

Dosimetry for Industrial Radiation Processing

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1 Introduction

The ability of ionising radiation to induce effects that are potentially of use industrially has been known for many decades. However, it was not until the development of large scale radiation sources, both radioisotopes and machines, in the nineteen fifties that industrial scale radiation processing became a practical reality. Since that time, growth has been continuous and radiation processing now forms an important component of several industrial sectors, for example the polymer and medical device industries. One of the principal advantages of ionising radiation as an industrial tool is the ability to achieve precise chemical and biological effects by the delivery of known doses of radiation. Accurate dosimetry has always been, therefore, an important component of industrial radiation processing, the high doses and dose rates involved providing particular challenges. In this article we will briefly describe the most important industrial radiation processes and indicate the dosimetric requirements for both operational control and statutory regulation. The role of bodies such as the ISO, ASTM, OIML and ICRU in producing written standards and guidelines will also be discussed.

2 Industrial processes and requirements for dosimetry

Currently there are three main applications for industrial radiation processing: the sterilization of medical devices, the treatment of foodstuffs and the modification of polymers. These will be discussed in detail below. Other applications include modification of semiconductor properties, treatment of sewage and waste water and cleaning of flue gas.

Medical Device Sterilization

Approximately 50% of single use medical devices are now sterilized by irradiation. The volume of irradiated products has been growing during the past years due in part to larger market demands for sterile medical devices and in part due to environmental concerns over the use of toxic gases, such as ethylene oxide, for sterilization. The volume of single use medical devices now sterilized annually by ionising radiation is estimated to be about 6 million cubic metres (Source: MDS–Nordion).

The majority of radiation sterilized medical devices are currently irradiated by gamma rays from cobalt-60, but a steadily increasing fraction is irradiated by electron beams, with energies of up to 10 MeV. There is also interest in the use of x-rays up to 5 MeV, and possibly higher, but so far only few facilities are able to offer this kind of treatment. The upper energies for the use of electrons and x-rays are governed by the requirement to avoid induced radioactivity in the processed products. The minimum electron energy is determined by the penetration requirements, and can be as low as 50 – 100 keV for surface treatments.

The validation and routine control of radiation sterilization relies on dosimetry. The minimum doses required for sterilization of medical devices are in the order of 10–30 kGy, but the actual dose depends on the regulatory requirement and on the level of initial microbiological contamination. Once the sterilization dose for a specific product has been determined, it must be

delivered accurately. All product must receive at least the sterilization dose, but there is also a requirement to limit the maximum dose to the product, in order to avoid deleterious effects on materials. The economics of the process will also be affected by an unnecessarily high dose. Taken together, these considerations lead to the need for tight dosimetric control of the process.

As a part of the validation of an effective radiation sterilization process, it may be necessary to irradiate product samples with smaller doses in the range of 1–10 kGy. These doses do not achieve full sterilization, but allow a determination of the effectiveness of the process.

Dosimetric accuracy of the order of 5–10% is generally considered to be necessary for the effective control of the sterilization process. Dose is usually measured in terms of absorbed dose to water.

Because of the implications for human health, the radiation sterilization process is under strict regulatory control. A number of international and national standards govern the practices and the required level of documentation (EN, 1994; ISO, 1995). It is a common requirement that dosimetry is traceable to national standards, and that the measurement uncertainty is known and documented.

Food irradiation

The irradiation of foodstuffs is a valuable method for extending shelf life and reducing contamination by pathogenic micro-organisms. The process has been used successfully in several countries for a number of years, although the total product volume is still relatively limited. Like the radiation sterilization process, the food irradiation process is highly regulated. Recently, significant changes in these regulations have occurred both in Europe and in the USA (see for example EU, 1999; Ross and Engeljohn, 2000).

