Radiological protection in medicine - current and prospective work of the ICRP

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Abstract

Current and planned activity of ICRP in the field of radiological protection in medicine includes work on recomendations aimed at: optimized reduction of diagnostic X ray doses to patients, reduction of probability of potential exposure in medicine, protection of humans in biomedical research, and updating dosimetric information related to radiopharmaceuticals.

The paper provides backgroung information for selection of these subjects and approximate time scheme for complection of the respective recommendations.

Introduction

The ICRP had been called to life in 1928 in Stockholm, by the Second International Congress of Radiology. This organisation has had always a medical character, even if prominent physicists and engineers played a determining role in the progress of radiological technology, health physics and radiation protection.

After World war II, the scope of ICRP activity has enlarged by including problems related to the protection in the nuclear field. However, special relationships with the International Society of Radiology still exists. This relationships is based not only on tradition. It reflects basic observations that population of medical workers exposed to ionizing radiations is very large and that exposure of the public to man-made radiation is dominated by the component resulting from radiological diagnostic activity. In the developed countries all other components, taken together, are lower at least by an order of magnitude compared with ab. ≈ 1 mSv E per annum from the medical sources [U2].

It would, perhaps, be reasonable at this stage to analyse briefly what exposure of the public to the effective dose of this order could mean in terms of biological effects. For brevity let's consider possible magnitude of the expected extra cancer mortality. If one takes the ICRP nominal cancer mortality coefficient as reflection of reality, then at face value, the number of possible cancer deaths resulting from repeated - year after year - mean population exposure (Poland) to ≈ 0.8 mSv per annum (Table 1) may approach 2 % of the actual cancer mortality rate. In absolute numbers this could be ab. 1500 cases per year in a country of ≈ 38 mln people.

Table I.

Possible cancer mortality rate resulting from exposure of the public to diagnostic X-rays (Poland, Staniszewska, 1986 [S1]).

Annual mean per caput effective dose:	0.8 mSv
Nominal cancer mortality coefficient (ICRP):	$5 \cdot 10^{-2}$ Sv^{-1}
Possible induced cancer mortality rate per year:	$\approx 40 \cdot 10^{-6}$a^{-1}
Actual over-all cancer mortality rate [Z1]:	1800 - 1900 10^{-6}a^{-1}

The view is sometimes expressed that such an estimate could be biased by neglecting following factors:

1. Difference between age distribution of patients and that of general population for which the risk coefficients have been specified. When comparisons were made, however (Staniszewska) [S1], of the above estimate with that, calculated using: 1/ real age and sex distribution of patients undergoing radiologic examinations in Poland; 2/ size of respective age and sex groups; 3/ age- and sex-specific cancer mortality coefficients for radiation-induced tumours proposed by BEIR V [N1], the difference between the latter estimate and the simple over-all assessment did not exceed + 20 % . This factor does not appear, therefore, to essentially modify the order of risk estimate.

2. The fact that a fraction of radiological examinations is performed in terminally ill patients in whom the risk cannot be expressed [R1]. There are very few credible estimates of the size of this fraction. In some parts of the U.K. the value did not exceed 5 % [R1] and there is no real indication that X-ray doses in the terminally ill are substantially higher than those in the rest of the population.

Therefore, total correction of the primary overall risk estimate appears negligible. Of course, an avoidable fraction of the collective dose (and therefore of the risk) is substantially lower. For instance, detailed considerations and estimates in the U.K. [N2] led the authors to conclude that the fraction amounts to ab. ≈ 45 % of the total collective dose from medical sources (7500 out of 17000 manSv per year). In those countries in which the contribution from medical sources to the collective man made dose is higher than in the U.K. (≈ 0.4 $mSva^{-1}$) the avoidable fraction could also be greater.

In any case, the estimated order of extra risk due to diagnostic medical irradiation, even if on all accounts the health benefits by far exceed the concomitant risks justifies, in opinion of the Commission, radical efforts to reduce unnecessary exposure. This is especially true because this can be done without any sacrifice of the diagnostic benefit (image quality).

With respect to this basic opinion there is no essential difference between Publication 60 [I2] and Publ. 26 [I1] (Recommendations of 1977). However, Publ.26 directed the postulate primarily to medical practitioners (mostly radiologists and nuclear medicine physicians). Accordingly, the series of following recommendations (ICRP, Publ.34, 44, 52, 53, 57) [I3 - I7]) had been addressed mainly - if not exclusively - to physicians of these professions, to hospital managements and health physicists.

