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SECTION H
LABELING, PACKAGING, TRANSPORT AND DISTRIBUTION

NT-H1.000 LABELS AND LABELING

NT-H1.100 NOMENCLATURE

Nomenclature used to describe *NAM* for education and/or research *shall* be specified in the *SOPM* and applied consistently.

NT-H1.200 LABEL LIST

A list of *labels shall* be maintained, as well as an example of every *label* that is utilized by the *NADO*. Dates of use (start and discontinuance) *shall* be *recorded*.

Current (2nd Edition)

NT-H1.300 LABELING INTEGRITY

Labels shall be designed and *qualified* to be legible, indelible, and to adhere firmly to the *container* under anticipated *storage* conditions for length of use (NT-L1.200). *Labels* and associated *labeling materials* applied by *NADO* staff *shall* not be removed, altered, or obscured except to correct *labeling errors*.

With amendments

NT-H1.300 LABELING INTEGRITY

Labels shall be designed and *qualified* to be legible, indelible, and to adhere firmly to the ~~*container*~~ *package* under anticipated *storage* conditions for length of use (NT-L1.200). *Labels* and associated *labeling materials* applied by *NADO* staff *shall* not be removed, altered, or obscured except to correct *labeling errors*.

As amended

NT-H1.300 LABELING INTEGRITY

Labels shall be designed and *qualified* to be legible, indelible, and to adhere firmly to the *package* under anticipated *storage* conditions for length of use (NT-L1.200). *Labels* and associated *labeling materials* applied by *NADO* staff *shall* not be removed, altered, or obscured except to correct *labeling errors*.

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NT-H1.400 CLAIMS

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All *labeling claims shall* be clear, accurate, substantiated, and not misleading.

NT-H2.000 LABELING PROCESS

NT-H2.100 GENERAL REQUIREMENTS

There *shall* be SOPs *established* and followed to ensure that proper *labels*, *labeling*, and *packaging* materials are used for *NAM*. *NAM labeling shall* be documented properly during intake and *acquistion*.

NT-H2.200 RE-LABELING

If *NAM* are to be *relabeled* for any reason, such as *label* detachment or to correct a *labeling error*, the *NADO shall establish* a *relabeling procedure* delineating the methods to be utilized, conditions under which *NAM may* be *relabeled*, and the staff authorized to perform such activities. The reasons for, and events surrounding, the *relabeling* of *NAM shall* be documented in the *records* (NT-H1.300).

NT-H2.300 CONTROLS

Labeling control *procedures shall* be *established* to ensure *label* integrity, legibility and accuracy, and the *establishment* of checks to prevent transcription and other *labeling errors*.

Electronic *labeling* systems *shall* possess adequate controls to prevent the erroneous *labeling* of *NAM*. *Labeling* reviews and checks *shall* be documented and *shall* be included in the records. If a sampling plan is used, it *must* follow a statistically valid method, such as ANSI/ASQ Z1.4: Sampling Procedures and Tables for Inspection by Attributes. The *labeling* area *shall* be inspected prior to the start of *labeling* activities to ensure that all *labels* and *packaging* materials from previous *labeling* have been removed. The inspection of the area *shall* be documented and included in the *records.*

NT-H2.310 LABEL INSPECTION

Labels shall meet written specifications and be approved by *quality assurance* staff prior to release for use by a designated person. *Labels* not meeting such specifications *shall* be discarded. Date of receipt, date of inspection, and the names of the staff involved in receipt and inspection *shall* be documented.

NT-H2.320 LABEL STORAGE

The *storage* area for *labels* and *labeling materials shall* be clearly identified. Access *should* be restricted to authorized personnel only.

NT-H2.330 LABELING PROCESS CONTROLS – OBSOLETE LABELS

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Procedures shall be *established* to retrieve obsolete and/or outdated *labels* and *labeling materials* from all *labeling* areas and inventory locations. As each type of *label* is removed from inventory, one *label shall* be retained for the archives and the surplus *labels shall* be discarded. The *label* list and the *SOPM shall* be updated accordingly.

NT-H2.340 PACKAGE – VISUAL INSPECTION

Prior to *labeling* a unit of *NAM*, the *package shall* be inspected per *established* procedures for evidence of impurities, defects, broken seals, or contamination that could compromise the *quality* or *safety* of the *NAM* or the persons handling the *package.*

NT-H3.000 PACKAGING AND LABELING INFORMATION

NAM for education and/or research *shall* be packaged in a manner to ensure *NAM* integrity, withstand *storage* conditions, and maintain *quality* for the labeled shelf life. *NAM* packaging must be compliant with applicable laws and regulations, and transporter guidelines (e.g., IATA, Dangerous Goods Regulations).

NT-H3.100 PACKAGING PHYSICAL PROPERTIES

The *package* shall be designed in a manner that does not produce toxic residues during *Storage. Packaging shall* be designed to ensure *NAM* integrity, prevent leakage, and prevent contamination of the contents of the final *Container(s)*.

