Clause-by-Clause tracking – TGO109 – New to Old

TGO109	Sunsetting TGO	Regulatory requirement	Summary of change from current standard
Part 1 - Preliminary			
4	TGO 83-87 – 4	No change	Definitions - Redrafted to clarify intent
6 (1)	*Not in standard*	Increase	Applications to all Biologicals. TGO83-87 apply only to Class 2 Biologicals
6 (2)(a)	*Not in standard*	No change	**New** – Clarification for standard does not apply to FMT products
6 (2)(b)	*Not in standard*	Decrease	Exemption to 'Exempt Autologous HCT products'
6 (2)(c)	TGO88 - 7(2)	No change	No change
Part 2 - Diseases and conditions that may compromise biologicals			
9	TGO88 9(13-15)	Increase	Scope increased from infectious disease or age to any condition or disease.
Part 2 - Critical materials			
10(1)(a)	TGO88 - 13(1)	No change	Redrafted to clarify intent
10(1)(b)	TGO83-86 7(1)	Increase	No change – Intent clarified for all biologicals
10(1)(c-e)	13(2)(a-c)	No change	No change
10(2)	TGO88 13(2)(d)	No change	No change
Part 2 - Microbial contamination control strategy			
11	TGO 88 12(1)	Decrease	Re-drafted to allow alternatives based on technical advancement
Part 2 - Samples for bioburden testing			
12(1)	TGO88 12(5)	No change	Redrafted to clarify intent
12(2)	TGO88 12(5)	No change	Redrafted to clarify intent

TGO109	Sunsetting TGO	Regulatory requirement	Summary of change from current standard
12(3)	*Not in standard*	No change	**New** - Clarifies exemptions for ocular tissue
Part 2 - Bioburden testing requirements			
13(1)	TGO83 7(9) & TGO86 7(4)	Increase	Redrafted to clarify intent - now applies to all biologicals
13(2)	TGO83 7(9) & TGO86 7(4)	Increase	Re Redrafted to clarify intent now applies to all biologicals
13(3)	TGO88 12(5)(a-b)	No change	No change
13(4)	*Not in standard*	No change	**New** - Clarifies exemptions for ocular & cardiovascular
13(5)	*Not in standard*	No change	**New** - Clarifies exemptions for musculoskeletal & cardiovascular
Part 2 - Sterilisation			
14(1)	TGO88 12(5)(e)	No change	No change
Part 2 - Collection from deceased donors			
15(1)	TGO88 12(2)	No change	Redrafted to clarify intent
15(2)	*Not in standard*	No change	**New** - Clarifies exemptions for musculoskeletal, ocular and amnion
Part 2 - Storage and transportation			
16(1)	TGO88 12(3)	No change	Redrafted to clarify intent
16(2)	*Not in standard*	No change	**New** - Clarifies exemptions for musculoskeletal, ocular and amnion
16(3)	TGO83 7(4), TGO86 7(2)	Increase	Redrafted to clarify intent – now applies to all biologicals
16(4)	TGO88 12(4)	No change	Redrafted to clarify intent
16(5)	*Not in standard*	No change	**New** - Clarifies exemptions for musculoskeletal, cardiovascular, ocular, skin and amnion

TGO109	Sunsetting TGO	Regulatory requirement	Summary of change from current standard
16(6)	*Not in standard*	Increase	**New -** Requirements for re-release of returned biological
Part 2 - Containers of biologicals			
17(1)	TGO83 7(11) TGO84 7(6) TGO86 7(7)	Increase	No change - Requirement now applies to all biologicals
17(2)	*Not in standard*	No change	**New** - Clarifies exemptions for ocular
Part 3 - Standard for human musculoskeletal products			
Collection from deceased donors			
20	TGO83 7(2)	No change	No change
Bioburden testing			
21	TGO83 7(5-8)	No change	No change
Demineralised products			
22	*Not in standard*	Increase	**New** - Limits for residual calcium in demineralised products
Freeze dried products			
23	*Not in standard*	Increase	**New** - Specifies residual moisture limits in freeze-dried products
Storage and transport			
24	TGO83 7(12)	Increase	Clarification that storage is from 'collection' and not 'completion of processing'.
24 (a) (iii)	*Not in standard*	Increase	**New** - Specifies storage conditions for freeze-dried products
Clauses from Part 2 which apply to musculoskeletal products			
Part 2 – 9, 10,11, 12,13(1), 14, 16(1), 16(4), 16(6) & 17(1)			
Part 4 - Standard for relevant human cardiovascular tissue products			

