



BBF Sterilisationsservice GmbH * Willy-Rüsch-Straße 10/1 * 71394 Kernen

Operational Qualification

Co-60 Reload November 2023

[Unsere Zeichen/Unsere Nachricht vom]

Co-60 Reload Nov. 2023/-

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Datum

2023-11-23

Analysis of Dose-Mapping Studies Performed Before and After the Cobalt-60 Reload in November 2023

Before and after the Cobalt-60 reload of our irradiation facility in November 2023, several dose-mapping studies were performed to ascertain the continuous functionality of the irradiation plant. Both, before and after the Cobalt-60 reload, dose mapping studies were conducted on simulated product of three different densities: 0.04 g/cm^3 , 0.14 g/cm^3 and 0.23 g/cm^3 . For each density, dose mappings were performed on five irradiation units (consisting of 2 standard boxes each). The dose mapping units were shaded exclusively by irradiation units of the same density to create a homogenous irradiation environment.

The evaluation is based on the ratios of the minimum dose to the reference dose in the reference measuring point (RMP) and of the maximum dose to the RMP dose.

The values of the five replicates of each density before and after reload were checked for differences using a t-test. It was 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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The evaluation is based on the ratio of the minimum dose to the reference measuring point (AF_{\min}) or the maximum dose to the reference measuring point (AF_{\max}).

$$AF_{\min} = D_{\min}/D_{\text{mon}}$$

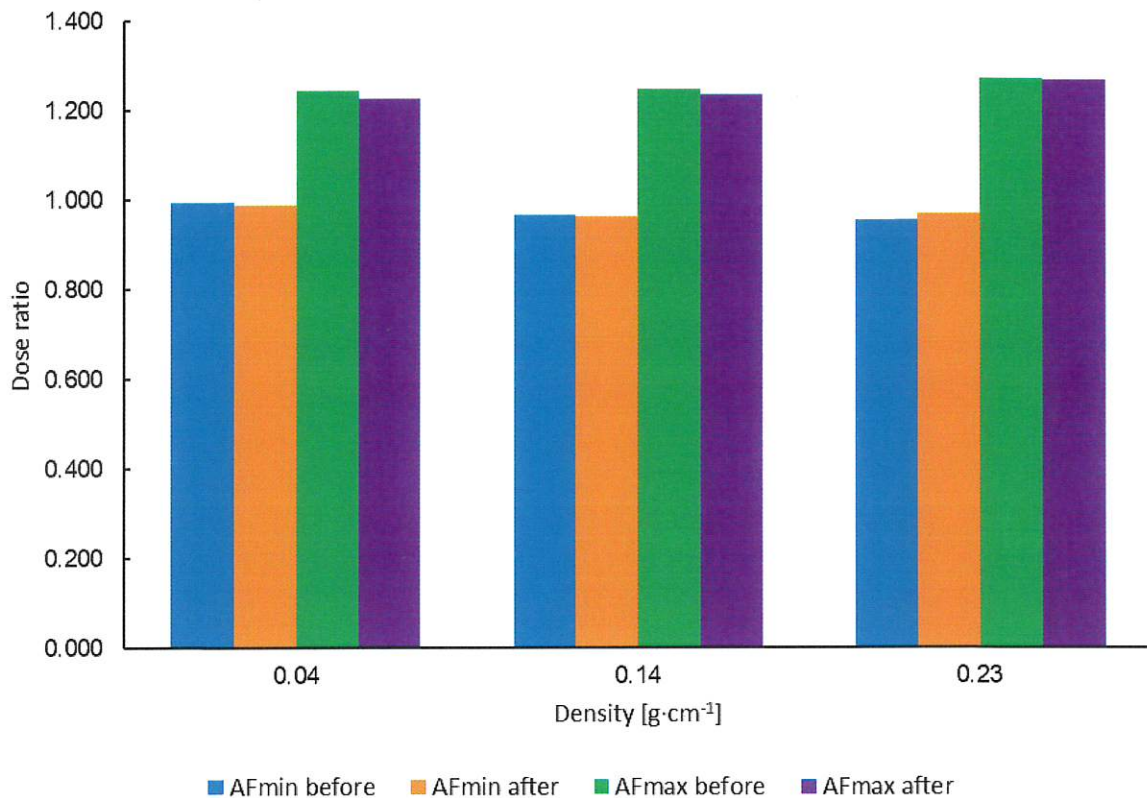
$$AF_{\max} = D_{\max}/D_{\text{mon}}$$

D_{\min} = dose minimum

D_{\max} = dose maximum

D_{mon} = reference dose, measured at routine measuring position

Dose ratios before and after ^{60}Co Reload



Dose ratios AF_{min} and AF_{max} as well as the results of the Student's t-test

Low density (0.04 g/cm³)				
Replicate	AF_{min}		AF_{max}	
	before reload	after reload	before reload	after reload
1	0.982	0.988	1.215	1.219
2	0.997	0.986	1.249	1.218
3	1.003	0.977	1.250	1.230
4	0.997	0.997	1.231	1.229
5	0.991	0.994	1.261	1.227
Mean	0.994	0.988	1.241	1.225
SD	0.008	0.008	0.018	0.006
Results of two-tailed Student's t-test				
	AF_{min}		AF_{max}	
Variance	equal		unequal	
P-value	0.312		0.111	
significantly different?	No		No	
Medium density (0.14 g/cm³)				
Replicate	AF_{min}		AF_{max}	
	before reload	after reload	before reload	after reload
1	0.957	0.961	1.229	1.238
2	0.980	0.951	1.259	1.228
3	0.953	0.955	1.246	1.217
4	0.963	0.980	1.250	1.237
5	0.966	0.961	1.237	1.244
Mean	0.964	0.962	1.244	1.233
SD	0.010	0.011	0.012	0.011
Results of two-tailed Student's t-test				
	AF_{min}		AF_{max}	
Variance	equal		equal	
P-value	0.783		0.139	
significantly different?	No		No	
High density (0.23 g/cm³)				
Replicate	AF_{min}		AF_{max}	
	before reload	after reload	before reload	after reload
1	0.952	0.982	1.271	1.279
2	0.966	0.960	1.284	1.257
3	0.966	0.956	1.289	1.276
4	0.945	0.971	1.245	1.265
5	0.945	0.971	1.247	1.254
Mean	0.955	0.968	1.268	1.266
SD	0.011	0.010	0.020	0.011
Results of two-tailed Student's t-test				
	AF_{min}		AF_{max}	
Variance	equal		equal	
P-value	0.079		0.909	
significantly different?	No		No	