RADIATION PROTECTION

ICRP PUBLICATION 17

Protection of the Patient in Radionuclide Investigations

A Report prepared for the International Commission on Radiological Protection

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This is one of a series of reports prepared as background material for the International Commission on Radiological Protection. These reports, published in blue covers, form part of the Commission's continuing review of information intended to provide scientific bases for its Recommendations, which are published in brown covers. The Commission hopes that the publication of the reports in blue covers, while not necessarily implying recommendations for present action, will stimulate discussion on matters having direct relevance to its work and to the development of the fundamental principles of radiological protection.

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Preface

In 1968 the Commission asked Dr. R. E. Ellis to prepare a report on protection of the patient in radionuclide investigations. The report describes the basic principles for minimizing the dose to patients receiving radiopharmaceuticals, and also presents a compilation of estimates of the absorbed doses resulting from the administration of the more commonly-used pharmaceuticals.

The report is complementary to the report, prepared by a task group of ICRP Committee 3, on *Protection of the Patient in X-ray Diagnosis* (ICRP Publication 16).

Contents

Protection of the Patient in Radionuclide Investigations

A. Introduction

During the last few years there has been a large increase in the number of patients who have been investigated using the widening range of radiopharmaceuticals available clinically. There is an increasing choice of alternative methods, from the well-established ones, using well-known nuclides, to those methods utilising new, and, in particular, short-lived nuclides. In consequence, some clinicians are unfamiliar with the radiation doses received, particularly from these new nuclides, and of the dose commitment to organs in which the highest concentrations occur. Appreciable doses to organs may arise from low concentrations with long retention of particular nuclides. There are also quite large gaps in metabolic information, making accurate estimates of dose difficult.

In the literature, the doses estimated for some investigations show quite large discrepancies. There is thus a need for a reassessed listing of estimated doses and also for a commentary on the protection of the patient undergoing investigations with radiopharmaceuticals. This review indicates the factors involved in minimizing the radiation dose necessarily received during diagnostic tests with radionuclides.

The listing has been given in terms of the dose in millirad per microcurie (mrad/μCi) administered for nuclides and pharmaceuticals in clinical use. Where the investigation has become reasonably well accepted, the typical activity in microcuries (μCi) ordinarily administered is also given. These data then allow an estimate of the dose to be calculated for a typical investigation. However, there will still be a considerable variation in the absorbed dose per microcurie, depending on individual metabolism within the normal range, apart from variations in individuals with abnormal metabolism.

These listings must be interpreted in the light of the clinical need, which must determine the precision required, whether in localisation or in quantitative uptake, and the number of repeated tests that are required. Thus, no absolute dose limit is appropriate, but in each case the need for information must be judged in the light of the risk entailed by the investigation itself. Nevertheless, it is still important to review the size of the dose commitment from a particular radiopharmaceutical and to compare it with that from alternative tests using other radiopharmaceuticals, and also to compare the resultant radiation hazards with the hazards from tests not involving irradiation of the patient which give equally adequate information. A selected bibliography pertinent to the dosimetry of the nuclides has also been included.

B. Choice of Nuclide and Compound

There is a variety of ways in which the same clinical information may be obtained and it is important that the method used should minimize the radiation dose received in obtaining the necessary information. The available methods may include the use of external x-ray, as well as of particular radiopharmaceuticals. (A listing of the doses received from x-ray investigations has been compiled by the ICRP Task Group on Protection of the Patient in X-ray Diagnosis [1].)

The particular properties of nuclides or pharmaceuticals that may determine which is the best for a particular investigation are:

1. Half-life.
2. Energy of emission.
3. Type of emission.
4. Chemical form.

5. Availability of substitute elements or compounds.
6. Requirement of test.

1. Half-life

It is important that an adequate counting-rate or detection-rate is obtainable at times biologically appropriate for the particular measurement required. Considerable activity should not persist beyond this time, nor should undue decay have occurred before the measurements can be started. There will thus be an optimal relationship between the half-life of the nuclide and the time of the test. A possible criterion is that the duration of the test should be equal to the effective mean-time for the activity in the limiting organ or tissue (the mean-time being 1.44 times the effective half-life). For example, where a 4-hour thyroid uptake is the appropriate test, then ^{132}I is much preferable to ^{131}I, but where a 48-hour protein-bound radioiodine is required, then ^{131}I is clearly preferable to ^{132}I. Similarly, the use of ^{197}Hg-labelled neohydrin in brain-scanning at a few hours after administration gives a smaller dose for a given counting-rate than occurs when ^{203}Hg is used as the labelling nuclide.