NT-H3.200 PACKAGE LABELS

NT-H3.210 DESIGN

Labels shall be designed to facilitate the use of uniform *labeling* techniques per the *established procedures*.

NT-H3.220 PACKAGE LABEL CONTENT

The following information *shall* be included on the *package label* unless space limitations require use of a corresponding insert:

1) names(s) and address(es) of *NADOs* responsible for determining donor acceptability;

2) *NAM Identification number*;

3) descriptive name of the *NAM; and* other information necessary for selection or use (e.g., size, right/left, medial/lateral, anterior/posterior);

4) *preservative* (if utilized) and/or method of *preservation* (if applicable);

5) a reference to the *package insert*; and

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6) a statement noting the *NAM* is for only non-clinical use.

NT-H3.300 SUMMARY OF RECORDS AND PACKAGE INSERT

NAM determined to be suitable and released for education and/or research *shall* be accompanied by a *summary of records* and *package insert*

NT-H3.310 SUMMARY OF RECORDS CONTENT

A *summary of records* is required when *donor eligibility assessment* has been completed and *shall* include:

1) a statement that the *NAM* was prepared from a *donor* determined to be eligible based on the results of screening and testing. All results of relevant communicable disease tests performed on specimens from the *donor* and used for release of *NAM shall* be listed. Relevant tests include those tests that are required (NT-D4.240).

2) If a test was performed it *must* be reported, if testing is not performed the records *must* indicate, "Not Tested for Infectious Agents";

2) the name and address of the establishment that made the *donor acceptability assessment*; and

3) when providing a summary and not the original serology results, a statement that the communicable disease testing was performed by a laboratory registered with *FDA* to perform *donor* testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).

NT-H3.320 PACKAGE INSERT CONTENT

The *summary of records shall* be included in the *package insert*. The *package insert may* contain the following information:

1) a statement that indicates that the *NAM may* transmit infectious agents;

2) a statement limiting use non-transplant anatomic tissue according to the *NADOs SOPM*

3) use of universal precautions

4) description of what *NAM* was supplied (e.g. cephalus, spine)

5) acceptable *Storage* conditions, including recommended *Storage* temperatures and/or *Storage* temperature range;

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6) a statement that it is the responsibility of the education and/or research requestor to maintain *NAM* in appropriate *storage* conditions prior to further *preparation;*

7) type of antibiotics present or other potential residues of *preparation* agents/solutions (e.g., ethanol, ethylene oxide, dimethyl sulfoxide), if applicable

8) concentration of *preservative(s)* and/or method of *preservation*, if applicable

9) Other relevant *NAM* information, as applicable.

Current (2nd Edition)
NT-H3.400 CONTAINER LABEL

In an effort to prevent inadvertent transplantation of *NAM*, *containers* shall be labeled, "NON-CLINICAL USE ONLY". The *label* must comply with applicable state and federal regulations and transporter guidelines.

With amendments
~~**NT-H3.400 CONTAINER LABEL**~~

~~In an effort to prevent inadvertent transplantation of *NAM*, *containers* shall be labeled, "NON-CLINICAL USE ONLY". The *label* must comply with applicable state and federal regulations and transporter guidelines.~~

As amended
NT-H3.400 TRANSPORT LABEL CONTENT

Announcement Date: January 31, 2019 (Bulletin 19-1)
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NT-H3.410 DOMESTIC SHIPMENTS

The *transport container label shall* include the following information:

1) name, address and telephone number of the *distribution facility*;

2) name and address of the destination;

3) prominent identification of contents as "Exempt Human Specimen"

3) if testing is not performed, the l*abel* must indicate, "Not Tested for Infectious Agents";

4) if known infectious agents are identified, a "BIOHAZARD LABEL" must be affixed to the *Container*;

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5) *validated* expiration date/time of the *transport container* when the *storage* temperatures must be controlled;

6) type and quantity of refrigerant or other hazardous materials enclosed in the transport c*ontainer* when applicable per local and federal regulations (e.g. dry ice, liquid nitrogen); and

7) any special handling instructions when applicable (e.g. "DO NOT FREEZE," "DO NOT X-RAY," "DO NOT IRRADIATE", educator or researcher special requests).

NT-H3.4520 INTERNATIONAL SHIPMENTS

Labels for international shipments *shall* contain all of the information required for domestic shipments; however, information *may* be modified to meet any regulatory requirements of the receiving country.

NT-H4.000 DISTRIBUTION

There *shall* be *SOPs* for the following: receipt of request for *NAM*, unit selection, final *container* and/or *package* inspection, shipping, and *transportation* of *NAM* for use in education and/or research (see also *series of standards* at NT-Section G).

NT-H4.100 DISTRIBUTING TO NADOs OR OTHER LOCATIONS

NAM moved between physical inventory locations shall be documented. Date of transfer, staff involved, and *verification* of receipt if transported by *Common Carrier*, shall also be documented.

