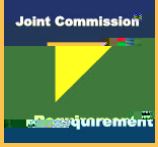




Prepublication Requirements

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New and Revised Laboratory Requirements Related to Histocompatibility

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D`YUgY`bchY.Ä Y @^!^Äæ]] |ä&æà|^ÉÄc@i•Ä!^] [!cÄ•@ [, •Ä& ~ !!^] cÄ•cæ} äæ!ä•Äæ} äÄÖÜ•Ä-ä!•cÉÄ , äc@Ää^|^c^äÄ|æ} * ~ æ*^Ä•c! ~ &\É c@! [~ *@ÉÄV@^} ÉÄc@^Ä!^Çj•ÄâÄ!^ ~ ä!^ { ^} cÄ- [|| [, •Ää} Äà [|äÄc^çcÉÄ , äc@Ä} ^ , Ä|æ} * ~ æ*^Ä ~ } ä^!|ä} ^äÉ



Leadership (LD) Chapter

LD.04.05.01

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Element(s) of Performance for LD.04.05.01

BYk`9D`' H\Y`UVcfUhcfm`X]fYWhcf`]g`cbg]hY`Uh`h\Y`UVcfUhcfm`Uh`YUgh`cbWY`Y jYfm`g]I`a cbh`gž`k]h`Uh`YUgh`Zc i f`a cbh`g`VYh kYYb`h\Y`a]b]a i a`h k c`cbg]hY` j]g]hg" BchY`%.`H\Y`UVcfUhcfm`X]fYWhcf`]g`UWWYgg]V`Y`hc`h\Y`UVcfUhcfm`hc`dfc j]XY`cbg]hYž`hY`Yd`cbYž`cf`Y`YWhfcb]W`Wcbg i`hUh]cb`Ug`bYWYggUfm" BchY`&.`H\Y`cbg]hY` j]g]hg`UfY`XcW i a YbhYX`UbX`]bW` i XY`Y j]XYbWY`cZ`dYfZcf a]b [`UWh] j]h]Yg`h`Uh`UfY`dUfh`cZ`h`Y`UVcfUhcfm`X]fYWhcf]g`fYgdcbg]V`]h]Yg" BchY`'.`H\Y`UVcfUhcfm`X]fYWhcf` a U`_Yg`WYfhU]b`h`Uh`U` [YbYfU`g`i dYf j]gcf`dfc j]XYg`cb!g]hY`g i dYf j]g]cb`cZ` \] [`Wc a d`Y I]hm`hYgh`dYfZcf a UbWY`Vm`hYgh]b [`dYfgcbbY`e i U`]YX` i bXYf (&`7`:`F`(-`"%(`,-`flVłfl)ł"

Ⓓ 8cW i a YbhUh]cb`]g`fYe i]fYX

BYk`9D`%\$ H\Y`DDA`UVcfUhcfm`X]fYWhcf`]g`fYgdcbg]V`Y`Zcf`h\Y`Zc`c k]b [. ! 9 jU` i Uh]b [`h\Y`Wc a dYhYbWm`cZ`U`hYgh]b [`dYfgcbbY`hc`Ybg i fY`h`Uh`h\Y`ghUZZ` a U]bhU]bg`h`Y]f Wc a dYhYbWm`hc`dYfZcf a`hYgh`dfcWYX i fYg`UbX`fYdcfh`hYghg`dfc a dh`mž`UWW i fUhY`mž`UbX`dfcZ]W]Ybh`m" ! 9 jU` i Uh]b [`UbX`XcW i a Ybh]b [`h\Y`dYfZcf a UbWY`cZ`]bX] j]X i U`g`fYgdcbg]V`Y`Zcf`DDA`hYgh]b [`Uh`YUgh`gY a]Ubb i U`m`X i f]b [`h\Y`Z]fgh`mYUf`h\Y`]bX] j]X i U`hYghg`dUh]Ybh`gdYW] a Ybg`H\Y`fYUZhYfž`Y jU` i Uh]cbg`UbX`XcW i a YbhUh]cb` a i gh`VY`dYfZcf a YX`Uh`YUgh`Ubb i U`m" BchY.`H\Y`dfcWYX i fYg`Zcf`Y jU` i Uh]cb`cZ`h\Y`Wc a dYhYbWm`]bW` i XY`V i h`UfY`bch`] a]hYX`hc`h\Y`Zc`c k]b [. ! 8]fYWh`cVgYf jUh]cbg`cZ`fc i h]bY`dUh]Ybh`hYgh`dYfZcf a UbWYž`]bW` i X]b [ž`ž`Udd`]WUV`Yž`gdYW] a Yb` \UbX`]b [ž`dfcWYgg]b [ž`UbX`hYgh]b [! Acb]hcf]b [`h\Y`fYWcfX]b [`UbX`fYdcfh]b [`cZ`hYgh`fYg i`hg



Quality System Assessment for Nonwaived Testing (QSA) Chapter

QSA 1201.01

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Element(s) of Performance for QSA 1201.01

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^--á&æ&^Á[-Ác@^Á { ^c@[!á•Á, ác@Á~ æ|æc^Á&[]c! [!Á]! [&^á~!^•É

