Version	Approval Dates		Announcement Date	Effective
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SECTION L
QUALITY ASSURANCE

NT-L1.000 QUALITY ASSURANCE PROGRAM

All *NADOs shall* have a *QA Program*.

Current (2nd Edition)

NT-L1.100 BASIC ELEMENTS

The *QA program shall* include, at a minimum:

1) designating and managing *quality control* functions, including:

a) *environment monitoring* at designated intervals;

b) performing periodic equipment and facility inspections;

c) reviewing equipment monitoring *records* for maintenance within specified *tolerance limits*, and reviewing *records* of other equipment or *preparation* functions that have specified *tolerance limits*;

d) performing *qualification* of reagents, supplies, materials, instruments, and equipment when deemed critical or applicable; and (NT-E2.300)

e) monitoring laboratory performance, if applicable.

2) *establishing* and maintaining *procedures* for monitoring and controlling processes to ensure that the specified requirements continue to be met;

3) performing *equipment qualification studies* as necessary;

4) establishing purchasing controls;

5) establishing procedures for implementing *corrective action* and *preventive action* and taking action when appropriate. The *procedures shall* include requirements for:

a) analyzing sources of *quality* data to identify existing and potential causes of *nonconforming NAM*, or other *quality* problems. Appropriate statistical methodology *shall* be employed where necessary to detect recurring *quality* problems;

b) investigating the cause of *nonconformities* relating to *NAM*, processes, and the *quality system*;

c) identifying the action(s) needed to correct and prevent recurrence of *quality* problems;

d) *verifying* or *validating* the *corrective action* and *preventive action* to ensure that such action is effective and does not adversely affect released *NAM*;

e) implementing and *recording* changes in methods and *procedures* needed to correct and prevent identified *quality* problems;

f) ensuring that information related to *quality* problems is disseminated to those directly responsible for assuring the *quality* of *NAM* or the prevention of such problems; and

g) submitting relevant information on identified *quality* problems, as well as *corrective action* and *preventive actions*, for management review;

6) reviewing as applicable at each *NADO* involved, *donor* screening, *authorization*, *acquisition,* and *preparation records;*

7) approving, as applicable, all *preparation records* and *relevant medical records* prior to release of *NAM* for education and/or research*;*

8) *establishing* procedures for the documentation of formal conclusions of all *accidents*, *error*, *complaints*, and returns of *NAM* are formally concluded and documented;

9) maintaining documentation including, but not limited to:

a) master copy of current *SOPM*;

b) *records* of names, *signatures*, initials, or identification codes and inclusive dates of employment for those authorized to perform or review tasks (e.g., onsite or at a central location);

c) reports and conclusions of *process validation* and *equipment qualification studies*;

d) *records* of supply and reagent acceptance or rejection;

e) archived documents; and

f) master list of preprinted *labels* when applicable.

10) *establishing* a *procedure* to evaluate training and competency of personnel and, requiring appropriate training concerning any modifications to the *SOPM*;

11) maintaining *labeling* and *labeling material* controls; and

12) Requiring a process for sharing information with other *NADOs banks* that are known to have *acquired* and/or received *NAM tissue* from the same *donor*.

With amendments

NT-L1.100 BASIC ELEMENTS

The *QA program shall* include, at a minimum:

1) designating and managing *quality control* functions, including:

a) *environment monitoring* at designated intervals, if applicable;

b) performing periodic equipment and facility inspections;

c) reviewing equipment monitoring *records* for maintenance within specified *tolerance limits*, and reviewing *records* of other equipment or *preparation* functions that have specified *tolerance limits*;

d) performing *qualification* of reagents, supplies, materials, instruments, and equipment when deemed critical or applicable (NT-E2.300); and ~~(NT-E2.300)~~

e) monitoring laboratory testing performance, if applicable.

