectations have evolved over time, so too has the system of radiological protection* [1]. From the commission's major *recommendations,* we infer something about radiation protection, particularly in medicine, at the time they were issued.

As well as a narrative on the ICRP recommendations, the paper provides a commentary at the end of each period, on how the commission might be viewed from the perspectives of *Governance and Ethics*. This is important, as the commission has made much of its independence. It is also part of understanding how radiation protection in medicine has gradually evolved and still has significant deficits. Early harms were so damaging and destructive that by the 1930's a *Monument to the X-ray and Radium Martyrs of All Nations* was erected in Hamburg (Fig. 1) [2]. It is difficult to underestimate the importance of the international radiation protection initiatives. Without them to limit and control the harms associated with Roentgen's gift to humanity, it is possible that it might have been side-lined through fear or even abandoned.

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Fig. 1. Memorial in Hamburg to the Radiology Martyrs, the Physicians, Physicists, Chemists, Technicians, Nurses, and others whose lives were given to the safe use of the X-ray and Radium rays in medicine [104].

The 125-years since 1895 divides neatly into four periods, A-D, each of approximately 30 years. During each there have been major developments, not just in the use of X-Rays, but also in the requirements for their safe application in medicine and related public health issues. The periods are taken as notionally: 1895–1928; 1928–1960; 1960–1990; and 1990 to the present.

1.2. Röntgen, X-Rays and early radiographs (1895–1928)

Wilhelm Röntgen was awarded the 1901 Nobel Prize for his 1895 discovery of X-Rays [3–5]. His reports included the first recorded human radiograph of the hand of his wife, Anna Bertha. A later radiograph of his friend Albert von Kölliker's hand is better, as are other early radiographs arising from a fashion for radiographing family and friends [3,6]. Röntgen held strong ethical views and did not patent his findings, which he felt should be freely available. Likewise, he donated his Nobel Prize money to research and later rejected an offer of nobility. He was invited to be an honorary member of the first medical X-Ray organisation, the Röntgen Society in the UK, and declined.

X-Rays were in use across the world for diagnosis and therapy within a year of Röntgen's paper. While there were real benefits, significant harms to operators and patients were noted. Intuitive protection measures began to be discussed, although much time had to lapse before they were considered by professional bodies and it was much later before they became legally binding. This pattern is often seen; innovation and development precede formal standards and the law, and it is important that those charged with responsibility in these areas be alert to this. The high level of interest in Röntgen's discovery led to over 1,100 papers on X-Rays in the year following his discovery. The harms, reported during the following decades, included skin burns, dermatitis, skin cancers, loss of hair and damage to the eyes [7–9].

Early attempts to provide safety advice, mainly but not only for workers, included that from Wolfram Conrad Fuchs, in Chicago in 1896, who advised keeping exposures as short as possible and placing the x-ray tube at least 30 cm from the body. Other workers suggested filtration of the x-ray beam and the use of collimation. William Rollins, a Boston dentist, recommended protective tube housings, the use of leaded glass goggles, collimated beams, and pulsed fluoroscopy. The suggestions from this period were noted and followed up on by, for example, the German Röntgen Society (Deutsche Röntgen-Gesellschaft) and others. The former issued a one-page warning on risks in 1913. The Röntgen Society (a predecessor of the British Institute of Radiology) issued rules for X-ray operators and in 1915. In 1921, a British Committee published a report that provided the basis for the first international recommendations in 1928, which is considered in Sections 3.2 and 4.1 below [7–9].

Röntgen withdrew early from involvement with medical development of his discovery, so further comment on the governance and ethics of positions taken by him is not necessary here. However, the radiograph of his wife's hand (as opposed to his own) and the early gratuitous enthusiasm for hand radiography invites some speculation. Obviously, by today's radiation protection standards, such radiographs would be unacceptable. However, at the time, there was little if any knowledge of the risk(s) that might be involved. It is also plausible that it in Röntgen's case the motivation was a wish to share the limelight (for which he had little taste) with his wife to whom he was dedicated. There was also the possibility of a social benefit in persuading people about the efficacy of the new discovery. Röntgen's generosity in not patenting or restricting access to his discovery, and in disposing of his Nobel Prize monies, were remarkable and it is apparent that he had many fine qualities [10–13].

2. Materials and methods

The materials used to examine the development of radiation protection at the international level are, in the first instance, the publications of ICRP and its predecessors since 1928. These are freely available on the ICRP website on an Open Access (OA) basis [1]. The primary area of focus is the commission's formal recommendations. Its other publications, though not enjoying the same status as the recommendations, are also referred to where necessary. Publications from other supra-national organisations active in radiation protection in medicine are also accessed, including some from: The Commission of the European Communities (EC); the International Atomic Energy Agency (IAEA); the World Health Organisation (WHO); and the International Electrotechnical Commission (IEC). Documents from individual countries or professional bodies are occasionally presented where they have smething special to offer. The general scientific literature is cited in the normal way.

A *Governance and Ethics Commentary* is provided at the end of each

Table 1
The pragmatic ethics value set used*

Dignity/Autonomy	*Of the individual*
Non-maleficence/Beneficence	*As in do no harm, do good*
Justice	*As in equity and fairness*
Prudence/Precaution	*As in precautionary principle*
Honesty/Transparency	*As in openness and transparency*
Solidarity	*Sharing risk or resources in the community*
Possible additional values under discussion: inclusiveness and empathy	

*Adapted from Malone et al., 2019; Malone & Zölzer, 2016 [10,14].

period. It comments on the framework ICRP was working out of, and on its approach as set out in its *recommendations* publications. The commentaries contain qualitative judgments made by the author based on the materials available at the time of writing. The following are considered when discussing governance:

- Governance is assessed by the presence or absence of conflicts of interest, freedom to act appropriately, independently, and on the culture of the organisation when it is evident in its publications.
- Governance is also assessed by the extent to which radiation protection in medicine, specifically of the patient, is treated in the publication.
- Good practice advice is sometimes considered. The standard for good practice is that which would be well known and understood by medical physicists with a good knowledge of the system of radiation protection as applied in medicine.

The values against which judgments in medical radiation protection are made are summarised Table 1 and include *Dignity/autonomy; beneficence/nonmaleficence; Prudence/precaution; Justice; Honesty/Transparency;* and *Solidarity*. This is essentially the set proposed by Malone and Zolzer with the addition of *solidarity*. [14] It is particularly well suited to medical and public health applications and like that adopted by ICRP for general purposes. It has also been used by WHO [11,13–15].

Briefly, the values are understood as follows [10]:

- **Dignity and autonomy**: Respect for autonomy is based on human dignity. It is widely accepted and emphasised in the recent Declaration of Geneva [10,15]. The balance in emphasis between dignity and autonomy is different in differing cultures.
- **Non-maleficence and beneficence**: *Doing no harm* is one of the central and most cited features of the Hippocratic Oath. So is *working for the good of the patient*. Non-maleficence and beneficence must be balanced. Acceptance of harm has a solid body of precedent for therapeutic actions, but its place in a diagnosis requires additional exploration.
- **Justice**: There are many ways of approaching the notion of justice. In radiation protection, its most significant impact is in distributional justice. It is important for dose limitation, equitable distribution of risk, and equitable access to resources, including access to health care.
- **Prudence:** In screening activities such as mammography, and medical radiation protection, prudence or precaution assume great importance. It is found in many written and oral traditions. It has been embraced by high-level United Nations (UN) conferences as the appropriate approach to decision-making when data are incomplete and cause–effect relationships may not be firmly established (e.g. global warming). To paraphrase: *where an action may cause a serious irreversible harm, measures to protect against it must be taken even when causal relationships are not fully established.*
- **Honesty/Transparency:** Extends well beyond financial matters and includes openness and transparency about benefits and harms. It requires that people not be nudged, coerced, manipulated, or deceived. Honesty, veracity, and truthfulness are guiding values for interaction between specialists and lay people exposed to radiation with its associated probable risks.
- **Solidarity:** Helps professionals to function in accord with contemporary social expectations and thereby strengthens the value set, where consideration of the common good is important – as it is with public health – and when community/social considerations arise [16–18].

The values must be nuanced in application as their varying requirements will inevitably conflict with each other and with existing practices. For example, dignity and autonomy require that the individual's preferences be attended to. In practice this can mean that implicit or explicit consent will be essential for justification. In addition, they may come into conflict with the beneficence/non-maleficence pair. The values also need "specification", i.e. concrete rules or guidelines must be derived for different areas of application and take due account of the interests involved.

Of course, there are other dimensions to governance and ethics. For example, openness to the social sciences, the humanities and indeed the law are important. These are considered where there is obvious evidence, but the analysis undertaken is constrained by space, material, and access to records at the time of writing. More research in this area is required.

3. Period A: Pioneering radiology up to 1928

3.1. Two outstanding radiology pioneers, Marie Curie and Edith Stoney

Many outstanding contributions to various aspects of the early radiological sciences occurred at the end of the nineteenth century and during the early part of the twentieth century. As well as Röntgen's work, they include the discovery of radioactivity by Becquerel, and the discovery of the first radioactive elements, Polonium and Radium, by the Curies. However, for a paper in the European Journal of Medical Physics, the work of two early physics contributors is, perhaps, appropriate. Both Marie Curie and Edith Stoney made major contributions to the practical development and deployment of radiology during WWI.

At the beginning of WWI Marie Curie put her research on hold, took her radium stock to the safety of a deposit box in a Bordeaux bank, and decided to devote herself to the application of radiology in the battlefield in support of the French war effort [19,20]. She was brave beyond normal, both in the physical sense as well as morally. For her work on radioactivity, she was awarded the Nobel Prize in 1903, two years after Röntgen. She took on herself the immense task of organising field and mobile radiology services, bringing Röntgen's discovery to the French army at war with Germany. She invented the "radiological car" – a vehicle containing an X-Ray machine and photographic darkroom equipment – which could be taken to the front. The electrical power problem was solved by incorporating a petrol driven generator. Eventually she had 20 fully equipped vehicles and trained over 150 women to staff them. She had her own vehicle that she took to the front, something that required her to relearn to drive, change flat tires, deal with accidents, and fix damaged equipment. She also developed up to 200 radiological rooms in field hospitals. It is estimated that over one million examinations of wounded soldiers were performed in her facilities. Many staff were injured from overexposure. But although it was known there was a problem, there had been no time to create and enforce adequate safe practices.

