National Marrow Donor Program
Record of Change 22nd Edition Standards

21st Edition STANDARD #	CHANGE	RATIONALE FOR CHANGE
1.1000	Revised content. Now reads: "These standards apply to activities performed by National Marrow Donor Program® (NMDP) participating centers and include processes from donor recruitment to distribution and administration of cellular therapy products facilitated through NMDP."	Edited for clarity
1.1100	New sub-standard "Centers shall have adequate staff, resources, space, equipment and supplies to perform and manage activities."	Consolidate sections
1.1200	New sub-standard "Centers shall establish and maintain written policies and procedures to define activities"	Consolidate sections
1.3000	Moved from 7.5211	Consolidate sections
1.3110	Moved from 1.7000	
1.3200	Moved from 7.5212	Consolidate sections
1.4000	Moved from 2.4120. Revised wording "Centers shall use laboratory(ies) certified by Centers for Medicare & Medicaid Services (CMS) (or non-U.S. equivalent) for all clinical tests required by NMDP"	Consolidate sections. Removed specific wording "ABO/Rh…"
1.7000	Moved from 1.4100	Repositioned to align similar content
1.7100-1.7300	New sub-standards. 1.7100 Any responsibility(ies) of the center medical director may be fulfilled by a designated center physician 1.7200 Center medical director is responsible for assuring that physician designees are trained and qualified 1.7300 Center physicians shall participate regularly in educational activities related to the field of hematopoietic cell collection or transplantation.	Consolidate sections. Added to clarify medical director duties.
(old) 2.1200	Removed. "Center shall have adequate resources to support its donor management activities, as applicable"	Now covered in 1.1100
new 2.1200 (formerly 2.1300)	Revised. Now reads: "Center shall have a private space for donor counseling sessions."	Edited for clarity.
new 2.1400 (formerly 2.1500)	Revised. Now reads: "Center shall have written agreement(s) defining roles and responsibilities with participating apheresis and/or marrow collection center(s)."	Edited for clarity.
2.1600	Removed. "Center shall have collaborative agreement(s) with participating apheresis collection center(s)."	Now covered in 2.1400
2.2100	Revised. Now reads: "Center shall have a medical director who is a licensed physician qualified by training and experience to evaluate and determine donor medical suitability and supervise donor management."	Edited for clarity.
2.2100	New sub-standard "The medical director or physician designee shall determine donor medical suitability"	Added to clarify medical director duties.
(old) 2.2200	Removed "Center medical director shall have at least one year experience in donor management."	Now covered in 1.7000

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New 2.2200 (formerly 2.2300	Revised. Now reads: "Center medical director shall be responsible for interpretation of NMDP eligibility criteria"	Now covered in 9.3200
2.2400	Removed "Center medical director shall be responsible for reviewing the medical evaluation of the donor for risks of donation and evidence of disease transmissible by transfusion or transplantation."	Now covered in 9.3000
2.3200	Removed "Center shall have staff sufficient to manage daily activities."	Now covered in 1.1100
2.4200	Removed "Center shall have technical support for information systems."	Now covered in 1.1100
(old) 3.1200	Removed "Center shall have adequate resources to support its recruitment activities"	Now covered in 1.1100
(old) 3.1300	Removed "Center shall have permanent or preliminary IRS designation as a 501(c) (3) tax exempt non-profit organization"	Obsolete requirement
new 3.1300 formerly (3.1500)	Revised. Now reads: "Center shall have a written agreement defining roles and responsibilities with each NMDP donor center that has agreed to accept the recruited HLA-typed donors."	Added to describe requirement for an agreement.
3.3200	Revised. Now reads: "Center shall have staff sufficient to perform required activities."	Edited to make requirements less specific.
4.1200	Revised. Now reads: "Bank shall have experience in cord blood recruitment."	Edited to make requirements less specific.
(old) 4.1300	Removed "Bank shall have adequate resources to support its recruitment and management activities."	Now covered in 1.1100
New 4.1300 (formerly 4.1400)	Revised. Now reads: "Bank shall have adequate and secure facilities for manufacturing HPC(CB) ."	Edited to make requirements less specific.
(old) 4.1500	Removed "Bank shall have designated site for secure record storage."	Now covered in 12.1100
(old) 4.1600	Removed "Bank shall have a secure information management system and exchange data according to NMDP requirements."	Covered in Section 12
4.1610	Removed "Bank shall have technical support for information systems."	Now covered in 12.2110
New 4.1400 (formerly 4.1700)	Revised. Now reads: "Bank shall have written agreements to collect cord blood"	Edited to make requirements less specific.
(old) 4.2100	Removed "Bank shall have a medical director who is a licensed physician."	Now covered in 1.7000
New 4.2300 (formerly 4.2400)	Revised. Now reads: "Bank medical director shall be responsible for: recruitment, informed consent, evaluation and follow-up of the potential donor, and participate in the development of the procedures for the collection, processing, testing, banking, selection and release of the unit."	Added verbiage to clarify medical director responsibilities.
(old) 4.3200	Removed "Bank shall have staff sufficient to manage daily	Now covered in 1.1100