2) *establishing* and maintaining *procedures* for monitoring and controlling processes to ensure that the specified requirements continue to be met;

3) performing *equipment qualification studies* as necessary;

4) establishing purchasing controls;

5) establishing procedures for implementing *corrective action* and *preventive action* and taking action when appropriate. The *procedures shall* include requirements for:

a) analyzing sources of *quality* data to identify existing and potential causes of *nonconforming NAM*, or other *quality* problems. Appropriate statistical methodology *shall* be employed where necessary to detect recurring *quality* problems;

b) investigating the cause of *nonconformities* relating to *NAM*, processes, and the *quality system*;

c) identifying the action(s) needed to correct and prevent recurrence of *quality* problems;

d) *verifying* or *validating* the *corrective action* and *preventive action* to ensure that such action is effective and does not adversely affect released *NAM*;

e) implementing and *recording* changes in methods and *procedures* needed to correct and prevent identified *quality* problems;

f) ensuring that information related to *quality* problems is disseminated to those directly responsible for assuring the *quality* of *NAM* or the prevention of such problems; and

g) submitting relevant information on identified *quality* problems, as well as *corrective action* and *preventive actions*, for management review;

~~6) reviewing as applicable at each *NADO* involved, *donor* screening, *authorization*, *acquisition,* and *preparation records;*~~

~~7~~6) approving, as applicable, all *preparation records* and *relevant medical records* prior to release of *NAM* for education and/or research*;*

~~8~~7) *establishing* procedures for the documentation of formal conclusions of all *accidents*, *error*, *complaints*, and returns of *NAM* are formally concluded and documented;

~~9~~8) maintaining documentation including, but not limited to:

b) master copy of current *SOPM*;

b) *records* of names, *signatures*, initials, or identification codes and inclusive dates of employment for those authorized to perform or review tasks (e.g., onsite or at a central location);

c) reports and conclusions of *process validation* and *equipment qualification studies*;

d) *records* of supply and reagent acceptance or rejection;

g) archived documents; and

h) master list of preprinted *labels* when applicable.

~~10~~9) *establishing* a *procedure* to evaluate training and competency of personnel and, requiring appropriate training concerning any modifications to the *SOPM*;

~~11~~10) maintaining *labeling* and *labeling material* controls; and

~~12~~11) *establishing* ~~Requiring~~ a process for sharing information with ~~other *NADOs*~~ *transplant Tissue Banks* that are known to have *acquired* ~~and/or received *NAM*~~ tissue from the same *donor*.

As amended

NT-L1.100 BASIC ELEMENTS

The *QA program shall* include, at a minimum:

1) designating and managing *quality control* functions, including:

a) *environment monitoring* at designated intervals, if applicable;

b) performing periodic equipment and facility inspections;

c) reviewing equipment monitoring *records* for maintenance within specified *tolerance limits*, and reviewing *records* of other equipment or *preparation* functions that have specified *tolerance limits*;

d) performing *qualification* of reagents, supplies, materials, instruments, and equipment when deemed critical or applicable (NT-E2.300); and

e) monitoring laboratory testing performance, if applicable.

2) *establishing* and maintaining *procedures* for monitoring and controlling processes to ensure that the specified requirements continue to be met;

3) performing *equipment qualification studies* as necessary;

4) establishing purchasing controls;

5) establishing procedures for implementing *corrective action* and *preventive action* and taking action when appropriate. The *procedures shall* include requirements for:

a) analyzing sources of *quality* data to identify existing and potential causes of *nonconforming NAM*, or other *quality* problems. Appropriate statistical methodology *shall* be employed where necessary to detect recurring *quality* problems;

b) investigating the cause of *nonconformities* relating to *NAM*, processes, and the *quality system*;

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d) *verifying* or *validating* the *corrective action* and *preventive action* to ensure that such action is effective and does not adversely affect released *NAM*;

e) implementing and *recording* changes in methods and *procedures* needed to correct and prevent identified *quality* problems;

f) ensuring that information related to *quality* problems is disseminated to those directly responsible for assuring the *quality* of *NAM* or the prevention of such problems; and

