EO-15

Safety Assessment For The Control Of Medical And Industrial Sources

1.0 Introduction

The hazards associated with nuclear power generation are well publicised through media coverage of accidents such as that at Three Mile Island in 1979, or that which occurred at Chernobyl in 1986 and by various studies which have focussed on reactor safety. As a result, the need to pay close detailed attention to controlling the risks associated with the operation of nuclear power plants is widely recognised. Radioactive waste disposal sites present somewhat different, but no less important radiological and environmental challenges. In all of these areas, the need to ensure that the safety of the worker, the public and the environment is maintained at a level consistent with societal expectation, is a constant challenge.

However, outside of the nuclear fuel cycle, there are other radiation sources existing in industry and medicine and it must be ensured that sight is not lost of the need to control the risks presented to the worker, public and the environment resulting from their use.

Regulation of the industry which uses radiation is the responsibility of the regulator. A comprehensive regulatory framework is necessary to ensure that a consistent approach is applied to the regulation of sources and that the level of hazard posed by a source is not disproportionate to the effort required to regulate it. The central feature in this is a process known as safety assessment. The first part of this document is intended to describe how safety assessment fits into the regulatory process. The second part provides some information on the elements of a safety assessment and also provides an example.

Part 1

2.0 What Is Safety Assessment ?

The Basic Safety Standards (BSS) of the International Atomic Energy Agency [1] establishes the basic requirements for protection against risks associated with exposure to ionising radiation and for the safety of radiation sources that may deliver such exposure. Safety assessment is defined in the BSS as;

"A review of the aspects of design and operation of a source which are relevant to the protection of persons or the safety of the source, including the analysis of the provisions for safety and protection established in the design and operation of the source and the analysis of risks associated with normal conditions and accident situations ."

Furthermore, in the context of verification of safety, the BSS states that ;

"Safety assessments related to protection and safety measures for sources within practices shall be made at different stages, including siting, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning, as appropriate, in order:

a) to identify the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment;

b) to determine the expected magnitudes of normal exposures and, to the extent reasonable and practicable, to estimate the probabilities and the magnitudes of potential exposures; and

c) to assess the quality and extent of the protection and safety provisions."

The assessment of the level of safety in the design and operation of a source is performed against criteria which are normally specified by the regulatory authority. The detail and scope of this assessment depend very much upon the magnitude and likelihood of the exposures expected from the practice or source under consideration. As an example, nuclear installations and radioactive waste management facilities, including disposal facilities, are typically subject to more stringent regulatory requirements than are, for instance, industrial gamma backscatter gauges. In the former case, a full safety assessment will normally be required by the regulatory authority. However, in the case of certain medical and industrial sources, a full safety assessment is not required because the magnitude and likelihood of the exposures expected from the source do not justify it.

It therefore makes sense to require that the extent of regulatory review be commensurate with the level of hazard presented by the source. The next section discusses how the "generic" regulatory process makes allowance for this.

3.0 Safety Assessment And The Regulatory Process

The BSS defines requirements which must be met for *practices* and *interventions*. A *practice* is defined in the BSS as;

"any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed".

For a practice, provisions for radiation protection and safety can be made before its commencement, and the associated radiation exposures and their likelihood can be restricted from the outset. In the case of intervention, the circumstances giving rise to exposure or the likelihood of exposure already exist, and their reduction can only be achieved by means of remedial or protective actions in the form of an Intervention. The following discussions refer to the application of safety assessment to practices.

One of the basic obligations of the BSS relating to the requirements for practices requires that ;

> *(2.7) No practice shall be adopted, introduced, conducted, discontinued or ceased and no source within a practice shall, as applicable, be mined, milled, processed, designed, manufactured, constructed, assembled, acquired, imported, exported, distributed, sold, loaned, hired, received, sited, located, commissioned, possessed, used, operated, maintained, repaired, transferred, decommissioned, disassembled, transported, stored or disposed of, except in accordance with the appropriate requirements of the Standards, unless the exposure from such practice or source is excluded from the Standards or the practice or source is exempted from the requirements of the Standards, including the requirements of* ***notification and authorisation****.*
>
> *(2.8.) The application of the requirements of the Standards to any practice or any source within a practice or to any of the actions specified in para. 2.7 shall be commensurate with the characteristics of the practice or source and with the magnitude and likelihood of the exposure and shall also conform to any requirements by the regulatory authority or, whenever applicable, by the relevant Sponsoring Organizations. Not all the requirements are relevant for every practice or source nor for all the actions specified in para. 2.7.*

These paragraphs introduce the requirements for notification and authorisation and also indicate that there are exposures which are excluded, and sources which are exempted from the requirements of the BSS. It is worth spending some time to define what these terms mean and how the generic regulatory process makes allowance for them. The generic regulatory process is depicted in Figure 1.

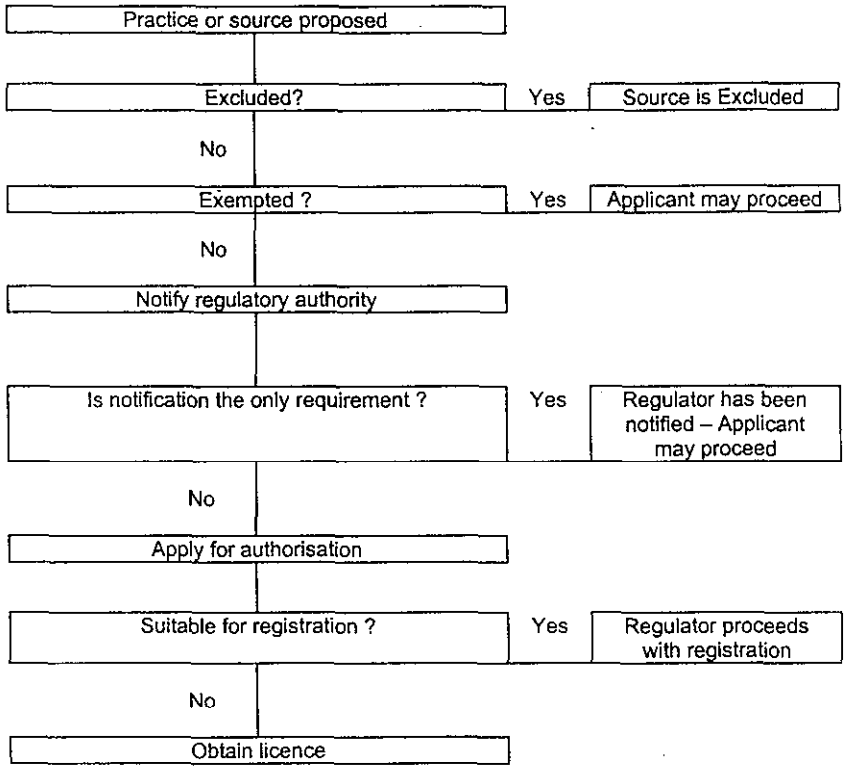


Figure 1 – The Generic Regulatory Process

3.1 Exclusion

Any exposure whose magnitude or likelihood is essentially unamenable to control through the requirements of the BSS is deemed to be excluded from the Standards. Examples of this are ^{40}K in the body or cosmic radiation at the surface of the earth and from unmodified concentrations of radionuclides in most raw materials.

3.2 Exemption

Practices and sources within practices may be exempted from the requirements of the Standards, including those for notification, registration or licensing, if the Regulatory Authority is satisfied that the sources meet the exemption criteria or the exemption levels specified in this Schedule or other exemption levels specified by the Regulatory Authority on the basis of these exemption criteria. Exemption should not be granted to permit practices that would otherwise not be justified.

The general principles for exemption are that:

(a) the radiation risks to individuals caused by the exempted practice or source be sufficiently low as to be of no regulatory concern;

(b) the collective radiological impact of the exempted practice or source be sufficiently low as not to warrant regulatory control under the prevailing circumstances; and

(c) the exempted practices and sources be inherently safe, with no appreciable likelihood of scenarios that could lead to a failure to meet the criteria in (a) and (b).

A practice or a source within a practice may be exempted without further consideration provided that the following criteria are met in all feasible situations:

(a) the effective dose expected to be incurred by any member of the public due to the exempted practice or source is of the order of 10 μSv or less in a year, and

(b) either the collective effective dose committed by one year of performance of the practice is no more than about 1 man.Sv or an assessment for the optimisation of protection shows that exemption is the optimum option.

An assessment is therefore required to determine the levels of activity and specific activity of radionuclides for which these criteria are satisfied under exposure conditions that are considered to be "feasible". The regulatory authority would normally publish a list of exempt radionuclide activities and specific activities and/or a list of sources which would qualify for exemption.

3.3 Notification

With regard to notification, the BSS states the following;

> *"2.10 Any legal person intending to carry out any of the actions specified under the General Obligations for practices of the Standards (see paras 2.7 and 2.8) shall submit a notification to the Regulatory Authority of such an intention]. Notification for consumer products is required only with respect to manufacturing, assembling, importing and distributing.'*
>
> *Notification alone is sufficient provided that the normal exposures associated with the practice or action are unlikely to exceed a small fraction, specified by the regulatory authority, of the relevant limits, and that the likelihood and expected amount of potential exposure and any other detrimental consequence are negligible.*

Even though notification is applied to those sources which present the lowest order of risk or complexity, it can still provide useful information ;

- In situations where a regulatory authority is in an organisational phase and does not know who is in possession of sources, the first step would be to identify users and what they possess prior to the initiation of an authorisation programme.
- To obtain data about distribution, volume and patterns of use and disposal prior to making a decision about granting an exemption for certain types of sources.
- To obtain information about those who own but do not take physical possession of sources

3.2 Authorisation

Authorisation can take the form of either registration or licensing.

3.2.1 Registration

Registration can be a relatively simple and efficient authorisation mechanism if certain criteria for its use can be met. These criteria are that;

- Radiation safety can largely be ensured by the design of facilities and equipment;
- Operating procedures are simple to follow;
- Radiation safety training requirements are minimal;
- Operations within a practice do not vary significantly among users;
- There is a history of few safety problems with operations;
- The number of users within the practice is large

There are two approaches to the organisation and operation of a registration system. The first is for the regulatory authority to establish in its regulations and advice, the safety requirements concerning the design of facilities and equipment, operating procedures, quality assurance etc. which must be met as a precondition for registration, and the safety requirements to be imposed on each registrant. The second approach is for the regulatory authority to conduct a pre-registration, one-time, "generic" safety assessment of a particular design of facilities and equipment as well as the related operating procedures, maintenance requirements, training requirements etc. as provided by a manufacturer or supplier.