The half-life of the nuclide, however, obviously limits the length of time for which labelled compounds and pharmaceuticals can be stored. Decomposition may occur from self-irradiation, and hence for a particular specific activity of a compound, the longer the half-life the greater the dose that the compound will receive, and thus the greater possibility of causing significant radiochemical changes. These are known to occur in compounds labelled with long-lived ^{14}C when they have been stored for a considerable period.

When the clearance rates of organs are fast, a high activity needs to be administered so that an acceptable number of disintegrations is recorded by the detectors. To counterbalance the high activities, short-lived nuclides are highly desirable for these investigations, to reduce the dose received. As the reduction of the effective half-life is the important criterion for the reduction of dose, the reduction of the biological half-life is also important. Therefore radiopharmaceuticals having shorter biological half-lives in the organ of interest will also contribute to the lowering of the dose received as long as the biological half-life is long enough compared with the period of the test.

2. Energy of Emission

The energy of the emission is an important factor in determining (1) the dose delivered, (2) the activity required to carry out a particular investigation, and (3) the design of the collimator used with the detector.

The dose delivered to an organ will increase proportionately with the β-ray energy of the emission. For a photon-emitting nuclide, even though the absorbed fraction will decrease in a particular organ with increasing energy, the actual energy absorbed in a large organ will increase.

When the uptake of a particular organ needs to be estimated, the optimal energy of emission is dependent on the depth and thickness of the organ. The requirement is to have a maximum counting-rate in the detector from the activity in the organ, but not to detect as efficiently activity within the tissues lying more superficially or deeper than the organ. A radionuclide having an optimal energy of emission will be one therefore for which the emitted radiation will be (a) substantially attenuated by depths of tissue greater than the depth of the organ of interest, and (b) adequately defined by a reasonably-sized collimator which will lead to the selective detection of radiation arising within the organ of interest and to the attenuation of radiation arising in the surrounding tissues.

It has been shown that for optimum organ scanning, a nuclide emitting photons only of energy in the range 100–200 keV is required. ^{99m}Tc, ^{113m}In and ^{75}Se are of current interest for scanning purposes, as they have emissions in this range. It is possible to build focused collimators

having good shielding properties at these energies.

In autoradiographic studies the resolution of the photographic image will be increased by the use of lower energy β-emitting nuclides. The divergence of the β particles into the emulsion from a particular labelled volume of the section will depend on the range of the β rays, since this range is directly proportional to the energy of emission.

3. Type of Emission

As has been stated in the previous section, photon-emitting nuclides are preferred for organ scanning or uptake measurements because with no β-emission, the doses to the organs are substantially reduced for a particular number of photons counted at the detector.

Accurate localization of uptake in organs can be carried out with positron-emitting nuclides by the use of coincidence-counting techniques to detect the annihilation radiation. ^{74}As, ^{64}Cu and ^{18}F are examples of positron emitters used for this purpose in clinical medicine.

4. Chemical Form

Initially, most of the radionuclides were used in simple forms for clinical investigations. Recently, efforts have been made to develop pharmaceuticals that concentrate in particular organs. These pharmaceuticals can be synthesized with the most suitable radioactive label incorporated. This then has altered the whole problem of the retention of the radionuclide. Initially, the metabolism of the ion itself had been considered, but now an understanding of the more complex metabolism of the pharmaceutical is required before an estimate of the radiation dose can be made. The use of column isotope generators for the production of solutions of short-lived daughter radionuclides has also been introduced during the last few years. Yet the loading of the column with the longer-lived parent nuclide must be such that under no circumstances can the parent nuclide be eluted from the column to contaminate the short-lived eluate. Similarly, if there were non-radioactive "breakthrough" products in the eluate, as, for example, the presence of zirconium in the eluate from ^{113m}In generators, there would be a chemical toxicity hazard.