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7) *establishing* procedures for the documentation of formal conclusions of all *accidents*, *error*, *complaints*, and returns of *NAM* are formally concluded and documented;

8) maintaining documentation including, but not limited to:

c) master copy of current *SOPM*;

b) *records* of names, *signatures*, initials, or identification codes and inclusive dates of employment for those authorized to perform or review tasks (e.g., onsite or at a central location);

c) reports and conclusions of *process validation* and *equipment qualification studies*;

d) *records* of supply and reagent acceptance or rejection;

i) archived documents; and

j) master list of preprinted *labels* when applicable.

9) *establishing* a *procedure* to evaluate training and competency of personnel and, requiring appropriate training concerning any modifications to the *SOPM*;

10) maintaining *labeling* and *labeling material* controls; and

11) *establishing* a process for sharing information with *transplant Tissue Banks* that are known to have *acquired* tissue from the same *donor*.

Announcement Date: January 31, 2019 (Bulletin 19-1)
Effective Date: July 31, 2019 (6-month implementation period)

Current (2nd Edition)
NT-L1.200 QUALIFICATION, VERIFICATION AND VALIDATION REQUIREMENTS

Each *NADO shall* develop, document, and implement *qualification* or *verification*, of critical components which may include:

a) facilities;

b) processes;

c) equipment;

d) reagents;

e) *labels; and*

f) containers.

Each *NADO shall* develop, document, and implement protocols for the *verification*, or *validation* of significant components which include:

a) Packaging materials, and

b) *electronic* identification and *tracability* systems.

Determination of which elements or items that *must* be qualified, verified, or validated shall be made by the *NADO* as defined in *established* policy or *procedure*.

With amendments

NT-L1.200 QUALIFICATION, VERIFICATION AND VALIDATION REQUIREMENTS

Each *NADO shall* develop, document, and implement *qualification* or *verification*, of critical components as defined and established by the NADO which may include:

a) facilities;

b) processes;

c) equipment;

d) reagents;

e) *labels;*

f) vendors; and

g) ~~containers~~ packages.

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Each *NADO shall* develop, document, and implement protocols for the *verification*, or *validation* of significant components which include:

a) ~~packaging materials~~ containers, and

b) *electronic* identification and *tracability* systems.

Determination of which elements or items that *must* be qualified, verified, or validated shall be made by the *NADO* as defined in *established* policy or *procedure*.

As amended

NT-L1.200 QUALIFICATION, VERIFICATION AND VALIDATION REQUIREMENTS

Each *NADO shall* develop, document, and implement *qualification* or *verification*, of critical components as defined and established by the NADO which may include:

a) facilities;

b) processes;

c) equipment;

d) reagents;

e) *labels;*

f) vendors; and

g) packages.

Each *NADO shall* develop, document, and implement protocols for the *verification*, or *validation* of significant components which include:

a) containers, and

b) *electronic* identification and *tracability* systems.

Determination of which elements or items that *must* be qualified, verified, or validated shall be made by the *NADO* as defined in *established* policy or *procedure*.

Announcement Date: January 31, 2019 (Bulletin 19-1)
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NT-L1.210 VALIDATION METHODS

Where *validation* is required or desired, evidence supporting *validation must* be demonstrated. Acceptable methods to demonstrate *validation* are:

1) studies conducting challenges such as temperature, time, as appropriate, and/or other factors that potentially affect user specifications;

2) *verification* of an *established procedure* or process known to be effective, with implementation of the same *procedure* or process, without modification; as specified in NT-L1.230. If any steps are modified, all such modifications *shall* undergo documented evaluation (e.g., through a risk assessment) for potential impact, and a potential result *may* be that a *re-validation* is necessary per method 1 of this section.

Current (2nd Edition)

NT-L1.220 PACKAGING QUALIFICATION AND TRANSPORT/SHIPPING VALIDATION

Packages used to ship *NAM* in-process, or to *distribute prepared NAM shall* be *qualified*. The method(s) used *shall* demonstrate that the packages can maintain the required conditions to meet user expectations and any applicable transport regulations.

