

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: SESLHD - NSW Tissue Banks - Response to post inspection letter [SEC=UNCLASSIFIED]
Date: Wednesday, 7 February 2018 1:31:42 PM
Attachments: [Review of T18 3348 TGA Close Out Record - SESLHD- Sydney NSW 14 - 07 November 2017_07 feb 2018.docx](#)
[image003.png](#)
[image004.jpg](#)

Dear [REDACTED]
 Thank you for the information provided to address the deficiencies raised at the TGA inspection of the SESLHD – NSW Tissue Banks site.

I am replying on behalf of [REDACTED] and informing you that we have conducted a review of the response you have provided.

I have requested further clarification on two points. Please see the attached record for more information. Please note that evidence is not required in your response and we will be reviewing the information provided in the close out record.

I will be back in the office on Monday 12th February 2018 so please feel free to contact me if you require further clarification.

Kind Regards,

[REDACTED]

[REDACTED]
 Inspections and Compliance
 Manufacturing Quality Branch

[REDACTED] [@health.gov.au](mailto:[REDACTED]@health.gov.au)

Therapeutic Goods Administration
 Department of Health
 PO Box 100
 Woden ACT 2606 Australia
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: [REDACTED] [\[mailto:\[REDACTED\]@health.nsw.gov.au\]](mailto:[REDACTED]@health.nsw.gov.au)
Sent: Wednesday, 31 January 2018 3:54 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: SESLHD - NSW Tissue Banks - Response to post inspection letter [SEC=No Protective Marking]

Dear [REDACTED]
 Please find attached our response to the post inspection letter.
 I will send through the evidence of the corrections to the observed deviations in two separate emails. Please let me know if you don't receive the emails as the file sizes are quite large.
 All corrections have been completed with the exception of the Microbiology, and Serology and Virology MOUs with NSW Health Pathology which are currently being finalised (attch 7; attch 8). We anticipate we will be able to provide you with executed copies of these by the end of next week (10 February 2018).
 Please note that while the change plans for skin and amnion have now been signed off, the change plan checklists still remain active documents as there are some tasks still to be completed and signed off (e.g. training of additional staff).

Please let me know if you require anything further.

Kind regards

[REDACTED]

[REDACTED] | NSW Organ and Tissue Donation Service
 Level 1 North Block, Sydney/Sydney Eye Hospital, Macquarie St, Sydney NSW 2000
 GPO Box 1614 Sydney NSW 2001

[REDACTED]
health.nsw.gov.au
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Deficiency:

4. The requirements of Clause 107 that corrective or preventive action should be taken to eliminate the cause of nonconformities in order to prevent recurrence or occurrence were not met as the investigation into DISC-17/648 that had been instigated by a number of recalls had as an outcome an “action plan” that did not address the need for primary input of an experienced and qualified physician in determining and reviewing the causality of the adverse events.

Manufacturer's Response:

Date: 18/01/2018

Corrections to observed examples:

The procedure *EATB-Q-WI-024 Incident Management Plan (Attch 15)* was updated to explicitly state that ‘the root cause analysis and review should seek the primary input of an appropriately qualified and experienced physician’ (section 4.7.3). The responsibilities of staff have also been updated for clarity, including the responsibilities of the Medical Director (section 3.0).

Inspector's Review:

The manufacturer has implemented corrective action, including the update of the relevant procedure and the update of the responsibilities of staff (in particular, the Medical Director).

Response accepted?

The information provided appears to be satisfactory and the response has been accepted.

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