When a *NADO distributes NAM* from another organization or *NADO*, all accompanying original *labeling materials* or other enclosures *shall* be *distributed* with the *NAM*.

NT-H4.200 DISTRIBUTION RECORDS

Records shall be maintained by the establishment performing *distribution* (including unprepared or as yet unreleased *tissue*) to other entities. These records *shall* be designed to permit *NTAD*/*NAM* to be *traced* from the *donor* to an educator and/or researcher and from an educator and/or researcher back to the *donor*. *Tissue* d*istribution records shall* include:

1) date of order placement;

2) name and address of educator and/or researcher;

3) name of individual placing the *NAM* request;

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4) type and quantity of *tissue* ordered;

5) information pertaining to *tissue* shipped including:

a) identification number(s) of *tissue(s)*;

b) *acquisition* date of *tissue*;

c) date of shipment;

d) type and quantity of hazardous refrigerant (e.g. dry ice) *must* be documented in accordance with IATA guidelines;

e) mode of *transport* and/or courier; and

f) name of the staff member filling the order.

NT-H5.000 PACKAGING AND TRANSPORT

Current (2nd Edition)

NT-H5.100 VALIDATION AND EXPIRATION OF TRANSPORT PACKAGING

If *NAM* to be shipped requires specific environmental conditions other than ambient temperature, the capability of the *transport package* to maintain the required environmental conditions *shall* be demonstrated and documented in a *validation* study. The length of time that these conditions can be maintained by the transport *package*, *shall* also be determined and documented. Expiration dates (and time if applicable) of the *transport package shall* be noted on the outside of the *transport package*.

With amendments

NT-H5.100 VALIDATION AND EXPIRATION OF TRANSPORT CONTAINER ~~PACKAGING~~

If *NAM* to be shipped requires specific environmental conditions other than ambient temperature, the capability of the *transport container* ~~*package*~~ to maintain the required environmental conditions *shall* be demonstrated and documented in a *validation* study. The length of time that these conditions can be maintained by the transport *container* ~~*package*~~, *shall* also be determined and documented. Expiration dates (and time if applicable) of the *transport container* ~~*package*~~ *shall* be noted on the outside of the *transport container* ~~*package*~~.

As amended

NT-H5.100 VALIDATION AND EXPIRATION OF TRANSPORT CONTAINER

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Current (2nd Edition)

NT-H5.200 QUALITY CONTROL OF REUSABLE SHIPPING PACKAGES

If *NAM* to be shipped requires specific environmental conditions other than ambient temperature, and the transport *package* can be reused, *QC* monitoring of *the* transport *container must* be performed according to the *SOPM* to verify *package* integrity has been maintained. These QC checks *shall* be documented.

With amendments

NT-H5.200 QUALITY CONTROL OF REUSABLE SHIPPING ~~PACKAGES~~ CONTAINERS

If *NAM* to be shipped requires specific environmental conditions other than ambient temperature, and the transport *container* ~~*package*~~ can be reused, *QC* monitoring of *the* transport *container must* be performed according to the *SOPM* to verify ~~*package*~~ *container* integrity has been maintained. These QC checks *shall* be documented.

As amended

NT-H5.200 QUALITY CONTROL OF REUSABLE SHIPPING CONTAINERS

If *NAM* to be shipped requires specific environmental conditions other than ambient temperature, and the transport *container* can be reused, *QC* monitoring of *the* transport *container must* be performed according to the *SOPM* to verify *container* integrity has been maintained. These QC checks *shall* be documented.

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NT-H5.300 PRE-TRANSPORT INSPECTION

Each *container shall* be visually examined prior to use and immediately after filling. *Containers* that are damaged and/or not meeting specifications *shall* not be used. These inspections *shall* be documented, including identification of staff conducting inspections.

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Prior to shipping, *packages shall* be *inspected* to ensure the external *packaging* and *container(s) labels* are undamaged, and the *NAM* being shipped is consistent with the request.

NT-H5.400 TRANSPORTATION

The mode of *transportation shall* be determined by any special shipping and handling requirements of the *NAM* and/or any shipping refrigerants, by shipping restrictions of commercial carriers, and the urgency of the request.

NT-H6.000 RETURN OF NAM FOR REDISTRIBUTION OR FINAL DISPOSITION

A *NADO shall establish* a policy authorizing or prohibiting the return of *NAM*. Information pertaining to the condition of the returned *NAM shall* be *recorded* in a written *records* for that return as follows:

1) original requestor or end user *NAM* was returned from;

2) reason for the return;

3) condition of the *NAM*;

4) date and name of the staff member authorized to evaluate and determine the status (e.g. re-*distribution*, *final disposition)* of the *NAM* outlined by the *NADO's established* policy or procedure (See Section J).

NT-H6.100 TEMPERATURE RECORDS

For *NAM* that requires controlled environmental temperatures, at a minimum, documentation is required that attests the *NAM* was maintained at required *storage* temperatures.