In either case, a safety assessment is necessary since the basis for the specification of safety requirements concerning the design of facilities and equipment, operating procedures, quality assurance etc. which must be met as a precondition for registration, can only be generated by performing such an assessment.

Once the safety requirements have been distilled from the safety assessment, the registrant needs only to submit the minimum necessary information to the regulatory authority to satisfy these requirements. Approval of an application for registration then becomes mainly an administrative task with little technical judgement required.

3.2.2 Licensing

Licensing is required for all practices not otherwise designated by the regulatory authority as suitable for the simpler processes of notification and registration. In particular, licensing should be required for the higher risk, more complex practices, including those where protection depends largely on human performance as, for example, medical applications and industrial radiography. The licensing process requires that each person proposing to use sources within a practice submit an application containing detailed information related to the proposed use of the source and the radiation protection and source safety provisions, as well as an assessment of the nature, magnitude and likelihood of the exposures attributed to the source. The regulatory authority then evaluates the application to determine that the applicant, and the manner in which the sources are to be used, are likely to comply with the applicable regulations and requirements. When issued, the licence grants authority to use sources for specific purposes under conditions which are derived from the safety assessment.

In general, licensing is a more resource intensive process than is registration because it requires a case-by-case evaluation of each proposed use within a practice.

4.0 Regulatory Criteria

As stated in section 2.0, certain safety criteria are specified by the regulator. The intended operator of the source, known as the applicant, must submit a safety assessment to the regulator which demonstrates that the source design and operation is in compliance with the regulatory criteria.

With the exception of sources used in medical exposure, criteria are specified for those who are occupationally exposed (the workers) and members of the public. Although these will be subject to some variation between countries, they will take the general form as depicted in Figure 2.

Figure 2 makes reference to two exposure circumstances. The first, which is known as normal operational exposure, is defined as exposure which is expected to be received under normal operating conditions of a source, including possible minor mishaps that can be kept under control. The second is described as potential exposure, which is defined as exposure that is not expected to be delivered with certainty but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors. In quantitative terms, the dividing line between normal operational and potential exposure is difficult to discern but the ICRP has offered some guidance in Publication 64 [2]. This guidance indicates that the annual frequency of sequences of events that lead to exposures which may be treated as part of normal exposures, is in the range 10^{-1} to 10^{-2}.

	Normal Operational Exposure Conditions	Potential Exposure Conditions
Operator	**Criterion** Annual dose Limit to the operator and requirement for ALARA Defence-in depth principle to be applied Safety assessment performed in terms of both system/layout design and operational Radiation Protection programme	**Criterion** Nominated risk limit and ALARA requirement Safety assessment performed by identification of events which could lead to exposure, determining the event frequency, consequence, and risk, and comparing to limit
Member Of The Public	**Criterion** Annual dose Limit to members of the public and requirement for ALARA Defence-in depth principle to be applied Safety analysis performed in terms of both system/layout design and operational Radiological Effluent And Waste Management programme	**Criterion** Nominated risk limit and ALARA requirement Safety assessment performed by identification of events which could lead to exposure, determining the event frequency, consequence, and risk, and comparing to limit
	Dose Limits Apply Deterministic Analysis Event Frequency $\geq 10^{-2}$ a^{-1}	Risk Limits Apply Probabilistic Analysis Event Frequency $\leq 10^{-2}$ a^{-1}

Figure 2
The Regulatory Criteria For Occupationally Exposed Persons And Members Of The Public

In the domain of medical exposure, it is also important to consider two other things. Firstly, dose limits do not play a part in the exposure of the patient, although there may be generic recommendations regarding doses to patients as a result of, for instance, certain diagnostic treatments. Secondly, there are additional criteria to those for protection of the public and the occupationally exposed group;

> Medical exposures should be justified by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.
>
> The dose limits applicable to comforters of patients, i.e., to individuals knowingly exposed while voluntarily helping (other than in their employment or occupation) in the care, support and comfort of patients undergoing medical diagnosis or treatment, or to visitors of such patients are as follows;

the dose of any such comforter or visitor of patients shall be constrained so that it is unlikely that his or her dose will exceed 5 mSv during the period of a patient's diagnostic examination or treatment.

The dose to children visiting patients who have ingested radioactive materials should be similarly constrained to less than 1 mSv.

5.0 Safety Assessment

The role of safety assessment in the regulatory process has already been discussed. It provides a formalised methodology for the judgement of the level of safety in the design and operation of a radiation source. Safety assessment conducted in terms of a practice, at the design stage of a source will also provide a basis for the establishment of the operational programs. It can also aid as a technique to evaluate the safety of proposed modifications to already operational equipment or procedures. It is sometimes convenient to design the structure of the safety assessment around the regulatory criteria introduced in the previous section.

5.1 Normal Operational Exposure

For normal exposure circumstances, which may be applicable to either those who are occupationally exposed or members of the public, the safety assessment must demonstrate that the design of the source and its operation are in compliance with the regulatory criteria. The performance of the source is analysed using deterministic and usually conservative analysis. This requires the selection of a safety limit which includes some margin added in for conservatism. Such deterministic analyses are characterised by rigidly specified (design basis) scenarios where the safety limit is chosen with a view to ensuring that the likelihood of exceeding it is small.

The regulatory criteria for normal operational conditions are expressed in terms of the quantity effective dose (hereafter called "dose"). Dose limits are applied to the workers and to members of the public in order to limit their risk as a result of exposure. However, it would be impossible to predict the annual dose associated with any identified worker or member of the public because of the uncertainty in the many parameters which must be known to do this. The provision of either good radiological engineering design in, for instance, the shielding or indeed good design of the operational radiation protection programme are not good enough on their own to ensure confidence that compliance with the annual dose limits and the ALARA principle can be achieved.

There must be good radiological engineering design in both the systems of the process and in the layout of the facility, which provide a quantitative basis upon which to establish the many tiers of the operational radiation protection programme. Defence-in-depth is thus built into the system.

In some facilities, there is a tendency to place more emphasis on reactive control of doses by instituting corrective action once a problem has been identified, rather than attempting to identify and solve the problem at the design stage by safety assessment techniques. By so doing, the importance of reviewing the impact on safety of modifications to either the engineering or to operating procedures is diminished and could lead to a situation where the safety assessment is eventually forgotten. Better control of safety can be achieved by establishing good radiological engineering design and superimposing a robust radiation protection programme upon it. Defence-in-depth is then achieved which should result in safety which does not rely on only one layer of protection.

The success of the operational radiation protection programme relies upon ;

- the application of good radiological design principles to the engineering (systems and layout)
- good symmetry between the operational radiation protection programme and the radiological design.
- A robust system of on-going modification review to ensure that the safety impact of operation has been quantified and is within the relevant criteria.

Therefore, in the assessment of risk resulting from normal operation two aspects should be addressed ;

- the radiological safety assessment of the engineering
- the design of the radiation protection programme (whether it be operational radiation protection programme affecting the protection of the worker or the waste management programme affecting members of the public)

In judging the level of safety of a facility, the safety analysis process in respect of normal operation is usually an iterative one which includes the following steps;

- The construction of a scenario intended to represent the design
- The assessment of the resulting dose
- Comparison with the acceptance (design) criterion
- Optimisation of protection (iteration of the above steps)

5.2 Potential Exposure

Potential exposure is not expected to be delivered with certainty but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors. The regulatory criteria for potential exposure events are specified in terms of the quantity risk (where risk refers to the risk of mortality following exposure), rather than dose. In simplistic terms, risk is calculated as the product of the absorbed dose, the probability of death following exposure at that absorbed dose, and the probability of the event which leads to the absorbed dose. It is therefore a central feature of risk assessment to estimate the probability of events which lead to such exposures. Probabilistic methods are available for the estimation of probability of such events and these are briefly discussed later. It is important to note that there are two types of effect which could, in principle, contribute to the total mortality risk following exposure of an individual. These are stochastic effects and deterministic effects.

Stochastic effects include cancers in the irradiated individual and hereditary effects in the progeny of exposed individuals. It is the probability of the stochastic effect which varies as a linear function of dose and this is assumed to have no threshold.

Deterministic effects occur in organs that are irradiated to such an extent that organ function is impaired due to the number of cells affected by the exposure. If the organ is vital and the dose is sufficiently high, the end result will be death. The probability of causing harm will be zero at doses up to about 1 Gy, depending upon the organ or tissue, and will then increase steeply to unity (or 100% probability of death) above some level of dose called the threshold for the clinical effect. Risk models are available to determine the mortality risk to an individual following irradiation of the lung, gastro-intestinal tract and the red bone marrow.

As in the case for the safety analysis process for normal operation, the process in respect of potential exposure is also an iterative one which includes a different routine;

- The construction of scenarios intended to represent the sequence of events leading to exposures
- The assessment of the probability of each sequence
- The assessment of the resulting dose
- The evaluation of the detriment associated with that dose
- Comparison with the acceptance criterion
- Optimisation of protection (iteration of the above steps)

More information is provided on this subject in the section on potential exposure.

6.0 Derivation Of Conditions Of Authorisation

Provided the applicant can demonstrate compliance with the regulatory criteria, an authorisation will then be granted but this will be subject to certain conditions. Most of these conditions should be traceable to the safety assessment. For instance, in the case of normal operational exposure of workers, a programme of pro-active dose prediction, measurement, assessment, and feedback may be referenced in the safety assessment in order to monitor the accrual of worker doses and thereby prevent any worker from encroaching on the limit. Provided the Regulatory Authority finds the detail of how this is done acceptable, this will then become a condition of the authorisation. Another example is the required reliability associated with a pump which has been assessed using probabilistic techniques. The study may demonstrate that this reliability can be achieved if maintenance of a defined scope is carried out once every 18 months with replacement of the bearing every 5 years. This would again be subject to a condition in the authorisation as part of the maintenance programme.

