

This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the World Health Organization

Use of ionizing radiation and radionuclides on human beings for medical research, training, and nonmedical purposes

Report of a WHO Expert Committee

World Health Organization
Technical Report Series
611



World Health Organization Geneva 1977

ISBN 92 4 120611 4

© World Health Organization 1977

Publications of the World Health Organization enjoy copyright protection in accordance with the provisions of Protocol 2 of the Universal Copyright Convention. For rights of reproduction or translation of WHO publications, in part or *in toto*, application should be made to the Office of Publications, World Health Organization, Geneva, Switzerland. The World Health Organization welcomes such applications.

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the Secretariat of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

PRINTED IN SWITZERLAND

WORLD HEALTH ORGANIZATION
TECHNICAL REPORT SERIES

No. 611

USE OF IONIZING RADIATION
AND RADIONUCLIDES ON HUMAN BEINGS
FOR MEDICAL RESEARCH, TRAINING
AND NONMEDICAL PURPOSES

Report of a WHO Expert Committee

CORRIGENDUM

Page 36, Annexe 5

Delete Table 1.

Insert revised Table 1 as follows :

Table 1
X-ray investigations

Type of examination	Skin dose (mGy)	Organ	Mean dose equivalent (rem) ^a	Category
Chest ^a	1.4	Lung	< 0.14	I
		Whole body	≤ 0.05	
Chest ^b	2.8	Whole body	~ 0.05	II
Bone in limb	4	Total bone	≤ 1.7	I
Abdomen	12	Gonads	< 0.22	I
Pelvis	33	Gonads	~ 0.3	II
Whole skeleton	25	Bone marrow	~ 1.1	III
		Whole body	~ 0.5	
Mammography	150	Breast (mean)	~ 5.0	III
Prolonged cardiac catheterization	2000 ^c	Lung (mean)	~ 40	Other

^a Using normal low-dose techniques.

^b Using high-dose techniques without collimation.

^c Mean skin dose given in reference 15 as 47 rad ; occasional cases will exceed the mean dose by a factor of 4.

^d To obtain values in mSv multiply the dose-equivalent figures by 10.

CONTENTS

	Page
1. Introduction	7
1.1 Ionizing radiation : benefits and risks	7
1.2 Sources of radiation	8
1.3 Scope of the report	8
1.4 Previous work	8
2. Biological effects of ionizing radiation and related risks	9
2.1 Damage from energy deposition	9
2.2 The dose equivalent	9
2.3 Somatic effects	10
2.4 Genetic effects	11
3. Ethical aspects	11
3.1 A statement of principles	11
3.2 Ethical considerations in medical research	11
3.3 Medical teaching and the demonstration of radiological procedures	14
3.4 Irradiation for nonmedical purposes	14
4. Methods for the surveillance of the irradiation of human subjects	15
4.1 Methods available	15
4.2 Recommended methods	16
5. The use of ionizing radiation in medical research	16
5.1 Introduction	16
5.2 Types of research	17
5.3 Types of irradiation	18
5.4 Procedure in medical research	18
5.5 Categories of research project involving irradiation of human beings	20
5.6 Radiation limitation	22
5.7 Repeated irradiation of the same subject	22
6. The use of ionizing radiation in education and training	22
7. Irradiation for nonclinical purposes	23
7.1 Introduction	23
7.2 Specific ethical considerations	23
7.3 Examples of such irradiation	23
7.4 Conclusions	28
8. Recommendations	28

	Page
References	29
Annex 1. Radiation quantities and units	31
Annex 2. Estimates of radiation risks	33
Annex 3. Some types of research involving irradiation of human subjects . .	34
Annex 4. Categories of research project involving irradiation of human beings	35
Annex 5. Selected clinical tests by project category	36
Annex 6. Statement by ICRP on security screening of airline passengers . .	39

**WHO EXPERT COMMITTEE ON THE USE OF IONIZING RADIATION
AND RADIONUCLIDES ON HUMAN BEINGS
FOR MEDICAL RESEARCH, TRAINING, AND NONMEDICAL PURPOSES**

Geneva, 1-8 March 1977

*Members : **

- Dr B. Kwaku Adadevoh, Director of Medical Research, Medical Research Council of Nigeria, Yaba, Nigeria (*Rapporteur*)
Dr A. R. Gopal-Ayengar, Institute for Biophysics, Technical University of Hanover, Hanover, Federal Republic of Germany
Dr Y. N. Kasatkin, Central Institute for Education of Postgraduate Physicians, Moscow, USSR
Dr M. M. Mahfouz, Professor of Radiotherapy and Nuclear Medicine, Cairo, Egypt (*Vice-Chairman*)
Professor P. Pellerin, Director, Central Service of Protection against Ionizing Radiations, Le Vesinet, France
Sir Edward Pochin, Curridge, Berkshire, England (*Chairman*)
Dr K. E. Scheer, Institute for Nuclear Medicine, Heidelberg, Federal Republic of Germany

*Representatives of other organizations : ***

International Labour Organisation :

- Dr N. Gavrilesco, Occupational Safety and Health Branch, ILO, Geneva, Switzerland

International Atomic Energy Agency :

- Professor K. E. Scheer, IAEA, Vienna, Austria

Council for International Organizations of Medical Sciences :

- Dr Z. Bankowski, Executive Secretary, CIOMS, Geneva, Switzerland
Mrs K. Carballo, Assistant, CIOMS, Geneva, Switzerland

International Radiation Protection Association and the International Society of Radiology :

- Dr G. Poretti, Section of Medical Physics, Department of Radiotherapy, University Hospital, Berne, Switzerland

* Unable to attend: Professor C. Chagas, Biophysical Institute, Federal University, Rio de Janeiro, Brazil; Dr S. Takahashi, Hamamatsu University School of Medicine, Hamamatsu, Japan.

** Unable to send representatives: International Commission on Radiological Protection; United Nations Scientific Committee on the Effects of Atomic Radiation.

Secretariat :

Mr S. Fluss, Senior Editor, Health Legislation, WHO, Geneva, Switzerland

Dr G. Meilland, Medical Officer, Cooperative Programmes for Development,
WHO, Geneva, Switzerland

Dr S. B. Osborn, Director, Department of Medical Physics, King's College
Hospital, London, England (*Consultant*)

Dr W. Seelentag, Chief Medical Officer, Radiation Medicine, WHO, Geneva,
Switzerland (*Secretary*)

USE OF IONIZING RADIATION AND RADIONUCLIDES ON HUMAN BEINGS FOR MEDICAL RESEARCH, TRAINING, AND NONMEDICAL PURPOSES

Report of a WHO Expert Committee

A WHO Expert Committee on the Use of Ionizing Radiation and Radionuclides on Human Beings for Medical Research, Training, and Nonmedical Purposes met in Geneva from 1 to 8 March 1977. Dr L. Bernard, Assistant Director-General, opened the meeting and welcomed the participants on behalf of the Director-General. The task of the Expert Committee was to consider all deliberate irradiation of human beings, particularly in the course of medical research, to evaluate the health risks involved, and to recommend measures for keeping such irradiation under proper control, taking into account the ethical principles laid down by the World Medical Assembly in Helsinki in 1964 and amended in Tokyo in 1975.

The report that follows does not attempt to prescribe exactly which decisions should be taken in specific cases nor what kind of legislation may be desirable to ensure appropriate control over the deliberate irradiation of human beings. It is intended rather to provide some ideas and guidelines that will be helpful for decision-makers, who in any case will have to take into account local conditions and the structure of legislation in the country concerned. Some of the recommendations may not be applicable in all countries; others may not need to be applied.

1. INTRODUCTION

1.1 Ionizing radiation : benefits and risks

Great benefits to human health have resulted from the use of radiological procedures in medical diagnosis and treatment and more recently in nuclear medicine. Valuable contributions have also been made by types of medical research involving the exposure of human beings to radiation in the course of similar procedures, and it is considered to be of the greatest importance that such research should continue.

