

Qualification of a new Cytocontrol® weighing scales prototype under isolator

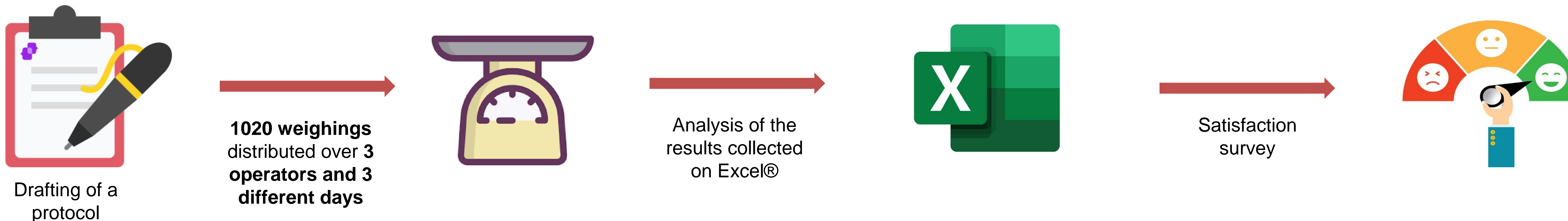
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For many years, Institut Curie has used *in-process* gravimetric control (via Chimio® software) within its chemotherapy production unit. This tool has empowered preparers, made preparation more secure and saved production time. We recently co-developed a new prototype of a "suspended" scale, notably allowing a significant saving of space within our isolators.

Objective: Validate 2 prototypes of "suspended" scales for application to *in-process* gravimetric control at the Institut Curie.