In later life, this was a cause of concern to her. Yet even in the 1920's neither she nor anybody else was really sure if radium had damaged her eyes. Some workers ignored the warning signs and continued to use it indiscriminately [19]. Her death and associated illness were often assumed to be associated with her radium work. But she was unconvinced and tended to attribute her illnesses to X-ray exposure during the war [7]. She did not acknowledge, with her laboratory colleagues, the possibility that her deteriorating condition, including

cataracts, might be due to radium. Yet, in a less formal setting, being accompanied home, nearly blind, she wondered aloud if there was a connection, following British reports of significant damage [19].

Marie Curie was dogged and idealistic, both as a scientist and as a patriotic humanitarian — if the latter is not an oxymoron. For example, like Röntgen, she believed humanity should have unfettered access to her science and she held no patents on use of intellectual property. She attempted to donate her gold Nobel Prize medals to the war effort, but the French National Bank refused to accept them [20]. She said:

> *I am going to give up the little gold I possess. I shall add to this the scientific medals, which are quite useless to me. ….. [By] sheer laziness I had allowed the money for my second Nobel Prize to remain in Stockholm in Swedish crowns. ….. I should like to bring it back here and invest it in war loans. The state needs it. Only, I have no illusions: this money will probably be lost* [21].

The second radiology contributor, Edith Stoney is of Irish origins and is identified as the first female medical physicist. She also made remarkable contributions to radiology during WW I on behalf of the UK [22–24]. She, and her radiologist sister, Florence Stoney worked at the Royal Free Hospital in London, and offered to provide radiological services on the day war was declared, but their offer was refused as they were women. Edith then took on the task of planning and operating X-ray facilities for a 250-bed tented hospital in France. She established stereoscopy to localise bullets and shrapnel and introduced x-rays to the diagnosis of gas gangrene. This was an important marker for immediate amputation. She had to retreat several times, but also established facilities in Serbia and Greece. Here is an impression of Edith during this period:

> *A learned scientist, no longer young, a mere wraith of a woman, but her physical endurance seemed to be infinite; she could carry heavy loads of equipment, repair electric wires sitting astride ridge tents in a howling gale, and work tirelessly on an almost starvation diet.* And another: *Grey hair, pale blue eyes, very intent on her job, – no special friend – no other interests, in and out of the x-ray rooms and developing rooms like a moth.*

She received many awards from the UK, France, and Serbia. As with Marie Curie, she was tough, single-minded, demonstrated bravery, imagination, and resourcefulness in the face of extreme danger. Her obituaries appeared in publications that few medical physicists reach, including *Nature, The Lancet*, *The Times of London*, and the Australian Press [22].

3.2. The international congress of radiology

By 1925, radiology was coming of age and held its first international congress (ICR) in London, facilitated by the British Institute of Radiology (BIR). Thereafter congresses were scheduled every three years until interrupted by WWII. The London congress resolved to address issues that had become matters of major concern among practitioners and their national societies (Section 1.2). They were the problems of safety, radiation measurement, and professional education for radiology. The congress established commissions to deal with each of these that met at the second ICR congress in Stockholm in 1928.

The 1928 congress adopted a set of recommendations to provide protection against the then known hazards of radiation. The three-and-a-half-page document, known as *International recommendations for X-ray and radium protection*, was produced in English, German and French and is accessible on an open access basis in the ICRP website [1,25]. This was the first in the series of documents and is the direct predecessor of ICRP international recommendations. The content of the recommendations is dealt with in Section 4.1. The governance, good practice, and ethics implications of their appearance are addressed in Sections 3.3 and 4.1 below.

3.3. Governance and ethics commentary

The history of the 1928 recommendations is complex and nuanced and possibly not fully appreciated by many of those using the recommendations of ICRP, including medical physicists. From a governance perspective, it is important to recognise that they were issued with the authority of an international medical congress, although not a well-established one. Training and professional recognition were also a major concern of the congress. This was an important seminal statement issued by a fledgling body and is the foundation statement for several professions today. Its importance is that without it, the good flowing from Röntgen's discovery might have been greatly attenuated or possibly side-lined by the increasing burden of harm that was coming to light.

Thus, the recommendations, while commendable in themselves, are clearly advocacy on behalf of a specialist group. They recall George Bernard Shaw's observation at the beginning of this paper, that *All professions are conspiracies against the laity* [26]. Here, Shaw is echoing Adam Smith's much earlier contention that *people of the same trade seldom meet together, even for merriment and diversion, but the conversation ends in a conspiracy against the public* …… [27]. Declaration of conflict (s) of interest is now embedded in scientific publication, but this was not so in 1928. The value of the recommendations (Fig. 2) must be judged with awareness of their origin. This raises an alert, and as will be seen in Section 4, possibly involves some lack of concern for patients and the public interest.

From an ethics perspective, the congress had prevention/limitation of harm from radiology as a major concern. This is consistent with the Hippocratic Oath which was part of the culture of medicine at the time. It is also probable that the congress would have been motivated toward *prudence* as much was still unknown, and *justice* to deal effectively with the known harms. But it is unlikely that the other values in the set (Table 1) would have figured strongly.

Both Marie Curie and Edith Stoney made remarkable personal contributions to radiology during WWI. Both were forces of nature, but nevertheless experienced gender difficulties which did not intimidate them. They displayed exceptional *solidarity*. It is possible that neither allowed *prudence* to impede a course of action they were determined on. Both had altruism and a sense of *justice* to an exceptional extent, especially Marie Curie in the disposal of her private resources. Neither was a good *communicator*, which can undermine *honesty*, and some of the difficulties they experienced may be related to this. Marie Curie was not fastidious with radiation protection measures and postponed addressing them almost indefinitely at great cost to her own health, which also suggests a problem with *honesty*. It is possible that Edith Stoney may have had a more enlightened approach which was beginning to take hold in London [9]. The recommendations and the behaviour of the two pioneers were important steps on a journey whose destination was not yet clear. Nevertheless, they were an important move in the right direction. In later sections it will be possible to see how the destination, and the vision for the professions, clarified.

4. Period B: Pioneering radiation protection 1928–1960

Several key publications from this eventful period are reviewed, including the 1928 international recommendations with their evolution over the following decade [25]. WWII then intervened and changed the context of radiation protection. In the 1950′s the first recommendations characteristic of today's ICRP began to emerge, particularly ICRP-1. An example of early successes of radiation protection in diagnostic radiology is presented.

4.1. The 1928 international recommendations for X-ray and radium protection

The effects of radiation to be guarded against in the 1928

INTERNATIONAL RECOMMENDATIONS FOR X-RAY AND RADIUM PROTECTION

on the proposal of the Radio-Physics Section adopted by the Second International Congress of Radiology in Stockholm, July 27th, 1928

1. The dangers of over-exposure to X-rays and radium can be avoided by the provision of adequate protection and suitable working conditions. It is the duty of those in charge of X-ray and radium departments to ensure such conditions for their personnel. The known effects to be guarded against are:
(a) Injuries to the superficial tissues;
(b) Derangements of internal organs and changes in the blood.

I. *Working Hours etc.*

2. The following working hours etc. are recommended for whole-time X-ray and radium workers:
(a) Not more than seven working hours a day.
(b) Not more than five working days a week. The off-days to be spent as much as possible out of doors.
(c) Not less than one month's holiday a year.
(d) Whole-time workers in hospital X-ray and radium departments should not be called upon for other hospital service.

II. *General X-Ray Recommendations.*

3. X-ray departments should not be situated below ground-floor level.
4. All rooms, including dark-rooms, should be provided with windows affording good natural lighting and ready facilities for admitting sunshine and fresh air whenever possible.
5. All rooms should be provided with adequate exhaust ventilation capable of renewing the air of the room not less than 10 times an hour. Air inlets and outlets should be arranged to afford cross-wise ventilation of the room.
6. All rooms should preferably be decorated in light colours.
7. X-ray rooms should be large enough to permit a convenient lay-out of the equipment. A minimum floor area of 250 sq. feet (25 sq. metres) is recommended for X-ray rooms and 100 sq. feet (10 sq. metres) for dark-rooms. Ceilings should be not less than 11 feet (3.5 metres) high.
8. A working temperature of about 18° C. (65° F.) is desirable in X-ray rooms.
9. Wherever practicable, the X-ray generating apparatus should be placed in a separate room from the X-ray tube.

Fig. 2. The first page of the first International Recommendations for X-Ray and Radium Protection, from the International Congress of Radiology, 1928 [25].

recommendations were*: (a) Injuries to the superficial tissues; (b) Derangements of internal organs and changes in the blood* [25]. They reflected the emerging consensus from the years prior to the London and Stockholm congresses.

The recommendations are a three and half page document (Fig. 2). Despite their simplicity, they include a clear statement about the responsibility of employers and assert that:

> *The dangers of over-exposure to X-rays and radium can be avoided by the provision of adequate protection and suitable working conditions. It is the duty of those in charge ….. to ensure such conditions for their personnel.*

These first sentences in this short document place duties on the employer that ICRP and the radiation protection community have championed since. In this they were ahead of their time as many enterprises continued with little regard for the safety of personnel.

The protective measures advocated were simpler than those in current recommendations:

> *….. for whole-time X-ray and radium workers: (a) Not more than seven working hours a day. (b) Not more than five working days a week. The off-days to be spent ….. out of doors. (c) Not less than one month's holiday a year. (d) Whole-time workers ….. should not be called upon for other hospital service.*

This reflects the reasonable self-interest of the professional group from which it comes. Concerns in this vein persisted and were still reflected in the special conditions of employment for radiation workers right up to the 1970 s.