At the same time, however, it must be recognized that exposure to large doses of radiation is harmful, and that even exposure to the small doses usually involved in medical diagnosis and research may carry a correspondingly small risk of harmful effects.

1.2 Sources of radiation

All human beings are inevitably and continuously exposed to ionizing radiation from a variety of natural sources : the radioactivity of rocks and of the soil, cosmic radiation reaching the body from space, and naturally radioactive nuclides which become incorporated in the body. To the natural level of ionizing radiation, exposure from man-made sources has now been added. Such sources form an integral part of processes associated with industrial development, which in itself enables considerable contributions to be made to the improvement of human health. However, in order to prevent avoidable harm to human beings any exposure of human subjects to ionizing radiation should be kept as low as practicable.

1.3 Scope of the report

This report deals only with the relatively small proportion of radiation to which people are exposed in the course of medical research, in medical teaching, and in various procedures not directly related to their health needs. It does not deal with deliberate applications of radiation for purposes of diagnosis or treatment (" clinical " exposure), or with occupational exposure to radiation or any other type of exposure occurring incidentally in the use of radiation sources but not planned deliberately. These categories of exposure have been dealt with in detail in a number of reports to which reference should be made—e.g., on clinical exposure (10, 11, 15, 22), on occupational exposure (2, 4, 7, 12, 14, 15), on environmental and incidental exposures (15, 19), and on public health aspects (20, 21).

1.4 Previous work

A consultation was held by WHO and IAEA in November 1972 on the use of ionizing radiation on human beings for medical research and training, including the use of radioactive materials. The report of this consultation (unpublished) was sent to a number of different experts for comment. The report and the comments have been taken into account in preparing the present report. The Committee has, however, also

included a review of matters that were not dealt with by the 1972 consultation, so as to cover the whole subject of the deliberate exposure of human beings apart from diagnostic and therapeutic procedures. Until now, few international or national recommendations have been made in regard to such exposure. Its increasing occurrence, particularly in pharmaceutical investigations with radioactively labelled drugs and in the evaluation of new radiological methods, makes it essential to have internationally accepted guidelines on the subject.

In this report, references to medical uses of radiation are intended to cover dental uses also, where appropriate.

2. BIOLOGICAL EFFECTS OF IONIZING RADIATION AND RELATED RISKS

2.1 Damage from energy deposition

The biological effects of ionizing radiation depend essentially upon the energy deposited in body tissues by the ionizing action of such radiation and the changes in biologically important molecular structures that may be caused when this energy is delivered to them. Such damage may be induced whether the radiation reaches the body tissues from sources outside the body or from radioactive materials that have become incorporated within the tissues themselves.

Thus, in the case of radiological procedures, the tissues are subjected to "external radiation" from diagnostic X-rays and in most forms of radiotherapy, but to "internal radiation" following the diagnostic or therapeutic administration of radionuclides in nuclear medicine.

2.2 The dose equivalent

Under most circumstances, the frequency with which harmful effects will result from a given exposure depends upon the amount of energy imparted to the tissues by radiation regardless of whether it comes from external or internal sources, and regardless of the type of source or of radioactive material from which it is derived. For this reason, risks of radiation exposure can be expressed in terms of the frequency of harmful effects per unit of energy deposition in the tissues. Traditionally, different levels of "dose equivalent" of radiation have been expressed in rem (see Annex 1). The rem is a unit that not only depends upon the amount of energy from ionization deposited in the tissues but also reflects the rather greater frequency of harmful effects (in some cases greater by a factor

of 10) resulting from exposure to certain types of radiation (e.g., from neutrons).

In 1975 the Conférence générale des Poids et Mesures (CGPM) adopted, at the request of the International Commission on Radiation Units and Measurements (ICRU), the gray (Gy) as a special name for the joule per kilogram for the measurement of absorbed dose. The gray is therefore an SI unit and is used for absorbed dose in this report, although equivalent values in rads are also given within parentheses. ICRU made no request regarding a unit for the measurement of dose equivalent. Recently, however, it has been proposed that the sievert (Sv) be used as a special name for the joule per kilogram for this purpose. Since the sievert has not been approved by CGPM, it is not an SI unit and does not have the same status as the gray. For this reason the rem is used for dose equivalent in this report, although equivalent values in sieverts are given within parentheses in the text.

In general, the frequency of harm from a given dose equivalent depends on the tissues irradiated and other factors, but not on the source of radiation involved.

The harmful effects of radiation may manifest themselves either in the individual exposed or in his or her descendants as a result of changes induced in the germ cells at the time of exposure. There is extensive literature on the subject (e.g., 1, 5, 6, 8, 16).

2.3 Somatic effects

In the individual, two types of effect are recognized. First, there are the so-called "stochastic" effects, whose frequency depends upon the level of radiation exposure, but whose severity does not. These include the induction of malignant changes that may follow the exposure of certain body tissues, but are typically not detectable until many years after exposure. The other type—"non-stochastic" effects—occurs only after high exposures, and their severity then depends on the dose equivalent received in tissues sensitive to them. Such effects are in general unlikely to occur at the levels of exposure considered in this report (see Annex 2).

Special problems arise, however, in connexion with exposures of the embryo or fetus during pregnancy, since, for example, effects may occur at relatively low levels of exposure early in pregnancy, when damage to a single cell or group of cells may prevent either the normal implantation of the conceptus in the uterine wall or the development

of a part of the body during stages of organogenesis. For this reason, radiation exposure during pregnancy demands special precautions.

2.4 Genetic effects

Radiation may also cause damage to the germ cells, leading to abnormalities in children conceived after the irradiation or in members of later generations whose inherited characteristics are derived from the germ cells originally damaged. It follows that inherited abnormalities of this type contribute to the total harm caused by radiation exposure, though to a rapidly decreasing extent in respect of exposures of persons aged 40 and over (particularly females) as the rate of child expectancy declines.

Estimates are available of the frequency with which serious somatic and genetic effects are likely to follow relatively high exposures to radiation; and inferences can be made of the probable frequency, or the maximum likely frequency, with which such effects may follow the much lower exposures with which this report is mainly concerned (see Annex 2). The different categories are suggested below (see section 5.5) in the light of the degrees of risk that might result from exposure at the dose equivalents specified.

3. ETHICAL ASPECTS

3.1 A statement of principles

General ethical principles for research involving human subjects were stated by the Eighteenth World Medical Assembly in Helsinki in 1964 (Helsinki Declaration) and revised by the Twenty-Ninth World Medical Assembly in Tokyo in 1975.¹ While these internationally accepted principles were formulated for biomedical research on human subjects, the Committee considers some of them to be applicable over a wider field of radiation use.

3.2 Ethical considerations in medical research

3.2.1 The principles

Medical progress demands that in research the "benefit of the patient" should not be interpreted in a narrow sense, since this could

¹ The full revised text of the declaration was reproduced in: *WHO Chronicle*, 30: 360-362 (1976).

hamper progress and deprive future patients of benefits. When a research project is of direct diagnostic or therapeutic relevance to the individual patient, the ethical problems involved tend to be simple ones. When, however, a research project is intended to extend medical and scientific knowledge in general, without specific benefit to the subject, the situation is different and the principles of medical ethics need to be applied in a broad sense, in relation to the benefit expected to accrue in the future to patients or human beings in general. A recent WHO report contains a particularly helpful analysis of the matter (3). The International Covenant on Civil and Political Rights (13) includes the provision that "no-one shall be subjected without his consent to medical or scientific experimentation".

It is important for medical progress that research workers should have considerable freedom in selecting and carrying out their projects. When research involves human subjects, however, the project must be planned so as to gain the maximum medical and scientific knowledge compatible with the minimum inconvenience and risk to the subject.