It is important to note, however, that there are some areas which are not and cannot be related to the safety assessment in a quantitative way. For these issues, provision in the conditions of authorisation are made on the basis of experience in regulation. One such issue is the rise in profile of the requirement for safety culture. Although confidence can be invested in the regulatory requirement for strategy of provisions in order to achieve adequate safety culture, no guarantee can be given that the conditions of authorisation will always be applied. Eternal vigilance is therefore necessary by both the Regulatory Authority and the operator to ensure ongoing compliance.

An example of conditions of authorisation which cover all aspects is given in Appendix 1 for information.

8.0 Compliance Assurance

Having identified all of the issues important to safety, it is necessary to ensure that the operator continues to comply with the conditions of authorisation. Safety culture demands that the operator accept most of the responsibility in doing this. However, some form of independent check must be made periodically by the Regulatory Authority to ensure that the conclusions of the operator compliance assurance programme are valid. This involves the preparation of safety assessment plans which should be derived from the safety assessment to ensure that the regulatory requirements important to protection and safety will be considered. In order to optimise resources, the operator is encouraged to develop performance indicators which provide rapid indication of the non-compliance in various areas.

Finally, a system of event and occurrence reporting is required to be in place as a condition of authorisation. This system requires the operator to report a range of events, which extend from those of insignificant actual consequence/major potential consequence to those whose actual consequence is significant, to the regulatory authority in accordance with a timescale which is commensurate with the safety significance.

Part 2

9.0 Detail Of The Radiological Safety Assessment

The regulatory criteria upon which the safety assessment should be structured has already been introduced in section 4. The purpose of this section will be to discuss how compliance with each of these criteria can be demonstrated in the safety assessment of a selected source in the medical and industrial domain.

In some cases, guidelines and codes of practice stipulate certain requirements which are designed to provide adequate protection and ensure compliance with the regulatory criteria. The applicant would be required to demonstrate compliance with these requirements rather than perform a safety assessment of the source. This approach has already been discussed in section 3 relating to the process of registration of sources. However, this approach is also used fairly commonly in the field of medical and industrial sources where the sources pose sufficient hazard to be regarded as candidates for licensing.

As noted in the generic regulatory process, the applicant will be responsible for the preparation of a safety assessment and the regulator will be responsible for its review. It is inevitable that a standard safety assessment process cannot be applied to all sources since some assessments are relatively simple to perform due to the source design and operational procedures whereas others are more complicated and require complex analysis procedures.

The following provides an example of the two areas of assessment which should be examined. The first is that of normal operation which could affect both the operator and members of the public. This section is written with the example of an X-ray facility in mind so that it will not provide a comprehensive list of aspects which may need to be addressed for another type of source. For instance, there are no considerations of surface contamination or airborne contamination. The second area of assessment which is examined is that of potential exposure. In this section, the principles of risk assessment are explained and a very simple example of a risk assessment calculation is given.

Before any discussion on safety assessment begins, it is necessary to describe the process to be assessed. That means an introduction to the process which generates the X-rays – the process which must be assessed. It is therefore necessary to spend some time on describing the process and the variables which have some bearing on the quality of the result.

9.1 Safety Assessment In X-Ray Diagnosis

9.1.1 Description Of The Process

9.1.1.1 The X-ray Generation Process

The process description shall be limited to a discussion of the main features of the process of generation of X-rays. The process of X-ray generation occurs when electrons generated by a heated wire cathode filament are then accelerated towards the anode or target by the application of a high voltage across the electrodes. The target is commonly composed of tungsten or tungsten set in copper which brings the electron to rest abruptly with the subsequent emission of X-rays. If the spectrum of X-rays is analysed, it will be found to constitute

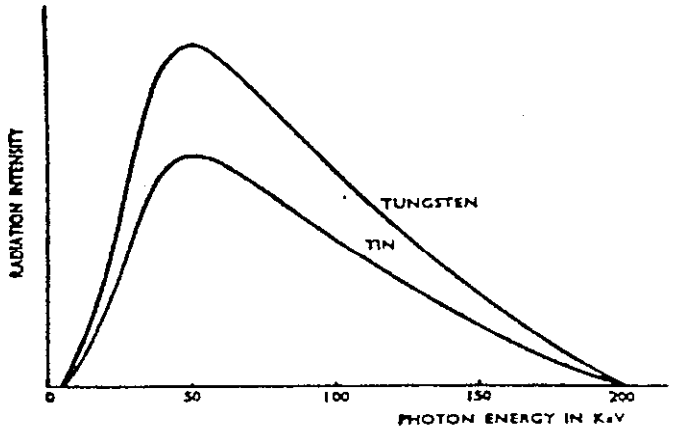
- a continuous spectrum of energies up to some maximum energy
  - the continuous spectrum results from interactions between accelerated electrons and the electron cloud around the target atoms and also the coulomb field of the nucleus. As an accelerated electron approaches an atom, there will be repulsion between its negative charge and the negative charges of the electrons in the cloud around the atom. There is a probability, which increases with electron energy, of an accelerated electron penetrating into the coulomb field of the nucleus. The accelerated electrons will therefore be slowed down and deflected and the energy lost will appear either as heat or X-rays. It is noteworthy that for most X-ray applications, it is the continuous spectrum which is of interest since it contributes about 90% of the X-ray output or doserate from the X-ray beam.

- a characteristic spectrum
  - whereas the continuous spectrum arises from interaction between the accelerated electrons and the whole electron cloud of the target atom, the characteristic spectrum results from interaction with individual electrons in the cloud. The immediate result of the interaction is the ejection of the orbital electron. The vacancy formed in the electron shell is quickly filled by an electron from an another shall and the appropriate X-ray photon is emitted which is characteristic of the target material.

The distinction between the two spectra is illustrated in Figure 3.

It is important to realise that the X-ray beam can be affected by various factors to influence the either the X-ray output (the doserate in the beam) or the beam quality (shape of the energy spectrum), or both.

(i)



(ii)

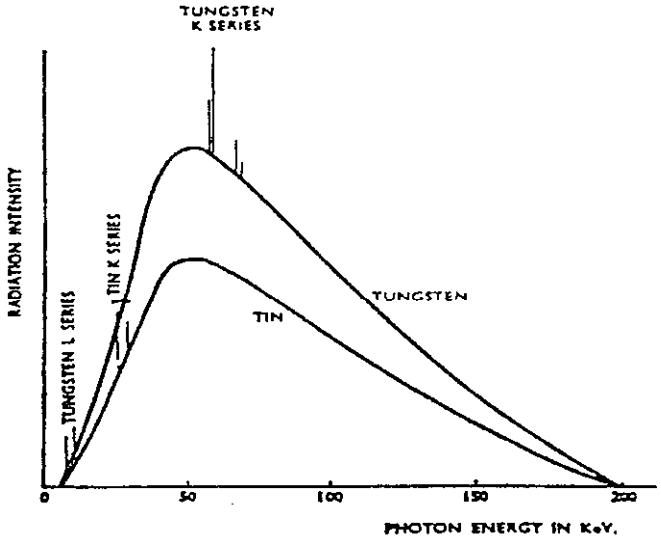


Figure 3 X-ray Spectra With Tungsten and tin targets at 200 kVp

(i) Shows the continuous spectrum only

(ii) Shows the continuous and the characteristic spectra

9.1.1.2 The Filament

The filament is almost invariably a small coil of fairly thick tungsten wire which is mounted into a shaped slot so as to focus the beam of electrons onto a small focal spot on the anode. It has been found that one single-sized focal spot is not adequate for all purposes of the radiographer. The use of two sizes of focal spots have been found to be a satisfactory compromise which require a broad focus filament and a fine focus filament. The former allows for heat dispersion over a greater area of the anode and therefore a greater output however this is at the expense of image quality because the X-rays no longer originate from a point source. Tungsten is chosen as the filament material due to its high melting point.

9.1.1.3 The Target

In most cases, the anode is composed of tungsten usually set in copper to aid in the dissipation of heat. As pointed out above, the problem of increasing the rating of the tube had led to poorer image quality because of the geometry of the target material area from which the electrons are emitted. This problem has been overcome by the use of techniques to dissipate the heat over a larger area whilst still maintaining an acceptably small focal spot.

Tungsten is most often chosen as the target material due to the need for balance of the need for a high melting point material and maximising of the X-ray output.

The quality of the X-ray beam is independent of the atomic number of the target material for the continuous portion of the X-ray spectrum. For the characteristic part of the spectrum, the energy is dependent upon the nature of the target material and therefore affects the beam quality.

9.1.1.4 Applied Voltage

For a given target material, the maximum photon energy of the X-ray beam and the X-ray output is a function of the peak of the voltage applied across the electrodes. When there is little or no filtration, the output is proportional to the square of the applied voltage.

$$I \propto [kV]^2$$

This is illustrated in Figure ..When there is filtration, the output increases more rapidly than with the square of the voltage – possibly nearer to the cube of the voltage.

The waveform of the applied voltage is also a factor which can influence beam quality and output. The difference in radiation output, as described by the radiation intensity, is illustrated in Figure 4 for the constant and full wave cases.