The requirements for staff take a page, and include, among other injunctions:

- X-ray departments should not be situated below ground-floor level.
- All rooms, including dark-rooms, should be provided with windows affording good natural lighting and ready facilities for admitting sunshine and fresh air whenever possible.
- All rooms should preferably be decorated in light colours.
- In the case of X-ray treatment, the operator is best stationed completely outside the X-ray room behind a protective wall
- Screening examinations should be conducted as rapidly as possible with minimum intensities and apertures.

In addition, generous room size, temperature, ventilation, location of the generator, the X-Ray tube, the operator, arrangements for

screening (fluoroscopy), some practical suggestions on technique, and protective gloves are all specified. The lead equivalents advised for shielding the tube and room in which it is used are inadequate by today's standards. An indication of the circumstances prevailing in practice can be gleaned from the statement that:

> *if the protective value of the X-ray tube enclosure falls short of the values given ….. the remaining walls, floor and ceiling may also be required to provide supplementary protection for adjacent occupants to an extent depending on the circumstances.*

There is little mention of patient issues in the diagnostic sections, other than the need to *make adequate arrangements for protecting the operator against scattered radiation from the patient*. Personal and area monitoring was taken care of ingeniously: *It should not be possible for a well rested eye of normal acuity to detect in the dark appreciable fluorescence of a screen placed in the permanent position of the operator.* Advice on radium handling for treatments is provided in a separate section and will not be addressed here, other than to note it proposes that: *Discretion should be exercised in transmitting radium salts by post.*

A full section is devoted to electrical safety to avoid electrocution of staff, which must have been a real hazard. This is not deemed necessary in today's radiation protection manuals, but in the author's department, electrical safety checks were part of QA system up to a decade ago. This was, among other things, to protect patients from the risk of microshock, which could be a real hazard [28].

4.2. Evolution of recommendations and WW II

The 1928 recommendations laid the foundations for further work. They were quickly followed by publications in 1931, 1934, and 1937 that made additions, dealt with omissions, and clarified the original [2,30,31]. The issues of time, distance and shielding were identified as unambiguously important. The publications addressed real fears of acute deterministic injury, and of genetic damage arising from gonad radiation (rather than pregnancy protection).

The 1931 version added about half a page to the original. Much good practical advice is included, for example: *Palpation with the hand should be reduced to the minimum.* It also includes some frankly wrong advice: *An operator should place himself as remote as practicable from the X-ray tube.* In addition, the authors appear to be exasperated with the practicalities of getting their recommendations implemented and noted: *One inevitably wonders in how many radiological clinics such continuous control of the state of health has really been accomplished!* Plus ça change, plus c'est la même chose. The 1934 and 1937 versions continued to draw on new developments, ideas, and knowledge.

Regarding dose limitation, the 1934 Congress set a quantitative permissible dose level of 0.2 R/day (1 R/week). Prior to this, the permissible level, though expressed in various ways and not always recognised, was up to 100 R/y (approximately equal to 1000 mSv/y) [7]. The U.S. Advisory Committee adopted a lower value, half of the 1934/7 level [7]. The evolution of dose limits from the 30's to the 90's is further dealt with in Sections 5.2.1 and 6.5 and Table 2.

Thereafter World War II intervened, and the 1940 congress planned for Berlin was cancelled. An indirect consequence of this is that all the records of the earlier congresses were destroyed during the war. The area then became inactive until late 1945 [7]. The creation and detonation of nuclear weapons ushered in an age in which radiation protection became important for strategic reasons outside medicine and scientific research. In addition, health physics became, out of necessity, a science in its own right with significant advances in survey instruments, monitoring techniques, and radiobiological research, often constrained under war-time secrecy [7]. Experimentation with radioactive materials led to potentially valuable uses in medicine. The use of nuclear weapons profoundly influenced radiation protection, including that in medicine, right up to the present time.

The legacy of the war effort contributed both positively and negatively to developments. On the positive side the epidemiological studies of the bomb survivors provided definite information on the induction of cancer and leukaemia in irradiated populations, and this shifted much of the emphasis of radiation protection from its traditional focus on deterministic effects, to the probable incidence of cancers possibly even at the low doses [32]. However, on the negative side, the general population fears arising from the Japanese bombings and continued nuclear testing, grew during the post war period until they became highly politicised movements in the 1960s and later. A powerful video installation illustrating the testing programme is on display at the IAEA headquarters in Vienna and can be seen at [33].

The impact of these was possibly underestimated by the radiation protection community including that in medicine. Links between civil nuclear activity, associated military enterprises, nuclear testing, and environmental destruction were consolidated. The distrust of both governments and science on nuclear and radiation issues is a legacy of this period. Attempts to disentangle medical and socially acceptable applications from the broader nuclear legacy have not generally been successful, and the social sciences and humanities were generally and unwisely excluded from attempts to do so (Sections 5.3 and 6.3).

The next recommendations from 1950 were published by the British Journal of Radiology in 1951 [34]. These were informed by much new work and many insights that had arisen because of the war efforts on both sides of the Atlantic. However, their starting point was the work accomplished between 1928 and 1937.

4.3. ICRP publications 1 recommendations

The 1950/1 publication recognised much of the new work on bioeffects, refines the 1937 document and adds to it. Further recommendations were produced in 1954, 1956, and 1959 and often published a year later [35–37]. The 1954/5 report is the first one that looks like a publication from ICRP and appeared as a supplement to the British Journal of Radiology. The 1956/8 one continued with important clarifications on dose limits and references to pregnancy as opposed just to gonad dose. The first recommendations from ICRP in the numbered series of its own publications, Publication 1, was at the end of the fifties, and initiated the long series that have come to enjoy a quasi-biblical authority in radiation protection [37]. This was an important step towards the modern era and set the scene for the period until 1977 when ICRP-26 was issued (Section 5.1).

It is important to note that ICRP continued to function within the governance arrangement provided by the ICR. Thus, for example, appointment of commission members was made by the ICR International Executive Committee based on nominations submitted by the commission. This aspect of governance has not received adequate attention and is difficult to research due to the loss of records during WW II. The new commission, over time, affiliated with many international organisations including UNSCEAR, WHO, IAEA, FAO, ILO and IRPA. Its funding sources included the International Society for Radiology (ISR), the Swedish government, and WHO. The work of the new commission was entirely voluntary; no secretariat had yet been appointed [37].

The emphasis in the 1959 recommendations moved away from a prescriptive list of practical advice toward a consistent framework referencing the related sciences. Most of its work was complete by 1956,

Table 2
Summary of Evolution of Dose-Limits*

Period/Dates	*Headline Recommended Dose Limit(Whole body and annualised)*
Pre 1928/1934	*Up to 100 rems (1000 mSv)*
1934/7 to 1950	*60 rems (600 mSv)*
At 1951	*15 rems (150 mSv)*
At 1959	*5 rems (50 mSv)*
At 1991	*20 mSv (2 rems)*

*See text and draws on Boice et al. 2020 [7].

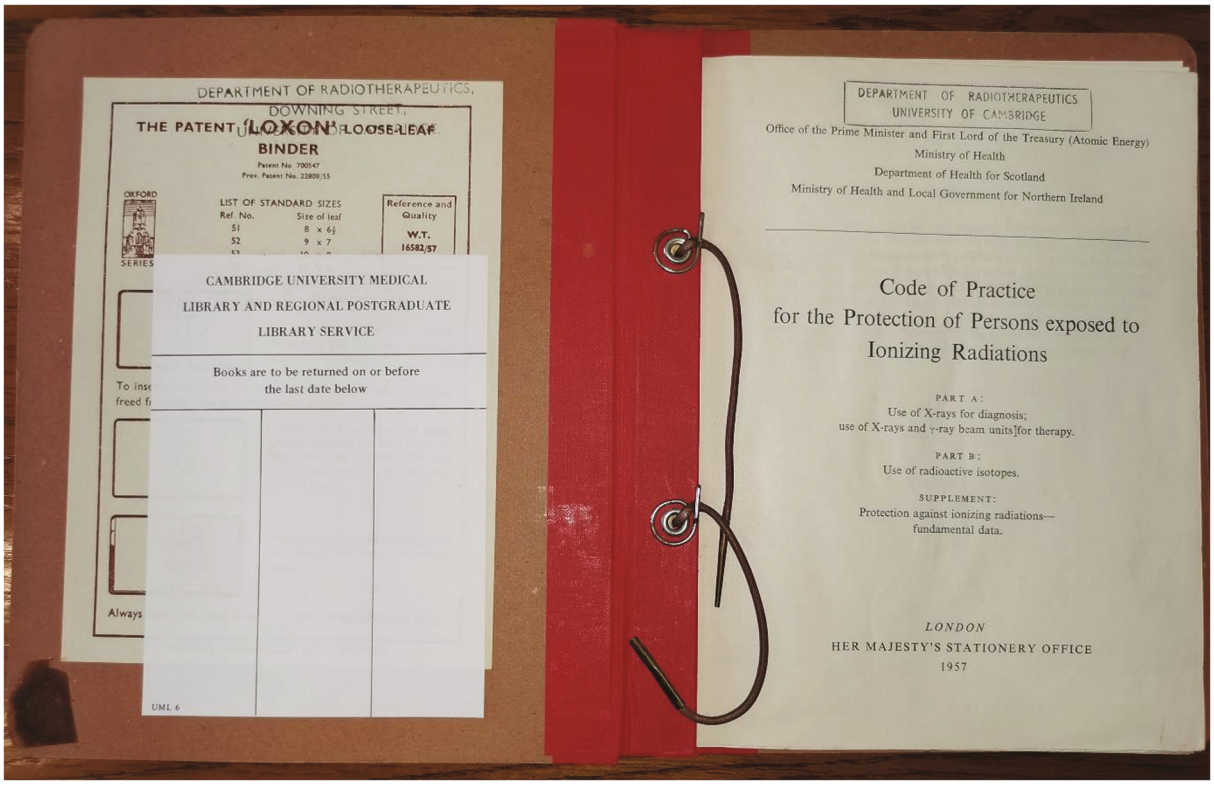

Fig. 3. Inside the front cover of the author's second-hand copy of the UK Code of Practice 1957 [38].

and it consolidated earlier findings. It dealt with basic concepts, objectives, critical organs, population exposure, genetic dose, medical exposures, permissible doses including public doses, categories of exposure, working conditions, controlled areas, monitoring, surveys, and health surveillance. About half a page, of 22 in total, was devoted to medical exposures. These were excluded from dose limits *as a matter of practical necessity*. The main thrust of the medical concerns was its increasing prevalence and gonad dose. The concept of the responsibility of *the person in charge* or *the owner* retained its central place, and the concept of qualified expert appears. Under many of these headings ICRP-1 breaks new ground.

