

# **Guidelines for the Calibration of Dosimeters for use in Radiation Processing**

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## **Abstract**

A set of guidelines has been developed to assist in the calibration of dosimeters for use in industrial radiation processing plants. Topics covered include the calibration of equipment, the performance of calibration irradiations and the derivation of mathematical functions to represent the calibration. Guidance is also given on methods for the estimation of uncertainty.

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Approved on behalf of Managing Director, NPL,  
by Dr J B Hunt, Head of Centre, Centre for Ionising Radiation Metrology

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## Foreword

The Guidelines in this Report were prepared as part of a wider project supported by the European Commission under the following contract:

### **SMT4-CT96-2077 “Dosimetry for Radiation Sterilization of Medical Devices”**

Additional support is gratefully acknowledged from the National Measurement System Policy Unit of the UK Department of Trade and Industry and from Risø National Laboratory, Denmark.

The Background and Objectives of SMT4-CT96-2077 are described briefly below. Further details can be obtained from the authors.

### **Background**

The validation and process control of radiation sterilization depends on the measurement of absorbed dose. New and more stringent requirements on measurement traceability are being put into force with the implementation of the Medical Device Directive 93/42/EEC and the associated European standards EN 552 and EN 556. This project was initiated in order to assist irradiation facilities in providing the documentary evidence that they are meeting these requirements. It thereby supports the uniform regulation of the sterile medical device industry throughout the EU.

### **Objectives**

The principal objective of the project was to improve the accuracy with which radiation dose is delivered in industrial radiation sterilization plants. This was achieved through:

- a) Intercomparisons between industrial irradiation facilities (electron accelerators and gamma facilities) and two calibration laboratories (Risø National Laboratory, Denmark, and National Physical Laboratory, UK);
- b) The development of protocols describing standard procedures for the calibration of industrial dosimetry systems.

## **Guidelines for the Calibration of Dosimeters for use in Radiation Processing**

### **1. Scope**

European standard EN552:1994, “Sterilization of medical devices - Validation and routine control of sterilization by irradiation”, states that *Measurements of absorbed dose shall be performed using a dosimetric system or systems having a known level of accuracy and precision. The calibration of each dosimetric system shall be traceable to an appropriate national standard.* Similar requirements are also found in ISO 11137:1995 “Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization”. The Standards do provide some guidance on how these requirements can be met, but do not include practical detail. The purpose of this document is to expand on the guidance given in EN 552 and ISO 11137, and to provide details of suitable methods for the calibration of dosimeters and the estimation of dosimetry uncertainty.

The objective of dosimeter calibration is to determine the relationship between the response of a dosimeter and the absorbed dose received. This relationship will be dependent on many external conditions associated with the irradiation, such as dose rate, temperature during and after irradiation, time after irradiation, humidity, radiation type, etc. The calibration methods described in these Guidelines are designed to minimise the effects of these external influence factors, and hence increase the overall accuracy of dose measurement.

### **2. Basic principles**

Calibration laboratories formally accredited to ISO Guide 25, EN45001, or equivalent, should be used in order to ensure traceability to national standards. Where reference dosimeters are referred to in this document, it is assumed that these will be supplied and measured by an accredited laboratory. If a laboratory not having formal accreditation is used, the laboratory's calibration certificate will not in itself be sufficient proof of traceability to national standards, and additional documentary evidence will be required.

### **3. Calibration of equipment**

The ability to make accurate dose measurements depends on the calibration and stability of the entire dosimetry system. This means that all equipment associated with the measurement procedure, not just the dosimeters themselves, must be adequately controlled and the performance validated.

According to the ISO 9000 series of standards, all measurement equipment must be calibrated and be traceable to national standards. In practice, certain dosimetry readout equipment cannot be formally calibrated as the readout is not in terms of a standardised quantity e.g. a scale reading from a wide bandwidth optical reader or the

peak-to-peak height from an EPR spectrometer. In such cases it is necessary to demonstrate the stability of the equipment by the use of standard test pieces, such as optical filters or stable EPR spin standards. The same consideration could be applied to equipment such as spectrophotometers and thickness gauges, but in general, traceable calibration is usually the easiest way to provide evidence of stability.

Typical items - in addition to the dosimeters themselves - requiring calibration include:

- a) Spectrophotometers / Dedicated optical readers  
 Absorbance scale: Use calibrated filters  
 Wavelength scale: Use rare earth filters or gas discharge lamps

The frequency of spectrophotometer calibrations and checks will depend on the particular equipment and should be based on both the manufacturers instructions and experience of the instrument.