FYj]gYX'9D'* -Z'h\Y''UVcfUhcfm' i gYg]a a i bc`c [JW'fYU [Ybhg'hc'ZUW]'hUhY'cf'Yb\UbWY'h\Y']gc`Uh]cb'cZ'
`m a d\cWmhYgž'cf`m a d\cWmhY'g i VgYhgž'h\Y''UVcfUhcfm' a cb]hcf'g'h\Y'YZZ]WUWm'cZ'h\Y' a Yh\cXg'k]h\
e i U]hm'Wcbhfc`dfcWYX i fYg"

ÒÚÁÌ V@^Á|æà[!æc[!^Á@æ•ÁæÁ•^•c^ { Áá}Á] |æ&^Á- [!Á]! []^!Á•c [!æ*^Áæ} áÁ { æá}c^}æ}&^Á[-Áà [c@Á!^&á]á^}cÁ•^!æÁæ}áÁ
!^æ*^}c^ÁæcÁæ}Áæ&&^}cæà|^Ác^ {]^!æc" !^Á!æ} *^Á- [!Á•^!æÁæ}áÁ&[{ []^}c•ÉÁá}&|~áá} *ÁæÁc^ {]^!æc" !^Áæ|æ! { Á
•^•c^ { Áæ}áÁæ}Á^ { ^! *^} &^Á] |æ}Á- [!Áæ|c^!}æcáç^Á•c [!æ*^É

FYj]gYX'9D', H\Y''UVcfUhcfm' i gYg'U'Wcbh]b i c i g' a cb]hcf]b ['UbX'U'Yfh'gmghY a 'hc' a cb]hcf'h\Y'ghcfU [Y
hY a dYfUh i fY'cZ'gdYW] a Ybg'fiXcbcf'UbX'fYW]d]Ybhl'UbX'fYU [Ybhg" H\Y'gmghY a 'bch]Z]Yg''UVcfUhcfm
ghUZZ' k \Yb'hY a dYfUh i fY''] a]hg'UfY'YI WYXYX"

UHDJPSSRQ RI



Current OSA.12.02.01 through OSA.12.07.01 were deleted and replaced with the following

OSA.12.02.01

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Element(s) of Performance for OSA.12.02.01

BYk`9D`% H\Y`UVcfUhcfm`i gYg` \ i a Ub`Y i _cWmhY`Ubh] [Yb`fl<@5k`hYf a]bc`c [m`h\Uh`WcbZcf a g`hc`h\Y`Kcf`X` <YU`h`Cf [Ub]nUh]cb`fiK <Cl`Bc a YbW`Uh i fY`7c a a]hhYY`Zcf` :UWhcfg`cZ`h\Y`<@5`GmghY a "

BYk`9D`& H\Y`UVcfUhcfm`XYjY`cdg`UbX`] a d`Y a Ybhg`k f]hhYb`Wf]hYf]U`Zcf`XYhYf a]b]b [`k \Yb`Ubh] [Yb`UbX` U`Y`Y`hmd]b [`UfY`fYe i]fYX"

- Ⓓ 8cW i a YbhUh]cb`]g`fYe i]fYX

OSA.12.03.01

V@^Á|æà [!æc [!^Á] ^!- [! { •Á@ ~ { æ } Á | ^ ~ \ [& ^c^Áæ } cá*^ } ÁÇPŠCEDÁ•^! [[! *á&Áæ } cáà [á^Á•&!^ } á } *Áæ } áÁáá^ } cá-á&æcá []É

Element(s) of Performance for OSA.12.03.01

BYk`9D`% H\Y`UVcfUhcfm` a U_Yg`U`fYUgcbUV`Y`YZZcfh`hc` \UjY`UjU]UV`Y` a cbh` \m`gYf i a `gdYW] a Ybg`Zcf`U` dchYbh]U` hfUb]gd`Ubh`fYW]d]Ybhg`Zcf`dYf]cX]W`Ubh]VcXm`gWfYYb]b [ž]XYbh]Z]WUh]cbz`UbX`Wfcgg a UhW` "

- Ⓓ 8cW i a YbhUh]cb`]g`fYe i]fYX

OSA.12.04.01

V@^Á|æà [!æc [!^Á&! [•• { æc&@^•Á] [c^ } cáæ]Á!^&á] á^ } c•Áæ } áÁá [] [!•Áá^~ [!^Ác!æ } •]]æ } cæcá [] Áá•Á] ^!- [! { ^áÉ

Element(s) of Performance for OSA.12.04.01



Element(s) of Performance for QSA.12.06.01

BYk'9D% H\Y`UVcfUhcfm'XcWi a Ybhg'U`Wcbhfc`dfcWYX i fYg'dYfZcf a YX'fY`UhYX'hc`\]ghcWc a dUh]V`]hm
hYgh]b["

Ⓓ 8cWi a YbhUh]cb`]g'fYe i]fYX

QSA.13.07.01

V@^Á|æà[!æc[!^Á!^cæä}•Á@ã•c[![*ã&æ]Á•]^&ã{^}•Á~[!Á]æcá^}cÁ&æ!^Á]~!][•^•É

Element(s) of Performance for QSA.13.07.01

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cã•~^Á•]^&ã{^}•Áæ!^Á!^cæä}^ãÁ}Áæ&&[!ãæ}&^Á, áç@Á]æ, Áæ}ãÁ!^*~|æcá[]Áæ}ãÁæ•Áã^~ã}^ãÁã^Á[!*æ}ã:æcá[]Á
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