With amendments

NT-L1.220 ~~PACKAGING~~ *CONTAINER* QUALIFICATION AND TRANSPORT/SHIPPING VALIDATION

~~*Packages*~~ *Containers* used to ship *NAM* in-process, or to *distribute prepared NAM shall* be *qualified, when being distrubuted via common carrier*. The method(s) used *shall* demonstrate that the ~~*packages*~~ *container* can maintain the required conditions to meet user expectations and any applicable transport regulations.

As amended

NT-L1.220 *CONTAINER* QUALIFICATION AND TRANSPORT/SHIPPING VALIDATION

Containers used to ship *NAM* in-process, or to *distribute prepared NAM shall* be *qualified, when being distrubuted via common carrier*. The method(s) used *shall* demonstrate that the *container* can maintain the required conditions to meet user expectations and any applicable transport regulations.

Announcement Date: January 31, 2019 (Bulletin 19-1)
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NT-L1.230 VERIFICATION METHODS

Where *verification* is required or desired, evidence supporting verification *must* be produced by one or both of the following methods:

1) review, examination, inspection, or testing of a defined number of samples (the justification of the number of samples *must* be documented) in order to *establish* and document that the *NAM*, service, or system meets specified regulatory or technical standards; or

2) *verification* of the implementation of an *established*, previously *validated*, *procedure* or process without modification; *such verification shall* be conducted using a defined number of samples (the justification of the number of samples *must* be documented, however statistical justification is not required.

Current (2nd Edition)

NT-L1.300 PURCHASING CONTROLS

For contracted services involving *donor* screening, *donor* eligibility, *acquisition*, *preparation*, *storage*, and/or *distribution*, refer to NT-B1.500 for additional requirements. Also refer to specific information at NT-B1.600 for contracted and non-contracted laboratory services for infectious disease testing.

Each *NADO shall establish* and maintain *procedures* to ensure that purchased or otherwise received products and services, including testing services, conform to specified requirements, if any. Each *NADO shall* establish and maintain the requirements, including *quality* requirements that *must* be met *by* suppliers, contractors, and consultants. Each *NADO shall*:

1) evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation *shall* be documented.

2) define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.

3) *establish* and maintain *records* of acceptable suppliers, contractors, and consultants Each *NADO shall* establish and maintain data that clearly describe or reference the specified requirements, including *quality* requirements, for purchased or otherwise received product and services. Purchasing documents *shall* include, where possible, an agreement in which the suppliers, contractors, and consultants agree to notify the *NADO* of changes in the product or service so the *NADO* can determine whether the changes *may* affect *quality.*

With amendments

NT-L1.300 PURCHASING CONTROLS

For contracted services involving *donor* screening, *donor* eligibility, *acquisition*, *preparation*, *storage*, and/or *distribution*, refer to NT-B1.500 for additional requirements. Also refer to specific

information at NT-B1.600 for contracted and non-contracted laboratory services for infectious disease testing.

Each *NADO shall establish* and maintain *procedures* to ensure that purchased or otherwise received critical products and services, including testing services, conform to specified requirements, if any. Each *NADO shall* establish and maintain the requirements, including *quality* requirements that *must* be met *by* critical suppliers, contractors, and consultants. Each *NADO shall*:

1) evaluate and select potential critical suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation *shall* be documented.

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As amended

NT-L1.300 PURCHASING CONTROLS

For contracted services involving *donor* screening, *donor* eligibility, *acquisition*, *preparation*, *storage*, and/or *distribution*, refer to NT-B1.500 for additional requirements. Also refer to specific information at NT-B1.600 for contracted and non-contracted laboratory services for infectious disease testing.