- b) Thickness gauge: Use calibrated gauge blocks  
 c) Humidity meters: Use saturated salt solutions, e.g.:

Salt	Temperature (°C)	Relative humidity (%)
CH <sub>3</sub> COOK	20	20
CaCl <sub>2</sub> .6H <sub>2</sub> O	24.5	31
	20	32.3
	18.5	35
K <sub>2</sub> CO <sub>3</sub> .2H <sub>2</sub> O	24.5	43
	18.5	44
NaHSO <sub>4</sub> .H <sub>2</sub> O	20	52

Source: "Handbook of Chemistry and Physics", CRC Press

- d) Thermometers: Use calibrated thermometers  
 e) Thermolabels: In-house testing in oven against calibrated thermometer. Tests should be carried out on both irradiated and un-irradiated labels.  
 f) Ohm-meter (for use with calorimeters): Use calibrated reference resistor.

Equipment calibration must be repeated at defined intervals depending on the known stability of the equipment. In the case of consumable items such as Thermolabels, checks need to be carried out on each batch.

## **4. Calibration of dosimeters - General considerations**

### **4.1 Dose range**

Irradiate over a dose range larger than that of intended use. Measurement uncertainty becomes greater at the extremes of the dose range. The non-linear nature of most dosimeter calibration functions means that extrapolations are not acceptable.

Chemical dosimeters may exhibit significant changes in response at doses towards the bottom of their operating dose range. In general, therefore, dosimeters should not be used to measure doses between zero and the lowest irradiated calibration dose point (i.e. zero dose should not be used as calibration point), unless the behaviour in this region is known.

### **4.2 Number of dose points**

For irradiations over less than one decade of dose, use at least 5 dose points distributed arithmetically (i.e. 10, 20, 30, 40, 50 kGy). For irradiations over greater than one decade use at least 5 dose points per decade and distribute dose points geometrically (i.e. 1, 1.5, 2.3, 3.4, 5.1, 7.6, 11.4, 17, 26, 38, 58, 87 kGy, for two decades)

Use at least four replicate dosimeters at each dose point.

### **4.3 Batch calibration**

Calibration must be carried out on each new batch of dosimeters. Different lots purchased at different times from a batch identified by the manufacturer as the same should be cross-checked to ensure equivalent response. This could be achieved by irradiating dosimeters from both lots together, in such a way that they are known to have received the same dose. A statistical test, such as a t-test, should then be used to determine if there is any significant difference between the lots. This should be repeated at several doses spread over the calibration dose range.

The calibration curve supplied by manufacturers of dosimeters should be considered as general information, and must not be used for dose calculation without further verification of its applicability.

### **4.4 Calibration frequency**

The calibration of existing batches should be checked approximately annually. This check could take the form of a Calibration Verification exercise (see Section 5.2.1.1).

Calorimeters for measurements at electron accelerators may need re-calibration at an interval determined by accumulated dose. This arises because of possible changes in the specific heat of the absorber. Polystyrene, for example, is reported to exhibit changes in specific heat of approximately 1% for each megagray of accumulated dose.

The readout device is an integral part of the dosimetry system and the effect of any changes, or repairs, must be assessed. In general, the calibration of a dosimetry system should be regarded as being specific to a particular readout device. A major repair to, or change of, the readout device may require either a calibration check (e.g. a Calibration Verification exercise) or a complete recalibration.

#### **4.5 Post irradiation stability**

The readout signal from many routine dosimeters is not stable and changes with time after irradiation. Tests should be carried out to determine the extent of post irradiation changes over the time scale between irradiation and readout that is likely to be encountered during the use of the dosimeters. If significant changes are observed, it will be necessary to control the time between irradiation and readout. This applies both for the preparation of the calibration curve and for routine dose measurement. Note: the extent of post irradiation changes may be dependent on both the dose level and the storage conditions of the dosimeters.

### **5. Calibration of dosimeters - Irradiation procedures**

Dosimeter response may be influenced not only by radiation type and spectrum, but also by environmental effects, such as temperature during and after irradiation, humidity, dose rate, and the measurement time relative to the time of irradiation. In order to limit errors due to these effects, it is necessary to calibrate using conditions as close as possible to those used during normal dose measurements. Two methods are possible:

- i) irradiation in the plant, or
- ii) irradiation in a calibration laboratory followed by a calibration verification in the plant.

The former potentially allows better correction for environmental effects and should be used if possible.

#### **5.1 Irradiation in plant**

This method involves irradiation of routine dosimeters alongside reference dosimeters in the irradiation plant where the dosimeters will be used.

- Advantage: Inherently takes environmental effects into account.
- Disadvantage: Difficult to obtain full dose range in certain plant designs.

