

14 / Nov / 2017.

SESLHD.Opening Meeting.

- Introductions.
- Attendance sheet.
- Plan.
- Complaints.

- Review of application.

- amendments - as per written notes.

FO

Retrieval - ?

managed by site

or

Retrieval for another manuf.?

Manufacturing steps - clarification of picking, labelling.

→ example - cardiovascular retrieval.

- no processing.

Request Copies.

① Governance structure:
EATB-Q-M-001.

② Over arching QM procedure.

- Annual QR - financial. (Product).

DISC - Devintan Management.

Product Alert Recall.

- ① x Recall.
 - ② x Notifications
- } ocular tissue.

2 September

- ① Internal notifications - sydelph.
- path lab testing.

"+" micro.

DISC-17/648. 27/4/17.

- Media - yeast transport media.
- Pre-cut corneas.
- Same donor pair.

2 corneas. - 1 ~~recep~~ donor.

- 2 recipients.

- Removal of transplants.

- Notified Tact. water.

↓
26th April 2017

↓
2 notification reports to Tact.

Incident Report.

- DISC 17/678.

- Raised.

- & pot. causes. ID.

↳ risk strategies introduced at control points

SAB media.

Media plate - some mapping of
of position of plates in BST

List of CT scans.

Clinical management - specified.

↳ refer to file.

As a result of DISC, all
surgeons were notified. —

CT- (1 eye each)
- 3 resp. - 3 donors } cornea
pre at

- DNA seq. - all 5.

↓
Recipients / Hospital.

→ 1 related. : Same day of
original contamination.

↙ donor - 1 eye.

Same genotype [(1st - 2nd) 1 donor.
→ (3rd) infection. } same day.
2 donor.

diff. genotype from ~~original~~
→ 4th infection - 4 days before.
→ 5th infection - 11 days after.

[same species
(diff. genotypes)]

Follow Up

- Medical directors involved in clinical management.
- Would variation to process need to be submitted
↳ lessor?
- Transport median
↳ 24 hrs testing.
 - new equipment.

Follow up

TCA. report - no response

Product Recall I R.
Sept 17.

↪ Amendments to
initial report.

Project plan - ~~As~~ ~~AMS~~ testing method.
- assay.

Deviation List

- HError.
- Equipment.
- Doc. Error.

DISC-17/615.	23/3/17.	HE	
DISC-17/769	6/4/17.	Eq.	
DISC-16/469.	20/1/16.	HE	Retrieval
DISC-16/468.	8/1/16.	HE	Retrieval
DISC-16/481	12/2/16	SF.	Retrieval
DISC- 17 17/682	19/5/17	HE	Retrieval
DISC-17/700	13/6/17	EF	Retrieval
DISC-17/733	22/8/17.	HE.	Retrieval

Outcomes?

Have actions been completed?

A N° have been raised for retrieval.
- any investigations?

A N° of actions are retracing

- is this sufficient?

Same questions on per
notes.
↳ clarification.

Def Summary - on deficiency ~~process~~ ^{process}.

- Inconsistencies with classifications of "Root Cause" ~~is subjects to~~

- Not always sufficient detail in records to preventative action.

Quality Review

2015 - 2016.

2016 - 2017.

} 6/11/17. (with).

2014 - 2015

Ref.

Did not maintained intervals.

Management Review.
- Quarterly.

- August 2017 Reviewed
OK ✓

Audit Schedule.

2016

Audit procedure.
- EATB-Q-WI-004

v1.

Def Define target dates for
DISC.

* Clause 112. → in regards to IAs.

↳ no definition or requirements
specified in regards to timelines
- close out of audit / CA.

1 / 1
LNEB-Q-IS-004 v.1
Validation Master Plan.

Information Systems

EATB-Q-WI-OIS.
v.3.

- Q-pulse.

- Microscan camp. ✓

- New: freezer work.

→ inventory systems.

→ off the shelf.

- camera cont.

- not implemented.

FU

change
control.

Recovery algorithm

Back up - Remate server
- Hard disk RAID

taking?

↓
Recovery of data

- Access.
- Spreadsheet. } task.

✓ Reviewed
& ok

Managed by Health
Support Services.
State-wide Service
Desk.

Documentation.

EATB-Q-WI-006 v2.

WI Template.

Doc. Request Form.

✓ Doc. Review - 12 monthly.



> Differed system.

↓
external
doc's

✓ Management Review Meetings.
Reviewed & ok.

Records

Archive storage

Donor records
- scanned

Recall.