By the late 1950's national publications began to appear, particularly in the UK and the US, but also in many other countries. An early example of the genre is the 1957 UK Code of Practice for the Protection of Persons exposed to Ionizing Radiations is shown in Fig. 3 [38]. This was a notable and accessible advance for practitioners. It is about 40 pages with approximately 40 further pages of practical information, including transmission curves for shielding, some of which would still be helpful. It had some unusual features. First, it was issued from the Prime Minister's Office, perhaps emphasising its importance and possibly a security connection. But it is also possibly because no other department felt they owned it. Second it was not a bound document like a book or booklet. Rather it was a loose-leaf production well secured in a cardboard folder with springs and string, possibly suggesting it had a provisional character. The author's second-hand copy was the first document widely available at the time he started working in medical physics. It is divided into parts dealing with X-Rays and radionuclides. The applications are clearly divided into diagnostic and radiotherapy. Thus, it foreshadowed divisions that are still present today in the certification of Medical Physics Experts (MPE).

4.4. An example from diagnostic radiology

Period B saw immense changes in diagnostic radiology. It would be difficult to overstate the importance of initiatives in education and training that occurred during these years. Yet, from a radiation protection perspective, the single most important development was probably in shielding: i.e. safe/effective tube housing, and beam collimation. Most of the impetus likely came from occupational exposure concerns, although patient protection also often benefited. Medical physics provided some impetus through testing and performance recommendations. Credit is due to equipment manufacturers for solutions that are so effective that tube housing seldom if ever fails today.

Another feature of this early period was the beginning of a more thorough approach to diagnostic room shielding. Early recommendations were not always followed or adequate [25,38]. They were not always related to the amount of work undertaken in the room and the occupancy of adjacent areas. It was clear that shielding was required in room walls, floor, and ceiling. In practice, walls were shielded more often than floors and ceilings. Even when walls were shielded, doors, windows and ducting areas were often omitted. The author has experience of such problems right up to the new millennium, and recalls an occasion at the IAEA circa 2010, when the need for door shielding in radiology departments was hotly disputed by a group of regulators and a senior IAEA radiation protection expert. Once tube housing and room shielding were dealt with, the aspects of radiation protection in diagnostic radiology that we now recognise began to receive more attention [34,37,38].

4.5. Governance and ethics commentary

From the perspective of governance, the close connection of ICRP with the International Congress of Radiology (ICR) continued throughout this period. For example, it is specified that:

> *selection of the members shall be made by the ICRP from nominations submitted to it by the National Delegations to the International Congress of Radiology and by the ICRP itself. The selections shall be subject to approval by the International Executive Committee (IEC) of the Congress. Members of the ICRP shall be chosen on the basis of their*

recognized activity in the fields of medical radiology, radiation protection, physics, health physics, biology, genetics, biochemistry and biophysics, with regard to an appropriate balance of expertise rather than to nationality.) The membership of the ICRP shall be approved during each International Congress [35].

The Commission could hardly be more exposed to a powerful interest group professionally devoted to the use of radiation. This connection lasted for 60 years and is an integral part of the heritage and culture of ICRP. Exclusion of the social sciences and humanities from the expertise range from which members might be chosen effectively persisted.

These features are somewhat at variance with the image of independence the commission fostered, and inevitably influenced its governance and the direction of its evolution. The commission projected itself as independent of governments, and in a literal sense this is true. During this period, it also became deeply involved with international organisations created and sustained by governments. Members of the commission were generally highly positioned scientists or doctors, often directly or indirectly employed by governments and actively involved in society's nuclear project. It is interesting to ask if the ICRP governance arrangements were adequate to deliver stakeholder trust to radiation protection communities including those in medicine. The exclusion of those from outside these enterprises and from the social sciences and humanities must, with hindsight, appear regrettable and inevitably diluted the commission's capacity to respond adequately to the growing concerns about radiation in the post war period [35].

The recommendations of this period addressed real fear of acute deterministic injury and genetic damage arising from gonad radiation. These were conflated with advice on fresh air, shorter working hours, longer holidays, bright ventilated rooms, and the risk of electrocution. They aspire to establish safe, comfortable working arrangements and this is what would be expected from a professional interest group. The 1928 recommendations mention patients once. In the ICRP-1 recommendations, only a half-page is devoted to medical exposures. Attention to them continued to be slight, and unsatisfactory from a governance point of view. However, it was an age of paternalism in science and medicine, and hopefully that compensated for the lack of a visible commitment to not harming patients.

Dose limitation was in transition during this period. The headline whole-body annual values are the maximum that could be adopted without direct risk of acute harm. This will be more fully discussed in Sections 5.2.1 and 5.5 (see Table 2). It is reasonable to hypothesise that the continuing exemption of medical exposures was probably due to the close governance arrangement with ICR.

In aspiring to eliminate acute deterministic injury and avoid genetic damage through avoidance of gonad radiation the recommendations are in the spirit of their time, and strongly influenced by the value of *non-maleficence or do no harm*. The notion of *justice* may also have contributed. The notion of the *dignity and autonomy* of the individual may be present for workers and is implied in the duties imposed on the owner or person in charge. However, it is missing for patients. *Prudence* is likely to have been a significant motivator of the whole project. There is something of *prudence and precautionary* thinking in avoiding gonadal radiation and the commitment to training and education. *Honesty, accountability,* and *solidarity*, as conceived today, do not feature, except in so far as they may have been manifested out of paternalism.

Finally, the equipment industry must be given credit, for its contribution to protection in both the occupational and the medical areas particularly in the development of good solutions to tube housing and collimation. In this they demonstrated a governance framework capable of responding to safety and standards issues.

5. Period C: Consolidation in medical RP (1960 – 1990)

The most significant publication of recommendations during this period was possibly ICRP-26, in 1977 [39]. It supersedes all previous recommendations of the commission, but not necessarily more technical committee reports [37,40,41]. The latter dealt with specific topics, such as diagnostic radiology, nuclear medicine, technical problems such as reference man, or the framework for the system including the no threshold idea, optimisation, and ALARA in everything but name [42–45]. The interim reports are generally more detailed scientifically, but lack the status attached to more formal recommendations. This pattern was repeated with numerous technical reports focused on specific issues paving the way for the 1990 recommendations issued at the end of Period C [46]. This period also saw the emergence of other international players, particularly the European Commission (EC), The International Electrotechnical Commission (IEC) and WHO.

5.1. ICRP-26

The most important innovation during this period was the new recommendations from the commission [39]. This was a major leap forward. It effectively created a rigorous coherent integrated framework for the system of radiation protection. It is the defining document for the commission's approach and its influence extends to the present today. The governance arrangements for the commission continued within the framework provided by the ICR. The document is longer than earlier publications, about 55 pages. The version cited here carries additional statements issued by the commission in 1978, 1980, 1983, 1984, and 1985 and extends to approximately 85 pages.

ICRP-26 is still familiar to many practitioners and hence will be overviewed less than earlier recommendations. It identified the risks of harm as somatic and hereditary. Somatic effects were classified as stochastic and non-stochastic, depending on whether the probability or severity of the effect is dose dependent. The former was assumed to have a no threshold dose response relationship and included cancer induction. Non-stochastic effects had a threshold dose below which they do not occur and included skin damage and cataracts. This is recognisable today, over 40 years on, even if the understanding of the phenomena is more nuanced.

The aim of radiation protection was stated as prevention of non-stochastic effects and limitation of the probability of stochastic effects to levels deemed to be acceptable. Notable attention was given to identifying and "quantifying" the acceptable level and comparing it with calculable radiation risk levels. Stochastic effects were to be limited by keeping all justifiable exposures as low as is reasonably achievable, economic, and social factors being considered and dose limits being observed. This, in effect gave the three principles of *Justification, Optimisation* (including ALARA) and *Dose Limitation*. ICRP-26 provided a solid and apparently rigorous, coherent framework for most of what has followed since.

The scope of ICRP-26 was expanded, compared with its predecessors, as was its depth, internal consistency, and coherence. The issues addressed include quantities, units, biological/epidemiological dose responses, risks, and tissue weighting factors for risk for the first time. The dose equivalent limits were based on an *acceptable level of risk*, and much less than those of the 1930's, with a headline annual value for whole body effective dose of 50 mSv or 5 rem (Section 4.5 and 5.2.1, and Table 2). The notion of dose constraints was introduced, as was classification of workplaces, and appropriate levels of oversight for different areas. Area monitoring, individual monitoring, medical supervision, and oversight of educational/ research activities, and occupational exposure of pregnant women were all addressed.

A relatively short chapter (two and a half pages) on medical exposures raised many of the areas to which full reports were later dedicated. These include: exposures for diagnosis or treatment of illnesses; systematic mass screening or periodic health checks; examinations for medical surveillance; examinations for medico-legal or insurance purposes; and examinations or treatment forming part of a medical research programme. Concerns about pregnant patients merited a paragraph. The value of the 10-day rule and good technique are

mentioned without recommendations (see also Section 6.5). The need for professional education and training get a perfunctory mention. Notable omissions/ problems included protection of patients and the impact of radiation on the environment. Protection of the patient, while addressed, was a secondary consideration to occupational and public exposures.