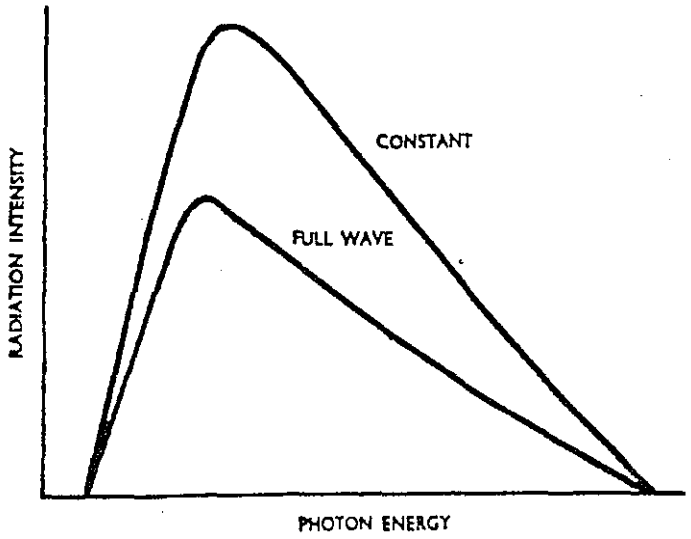


Figure 4
Effect Of Voltage Waveform On The Spectrum

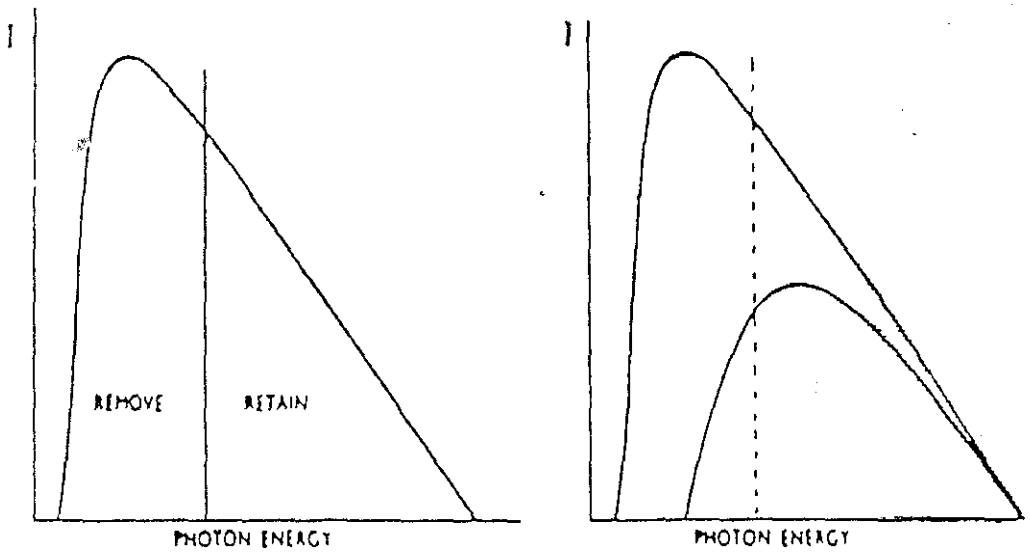
9.1.1.5 Tube Current

The tube current represents the mean flow of electrons within the tube. The X-ray output will be directly proportional to this current and the beam quality will be effectively independent of it.

9.1.1.6 Filtration

The factors mentioned previously have been intrinsic to the mechanism producing the X-rays or to the electrical supply applied to the X-ray tube. The issue of filtration is different in that it is introduced as an external factor to modify the beam quality but which also effects the output. The purpose of filtration is to remove the unwanted lower energy radiation which would be absorbed in the superficial surface layers of the body and either do not reach the organs or tissues of interest, or do not emerge from the far side of the patient and so contribute to the radiograph. These lower energy photons therefore contribute patient dose without any additional benefit. It is therefore clearly desirable to reduce this component to a minimum.

Some filtration is provided by the inherent filtration of the tube itself whilst, to achieve the optimum situation, some external filtration must be added. In the diagnostic use of X-rays in medicine, the total tube filtration for normal work should not be less than 1.5 to 2.5 mm of aluminium, depending upon the applied voltage. The ideally desirable and practically attainable situations are illustrated in Figure 5.



(a) The ideally desirable

(b) The practically attainable

Figure 5
The Effect Of Filtration

The choice of proper filtration must be made with an understanding of how it will affect the X-ray beam. In this regard, the following principles are important;

- The material chosen must attenuate principally by means of the photoelectric effect in the photon energy range being dealt with in order to discriminate against lower energy photons.
- The materials should not have an absorption edge at an energy close to the energies of the photons that it is desired to use.
- Filters should not be too thin otherwise non-uniformity in thickness will create problems.

9.1.1.7 Summary Of The Process Description

At this point, it should be evident that all associated procedures, whether operational, quality assurance or maintenance etc., will not involve the *consideration of radioactive contamination control because no radioactive* contamination is produced. Therefore no consideration of internal dose assessment is necessary either. The safety assessment must therefore focus on aspects relating to protection against external dose.

In this regard, the strength of the source or the X-ray output is primarily determined by ;

- the maximum kilovoltage at which the X-ray tube is operated
- the maximum milliamperes of beam current
- the atomic number of the anode or target material

The output is also dependent upon the wave form of the applied voltage and is reduced by the total tube filtration.

The beam quality is determined by;

- the maximum applied kilovoltage
- the total beam filtration
- wave form of the applied voltage

From this review of the procedure and process, it is evident that the safety assessment should focus on the following;

Measures to ensure that adequate shielding is provided in the design of the equipment to ensure that radiologist external dose is kept below dose limits and is ALARA during operation.

Measures to ensure that adequate shielding is provided in the design of *the facility to ensure that external dose to members of the public is kept* below dose limits and is ALARA.

Measures to ensure that the radiologist cannot be exposed unwittingly to *the useful x-ray beam*

Measures to ensure that the exposure of the patient is justified and optimised

All of these requirements can be related to the regulatory criteria specified in section 4. The equipment/facility design and the design of the operational programmes will be addressed separately.

9.1.2 Assessment For Conditions Of Normal Operation

9.1.2.1 Engineering Design

9.1.2.1.1 Protection Of The Operator (Radiologist)

In design of x-ray equipment, the dose to the radiologist is constrained by imposing limits on the amount of allowed radiation doserate. In the design of X-ray facilities, it is common to refer to the shielding as either associated with the X-ray equipment itself, such as the shielding provided by the tube housing or that which is associated with the facility in which the equipment is situated, where the shielding is known as either primary or secondary.

A distinction is also made between radiation transmitted through shielding and that which is scattered. In the former case, the transmission through the shield results in spectrum hardening where the lower energy photons are attenuated out of the beam. The result is a spectrum which is rather more biased towards the higher energies of the original unattenuated spectrum. In the latter case, the scattered component is degraded in energy relative to the original spectrum due to the scattering interaction.

9.1.2.1.1.1 The Tube Housing

The objective in terms of shielding provided by the X-ray tube housing is to limit the doserate at 1m from the anode to 1 mSv h^{-1} (see Figure 8 position T). The required thickness of shielding can be determined from graphs in the same way as the thickness of primary shielding can be determined as set out below.

Demonstration that the doserate objective is attainable can be achieved by acceptance testing at the user end. The generality in the design of such equipment is amenable to the establishment of guidelines for the practice.

9.1.2.1.1.2 Primary Shielding

The equipment or facilities should be designed to meet a level which is stipulated by the safety authorities. In the UK, for example, this can be between 7.5 and 2.5 μSv h^{-1}. The upper level of 7.5 μSv h^{-1} translates to an annual dose of 15 mSv for a working year of 2000 hours (implying 100% occupancy). This implies that the area must be classified as a controlled area and persons who are allowed access to such areas must be classified as occupationally exposed because the potential exists to exceed an annual effective dose 6 mSv. If the lower figure of 2.5 μSv h^{-1} is selected as the objective against which the shielding is designed, then the area can be classified as supervised.

Take for example, the case where the primary shielding barrier thickness is required for a 250 kVcp, 10mA set with 0.5 mm of copper total filtration in order to reduce the doserate at point P in Figure to 7.5 μSv h^{-1}. Assuming the distance from the anode to the barrier is 1m ;

An X-ray output of 250 kVcp provides a doserate of 18.5 mSv $minute^{-1}$ mA^{-1} (from Figure 6)

If the output is 10 mA, then the doserate provided is 185 mSv $minute^{-1}$ at a distance of 1m from the anode, or at the inside wall of the barrier.

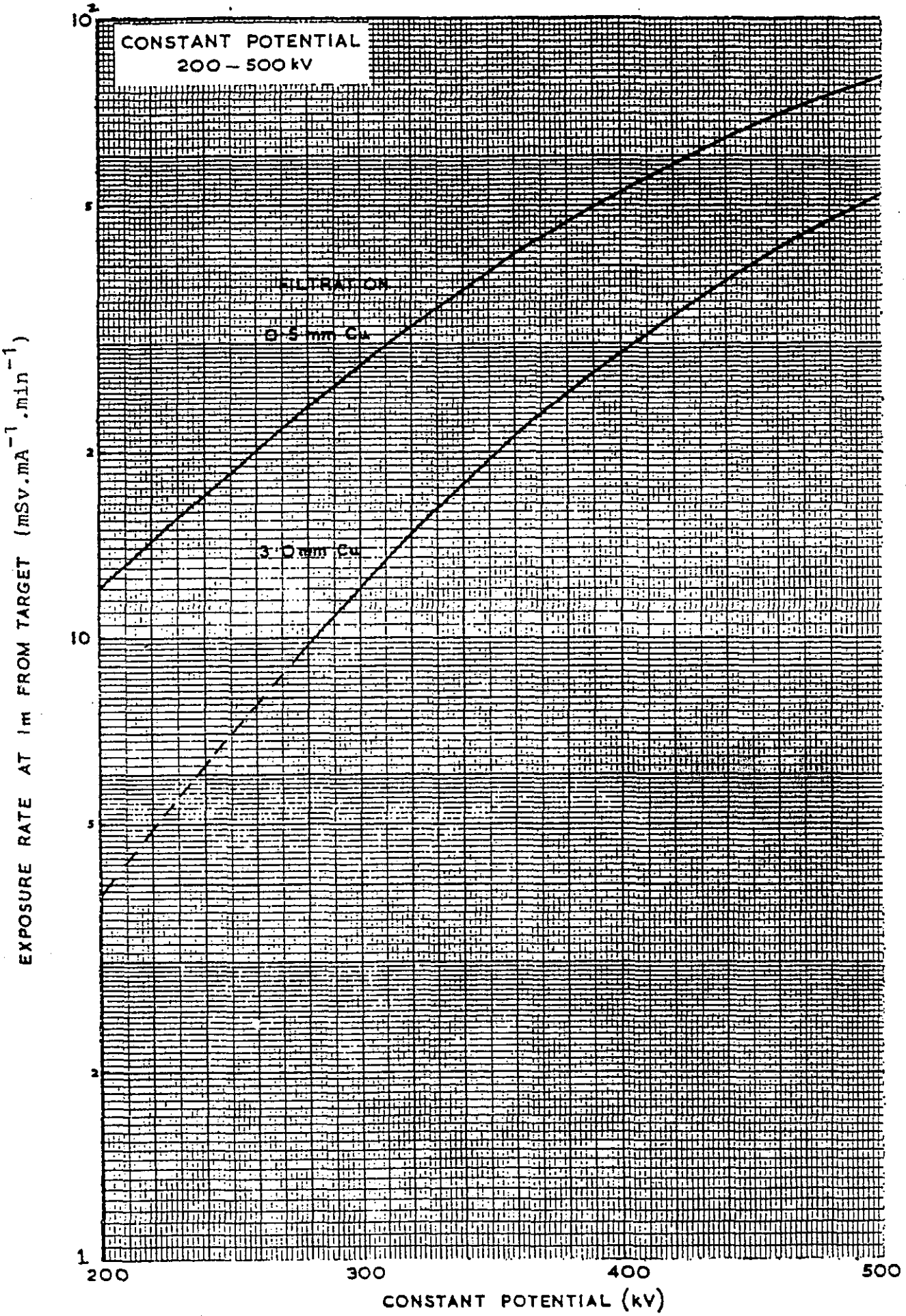
The amount of shielding required can then be determined from the required transmission which is the ratio of the doserate required on the outside of the shield to that on the inside of the shield. In this case, the transmission is ;

$$\frac{7.5 \quad \mu Sv\ h^{-1}}{185 \times 60 \times 10^{3} \quad \mu Sv\ h^{-1}} \text{ or } 6 \times 10^{-7}$$

From Figure 7, a thickness of about 55 cm of concrete would provide the required shielding.

