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ESTIMATION OF ABSORBED DOSE DURING PROCESS INTERRUPTION IN RADIATION PROCESSING

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Abstract

The quality control system enables the standardization of product quality. Dosimetry has an important role in the quality control of radiation processing. The area of radiation processing which is governed most strictly by regulations is radiation sterilization. This process is used as the example to describe the new method for establishing the effect of process interruption on absorbed dose in the ^{60}Co irradiation plant at the Vinča Institute of Nuclear Sciences. Establishing the effect of process interruption is one of requirements in international regulations, but there are no recommendations for its implementation. A new method has been worked out by graphical extrapolation. The advantage of this method is the ability to carry it out during the sterilization process.

The ethanol-chlorobenzene (ECB) dosimeter is used to select the suitable place where absorbed dose is expected to be the most influenced by source transit, i.e. the most close to the source. In the same time, it should be convenient and reproducible for placing dosimeters. Alanine dosimeters were irradiated on this place in time intervals: 2 min., 4 min., 6 min., 8 min., 10 min. Measurements of time starts when the button to lift source is pressed and stops by pressing the button for process interruption (to sink source down). The absorbed doses were measured by ESR spectrometer. The function of absorbed dose versus irradiation time is linear as expected. The extrapolation back to zero time gives the maximal absorbed dose that can be delivered to product during source transit. In our experiment this absorbed dose obtained by this method is 154 Gy.

Key words: radiation processing, cobalt-60, ethanol-chlorobenzene dosimetry, alanine dosimetry

1. INTRODUCTION

Radiation processing includes irradiation of various products for different purposes. It covers many areas, like radiation sterilization, food irradiation or polymer modification. In all cases, the quality of products depends on absorbed dose during the irradiation process. The delivered absorbed dose has to be within certain prescribed limits. The lower limit must be high enough to accomplish certain desired effect, but the upper limit should not be so high to cause adverse effects. For this purpose, there are the international standards for quality control of radiation processing⁽¹⁻⁷⁾.

In recent years, there was a lot of activity to implement the international standards, mainly ISO 11137 – Sterilization of health care product – Radiation. This Standard describes requirements that, if met, will provide a radiation sterilization process intended to sterilize medical devices, that have appropriate microbicidal activity⁽¹⁾. In part 3, it gives guidance on the requirements relating to dosimetry in development, validation and routine control of a radiation sterilization

process. According to Standard⁽¹⁾, the sterilization process is validated through installation, operational and performance qualifications. The purpose of operational qualification is to demonstrate that the irradiator, as installed, is capable of operating and delivering appropriate doses within defined acceptance criteria. This is achieved by determining dose distributions through dose mapping exercises and relating these distributions to process parameters. Dose mapping for operational qualification is carried out to characterize the irradiator with respect to the distribution and reproducibility of dose and to establish the effects of process interruption on dose. The Standard gives only requirements for assessing the effect of process interruption: to interrupt the process when the container is close to the source where the absorbed dose expected to be the most influenced by source transit⁽¹⁾. The effect of process interruption is evaluated by comparing the result with those of dose mapping exercises carried out under normal process conditions. For radiation sterilization process itself, it is desirable that the effect of process interruption is negligible, so it might be necessary to

interrupt the process multiple times in order to evaluate the effect. Following this guidelines, it is possible only to estimate the effect of process interruption.

This article presents the new method for determination of absorbed dose during the source transit, instead of only estimation of the effect of process interruption.