3.2.2 The responsibility of the investigator

After laying down relevant criteria, the investigator is responsible for selecting the particular patients or volunteers who are to take part in the project. When a patient receiving medical care is involved and it is at any time clear that his interests would be best served if he were withdrawn from the project in order, for example, to undergo a particular form of treatment, the investigator is unquestionably under the obligation to see that this is done. The investigator is responsible for using the most suitable and effective methods and equipment, and for ensuring that all those associated with the project are adequately trained and experienced in the methods used, including the application of ionizing radiation where relevant. He is also responsible for seeing that each subject involved fully understands enough of the project to enable him to give free consent and that he is exposed to the minimum risk and inconvenience.

3.2.3 The status of the subject

It is generally accepted that an individual should not be the subject in an experimental investigation without his knowledge and consent. The details should be explained to him in advance in such a way and to such an extent that he can give his free consent. He has the right to

accept the risk voluntarily, and he has also the right to refuse to accept. By free consent is meant genuine consent, freely given, with a proper understanding of the nature and consequence of what is proposed, obtained from adults who are of sound mind. This makes it difficult to carry out any experiments on children or those who are mentally ill or defective, as they cannot give free consent in this sense, and it is doubtful to what extent it can be given by others on their behalf. When such experiments are likely to benefit children or mental defectives in the future and the risks are sufficiently small, those responsible for such individuals might be able to agree to their participation. However, in some countries legal considerations may dominate the situation.

A difficult situation arises when the subject is in a position of obligation towards the investigators, e.g., in the case of a patient and his physician, or a student and his teacher. A somewhat similar situation occurs when the subject expects to obtain some benefit, e.g., promotion for a soldier or special privileges for a prisoner. It is particularly important in such circumstances that consent should not be influenced unduly and should be given as freely as possible. Whether the consent is oral or written matters less than that it is given freely in full foreknowledge of the relevant circumstances.

The Committee is aware that monetary payment is sometimes made to research subjects and considers this acceptable if it consists of compensation for out-of-pocket expenses such as fares, or for inconvenience suffered, rather than for the supposed radiation risks involved, which should not be on a scale or of a nature to require compensation.

3.2.4 *The ethical committee*

Research projects involving human subjects should normally be reviewed by a committee from the ethical standpoint before they are undertaken. This is, however, not the situation in most countries. The Committee understands that the Council for International Organizations of Medical Sciences (CIOMS) is undertaking a full study of this question. The Committee recommends reviews by ethical committees as a means of ensuring the proper surveillance of research, including projects involving the irradiation of human beings.

Ethical committees can be formed at the local, regional, or national level, depending on the specific conditions prevailing in a region or country. They should be composed of persons not engaged in the research project under question and should be independent of the investigators. It is suggested that they should include people to whom the investigators are known and also people able to assess the medical

and nonmedical aspects of the project. These committees should have the duty of reviewing each project as a whole and should be able to advise research teams on the best ways of fulfilling their ethical responsibilities. They should be able to review projects that are in course of implementation if the ethical considerations change. If the members of an ethical committee lack the technical expertise necessary to assess a proposed project properly, an appropriate expert should be asked to advise it.

3.3 Medical teaching and the demonstration of radiological procedures

In teaching, radiological procedures or results will normally be demonstrated on patients irradiated for clinical reasons. When this is done, no specific ethical problems arise, as any radiological risk incurred is to be set against the medical benefits obtained. On the other hand, when additional films are taken, or prolonged fluoroscopy is undertaken for teaching purposes, it is future doctors and patients who will benefit, and such additional irradiation should clearly be reduced to the minimum. Whatever the dose level involved, it is quite impracticable for permission to be sought for the irradiation of specific patients if only because teachers must be able to decide rapidly which patients are appropriate for teaching purposes. It would be more practicable to seek general permission for a particular type of teaching using subjects within defined groups, and the Committee recommends a system of "review by peers" (see section 4.1.3) for the purpose.

3.4 Irradiation for nonmedical purposes

Where irradiation is unrelated to health and there are no medical benefits, there may nevertheless be other benefits—for example, economic ones. In the opinion of the Committee a radiation risk may be set against the economic benefit for the same individual only if other methods of achieving the same result with a lower risk are unavailable, and if any radiation used is restricted to the minimum practicable. At present, somebody refusing radiography in, for instance, applying for an insurance policy may be refused cover or accepted only at an increased premium. In the view of the Committee this is an excessive penalty to pay; whenever possible, alternative methods of examination should be available and the individual concerned be given an opportunity to choose. This matter is considered further in section 7.3.7.

4. METHODS FOR THE SURVEILLANCE OF THE IRRADIATION OF HUMAN SUBJECTS

4.1 Methods available

4.1.1 *The definition of radiation limits*

Limits can be set which must not be exceeded for any one application. Such limits may depend on the type and purpose of the irradiation, the radiosensitivity of the tissues irradiated, and possibly the number of people involved in the particular application. They can be issued as professional recommendations, as codes of practice, or as state regulations having the force of law. This mode of control could, in its most extreme form, constitute a total prohibition of particular uses of radiation.

4.1.2 *Licensing of persons responsible for particular practices*

Legislation may specify that radiation may only be used for a particular purpose under licence. The efficacy of this method depends on the knowledge and responsibility of the licensee, and it will be appropriate for some applications. It will not necessarily, however, exclude occasional misuse of the licence.

4.1.3 *Review by peers*

In some situations it is possible to set up a review system whereby the person responsible for a project has to justify it convincingly to a group of his colleagues. This is known as "review by peers".

4.1.4 *Project review*

The Helsinki Declaration, as amended in Tokyo in 1975, recommends that the review of each project for medical research involving human beings should be mandatory, and it is clearly appropriate that the relevant ethical committee should take the radiation aspect into account in arriving at its decisions.

4.1.5 *No formal restrictions*

For some applications of radiation to human beings, e.g., in clinical radiology, decisions regarding the necessary amount of radiation exposure may have to be taken in the light of the individual circumstances of each patient, and formalized control limits are likely to be inappropriate. Reliance must be placed on the education and training of those responsible. This can be achieved by laying down specific criteria for

such education and training, or by issuing guidelines or codes of practice to guide doctors on ways of reducing radiation exposure without reducing the quality of medical care (9, 10).

4.2 Recommended methods

4.2.1 For medical research

In the case of medical research, the Committee recommends surveillance based on a review by an ethical committee (see section 3.2.4). In the case of a proposal for research that would entail the exposure of human subjects to radiation, relatively complex questions of tissue dosimetry and risk evaluation may be involved ; these may be relevant to the potential level of risk and thus to the ethical implications. It should be the responsibility of the investigator to prepare a document for the ethical committee setting out the protocol for the project in some detail, including estimates of the radiation doses expected to be delivered to particular parts of the body. It may be found valuable to establish national or regional committees dealing with radiation dosimetry and radiation effects to offer advice to local ethical committees when necessary or to act in a more regulatory capacity, approving research proposals according to the category of whole-body or organ exposure involved.

4.2.2 For medical teaching

The Committee recommends that the various suggestions in section 6 be brought to the attention of all teachers concerned. In addition, a system of review by peers should be used in the case of proposals relating to the types and number of patients to whom additional irradiation could be administered for teaching purposes.

4.2.3 For irradiation for nonmedical purposes

In view of the variety of applications coming under this heading, the reader is referred to section 7 (page 23). However, since that section is not comprehensive, there are bound to be other instances of irradiation of a similar kind, and it is hoped that the report provides sufficient general guidance on the principles to be applied in dealing with them.