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	activities."	
4.3210	Removed "Bank shall provide staff for each working day and coverage for emergencies"	Now covered in 1.1100
New 4.3200 (formerly 4.3220)	Revised. Now reads "Bank shall have adequate trained and competent personnel available to perform tasks related to HPC(CB) manufacturing and sample management"	Edited to make requirements less specific.
4.3300	New Standard. "Bank should have a designated, independent Quality Unit to audit, monitor, and authorize release of cord blood units as defined in facility-specific procedures"	Added to align with FDA requirements for Quality Unit.
(old) 4.4120	Removed "Laboratory certified by Centers for Medicare & Medicaid Services (CMS) (or non-U.S. equivalent) for infectious disease marker testing"	Now covered in 1.4000
4.4200	Removed "Bank shall have technical support for information systems."	Now covered in 12.2110
(old) 5.1300	Removed "Center shall have adequate resources to support its collection and management activities."	Now covered in 1.1100
5.1400	Removed "Center shall have a designated site for management of collection activities."	Now covered in 1.1100
New 5.1300 (formerly 5.1500)	Revised. Now reads "Center shall have written agreement(s) defining roles and responsibilities with participating donor center(s)."	Edited for clarity.
5.2100	Removed "Center shall have a medical director who is a licensed physician qualified by training and experience to supervise HPC, Marrow collections."	Now covered in 1.7000
5.4210	Moved to 5.5500	
(old) 5.4300	Moved to 5.5310	
5.4400	Moved to 5.5600	
6.1100	Revised. Now reads "Center shall be registered with the FDA."	Edited for clarity.
(old) 6.1300	Removed "Center shall have adequate resources to support its collection management activities."	Now covered in 1.1100
6.1400	Removed "Center shall have a designated site for management of collection activities."	Now covered in 1.1100
New 6.1300 (formerly 6.1500)	Revised. Now reads "Center shall have written agreement(s) defining roles and responsibilities with participating donor center(s)."	Edited for clarity.
(old) 6.2110	Removed "Center medical director shall have postdoctoral training in hematopoietic cell collection or transplantation"	Now covered in 1.7000
(old) 6.2200	Removed "Center medical director shall take responsibility for assuring that other center physicians supervising apheresis collections are appropriately trained in the procedure"	Now covered in 1.7200
(old) 6.3100	Removed "Center physician supervising the apheresis collection shall be qualified by training and experience:"	Now covered in 1.7000

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6.3100	Removed "Center supervising physician shall have at least one year experience in the collection procedure"	Now covered in 1.7000
6.3120	Removed "Center supervising physician shall participate regularly in educational activities related to the field of hematopoietic cell collection or transplantation"	Now covered in 1.7300
6.4100	Combined with 6.4120. Now reads "Center shall use a laboratory with documented proficiency for measuring the quantity of CD34-positive cells in the component collected."	Consolidated standards.
6.4110	Removed "…Laboratory(ies) certified by the Centers for Medicare & Medicaid Services (CMS) (or non-U.S. equivalent) for assessing cell counts, blood chemistries, infectious disease markers, ABO group, Rh type, red cell antibodies, and for other tests required by NMDP"	Now covered in 1.4000
(old) 6.5200	Removed "Responsible physician shall perform and/or review a complete medical evaluation to determine if the donor is an acceptable candidate for mononuclear cell donation."	Covered in 6.2200
7.1300	Revised. Now reads "Center shall have a designated inpatient unit that minimizes the risk of infection"	Edited for clarity.
7.1600	Removed "Center shall have adequate resources to support its search management activities."	Now covered in 1.1100
7.1700	Removed "Center shall have a designated site for management of search activities."	Now covered in 1.1100
7.2100	Removed "Center shall have a medical director who is a licensed physician."	Now covered in 1.7000
7.3100	Moved to 7.2400 and added …."one of whom may be the medical director"..	Edited for clarity.
7.3110	Moved to 7.2410	
7.3120	Moved to 7.2420	
7.3130	Removed "Center attending physicians shall participate regularly in educational activities related to the field of hematopoietic cell transplantation"	Now covered in 1.7300
New 7.3400 (formerly 7.3500)	Revised. Now reads: "Center shall identify a patient advocate who is familiar with the center's program and issues of unrelated donor hematopoietic cell transplantation."	Removed the requirement that the advocate not be a member of the transplant team.
7.3600	Moved to 7.4200	
7.4110	Combined with 7.4100.	Consolidated standards.
7.4120	Removed "Laboratory(ies) certified by the Centers for Medicare & Medicaid Services (CMS) (or non-U.S. equivalent) for tests required by NMDP"	Now covered in 1.4000
New 7.4500 (formerly 7.4400)	Revised. Now reads "Center shall have experienced physicians who provide consultative services in at least the following disciplines: Cardiology, Gastroenterology, Infectious Diseases, Intensive Care, Nephrology, Pathology, Pulmonary Medicine, Psychiatry, Surgery,	Edited for clarity.