2. MATERIALS AND METHODS

The Radiation Plant has been described in more detail elsewhere⁽⁸⁾, and only a brief description illustrative of the irradiation geometry will be given here. It consists of a ⁶⁰Co plaque source, associated storage pool and shielding, product handling areas, and a shuffle-dwell conveyor system designed for either continuous or batch operation. The plant was designed jointly by the Commission Energie Atomique and Conservatoire, France, and the conveyor system was built by ABP Company, Paris, with financial support by the UN Development Programme and technical assistance by the International Atomic Energy Agency. Fig.1 shows a schematic diagram of the arrangement of product boxes around the radiation source. At the present time, the source frame (1 m x 3 m) is loaded with 5.41×10^{15} Bq of ⁶⁰Co placed into source rods (diameter 11.1 mm, length 451 mm). Several generations of source rods are arranged in this source frame. An automatic conveyor carries boxes (46 cm x 46 cm x 43 cm) through the source. A single irradiation run consists of four sequential irradiation cycles, and in each cycle a given box passes through the irradiation room at one of four vertical levels organized in 6 rows (3 rows on each side of the source) with 12 horizontal positions in each one, i.e. every box is irradiated in the same way. The distance between boxes in neighboring rows, as well as between the source frame and the boxes in the rows next to them are small (a few cm), and the dose gradient, particular in rows nearest to the source, is large. Dose distribution was measured at a distance of approximately 7 cm from the front of the source frame, using ethanol-chlorobenzene (ECB) dosimeters. ECB dosimeters were prepared at Vinča Institute in accordance with the procedures described in the corresponding standard⁽⁹⁾ and placed in 2 ml glass flame-sealed pharmaceutical ampoules. The irradiation time of ECB dosimeters is one hour. Measurement of irradiation time starts when the source is in position for irradiation. The absorbed dose was measured by the OK-302/2 oscillotitrator⁽⁹⁾ using a calibration curve made earlier⁽¹⁰⁾. The

measurement traceability is achieved by the Risø National Laboratory, Denmark, with alanine as transfer dosimeter in in-plant calibration^(4,11).

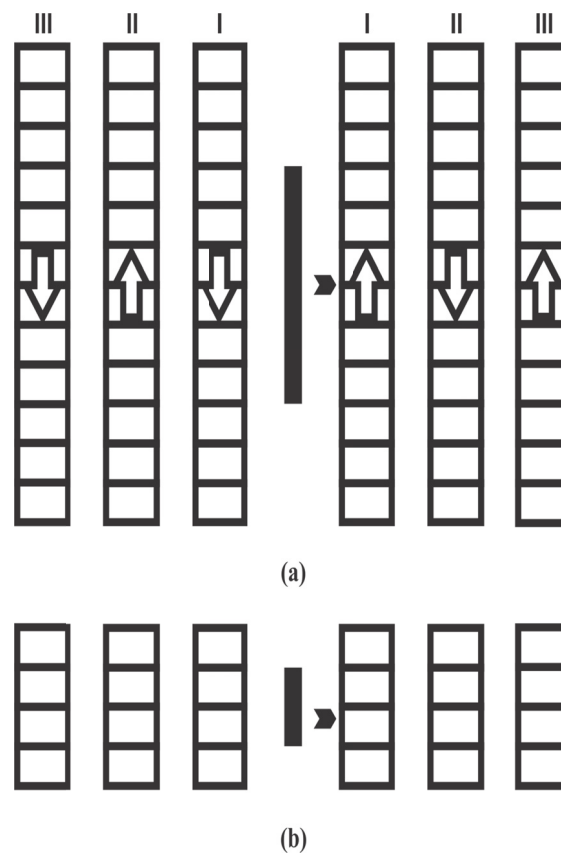


Fig. 1 Horizontal (a) and vertical (b) arrangements and movements of box carriers within the irradiation room (►) alanine dosimeters location