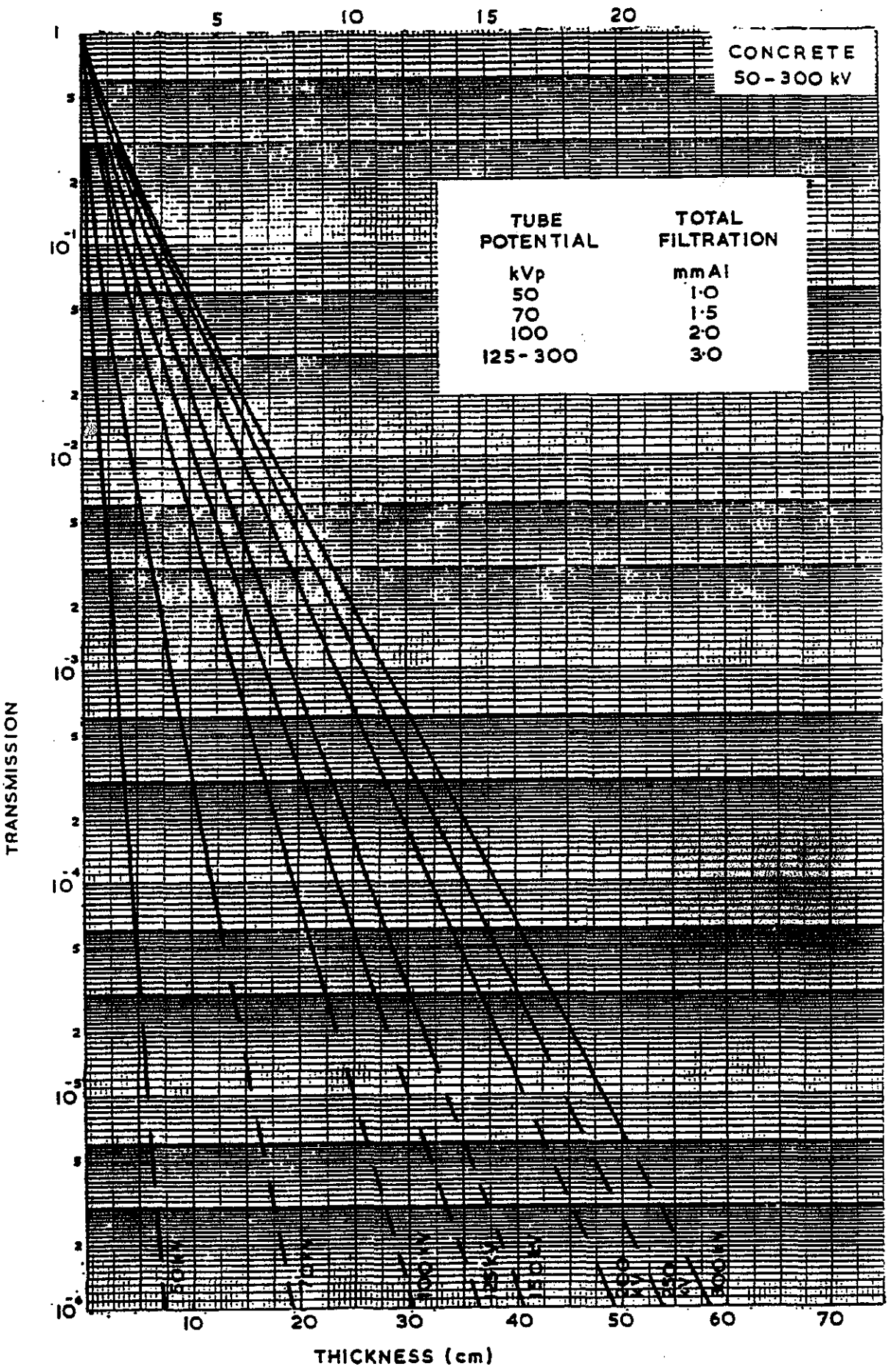
9.1.2.1.1.3 Secondary Shielding

The secondary shielding barrier is described in Figure 8, and is a barrier which extends in a direction parallel to the beam. There will be components of both scattered radiation from the main beam, and leakage radiation which have been transmitted through the tube housing. The calculation of the thickness of shielding required to meet the doserate objective specified for a point outside the secondary shield barrier (see Figure 8 point S), is calculated in the same way but must consider both components. This point is raised because the practice for calculating the shield thickness for scattered radiation is to select a transmission curve which relates to a lower applied voltage than that actually is the case. This is allowable because scattered radiation is degraded in energy. This practice should be used with caution where leakage radiation is involved as the gradient of the transmission curve for a "hardened" spectrum will be different.



Output of constant potential X-ray tubes (200 – 500 kV).
For pulsating potential generators, the output is about ¾ of that plotted.

Figure 6



Broad beam transmission of X-rays (pulsating potential) through concrete (50 - 300 kV).
These curves may also be used for constant potential, if necessary.

Figure 7

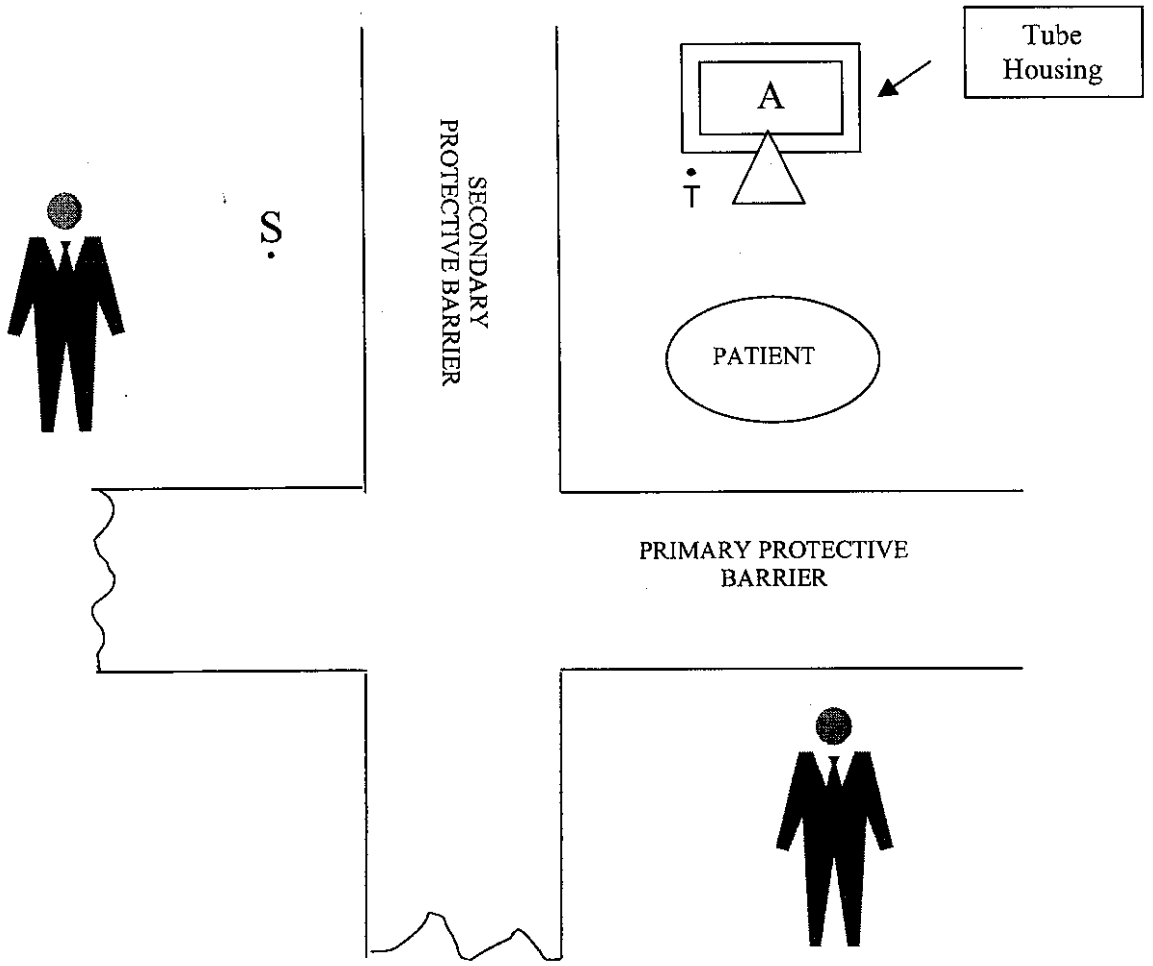

Tube
Housing
A
T
S
SECONDARY
PROTECTIVE BARRIER
PATIENT
PRIMARY PROTECTIVE
BARRIER

Figure 8

9.1.2.1.2 Protection Of Members Of The Public

9.1.2.1.2.1 Shielding

The design of the facility must also ensure that sufficient shielding is provided to limit public exposure. If, for instance, the area on the "safe" side of the primary or secondary shields is an area where free public access is possible, then a doserate objective for shielding, which is consistent with public dose limitation must be selected.