5. THE USE OF IONIZING RADIATION IN MEDICAL RESEARCH

5.1 Introduction

In general, it is accepted that the advantages of the medical uses of ionizing radiation greatly outweigh the risks. It is recognized that

irradiation in medical research can present certain calculable risks to mankind and his environment, but when it is used at the lowest readily achievable levels, it carries a smaller risk to the health of man than many chemicals, pharmaceuticals, and other agents in common use.

While appreciable radiation exposure may be unavoidable in some forms of medical research, the total exposure of people to radiation for research purposes is certain to be considerably smaller than that from the regular use of radiological procedures in the diagnosis and therapy of disease.

5.2 Types of research

5.2.1 Research involving radiopharmaceuticals

This may involve the use of radioactively labelled drugs to evaluate their modes of action, metabolic pathways, etc., or a radioactive material may have to be used separately from the drug in order to measure its effect. Radiography of the patient may be necessary to assess the action of the drug, particularly where drugs affecting bone metabolism are concerned.

5.2.2 Research into and development of new diagnostic applications of ionizing radiation

Much of this work will be incidental to the irradiation of patients in the course of their diagnosis and treatment, but it will sometimes be necessary to evaluate normal subjects as well. The establishment, in any geographical area, of medical and biological reference values based on an adequate selection of known normal subjects provides standards against which abnormalities can be judged. In circumstances where there are difficulties in using such subjects, the relevant reference values may sometimes be deduced provisionally from the results of routine clinical examinations of subjects for suspected disease, which they are subsequently shown not to have ; this method, however, is often of doubtful validity.

5.2.3 Other research involving the deliberate irradiation of human beings

This heading covers studies in physiology, pathology, and anthropology, including nutritional studies using radioactive labels to investigate, for instance, iron absorption and the fate of food additives swallowed or pesticides inhaled or swallowed ; it also covers research into diseases

of epidemiological importance (such as tuberculosis) in which radiation is used (see also section 7.3.3). It does not cover research on the incidental ingestion or inhalation by humans of labelled compounds used for purposes other than medical research, e.g., studies on the distribution of water supplies or on the movement of dust clouds in different meteorological conditions.

5.3 Types of irradiation

It must be stated again that the types of research considered involve both external and internal irradiation. In some countries, checks have been organized to ensure that medical research involving radioactive materials is conducted with due attention to the possible risks involved. As far as is known, few countries have established similar checks on the use of external diagnostic X-radiation in medical research. In some countries, therefore, control is exercised over the very small doses that frequently result from radioisotope research, but not over doses resulting from the use of diagnostic X-rays in research, which could in some cases be several orders of magnitude greater. Mention must be made of the fact that, in some countries, patients are subjected to diagnostic X-ray procedures without the surveillance of a radiologist. For example, research may be conducted on the basis of radiographs taken by dentists, by cardiologists, by chest physicians, or by orthopaedic surgeons, in their respective clinics. Radiotherapeutic research, especially with accelerated particles, has been of importance in recent times, and valuable data may be obtained from a study of radiotherapeutic results. In addition, *in vivo* neutron activation analysis can be valuable in clinical medicine as it offers a direct method for measuring the total content of specific elements such as sodium, calcium, nitrogen, phosphorus, chlorine, etc. in the whole body or in particular organs. A selected list of medical research projects involving the irradiation of people is given in Annex 3.

5.4 Procedure in medical research

It is desirable first to carry out such experimental tests as are appropriate, including *in vitro* and animal tests, before embarking on human experiments.

5.4.1 Number of individuals involved

Although it is desirable that the number of human beings exposed to radiation for medical research purposes should be kept under constant review, it is difficult to arrive at an annual estimate. Only a small per-

centage of the population that enters hospitals each year receives radiation in the course of medical research. As the number of outpatients irradiated in the process of medical research will presumably be much smaller, it follows that the annual figure for the proportion of the population participating in medical research involving the use of radiation is very small indeed.

5.4.2 *Proposed guidelines*

(a) *Research projects involving radiation*

In the recommended guidelines, the different projects involving the irradiation of subjects are classified according to the amount of radiation administered to the subject in each project. Here, a project means a scheme of research that is intended to achieve a particular purpose and, in order to do so, commits the subject to receiving a certain amount of radiation. Whether this is external or internal radiation, the dose level is the amount of radiation to which a subject will be exposed during the entire project.

(b) *Selection of subjects*

In considering the selection of subjects for a research project involving radiation, the following general principles should be applied, where appropriate :

- (i) *Age.* The age of the subjects available must be considered. Partly because of the possibility of genetic effects and partly because of the long latent period associated with certain somatic effects of radiation, subjects should, where practicable, be aged over 40 years, preferably over 50.
- (ii) *Number of individuals.* The number of individuals participating in a research project should be restricted to the minimum necessary to acquire the information needed with sufficient accuracy, especially when individuals of reproductive age must be used.
- (iii) *Special groups.* Projects should not involve pregnant women except when problems specific to pregnancy are under investigation. When the irradiation of pregnant women is unavoidable, special consideration should be given to the high radiosensitivity of the embryo or fetus. The possibility of early pregnancy should always be borne in mind in connexion with the use of women of reproductive age as experimental subjects. Subjects under 18 years old should not be used except when problems specific to their age are under investigation.

5.5 Categories of research project involving irradiation of human beings

For convenience, the different kinds of project have been divided into categories depending on the amount of total body radiation to be received by the subject in each project, each category of project differing from the next by one order of magnitude of dose equivalent (see also Annex 4). This division into categories is justified by the differences in the associated risks and makes it possible to plan a reasonably flexible system of assessment. Some examples of clinical procedures involving irradiation of human beings and the categories into which they would fall are given in Annex 5.

(a) *Category I.* The total body radiation permitted to the subject in experiments of this category—in the region of 10 mrem (0.1 mSv)—would be within the variations of natural background radiation received by the subject during a period of one year. The additional amount of radiation is similar to that to which the subject might be exposed within one year if, for instance, he moved from a house built of one material to one built of another (17). It is, at any rate, less than the actual annual amount of radiation received from natural sources. The Committee therefore felt that, in projects in this category, no particular radiation protection or radiobiological problems arise and any resultant risk would be negligible.

(b) *Category II.* The total permissible body radiation of a subject taking part in a project in this category would be in the region of 10^2 mrem (1 mSv), i.e., of the same order of magnitude as the annual exposure from natural sources. This falls within the individual dosage limits recommended by the International Commission of Radiological Protection (ICRP) for small groups of members of the public.

(c) *Category III.* The total permissible body radiation of a subject taking part in a project in this category—in the region of 10^3 mrem (10 mSv)—is of the same order of magnitude as the annual dosage limits recommended by ICRP for occupationally exposed persons.

(d) *Others.* Projects at higher doses should be acceptable only in special instances, e.g., in radiotherapy. It would need to be shown that the information desired was important enough to justify the risks involved and could not be obtained at lower dose levels. The radiation permitted in this category would be comparable with, or higher than, the ICRP “planned special exposures” for those occupationally exposed.

5.5.1 Single organs

When body organs are selectively irradiated, as is usually the case when radiopharmaceuticals are administered, the risks are less than those from irradiation of the whole body at the same dose level. ICRP (12) has published "weighting factors" for the various organs, corresponding to the expected risk of somatic or genetic harm attributable to the selective irradiation of each organ, relative to the risk of whole body irradiation at the same dose level (Table 1). In investigations that

Table 1
Single organ weighting factors ^a

Tissue	Weighting factor
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone	0.03
Any other organ	0.06
Whole body	1.00

^a Source : see reference 12.

involve selective irradiation of single organs only, therefore, the mean doses in these organs that would correspond to the categories given above would be higher—by factors of 4 or more according to the organ involved—than those given for irradiation of the whole body. Where, as commonly occurs, several organs are selectively irradiated through the administration of a radiopharmaceutical, the same weighting factors can be used, taking account of the organs involved and the irradiation of each. For organs not specifically listed in Table 1, a weighting factor of 0.06 would apply. Thus, for example, if thyroid and liver were equally irradiated, the dose permitted in each in any given category would be $1/(0.03 + 0.06) = 11$ times that which would apply if the whole body were uniformly exposed. (Data are in course of publication by ICRP indicating the levels of intake of various radiopharmaceuticals corresponding to the same level of risk, taking into account the organs they irradiate and the estimated somatic or genetic harm from the irradiation of each organ.)