A large number of compounds have been labelled with tritium and carbon 14. Even though the metabolism of some of the simple compounds is well known, a very large number of compounds labelled with these particular nuclides have poorly understood metabolism. Sometimes, in fact, the whole purpose of the labelling is to investigate and determine the metabolic pathways. In many of these cases, 70% to 80% of the administered compound and nuclide may be accounted for, but the metabolism of the remainder is unknown.

As more pharmaceutical agents are synthesized, there is the possibility of being able either to enhance or to block the uptake of a particular radionuclide or compound into certain tissues. If the uptake is enhanced in the organ of interest, less activity needs to be administered, and the dose to other organs will be reduced. If, on the other hand, some organ on which measurements of uptake are not required would otherwise receive a high dose, its uptake may be blocked by choice of a suitable drug.

5. Availability of Substitute Elements or Compounds

It is sometimes possible to use particular tracer nuclides as substitutes to follow the metabolism or distribution of other nuclides for which convenient radionuclides are not available. For example, radioactive bromine may be used to estimate chlorine spaces, and krypton to estimate the uptake of oxygen. Similarly, pertechnetate (containing labelled technetium) behaves like iodide in entering the thyroid and some other glands, although it does not become retained by organic binding in the thyroid gland, as iodine does.

The choice of the label for pharmaceuticals

may be based on one of the previously discussed considerations in those cases where the label does not influence the chemical properties. However, it is very important that the label must remain adherent, and, if it is shown that metabolism of the compound occurs, as in iodine-labelled human serum albumen, or if the label becomes detached, as the chromium does from tagged blood cells, then it is essential that due consideration be given to the metabolism and organ of concentration of the released activity.

The localization of some pharmaceuticals in particular organs arises not only from the selective metabolic absorption, but also from the increased permeability of some tissues to particular pharmaceuticals, such as occurs in the concentration of neohydrin in cerebral tumours.

6. Requirement of Test

The main divisions of investigations are:
(a) Uptake or dilution in a particular organ.
(b) Clearance rates of organs.
(c) Scan of organs.

A consideration of the particular type of investigation shows that the choice of nuclide is dictated by the speed with which the uptake in the organ occurs when considering the time after the administration at which an uptake or scan needs to be performed. When a measurement of a turnover rate is being made, the half-life of the nuclide must be sufficiently long compared with the duration of the turnover period. Similarly, in dilution studies the time taken for equilibration through the body spaces must be taken into consideration when choosing the nuclide to ensure that sufficient activity is present at that time.

The use of sufficient activity to obtain accurate measurements of clearance rates has already been commented on in section B.1.

The design and type of detecting equipment used for a test should be that which has maximum sensitivity and therefore allows the minimum activity of a particular nuclide to be administered. For example, uptake measurements with scintillation counters usually allow lower activities to be administered compared with those when Geiger counter detectors are used. The administration of unnecessarily high activities should not be condoned because of the continued use of inadequate equipment, if this can be avoided; however, in some cases, this may be inevitable. Likewise, in some cases, the available facilities may quite properly determine the choice between alternative tests involving comparable doses for equal information.

C. Organ of Reference

In any particular investigation the "organ of reference" will be that organ the dose to which is of greatest concern, from a radiation hazard viewpoint. Frequently, this will be the organ receiving the highest dose. Information as to which organs are likely to receive the higher doses is therefore required, so that any limitation of dose, and hence of administered activity, may be considered. A knowledge of the total dose in rads received during the decay of all the administered activity, i.e. the dose commitment, is, in any event, required. This dose will depend on the metabolic factors involved and also on the route of administration.

The assumption that the organ of reference will be the organ receiving the highest dose may not always be correct. For example, in the case of oral administration, some portion of the gastro-intestinal tract may receive the highest dose, but one will also be concerned with the organs which accumulate the greatest dose from the activity absorbed into the blood. Again, especially in young people or pregnant women, the dose to the gonads or to the foetal gonads may be the determining factor in the amount of activity administered.

Problems often arise in the calculation of the dose received by the organ of reference because the physiological parameters are not accurately known, and only approximate values of organ uptake are known. In some cases, these have to be deduced from information on similar chemical substances. For example, when considering

nuclides in the blood, the dose to the blood itself or to the bone marrow may not be accurately known. The marrow dose must be a function of the dose to the blood flowing through the marrow; however, the trabecular formation of bone containing marrow will reduce the dose. The proportion of blood in a given specimen of marrow is poorly known, so that estimates of the dose delivered are inadequately known. Further, any retention of a nuclide in the marrow itself will increase the dose to the marrow correspondingly.