Cleaning records, } on-site.
DISC }
Training } (3 yrs).

Inventory System

~~Access~~

Record register.

15 / Nov / 2017

Lockable cabinets.

Key Register. (P)

- Clyde - eye bank.
- Cadaveric cabinet No 117.
- living donor 117.
- cabinet 2 - 192.
- for review medical director. - 067.

Cadaveric

Donor file - on-site.
- scanned.

↓
send af site.

Eye Bank

Donor files - on-site,
- scanned.

↓
longer time.

Governance.

15 / Nov / 2017.

Governance of the NSW Tissue Banks.
NSW TB-Q-M-001 v02.

✓ reviewed & ok.

Quality Manual.

roles & responsibilities
reviewed & ok ✓

Auditor training

Helen. (Living donor. co-ord)

Ang. (Q. officer.)

QM. (

Manager PD. - reviewed & ok ✓

Quality Manager PD - reviewed & ok ✓

Quality officer. - A.D.

① Auditor Training - QMS. → cont. ^{5 Sep. 17.} ~~18 Sep~~ ✓

→ Assessment

- GMP (Training). - Generic.

reviewed
& ok.

②

↳ Brief outline.

↳ powerpoint.

- Auditing Training.

③

- Module. ✓

- QMS.

- Monitoring System.

Trained Auditors..

Reviewed ✓
\$ ok

AD.

- Auditor assessment.
- Module / Questionnaire.
- Monitoring - observations / observed.
- Reviewed file records included.
- Comp. assessment.
- training file.

HH

- Auditing training - record. 2013.
 - Auditor assessment
- 2013.

"in-service
/ record"

→ Tissue Retrieval Co-ordinator.

~~Audit passed~~

Quality Management.

→ John Hunter B.B.
→ Report.

external.

30/3/17.

Reviewed
& ok ✓

Internal Audit Procedure.

EATB-Q-WI-004 001

Training

- Q. Co.
- Tissue Retrieval Coor.
- Lab.

- Retrieval Team Leaders

T & A, EATB-Q-WI-014 01.

All.

In-house training.

All ~~full~~ - medical/science qualifications

- Group based assessment.
- Training plan - specific to role.
- Mandatory training.

Examples.

- Tissue Product Saver.
- Certificates. - e-cpd program.

examples

EBAANZ04

23rd. March 17

- Cert. of attendance

- NSW organ & tissue donation
service sym.

18 Oct 17.

Statement.

- Retrieval.

- Tech camp. ✓/reviewed.

- Orientation plan 2016.

- Introduction to GMP.

- initial assessment
2016.

- in-house records
- annual GMP.

- Training Plan - retrieval tech.

↳ orientation
records as
per training
plan.

↳ frozen PM.
11 Aug 2016

- Camp.
checklist for
tech.

- deceased tissue retrieval
24/10/16.

↳ all records
through
abs - scout
- camp.

↳ donor ID, tasks performed.
trainer.

training
log

Amy moved from Retrievalist.
→ technician.

Cent. of supervised excubation

→ camp.

→ records.

→ camp. 24/10/16.

NSW Bone Bank. Cadaveric
Retrieval Program.

- Retrieval of M. Tissue

In-house records.

GMP. - refresher ^{at} 2017

Training Plan: tissue Production
Scientist.

2017

✓ reviewed
& ok.

Record of signatures.

- reviewed each
year.

2017. ✓

2016. ✓
Reviewed
& ok.

Training Matrix

Expt. doc.

→ Each role related tasks & level of comp.

↳ Training module & sections.

↳ still being update.

reviewed
OK

Eye retrieval.

↳ non-medical cache manual.

↳ retrieval.

LNEB-C-M-001 V2.6.

Training P & P.

↳ WI's - read & acknowledge.

GMP refresher training. ✓

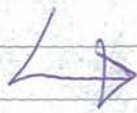
→ 2 files. Prof development.

Ref

Training & Assessment

EATB-Q-WI-014

101



Specific Procedure-related training.

↳ still refers to the procedure training record.

Procedure does not reflect current process.

Cleaning Instructions.

EATB-0-15-003

V3.

Cleaning checklist

Copy N° 3

Nov. 2017.

7/11/17

Latched Gas-key

Skin & Ammonia Freezer.

Asset 3200390.

'+' pressure.

'-' pressure.

→ for critical control points.

2 record of these actions & critical points.

→ signed.
- date.

- ~~21~~ eq's 2 hrs.