The Commission took a somewhat different view in Publ. 60 [I2] (para 180). The text reads: ....." As a result, there is considerable scope for dose reductions in diagnostic radiology. Simple, low cost, measures are available for reducing doses without loss of diagnostic information, but the extent to which these measures are used varies widely. Doses from similar investigations cover ranges of as much as two orders of magnitude. Consideration should be given to the use of dose constraints, or investigation levels, selected by the appropriate professional or regulatory agency, for application in some common diagnostic procedures. They should be applied with flexibility to allow higher doses where indicated by sound clinical judgement."

This change in approach results from the conviction that appeals addressed to individual radiologists had not been sufficiently effective (at least on a large scale). This has been borne out by a fundamental, regular observation that frequency distribution of doses (entrance skin kerma or exposure) for a given diagnostic procedure, within a country or region, displayed a typical shape, exemplified in fig. 1 [U1]. When such distributions had been corrected [L1] for variation in patients body size, a variation in dose was less pronounced but that which persisted spanned still an order of magnitude.

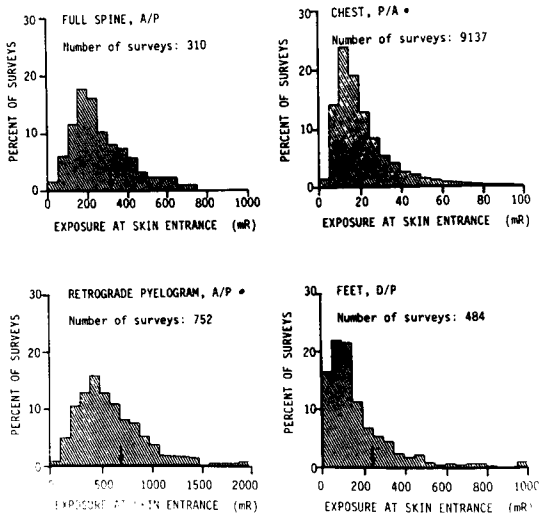

Fig.1. Frequency distribution of exposure at skin entrance for selected examinations in the USA (mR); arrow refers to mean exposure value (from [U1]).

This has been a regular finding in numerous surveys and, of course, such wide distributions cannot be accepted as justified, and much more so, as being consistent with requirement of the optimisation of protection. If optimal value of the dose lies somewhere in the shaded brackets (fig.2), the values above may be taken as excessive, and below as most likely insufficient for obtaining a good image. In other words, current situation results from a common lack of a functioning protection system, securing the feedback: magnitude of the dose → correcting action.

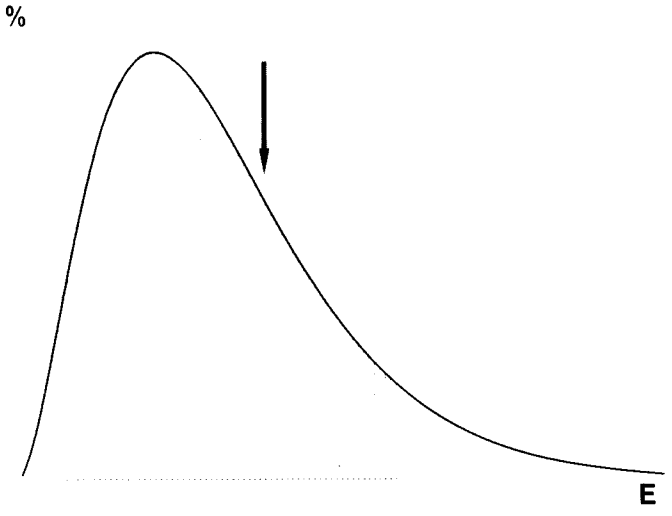

Fig.2. Idealised distribution of effective dose per examination
--- Upper constraint - 75 percentile (?)
... Lower constraint - a dose too low for a satisfactory image.
Arrow - mean dose.

Therefore, the Commission believes that constraints, or investigation levels, applied to diagnostic procedures have become necessary.

A. Task Group on Optimisation of Protection in Diagnostic Radiology

To look carefully into the subject and the experience gained so far in some countries and communities (USA, countries of the EEC) the Commission has made a decision to call into life in a short time, perhaps in 1992, a Main Commission - Task Group on "Image, Dose and Optimisation in Medical Radiology".

This group will collaborate closely with Committee 3.
The principle objectives of this action would be:

1. To collect and analyse the experience obtained so far in those countries where such action has been already started on a wide scale, assessing and assuring image quality, combined with dose assessment in selected radiological procedures.