This procedure involves the selection of a dose constraint which is below the public dose limit of 1 mSv a^{-1}. The actual value of the constraint chosen should be the result of an optimisation study to ensure that, under the conditions of operation, the cost of the shielding is not disproportionate when compared to the protection provided. Let it be assumed that a constraint of 200 μSv y^{-1} is selected. Assuming an annual operating time of 2000 h y^{-1} sufficient shielding must be provided to achieve a doserate of 0.1 μSv h^{-1}. Standard tables can be used to calculate the shielding thickness necessary.

In the general design of shielding, there are some practical problems which could lead to weaknesses. These are;

Scattering through, for instance, a concrete base which supports a lead shielded wall
Leakage through two adjoining flat surfaces
Shielding voids
Lack of care in the positioning of service ducts

Detailed design rules can be specified which can reduce the propensity for shielding weaknesses but the requirement for a commissioning test is the only reliable method to ensure the integrity of shielding prior to allowing operation.

9.1.2.1.2.2 Access Control

The implementation of access control prevents access of members of the public to a potentially dangerous area by presenting some form of a barrier. The basis of good access control is the design of the access point into the facility. Normally, the access point to an X-ray facility is controlled at a rather lower level than, for instance at the entry point to the controlled zone of a nuclear power station. The precise details of the access control will depend upon the facility design.

9.1.2.1.3 Protection Of The Patient

Protection of the patient is achieved at the design stage by ensuring that the dose given to the patient in the course of the X-ray procedure is no greater than it should really be to achieve an acceptable result. In this regard, a number of factors must be considered.

9.1.2.1.3.1 The Energy Spectrum And Intensity Of The Radiation

Firstly, in designing the X-ray equipment to deliver an adequate flux, one has to consider the spectrum of energies that will be produced and the intensity at which this spectrum of energies can be delivered. However, these considerations must also include the effects of beam filtration which also effects the energy spectrum. The choice of tungsten as the target material most frequently used has been made with the large amount of experience accumulated to date. This experience has led to the convergence of opinion on what the guidance levels of dose for typical radiographs should be. An example is provided in Schedule III of the BSS [1].

9.1.2.1.3.2 Size Of The X-ray Field

The larger the X-ray field, the greater the area irradiated. If the area of the field happens to cover organs or tissues which are not required for the examination and the avoidance of irradiation of these tissues is possible, then one is imparting unnecessary dose by not reducing the area of the field This also reduces the amount of scattered radiation reaching the image receptor thereby improving the image quality.

9.1.2.1.3.3 The Total Beam Filtration

Beam filtration allows the removal of the lower energy component of the spectrum which would otherwise have contributed dose to the superficial tissue without any benefit. Experience has led to the recommendation that total filtration in the X-ray beam for conventional diagnostic radiology should be equivalent to not less than 2.5 mm of aluminium.

9.1.2.1.3.4 Distance From The Focal Spot To The Skin Or Image Receptor

If one considers any source of radiation, the closer that one approaches the source, the higher the doserate will be. It is therefore necessary to specify some minimum distance from either the focal spot to the skin of the patient, or focal spot to the image receptor. For mobile and permanent X-ray facilities, the distance is 30 and 45 cm respectively for focal spot to skin of the patient.

9.1.2.1.3.5 Use Of Carbon Fibre Material

The use of carbon fibre material for patient supports results in decrease of backscatter and hence patient dose reduction. In addition, use of carbon fibre for anti-scatter grids and the radiographic cassette face also reduces scatter.

9.1.2.1.3.6 Control Of The Irradiation

It is a design principle that all X-ray equipment should be constructed such that irradiation can be terminated manually at any time. This means that if the irradiation is controlled by a timer, this control can be over-ridden manually by the operator once the irradiation has started.

9.1.2.2 Design Of The Operational Programmes

9.1.2.2.1 Protection Of The Operator

9.1.2.2.1.1 Designation Of Areas

The control of occupational exposure can be simplified and made more effective by the designation of workplaces into two types.

Designation as a Controlled area is necessary when specific operational procedures are required because the engineered controls are considered insufficient by themselves to achieve the desired level of protection. The minimum requirements are that they are appropriately delineated and that access be restricted to those who are adequately trained so that they recognise the need for and are capable of implementing and maintaining the system of operational procedures necessary to limit exposures. Other persons may be allowed access provided they are accompanied by a trained individual.

Designation as a Supervised area would be recommended where the working conditions are required to be kept under review to determine whether it is necessary to change the status of the area. Therefore, the minimum requirement is that a programme of surveillance should be established to detect any deterioration in the protection arrangements.

In the case of a typical diagnostic X-ray facility, the area should be designated as a controlled area.

9.1.2.2.1.2 Personal Protective Clothing And Equipment

Personal protective clothing and equipment is necessary in situations where engineered controls and operational procedures cannot, either separately or together provide the necessary level of protection. Examples are the use of lead rubber aprons and gloves in medical radiology.

9.1.2.2.1.3 Routine Monitoring Of The Workplace

Routine monitoring is required for continuing operations and is intended to demonstrate that the working conditions remain satisfactory. It is therefore necessary to establish a monitoring programme for the workplace which specifies what must be measured and how often. The design shielding calculations for the equipment provide an acceptance criterion In the case of an X-ray facility, the monitoring need only be conducted occasionally because of the generally unchanging nature of the practice.

The instrumentation to be used must have the response characteristics appropriate for the type and energy of the radiation likely to be encountered.

One aspect worthy of note here is that relating to a pre-operational survey to determine the adequacy of primary and secondary shielding, and verification that doserates in the vicinity of the X-ray equipment are as predicted, particularly at the point where the radiologist would operate the equipment.

9.1.2.2.1.4 Routine Individual Monitoring

The principle objective of a programme of routine individual monitoring from external radiation is to obtain an assessment of the effective dose and, where appropriate the equivalent dose in significantly exposed tissues to demonstrate compliance with managerial and regulatory requirements. Current recommendations state that groups in which the annual effective dose to some individuals is liable to exceed a value between 5 and 10 mSv a^{-1} should be subject to individual monitoring. An interpretation of this could be that, where the potential exists to exceed an annual dose of 6 mSv, individual monitoring would be necessary.

Groups in which all members are likely to receive a dose of less than 1 mSv a^{-1} will not need monitoring.

Monitoring of the intermediate group between 1 and 5 mSv a^{-1} is desirable but can be conducted at a less formal level than the case for individual monitoring. where the monitored for external radiation individual monitoring is necessary where the in groups of the wearing of a dosimeter.

9.1.2.2.1.5 Individual Dose Assessment

The dosimetry provided for the operator must be chosen for compatibility with the radiation type and energy. In the case of diagnostic radiology, TLD or film badge systems are commonly used with the appropriate filters in order to distinguish between personal dose equivalent at depths of 10 and 0.07mm

9.1.2.2.1.6 *Reference Levels*

Reference levels are values of measured quantities above which some specified action or decision should be taken. There are two types of reference level in common usage in operational radiation protection;

- The Recording level which is the level of dose below which the measurement is not of sufficient interest to record.

- The Investigation level which is the level of dose above which the cause or the implications of the result should be examined and an investigation is initiated.

Both types of reference level could be applied to occupational exposure in the context of individual monitoring and monitoring of the workplace. In most circumstances involving external radiation exposure, the Recording level is not really used. For individual monitoring, the dose record normally reflects the actual dosimeter reading regardless of whether it is below the recording level or not. For workplace monitoring, the recording level is not commonly applied.

For individual monitoring for external radiation, the Investigation level is set according to either operational experience at another similar facility, or, in the case of a new operation, on the basis of the anticipated operational doses predicted using the shielding calculation assumptions. As an example, let it be assumed from a shielding calculation that the operator will be exposed to a doserate of 15 $\mu Sv\ h^{-1}$ for 1000 h a^{-1} and that the circumstances of diagnostic X-ray exposure dictate that this field will not be subject to fluctuation with time. The annual dose predicted, without the additional benefit of protective clothing etc. is 15 $mSv\ a^{-1}$. If this dose is accrued at a more or less constant rate, then assuming a monitoring period of one month, one would expect the radiologist to accrue a dose of about 1.25 mSv in a month. Therefore, one could reasonably set the investigation level at 1.25 $mSv\ month^{-1}$ and review the level with the accumulation of experience.

With monitoring of the workplace, the investigation level could be set at the expected level of doserate to be encountered. In the above example, that doserate would be 15 $\mu Sv\ h^{-1}$ under operational conditions.

9.1.2.2.1.7 Record Keeping

The records associated with a monitoring programme should include details of the programme, details of the method of measurement and of interpretation, results of the workplace monitoring, and results of individual monitoring. All record should be available to the operating management and to the radiological protection and medical advisors.

9.1.2.2.1.8 Health Surveillance

As in other health surveillance programs, special health surveillance may be required, depending upon the type of work and the state of health of the worker. Three situations need to be considered.

- Where workers are required to use respiratory protective equipment
- Where workers with skin disease or skin damage are required to handle unsealed radioactive substances
- Where workers are known to have psychological disorders

Only the last of these could be of relevance to the case under consideration.

9.1.2.2.2 Protection Of Members Of The Public

9.1.2.2.2.1 Verification Of Primary And Secondary Shielding

Because there are no routine releases of radioactivity associated with the X-ray diagnostic procedure, only external exposure needs to be considered. In this regard, it is important to verify the integrity of the primary and secondary shielding during operation to ensure that doserates are as predicted by the shielding calculation. The shielding calculation therefore provides the acceptance criterion for the verification survey.

9.1.2.2.2.2. Access Control

The access control procedure must be designed around the access control provisions which have been engineered and against the degree of need for exclusion of persons from the area. Particularly in the case of hospitals or radiology units where the need to address patient needs is important, the control process can be focused on preventing inadvertent access. For the case under consideration, a receptionist would probably provide the appropriate degree of vigilance coupled with the relevant signposting to give the required assurance of access restriction unless operational experience elsewhere had proven otherwise.

9.1.2.2.3 Protection Of The Patient

9.1.2.2.3.1 Type Approval

In order to highlight design errors which may not otherwise be identified until operation, it is wise to adopt some form of Type approval for the radiographic unit. The ideal is for some form of testing to be done at the manufacturers end to satisfy the regulator.