EQPM std's - equivalent

Class D. or

A program 1

Follow up

→ Same design spec as std

↓
has been validated.

→ commissioning report.

Equipment

- freezer
- positive isolator
- fridge
- incubator

ISOLATOR
①

FW

Environmental monitoring?

Skin & Amniotic lab.

15 / Nov / 17.

✓ Location: ? Basement. — ^{Lower.} level. clinical
Sciences
Bld.

✓ Storage area? Non critical /
critical store

→ same for
bone & eye.

Follow up -

Def

- NSWBB & SEALS.

Draft Micro Agreement.

↳ still in draft.

NSWBB-AG-023 v3.

↳ change plan.
↳ indicates that it has been closed out.

MoU →

however.

↓
EATB-CP-16-001.

Cleaning services.

MoU.

1/11/17 - 1/11/20

↓
Reviewed & ok.

↳ NSW Tissue Bank.

↳ follow up cleaning records.

Ⓟ. Perf

control - hospital

location.

↳ records.

FW

Records.

- SE5 LHD
internal briefing 10/12/15.
- Eye tissue hca bank report
14 Oct 14.

MoU. Tissue bank.

↓
Eurofins/ANS.

(just for) → (sterility testing).
01/11/17 - 1/11/20.

↓
will use
SEALS for
micro on-going.

Signed 13/11/17.

Ocular Tissue.

16 / Nov / 2017.

Egg - whole eye. - warm.
- blood.

→ Assessment fun.

12656.

Reagents?

Media bottles.

- Storage 30 days.
- Media - preparation
- Batch tested - AMS Enrichers.
- ToA tested each

Quarantined Tissue.

- Blood - SEALS (NAT)
- BTAC - Sympath. } Validated process
- 5 days.

Surgery scheduled.

→ Cell count / viability count.

→ Petri dish (critical material)

↳ imaging

→ 5 days.

→ Tissue for surgical practice
- dirty material.

→ Micro incubator.

↳ ID.

→ Tissue storage $2-8^{\circ}\text{C}$,
- 1 year.

OT

40
?]

- 3 staff - Reg.

- Amyghar
- Med. dir.

→ Freezer. - Media (quantitative)
tissue

1.8% sucrose

Cleaning hoods - viroclean
- wed.

- Processing shot

- Annual services
(fungicide)

- Cleaning of room

- Cleaning

✓ Allocation of ID.

✓ 14 days - Box not opened.
3 months.

- Pre-cats - performing.

→ Radio "wireless" - microscan.
- tiny tag.

→ Temp mapping - look at every
- monthly review.

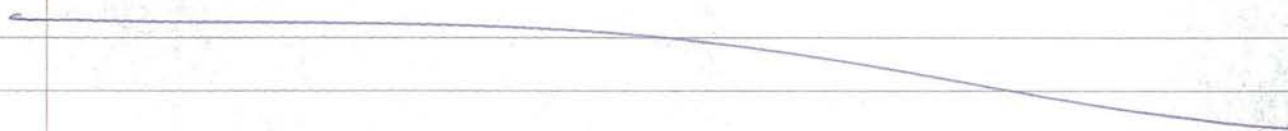
→ Training, monitoring, observation.

Laminar Flow 1
Laminar Flow 2.

Cleaner - gloves.

Freezer 6310159860.
Fridge TF1
TF2 - cleaned.

Lab Incubator 1
" " 2



Blood Test, 4/11/17.

1
1

Questions

1. Decontamination of laminar flow.

↳ person cleans
same as processor?

2. Records - typed? date & time

↳ entered into comp
or transfer after?

↳ Corneal cutting
consumables
wastebasket,

3. ^{Progress sheet} Nam. Coated agent used in.

↳ Growth / no growth.

4. Temp of fridge / freezer

in Fridge 2-8°C

Freezer 80.

§ Incubator

5. Label - incubator. ?

- Donor N^o.
- R & L.
- Donor Age.
- Date processed.

Del

Examples of records being
completed without
handwritten sig. & date
(pre populated).

eg. Lab. consumables for organ
culture micro cont. testing
of media.

13/3/17

LNEB-L-F

-032

V2

Also, typed initials in same
form for viradex
decontam. laminar flow
cabinet.

13/3/17

→ initials again.

on lab. consumables
for organ culture cell
counting & transfer to
OCT media.

LNEB-L-F-024

V2

Correct cutting consumables
worksheet.

→ clean with
viradex

LNEB-L-F-021

V2

✓ Reviewed.
with a def.