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	Transfusion Medicine, and, if applicable, Radiation Therapy."	
7.5100	Revised. Now reads: "Center shall maintain written policies, procedures and clinical practice guidelines to address all aspects of allogeneic transplantation"	Edited to include "clinical practice guidelines..."
7.5110-7.5170	Removed. 7.5100 Donor or product selection 7.5120 Financial approval 7.5130 Infection prevention and control 7.5140 Processing ABO incompatible hematopoietic cell products to reduce the risk of hemolysis 7.5150 Hematopoietic cell product infusion 7.5160 Blood component transfusion to include transfusion of blood components when the donor and recipient are ABO mismatched 7.5170 Education of the patient pre and post transplant	Edited to make requirements less specific.
7.5210	Removed "Clinical research protocols shall be approved by center's institutional review board (IRB)"	Now covered in 1.3100
7.5220-7.5226	Removed "7.5220 Written clinical practice guidelines shall include at least the following: 7.5221 Criteria for recipient selection 7.5222 Procedures for recipient evaluations 7.5223 Preparative regimen 7.5224 Procedures for the prevention and treatment of graft-versus-host disease 7.5225 CMV prophylaxis, surveillance and treatment 7.5226 Procedures for post-transplant care	Now covered in 7.5100. Removed to make requirements less specific.
7.5400	New Standard "Center shall have policies to ensure timely communication with patients, families and physicians, including the progress of the search and other treatment options."	Replaces former Section 7.6000 Donor Advocacy.
8.1400	Revised. Now reads: "Pertinent donor medical history shall be evaluated for acceptance or deferral according to the current NMDP procedures and criteria of local donor center medical director."	Edited for clarity.
8.1500	Revised. Now reads: "Donor shall be given educational materials regarding the risks of infectious disease transmission by hematopoietic cell transplants."	Edited to make requirements less specific.
8.2100-8.2120	Moved to 9.8200-9.8220	
New 8.2100 (formerly 8.2200)	Revised. Now reads: "Consent shall be obtained from the biologic mother for collection and voluntary donation of the HPC(CB) to a cord blood bank for use in unrelated cellular therapies per cord blood bank specific policies."	Edited for clarity.
8.2400-8.2420	Moved to 9.8300-9.8320	
8.2500	Moved to 9.8400	
9.1220	Moved to 9.1100	