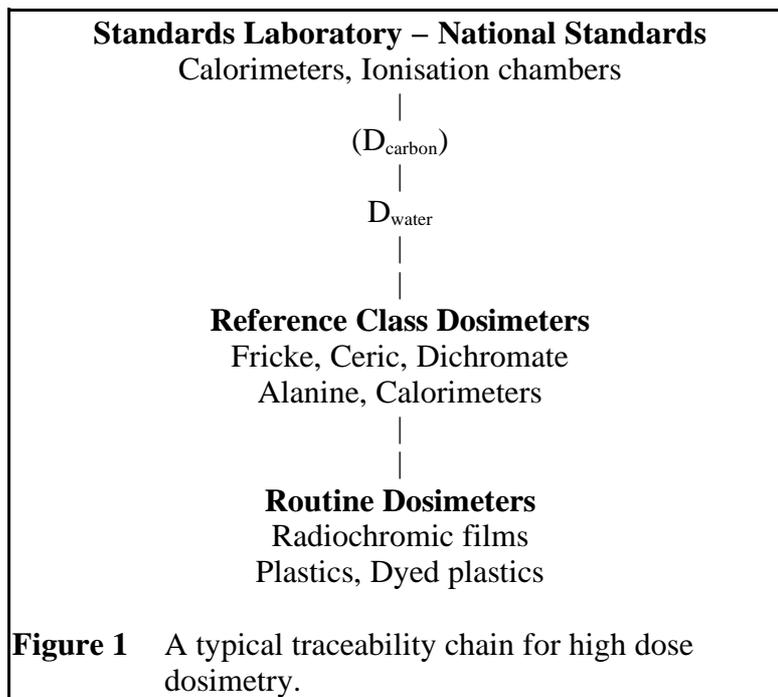
The process, and the documentation requirements, for food irradiation are essentially the same as for radiation sterilization and the same types of radiation sources are used. The dose ranges are, however, generally lower (0.1 – 15 kGy). Depending on the particular process, or product, the requirements for dosimetric accuracy can be as strict as for radiation sterilization.

Polymers

Irradiation of polymers in order to modify material properties is the largest radiation process in terms of economic value. Effects achieved include crosslinking, for heatshrinkable products, increased melting points for cable insulation, and curing (polymerization) of coatings and inks. Some processes require tight dose specifications, but the majority are operated on the basis of the effect achieved, rather than on specific dose measurements. The dose varies widely with the process, and can be as high as 500 kGy. Electron irradiation is the predominant radiation source with energies ranging from 0.1 to 10 MeV (see for example Singh and Silverman, 1992).

3 Dosimeter classification

It is useful to classify dosimeters for radiation processing into a hierarchy according to their intrinsic accuracy. Such a classification is shown in figure 1 and includes dosimeters classified as primary, reference and routine. The figure also represents a traceability chain in that it outlines how primary standard dosimeters are used to calibrate reference standard dosimeters, which in turn are used to calibrate the routine dosimeters, used for day-to-day measurement. Each class of dosimeter is described in more detail below.



In many cases, the underlying standards for high dose measurements held by national standards laboratories are the primary standards designed to operate at therapy dose levels i.e. doses of a few gray. The move from grays to kilograys is achieved by the use of transfer dosimeters, which can be irradiated to similar doses in both the low dose rate fields of the primary standard and the high dose rate fields used in radiation processing. The accuracy of irradiation timing and the magnitude of dose rate effects in the transfer system become important components in the overall accuracy achieved. Typical calibration uncertainties of the high dose fields in national standard laboratories are of the order of 2% (2σ). This compares with typical uncertainties for the therapy level fields of approximately 1% (2σ). Radiation processing doses are almost always quoted in terms of absorbed dose to water, the only significant exception being the semiconductor industry, which uses absorbed dose to silicon. Unless otherwise stated, the use of the word *dose* in this article should be taken to mean *absorbed dose to water*.

A reference dosimeter is defined as a dosimeter of high metrological quality that can be used as a reference standard to calibrate other dosimeters. To be of use, it must satisfy well-established criteria. It must have a radiation signal that is accurately measurable and this signal must have a well-defined functional relationship with absorbed dose. The effect of parameters, such as irradiation temperature, post-irradiation stability, etc must be well characterised and capable of expression in terms of simple correction factors. Examples of commonly used reference dosimeters include chemical dosimeters, such as the Fricke, ceric-cerous, dichromate and alanine dosimeters. Overall accuracy achievable with reference dosimeters is of the order of 3% (2σ).

A routine dosimeter is a dosimeter whose performance is often not as good as that of a reference dosimeter, but whose cost and ease of use make it suitable for day-to-day measurements in a radiation processing facility. The effects of environmental factors such as irradiation temperature, humidity and dose rate on a routine dosimeter tend to be complex and interrelated, with the result that it is often not possible to apply straightforward correction factors. This means the calibration of a routine dosimeter is often specific to a particular environment. Examples of commonly used routine dosimeters are systems based on polymethylmethacrylate (PMMA), both dyed and un-dyed, cellulose tri-acetate and thin radiochromic films. Overall accuracy of the order of 5% (2σ) is achievable with routine dosimeters, although large systematic errors can be introduced if environmental influence factors are not taken properly into account.