9.1.2.2.3.2 Quality Assurance Programme

A programme of quality assurance tests should be implemented to periodically check on all parameters which bear influence over the patient dose and the image quality. The following should be included when designing the quality assurance programme;

- Congruence of the optical and radiation fields and the central beam
- Focal Spot Size
- Exposure time
- Applied tube potential and the wave form
- Total filtration
- Linearity of current
- Linearity of timer
- Consistency of radiation output

9.1.3 Potential Exposure

9.1.3.1 Potential Exposure In The Domain Of Medical Exposure

In the case of medical exposure which is exposure of the patient, the operative requirements are for optimisation and justification of the exposure to be delivered in the diagnosis or treatment of the patient. Whilst specifications are applied to the dose to be delivered, dose limits do not play a role in the system of protection in medical exposure.

In a medical exposure, a specified dose is delivered to a specified portion of the patient, such that the intended diagnostic or therapeutic result is obtained. Errors, or unintended exposures may be of two types.

First, the exposure may be either greater or less than that intended. The difference between the delivered and the intended dose is a measure of the performance in terms of accurately filling the prescription but not necessarily the harm. For example, unlike many other situations in risk assessment, safer does not always equate to a lower dose , since a lower dose may fail to cure a disease that may become fatal.

Second, there may be exposure of a different portion of the patient or indeed a different patient than that intended. The risk of exposure when a different portion of the patient is exposed includes both the harm to that portion exposed and the harm from the lack of diagnosis or treatment because the exposure was not delivered to the intended site.

In the normal domain of occupational exposure, exposures are required to be kept as low as reasonably achievable. However, in medical exposure this may not be the case for the reasons stated above. The situation is similar for the case of potential exposure. Even so, the analysis of the probabilities and the differences between the delivered and intended dose is still of interest because it serves to identify the major contributors to risk and focus on the measures that might be taken to reduce them.

9.1.3.2 The Procedure For The Evaluation Of Potential Exposures

The evaluation of potential exposures, for the purposes of planning or judging protection measures, is usually based upon;

- The construction of scenarios intended to represent the sequence of events leading to exposures
- The assessment of the probability of each sequence
- The assessment of the resulting dose
- The evaluation of the detriment associated with that dose
- Comparison with the acceptance criterion
- Optimisation of protection (iteration of the above steps)

Each of these components will be discussed in turn with reference to the X-ray example but the reader is directed to ICRP publication 76 [3] for a more comprehensive discussion.

9.1.3.3 Identification Of Scenarios

The conceptual approach for the analysis of potential exposures is to assume that demands will be placed on a protection system to function at a certain rate, and then to determine if the system fails following these demands. The rate of demand is an important parameter of the scenario and the probability of the failure of the system is a function of both human and equipment failure rates.

9.1.3.4 The Assessment Of The Probability Of The Sequence

In order to analyse statistically the behaviour of a system from the known behaviour of components or sub-components, the logical structure of the interdependency of the components must be determined. Two models are used widely to present logical structures in a manner suited to quantitative analysis – event trees and fault trees. Although the detail of each model is discussed in many other publications, it should be noted that the modelling of a scenario of events (a system, a succession of human and machine actions etc.) with logical structures facilitates assessments of reliability or probability of failure. With these procedures, calculations relating to a complex event or fault tree can be simplified by replacing an assembly of components with a single probability of failure as if it were a single component.

9.1.3.5 The Assessment Of The Dose And The Evaluation Of The Risk Of Mortality Associated With The Exposure

The calculation of the dose will be used in order to determine the risk resulting from the exposure. As stated before, one could be concerned with mortality risk or total detriment which would include the probability of attributable fatal cancer, attributable non-fatal cancer, and severe hereditary effects weighted as appropriate for severity, mortality, and the relative time of life lost or impaired. The current discussion is concerned only with mortality but depending upon how the acceptance criteria are expressed, total detriment may be also be valid. Therefore, some care must be exercised in the calculation of dose since there will definitely be a stochastic component to the risk and, if the dose and the doserate is high enough, a deterministic component of risk as well.

A measure of the risk of stochastic effects will be given by the calculation of the effective dose. This quantity is suitable for both uniform whole body and partial body irradiation. At high doses and doserates, the nominal probability coefficient used in normal exposure may be unsuitable. The ICRP has chosen to use a dose and doserate effectiveness factor of 2 which means that at doses exceeding about 0.2 Gy or doserates exceeding about 0.1 Gy h^{-1}, the nominal probability coefficient can be multiplied by 2. So, if the mortality risk attributable to cancer as used in occupational exposure, is $4 .10^{-2}$, once this figure can be doubled to provide a stochastic risk coefficient when the doses and doserates are found to exceed doses of about 0.2 Gy or doserates of about 0.1 Gy h^{-1}.

Condition	Dose And Doserate	Radiological Mortality Risk Coefficient
Low Doses And Doserates	< 0.2 Gy < 0.1 Gy h-1	4.10^{-2} Sv^{-1}
High Doses And Doserates	> 0.2 Gy > 0.1 Gy h-1	8.10^{-2} Sv^{-1}

If the doses and doserates are high enough for the onset of deterministic effects, then the absorbed dose to each organ of importance should be calculated. Mortality risk models are available for the assessment of risk of mortality from deterministic effects following exposure for certain organs and tissues. Among these models are those for the more radiosensitive organs, the lung, red bone marrow, and gastro-intestinal tract. The dose-effect relationship is sigmoidal ijn shape above some threshold dose – the value of which is dependent upon the rate at which the dose is delivered. Let $R^{DET}_{i,j}$ represent the risk of mortality due to deterministic effects as a result of irradiation of sensitive organ I, at doserate j.

The risk is expressed mathematically as a weibull function of the form;

$$R_{i,j}^{DET} = (1 - \exp^{-H_{i,j}})$$

The parameter $H_{i,j}$ is known as the hazard function and its value is given by the following;

$$H_{i,j} = LN(2).X_{i,j}^{V_{i,j}}$$

Where

$V_{i,j}$ is the shape parameter

$X_{i,j}$ is the normalised dose which is represented by $X_{i,j} = \frac{E_{i,j}}{E(50)_{i,j}}$

And

$E_{i,j}$ is the absorbed dose delivered to tissue I at doserate j.

$E(50)_{i,j}$ is the dose to tissue I delivered at doserate j at which 50% of the exposed population exhibit the effect. In this case, the effect is mortality due to damage to tissue or organ I.

Values of the parameters for lung, GI tract and red bone marrow are given in Appendix 2.

The cumulative hazard H^{DET} from all effects is simply the sum of the parts;

$$H^{DET} = H_{LUNG}^{DET} + H_{GIT}^{DET} + H_{RBM}^{DET}$$

The total risk of mortality is then given by the expression;

$$R_{TOTAL}^{DET} = (1 - \exp^{-H_{TOTAL}^{DET}})$$

The total mortality risk is then the sum of the risk from stochastic effects and deterministic effects, multiplied by the probability of the event which led to the exposure.

9.1.3.6. Acceptance Criterion

In publication 64, the ICRP recommended that for potential exposure, limits on risk should be the same order of magnitude as the health risk implied by the dose limits for normal exposure. In addition, ICRP publication 76 assumed no additional weighting for a deterministically caused death over that caused by stochastic effects. This means that the numerical values of each type of risk can be added as proposed above. Once the sum of the stochastic and deterministic risks have been determined, then this can be compared to some criterion in order to judge acceptability. The risk criterion implied by ICRP 76, assuming that the implementation of the system of dose limitation in most industries has led to an annual average individual dose of around 5 mSv, can then be determined from the radiological mortality risk coefficient of 4.10^{-2} Sv^{-1} to give a mortality risk of 2.10^{-4}. This could then be used to provide an appropriate mortality risk criterion. If the objective was to set a criterion expressed in terms of total detriment rather than for mortality alone, then the appropriate radiological risk coefficient for the aggregated detriment would have to be used.

Table 1
Probability Coefficients For Individual Organs And Tissues

	Probability of fatal cancer (10^{-2} Sv^{-1})		Aggregated detriment (10^{-2} Sv^{-1})	
Tissue Or Organ	Whole Population	Workers	Whole Population	Workers
Bladder	0.30	0.24	0.29	0.24
Bone Marrow	0.50	0.40	1.04	0.83
Bone Surface	0.05	0.04	0.07	0.06
Breast	0.20	0.16	0.36	0.29
Colon	0.85	0.68	1.03	0.82
Liver	0.15	0.12	0.16	0.13
Lung	0.85	0.68	0.80	0.64
Oesophagus	0.30	0.24	0.24	0.19
Ovary	0.10	0.08	0.15	0.12
Skin	0.02	0.02	0.04	0.03
Stomach	1.10	0.88	1.00	0.80
Thyroid	0.08	0.06	0.15	0.12
Remainder	0.5	0.40	0.59	0.47
Total	5.00	4.00	5.92	4.74
	Probability Of Severe Hereditary Disorders			
Gonads	1.00	0.60	1.33	0.80
Grand Total			7.3	5.6

Comparison of the mortality risk from all relevant scenario's against this acceptance criterion provides an idea of the acceptability of the design in terms of safety. Should a weakness in the design be found, then the design can be modified and re-tested.

9.1.4 Risk Assessment Applied To X-Ray Example

9.1.4.1 The Construction Of Scenarios Intended To Represent The Sequence Of Events Leading To Exposures

Let it be assumed that we are concerned with the risk to the patient due to overexposure during a chest X-ray because of timer failure. The radiologist is present in the room during the procedure and terminates the X-ray dose once it is realised that the timer has failed.

9.1.4.2 The Assessment Of The Probability Of Each Sequence

Let it be assumed that the probability of failure of the timer, given that an operational demand is placed on it is 10^{-4} per event. Assuming 10^4 operations a^{-1}, the annual failure frequency is 1 a^{-1}.

9.1.4.3 The Assessment Of The Resulting Dose

The patient is exposed for double the normal time before the radiologist terminates the exposure (It is assumed that the timer always fails such as to exceed the intended irradiation time).

The normal dose associated with a chest X-ray is about 0.15 mSv. The resulting total dose to the patient is 0.3 mSv.

9.1.4.4 The Evaluation Of The Detriment Associated With That Dose

The external dose is far below the thresholds given in Appendix 2 for the onset of deterministic effects. Therefore, there will be no component of deterministic effect mortality risk from this scenario.