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New 9.1300 (formerly 9.1200)	Revised. Now reads: "Donor center shall provide potential donor with educational materials including the risks of infectious disease transmission by transplantation." Added "Stage" to title.	Confirmatory Testing Stage identified in section title
New 9.1360 (formerly 9.1270)	Revised. Now reads "Transplant Center shall verify the HLA typing of the donor, in accordance with NMDP policy, using a new sample"	Edited for clarity.
9.2240	Revised. Now reads "Possibility that he/she may be asked to provide other cellular therapy products for the same recipient"	Edited to make less specific.
9.2410	Moved to 9.2430	
9.2430	Moved to 9.2410	
9.3220	Revised. Now reads "Medical history indicative of disease or risk of infectious disease shall be evaluated by a donor center medical director or designee \ to determine the donor's suitability to donate and eligibility status"	Edited to clarify medical director responsibility.
9.3300 Section	Revised. "physician" changed to "practitioner" throughout section	"Examining Practitioner" now included in Glossary section
9.3310	Removed "Examining physician shall be a licensed physician or appropriately licensed supervised mid-level practitioner"	"Examining Practitioner" now included in Glossary section
New 9.3360 (formerly 9.3340)	Revised. Now reads "Examining practitioner shall report results of the medical evaluation in writing to the donor center"	Edited to make less specific.
(old) 9.3350	Removed. "Examining physician or appropriately licensed supervised mid-level practitioner shall assess changes in donor history and physical exam according to NMDP guidelines"	"Examining Practitioner" now included in Glossary section
New 9.3370 (formerly 9.3360)	Revised. Now reads: "Final approval of the donor shall not occur until the medical director/physician designee of the collection center or apheresis center and the donor center medical director or designee document that the donor meets the criteria for collection and the donor has signed the consent to donate"	Added "designee"
9.4110	Revised. Now reads "Donor shall be notified of the findings and documentation of donor notification shall be maintained"	Edited for clarity
(old) 9.4120	Removed "Documentation of counseling regarding abnormal finding shall be maintained at the donor center"	Consolidated with 9.4110.
9.4200 and 9.4220	"Clinically significant abnormal finding".	"Clinically significant" added for clarification.
Section 9.6000 and 9.7000	"Adult" added	Clarify sections are applicable to adult donors
9.7220	Revised. Now reads "Donor may be asked to provide an additional cellular therapy product collection for the same recipient following NMDP guidelines"	Edited to make less specific.
(old) 9.7222	Removed "Donor center shall ensure repeat infectious disease testing is performed if previous results were obtained more than 7 days prior to NC, Whole Blood or MNC, Apheresis donation.	NMDP no longer facilitates NC, Whole Blood. See 9.1330 for information on IDM testing requirements.

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10.2130	New standard. "For central venous access see Section 6.5400"	Added to section with reference to 6.5400
(old) 10.2500	Removed "After collection, the apheresis center shall not cryopreserve product or manipulate the product without the direct consent of the transplant center and approval of the NMDP."	Now 10.4100
(old) 10.2510	Removed. "Any further processing shall only be performed by transplant center or laboratory designated by the transplant center"	Now 10.4110
New 10.2510 (formerly 10.2410)	Revised. Now reads "Apheresis center shall obtain component cell counts, including CD34 counts for HPC(A), and promptly transmit results to NMDP and to the transplant center"	Edited for clarity.
10.3100	Removed "HPC, Cord Blood [HPC(CB)] units shall not be collected or stored with non-human sources of blood or blood components."	Negative standard.
New 10.3100 (formerly 10.3200)	Revised. Now reads" Testing, collection and processing of the HPC(CB) units shall be consistent with AABB Standards and/or NetCord-FACT Standards. (See Resources)"	To be consistent with AABB & FACT.
10.4110	New standard. "Any further processing shall only be performed by transplant center or laboratory designated by the transplant center"	Added information to clarify that TC/lab can do further processing
10.5100	Revised. Now reads "Labeling shall conform to applicable regulations and labeling information in the Circular of Information (COI) or package insert for licensed products and shall be consistent with AABB, FACT-JACIE and/or NetCord-FACT Standards, as applicable. (See Resources)"	Edited for clarity. Added information pertaining to licensed products.
10.5120-10.5124	Removed. 10.5120 Labels are supplied for the following specific products: 10.5121 For marrow collection: "HPC, Marrow" 10.5122 For mobilized leukocytapheresis: "HPC, Apheresis" 10.5123 For non-mobilized leukocytapheresis: "TC, Apheresis" 10.5124 For non-mobilized peripheral whole blood collections: "TC, Whole Blood"	Removed to make more general.
10.5200	Revised. Now reads "Biohazard and Warning Labels, as required by the US Food and Drug Administration, shall conform with labeling as outlined in 10.5100. (See Resources)"	Clarified requirements and removed redundancy with 10.5100.
New 10.5300 (formerly 10.5210)	Revised. Now reads "Documents accompanying the product shall conform to applicable regulations and labeling information in the Circular of Information (COI) or package insert for licensed products and shall be consistent with AABB, FACT-JACIE and/or NetCord-FACT Standards, as applicable. (See Resources)"	Edited for clarity and redundancy.
New 10.5400 (formerly 10.5300)	Revised. Now reads "Each item recorded on the label and accompanying documents shall be verified for accuracy by two	Edited for clarity.