Whenever there is uncertainty as to the sites and lengths of retention for a projected new use of nuclide or method, animal data should first be obtained to indicate the organs most likely to be important during human investigations and to indicate possible unexpected hazards. These results cannot, however, be used to give quantitative values or replace estimates obtainable from experience in man.

D. Estimates of the Dose per Unit of Activity Administered

The dose received by an organ will depend on the activity administered, on the route of administration used and on the fractional uptake of that particular organ.

In general, the nuclide will be administered either orally or intravenously, but other routes may be used, such as intramuscular for clearance studies, and intrathecal for various neurological investigations. Each route of administration requires a knowledge of the physiological pathways and a separate consideration of the dose received.

The data classified in ICRP Publication 2 [2] and in ICRP Publication 10 [3] contribute greatly to this information, but one must remember that these are for healthy adults and that metabolism may be radically changed in particular diseases. Also, these data have not contained information regarding the distribution of radionuclides in pregnant women, foetuses or children. The present revision of the ICRP Committee 2 report will include some data for organic compounds and labelled pharmaceuticals. As has been considered earlier, metabolism may be quite different when labelled pharmaceuticals are used, compared with the metabolism of nuclides in simpler forms.

Another problem has arisen in that the organ may not take up the nuclide or pharmaceutical uniformly. For example, the concentration in the cortex of the kidney may be greater than that averaged throughout the whole kidney. One can conceive that this can be taken to the cellular level and the activity concentrated in groups of cells may require consideration. It is essential therefore that the organ, tissue or structure of reference be clearly defined when making estimates of dose.

Obviously, in these cases, an estimate of the radiation dose likely to be received by a particular patient can only be made on the basis of the best possible information available. When the actual activity has been administered, and measurements of concentration of activity made, then a more accurate assessment of the radiation dose to that particular patient could be undertaken. Considerable discrepancy may arise between the prior estimate and the actual calculated dose, owing to the differences in metabolism and concentration referred to in a previous section.

E. Recommendations on the Clinical Use of Radionuclides

The clinical urgency or importance of the investigation may influence the activity of a nuclide that needs to be used in the investigation of any particular subject. If the activity used is unduly restricted, the diagnostic information obtained from the investigation may, in some cases, be insufficiently exact or detailed for the clinical needs, and the test may then either be wasted or may need to be repeated with a higher activity. This leads to unnecessary irradiation and to a loss of time which may be vital to a patient's health.

1. Categories of Subjects

Bearing these principles in mind, and to help in deciding the activity of a nuclide which should

be administered to a particular subject, it is suggested that the following categories should be considered. In this way, general principles and precautions can be stated for each category.

(a) Adult patients who may benefit from the investigation.
(b) Pregnant patients who may benefit from the investigation.
(c) Children who may benefit from the investigation.
(d) Groups of subjects investigated to establish normal values for tests that give abnormal values in certain diseases. These subjects will not themselves necessarily benefit from the test.

2. Basic Principle

The main principle in investigation of subjects is that the activity administered should be the minimum consistent with adequate information for the diagnosis or investigation concerned. This will ensure that the minimum radiation dose is delivered to the patient.

3. Adult Patients

Experience has shown that most tests can be satisfactorily carried out with activities that give rise in adult patients [category (a)] to organ doses of the order of 1 rad, and not usually greater than 5 rads, per investigation. (Tests involving ^{131}I may lead to thyroid doses much greater than this.) However, for a few scanning procedures, it has been found that organ doses of several times these levels are required. Compared with point to point counting, it is necessary with present scanning detecting equipment to use somewhat higher activities to get adequate information on the scan. However, the value of the test to the patient's well-being and/or the seriousness of the disease being investigated may often outweigh any possible long-term radiological hazard, and, in these cases, a higher administered activity may be acceptable.