Methods



Results

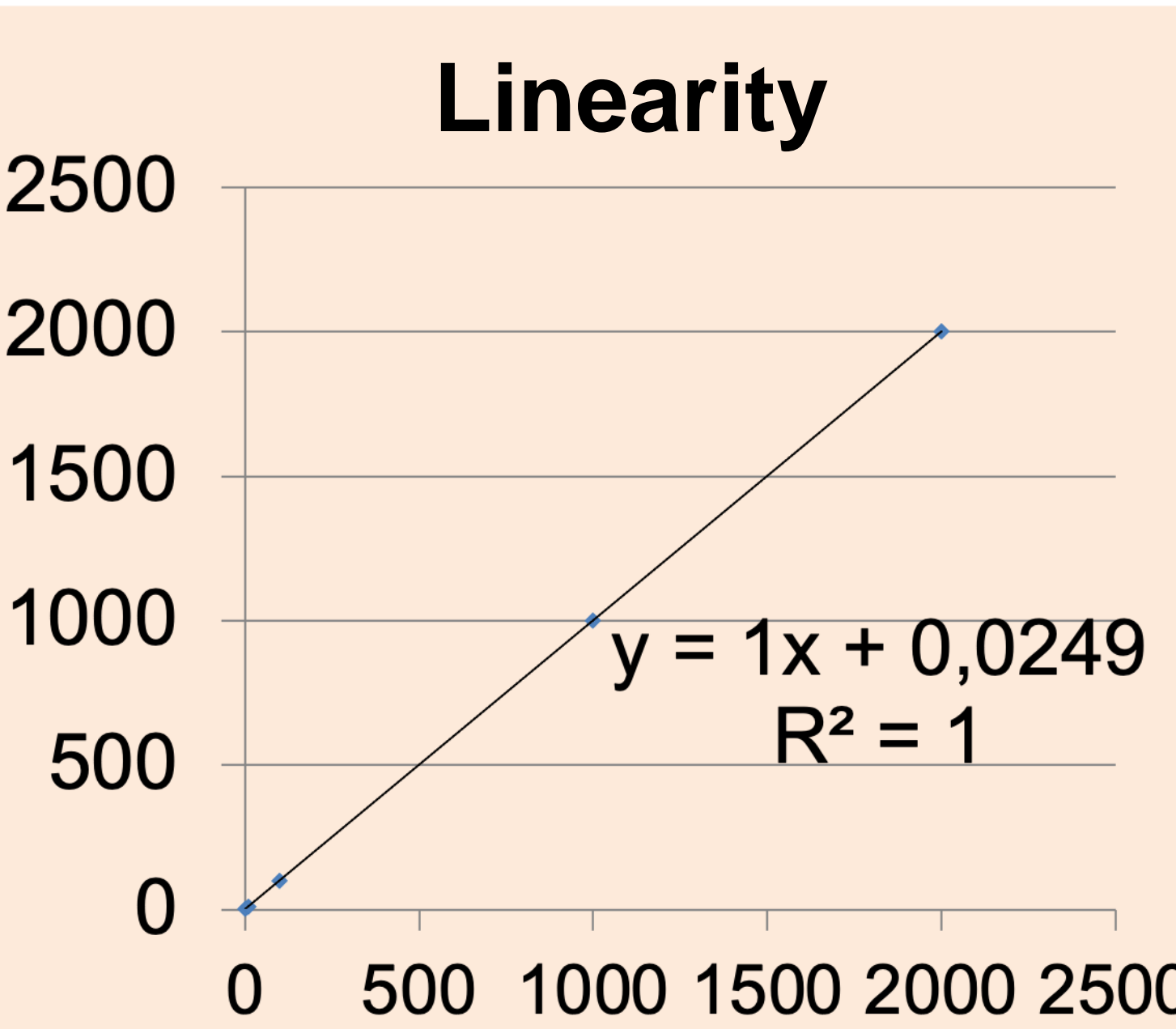
Performance Qualification

Fidelity					
Weight (g)	1	10	100	1000	2000
Max deviation	0,02	0,04	0,04	0,06	0,06
MTD	0,1	0,1	0,1	0,2	0,2
Max dev ≤ MTD	Yes	Yes	Yes	Yes	Yes

Accuracy					
Weight (g)	1	10	100	1000	2000
Max error	0,02	0,02	0,04	0,04	0,04
MTD	0,1	0,1	0,1	0,2	0,2
Max dev ≤ MTD	Yes	Yes	Yes	Yes	Yes

Eccentricity					
	Center	LB	RB	LF	RF
Mean	499,97	499,95	499,95	499,95	499,95
SD	0,010	0,010	0,010	0,017	0,011
CV	0,002	0,002	0,002	0,003	0,002
CV < 0,05%	Yes	Yes	Yes	Yes	Yes

Precision					
Weight (g)	100	1000			
SD	0,014	0,015			
SD < 5d	Yes	Yes			
Inter-test precision					
	1g	10g	100g	1000g	2000g
	3,900%	0,200%	0,015%	0,004%	0,002%



Survey	
Advantages	Disadvantages
<ul style="list-style-type: none"> « Ergonomics » +++ « Space saving » 	<ul style="list-style-type: none"> « Uncomfortable posture » ("arms raised") "A little small scale plate for large volumes" "Non-optimal installation in our isolator"