##### **5.1.1 Gamma - specific aspects**

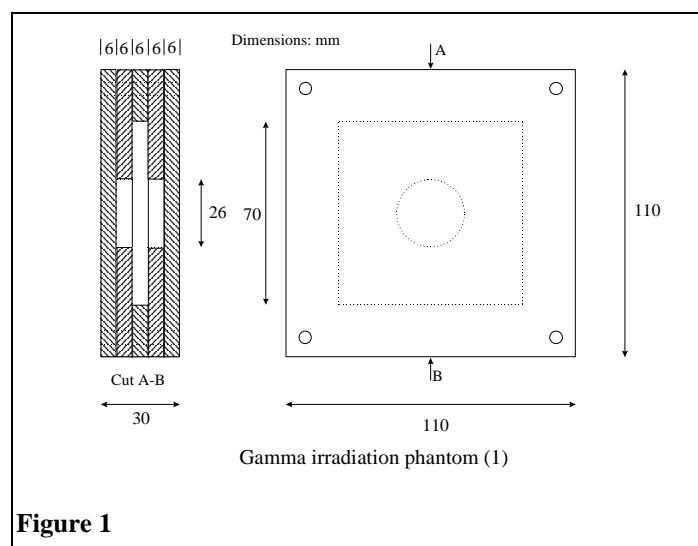
In irradiation plants giving doses in multiple dose fractions with each fraction obtained by a full cycle around the source, the calibration doses can be given as multiples for each cycle.

In other plants, which deliver the dose in one full cycle, it may be necessary to interrupt the process and to insert (or remove) dosimeters at points throughout the cycle in order to achieve a range of doses. In designing a procedure, consideration has to be given to the ease of access to boxes containing dosimeters at various points in the cycle. Dose should be delivered in one continuous period, as dose fractionation may lead to additional uncertainties. The use of increased shielding to reduce delivered dose is not recommended as that may result in significant changes to the radiation spectrum, which could influence dosimeter response. Similarly, it is not recommended to irradiate at a fixed position in the irradiation room, with normal product shielding the dosimeters. Care must be taken to ensure that the procedure does not unacceptably influence the dose to normal product being irradiated at the same time.

#### 5.1.1.1 Irradiation phantom

It is recommended that the dosimeters to be calibrated and the reference dosimeters are irradiated in a phantom, or standard absorber, that will ensure that the dosimeters are irradiated to essentially the same dose. The phantom should be placed in a region of low dose gradient, for example, in the middle of a homogeneous product. The wall should be thick enough to ensure that the dosimeters are surrounded with material which is similar to the dosimeter material in order to limit effects from interfaces. Recommended material is polystyrene or similar radiation-resistant plastics with wall thicknesses of 5-8 mm. Increasing the wall thickness beyond this may create dose gradients within the phantom due to attenuation. Similarly, the mass of dosimeter material must not be so large that significant dose gradients are introduced - for double sided irradiations the thickness of unit density material should not exceed 15 mm. Single sided irradiation will introduce larger uncertainties, but provided the reference and routine dosimeters are arranged in a symmetrical “sandwich” along the direction of irradiation, no significant error will be introduced.

Examples of irradiation phantoms for in-plant gamma irradiation are given in figures 1 and 2. In fig. 1 the phantom allows routine dosimeters (e.g. up to 5 PMMA dosimeters) to be irradiated with a 6 mm thick alanine reference dosimeter on either side of them. Figure 2 contains a larger rectangular insert intended to hold a dosimeter box containing routine dosimeters and two cylindrical reference dosimeters arranged in a line. This geometry is suitable for either dichromate dosimeter ampoules or alanine pellets in cylindrical holders.



**Figure 1**

## 5.1.1.2 Temperature

For in-plant irradiations, the effect of irradiation temperature on the reference dosimeters must be considered. The irradiation temperature in a gamma plant is a complex function of the passage of the product box through the plant, but an effective temperature for the purpose of reference dosimeter correction may be calculated as 2/3 of the temperature difference

between the minimum and maximum temperature that the dosimeter experiences. This is only an approximation and the effect of uncertainties in this estimate are considered in Sec 8.1.3

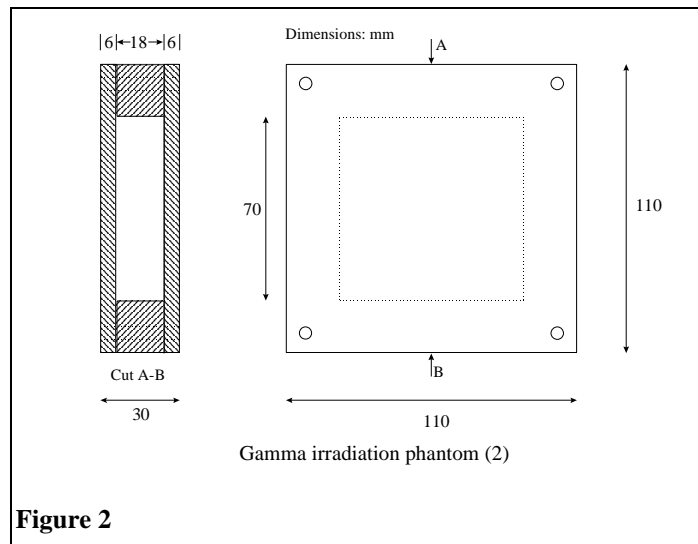
$$T(\text{effective}) = T(\text{min}) + 2/3(T(\text{max})-T(\text{min})).$$

The maximum irradiation temperature can conveniently be estimated by the use of temperature sensitive adhesive labels, although the minimum temperature detected by many labels is 37°C. Temperatures below this may require a more subjective estimate, but the effects on the overall uncertainty should not be great when the magnitude of the reference dosimeter temperature coefficient is taken into account (approx 0.2% per degree Celsius). Mechanical recording thermometers can also be used, but care must be taken to ensure that the device does not "over-read" due to local heating of the metal temperature sensor.