4. Pregnant Patients

Investigations carried out on pregnant women involve radiation doses to both the mother and the foetus. Consideration must be given to the quantity of activity transmitted across the placenta, and to the resulting foetal uptake. In view of the data from the surveys by MacMahon [4], and by Stewart and Hewitt [5], radiation doses of the order of a few rads may be associated with an increased incidence of leukaemia and childhood malignancies. It is therefore prudent to keep the foetal doses below these levels and to carry out only such investigations that are imperative during pregnancy. The Commission's recommendation (ICRP Publication 9 [6], paragraph 76) regarding the restriction of radiological examinations for women of reproductive capacity should be taken into consideration for the timing of radionuclide investigations.

5. Children

Investigations of children with radionuclides will ordinarily be restricted to those who will benefit from the investigation. The activities to be administered may be calculated approximately by correcting on a weight basis the activity given to an adult, so that the activity administered per kilogram of body weight is comparable. This presumes that the fractional uptake in organs will be similar in children and adults. This will apply for most organs and to most ages of children except for the newborn and children under about one year. In these latter cases, the organ size in relation to the whole body and its uptake must also be considered, as these may be considerably different from those in later childhood. It should be noted that the uptake of bone-seeking nuclides, particularly the alkaline earths, is greater in the growing bone of children than in adult bone. In general, the doses to the organs should be of the same order as (or, if possible, less than) those received by adults during the same investigation. Particular care is required to ensure that the radiation dose received by the gonads is as low as possible, in

view of the subsequent child-expectancy of the children.

6. Normal Controls

A requirement for the interpretation of all clinical investigations designed to detect abnormality is that measurements are obtained in subjects who are known to be normal in the relevant respect, in order to establish what are the normal results of the test and their range of variation. This is equally true for investigations involving radionuclides, and hence there is a need for investigations on matched control individuals who may not themselves benefit from the investigation. For investigations in which the standard deviation within normals is small, such volunteer groups can ordinarily be limited to a small number, say 6–10 individuals. The purpose and exact nature of the investigation and the possible hazards should be explained to them before obtaining their consent. The investigations should then be carried out with the minimum activity consistent with obtaining the required information.

The source of such control groups may be individuals attending hospital for other purposes, but if so care must be taken that they are normal in regard to the particular response that is under investigation, which may not be the case if the patients are suffering from another disease. Alternatively, they may be relatives of the patient or members of the general public. There should be reluctance shown in the use of other members of staff or of other groups (such as medical students) if they feel under some obligation to volunteer, and also because they are liable to be used in this capacity by a number of workers independently, without regard to the total dose received by the volunteers.

7. Repeat Investigations

After an investigation has enabled a diagnosis to be made, it is often desirable to test the efficacy of treatment by carrying out a repeat investigation. Similarly, it is sometimes important to carry out serial tests. The overall dose received during each series of tests should be considered, rather than the dose in any one investigation. The use of short-lived nuclides often facilitates serial tests being carried out without the build-up of background activity in the body, which, under some circumstances, necessitates the use of higher activities in the later investigations of the series.

It is inappropriate to specify the number of repeat investigations which should be carried out, because the clinical needs of the patient are of paramount importance. The essential guiding rule is that unnecessary repeat investigations should be avoided.

8. The Use of Blocking Agents

The use of blocking agents (see section B.4), where they are available, should always be considered before administering a radioactive nuclide. An estimate must, however, be made of the dose to the organ which then is likely to receive the maximum dose.

F. Notes on Further Metabolic Information Required for Dosimetry

Besides the information required from the investigation itself, the use of radionuclides and labelled compounds in patients can yield additional scientific knowledge, which can be of great value in assessing the tissue doses involved. Such information, which would be of great importance in the proper use of such tests and to the Commission, may be obtained if investigators, whenever appropriate, secure the maximum information practicable from any investigation, and if this information is subsequently published. The particular data which are not readily available, even though many patients have been investigated over short periods, are the fractional long-term retention of nuclides and labelled compounds, especially those labelled with carbon 14 and tritium and the data on the turnover of

particular substances and metabolites. Also, the fraction of orally administered compounds that are absorbed across the gastrointestinal tract is required for normal individuals and for those having particular diseases or surgical resections involving the gastrointestinal tract. Further information on the distribution of radionuclides within organs on the macroscopic and cellular scale is also of great interest. It is only by the collection of more data on the physiological parameters of the metabolism of these compounds and pharmaceuticals that more accurate estimates of the radiation dose to organs, and of its variations in different clinical conditions, may be made.