4 Calibration methods

One of the major problems associated with high dose dosimeter calibration is the effect that environmental factors such as temperature (both before and after irradiation), dose rate, humidity etc can have on the response of the dosimeter (Sharpe and Miller, 1999). In the case of the relatively "well behaved" reference dosimeters, it is necessary to state under what conditions a calibration was carried out in order that corrections can be made subsequently if the dosimeter is used to measure dose in different conditions. In the case of routine dosimeters it is necessary to calibrate the dosimeter under the conditions of final use, as post-calibration corrections are generally not possible. Before starting to calibrate a dosimeter it is necessary to have detailed knowledge of what environmental factors are likely to influence the particular system and to then devise a scheme which will allow any important factors to be taken into account.

Ideally routine dosimeters should be calibrated in the plant in which they are to be used. This involves irradiating routine dosimeters alongside reference dosimeters to a series of doses spanning the dose range of intended use. The actual dose received will be determined by the reference dosimeters, after correction for known influence factors, such as irradiation temperature. Unfortunately, the design of some industrial plants means that it is not possible to easily obtain a range of calibration doses, and calibration irradiations have to be carried out in some other irradiator. Differing environmental conditions in the two irradiators can potentially lead to significant systematic errors and, in order to detect these, some form of subsequent verification of the calibration has to be carried out. This often involves the use of reference dosimeters to check the validity of the routine dosimeter calibration at a number of dose points in the plant of final use.

Only a very few dosimeters exhibit a strict linear relationship between the readout signal and absorbed dose. This means that it is generally not possible to define a single calibration factor for a dosimeter, and a curved calibration function has to be used instead. The form of the function is somewhat arbitrary, and can be any mathematical expression that is capable of reproducing the observed response.

5 Current dosimetry performance

Standards laboratories

As mentioned previously, the overall uncertainty associated with high dose calibrations from national standards laboratories is of the order of 2% (2σ). Agreement between a number of national and international laboratories providing high dose calibrations has recently been demonstrated in an intercomparison carried out by the BIPM (Burns and Allisy-Roberts, 1999). Figure 2 shows the agreement between the participating laboratories, the error bars indicating the statistical uncertainty of the intercomparison results. The agreement between laboratories is well within the overall uncertainty of approximately 2% (2σ) quoted by each laboratory.

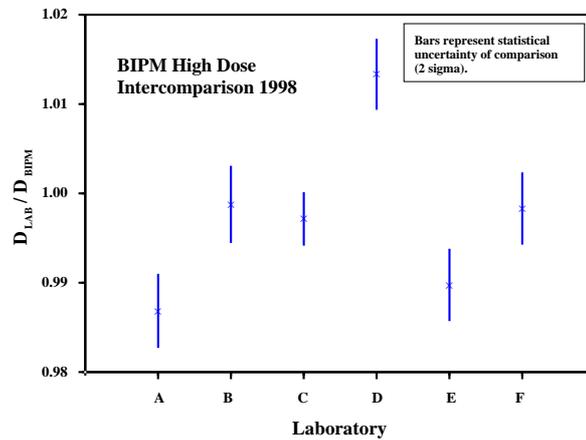


Figure 2 Results of an intercomparison amongst national standards laboratories at industrial dose levels.

Industrial plants

An indication of the current status of dosimetry in industrial plants can be obtained from the results of an intercomparison carried out within the European Union involving 27 Co-60 gamma and 11 electron beam facilities (Miller and Sharpe, 2000). The plants were asked to irradiate a number of reference dosimeters to a series of doses and to return them to a calibration laboratory for evaluation. The dose measured was compared to the dose estimated by the industrial plant based on their normal dosimetry procedures. The difference between the two doses is shown as the dose error in the histograms in figures 3a and 3b. The standard deviation of both distributions is approximately 5%. This is twice as large as might be expected from routine dosimetry under ideal conditions and indicates the difficulties of dosimetry in an industrial environment.