Based on these measurements, the place where the influence of source transit is the highest to absorbed dose is located. This place is presented in Fig.1, where the alanine dosimeters (diameter 3 mm, thickness 1.5 mm and mass between 37.5 – 37.6 mg, purchased from Aerial, Illkirch, France) were irradiated in time intervals: 2 min., 4 min., 6 min., 8 min., 10 min. Measurements of time started when the button to start the irradiation was pressed and stopped by pressing the button for irradiation interruption, which means that the time of source transit was included in irradiation time. The alanine dosimeters were measured by MiniScope MS300 ESR spectrometer using AER'EDE Version 2.0.4. software for absorbed dose calculation. For dose calculation, the calibration curve was obtained from the set of alanine dosimeters from same batch irradiated by ⁶⁰Co laboratory

source for internal calibration at known doses determined by Fricke dosimeter⁽¹²⁾. The ESR measurement parameters were: center field 334.8 mT; modulation amplitude 0.6 mT; microwave power 10 mW; magnetic field sweep width 2.1 mT; sweep time 12 s; scan number 5; gain 2; Phase 180. The serial interfaces directly capture the reading parameters of the dosimeters as Hpp-signal from spectrometer and software calculates Sn as

$$Sn = \frac{Hpp}{m} \quad (1)$$

where Hpp is the peak –to-peak height of the dosimeter ESR signal, and m is the dosimeter weight in milligram. The calibration curve coordinates absorbed dose to Rc value given by:

$$Rc = Sn k_{rpe} k_m (1 + (T_{etal} - T_i)k_T) \quad (2)$$

Sn – dosimeter response

k_{rpe} – correction factor of ESR spectrometer

k_m – correction factor of spectrometer variation during measurement period (assuming that this variation is linear)

T_i – temperature of dosimeter irradiation

T_{etal} – main irradiation temperature of reference dosimeter

k_T – temperature correction factor

The software chooses automatically the best polynomial fit with RMS, F-value and r^2 criteria. Calibration parameters are directly stored under a data base to be available for absorbed dose measurements without any transcription error.

3. RESULTS AND DISCUSSION

Vertical dose distribution just in front of the central part of the source plane is presented in Fig.2. The dose distribution shows a small local minimum in the center of the source, because source rods are placed in the frame at two vertical levels. Absorbed dose maximum is at 90 cm and 120 cm distance from the bottom of the box carrier. The position at 90 cm from the bottom of the box carrier was chosen for alanine dosimeters irradiation since it was the most convenient for placing dosimeters. The place with dose rate maximum was also chosen to maximize the sensitivity of absorbed dose measurements by alanine dosimeters. Since the dose rate maximum is at this place, it is expected that it can only be lower during source transit. In the same time, it is expected that the dose rate increases at the bottom of

the box carrier, but the upper limit is the maximal dose rate measured at the selected distance from the source. The maximal increase in dose rate corresponds to the decrease at the place of maximum dose rate during source transit and this is the main reason for choosing this place for further measurements.

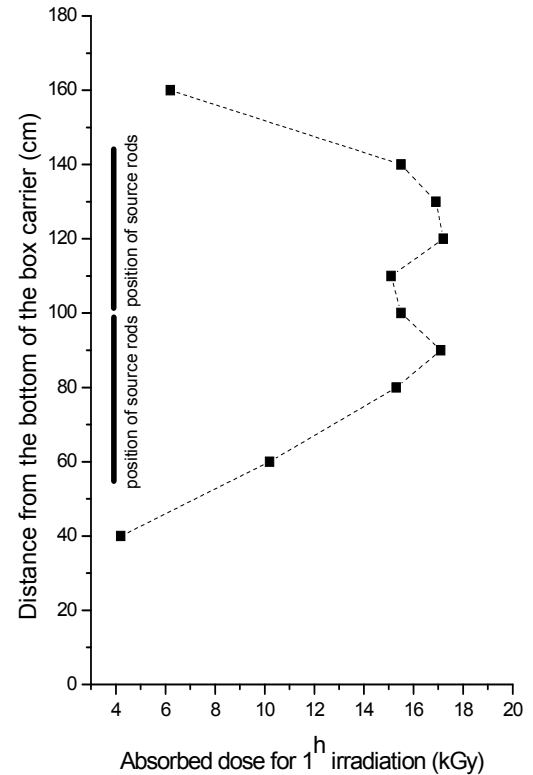


Fig. 2 Vertical dose distribution at a distance of approximately 7 cm from the central part of the source plane, as measured by ECB dosimeters