G. Tabulation of Data

The data tabulated in the last section of this report have been arranged so that each nuclide is dealt with separately. For each nuclide the data are separated according to the different routes of administration and to the different compounds and pharmaceuticals used. For each particular mode of administration the dose received by the principal organs or tissues is given in terms of the dose per unit of activity—usually expressed in millirad per microcurie. The typical activity used in the investigations is usually given where the investigation is in regular use. This statement should not be interpreted as a recommendation of the optimal activity to be administered, but as that which has been found generally necessary in the past. As the sensitivity of detecting systems improves, it should be possible to reduce these activities, in some cases considerably. For the particular subjects in categories (b), (c) and (d) in section E.1 it will be desirable to reduce the activities administered.

The source of the dose calculations has principally been the open literature, amplified, where necessary, by calculations by the compiler, and by reference to calculations submitted by various workers to the Medical Research Council of the United Kingdom. Their contributions to this work are gratefully acknowledged. Not all the calculations published have been included, for many have been calculated from the same physiological factors; however, a range of values has been included where these exist. It has not been possible to give the physiological data used in each calculation, as these are frequently not included in the publication. It has been assumed that the workers in the field had chosen what they considered were the most appropriate factors.

Where particular physiological data are available, which are not considered to be well known, they have been included in the text.

References to papers containing pertinent dosimetric or physiological data have been given for most nuclides. Again, it has not been the aim to give a bibliography of all references on a particular investigation, and reference may be made to the Nuclear Medicine lists published by the International Atomic Energy Agency and to such sources as Excerpta Medica for such comprehensive bibliographies. During the preparation of this report similar tabulations of data have been compiled in Sweden [7] and in the U.S.A. [8].

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8. Hine, G. J. and Johnston, R. E. *J. nucl. Med.* 1970, **11,** 468.

Arsenic 74 — ^{74}As

Oral

Organ	mrad/μCi	References
GI tract	38	1
Kidney	0.43	1

Intravenous

Typical 1–2 mCi/test.

Organ	mrad/μCi	References
Kidney	14	1
	6	2
Liver	8.4	1

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1. Vennart, J. and Minski, M.: *Br. J. Radiol.* 1962, **35**, 372.
2. Vennart, J.: PIRC 180(a) of Medical Research Council, U.K. Abstracted from the literature.

Arsenic 76 — ^{76}As

Oral

Organ	mrad/μCi	Reference
Kidney	0.09	1

Intravenous ^{76}As

Organ	mrad/μCi	References
Kidney	3	1
	3.2	2

References

1. Vennart, J. and Minski, M.: *Br. J. Radiol.* 1962, **35**, 372.
2. Kniseley, R. M., Andrews, G. A. and Harris, C. C.: Editors of *Progress in Medical Isotope Scanning*, Oak Ridge Institute of Nuclear Studies, Tennessee, U.S.A. (TID 7673, 1963), page 375.

Gold 198 ^{198}Au

Oral

Organ	mrad/μCi	Reference
Kidney	0.82	1

Intravenous

Organ	mrad/μCi	Reference
Kidney	8.2	1

Gold 198 Colloid **^{198}Au**

Intravenous

Typical 150 μCi/test.

Organ	mrad/μCi	References
Liver	41	2
	44	3
	38	4
	27	5
	40	6
Spleen	37	7
	48	6
Average whole body	1.7	7
Male gonad	0.11	6
Female gonad	0.25	6

Variation of Organ Dose with Age

Organ	Age	mrad/μCi	References	mrad/μCi	References
Liver	Newborn	490	8	380	9
	1 yr	200	8	160	9
	5 yr	120	8	90	9
	10 yr	80	8	70	9
	15 yr	50	8	40	9
	Adult	40	8	30	9
Spleen	Newborn	490	8		
	1 yr	200	8		
	5 yr	120	8		
	10 yr	80	8		
	15 yr	50	8		
	Adult	40	8		

Other Methods of Administration

Treatment Knee Effusions

Typical: Up to 10 mCi. Surface area *circa* 140 cm^2 (refs. 10, 11, 12).
Dose at 1 mm depth 70 rad/μCi deposited over 1 cm^2
Dose at 2 mm depth 0.7 rad/μCi deposited over 1 cm^2
} Deduced from ref. 13.