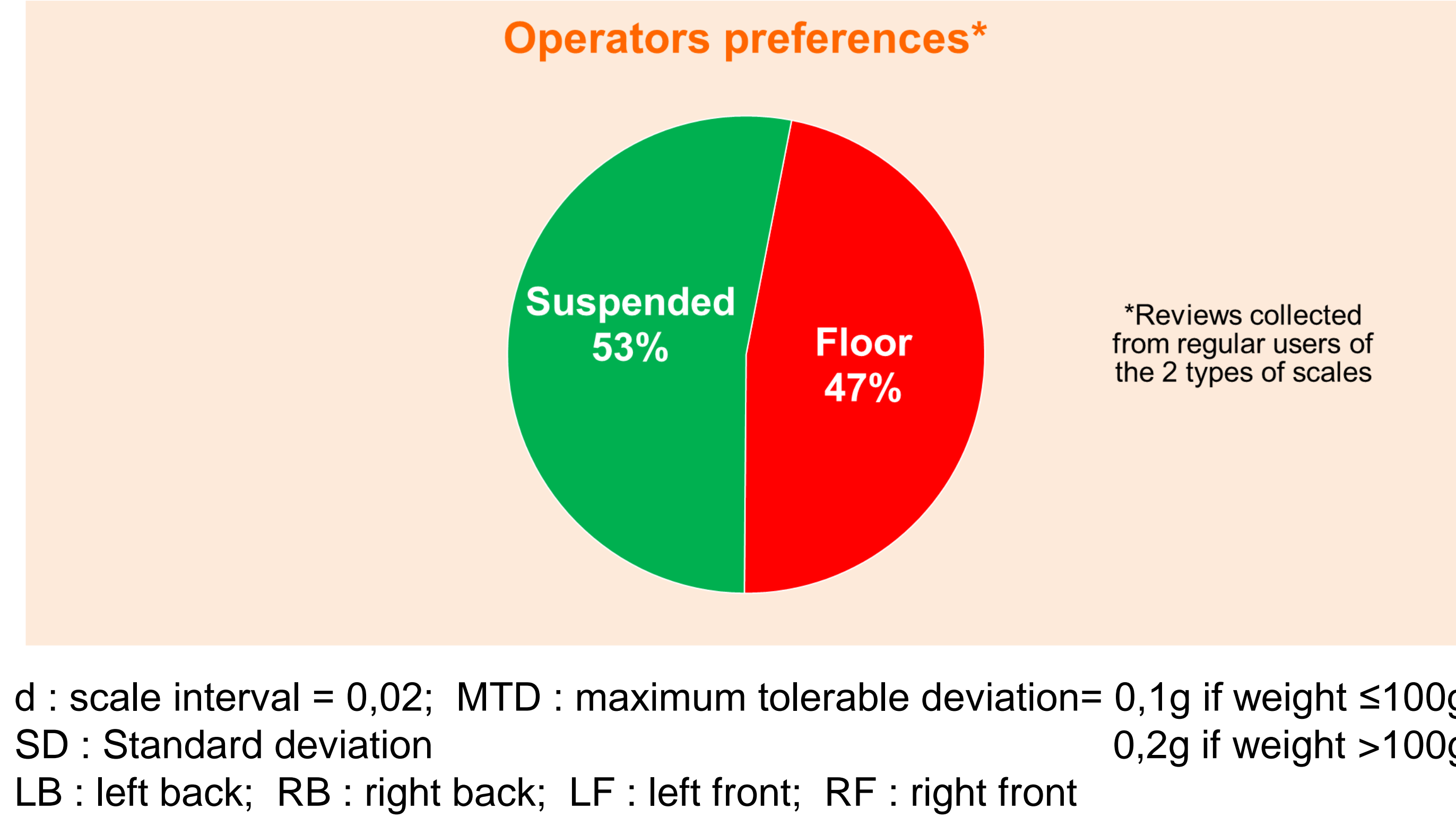
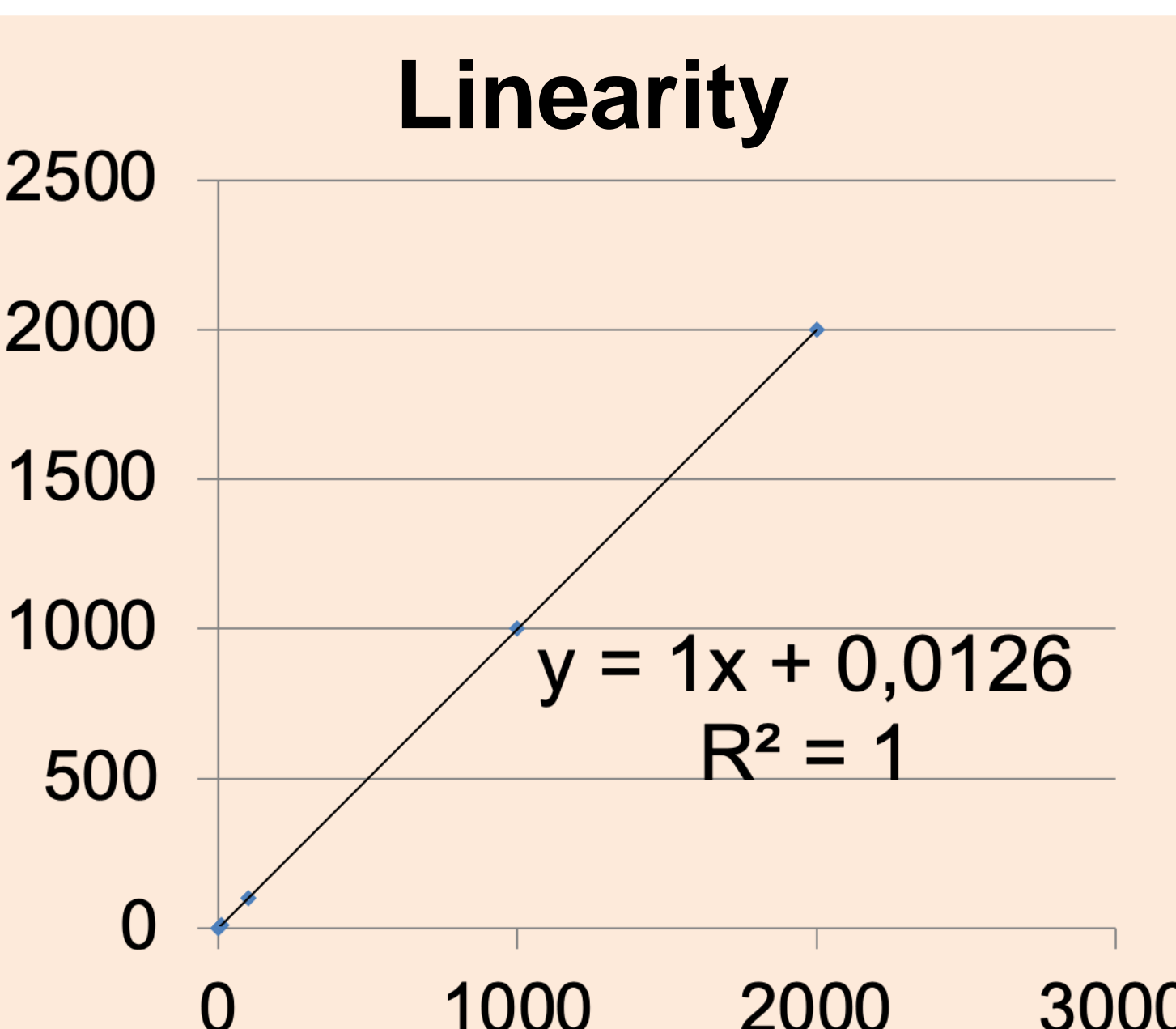
Operational Qualification