This was particularly notable for justification which was framed only in term net benefit without reference to patients' wishes, reflecting an almost moribund paternalism. The idea that net benefit could be quantified accurately initiated a fiction from which radiation protection has yet to escape [10]. Outcomes research is too inadequately developed to allow such calculations [46,47].

ICRP 26 was, perhaps, even more successful than might have been expected. Its rigorous scientific style impressed and won the loyalty of generations of radiation protection professionals who found it to be a good fit to their scientific culture. For scientists it was a framework to be proud of and worked on the assumptions that appeared both scientific and evidence based. It took almost two generations of successful application before the unwarranted assumptions began to be questioned at the operational level.

5.2. ICRP-60

In producing its 1990 recommendations the commission had three aims: to take account of new biological information including trends for safety standards; to improve the presentation of the recommendations; and to maintain as much stability as was consistent with the new information [46]. The length was increased to 77 pages supported by 120 pages of Annexes and references. The annexes relate to studies of biological effects, epidemiology, units/measurement, and the basis for judging the significance of biological effects.

One of the more surprising aspects of ICRP-60 is that the formal governance arrangements had changed since ICRP 26 [39,46]. The new arrangements are silent, although they are acknowledged in later publications. In 1988, the commission moved from the protective wing of ICR and was established as a registered charity in the UK, although it retained its international character. There is no evidence that the change in governance changed the approach and content of ICRP 60. It continued with a rigorous quasi-scientific approach drawing on the physical sciences, radiation biology and the growing body of post war epidemiological evidence. There is little reference to the social sciences, ethics, values, social or legal considerations.

The main chapters deal with: background to the commission's work; quantities and units; biological aspects of radiological protection; system of radiological protection for various practices including occupational and medical exposures; justification, optimisation and dose limitation; intervention in various situations; and implementation issues including management and compliance.

It is not practical to discuss all the measures mentioned in the report here but, because of their enduring impact, most are familiar to radiological protection practitioners today. However, three topics are briefly addressed with a view to further commenting on them again in Section 5.5 below. They are dose limits, the treatment of medical exposures, and the treatment of diagnostic exposures of pregnant or potentially pregnant women.

5.2.1. Dose limits and medical workers

Regarding dose limits, the main conclusions of ICRP-60 still prevail today, almost thirty years later. Prior to that for almost 80 years there was regular change (Table 2). Prior to the 1928/34 recommendations there were no limits. The limits have been expressed in a variety of ways, so that comparisons can be difficult. In broad terms, however, the headline annual whole body limit was reduced by a factor of about 4, from 600 mSv to 150 mSv between 1934 and 1950, by a further factor of 3 to 50 mSv by 1959, and an additional factor of 2.5 in 1990 when it reached 20 mSv, and there it has remained [7,29,34,37,39]. The average annual occupational effective dose to medical workers trended downward from ~ 70 mSv prior to 1939, to ~ 2 mSv in the late 1970 s and below ~ 1 mSv today, except for those performing fluoroscopically guided interventions [7]. Much of the decrease can probably be attributed to the strong emphasis on optimisation, ALARA, and the emergence of dose constraints.

The case for the 50 mSv value was most coherently stated in ICRP-26 when the risk of apparently safe occupations was used as a benchmark. When ICRP 60 further reduced the headline value to 20 mSv, it was partly based new biological findings and risk levels. Some felt that the case for 20 mSv was not convincing and the limit should be further reduced. Others felt that, even at 20 mSv, it was so low it would create practical difficulties. In the event, the commission settled on 20 mSv, but this somewhat damaged its image and led to questioning of the validity of its scientific approach, which up to that point was relatively unchallenged.

5.2.2. Treatment of medical exposures in general

Regarding medical exposures, the commission's approach is paradoxical. Despite its close relationship with ICR, its attention to medical exposures in the recommendations continued low, possibly to an extent that medical issues began to be addressed by other agencies (Section 5.3). The section on medical exposures in ICRP 60 is only one page from a 200-page document and lacks alertness to emerging problems in both justification and optimisation. The commission states: *medical exposures are clearly justified and because the procedures are usually for the direct benefit of the exposed individual* [46]. It was then, and still is the case that a significant proportion of radiological examinations are not justified in practice [49–52]. The commission continues that because justification of medical exposure is good: *less attention has been given to the optimisation of protection in medical exposure than in most other applications of radiation sources. ….. Doses from similar investigations cover ranges of as much as two orders of magnitude.* By the late 1980 s this problem was clearly articulated, particularly in Europe and remains significant even today [53–55].

The commission continued not applying a dose limit to medical exposures.. It seems likely that it was not sufficiently attuned to the emerging problems noted above. It pointed out that it ….. *has had historical links with medical radiology and its advice in this area has often been more detailed,* presumably referring to ancillary committee reports [46]. However, committee reports though often technically excellent, were of variable quality, and did not have the status or mandate of the recommendations.

5.2.3. Pregnant or potentially pregnant patients

A concern in medical radiation protection is exposures of women who are pregnant or potentially pregnant. Earlier recommendations were focused on possible genetic damage to future generations and addressed these in diagnostic exposures with collimation and gonad shielding. The latter is an emerging current concern (Section 7). In ICRP-60, possible damage to the embryo/foetus in pregnant women is raised as it was in ICRP-26. However, in ICRP-60 the earlier advice that the 10-day rule might be helpful is omitted and replaced by advice that: *the necessary information on possible pregnancy can, and should, be obtained from the patient herself.* This was an unreliable and insensitive approach and leaves much to be desired. However, it further recommended that exposure of pregnant or potentially pregnant women be avoided in *the absence of strong clinical indications*. In addition, it commented that: *exposure of the embryo in the first three weeks following conception is not likely to result in deterministic or stochastic effects in the liveborn child.* (See Section 6.5 for further comment).

5.3. Other influential international publications

In 1984, the European Commission (EC) issued new Directive 84/466/Euratom (a legally binding Directive to member states of the

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Whereas it is therefore appropriate that other provisions be enacted, to complement those contained in the aforementioned Directives, laying down suitable measures relating to the radiation protection of patients;

Whereas the Member States will also take into account the results achieved to date by the five-year Euratom research and training programme in the field of biology and health protection adopted by the Council,

HAS ADOPTED THIS DIRECTIVE:

Article 1

All medical exposures must be medically justified and kept as low as reasonably achievable, as defined in (a) and (b) of the first paragraph of Article 6 of Directive 80/836/Euratom.

Article 2

1. Without prejudice to Directives 75/362/EEC (1) and 75/363/EEC (2), as amended by Directive 82/76/EEC (3), and Directives 78/686/EEC (4) and 78/687/EEC (5), Member States shall take all appropriate measures to ensure that any ionizing radiation used in medical procedures is effected under the responsibility of doctors or dental practitioners or other practitioners who are entitled to perform such medical procedures in accordance with the national legislation and who, during their training, have acquired competence in radiation protection and received adequate training appropriate to the techniques used in medical and dental diagnostic radiology, in radiotherapy or in nuclear medicine.

2. Complementary training must be provided, if necessary, for the persons referred to in paragraph 1 who are already in practice where their competence in radiation protection has not been approved by the competent authorities.

3. Assistants shall receive instruction in the techniques applied and in suitable radiation protection procedures; they shall receive training appropriate to their work.

Article 3

The competent authorities shall draw up an inventory of medical and dental radiological equipment and nuclear medical installations and shall establish criteria of acceptability for radiological installations and nuclear medical installations. All installations in use must be kept under strict surveillance with regard to radiological protection and the quality control of appliances.

The competent authorities shall implement the necessary measures to improve inadequate or defective features of installations subject to such surveillance. They shall ensure as soon as possible that all installations which no longer meet the criteria specified in the first paragraph are taken out of service or replaced. Direct fluoroscopic examinations without the use of image intensification shall be carried out only in exceptional circumstances.

Article 4

Each Member State shall take such steps as it may consider necessary to discourage the unnecessary proliferation of equipment for radiotherapy, radiodiagnosis and nuclear medicine.

Article 5

A qualified expert in radiophysics shall be available to sophisticated departments of radiotherapy and nuclear medicine.

Article 6

Practical recommendations to which Member States may refer are set out in the Annex to this Directive.

Article 7

Member States shall take the measures necessary to comply with this Directive before 1 January 1986.

Member States shall inform the Commission of the provisions they have adopted to comply with this Directive.

Article 8

This Directive is addressed to the Member States.

Done at Brussels, 3 September 1984.

For the Council

The President

P. BARRY

(1) OJ No L 167, 30. 6. 1975, p. 1.
(2) OJ No L 167, 30. 6. 1975, p. 14.
(3) OJ No L 43, 15. 2. 1982, p. 21.
(4) OJ No L 233, 24. 8. 1978, p. 1.
(5) OJ No L 233, 24. 8. 1978, p. 10.

Fig. 4. The first page of the 1984 first European Directive on protection of patients undergoing medical exposures. The Directive was only one page (excluding front material and definitions), but due to its legal force had a profound impact [56].

European Union). It laid down basic measures for the radiation protection of persons undergoing medical examination or treatment (Fig. 4) [56]. The EC already had directives in place for protection of workers and the public. In addition, it had an extensive research programme, and had embarked on publication of a series of related periodic reports [70]. In a global context, this was a unique initiative. Singling out medical exposures for special attention was new and attracted opposition from both regulators and from the radiology communities in some member states. It is possible that the initiative arose, at least in part, from the absence of ICRP recommendations that were explicit enough to influence medical exposures, combined with a lack of self-regulation in some national radiology communities. The Directive is short but introduced ground-breaking requirements for training and education for radiologists and allied staff, equipment performance standards and their assessment, quality assurance, patient dose monitoring, as well as the requirement for an expert in *radiophysics* which preceded the current requirement for a Medical Physics Expert.