5.6 Radiation limitation

An appropriate body should be set up at the local, regional, or national level for the technical review of research projects and the assessment of the risks and ethical problems involved, the aim being to ensure the judicious use of research procedures for the benefit of mankind.

Thus it has been found valuable to establish small ethical committees within hospitals or other institutions to review any proposals for investigations on human beings, approving or rejecting these proposals or suggesting modifications.

5.7 Repeated irradiation of the same subject

In general, it is undesirable that an individual should repeatedly take part in research projects involving substantial radiation exposures. The investigators should therefore invariably obtain and review the available data on previous irradiations of the proposed participants, so that their total exposure will not exceed the annual permissible limits laid down by relevant international or national bodies. The first three categories given in section 5.5 are specified in terms of the dose levels applicable to single investigations in any one year. If, however, several such investigations were to be made within one year, the category of exposure might clearly be raised to a level requiring correspondingly greater justification. If, in the interests of the individual or the community, repeated investigations appear justified (as in the study of patients with rare metabolic disorders that cannot be investigated in other ways), repeated investigations involving a higher dose category may seem permissible.

6. THE USE OF IONIZING RADIATION IN EDUCATION AND TRAINING

The increasing use and practical value of ionizing radiation in the prevention and cure of human diseases demand that all categories of health personnel should be given sufficient basic knowledge of radiation effects by personnel qualified in this field. This will contribute to the appropriate utilization of ionizing radiation as well as allaying unwarranted fears. While training may be aimed primarily at medical, paramedical, pharmaceutical, and dental practitioners, consideration should also be given to the special training needs of those who operate radiation generating equipment, e.g., radiologists, radiographers, dental assistants, and radiological technicians, and of physicians and dentists who may use radiation for diagnostic and therapeutic purposes as well as research.

During teaching, the exposure of students and instructors to radiation should be kept to the barest minimum. This also applies to the education and training of persons in industry on the use of ionizing radiation procedures. Any illustrative demonstrations to the public should avoid deliberate exposure of any individuals.

In order to avoid the unnecessary exposure of human beings, including patients, to further ionizing radiation in the course of education and training, educational material should be taken as far as possible from available routine clinical investigations and therapeutic applications. The maximum utilization of available audiovisual and other teaching aids as well could further reduce the radiation exposure of humans. Students, trainees, teachers, and other volunteers should not normally be accepted as subjects solely for the procurement of educational material.

Methods of surveillance are dealt with in section 4 of this report.

7. IRRADIATION FOR NONCLINICAL PURPOSES

7.1 Introduction

The Committee reviewed some examples of situations in which individuals receive radiation, deliberately administered, for purposes unrelated to health. In certain cases the irradiation is related in some way to medical objectives, and there are instances in which medical benefit may follow the irradiation. The purpose of irradiation in these situations, however, is not a medical one and the medical history of the individual is normally not given consideration.

7.2 Specific ethical considerations

In the context of clinical exposure, it is acceptable to set the small risk from radiation against the medical benefits. While the general principles set out in section 3.4 are applicable, an individual may sometimes be obliged to undergo irradiation for the benefit of the community, e.g., a chest radiograph for tuberculosis. In such circumstances, the interest of the community may well be of more importance in relation to particular national policies or programmes than that of the individual. Particular instances are discussed in section 7.3.3.

7.3 Examples of such irradiation

7.3.1 Compensation claims

(a) *Compensation claims for injury.* The type of irradiation referred to here is that involved when an individual claims that he has sustained

injury as a result of another's actions and is required to produce radiological evidence to support his claim. In most cases the irradiation will be from diagnostic X-rays, and any part of the body may be involved, the skeleton being more often exposed than the soft tissue. The subjects involved may be of any age, and the somatic risk seems likely to be more important than the genetic risk. Benefits, if any, will be economic and, in the view of the Expert Committee, irradiation is acceptable in this situation provided that the person concerned agrees and that other methods involving a lower risk are inappropriate.

(b) *Compensation claims for disability.* In cases of this type, the individual will already have undergone a period of illness probably involving radiological examinations. A specific claim for compensation in relation to any disability may, however, need to be supported by radiological evidence. Again, the subjects concerned may be of any age, but are more likely to be adults than children. In the Committee's view, radiation is acceptable in this situation provided that the individual concerned agrees, other methods involving lower risk are inappropriate, and previous films provide an inadequate basis for a decision.

7.3.2 *Healthy people seeking insurance cover*

Clearly, before providing cover, an insurance company needs to evaluate the state of health of the individual seeking cover, and there are circumstances in which radiological examination, particularly of the chest, is a routine requirement for this purpose. Most of the individuals concerned will be adult men; there will be few children or old people. In the view of the Expert Committee, their irradiation is unjustified if it is prompted solely by routine administrative directive. It would, however, be justified in individual cases if the medical history and a clinical examination revealed a situation that could be clarified by a radiological examination, and if other methods involving lower risk were inadequate.

7.3.3 *Health screening of population groups*

Ionizing radiation may be used to screen population groups for public health purposes, e.g., in the control of diseases of particular importance to the community, such as pulmonary tuberculosis, or diseases mainly of importance to the individual, such as carcinoma of the breast, stomach, or lung and Perthes' disease. In either situation, the decision to undertake screening should be based on adequate epidemiological data relating the disease to the particular population or population group. For example, for tuberculosis, those likely to suffer from, or

be involved in, the spread of the disease will be screened, whereas, for carcinoma of the breast, screening will be mainly confined to women in the late reproductive age. In the former case, large numbers of a population will be involved and, in the latter, far fewer. In selecting techniques for screening examinations, those associated with the least exposure to radiation are preferable, although techniques which avoid exposure to radiation and yet do not reduce the overall rate of disease detection should be employed where applicable. For example, skin tests may be used along with radiology of the chest for tuberculosis, and clinical examinations may contribute to a better selection of women for radiation screening for carcinoma of the breast. Repeated screening of selected groups at risk of, or likely to spread, a disease, e.g., teachers and nurses in the case of tuberculosis, needs to be specially justified. In other instances where repeated examination of a group is dictated, appropriate techniques not involving radiation should be sought.

7.3.4 Repeated health screening of industrial employees

When an industrial process may involve a hazard in certain circumstances, the management concerned requires, for economic reasons, to know as soon as possible whether workers are affected by this hazard. Circumstances in which dusts are involved, or working conditions might lead to an enlarged heart, may require radiological examination of the chest as part of the screening. This could legitimately be regarded as medical exposure, except that, for the benefit of a factory management, it may in some circumstances be carried out at more frequent intervals than would be justified on medical grounds. In the view of the Expert Committee, the irradiation of workers should continue to be dictated by individual health requirements rather than by the requirements of the management.

7.3.5 Determination of age by bone radiography

Evidence as to the age or development of a child or adolescent may be obtained by X-rays, particularly of the limbs, to determine which of the bone epiphyses have closed. This procedure involves an appreciable dose to growing tissue, e.g., about 10 mGy (1 rad), and should not be performed for nonclinical reasons unless absolutely necessary.

