

## Clause-by-Clause tracking – TGO108 – New to Old

TGO108	Sunsetting TGO 88	Regulatory requirement	Summary of change from current standard
<b>Preliminary</b>			
4	5	No change	Definitions - Redrafted to clarify intent
5	6	No change	No change
6 (a)	<i>Not in standard</i>	No change	<b>New</b> – Clarification for standard does not apply to FMT products
6 (b)	7(2)	No change	No change
6 (c)	<i>Not in standard</i>	Decrease	<b>New</b> – Autologous exemption
<b>General requirements</b>			
8(1)	8(1)(a)	No change	No change
8(2)	<i>Not in standard</i>	No change	<b>New</b> - Clarification of intent of TGO
8(3)	8(1)(c)	No change	No change
8(4) (a,b)	10(3, 4)	No change	No change
8(4) (c)	<i>Not in standard</i>	No change	Clarification of intent in TGO88 10(6)
8(5)	10(6)	No change	Redrafted to clarify intent
8(6)	10(7)	No change	Redrafted to clarify intent
8(7-8)	10(5)	No change	No change
8(9)	10(11)	No change	No change
8(10)	8(1)(b)	No change	No change
<b>Medical and Social history</b>			
9(1,2)	9(1)	No change	No change
9(3)	9(2)	No change	No change

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9(4)	9(6) & 9(11)	No change	No change
9(5)	9(7)	No change	No change
9(6)	9(8)	No change	No change
9(7)	9(3)	No change	Redrafted to clarify intent
9(8)	9(4)	No change	No change
9(9-12)	9(9)	No change	Redrafted to clarify intent
9(13)	7(b)	Increase	Exemptions for directed allogeneic HCT products
<b>Blood sampling and testing</b>			
10(1,2)	10(1)	No change	No change
10(3)	10(2) & 11(3) & 11(4)(a) & 11(4)(b)	No change	No change
10(4)	10(2), 10(9)(a) & 11(3) & 11(4)(c)	No change	No change
10(5)	10(2) & 11(3) & 11(4)	No change	No change
10(6)	10(3) & 11(3) & 11(4)	Increase	Proposal not to exempt cornea only donors from NAT
10(7)	11(3) & 11(4)	Increase	Proposal not to exempt cornea only donors from NAT
10(8)	11(3) & 11(4)	No change	No change
10(9)	11(3) & 11(4)(c)	No change	No change
10(10)	11(3)	Increase	Mandate NAT HBV testing for plasma for fractionation donors

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10(11)	11(4)(d)	No change	No change
10(12)	11(3)(b)	No change	No change
10(13)	11(4)(d)	No change	No change
10(14)	10(8)	No change	No change
10(15)	11(3)(a)(i)	No change	No change
10(16)	7(b)	Increase	Exemptions for directed allogeneic HCT products
10(17)	10(9)(b) & 10(9)(c)	Decrease	Allowance for alternative archival timeframes subject to appropriate validation
10(18)	10(10)	No change	No change
<b>Physical assessment</b>			
11(1) (a)	11(2)(a)	No change	No change
11(1) (b)	TGO83 7(3)	Decrease	Musculoskeletal - Allowance for conducting on the day or 30 days after collection for living donor
11(1) (c)	11(2)(b)	No change	No change
11(2)	11(2)	No change	No change
<b>Ineligibility criteria for donor selection – Schedule 1 in TGO108</b>			
Item 1	Table 1 (a)	No change	No change
Item 2	Table 1 (a)(iii)	No change	No change
Item 3	Table 1 (b)	No change	No change
Item 4	Table 1 (b)(iii)	No change	No change
Item 5	Table 1 (c)	No change	Redrafted to clarify intent

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Item 6	Table 1 (d)	Increase	Ineligibility criteria extended to persons injecting a substance for cosmetic use
Item 7	Table 1 (e)	No change	No change
Item 8	Table 1 (f)	No change	No change
Item 9	Table 1 (g)	No change	No change
Item 10	Table 1 (h)	Increase	Ineligibility criteria clarified to include 'other bodily fluids', 'earrings' and 'dry needling'.
Item 11	Table 1 (j)	No change	No change
Item 12	Table 1 (k)	Decrease	Decrease in period of ineligibility for high risk sexual behaviour donors ( <i>conditions for 3month deferral period may be specified based on consultation</i> )
Item 13	Table 1 (l)	No change	No change
Item 14	Table 1 (m)	Increase	Ineligibility criteria clarified to include 'active infections'.
Item 15	Table 1 (s)	No change	No change
Item 16	Table 1 (n)	No change	Malaria - Requirements re-articulated to clarify intent in TGO88. ( <i>alternatives to immunological test may be specified based on consultation</i> )
Item 17	Table 1 (p)	No change	
Item 18	Table 1 (o)	No change	
Item 19	Table 1 (q)	No change	
Item 20	Table 1 (r)	No change	No change
Item 21	Table 1 (i)	No change	No change
Item 22	Section 11(2)(c)	No change	Included in table for social and medical history ineligibility criteria from physical assessment. Term 'autopsy' replaced with 'post-mortem'

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Item 23 - 26	Table 2	No change	No change