2. To work out and recommend measurement - and analytical procedures for dose-frequency distribution studies and to postulate criteria upon which ranges for exposure could be defined that may be accepted as justified at the current state of practice. (Below and above these some intervention would be warranted).

3. To compare the current state of practice with the available state of radiological art and technique. The latter should reflect nominal (reference) levels of dose that could be taken as representing at present the optimum range. Reaching an optimised level (consistent with the attainable current radiological technology), should be final objective of the exercise.

4. To reach this goal expenditures, sometimes quite high, are of course necessary. On the other hand, several simple modifications of the technique (both material and procedural) are possible which require basically very little or no capital input (stricter referral criteria, minimisation of a number of radiograms per examination, selection of appropriate projection, minimisation of fluoroscopy time, due collimation of the beam, shielding of organs, selection of optimal film/screen combination, optimal processing of the film etc, etc) [N2, I3]. With limited resources for health care in most countries it appears essential to optimise protection of the patient, to specify priorities for action and to obtain the best financial input-dose-reduction ratio. The Task Group shall carefully study both available methodology (generic and formalized optimisation) and will, hopefully, recommend adequate procedures for respective long-term action by professional societies, authorities (policy makers), hospital administrators and chiefs of radiology departments.

At this stage some remarks are warranted regarding selection of a nominal cost of a unit of collective dose for purposes of the optimisation of protection in the medical field. First, the cost of saving human life in various fields of medicine [N2] is lower than the up to now assumed cost of one manSv in other fields of radiation protection ($\approx 2 \times 10^4$ dollars). Therefore, selecting the latter, or even a higher value would, perhaps unduly, shift in most countries the resources in health protection into the less effective direction. Moreover, from the total cost of detriment per unit dose in medicine one should perhaps subtract the value of benefits accrued by the patients themselves(improved diagnosis, therefore more adequate and sometimes cheaper treatment, etc, etc). These questions, and some others, e.g. is it realistic to recommend an α value independent of expenditures for health protection per year per caput in a country, should be addressed by the Task Group.

5. The Task Group, Committee 3 and the Main Commission shall analyse and decide to what extent the question of referral criteria and the connected efficacy of individual radiological procedures shall be dealt with. In my opinion it is a difficult subject. There is, however, an obvious room for reduction of the frequency of practices and procedures of very low efficacy, provided the recommendations will avoid schematic treatment of the subject.

Elimination of a large fraction of retakes is also feasible.

6. There are specific aspects of patients protection in paediatrics, cardiology, interventional radiology, mass screening and dental radiology. In the prospective Task Groups' recommendations they should be treated in form of annexes and addressed to professionals directly concerned and active in these fields.

I believe that the task, just presented, is strategically the most basic and important among those related to the protection in medicine, being undertaken currently by Committee 3 and the Main Commission.

If implementation of prospective recommendations would result in substantial reduction of the total collective dose and within this of the avoidable fraction from medical sources by a factor ≈ 3 or 4 (this seems quite feasible), the merit shall justify the efforts.

B. The project "Potential Exposures in Medicine".

Potential exposure has been defined in Publ. 60 as (para 127): "Not all exposures occur as forecast. There may be accidental departures from the planned operating procedures, or equipment may fail..... ....Such events can be foreseen and their probability of occurrence estimated, but they cannot be predicted in detail."

There is obviously a room for such exposures (patients, personnel) in medicine. There are well known, dramatic examples of this kind (related mostly to therapy): therapeutical accelerator accidents in Texas, U.S. (1986) and Zaragoza, Spain (1990), a series of accidents with ^{60}Co therapy units; misadministrations of therapeutic instead of diagnostic activities in nuclear medicine, etc.

Exhaustive statistics of such incidents or accidents, involving patients and sometimes also medical personnel, are not widely available. The respective working group of Committee 3 (to become most likely a task group), will collect available data on overexposures and mis-administrations (doses in therapy, radiopharmaceuticals), on dominant sources of the failures, and will try to develop recommendations aiming at reduction of the probability of their occurrence to the lowest reasonably attainable (i.e. optimised) level. The recommendations should have both technical and systemic character. The work has just started and will continue for few years.

C. Protection of humans in biomedical research.

The subject has been treated in the past both by the Commission and by other organisations (e.g. World Health Organisation)[W1]. General principles of the Helsinki accord on the subject - as amended in Tokyo in 1975 - [W2], form still an acceptable backbone of the system. Situation is relatively straight-forward in those fields where exposure to various noxae, is reflected by a threshold type dose-response relationship. Ionizing radiation is exceptional in this context as the probability of detrimental stochastic effects decreases with reduction of the dose but is not expected to reach zero level unless the dose does the same.