7.3.6 Immigration regulations

Immigration regulations frequently demand chest radiography and this may, of course, involve subjects of any age. In some circumstances,

large numbers of people may be involved so that the problem is not a small one. The Committee suggests that, where practicable, consideration be given to the use of clinical methods presenting a lower risk than radiography. Whether radiation is to be used should be determined partly by the current health needs of the country of entry, but also partly by the disease pattern in the country of origin of the immigrant.

7.3.7 Irradiation as a routine administrative procedure

Several situations in which irradiation seems to be ordered as a routine administrative procedure were considered, and four examples were cited of cases in which—the Committee suggests—irradiation should be ordered only if justified in the particular individual circumstances on medical advice.

In some instances, the first procedure in a medical examination on appointment to a post is radiography of the chest, followed only later by the completion of a personal history form and, presumably, consideration of the details on the form and the radiograph by the medical officer concerned. The Committee suggests that it would be preferable for the personal history form to be filled in first and that, only after this has been considered by the medical officer, should a decision be taken whether, in the circumstances, a chest radiograph will add useful information. The Committee suggests that, when this procedure is impracticable, radiography should, at the very least, be confined to selected groups, e.g., people within a particular age-range or having suffered from a particular disease.

It is noted that in one country no pregnant woman may receive maternity benefit unless an X-ray examination of the chest is carried out during the second antenatal examination. In another country, a marriage certificate cannot be issued unless the couple concerned have each undergone a medical examination including “ a fluorographic examination of the lungs, except in the presence of contraindications certified by the physician ”. In yet another country, the medical examination required before marriage includes a radiological examination of the pelvis of the woman.

In many instances such as these, medical advice may have been drawn upon in framing the administrative or legal requirements, but possibly many years ago. As far as the irradiation of people is concerned, the climate of opinion has greatly changed in the last decade or two and the Committee suggests further review to reduce as far as possible the number of instances in which people are irradiated for reasons not justified on clinical grounds.

7.3.8 *Irradiation to guard against possible claims for professional negligence or malpractice*

It has become clear in the radiological examination of accident cases that, in certain circumstances, X-rays are taken not only to detect fractures suspected on clinical grounds but also to provide a defence against possible claims for negligence if fractures not suspected on clinical grounds are in fact found to have occurred. It is obviously difficult to establish any criterion as to the appropriate range of such examinations, particularly in the case of the skull, where fractures may be difficult to exclude on clinical grounds but are of importance if they have occurred. The Committee, however, strongly emphasizes the undesirability of radiological examinations that are not judged to be clinically necessary, and indeed considers that the performance of unjustified radiological examinations could in itself be regarded as a form of professional negligence or malpractice.

7.3.9 *Irradiation for commercial purposes*

An example is the use of fluoroscopy in the fitting and sale of shoes. Widely used in the past, the relevant equipment delivered appreciable radiation doses to the foot, even if used properly, and it was impossible to prevent children (and adults) from treating it as a fascinating toy to be played with indiscriminately. Moreover, there was no evidence that in general its use led to the purchase of better-fitting shoes. The Committee notes that the use of this equipment has been restricted in many countries and banned completely in others, and it expresses the hope that such a ban will become universal.

7.3.10 *Weapon detection*

At some airports, people are X-rayed, usually with extremely sensitive low-dose equipment, to see if they are concealing weapons. Travellers making frequent journeys may, however, receive appreciable radiation. The Committee is aware that the Council of the International Civil Aviation Organization (ICAO) has agreed that the use of radiological searching techniques to screen passengers for possession of weapons should be avoided, and an ICRP recommendation on the subject (18) is given in Annex 6. The Committee recommends the use of procedures presenting a lower risk.

7.3.11 *Detection of smugglers*

The Committee understands that radiological methods are sometimes used to detect smugglers and recognizes that in some situations no satis-

factory alternative may exist, e.g., in checking that workers leaving a mining compound have not swallowed precious stones or metals. The Committee advises in general against the use of methods involving radiation exposure to detect smugglers. It considers, however, that such methods could be accepted if, and only if, individuals receiving radiation in excess of that recommended by ICRP as the limit for members of the public were regarded as occupationally exposed to radiation. This would mean their being subject to all the requirements of ICRP and national authorities relating to occupationally exposed persons.

7.4 Conclusions

Apart from the detailed recommendations made above the Committee points out that ICRP has suggested that, in the circumstances considered, the irradiation should be at the lowest level that is readily achievable. Although radiation hazards will be small in most instances, the Committee recommends as a general policy that, when people are to be irradiated for purposes unrelated to health, this should be done only when no satisfactory alternative methods presenting an even lower risk exist and the amount of radiation used should be restricted to the minimum practicable.

8. RECOMMENDATIONS

(1) Surveillance over the use of ionizing radiation on human beings for non-clinical purposes is required in one form or another.

(2) Irradiation for medical research purposes should be considered in the widest context, and, as a general policy, any research project involving human subjects should be reviewed beforehand by an ethical committee to determine the extent to which the principles of medical ethics would be observed. Such committees could be local, regional, or national, but should be so constituted that securing their approval would not necessitate undue delays or formalities. When dealing with projects involving radiation, ethical committees would be likely to need advice on dosimetry and risk estimates from experts available locally or in national or regional advisory committees.

(3) Medical teachers should take responsibility for restricting additional irradiation for teaching purposes to the minimum. They should take the requisite educational material from the results of routine clinical investigations and therapeutic applications as far as practi-

cable, and they should make full use of techniques that can minimize human radiation exposure, such as audiovisual aids and copying facilities.

(4) The deliberate irradiation of human subjects should never be carried out for commercial purposes, nor simply as part of a routine administrative procedure. Whenever possible, the irradiation of a human subject should be carried out only after a decision has been taken that it is justified in the case of that particular individual.

(5) The free consent of the subject should be obtained not only for medical research but for almost all deliberate irradiation of human beings; the only exceptions should be applications of public health importance.

(6) Techniques permitting radiation exposure to be minimized should be applied whenever they can be made available.

(7) Three categories of radiation doses are recommended for grouping radiation risks involved (see Annex 4). Doses exceeding the highest category (III) should not be accepted except for special reasons, e.g., for research in radiotherapy.

(8) Encouragement should be given to the programme initiated by CIOMS, under the auspices of WHO and UNESCO, on the role, function, and effectiveness of ethical review committees in protecting the rights and welfare of human subjects in biomedical studies. The results of these studies should be made fully available as soon as possible in order to assist in the establishment and functioning of ethical review committees.

(9) Guidelines on the radiation doses involved in typical applications should be made available to ethical committees, particularly those at a local level, in order to help them in reviewing projects. It is recognized that WHO should play a leading and coordinating role in this context as well as in the distribution of relevant information.

(10) WHO should continue and, whenever possible, increase its efforts to discourage the abuses that still exist in connexion with the deliberate irradiation of human beings and also to help in overcoming unjustified public anxiety about radiation risks.

REFERENCES

1. BRAESTRUP, C. R. & VIKTERLÖF, K. J. *Manual on radiation protection in hospitals and general practice. Volume 1 : Basic protection requirements.* Geneva, World Health Organization, 1974.