Fig.3. presents the absorbed dose measured by alanine dosimeters at 90 cm vertical distance from the bottom of the box carrier and approximately 7 cm from the central part of the source plane as a function of irradiation time when the source transit is included in measurement of irradiation time. The function is linear, as expected. It is obvious that the dose rate in this place is 287 Gy/min, which is 17.2 kGy/h. The same result was obtained by ECB dosimeters (Fig.2.).

The function presented in Fig.3. is extrapolated to zero time and under. The absorbed dose for zero time actually represents the absorbed dose during source transit in the place of alanine dosimeters. As the time of source transit is included in irradiation time,

the absorbed dose in selected place has to be less during source transit than without it when the source is in position for irradiation and the dose rate value is constant (287 Gy/min). This is a reason why the sign of absorbed dose is negative in Fig.3.

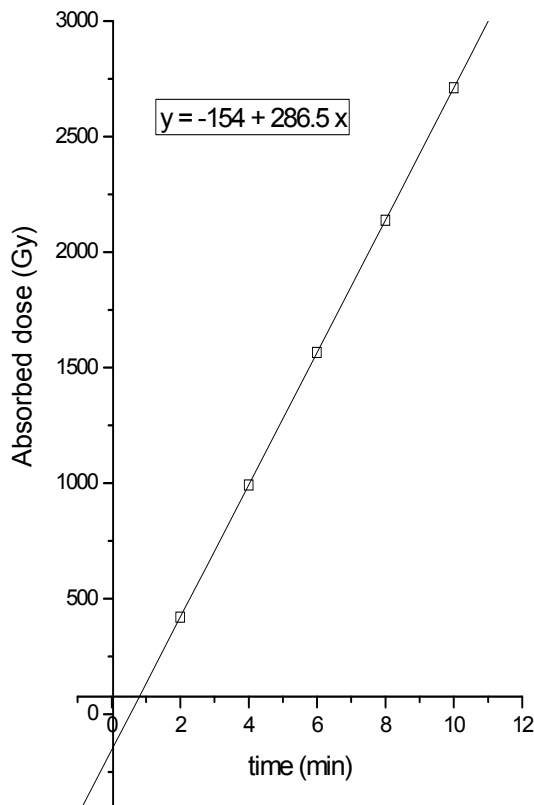


Fig. 3 Absorbed dose at a distance of approximately 7 cm from the central part of the source plane and 90 cm vertical distance from the bottom of the box carrier versus irradiation time, as measured by alanine dosimeters

The graphical extrapolation to zero time gives the result of 154 Gy absorbed dose during process interruption in the nearest place of irradiated product with regard to the source, where the influence of source transit to absorbed dose is the most. This value of the absorbed dose is the upper limit of the influence of one irradiation interruption to radiation sterilization process. It can be said that the effect of one process interruption to absorbed dose in irradiated product is not greater than 154 Gy when the source activity is 5.41×10^{15} Bq in the Radiation Plant in Vinča Institute. Knowing that the sterilization dose is 25 kGy, the influence of process interruption is not greater than 0.004%, i.e. it is negligible. Compared with the uncertainty of irradiation process which is $\pm 3.5\%$ ⁽¹³⁾, the number of process interruptions should be more than ten to be noticed in direct measurements of absorbed dose in sterilization process.

It should be noted that the time of source transit can be determined using the linear regression extrapolated to the x axis presented in Fig.3. The absolute value of the x intercept is the equivalent of the transit time. In this case the transit time is 32s.

In conclusion, the above-described method allows the determination of absorbed dose during source transit and its effect of process interruption by graphical extrapolation to zero time of irradiation, as presented in Fig.3. For this method it is important to determine the position of the dose rate maximum at the selected distance from the source.

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