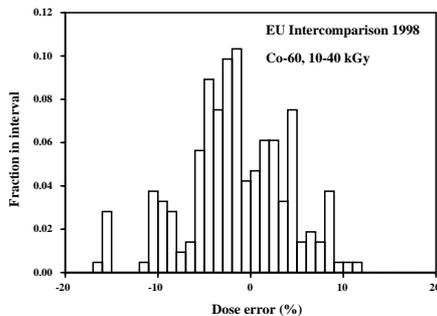


Figure 3a

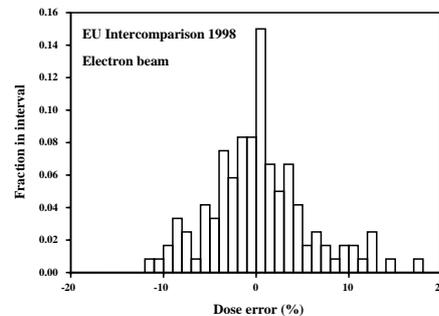


Figure 3b

Results of dose intercomparisons in industrial irradiation plants.

6 Use of dosimetry in the validation and routine control of radiation sterilization

In this section we outline the use of dosimetry for validation and routine control of medical device sterilization, but the general concepts are equally applicable to other processes, such as the irradiation of food. The international standards for radiation sterilization (EN, 1994; ISO, 1995) describe three main aspects of the process: installation qualification, process qualification and routine process control.

Installation qualification – This involves obtaining and documenting the performance characteristics of the irradiator under well defined reference conditions. One aspect of this is the determination of dose distributions throughout standard volumes of homogeneous material. Typically, measurements are made using a number of different densities of absorber, encompassing the range of densities of products that are to be processed. The determination of dose distributions (dose mapping) for installation qualification usually involves the placement of dosimeters in a regular grid pattern, the spacing of the grid being determined by the resolution required and the attenuation characteristics of the radiation in the absorber.

Process qualification – This involves obtaining and documenting evidence that the sterilization process will result in product that meets the specified requirements. There are many aspects to this, including determining the required minimum and maximum doses the product should receive and specifying how the product should be packaged and oriented within the irradiator. From the dosimetric point of view, the main activity required is dose mapping of representative samples of actual product, to determine the positions and values of maximum and minimum dose. The relationship between maximum and minimum dose and dose at an easily accessible position is also determined, in order to facilitate subsequent monitoring of the process (see below). The positioning of dosimeters for process qualification dose maps will generally not be on a regular grid layout. The dosimeters will, instead, be concentrated in locations most likely to receive extremes of dose, based on knowledge of the irradiator and previous dose maps of similar product. Significant dose variation can occur over short distances, especially in electron beam irradiators, and considerable skill is required to locate the true maximum and minimum positions.

Routine process control – This involves monitoring of the dose received by product during processing. The important parameters are the minimum and maximum doses received, but these very often occur at inaccessible locations within product boxes. The dose at a convenient monitoring location is, therefore, measured and related to the minimum and maximum doses by the ratios obtained during process qualification dose mapping. The frequency of routine dosimetric measurements will depend on a number of factors specific to the particular irradiator and product, but will always be a balance between cost and effort involved and the consequence of finding a reading outside specification.

7 Written standards

In addition to the ISO and CEN standards discussed above, various international organisations are writing standards in the field of dosimetry relevant to radiation processing. The most important is ASTM subcommittee E10.01, that has produced more than 25 standards and guides (Farrar, 2000) on the application of dosimetry and dosimeter systems. A number of these ASTM standards have also been adopted by ISO. Many of these standards describe in detail the method to be followed when using a particular dosimetry system, whilst others cover more general aspects, such as criteria to be used in the selection of dosimetry systems for particular applications, or methods for estimating uncertainty.

The OIML (International Organisation of Legal Metrology) is also drafting standards aimed at setting minimum requirements for manufacturers supplying dosimetry systems for radiation processing. To date, standards covering radiochromic dye films (OIML, 1999), alanine and PMMA based dosimeters have either been approved, or are in an advanced stage of preparation.

8. ICRU activities

As has already been mentioned, a number of international bodies are involved in the production of written standards and guidelines dealing with various aspects of radiation processing dosimetry. Recently, the ICRU has assessed the coverage of these existing documents and has identified the need for a more fundamental treatment of the subject. As a result, a new ICRU Report Committee has been established and charged with the task of producing a report on "Dosimetry Systems for Use in Radiation Processing". The report will cover commonly used dosimetry systems for use in radiation processing and will complement the work of other bodies by providing a solid scientific background for radiation dose measurements at the levels required for radiation processing. The Report Committee is chaired by Rod Chu and sponsored by Mitio Inokuti and Stephen Seltzer.

9 References

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