As stated above, the mortality risk coefficient for stochastic effects changes at the point of exceeding a dose threshold of dose of 0.2 Gy or a doserate threshold of 0.1 Gy h^{-1}. The dose received in the scenario is well below the 0.2 Gy threshold but the doserate threshold of 0.1 Sv h^{-1} is exceeded. If it is assumed that the dose is delivered in 5 seconds, then the rate of dose delivery is about 2 Sv h^{-1}. It is therefore acceptable to invoke the higher mortality risk coefficient for stochastic effects of $1.2.10^{-1}$ Sv^{-1} appropriate for a member of the general population. The mortality risk resulting from the exposure, assuming the probability is 1 that the individual will get the exposure, will then be the product of the dose and the risk coefficient giving a figure of $3.6.10^{-5}$.

This figure must then be multiplied by the annual frequency of the event which is 1 y^{-1}. The risk is then $3.6 \bullet 10^{-5}$ y^{-1}.

9.1.4.5 Comparison With The Acceptance Criterion

Taking the acceptance criterion of $2 \bullet 10^{-4}$ y^{-1}, the reliability of the timer would appear to be acceptable.

[1] International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources
Safety Series No. 115,
IAEA,
Veinna
1996

[2] ICRP Publication 64 (Annals Of The ICRP Vol 23 No.1)
Protection From Potential Exposure : A Conceptual Framework
ICRP,
1993

[3] ICRP Publication 76 (Annals Of The ICRP Vol 27 No.2)
Protection From Potential Exposures : Application To Selected Radiation Sources
ICRP,
1997

Appendix 1
Typical Conditions Of Authorisation

The requirements during operation are as follows-

4.1 *Safety Assessment*

4.1.1 The safety assessment, which must be submitted by the applicant for approval by the NNR, must be of sufficient scope and be established, conducted and maintained in order to demonstrate ongoing compliance with the safety standards.

4.1.2 The safety assessment must establish the bases for all the *operational safety-related programmes, limitations, and design requirements.*

4.2 Controls and Limitations on Operation

4.2.1 The holder of a nuclear authorisation is restricted to the actions within the specified site and within any limitations imposed therein.

4.2.2 The holder of a nuclear authorisation may be required to establish, *implement and maintain operating technical specifications which must provide a* link between the safety assessment and the operation and must, as a minimum, include the following-

> **4.2.2.1** operating safety limitations as imposed by the design or by the safety criteria;
>
> **4.2.2.2** surveillance requirements to verify that equipment important to *safety is operating satisfactorily or that parameters are within the safety* limitations; and
>
> **4.2.2.3** limitations on the operation, in the event that equipment important to safety becomes inoperable or in the event of exceeding safety limitations.

4.2.3 The holder of a nuclear authorisation must establish waste *acceptance criteria in respect of waste disposal facilities.*

4.2.4 The holder of a nuclear authorisation must ensure that operations are conducted in accordance with approved procedures as contained in the conditions of the authorisation.

4.3 Maintenance and Inspection Programme

4.3.1 The holder of a nuclear authorisation must implement the appropriate maintenance and inspection programme which he/she established, after the programme has been acceptance by the NNR, in order to maintain the level of reliability and integrity of the installation, equipment or plant commensurate with the fundamental safety criteria.

4.4 Staffing and Qualification

4.4.1 The holder of a nuclear authorisation must demonstrate to the satisfaction of the NNR, that an adequate number of competent, qualified and trained staff are available to execute all functions associated with safety and maintain an appropriate safety culture. The staff must be sufficiently independent from production and operational responsibilities to ensure that conflict of interests does not prejudice the proper execution of their functions. The appropriate staff must be consulted on all decisions which may impact on safety.

4.5 Radiation Protection

4.5.1 Radiation Dose Limitation

4.5.1.1 Activities, which potentially involve exposure to radiation, must be justified where required by the NNR.

4.5.1.2 The annual effective dose limit for persons occupationally exposed to radiation is 20 mSv. The annual dose equivalent limit for individual organs and tissues of such persons is 500 mSv except for the lens of the eye, for which the limit is 150 mSv.

4.5.1.3 The annual effective dose limit for visitors to the sites and those not deemed to be occupationally exposed is 1mSv. The annual dose equivalent limit for individual organs and tissues of such persons is 10 mSv.

4.5.1.4 The annual effective dose limit for women of reproductive capacity is the same as that which is generally specified for occupational exposure under 4.5.1.2. Following declaration of pregnancy, a limit on the equivalent dose to the abdomen of 2 mSv for the remainder of the pregnancy applies.

4.5.1.5 In the event of an emergency or when responding to an accident, a worker who undertakes emergency measures may be exposed to a dose in excess of the annual dose limit for persons occupationally exposed as specified in 4.5.1.2;

(a) for the purpose of saving life or preventing serious injury;
(b) if undertaking actions intended to avert a large collective dose; or
(c) if undertaking actions to prevent the development of catastrophic conditions.

Under any of the circumstances referred to in (b) or (c) above, all reasonable efforts must be made to keep doses to the worker below twice the annual dose limit. In respect of life saving interventions as contemplated in (a) above, every effort shall be made to keep doses below ten times the annual dose limit. In addition, workers undertaking interventions which may result in their doses approaching or exceeding ten times the annual dose limit may only do so when the benefits to others clearly outweigh their own risk.

4.5.1.6 *The annual effective dose limit for members of the public arising* from operations at the site is 0,25 mSv. This limit applies to the average member of the critical group within the exposed population. No nuclear installation, vessel or action may be authorised which would give rise to any member of the public receiving a radiation dose from all sources in excess of 1 mSv per year.

4.5.2 Operational Radiation Protection

4.5.2.1 The holder of a nuclear authorisation must provide for the establishment, implementation and maintenance of an operational radiation protection programme.

4.5.2.2 The holder of a nuclear authorisation must provide for a programme to be established, implemented and maintained to ensure that exposures are maintained as low as reasonably achievable (ALARA).

4.5.3 Health Register

The holder of a nuclear authorisation must ensure that a health register is established and maintained. All entries in the health register must be made by an appointed medical practitioner or a person so authorised.

4.5.4 Dose Register

The holder of a nuclear authorisation must ensure that a dose register is established and maintained.

4.6 Waste Management Requirements

4.6.1 The holder of a nuclear authorisation must provide for the establishment, implementation and maintenance of a waste management programme which must ensure the identification, quantification, characterisation and classification of any radioactive waste generated. The programme must provide for the necessary steps leading to safe clearance, discharge, disposal or authorised re-use or recycling. It must also make provision for the safe storage of radioactive waste between any waste management processes.

4.6.2 The holder of a nuclear authorisation must ensure that the safety of long term waste storage options is assured for the envisaged period of storage.

4.6.3 The holder of a nuclear authorisation must ensure that materials can only be cleared from further compliance with the requirements of the authorisation under one of the following conditions;

4.6.3.1 if such material complies with the requirements of an authorised discharge;

4.6.3.2 if such material complies with the requirements for clearance;

4.6.3.3 if such material complies with waste acceptance criteria and is transported directly to an authorised radioactive waste storage or disposal facility; or

4.6.3.4 if such material is transported to another authorised site or facility.

4.7 Environmental Monitoring and Surveillance

4.7.1 The holder of a nuclear authorisation must provide for the establishment, implementation and maintenance of an appropriate environmental monitoring and surveillance programme to ensure that the storage, disposal or effluent discharge of radioactive waste does not result in unacceptable contamination of the environment and complies with the dose limits and the ALARA principle.

4.8 Accident Management and Emergency Planning and Preparedness

4.8.1.1 The holder of a nuclear authorisation must provide for the establishment, implementation and maintenance of an appropriate arrangement to deal with any nuclear accident. This arrangement must address accident management procedures including emergency planning and preparedness.

4.9 Transport of Radioactive Material

4.9.1 The holder of a nuclear authorisation must ensure that the transportation of radioactive material or of any equipment or objects contaminated with radioactive material off the site or on roads which are accessible to the public is carried out in terms of the provisions of the Regulations for The Safe Transport of Radioactive Material of the International Atomic Energy Agency.

4.10 Physical Security

4.10.1 The holder of a nuclear authorisation must provide for physical security arrangements to be established, implemented and maintained in order to demonstrate that all necessary measures are taken to prevent unauthorised access to sites, diversion, theft or removal of radioactive material.

4.11 Quality Management

4.11.1 The holder of a nuclear authorisation must ensure that the activities are subject to the requirements of a quality management programme in order to ensure compliance with the conditions of such authorisation.

4.12 Records and Reports

4.12.1 The holder of a nuclear authorisation must provide for a system of record-keeping to be established, implemented and maintained.

4.12.2 The holder of a nuclear authorisation must ensure that operational reports are submitted to the NNR at predetermined periods and must contain such information as the NNR may require.

4.12.3 The holder of a nuclear authorisation must provide for the establishment, implementation and maintenance of an occurrence reporting mechanism to ensure that occurrences relevant to safety or of public concern are reported to the NNR.

4.13 Schedules

4.13.1 The holder of a nuclear authorisation must ensure that any schedules contained in the nuclear authorisation are complied with.

Appendix 2
Parameters For The Deterministic Effect Models

Median Dose Estimate E(50) And Shape Parameter V Of Mortality From Injury To The Gastro-Intestinal Tract

Parameter	Brief Exposure [1]	Protracted Exposure [2]
E(50) Central	15 Gy	35 Gy
Threshold	8 Gy	18 Gy
Shape Parameter	10	10

[1] Brief exposure > 0.06 Gy h^{-1}
[2] Protracted Exposure < 0.06 Gy h^{-1}

Median Dose Estimate E(50) And Shape Parameter V Of Mortality From Injury To The Red Bone Marrow

Parameter	Brief Exposure [1]	Protracted Exposure [2]	Protracted Exposure [3]
E(50) Central	3.1 Gy	4.4 Gy	10 Gy
Threshold	1.6 Gy	2.2 Gy	5.0 Gy
Shape Parameter	6	6	6

[1] Brief exposure > 1 Gy h^{-1}
[2] Protracted Exposure 0.05 - 1 Gy h^{-1}
[3] Protracted Exposure < 0.05 Gy h^{-1}

The data presented in this appendix has been taken from NUREG 4214