The International Electrotechnical Commission (IEC) is headquartered in Geneva and has responsibility for global international equipment standards. A total of 117 Technical Committees (TC) and Subcommittees (SC) is responsible for developing standards for all types of equipment. Electro medical equipment is dealt with under TC 62 which was established in the 1960s. It has four subcommittees and two, SC 62B and SC 62C, deal with imaging and radiotherapy equipment [28]. These committees, often chaired by medical physicists, have a significant role in ensuring equipment safety and performance. In Europe this is underwritten by the CE mark. In this period, the contribution of national and regional standards organisations such as BSI, DIN, CEN, CENELEC and the FDA held sway, but as trade became international, the development of European and international standards was gradually outsourced to IEC (see also Section 6.2.2). Standards are important for radiation protection, although their impact is often underestimated by medical physicists.

A 1975 WHO publication became a *vade mecum* for many medical physicists. It was the Manual on Radiation Protection in Hospitals and General Practice, Volume 3, X-Ray Diagnosis [57]. It dealt comprehensively with protection of staff and the public, purchase of equipment, design and shielding of facilities, and management of equipment through its life cycle. It also had an eleven-page appendix on medical aspects of diagnostic x-ray protection which, incidentally, advised use of the ten-day rule for women of reproductive capacity. The IAEA was active in supporting radiation protection initiatives in the medical context, although it focused largely on occupational issues until the turn of the century. In addition, much readily applicable advice on room shielding became available at both international and national levels during this period [57,58].

5.4. The CT scanner

It may be surprising to learn that EMI (Electric and Music Industries) which benefited from the sales of the Beatles' records invested in the creation of the first CT scanner. For a long time, these imaging systems were known as *EMI Scanners*. The first commercially available CT scanner was the work of Godfrey Hounsfield of EMI Laboratories in 1972. The CT scanner mirrors Röntgen's original discovery in entering widespread application and receiving a Nobel Prize within a decade [59]. Röntgen received his in 1901 and the prize for CT scanning was shared between Hounsfield and physicist Alan McCormack in 1979 [60]. However, the high cost of the early generations of CT scanner exercised some limitation on the speed of its dissemination.

The earliest CT scanners, even though limited to head studies, offered new imaging capabilities that served patients well. During the decades that followed, much innovation occurred culminating in the multislice ultra low-dose performance of the current and new generation of scanners that can image the body from head to toe. The radiation protection problems associated with CT systems were dealt with largely through good equipment design by the industry and room/facility design that meant that staff did not have to be in the room with the scanner. The useful beam was usually fairly well confined and scattered radiation was not a great problem. Patient protection issues were seldom discussed, and population doses were constrained by the limited numbers of scanners deployed. However, all of this was to change radically within a decade of the appearance of ICRP-60 (Section 6.2.3).

5.5. Governance and ethics commentary

The governance issues already identified persisted into this period. The relationship with ICR remained unchanged during and after the preparation and publication of ICRP-26. However, by the time ICRP-60 was published this relationship had radically altered and the commission had been established as a registered charity. There is little evidence of this change in the text of ICRP-60, and no evidence of a change in direction or preoccupations. It is probable that the culture of the commission was well established during the sixty years from 1928 to registration of the charity.

The depth, internal consistency, and coherence of the treatment in both ICRP-26 and ICRP-60 is impressive. The commission's analysis of the atomic bomb and revised dosimetry data probably gave rise to much heart searching, but led to the conclusion that stochastic effects should provide the basis for dose limits. For the greater part this stands the test of time. From an ethics point of view, the recommendations, particularly in the downward revision of the headline annual whole-body dose limit, impressively address issues *of non-maleficence* and *justice*. Likewise, they also address, though often not explicitly, the demands of *prudence*. While some would doubt the *honesty* of the reasons given for the 20 mSv decision in ICRP-60, it has stood the test of time, and is still used throughout the world to this day. In addition, the fact that the US did not adopted the 20 mSv value demonstrates the pressure the commission was probably exposed to at the time.

The lack of engagement with medical issues in the recommendations continued, and they were relegated to committee publications of varying quality. There was little evident appetite in the recommendations to address aspects of justification, optimisation, systemically variable patient doses, or management of potentially pregnant females. In these areas, issues involving *beneficence/ non maleficence* were often discussed, but reasonable expectations from other values including *dignity/ autonomy, justice* and *prudence* were somewhat neglected. Likewise, the absence of engagement with environmental issues and with the social sciences and humanities remained a feature of the commission's stance. With the benefit of hindsight, this is a serious omission. After all Rachel Carson's *Silent Spring* had already been published to considerable acclaim [61].

The *dignity and autonomy* of patients, *solidarity*, and an explicit consideration of *prudence*, were probably not on the commission's agenda during this period. While this might have been understandable in the run up to ICRP-26, it was not so by the eighties when ICRP-60 was in train and the expectations of society and many individuals had radically altered. This was clearly signalled in the initiative of the European Commission with respect to medical exposures and the IEC with respect to having safe equipment meeting transparent safety and performance standards. The importance of *honesty* and communication in the medical context received little attention in a world in which *consent* was coming to the fore. *Honesty* was also systemically undermined by fostering the unchallenged illusion that harms and benefits could be routinely compared in a quantitative fashion [10,11].

The issues around radiology of pregnant or potentially pregnant women have long been a source of dilemmas in radiology. The commission's contribution in the ICRP-160 recommendations did little to resolve these and was somewhat at variance with a tentative initiative in ICRP-26. At best, this is a failure of imagination in terms of the *dignity and autonomy* of generations of women and an absence of *honesty*,

prudence, and *solidarity* with them. This will be further discussed in Sections 6 and 7.

Use of the Sievert (Sv) for two quantities, effective dose, and equivalent dose continued. Briefly, the former is used to specify the amount of radiation received by an organ with some adjustment for different radiation types. The latter sums together all the organ exposures weighted for the risk attaching to each [62,63]. Clearly, they are quite different quantities, may vary greatly in numerical value, and may be mentioned in the same sentence. Their continued use in this way displays an arrogance about communication with those outside the radiation physics community. It is offensive to the *dignity* of members of other professions and the wider community. It also undermines opportunities for *honesty* and *transparency*. This can't be shrugged off; it continues as one of many barriers to effective communication.

6. Period D: The current situation (1990 to present)

In the period from 1990 to the present, the focus on medical radiation protection has greatly increased [56]. In the international communities the impetus for this was initially most evident in initiatives from the European Commission, supported directly or indirectly by the IAEA, WHO, and IEC. ICRP continued to revise and update its recommendations with two publications in 2007, one ICRP-103, dealing with the system in general, and the other, ICRP-105, setting out how it should be applied in medicine [62,63]. Almost a decade later, toward the end of this period, ICRP broke with its traditional pattern with respect to the social sciences and humanities, and issued a publication explicitly addressing the ethics framework for the system of radiological protection [13]. The period also saw two new directives from the EC further developing its commitment to medical exposures, as well as initiatives from the IAEA, WHO, IEC, others. These are addressed in this section together with two examples illustrating how some CT doses have become problematic.

6.1. ICRP-103 and ICRP-105

Both ICRP-103 and ICRP-105 reiterate the framework established in ICRP-26 and refined in ICRP-60 [62,63]. ICRP continues as a registered charity and the methods of appointment to it and its committees remained practically unchanged although they are refined and streamlined. However, its essential culture, focus, and direction remained unchanged, except for some engagement in consultation when preparing documents for publication. It hoped that this move toward transparency and involvement of some stakeholders would result in a clearer understanding and wider acceptance of its recommendations. During this period ICRP also successfully embarked on an ambitious initiative to make all its publications available on an open access basis [1]. The success of this process made this paper possible.

As with the 1990 recommendations, ICRP-103 is a long document, extending to 322 pages. The main *recommendations* are 135 pages and the remaining 187 are taken up with references and two appendices, one on units and quantities, and the other on biological and epidemiological considerations. It draws on but does not supersede many ICRP committee reports of varying quality, dealing with, for example, medical issues, pregnancy, and CT dose management [64–66].

The 2007 recommendations update tissue weighting factors, and information on harms based on new data published since ICRP-60. While the position on deterministic effects generally remains much the same, the situation regarding eye doses evolved and required a revision to the (eye) dose limit. The estimates of cancer risk attributable to radiation exposure had not changed greatly since ICRP-60, while that for heritable effects was lower. The revised recommendations did not propose fundamental changes, but they clarified the system's application in a plethora of practical exposure situations. They maintained the principles of justification, optimisation, and the application of dose limits.

With medical applications, there is a significant development in the 2007 recommendations compared with ICRP 60. A full chapter (8 pages) is devoted to them and addresses justification, optimisation, special issues in radiotherapy, comforters, and carers; use of volunteers in biomedical research, exposures during pregnancy, and use of the quantity *effective dose* in medicine. Brief comments on both the pregnancy issue and effective dose are in order. Regarding the pregnancy situation there is a notable improvement in the framing of the problem and the recommended actions. For example, there is clear advice that pregnancy status be determined prior to procedures, although it is silent on how this might be achieved. In addition, there is an emphasis on a pregnant patient's right to know the magnitude, nature, and consequences of in utero exposures. There is also information on prenatal exposures. The recommendations state that *most correctly performed diagnostic procedures ——— present no measurably increased risk of prenatal or postnatal death, [or] developmental damage* [62]. Regarding terminations, clear advice that they need not be considered at doses below 100 mSv is offered. All of this is a significant improvement on ICRP-60.

ICRP-103 is less than enthusiastic about the use of effective dose to quantify risk from medical exposures. It offers reasonable considerations in defence of this position. Principally, the age distributions of workers (for which the effective dose is derived) will usually be quite different from the age distribution of patients undergoing procedures. The exposed organ distribution also differs greatly from one type of medical procedure to another. For these reasons, the commission recommends that the risks from medical diagnosis be evaluated using the dose and calculated risk for individual organs and tissues. In practice this advice is often ignored. The burden of undertaking the required calculations is often beyond the resource and skill base of those undertaking medical dose studies. It is a matter of concern that this has been the best the commission can suggest in terms of quantities for medical exposure, given its enormous commitment to quantities and units for occupational exposures. However, thinking in the area has developed and the commission is expected to issue a report identifying conditions under which a form of effective dose could be reasonably applied in some medical studies. The medical chapter is followed by a slightly churlish two-page chapter on the environment, although a focused report on the environment was later produced by a special committee tasked with that purpose [67]. It is difficult to avoid the conclusion that medicine, and the environment are straining the commission's patience.