In situations where significant uncertainties may be introduced by the lack of information about irradiation temperature, it is possible to "factor out" the effect of irradiation temperature by using both dichromate and alanine reference dosimeters irradiated in close proximity. The effect of irradiation temperature on these two dosimeters is almost equal in magnitude, but opposite in direction, allowing correction for the effect of irradiation temperature.

## 5.1.2 Electron - specific aspects

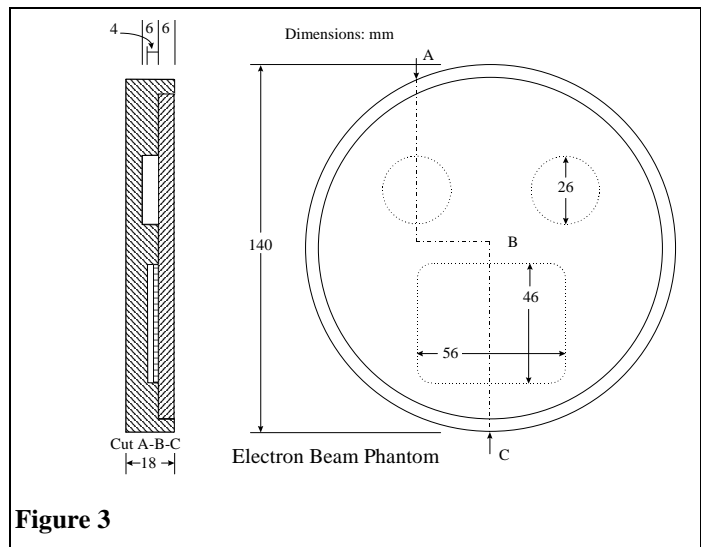
Electron accelerators can normally be set to deliver doses for calibration over the full dose range of the dosimeter, although very small doses may present problems if an unusually high conveyor speed has to be used. Calibration doses should, whenever possible, be delivered using the same accelerator, and the same operating conditions, that would be experienced during actual use. If calibration doses are given using an accelerator or operating conditions different from those of normal use, then additional "cross-check" irradiations should be carried out to ensure that the change in conditions has not significantly influenced dosimeter response.



**Figure 2**

### 5.1.2.1 Irradiation phantom

An irradiation phantom must be used to ensure that the dosimeters to be calibrated and the reference dosimeters receive the same dose. This phantom is irradiated separately, not in reference or dummy product. The same general consideration as for the gamma phantom apply, with the difference that due to the inherent dose gradients with electron accelerator irradiation, a specific location on the depth dose curve should be chosen, e.g. at the peak of the depth dose curve or at the ascending slope of the curve. If the size of the dosimeter in the direction of the beam is such that there is significant variation in dose within the dosimeters, then the dosimeters should be placed in an approximately linear portion of the depth dose curve, rather than at the peak. The effects of beam asymmetry and non-uniformity need to be considered when deciding dosimeter layout within a phantom.



**Figure 3**

An example of an irradiation phantom for 10 MeV electron irradiation is shown in fig 3. This phantom will hold alanine reference dosimeters (in the form of 3 mm pellets enclosed in disc holders 25mm diameter, 6 mm thickness) and film routine dosimeters. It also allows comparison with calorimeters, which are available commercially with the same geometry. If used without the 6mm thick top plate, this design is also suitable for use at energies down to 4 MeV.

### 5.1.2.2 Temperature.

Because of the short irradiation time, the irradiation temperature will rise almost adiabatically during irradiation, and the effective irradiation temperature can therefore be considered to be equal to the mean temperature

$$T(\text{effective}) = (T(\text{min}) + T(\text{max}))/2$$

## 5.2 Irradiation at a calibration laboratory

This method involves irradiation of the dosimeters to be calibrated in the reference radiation field of a calibration laboratory, followed by a "calibration verification" in the irradiation plant. Calibration verification involves checking the derived calibration curve in actual plant conditions by the use of reference dosimeters. Without this step systematic errors arising from environmental effects could go undetected and as a result large uncertainty values would have to be ascribed to the calibration process.

Advantage: Easy to obtain full dose range.

Disadvantage: Environmental effects may not be dealt with in an adequate way.