Each *NADO shall establish* and maintain *procedures* to ensure that purchased or otherwise received critical products and services, including testing services, conform to specified requirements, if any. Each *NADO shall* establish and maintain the requirements, including *quality* requirements that *must* be met *by* critical suppliers, contractors, and consultants. Each *NADO shall*:

1) evaluate and select potential critical suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation *shall* be documented.

2) define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.

3) *establish* and maintain *records* of acceptable critical suppliers, contractors, and consultants Each *NADO shall* establish and maintain data that clearly describe or reference the specified requirements, including *quality* requirements, for purchased or otherwise received product and services. Purchasing documents *shall* include, where

possible, an agreement in which the suppliers, contractors, and consultants agree to notify the *NADO* of changes in the product or service so the *NADO* can determine whether the changes *may* affect *quality.*

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NT-L1.310 CONTRACTED TESTING SERVICES

An evaluation of testing services *shall* be documented for those contracted testing services performed remotely (e.g. contracted laboratory) and those performed on-site at the *NADO,* as applicable.

NT-L1.311 TYPES OF TESTING SERVICES

Examples of contracted testing services *may* include, but are not limited to, the following:

1) donor infectious disease testing (also see NT-B1.600);

2) *environmental monitoring*;

3) calibration services (e.g. temperature monitoring devices, equipment); and

4) ventilation/airflow testing certification.

NT-L1.312 EVALUATION OF TESTING SERVICES

Each *NADO* utilizing outside testing services *shall* ensure testing is adequate for the intended use of the test results. This evaluation *may* include, but is not limited to, the following:

1) FDA registration, if required;

2) applicable state licenses, certifications and accreditations;

3) maintenance of an adequate *quality assurance program* to ensure the validity of results (e.g., test sample integrity, *quality control* samples, personnel *competency,* equipment maintenance, materials management);

4) participation in a laboratory *proficiency testing* program, if available;

5) adherence to relevant standards (e.g., CAP, ISO, ASTM, AAMI, USP);

6) follow manufacturers' instructions (e.g., package inserts, equipment manuals, electrical, and/or environmental conditions);

7) appropriate test method selection and *validation/qualification*;

8) use of traceable reference materials and calibration standards, where applicable; and

9) results from a paper, virtual, or on-site *audit*.

NT-L2.000 QUALITY CONTROL PROGRAM

The *QA program shall establish* and maintain *QC procedures* for equipment maintenance and monitoring.

NT-L2.100 ANNUAL CALIBRATIONS

Each *NADO shall* ensure at least *annual* calibration of mechanical devices used for *storage* with a *NIST* traceable thermometer. The overall *QA program shall* include maintenance of calibration *records.*

NT-L3.000 INVESTIGATIONS

The *QA Program shall* ensure for the completion of any investigation and perform a review for completeness of *accidents*, *errors*, *complaints, deviations,* and *NAM* returned from any of the preceding conditions. Investigation *shall* include a summary report*,* precipitating events, recommendations, and *resolutions*. The *QA program shall* retain for 10 years all reports generated.

NT-L3.100 ERRORS AND ACCIDENTS

The *QA program shall* ensure a documented investigation of any *errors* or a*ccidents* in obtaining *authorization*, in *donor* screening, *acquisition,* or *NAM preparation*, *quarantining*, releasing, *labeling*, storage, *distribution*, *final disposition*. When *NAM may* have been contaminated, the *QA program shall* ensure the documented review and evaluation both of *preparation procedures* and of any other *NAM processed* simultaneously or from the same *donor.* If the *error* or *accident* may affect the safety of *NAM* to be released or that has been released, the Medical Director, licensed physician designee, or *responsible person shall* also review and evaluate the incident.

