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Operational Qualification

Co-60 Reload May 2020

[Unsere Zeichen/Unsere Nachricht vom]

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Analysis of Dose-Mapping Studies performed before and after the Cobalt-60 Reload in May 2020

Before and after the Cobalt-60 reload of our irradiation facility in May 2020 several dose-mapping studies were performed to ascertain the continuous functionality of the irradiation plant. In these studies four irradiation units (consisting of 2 standard cartons each) were used which had the following densities: 0,03 g/cm³, 0,10 g/cm³, 0,13 g/cm³, 0,20 g/cm³. Three dose-mapping studies each were performed for every unit before and after the reload.

The evaluation is based on the dose ratios between the minimum dose and the reference dose in the reference measuring point (RMP) and between the maximum dose and the RMP dose. The mean values of the three replicates of each density before and after reload were checked for differences using a t-Test.

It could be confirmed that the dose quotients before and after reloading do not differ significantly.

This proves that the reloading was successfully completed and that the functionality of the irradiation plant as well as the irradiation field is well maintained. All existing dose mapping studies stay valid. There is no need for further product specific performance qualification.

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Seite 1/3

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Dose Mapping before and after Co-60 reload (May 2020)

The evaluation is based on the dose ratio between the minimum dose and the reference measuring point or the maximum dose and the reference measuring point (min / RMP or max / RMP). The mean values obtained at 4 different densities before and after reloading were checked for significance using a t-test.

Density g/cm ³	min/RMP before reload	min/RMP after reload	max/RMP before reload	max/RMP after reload
0,03	0,932	0,943	1,193	1,225
0,10	0,989	0,983	1,313	1,291
0,13	0,954	0,991	1,310	1,313
0,20	0,968	0,992	1,360	1,401

Zweistichproben t-Test bei abhängigen Stichproben (Paarvergleichstest)
 (two-sample t-test for dependent samples (pair comparison test))

<i>min/RMP</i>	<i>Variable 1</i>	<i>Variable 2</i>	<i>max/RMP</i>	<i>Variable 1</i>	<i>Variable 2</i>
Mittelwert	0,961	0,977	1,294	1,308	
Beobachtungen	4	4	4	4	
Freiheitsgrade (df)	3		3		
t-Statistik	-1,758		-0,941		
P(T<=t) zweiseitig	0,177		0,416		Significance is assumed at P < 0.05
Kritischer t-Wert bei zweiseitigem t-Test	3,182		3,182		

The t-tests show that the dose ratios before and after reloading do not differ significantly.