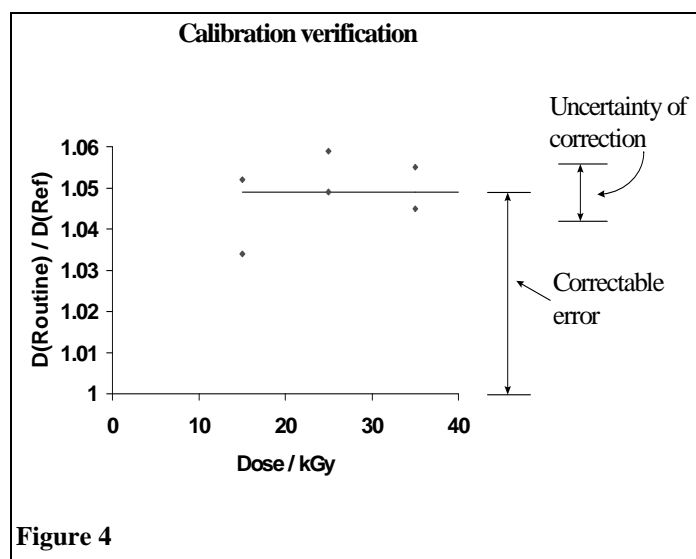
### 5.2.1 Gamma - specific aspects

It is generally not possible to match actual plant conditions in a calibration irradiator, but an attempt should be made to irradiate dosimeters under conditions of dose rate and temperature as close as possible to those that will be experienced in actual use. Dose rate can usually be matched only in very broad terms, but would not be expected to present significant problems, except possibly in the case of very low dose rates (full cycle times of more than one day). An effective temperature for the plant can be estimated as described in Section 5.1.1.2. Transport of dosimeters from the calibration laboratory to the industrial plant can potentially introduce significant errors if, for example, dosimeters are delayed or experience extremes of temperature or humidity during transport.

#### 5.2.1.1 Calibration verification

Having prepared a calibration curve using dosimeters irradiated at a calibration laboratory, it is necessary to perform a calibration verification exercise in order to detect any systematic errors that may have arisen due to differences between the conditions of calibration and use. Irradiate dosimeters from the batch being calibrated alongside reference dosimeters in the industrial plant. Both types of dosimeter must be in close proximity in order to ensure they receive the same dose. The points discussed in Section 5.1.1 concerning the irradiation phantom and estimation of temperature apply. At least three dose points should be chosen at as wide a range of doses as possible within the calibration range. Each reference dosimeter pack should be accompanied by several of the dosimeters being calibrated, although care must be taken to avoid attenuation in a large bulk of material (see Section 5.1.1.1).

The difference between the dose readings of the reference dosimeters and those from the batch being calibrated should be determined and the results examined for any systematic trends. Differences greater than 5% may indicate the presence of an error somewhere in the procedure and this should be investigated before applying any corrections. If the results indicate a significant offset between readings from the two types of dosimeter, that is essentially constant over the dose range of use, then a correction factor should be



applied to the calibration curve to bring the dose measurements from the batch being calibrated into line with those from the reference dosimeters. An example of such results is given in Fig 4, where a correction of 5% is indicated. Corrections that are not constant over the entire dose range should not be applied without some other supporting evidence that justify the form of the correction. An alternative approach is to set an acceptance limit and not make any corrections if ratios smaller than this value are obtained. This is a straightforward approach, but, depending on the action limit chosen, may unnecessarily increase the calibration uncertainty (see Section 8.1.3)

### 5.2.2 Electron - specific aspects

Irradiation at a calibration laboratory would not usually be employed for dosimeters to be used in electron beams, as a sufficient range of calibration doses are usually easily obtainable on the industrial machine. If special circumstances dictate that irradiation at a calibration laboratory is necessary for electron beam dosimeters, then the same general procedure as outlined above for gamma should be used, except that the specific sections on electron beam phantoms and temperature measurement apply (Sec 5.1.2).

## 6. Preparation of calibration curve

It is necessary to convert the measured calibration data into some form of smooth function that will enable dose to be obtained from a measured dosimeter signal. This could be as simple as a hand drawn graph, but in practice a mathematical fitting procedure of some form is generally used to obtain the relationship between dosimeter signal and absorbed dose. The most common methods are based on least squares techniques, in which the best fit is determined to be that which results in the smallest difference (residual) between the measured and predicted values. Strictly, the least squares fitting procedure will result in different answers depending on whether a fit is made in terms of  $signal=f(dose)$  or  $dose=f(signal)$ . A function of the form  $signal=f(dose)$  is more correct, but can result in expressions which are difficult to solve for dose, the quantity required. (Note: Many spreadsheets have functions which will solve equations of the form  $signal=f(dose)$  for dose given a signal value, e.g. in EXCEL the “solver” function may be used). In practice, for radiation processing dosimeters, functions of the form  $dose=f(signal)$  will not result in appreciable error provided the dose range is not greater than one decade. If the dose range is significantly greater than one decade, then the fitting procedure becomes more complex with functions of the form  $dose=f(signal)$  and care should be taken to ensure that unnecessary errors are not being introduced.