2. FROST, D. & JAMMET, H. *Manual on radiation protection in hospitals and general practice. Volume 2: Unsealed sources.* Geneva, World Health Organization, 1975.
3. *Health aspects of human rights with special reference to developments in biology and medicine.* Geneva, World Health Organization, 1976.
4. INTERNATIONAL ATOMIC ENERGY AGENCY. *Basic safety standards for radiological protection.* Vienna, 1967 (Safety Series, No. 9).
5. INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION. *The evaluation of risks from radiation.* Oxford, Pergamon Press, 1966 (ICRP Publication No. 8).
6. INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION. *A review of the radiosensitivity of the tissues in bone.* Oxford, Pergamon Press, 1968 (ICRP Publication No. 11).
7. INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION. *General principles of monitoring for radiation protection of workers.* Oxford, Pergamon Press, 1969 (ICRP Publication No. 12).
8. INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION. *Radiosensitivity and spatial distribution of dose.* Oxford, Pergamon Press, 1969 (ICRP Publication No. 14).
9. INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION. *Protection against ionizing radiation from external sources.* Oxford, Pergamon Press, 1970 (ICRP Publication No. 15).
10. INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION. *Protection of the patient in X-ray diagnosis.* Oxford, Pergamon Press, 1970 (ICRP Publication No. 16).
11. INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION. *Protection of the patient in radionuclide investigations.* Oxford, Pergamon Press, 1971 (ICRP Publication No. 17).
12. INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION. *Recommendations of the ICRP (adopted January 17, 1977).* Oxford, Pergamon Press, 1977 (ICRP Publication No. 26).
13. *International Covenant on Civil and Political Rights (1966).* In: *Human rights. A compilation of international instruments of the United Nations.* New York, United Nations, 1967, pp. 8-16.
14. INTERNATIONAL LABOUR OFFICE. *Manual of industrial radiation protection. Part 1: Conventions and recommendations.* Geneva, 1963.
15. *Ionizing radiation: Levels and effects. A report of the United Nations Scientific Committee on the Effects of Atomic Radiation to the General Assembly. Volume 1: Levels.* New York, United Nations, 1972.
16. *Ionizing radiation: Levels and effects. A report of the United Nations Scientific Committee on the Effects of Atomic Radiation to the General Assembly. Vol. 2: Effects.* New York, United Nations, 1972.
17. *Report of the United Nations Scientific Committee on the Effects of Atomic Radiation.* In: *General Assembly. Official Records: 17th Session. Supplement No. 16.* New York, United Nations, 1962, p. 243 (Table V).
18. SOWBY, F. D. *Radiology*, **101**: 205-206 (1971).
19. WHO Technical Report Series, No. 248, 1962.
20. WHO Technical Report Series, No. 254, 1963.
21. WHO Technical Report Series, No. 306, 1965.
22. WHO Technical Report Series, No. 492, 1972.

Annex 1

RADIATION QUANTITIES AND UNITS

In 1975 the Conférence générale des Poids et Mesures (CGPM) adopted new units of measurement in the field of ionizing radiation that now form part of the SI system of units. The definition of the quantities has, however, not been changed and may be briefly explained as follows.

Any biological effect of ionizing radiation is related to the amount of energy which is absorbed per unit mass of tissue, called "absorbed dose" (symbol: D) and formerly expressed in "rad" = 100 erg/g. In the SI system the absorbed dose is expressed in J/kg, for which the special name "gray" (symbol: Gy) has been adopted. Thus:

$$1 \text{ Gy} = 1 \text{ J/kg} = 10^4 \text{ erg/g} = 100 \text{ rad}$$

For the same absorbed dose, radiation in the form of neutrons or alpha particles is, however, biologically more effective than X-rays, beta particles, or gamma-rays. In order to make the absorbed dose of different kinds of radiations biologically comparable and to allow them to be added up, the value of the absorbed dose is multiplied by a "quality factor" and possibly other modifying factors without physical dimensions and the resulting quantity called "dose equivalent" (symbol: H). The factors are 1 for X-rays, beta particles, and gamma-rays and, for example, 10 for alpha particles. The traditional unit for dose equivalent has been the rem, and for a quality factor of 1 the rem is equal to the rad.

In a recent publication (12) the International Commission on Radiological Protection (ICRP) introduced the special unit "sievert" (symbol: Sv) for the dose equivalent corresponding to the absorbed dose expressed in "gray", giving the following relationship for radiations with quality factor 1:

$$1 \text{ Sv} = 100 \text{ rem} = 1 \text{ Gy} = 100 \text{ rad}$$

dose equivalent absorbed dose

As the sievert is not yet accepted by the CGPM and is therefore not an SI unit, dose equivalents are expressed in rem in this report, followed by the value in sieverts in parentheses.

The activity of a radioactive substance is defined by the number of atoms disintegrating per second. The new SI unit is the "becquerel" (symbol: Bq) which represents one disintegration per second. The old

unit "curie" (symbol: Ci) was practically equivalent to one gram of radium with 3.7×10^{10} disintegrations per second. Hence:

$$1 \text{ Ci} = 3.7 \times 10^{10} \text{ Bq}$$

For practical purposes all these units are frequently used with prefixes indicating multiples and submultiples of the unit, e.g., milli- (symbol: m) = 1/1000, micro- (symbol: μ) = 1/1 000 000, kilo- (symbol: k) = 1000 \times , mega- (symbol: M) = 1 000 000 \times , etc. Thus:

$$1 \text{ mGy} = \text{one thousandth of a Gy}$$

$$1 \text{ MBq} = \text{one million Bq}$$

As an indication of the radiation exposure involved in various circumstances, the dose equivalent received by man annually from natural radiation sources is ordinarily about 0.1 rem (1 mSv), while that to issues from diagnostic X-ray applications is about 0.1–1 rem (1–10 mSv) per radiograph. The maximum recommended as permissible for adult workers involved in work with radiation is 5 rem (50 mSv) from occupational exposure in any year, while the limit recommended for any member of the public from all man-made radiation sources (except in medical examinations or treatment) is 0.5 rem (5 mSv) per year. Local exposures of body tissues in radiotherapy reach dose equivalents of some thousands of rem and, in one form of cancer therapy using radionuclides, some ten thousands of rem.

Annex 2

ESTIMATES OF RADIATION RISKS

Numerous studies have been made of the frequency with which harmful effects, and particularly various forms of cancer and leukaemia, develop in human populations during prolonged periods of time—i.e., 20–30 years—after exposure of the whole body or of particular organs or parts of the body to known doses of ionizing radiation. From such epidemiological studies it is possible to estimate the likely frequency with which malignant disease will develop, in excess of the normal expectation, after exposure to relatively high doses—1 Gy (100 rad) or more—of the whole body, or of each of the principal body organs individually. Corresponding estimates can be made of the risk of the much lower doses—of some 10 mGy (1 rad), or less—normally involved in the procedures discussed in this report. It seems likely that the risk of inducing malignant disease which may ultimately develop and prove fatal is in the region of 10^{-2} per Gy (10^{-4} per rad) of whole body dose. When the radiation is absorbed mainly in a single organ, the corresponding risk is lower by a factor of 4 or more, according to the organ concerned.

The risk that any substantial inherited abnormality may follow irradiation of the reproductive organs is based essentially on experimental work in animals, notably the mouse, and on estimates of the natural frequency with which such abnormalities occur in man. The frequency with which such defects are likely to occur in man as a result of irradiation falls progressively with age, but is estimated also to have an average value of 10^{-2} per Gy (10^{-4} per rad), about half of the abnormalities occurring in the first two generations after exposure.

