Standards for Non-Transplant Anatomical Donation, 2nd ed. Executive Summary of Revisions

The first set of NADO standards were created in 2011. The purpose of this revision is to get the standards more in line with day to day functions of NADO's as well as become more stringent in nature. Throughout the whole edition, edits were made to match quality language used in the 14th edition of the transplant standards. All additions, deletions, and changes were previously reviewed and approved by a sub-committee of representatives from Standards Committee and Physicians Council.

Major changes include:

- **Section A**
  - Added following definitions - Adverse Outcome, Claim, Clean Technique, Colloid, Contracted Services, Crystalliod, Decontamination, Disinfection, Donor referral Sources, Electronic System, Environmental Monitoring, Establish, Exceptional Release, In-Process Controls, Lot, Management with Executive Responsibility, Nonconformity, Package Insert, Physician Designee, Plasma Dilution, Pooling, Preservation, Preventive Action, Process Controls, Process Validation, Quality Agreement, Quality Policy, Quality System, Recall, Relabel, Relevant Communicable Disease or Agents of Disease, Relevant Medical Records, Safety, Series of Standards, Summary of Records,
  - Removed the following definitions - Certified Copy, Director, Informed Consent, Living Donor, Physician Advisor, Universal Precautions
    - For all removed definitions, the standards were reflected by removing any associated references
    - Note: there are no Living Donor NTAD programs and all references associated with Living Donors were deleted from all section
- **Section B**
  - Deleted *physician advisor* and replaced with *medical director* with defined tasks
  - Deleted *Director* and replaced with *MwER* (*Management with Executive Responsibility*)
- **Section C**
  - All record retention time lengths made consistent (10 Years)
  - Requirement for an audit trail was added
- **Section D**
  - Authorization records - added sampling plan requirements
  - Deleted all requirements pertaining to pediatric and living donors
  - Added requirement of serology testing for a minimum of Hep B, Hep C and HIV
  - Added requirement of Plasma dilution
  - Added standards for information sharing
  - Deleted Reference V: TISSUE DONOR PHYSICAL ASSESSMENT FORM Guidance Document which was released in the 14th as Appendix III: TISSUE DONOR PHYSICAL ASSESSMENT FORM REQUIREMENTS as this is not applicable to NTAD
- **Section E**
  - Remove all environmental control standards
  - Outlined quarantined guidelines in better detail
  - Added more guidelines for supplies maintenance, management and approval
  - Added the requirement to monitor storage temperatures
- **Section F**
  - Added definition for exceptional release and outlined associated tasks and requirements
- **Section G**
  - Updated NAM usage and venue requirements (reference to Section E removed and replace with the list of requirements)
- **Section H**
  - Updated all labeling and package insert requirements
    - Removed expiration date
    - Added requirements for exceptional release NAM

- Added redistribution standards
- Duplicate requirements deleted (still exist in NT-E and NT-C)

- **Section J**
  - Added cremation records to disposition record requirements
  - Distinguished between NAM and NTAD labeling
- **Section K** General operations
  - edited to align with 14th Section J
    - SOP ID, implementation, and control alignment
  - Added calibration to equipment requirements
  - Clarified decontamination requirements
- **Section L** Quality Assurance
  - Edited to be more closely related to 14th edition Section K
    - Added correction, corrective action section
    - Added purchasing controls
    - Added complaint investigation requirements
  - Clarified Qualification, verification, and validation requirements