ICRP-105, on medical exposures, is a report of the medical committee of ICRP (Committee 3). It is 64 pages long with the main content extending over 52 pages. The annexe to ICRP 105 is 12 pages devoted to previous ICRP committee reports on topics including pregnancy [63,65]. ICRP 105 does not add much to ICRP-103 except for short chapters/subchapters on justification, DRLs and the unique aspects of medical exposures. The section on justification essentially endorses the publication 103 view and parses and refines the concept a little. Likewise, there is some more discussion on DRL's. The chapter on the unique aspects of medical exposures is valuable and though less than three pages, summarises the situation well. Apart from these, the value of publication 105 lies in its brevity. It is essentially ICRP-103 with the non-medical material stripped out. The medical reader will certainly find its 50 or so pages less forbidding than the 320 in 103. Interestingly, while it provides specific guidance on ten areas in an Appendix, there is no specific guidance on justification, with the exception of an opaque half page ostensibly directed at GP's which is so general and patronising that it is unlikely to have much impact on its target audience.

6.2. Other influential international publications

Around 1990, it became clear that the EC was taking a lead in medical radiation regulatory and guidance initiatives. From the mid-

nineties onward, a series of significant initiatives came from the European Commission, its radiation protection unit in Luxembourg, and research consortia funded by the EC. By the turn of the century UN organisations including the IAEA and WHO also assumed leadership roles in aspects of the medical area. ICRP continued to produce good work, including publications 103, 105 and 138 (Section 6.3), as well as a stream of reports from its medical committee. But it had missed major opportunities at the level of recommendations and advice to regulators, and international bodies.

6.2.1. European radiation regulatory standards

In 1997 the European Commission replaced the 1984 medical exposures directive with a new more comprehensive legal instrument on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure [68]. This highly developed regulation became national law in all member states of the European Union and exercised considerable influence beyond it, both in the rest of Europe and throughout the world. This regulation was later replaced and enhanced in the new European Basic Safety Standards of 2013 [69]. The EC also produced publications, the RP series, in support of the medical exposures Directive and continued to foster substantial related research programmes [70]. During the last decade, these initiatives extended to exploring contributions of the social sciences and humanities to radiation protection [71,72].

The topics of the RP publications are wide-ranging and served to guide, regulators, practitioners, policy makers and member states on practical implementation of sections of the Directives. They include: medico legal exposures; interventional radiology; exposures during pregnancy; early in utero exposures; dental radiology; population doses from medical exposures; radiation induced circulatory disease; non-medical imaging exposures; the medical physics expert; referral guidelines; audit of radiological practice; and criteria for the acceptability of equipment, among many others. The net impact of the directives, their implementation in national legislation, and these support publications was widespread informed debate within medical physics on medical radiation protection which found its way into practice, some of it without passing through ICRP. Successful policy actions on justification of medical exposures are an example [49–51,73].

6.2.2. International equipment standards

The IEC committee developing standards for medical imaging equipment (SC 62B) was, during this period, a reserved but highly effective participant in an industry transitioning from national providers to global players (Section 5.3). Traditionally, the approach in radiology was to have a separate standard for each system component, e.g. separate standards for X-Ray tubes, for image intensifiers, and so on. This changed as newer whole system standards evolved. For example, there are now system standards for mammography, CT, general x-ray – fluoroscopy, interventional systems, dental, Ultrasound and MR systems [28]. For end users, these are more applicable. This has also had a profound influence on aspects of equipment design, safety, and international marketability. Examples of component standards include those for tubes/housing, generator accuracy/ reliability, CT dose specification and measurement protocols, interventional displays, and dose display/management in radiology and fluoroscopy.

National/regional standards bodies now tend to outsource much of standards development to IEC. There is enthusiastic participation in standards development from Asia, Latin America, and the southern hemisphere, for example from Korea, China, Japan, Brazil and other countries that did not participate 20 years ago. Participation from the US is more episodic, though when it occurs, often through the FDA, it is effective. Finally, many of the EC criteria for acceptability of radiological equipment published in RP 162 are taken from the appropriate IEC standards [74].

6.2.3. IAEA, WHO, IRPA, National and Professional bodies

During this period, the IAEA reoriented its medical programmes to include a significant emphasis on radiation protection of patients (RPoP) and established a dedicate unit and website for this purpose [75,78]. The successes of this unit include significant influence on the development of the medical exposures section of the International Basic Safety Standards; a joint conference with the European Commission on Justification of Medical Imaging; and the Bonn Conference and call to action on medical exposures for the decade following 2012 [49–51,76–78]. In these initiatives it was partnered with WHO, which had been a strong contributor to the area since its 1975 document [57]. In this period, it established the Global Initiative on Radiation Safety in Health Care Settings with many contributions including the defining one on imaging asymptomatic persons which is discussed below (Sections 6.4.2 and 6.5). Finally, the International Radiation Protection Association (IRPA) took the lead with an initiative on developing a good culture of radiation protection in the various settings in which it is applied [79].

During this period, developments in multislice and more intensive CT greatly improved its contribution to patient management. The net result was a huge increase in patient numbers and in the dose per examination. The radiation output of machines greatly increased as did the patient workload and the intensity of examination types. The net result was a significant increase in the shielding requirements for facilities, which was also driven in some regions by a reduction in the regulatory dose constraints for facility design. This was often contested at the time. The publications addressing and resolving this major problem for medical physicists all came from national or professional bodies [80–82].

6.3. Ethics sensibility, ICRP, and the medical context

Lauriston Taylor, a pioneer and father figure in both the US NCRP and the ICRP declared that '*Radiation protection is not only a matter for science. It is a problem of philosophy, and morality, and the utmost wisdom*' [83]. Taylor's statement makes it clear that radiation protection, both as a system and in practice, extends beyond the science that supports it and leans on ethics, experience, common sense, and occasionally for the privileged, wisdom. While ICRP's formulations explicitly recognise and emphasise the science, and many practitioners value common-sense, the explicit place of ethics in the system had to wait until 2018 to be formally recognised in report 138 [13]. The initiative for the report arose at a 2012 meeting in Fukushima City, and may be related to difficulties implementing the system in practice at the time.

This report describes the set of ethical values that ICRP believes informed the system of radiation protection since its inception. It is based on a set of values to which all can subscribe and are commonly used in medical ethics [84]. It identifies four core values: beneficence/non-maleficence, prudence, justice, and dignity, as well as three procedural values that are required for the practical implementation, i.e. accountability, transparency, and inclusiveness.

While these are essential to the system, it is not always clear how they can be applied in specific areas. They cannot be directly mapped onto justification and optimisation. Medical applications are recognised as needing an additional publication, in preparation by ICRP TG 109 [12,10]. In addition, there is a rich ethics tradition in medicine, including the Hippocratic Oath. The most recent reiteration of the latter, the Geneva Declaration, overlaps to a considerable extent with ICRP-138 [15,10,85]. These considerations are crucial to the development of radiation protection in medicine. Pending the report of ICRP TG 109, considerable progress has been made in the published literature on application of a five-value system to practice in diagnostic imaging. The values are: Dignity/autonomy; Beneficence/non-maleficence; Prudence/precaution; Justice; and Honesty (Section 2). Additional values also under consideration, include solidarity and empathy [10,11,17].

6.4. Examples of current dilemmas in imaging: Issues with CT scanning

The use of medical imaging technologies has greatly increased over the past few decades. It has served medicine well in addressing the needs of patients and opening new horizons to improved care. However, it also brought with it, alarming sometimes poorly justified, increases in population and individual doses, and requirement for much greater shielding of CT facilities, all of which have been the subject of much debate and anxiety [32,86–88]. These have been well discussed elsewhere, as have the new ultra-low-dose CT systems and they won't be further addressed here. However, two less well rehearsed examples of CT dose dilemmas are introduced and analysed in Sections 6.4.1, 6.4.2 and 6.5, and the shielding issue is briefly addressed in Section 6.2.3.

6.4.1. Problems or repeat CT scans

A 2019 IAEA meeting focusing on repeat CT scans and found cause for concern in three prior publications. The cumulative effective doses were larger than expected. The dose from one scan is in the range 1–20 mSv. Yet repeat scans were accumulating doses in the 50–500 mSv range with greater than 1% receiving more than 100 mSv. The patient profiles indicated that 10 to 20% were less than 50 years of age [89–92].

Multiple "repeat" radiological imaging is justifiable in many circumstances. However, repeat scans frequently do not need all the features of the original diagnostic scan. A much more limited protocol may provide the information required at "repeat" which is often predicated on, for example, seeing if a mass is growing or shrinking. This requires the clinicians directly involved, equipment suppliers, allied health professionals and health authorities develop and implement suitable strategies for nuancing justification and protocols for repeat examinations. Professional medical societies must develop, adapt, or improve appropriateness criteria/ referral guidelines for patients who require multiple and/or long-term follow-up imaging studies. When a series of procedures can be reasonably foreseen, the justification process should consider the entire series not just the initial diagnostic event. The reasons for this are both practical and grounded in the ethics of medicine and radiation protection (see Section 2 and 6.5).