**SOME TYPES OF RESEARCH INVOLVING IRRADIATION
OF HUMAN SUBJECTS**

Projects in radiation medicine

- Fractionation in radiotherapy
- New imaging techniques in nuclear medicine
- Combination of immunotherapy with radiotherapy
- Studies on a medical flash X-ray system
- Radiosensitization in radiotherapy
- Exploration of new methods of imaging in diagnostic radiology

Other projects in medical research

- Research on kidney function changes in schistosomiasis, using X-ray and nuclear medicine techniques
- Pharmacological research using radioactively labelled drugs
- Iron absorption studies in tropical medicine, using radioactive iron
- Use of labelled antigens to check the immunological response in infection
- Research in human reproduction, using pelvic radiography
- Studies of iodine metabolism in women and children with endemic goitre

Annex 4

CATEGORIES OF RESEARCH PROJECT INVOLVING IRRADIATION OF HUMAN BEINGS

Table 1
The three categories (as recommended in section 5.5)

	Category		
	I	II	III
Order of magnitude of total body dose commitment	10 mrem	10^2 mrem	10^3 mrem
Derived range of total body dose in one year	less than 0.05 rem	0.05 but less than 0.5 rem	0.5 but less than 5 rem
Level of risk	Within variations of natural background radiation	Within dose limits for members of the public	Within dose limits for persons occupationally exposed to radiation

Table 2
Organ dose equivalents (rem) for the three categories

Organ	Weighting factor	Category		
		I	II	III
Whole body	1.00	< 0.05	0.05-0.5	0.5-5
Gonads	0.25	< 0.20	0.20-2.0	2.0-20
Breast	0.15	< 0.33	0.33-3.3	3.3-33
Red bone marrow	0.12	< 0.42	0.42-4.2	4.2-42
Lung	0.12	< 0.42	0.42-4.2	4.2-42
Thyroid	0.03	< 1.7	1.7-17	17-170
Bone	0.03	< 1.7	1.7-17	17-170
Any other organ (not more than five organs)	0.06	< 0.83	0.83-8.3	8.3-83

Note: To obtain values in mSv multiply the above figures by 10.

SELECTED CLINICAL TESTS BY PROJECT CATEGORY

A clinical test using radiation can be evaluated to determine the project category (see Annex 4) into which it falls ; this has been done for a selected list of tests widely used in medical research. The accuracy of the classification, however, depends on the individual characteristics of the subjects and also on the technique applied, so that the categories indicated below must be regarded only as those that usually apply to normal adult subjects and the use of a normal technique. Most of the data on which the calculations are based have been taken from references 10, 11, and 15.

Table 1 lists selected X-ray procedures, indicating for each the skin dose to be expected, the dose equivalent to the organ most likely to be critical in the determination of the category, and the resulting category.

Table 2 lists selected nuclear medicine procedures. For each an indication is given of the organ or organs that may be most critical in the determination of the category, together with the activity usually applied in MBq (μCi), the mean dose per unit activity in mGy/MBq (mrad/ μCi) and the resulting dose equivalents for different organs in rem. The category number appears against the organ which primarily determines the category.

Table 1
X-ray investigations

Type of examination	Skin dose equivalent (rem)	Organ	Mean dose equivalent (rem)	Category
Chest ^a	1.4	Lung	< 0.14	I
		Whole body	≤ 0.05	
Chest ^b	2.8	Whole body	~ 0.05	II
Bone in limb	4	Total bone	≤ 1.7	I
Abdomen	12	Gonads	< 0.22	I
Pelvis	33	Gonads	~ 0.3	II
Whole skeleton	25	Bone marrow	~ 1.1	III
		Whole body	~ 0.5	
Mammography	150	Breast (mean)	~ 5.0	III
Prolonged cardiac catheterization	2000 ^c	Lung (mean)	~ 40	Other

^a Using normal low-dose techniques.

^b Using high-dose techniques without collimation.

^c Mean skin dose given in reference 15 as 47 rad ; occasional cases will exceed the mean dose by a factor of 4.

Note: To obtain values in mSv multiply the dose-equivalent figures by 10.

Table 2
Radionuclide investigations

Nuclide	Form	Test	Activity in MBq (μ Ci)	Reference organ	Mean dose per unit activity in mGy/MBq (mrad/ μ Ci)	Dose equivalent in rem	Category
^3H 125I	H ₂ O	body water	9 (250)	whole body ^a	0.03 (0.11)	0.028	I
	hippuran	kidney function	0.4 (10)	kidneys gonads	0.01 (0.04) 0.001 (0.005)	0.0004 0.00005	I
	HSA	blood volume	0.2 (5)	whole body ^a	0.7 (2.8)	0.014	I
131I	denatured HSA	lung scan	11 (300)	whole body ^a	0.08 (0.3)	0.09	II
	rose bengal	liver scan	7 (200)	liver gonads	0.7 (2.5) 0.05 (0.17)	0.5 0.034	I
$^{99\text{m}}\text{Tc}$	colloid	liver scan	75 (2000)	liver spleen	0.09 (0.33) 0.06 (0.22)	0.66 0.44	
			gonads	0.005 (0.02)	0.04		
		whole body ^a		0.005 (0.02)	0.04		
		TBE ^b			0.10		II
	iodide	thyroid uptake	0.9 (25)	thyroid whole body ^a TBE ^b	5.4 (20) 0.02 (0.07)	0.5 0.0018 0.017	I
132I	iodide	thyroid uptake	0.9 (25)	thyroid	5.4 (20)	0.5	I
				whole body ^a TBE ^b	0.03 (0.1)	0.0025 0.017	
$^{99\text{m}}\text{Tc}$	pertechnetate	brain scan	185 (5000)	whole body ^a	0.003 (0.012)	0.06	
				thyroid	0.07 (0.25)	1.25	
		stomach	0.06 (0.23)	1.15			
		gonads	0.004 (0.015)	0.075			
		salivary glands TBE ^b	0.1 (0.4)	2.0 0.42		II	

Table 2 (continued)

Nuclide	Form	Test	Activity in MBq (μ Ci)	Reference organ	Mean dose per unit activity in mGy/MBq (mrad/ μ Ci)	Dose equivalent in rem	Category
¹³¹ I	iodide	thyroid uptake	0.4 (10)	thyroid	540 (2000)	20	III
				parathyroid	89 (330)	3.3	
				whole body ^a	0.16-0.97 (0.6-3.6)	0.006-0.036	
⁷⁵ Se	methionine	pancreas scan	7 (200)	TBE ^b	0.80-0.82	0.80-0.82	III
				whole body ^a	2.2 (8)	1.6	
				pancreas	1.4 (5)	1.0	
				liver	1.4 (5)	1.0	
				kidney	15 (56)	11	
¹⁹⁸ Au	colloid	liver function	6 (150)	TBE ^b	2.1	2.1	III
				liver	11 (40)	6.0	
				spleen	11 (40)	6.0	
				whole body ^a	0.5 (1.7)	0.255	
				TBE ^b	0.94	0.94	
⁵¹ Cr	RBC	blood volume	0.9 (25)	spleen	14 (50)	1.25	III
				liver	0.5 (1.8)	0.045	
				whole body ^a	0.07 (0.25)	0.0063	
				TBE ^b	0.083	0.083	

^a Values as given in reference 11.

^b TBE = Total Body Equivalent, calculated by summing the w_TH_i values for the different organs listed (12, para. 104).

NB: The above values were calculated from data available in old units (μ Ci; mrad/ μ Ci) and the results converted into SI units and appropriately rounded off:

$$1 \mu\text{Ci} = 3.7 \times 10^{-2} \text{MBq}$$

$$1 \text{ mrad} = 10^{-2} \text{ mGy}$$

$$1 \text{ mrad}/\mu\text{Ci} = 0.27 \text{ mGy}/\text{MBq}$$

To obtain values for dose equivalent in mSv, multiply the figures given in that column by 10.

Annex 6

STATEMENT BY ICRP ON SECURITY SCREENING OF AIRLINE PASSENGERS ¹

The Commission has been asked for its views on an international proposal to use radiography as part of a system for the security screening of airline passengers. This envisages that a small proportion of passengers might be examined radiographically, using specially developed techniques that would restrict the exposure to 1 milliroentgen or less in any part of the body, to be used only when other methods have indicated the presence of unexplained objects on the passenger. Such passengers would be given the choice between an X-ray examination and a body search. The Commission has already recommended that the irradiation of persons for nonmedical purposes, such as in anti-crime and customs examinations, is generally to be deprecated. However, in view of the grave risks involved in the seizure of aircraft, the Commission believes that the proposal, if performed under the conditions already specified, could be justified in the light of the benefits that might be expected.

¹ See reference 18.