- 5 donor files reviewed.

- Donor File Progress checklist.
 - Death notification & Donor info.
 - Consent & authority for removal tissue.
 - Enucleation & physical examination record.
 - Medical records.
 - Health summary.
 - Manifest Progress sheet.
 - Consent.
 - Section.
 - Path / Micro results.
 - Lab. consumables worksheet.
 - Corneal cutting consumables worksheet.
-

→ continued.

Chem with : initials (typed).
viradum

Tissue processed : date &
& chem. time
(typed)

✓ RMS organ Durar. Carat detekane

Critical Material.

~~Premises & Equipment~~

18 / Nov / 2017

→ Collection / Retrieval kits.

- instruments.

- sterilisation.

- Eskies.

→ 1 store area: critical & non-critical material.

→ Spec folder → specification of CM.

Eye Bank

No specification folder.

- Incoming log sheet.
- Eye bank invoice.
- Record on packing slip. - 1st N°
- also adhere sticker
- ↳ consumables sheet.

Examples of items (eg. medical gloves).

↓
dated, name signed.

- examples of items in which individual has been pre-populated.

eg.

Del

- Designation of areas is
CM room

↳ Some shelves
not clearly labelled
as non-critical
(no label).

- Critical material areas.
- don't have a
label.

Access to CM room.

↳ open during
day.

↳ locked evening.

- Labels ~~to~~ located in Room.

④ Training record.

↳ skin
record.

2 procedures for CM.

✓ Reviewed
& ok.

1) Bone ^{1 skin} bank.

- Receipt of material
NSWBB-E-004 v3.

~~Spec~~ - Specification folder.

- Observed process.

2) Lab. Maintenance & QC
procedure.

LNEB-L-005 v2. ✓

Def

↳ 4.4. Receipt of goods.



Does not describe ~~the~~
all elements of handling of
material (as per clause 501)

↳ Receipt & signature, sampling,
release, storage, labelling.

- Specification folder.

- Observed process.

Def

Labels: Pre-populated - initials.

Bialbank.

Equipment. - Isolator.
- freezer
- firdy.

2 - probes.

16 / 11 / 17

Buildings & Facilities. EATB-Q-WI-019 V2.

→ Key register reviewed
SwiP card form reviewed.

→ Generator. Testing.
- M power.
28/9/17.
6/6/17.

→ Pest control. - Sam-O-Kill.
- 4/10/17.
14/6/17
4/4/17
7/3/17
22/2/17.

→ Cleaning Records
- Eye & tissue bank cleaning
checklist.
eg's May, June,
March, April
/2017.

→ Cleaning records
- Bone Bank Freezer Room.
checklist.
eg's May, June, March
Apr-1.

Eye Bank Lab.

1
Rev. recd.

- Cleaning records.

May, June, March,
April.

1.1

- Validation - Processing
↳ "out of head"

- Media - Sampling
- "are" - before sampling

- Lab. Coated Med

Media
- Micro. Results.
from

✓ Reviewed
& ok.

2.7%

~~Not~~
2017

Reviewed biological safety cabinet
micro & air control monitoring

L ✓ Reviewed
& ok.

Aud: +

16/11/17.

AUD16/56 Security (Access).

10/11/17.

✓ Reviewed
& ok.

~~Equipment Certifications 2016.~~

Microscan

Monthly.

- Maintenance - check alarm
- alarm log.

✓ Reviewed
& ok.

↓
Maintenance log.

↓
Microscan procedure.

+ Tray tag system.

✓ Reviewed
& ok.

Equipment Maintenance 2016.

2017.

Calibration certificates.

- Data logger.

eg's. 617546.

617547.

734862-B.

734862-D.

- Microscope.

eg's. 617104.

- Blood fridge.

eg's.

30564940.

60813383.

- Centrifuge.

eg's.

12656.

Repair ✓

- Data Loggers Service Report.

eg's. 54310.

- Temp device Service.

egs. 38098.

- Compound Micro

eg. 670780.

- Balance

D3076000018.

Bus cabinets.
- BHA - 180.

2017

Bone Bank.

- 4 x -80°C.

- Heat sealer.

Preventative Maintenance,
- Freezer.

CDQ2.

LDQ1.

21/6/17.

21/6/17.

4/10/16.

4/10/16.

✓ Reviewed 20/1/16.
ok.

20/1/16.

Preventative freezer maintenance

- Oct 2017

LDQ1 & CDQ1.

- Sept.

