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

Operational Qualification

Co-60 Reload September 2024

[Unsere Zeichen/Unsere Nachricht vom]	Telefon	Fax	Datum
Co-60 Reload Sep. 2024/-	(07151) 94570-10	(07151) 94570-19	2024-10-10

Analysis of Dose-Mapping Studies Performed Before and After the Cobalt-60 Reload in September 2024

Before and after the Cobalt-60 reload of our irradiation facility in September 2024, 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 mean 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}).

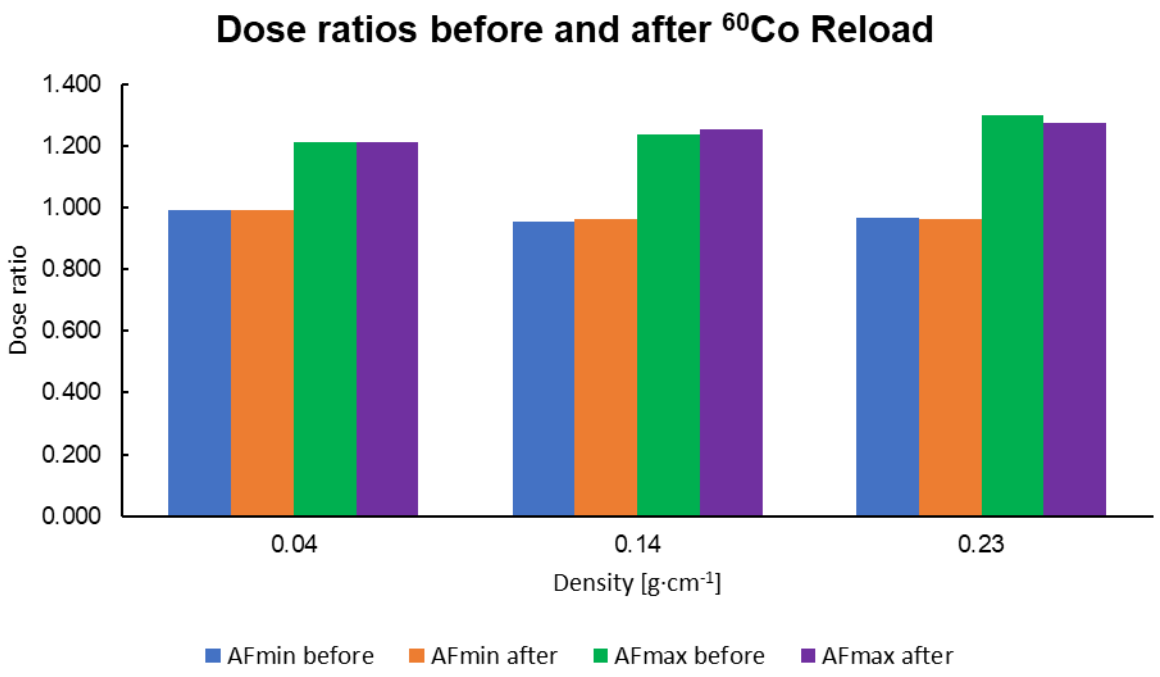
$$AF_{min} = D_{min}/D_{mon}$$

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

D_{min} = dose minimum

D_{max} = dose maximum

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



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

Low density (0.04 g/cm³)				
	AF_{min}		AF_{max}	
Replicate	before reload	after reload	before reload	after reload
1	0.988	0.997	1.203	1.218
2	0.997	0.980	1.226	1.197
3	0.991	1.009	1.217	1.222
4	0.988	0.980	1.210	1.216
5	0.994	0.994	1.215	1.218
Mean	0.992	0.992	1.214	1.214
SD	0.004	0.012	0.009	0.010

Medium density (0.14 g/cm³)				
	AF_{min}		AF_{max}	
Replicate	before reload	after reload	before reload	after reload
1	0.951	0.956	1.227	1.249
2	0.947	0.962	1.224	1.256
3	0.966	0.959	1.246	1.244
4	0.963	0.959	1.247	1.263
5	0.946	0.969	1.242	1.251
Mean	0.955	0.961	1.237	1.253
SD	0.009	0.005	0.011	0.007

High density (0.23 g/cm³)				
	AF_{min}		AF_{max}	
Replicate	before reload	after reload	before reload	after reload
1	0.970	0.955	1.288	1.264
2	0.973	0.951	1.304	1.261
3	0.985	0.984	1.312	1.306
4	0.951	0.962	1.292	1.278
5	0.959	0.973	1.292	1.272
Mean	0.968	0.965	1.298	1.276
SD	0.013	0.014	0.010	0.018

Results of paired Student's t-test				
	Mean AF_{min}		Mean AF_{max}	
Density	before reload	after reload	before reload	after reload
Low density (0.04 g/cm³)	0.992	0.992	1.214	1.214
Medium density (0.14 g/cm³)	0.955	0.961	1.237	1.253
High density (0.23 g/cm³)	0.968	0.965	1.298	1.276
P-Value	**0.677**		**0.862**	
significantly different?	**No**		**No**	

t-Test: Paired Two Sample for Means;
AF_{min}

AF_{min}	*before reload*	*after reload*	
Mean	0.971	0.973	
Observations	3	3	
df	2		
t Stat	-0.482		
P(T<=t) two-tail	0.677		**Significance is assumed at < 0.05**
t Critical two-tail	4.303		

t-Test: Paired Two Sample for Means;
AF_{max}

AF_{max}	*before reload*	*after reload*	
Mean	1.250	1.248	
Observations	3	3	
df	2		
t Stat	0.197		
P(T<=t) two-tail	0.862		**Significance is assumed at < 0.05**
t Critical two-tail	4.303		