6.4.2. CT-IHA (Individual health Assessment) in asymptomatic persons and executive health checks

CT is increasingly applied to screen asymptomatic people for the early detection of disease. A limited study indicates that this practice occurs in most countries [48]. Such screening practices arise in both organized population-screening programmes and less structured settings. Even with organized programmes, balancing benefits and harms is critical to ensuring positive outcomes. Less structured situations including individual health assessment (IHA) can often challenge justification. ICRP recommended that social benefit can be balanced against the risk to individuals participating in medical radiological screening activities. In some well organised screening programmes, benefit/risk studies indicate a net social gain and the programme is therefore justified. National mammography screening programmes working out of an evidence-based framework often meet these requirements, although the area is not without dispute. However, it is important to realise that benefits can be over emphasised, and harms under-played by enthusiastic advocates. This exacerbates the already troubled traditional benefit/risk considerations and leads to activities that challenge justification [11].

There is little evidence that CT-IHA is of benefit in asymptomatic individuals. The obvious harms include probable radiation harms, mortality, morbidity, false-positives and negatives, incidental findings, related stress, and direct/indirect costs. Incidental findings of unexpected pathology can precipitate overdiagnosis, unnecessary worry, and sometimes aggressive overtreatment with its attendant risks. Incidental findings can also create unplanned expenditure that often falls on the public health service, while the CT-IHA usually occurs in the private sector [11].

Commercial services are widely available in many countries and offer CT-IHA scans to individuals for the early detection of lung, cardiac and colorectal disease. An example is the executive screening programmes offered at top-ranked cardiology hospitals in the United States, which include a coronary artery CT scan to determine the calcium score or visualize arteries. The packages include up to 12 cardiovascular tests at a cost ranging from about 1000 to 25 000 US dollars. The underlying assumption is that this aggressive and potentially comprehensive screening prevents people from dying but there is no evidence supporting this in imaging guidelines [93,94].

Formal standards and legal frameworks for addressing CT-IHA are provided by the International and European communities respectively [77,69]. Yet, even where authorities identify CT-IHA practices, they are sometimes reticent about imposing regulation for various reasons [95]. In some countries, consumers may expect CT-IHA to be available and have little awareness about the justification issues raised by radiation protection experts [96,97].

6.5. Governance and ethics commentary

During this period, ICRP continued as a registered charity. Within this envelope, there was much change including a new secretariat aligned with modern management priorities. However, the organisation's culture, as manifest in concerns, membership and output remained relatively unchanged, with a few exceptions. For example, toward the end of the period, it produced ICRP-138 on the ethics basis for the system of radiation protection [13]. It became more outward looking and a little more transparent in appointing members of the commission. It also instituted consultation on draft documents prior to publication and undertook a courageous initiative to make its publications available on an open access basis.

Following a decade during which medical exposures were receiving much more attention from the EC, the IAEA, WHO, IEC, and IRPA and the medical physics profession, its place in ICRP was, on the surface at least improved. It was given a separate chapter, not just be an afterthought, in ICRP-60. In addition, a report on medical exposures, ICRP-105, was issued, which though a well-written summary of the commissions position did not address the emerging problems in the area. Perhaps the area from which ICRP was most spectacularly absent (and continues to be so) is in justification of medical exposures. In this, the IAEA, the EC and WHO led with numerous initiatives up to and including the Bonn Call to Action [51].

The 20 mSv headline dose limit was retained, but the unease that accompanied its introduction is not completely at rest. The reduction in the occupational dose limit to eyes is a welcome response to developing evidence. The continued use of the Sievert for two quantities remains an obstacle to good communication and undermines *honesty*. As does the absence of a single understandable quantity that can be used in discussion of harms and outcomes from patient doses.

How to handle irradiation of pregnant patients remains an uncomfortable and inadequately addressed concern that undermines the *dignity and autonomy* of at least some women, and might benefit from a greater presence of the social sciences and the humanities [98–100,65]. Advice continued to be given to the effect that: *exposure of the embryo in the first three weeks following conception is not likely to result in deterministic or stochastic effects in the liveborn child* (ICRP-60, Section 5.2.3). This approach to pregnancy, though widely adopted, is not uncontested [100,101]. It is also remarkably insensitive to the fact that women who have difficulty conceiving may regard loss of an embryo or foetus as a significant harm. Limiting recognition of damage to that evident in the liveborn child is an inadequate approach to protection of early pregnancy.

During the decade to 2020, ICRP excavated the implicit ethics basis of the system of radiological protection [13]. Almost twenty years

earlier, significant ethical questions were emerging in medical radiation protection. *Honesty and consent* were coming to the fore and not only *de rigeur,* but also legally binding in many jurisdictions. These and other values, including *dignity and autonomy*, were addressed in European, IAEA, RICOMET and the DIMOND projects among others [71,14,10]. This period also saw serious challenges from other disciplines including the social sciences and the history of science. Documentary research after the Chernobyl accident found a basis for criticism in the behaviour of influential members of the commission who were also active in other international organisations [102].

All of this confirmed the importance of an ethics-based approach like that outlined in Section 2, which will now be applied to the two CT scanning examples in Section 6.4. The papers on repeat CT examinations bring to light a perennial problem. The fundamental question relates to how necessary repeats are, and if a "repeat" is required, must it fully reproduce the original. We do not have a full answer to the first question, but they are probably not all necessary. The answer to the second question is that repeats seldom need to reproduce the initial diagnostic investigation, but often do. The harms involved in the unnecessary components are real and reflect failures in:

- respecting the patient's *dignity and autonomy*;
- *doing unnecessary probable harm*;
- *justice* through poor use of radiological resources;
- the absence of *prudence* in radiological thinking;
- *honesty* through possible inadequate communication with the patient and staff; and
- *solidarity* with the wider community which may need the resources unwisely used.

These problems can be resolved through thoughtful multidisciplinary approaches to appropriate protocol development and technical implementation. Doing so would enhance the ethical positions of the professions involved and save resources.

In the IHA example, there may be a governance problem in institutions providing it, and there are clear ethical problems in conducting CT examinations with no benefits and which do *unnecessary harms* to healthy symptom free individuals. However there is a dilemma, and set against this, is a requirement to respect the *dignity and autonomy* of an individual who may request or even insist on such a procedure. This illustrates the situation that arises when values compete with eachother and must be balanced. The dilemma may be mitigated if *honest* comprehensible information about the benefits and harms is presented to the person requesting the scan. They may choose to go ahead, or realizing it is a zero-gain situation and opt out of the examination. *Honest* comprehensible information is critical to ethical behaviour and patient consent. Without it, there are failures of the other values including *prudence, justice,* and *solidarity*.

Regulators have been reticent about intervening in CT-IHA for various reasons, including the importance of personal freedom and empowerment, situations involving partially developed evidence bases, subtle approaches in some countries requiring additional attention, as well as uncertainty about the wisdom of intervention in medical practices [95,11]. This is an example where both ICRP and the radiation regulators have not made an impact. WHO has stepped into this space and developed a deep and broad framework of guidance for policy makers who are anxious to deal with this difficult problem [11].

7. Discussion and conclusions

Röntgen's discovery and its application in medicine have been one of the great success stories of science during the last 125 years. A sometimes uncelebrated part of this success is the incisive and often timely contributions of ICRP during most of the last century. They ensured that Röntgen's heritage is much safer and more effective than it might otherwise have been. It continued to benefit millions of lives and wasn't abandoned or diminished out of fear of its destructive impact on the lives of the early martyrs or later fears associated with nuclear projects. In the coming decade, while celebrating ICRP's centenary, we must also question how it may best be continued. This review suggests some aspects of governance, culture, and focus that might be considered when framing its future contributions to medical radiation protection.

The commission has long declared, and to some extent overstated, its independence. While it has strongly protected itself from some conflicts of interest, its culture has been shaped by its initial dependence on the executive council of the ICR. This lasted for ~ 60 years and may account for some of its policies, including a hands-off approach to recommendations on medical applications. While it has been attentive to medicine in numerous committee reports, these don't find their way into its recommendations, and therein lies a weakness. Systemic problems in justification and optimisation are not addressed with proportionate recommendations. Likewise, problems with identifying appropriate objectives for shielding in diagnostic imaging, management of exposure of pregnant or potentially pregnant females and other commonly encountered issues might have been more energetically tackled in the recommendations.

A significant shortcoming in the approach to developing radiation protection has been the absence of the social sciences and the humanities. This issue is presently being played out in ethics, but there are many other areas where interaction across these borders would pay rich dividends. The values identified by ICRP, including *dignity/ autonomy; non-maleficence/ beneficence; justice; prudence/ precaution*; and others, especially *solidarity*, are shared with medical ethics and are regularly discussed in the wider professional and academic literature. We must learn to balance and be alert to them when embracing innovation. For example, when considering AI, it is essential to adopt a prudent approach that doesn't under-price risk [103].

Ethically sound medicine leans on more than scientific knowledge. Uncertainty must be treated with respect and include the fact that we do not know how to balance benefit and risk as we seldom have a full knowledge of both. It can be an illusion to think they can be compared in a quantitative way. Outcomes research in medicine is often primitive and not adequate to this task. The one exception is when there are known or probable harms and zero benefit. This corresponds with when an examination is unjustified and such conclusions can safely be reached. However, in more subtle situations the comparison is subject to uncertainties, even in the definition of what should be included, and this underlies much of the heat about screening programmes including mammography.

Today the pressure on science is greater than ever before, and it is expected to deliver evidence in the service of politics, medicine, or the market. In many circumstances, this does not, and possibly never will, transfer smoothly [10]. This dilemma applies to numerous areas including nanotechnology, mobile phones, pharmaceuticals, genetically modified organisms and use of radiation in medicine. Scientific hypotheses are released from the laboratory, without full evidential support, but with political or medical tasks to accomplish. The parallels with Röntgen in 1895, ICRP over the decades since 1928, and Covid-19 today are obvious. All grapple(d) with incomplete uncertain knowledge making a fitful troubled journey toward safe medicine.

Of course, the judgments made here are provisional, and very much *post hoc*. They are the author's and based on the information available at the time of writing. A different person, or a person with new information or different perspectives might reach different conclusions. Hopefully, they will encourage further exploration of the heritage of ICRP as we approach the celebration of its centenary and get to know it even better. One can speculate that Röntgen might be pleased with such an approach.

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