Assessment of the detriment vs. dose has increased in Publ. 60 by a factor 3-4 relative to that which served as basis for previous WHO documents, pronounced age effects have been documented, and new effects on human conceptus discovered. Ethical committees and other interested bodies are in obvious need for guidance in this field. Committee 3 will prepare a new document providing respective recommendations related to the diagnostic application of X rays and radiopharmaceuticals, to experimental procedures in radiotherapy and biological research, with and without actual or potential medical benefit to the participants. The Committee hopes to be able to issue the document not later than 1993, possibly still in 1992.

D. Updating dosimetric information related to radiopharmaceuticals.

A common Task Group of Committee 3 and Committee 2 works on updating information on doses incurred from radiopharmaceuticals. The subject has received extensive treatment in Publ.53 - "Doses from Radiopharmaceuticals", published in 1987 [I6]. There are, however, one or two new substances of this

kind being introduced into medical practice every year, and substantial proportion of them is going to stay with us for long time. For instance, since adoption of Publ.53 three new substances, utilizing ^{99m}Tc as the radioactive label, have been introduced into a wide use:

1/ ^{99m}Tc-MAG_3 (mercaptoacetyltriglycine) for renal functional diagnostics, and ^{99m}Tc-HmPAO (CERETEC, heksamethylopropylenoamineoxine) mainly for studies of the regional cerebral blood flow; 2/ ^{99m}Tc-hexakis MIBI (2-metoxyisobuthyl isonitrile) for heart perfusion studies. The latter two are administered at particularly high activities of ^{99m}Tc (500-1000 MBq) and the resulting doses need to be known. There are also other substances, like labelled fatty acids, ^{68}Ga-EDTA, labelled antibodies etc, of sufficient clinical interest to be treated similarly.

For several of these substances respective kinetic (and/or metabolic) models have been developed and organ doses calculated by the Task Group (they will be published in late 1992 or early 1993). In addition, values of E for those radiopharmaceuticals that had been included in Publ.53 will be included in the updating document, recalculated according to the currently recommended procedure, and with organ weighting factors, specified in Publ. 60. Some kinetic models will also be reviewed acc. to the fresh data (e.g. ^{201}Tl). It is perhaps interesting to note that new E values are generally lower than the old H_e, except for those radiopharmaceuticals that irradiate predominantly the thyroid gland [J10] (fig. 3); the latter E values have increased mostly due to the respective change of W_T. For radiopharmaceuticals included in Publ.53 the average value of E per unit administered activity is numerically lower by ≈12 % than the mean H_e. We hope this information will be useful for the professional community of nuclear medicine in their daily practice, and for optimisation of patients protection (selection of substances, selection of optimal administered activity).

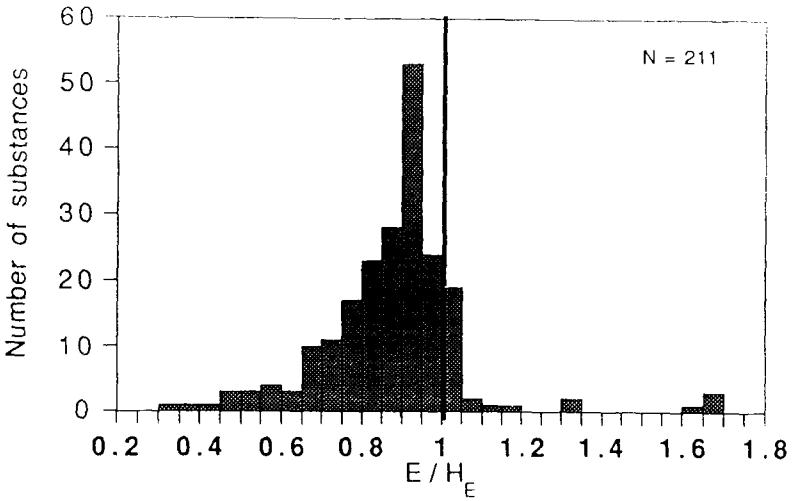

Fig.3. Distribution of the quotient effective dose (E): effective dose equivalent (H_e) using the new (ICRP 60) and old (ICRP 26) weighting factors, respectively. All substances found in ICRP 53 are included [J1].

I believe I have given you a rather detailed picture of Main Commissions' and Committee 3 activity aimed at radiological protection in medicine.

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