✓ Reviewed
& ok.

DISC 17-620.

↳ Temp dev.

↳ Microscan
data to
confirm the range.

Microscan Environmental Monitoring
System

1/1
EATB-E-W1-001 V1

- Microscan Maintenance Plans.
2016 - 2017.

✓ Reviewed
& ok.

Rotosealer calibration.

↳ 3206192.

↳ not in use,

Reviewed
date.

Heat Sealer.

104912.

15/6/17.

10, 00.

↳ 15/6/17.

Bone Bank

17 Nov 17.

- Kits. - supplied by Tissue Bank.

- ① Femoral Head. injected. (man).
② Bundle. ~~Aushio~~ Delivery 99.9%
→ Aushio.
→ no processing.

FU

Aushio

Aushio - contracts.

Centrifuge. ?

② Cadaveric.

- Recovered (Temp).

injected. Aushio

4.8.

- packing & transportation?

Cyroguard

4.5.

(example of
file).

Cyroguard.

Tissue Samples.

Reviewed
& ok

17 / Nov / 17.

✓ Validation Report.

- "dump freezing" cryopreservation

EATB-VR-15-007 V1.

↳ Approved.

- dossier submission

Data example - Table 1.

Run 3.

→ Raw data → Data logger.

↳ exported data.

Subcontracts.

Terms of Business. w/ ANSTO.

↳ asc017202.

AF-1885. 2010.

- Examples were reviewed for ANSTO.

↓
Reviewed
& ok.

↳ Agreement for
service work.

- 23rd Sept 2015.

↳ copy located
in 2 drawer files.

④ Service Level Agreement: NSW Bank
Banks.

0700 F:47.

Dec 2015.

Archiving - Grace records?

Monthly fee.

Donor files

✓ Reviewed
& ok

Funeral Home

Questions - Courier Booking sheet?

Cadaveric Tissue x2

- In progress (awaiting ^{cause of} death)

- Retrieval.

- Donor Criteria & Authorization.

Funeral Home x2

- In progress.

↓
Irradiated x2 ✓

→ Secondary Access. (Swipe).

→ Key Access. - into freezer

→ Living donor tissue.

→ Gowning, gloves, eye protection.

↓
co-ordinator - responsible.

↳ donor testing.

3 Bone - Histo

- Micro.

- Store (graft) - if irradiated

+ Swabs. } Packaging reg.

+ tubes

Freezer register.

↳ Quarantine Freezer.

Cleaning log -

Freezer works - validation
process.

Early - temp track } Validation
- Cammer } process

LD-Q1 (living donor).

CD-Q2.

LD-C1. (demed).

CD-Q1 (Quarantine).

⑤ Cleaners - log.

Tissue bank staff
cleaning log.

✦ location of freezer log.

Transported on dry ice.

↳ Validation
of transport.

→ Cryoguard.

Bundle.

Station of cyrogrand
↳ freezer register

NSWBB-R-15 001 02.

Packing a graft.
dispatch.

MicroScan

No issues.

Freezers - micro scan.

- Protection to staff.
- Removal of waste - cleaners.
- Sealed packaging.

①

The training & Assessment procedure
(EATB-Q-WI-014, 001)
~~refers to the procedure to~~

does not reflect current practice as
procedure still refers to the use of
the procedure training record.

② The change plan~~s~~ ~~Actions~~
checklists for skin (EATB-CP-
16-001)

& Amnion (EATB-CP-16-003)

indicated that a N° of actions
had been completed (with
date of completion), however
~~the actions were~~

The change plan checklists for
skin & Amnion indicated
that ~~the~~ ^{the} ~~Agreements~~ the task relating
Microbiology & serology testing &
~~HAT~~ service agreements

~~had been updated~~ ~~updating~~
being updated

~~the completion~~ service agreements

for micro/serology had been
completed, however agreements
were still in draft format

There were examples of records being prepopulated with sign and/or initial and/or date.

eg. Lab consumables for organ culture micro contamination testing of media (LNEB-L-F-032, V2).

13/3/17.

Lab. consumables for organ culture cell counting & transfer to OCT media.

Corneal cutting consumables worksheet.

The Lab. Maintenance & QC procedure (LNEB-L-003, V2) describes the receipt of goods process for ~~eye banking~~ ~~proc~~ eye bank area, however it does not describe ~~the~~ all elements of handling of material including quantitative sampling, ~~retest~~ & storage.

~~that all~~ It was observed that some shelves in the CM store room had not been labelled as non-critical as per