In general there is not a specific form to express the relationship between signal and dose and a mathematical expression has to be chosen that will successfully approximate the observed relationship. In many cases a polynomial function (e.g.  $signal=a + b \cdot dose + c \cdot dose^2 + \dots$ ) will adequately describe the relationship, but other functions, such as exponentials can be used. Because of their general applicability, polynomial functions will be described in this document, although the general principles could be applied to other functions.

In selecting a function the main consideration is to use the lowest order of polynomial that will adequately represent the data. One of the best methods of determining the required order is by examination of the residuals for increasing orders of the polynomial, as described below:

a) Use a statistical software package to determine the coefficients of the selected polynomial (start with a first order polynomial unless the data is obviously non-linear). Use individual dosimeter points from the batch being calibrated i.e. do not average the readings from replicate dosimeters irradiated to the same dose. This enables an estimation of the dosimeter-to-dosimeter precision and allows outlying results to be identified.

b) Using the coefficients derived in a), calculate the dose for each of the dosimeters from the batch being calibrated, based on its measured signal.

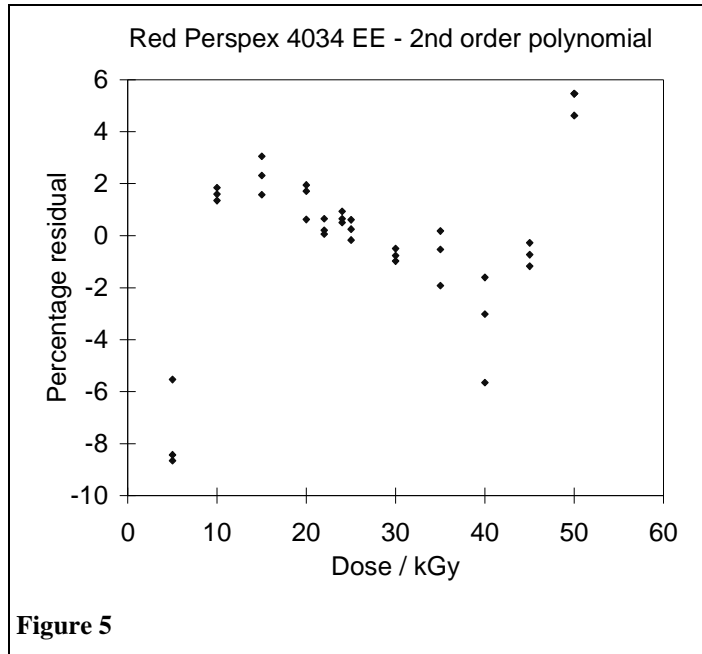


Figure 5

c) Calculate “percentage residuals” as follows:

$$(D_{\text{calculated}} - D_{\text{delivered}}) / D_{\text{delivered}} * 100$$

d) Plot “percentage residuals” against dose and examine the data for any systematic trends i.e. patterns of residuals gradually moving from positive to negative and vice versa, (see Figs 5 & 6). If such patterns are apparent then repeat the exercise using the next highest order of polynomial. The polynomial order of choice is the lowest order that does not exhibit systematic trends.

Alternative methods to determine the optimum order of polynomial are generally based around the “correlation coefficient” or “F-statistic”. These factors have the advantage of often being generated automatically by statistical packages, but in general are less sensitive than the examination of residuals method outlined above.

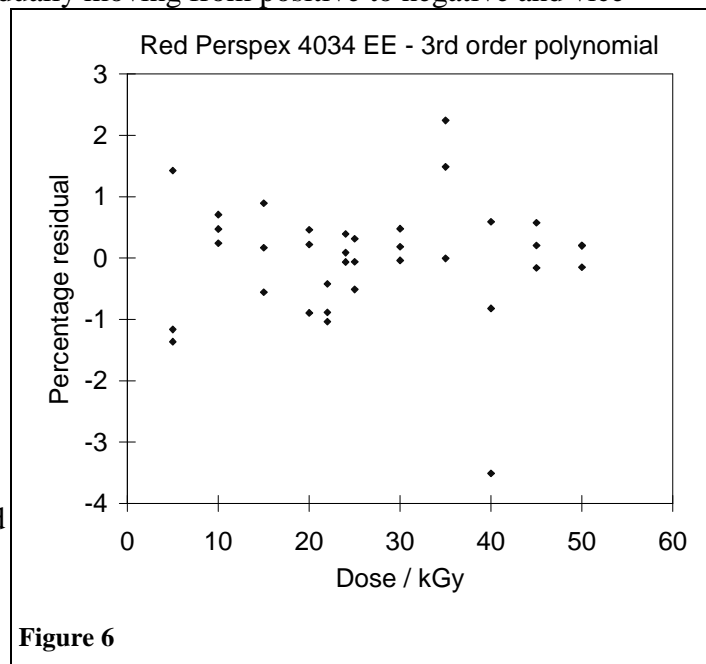


Figure 6

As an example, the “correlation coefficients” and “F-statistics” derived for the polynomial fits shown in Figs 5 & 6 are given below:

Order of fit	2	3
Correlation coefficient ( $R^2$ )	0.998819	0.999727
F-statistic	13953	39123

## 7. Software considerations

All software used to manipulate dosimetry data must be validated to ensure its correct operation, and the results of the validation must be documented. Spreadsheets are particularly prone to error and the in-built “auditing” procedures available in some packages should be fully utilised. It is essential that results are checked either manually or by the use of another independent package (Note: the method of examination of residuals, described above, implicitly provides a degree of self checking of the system). Protection of the software and data against unauthorised changes is also a vital consideration, particularly when the system is to be used by relatively unskilled personnel.

## 8. Estimation of uncertainties

In order to establish the accuracy of a dose measurement, it is necessary to first identify and then quantify all possible sources of uncertainty. This is most easily done by considering in turn each step in the calibration and use of a dosimeter, and assessing what uncertainties are likely to be associated with each stage. The uncertainty associated with a dose measurement can then be calculated by combining the individual components together. The philosophy used is to ascribe to each component of uncertainty an effective standard deviation, known as a standard uncertainty, and it is these standard uncertainties that are then combined to produce the overall uncertainty.

When dealing with statistical effects, such as the random scatter between replicate dosimeters, the concept is clear and it is straightforward to calculate the relevant standard uncertainty. Such components of uncertainty are known as “Type A” components.

Other components of uncertainty, for example the effect of irradiation temperature on dosimeter response, are not easily calculated from a set of statistical data, and a more subjective approach has to be taken. A common situation is that prior knowledge indicates that an effect is very unlikely to be greater than  $\pm a\%$ , but no other information is available as to its exact value. An alternative way of stating this is to

say that there is a 100% probability of the effect being between  $\pm a\%$ , and a 0% probability of it taking any other value. If, in addition, the value is equally likely to be anywhere between  $\pm a\%$ , then this is known as a “rectangular probability distribution” and an effective standard deviation can be calculated for it. The mathematics behind the calculation of an effective standard deviation for a rectangular distribution are beyond the scope of this document, but its value can be taken as  $a / \sqrt{3}$ . Components of uncertainty derived by non-statistical methods, such as this, are known as “Type B” components.

The combined uncertainty associated with a particular measurement is obtained by summing in quadrature the individual component standard uncertainties i.e. by taking the square root of the sum of the squares of the individual components:

$$u_c = (u_1^2 + u_2^2 + u_3^2 + \dots)^{1/2}$$

In reporting the uncertainty associated with a particular measurement, the value given should imply a high level of confidence that the correct result will lie within the reported range. Historically, uncertainties have been reported based on either a 95% or a 99% probability that the correct value is within the range. The accurate calculation of such values is, however, complex, and current practice is to report standard uncertainties multiplied by a *coverage factor* ( $k$ ) of either 2 or 3. For most situations, a coverage factor of 2 is very close to a 95% confidence interval, and a coverage factor of 3 is very close to a 99% confidence interval.

## 8.1 Uncertainties in the Preparation of a Calibration Function

- 8.1.1 *Uncertainty in calibration doses* - The certificate provided by the calibration laboratory will contain statements about the uncertainty of dose delivery or dose measurement. Unless specifically stated otherwise in the certificate, the overall uncertainty should be taken as the value to be used in subsequent calculations. Uncertainties quoted at 95% or 99% confidence should be interpreted as being equivalent to 2 or 3 standard uncertainties, respectively.

Variability in the positioning of dosimeters within a phantom may also contribute significantly to the uncertainty in delivered dose. This is a particularly important consideration for electron beam irradiations. The magnitude of the uncertainty can be estimated from a knowledge of the possible variation in positioning of dosimeters, and the depth dose curve in the phantom (see also Sec 8.1.3).

- 8.1.2 *Uncertainty due to fit of calibration function* - The calibration function will have associated with it an uncertainty arising both from the fact that the form of the expression may not truly represent the data, and also from the fact that it was derived from a finite number of data points, each of which have an associated uncertainty. Accurate determinations of the uncertainty due to curve fitting are complex for all but straight lines, and uncertainty data is not generally produced by curve fitting software packages. In general terms, the uncertainty will be smallest in the centre of the calibration dose range and increase steadily towards the extremes. Uncertainty often increases markedly at low doses, where the “signal-to-noise” ratio increases, and also at high doses if the calibration function begins to “saturate”.

