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Dose Mapping for Performance Qualification of Electron Beam Sterilization Facility using B3 Riso Scan Dosimetry System

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Abstract : Dose mapping exercises for Performance Qualification(PQ) are used to identify locations and magnitudes of minimum and maximum doses within the product and to show the relationship between these doses and the dose at a monitoring position. This experiment was performed at 10 MeV/ 10kW electron beam accelerator which is operating in institute of Nuclear Chemistry and Technology (INCT), Warsaw, Poland. In this experiment, the acceptable dose for medical device sterilization 28kGy is applied B3 films and the dose was read out by B3 Risø Scan system. From the absorbed dose measurements, D_{min} is 24.3 kGy and D_{max} is 35.8kGy.The overall dose received in container is 88.5 % to 136%. Dose Uniformity Ratio DUR is 1.4.

***IndexTerms* - Dose mapping, electron beam sterilizaition, B3 Riso scan .**

I. Introduction

Dosimetry is as part of the total quality system and provides quality assurance and documentation that the irradiation procedure has been carried out according to specifications. Accurate, traceable dose measurements provide independent, inexpensive means for quality control in radiation processing. Dosimetry is applied for installation qualification, operational qualification, performance qualification and process control. For Performance Qualification, dose mapping experiment was done in medical sterilization activities. Dose mapping is not only used in PQ, but also in OQ, where the process load is a dummy or homogenous reference material such as polyethylene foam and not the actual product. This procedure allows the dosimetric release of the product: when the routine monitoring dosimeter shows a magnitude which is within the specified dose window, it can be inferred that the minimum and maximum doses in the product are also in the correct specified window. This ensures that the product was properly treated and can be released.

II. Electron Beam Irradiation Experimental Work

This experiment was performed at 10 MeV/ 10kW electron beam accelerator which is operating in institute of Nuclear Chemistry and Technology, Warsaw, Poland. In this experiment, B3 Riso Scan Dosimetry System was used and applied dose of 28kGy which is acceptable for medical device sterilization. This is typically used in IQ/OQ and PQ dose mapping applications, as well as other testing and research. B3 Risø Scan system uses a MS Windows-based software program that estimates dose from bitmap image files specially designed for high-resolution dose mapping. In this study, there are seven layer of B3 dosimeters are used in electron beam sterilization facility. 10 MeV electron beam accelerator is used for irradiation dose 28 kGy on the irradiation containers 46 x 58 x 20(cm). B3 film dosimeters were placed on polyethylene board in five positions. Seven layers of boards were placed in single container as shown in Figure 1. Electron Beam Irradiation was applied with 28kGy which is acceptable for medical device sterilization.

Before Irradiation Electron Beam Irradiation After Irradiation

Figure 1 B3 film Dosimeters Placement in seven layers and Electron Beam Irradiation

III. RESULT AND DISCUSSIONS

The purpose of dose mapping is to demonstrate that: D (min) >D (Steril) and D (max) < D (acceptable) and D (min) determined by sterilization, D (max) determined by radiation -induced changes in product. For sterilization, the D min should be 25kGy and D max should be 40kGy according to customer requirements. In this experiment, the absorbed dose was read out by Riso scan dosimetry software in Figure 2 . The previous calibration was done with Riso graphite dosimetry system for reference. Graphite calorimeters are mainly used for calibration purposes at standard national laboratories (National Institute of Standards and Technology, USA; Risø National Laboratory, Denmark; National Physical Laboratory, UK), Dose mapping experiment was performed during operational and performance qualification. (ISO 11137-3standard); From this experiment, the routine energy measurement using Graphite calorimeter is 27.7kGy. The absorbed dose measurements for seven layers of B3 dosimeters which are placed in five positions on each layer can be seen in Table 1. It can be noted that from the absorbed dose measurements, D_{min} is position (2.1) 24.3 kGy and D_{max} is at position (3.3) 35.8kGy. 100% dose received is at (2.5)position.

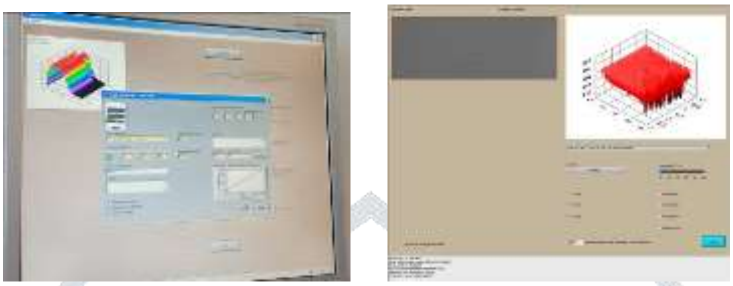

Figure 2 Read out by Riso scan software

Table 1. Absorbed dose measurement of B3 film dosimeters in seven layers read out by B3 Riso scan dosimetry software

Layer 1	**Dose (kGy)**	**Layer 2**	**Dose (kGy)**	**Layer 3**	**Dose (kGy)**	**Layer 4**	**Dose (kGy)**	**Layer 5**	**Dose (kGy)**	**Layer 6**	**Dose (kGy)**	**Layer 7**	**Dose (kGy)**
1.1	24.8	2.1	24.3	3.1	35	4.1	31.5	5.1	30	6.1	28.3	7.1	26.6
1.2	25.8	2.2	25.5	3.2	35	4.2	31.5	5.2	30.1	6.2	27.5	7.2	26.7
1.3	26.1	2.3	27.4	3.3	35.8	4.3	32.5	5.3	32	6.3	29.1	7.3	27.6
1.4	26.4	2.4	27.5	3.4	29.6	4.4	32.7	5.4	32.4	6.4	30.8	7.4	27.6
1.5	25.4	2.5	28.1	3.5	27.3	4.5	27	5.5	32.5	6.5	30.6	7.5	28.4

IV. CONCLUSION

It can be concluded that the overall dose received in container is 88.5 % to 136%. Dose Uniformity Ratio DUR is 1.4. Dose mapping is a core instrument to render a sterile product while sparing product from harm by preventing overdosing. A fine-tuned, robust method, state of the art dosimeters and advance modeling are vital in achieving this goal**.**

V. ACKNOWLEDGMENT

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