TGO109	Sunsetting TGO	Regulatory requirement	Summary of change from current standard
Tissue not subjected to a bioburden process			
27	TGO84 7(2)	No change	No change in requirement. Term 'manufacture' replaced with 'processing' and bioburden sampling point clarified
Tissue subjected to a bioburden reduction process			
28	TGO84 7(3)	No change	Redrafted to clarify intent
Heart valves			
29	TGO84 7(5)	No change	No change
Storage and transport			
30(1)	TGO88 12(3)	No change	No change in requirement – Clarification that timeframes for 72 hours in transportation do not apply as processing to be completed or initiated prior to that. Clarification that temperature below 10°C imply 0° -10°C
30(2,3)	TGO84 7(7)	No change	No change in requirement Clarification that storage duration is from 'collection'.
Clauses from Part 2 which apply to Cardiovascular products			
Part 2 – 9,10,11,12, 14,15,16 and 17			
Part 5 - Standard for relevant human ocular tissue products			
Collection			
33	TGO85 7(2,3)	Increase	Clarification that collection must be 'completed' and not 'commence' consistent with timeframes and requirements specified in rest of the standard.
Storage and transportation			
34 (a, b and d)	TGO85 7(4)	No change	Clarification that storage duration is from 'collection'.
34 (c)	*Not in standard*	Increase	**New** - Specifies storage conditions for sclera
Testing of storage medium			

TGO109	Sunsetting TGO	Regulatory requirement	Summary of change from current standard
35	TGO85 7(5)	No change	No change
Containers			
36	TGO85 7(6)	No change	No change
Examination and evaluation			
37	TGO85 8(1)	No change	No change
Clauses from Part 2 which apply to ocular products			
Part 2 – 9,10,11,14 and 16(1)			
Part 6 - Standard for relevant human skin products			
Collection			
40(1)	TGO86 7(2)	No change	No change in requirement – Re-drafted for clarification
40(2)	*Not in standard*	Increase	**New** - Specifies time limits when collection must commence
Microbial contamination			
41	TGO86 7(4,5)	No change	No change
Freeze-dried products			
42	*Not in standard*	Increase	**New** - Specifies residual moisture limits for freeze-dried products
Storage and transportation			
43(1)	TGO88 12(3)	No change	No change in requirement – Clarified that timeframes for 72 hours in transportation do not apply as processing initiates or completes prior to that based on other requirements for such products
43(2)	TGO86 7(8)	No change	No change
Clauses from Part 2 which apply to skin products			

TGO109	Sunsetting TGO	Regulatory requirement	Summary of change from current standard
Part 2 – 9,10,11,12, 13(1-2), 13(5),14,15,16(2-6) and 17			
Part 7 - Standard for relevant human amnion products			
Collection			
46	*Not in standard*	Increase	**New** - Specifies collection times
Terminal sterilisation			
47	*Not in standard*	Increase	**New** - Specifies requirements for amnion collected from vaginal delivery
Dehydrated products			
48	*Not in standard*	Increase	**New** - Specifies residual moisture limits
Freeze-dried products			
49	*Not in standard*	Increase	**New** - Specifies residual moisture
Storage and transportation			
50(1)	*Not in standard*	Increase	**New** - Specifies transport conditions for material pre-processing
50(2,3)	*Not in standard*	Increase	**New** - Specifies storage conditions for amnion products
Clauses from Part 2 which apply to amnion products			
Part 2 – 9, 10, 11, 12,13,14,16(3-6) and 17			