An approximate value for the uncertainty due to the fit of the calibration function can be obtained from a percentage dose residual plot of the type described above (Sec 6). In this case the replicate residuals at each dose point should be averaged in order to reduce the influence of dosimeter-to-dosimeter scatter. Assuming the residuals do not show any significant tendency to increase, or decrease, in magnitude with dose, the root-mean-square residual can be calculated and used as a reasonable approximation of the standard uncertainty of fit. This approximation is, however, likely to be an overestimate at the centre of the dose range, and an underestimate at the extremes.

- 8.1.3 *Uncertainty due to environmental influence factors* - In the case of an “in-plant” calibration against reference dosimeters it is necessary to consider two significant sources of uncertainty a) the effect of uncertainties in irradiation temperature on the reading of the reference dosimeters, and b) the possible difference in dose delivered to the reference and calibration dosimeters due to dose variation within the calibration phantom. Both of these are best treated as Type B estimates i.e. prior knowledge of the temperature variation in the plant or the dose distribution in the phantom will enable maximum limits of the likely effects to be estimated. These can then be converted into standard uncertainties using the formula “ $a / \sqrt{3}$ ”, discussed above.

An additional component of uncertainty due to environmental effects must be considered when calibrations are carried out using irradiations at a calibration laboratory followed by calibration verification using reference dosimeters. This additional uncertainty arises from the incomplete correction for environmental effects, and can be estimated from the difference between the readings of the reference dosimeters and those from the batch being calibrated - in this case, the dosimeter readings are those obtained **after** replicates have been averaged and correction made for any systematic offsets (see Sec 5.2.1.1). Two approaches are suggested for estimating an approximate value for this standard uncertainty: a) calculate the root-mean-square value of the individual differences observed between the two types of dosimeter, or b) use the formula “ $a / \sqrt{3}$ ”, where a is the maximum difference observed between the two types of dosimeter.

## 8.2 Uncertainties in use of dosimeters

- 8.2.1 *Uncertainty due to dosimeter-to-dosimeter scatter* - This can be obtained from the percentage dose residual plot described above. Use individual calibration dosimeter points i.e. do not average the readings from replicate dosimeters irradiated to the same dose. Calculate the standard uncertainty using the following formula:

$$u = \sqrt{\frac{\Sigma(\text{Residuals})^2}{n_d - n_c}}$$

where  $n_d$  is the number of dosimeters and  $n_c$  is the number of coefficients in the selected mathematical fitting function.

- 8.2.2 *Uncertainty due to variation in plant environmental conditions* - Changes in the environmental conditions in the plant (e.g. temperature, dose rate or humidity) can potentially influence the response of routine dosimeters and lead to additional uncertainties. It is necessary to estimate the maximum effect of such changes on the routine dosimeters and then calculate an effective standard uncertainty using the formula " $a / \sqrt{3}$ ". If seasonal variations in temperature and humidity lead to significant effects, it may be necessary to recalibrate dosimeters at intervals during the year.
- 8.2.3 *Uncertainty due to instability of dosimeter reading* - The signal from many routine dosimeters is not stable and changes with time after irradiation. The magnitude of such instability needs to be determined and then limits estimated for the maximum effect that variability in read-out time will have on dosimeter reading. The standard uncertainty can then be calculated using the " $a / \sqrt{3}$ " formula.
- 8.2.4 *Uncertainty due to instability of instrumentation* - Variations in the performance of the readout instrumentation e.g. spectrophotometers, thickness gauges, etc., will have a direct effect on dosimetry uncertainty. Periodic recalibration of the instrumentation, and/or checks using standard reference items, enable the stability to be determined, and this can be expressed in terms of its effect on dose readings. If frequent stability data are available it may be possible to derive a Type A uncertainty estimate from the measured distribution of results, but it is more likely that a Type B estimate will have to be made using limits of stability data.

## 9. Uses of dosimetry uncertainty data

Interpretation of dosimetry data is an essential part of the validation and control of irradiation processes. A knowledge of the sources and magnitudes of the various components of dosimetry uncertainty can be used both to assess the significance of individual measurements, and also to establish a statistical control regime for the process. The specific components of dosimetry uncertainty that need to be considered will depend on the use to which a particular dose measurement is being put. A combination of all the components discussed in Sec 8 will lead to the overall uncertainty of a single dose measurement. However, in, for example, the case of relative dose-mapping, the absolute value of a dose measurement is not required, and only those components of uncertainty that affect the random scatter of the dose readings need to be considered. Detailed discussion of this topic is outside the scope of this document, but possible areas of application of dosimetry uncertainty data include:

- a) Interpretation of dose mapping data - establishing the significance of small variations in measured dose, identification of low and high dose zones.
- b) Interpretation of routine dosimetry data - establishing the origin of observed dose variability.
- c) Establishment of routine operating parameters to ensure dose delivery within defined confidence limits.

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