NT-L3.200 COMPLAINTS

The *QA program shall* ensure that all written and oral *complaints* regarding *NAM quality*, *safety*, packaging, or utility, are expeditiously investigated to determine whether the *complaint* is related

to an *error*, *accident*, *adverse outcome*, or other factor, unless such investigation has already been performed for a similar complaint. If it is determined that no investigation is necessary, a *responsible person shall* document the reason that no investigation was made and the name of the individual responsible for the decision not to investigate. Each investigation *shall* determine whether associated *NAM may* be affected. If it is determined that they may be affected, *then* the associated *NAM shall* be located and *quarantined* until *resolution* of the incident (which *may* involve initiation of a *recall or* returning the *NAM*). The Medical Director, licensed physician designee or *responsible person shall* review *complaints* that are of a medical nature. When an investigation is made, a *record* of the investigation *shall* include:

1) the date the *complaint* was received;

2) the name of the *NAM*;

3) the *unique identifier*;

4) contact information of the complainant;

5) the nature and details of the *complaint*;

6) the dates and results of the investigation;

7) any *corrective action* taken; and

8) any reply to the complainant if provided.

NT-L3.300 ADVERSE OUTCOMES

The *QA program shall* ensure that all reported *adverse outcomes* that are potentially related, directly or indirectly, to *NAM* are investigated thoroughly and expeditiously. The Medical Director or licensed physician designee *shall* review all potential *adverse outcome* reports and participate in determination of the impact and *resolution* of any *adverse outcome.* If investigation indicates that the *adverse outcome* is related to an *error* or *accident*, then the *NADO shall* follow *procedures* for *errors* and *accidents* (see NT-K1.200).

NT-L3.310 REPORTING

The *QA program shall* ensure that all cases of transmissible disease in an educator or researcher attributed to the *NAM* are reported in writing as required by public health authorities, and in a timely fashion to organizations and *NADO's* involved in any manner with *NAM recovered* from the same *donor* and to the educator or researcher(s) involved in the use of *NAM* from that *donor.* Reporting *shall* be documented in the *donor's record.*

See the Accreditation Policies (APPENDIX II) for other required reporting.

NT-L4.000 INTERNAL AUDITS

All *NADOs shall* establish policies and *procedures* regarding the scope and frequency of routine and focused *QA audits*. The *QA program* staff *shall* perform *audits*, at least *annually*, of the major *NADO* operational systems to identify trends or recurring problems in: *donor* evaluation and acceptance, *acquisition, quarantine, preparation, packaging*, *donor* and *NAM* testing, *labeling*, *storage*, release, *distribution, final disposition*, *electronic systems*, and *records* management. The *QA program shall* perform focused *audits* of *critical areas* (unless the *annual* routine *audit* covers all *critical areas*), and of any area with a pattern of *quality* problems. All a*udits shall* be performed by persons who do not have direct responsibility for the process being *audited*. The *NADO shall* take *corrective action(s)* when necessary, including a re-*audit* of deficiencies. The *QA program* staff *shall* document and report the dates and results of each quality *audit* (and re-*audit*) to management responsible for the *audited* systems, who *shall* review each report.

NT-L4.100 EXTERNAL AUDITS

External *audits may* be indicated for certain services, suppliers, contractors, and consultants (NT-L1.300 and NT-B1.520).

NT-L5.000 ELECTRONIC SYSTEM CONTROLS

NT-L5.100 AUTHORIZED ACCESS

Each *NADO shall* exercise appropriate controls over *electronic systems* to limit general access to authorized personnel and to permit only *authorized personnel* to alter production and control *records* or other *records*.

NT-L5.200 ERROR REDUCTION

When automated data processing is used for decision-making, adequate *procedures shall* be designed and implemented to prevent inaccurate input or output of data and programming *errors*.

NT-L5.300 BACKUP FILES

A backup file *shall* be maintained of all data that are entered into an *electronic system* and subsequently used for decision-making purposes and of all data that are not otherwise *recorded* and accessible.

NT-L5.400 SECURITY

*Electronic system*s *shall* be designed and *validated* to assure data integrity and maintained in a secure manner to prevent alteration or, loss.

NT-L5.500 AUDIT TRAIL

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Records revised electronically *must* have an *audit trail* that includes the altered information, date of the revision, and the individual that made the revision.