Fidelity					
Weight (g)	1	10	100	1000	2000
Max deviation	0,06	0,1	0,1	0,12	0,14
MTD	0,1	0,1	0,1	0,2	0,2
Max dev ≤ MTD	Yes	Yes	Yes	Yes	Yes

Accuracy					
Weight (g)	1	10	100	1000	2000
Max error	0,04	0,06	0,06	0,08	0,12
MTD	0,1	0,1	0,1	0,2	0,2
Max dev ≤ MTD	Yes	Yes	Yes	Yes	Yes

Eccentricity					
	Center	LB	RB	LF	RF
Mean	499,94	499,93	499,93	499,94	499,97
SD	0,029	0,041	0,011	0,032	0,048
CV	0,006	0,008	0,002	0,006	0,010
CV < 0,05%	Yes	Yes	Yes	Yes	Yes

Precision					
Weight (g)	100	1000			
SD	0,032	0,036			
SD < 5d	Yes	Yes			
Inter-test precision					
	1g	10g	100g	1000g	2000g
	2,100%	0,260%	0,025%	0,004%	0,002%



Discussion-Conclusion



The prototype complies with the recommendations of the OMCL 2013 for the studied criteria.

The mock-up of the isolator and its contents upstream is therefore an essential step in optimizing the installation of this type of equipment.