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	individuals or by one individual and a validated electronic equivalent and verification documented."	
(old) 10.6000-10.6410	Removed. ***10.6000 Cord Blood Products (HPC, Cord Blood; Cryopreserved HPC, Cord Blood)*** 10.6100 Labeling of HPC, Cord Blood and Cryopreserved HPC, Cord Blood shall conform to labeling information in the Circular of Information (COI) and be consistent with AABB and/or NetCord-FACT Standards. (See References) 10.6200 Biohazard and Warning Labels, as required by the US Food and Drug Administration, for HPC, Cord Blood and Cryopreserved HPC, Cord Blood shall conform to labeling information in the Circular of Information (COI) and be consistent with AABB and/or NetCord-FACT Standards. (See References) 10.6300 For products collected in or designated for allogeneic use in the U.S., documents accompanying the product shall contain at least the elements listed in the Accompanying Documents at Distribution Table in Appendix II (unless otherwise present on the label). 10.6400 Each item recorded on the label and accompanying documents shall be verified for accuracy by two individuals or the electronic equivalent. 10.6410 Label verification shall be documented	Covered in 10.5000
New 10.6100 (formerly 10.7100)	Revised. Now reads "Each non-cryopreserved product shall be placed inside a secondary container which is sealed to prevent leakage. (e.g. an outer bag)"	Edited for clarity.
New 10.6200 (formerly 10.7200)	Revised. Now reads "Products shall be enclosed in a rigid shipping container with temperature insulating properties."	Edited for clarity.
New 10.6210 (formerly 10.7210)	Revised. Now reads "The rigid shipping container shall include a document on the inside of the container and a label on the outside of the container according to NMDP policies and procedures."	Edited for clarity.
10.7310	Removed "Product shall be insulated from direct contact with wet ice or reusable cooling packs"	Removed to allow use of Credo Cube
10.7320	Removed "Dry ice shall not be used"	Not needed
Section 11.0000	"Reactions" changed to "Events" throughout section	Aligns with FDA terminology
11.1120	Revised. Now reads "Center shall notify NMDP of serious adverse events possibly related to the product as defined in NMDP protocols and procedures"	Edited for clarity.
11.1130	Revised. Now reads "Fatal or potentially life threatening adverse	Edited for clarity.

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	events possibly related to the product shall be reported to NMDP by close of the next business day following determination of the event"	
12.1100	New standard. "Center shall have secure record storage."	Consolidate sections
New 12.1500 (formerly 12.1400) & New 12.1700 (formerly 12.1600	Added the term "donor mother"	Added for clarification
12.2110	New standard "Center shall have technical and operational support for information systems management"	To address requirements for electronic records. Consolidate sections
12.2200	New standard "Records shall be maintained in a way to ensure their integrity and preservation for the duration of the defined retention period and be retrievable"	To address requirements for electronic records.
12.2210	New Standard "Before destruction of original records, copies of such records shall be verified as legible, indelible, and complete	Added to ensure good documentation practices
12.2350	Revised. Now reads "All modifications to the system shall be authorized according to institutional procedures"	Edited for clarity.
12.3250	Revised. Now reads "Records pertaining to collection and all manufacturing steps though final distribution of cord blood products"	Edited to address requirements for manufacturing records.
12.3332	Revised. Now reads "Records pertaining to qualification, calibration, maintenance, monitoring and use of equipment shall be traceable to collected product"	Edited to address requirements for manufacturing records.
12.3410	Revised. Now reads "Informed consent documents related to NMDP facilitated cellular therapy products"	Revised to limit scope of documents for which indefinite storage is required.
12.3420	Revised. Now reads: "For recipient formal (activated) search activity, results of donor and recipient HLA typing and other test results at the Transplant Center including the identification numbers of participating donor(s)."	Revised to limit scope of documents for which indefinite storage is required.
12.3430-12.3433	Revised. Now reads: " 12.3430 Records pertaining to any NMDP facilitated search including: 12.3431 The identification numbers of participating donor(s)/cord blood unit(s) 12.3432 Abnormal donor/cord blood unit or recipient findings and notification/counseling of relevant parties 12.3433 Product testing results, including ABO/Rh typing and microbial cultures"	Revised to limit scope of documents for which indefinite storage is required.
12.3440	Revised. Now reads: "Records related to adverse events associated with NMDP facilitated cellular therapy products"	Revised to limit scope of documents for which indefinite

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		storage is required.
12.3450	Revised. Now reads: "Records related to final disposition of NMDP facilitated cellular therapy products"	Revised to limit scope of documents for which indefinite storage is required.
12.3460-12.3490	Removed.	Now covered in 12.3410, 12.3433
References – now Resources	Section renamed "Resources"	
Resources	"NOTE: The 22nd Edition of the NMDP Standards contains a list of internet resources that are provided as a courtesy. At the time of publication of this Edition, the website addresses were current. The NMDP does not control the content of all referenced websites, however, and the website addresses and associated content are subject to change. NMDP does not guarantee the accuracy of information provided on the websites, nor is it liable for reliance on the information."	Added disclaimer
Glossary – Adverse Reactions – now Adverse Event	Revised definition. Now reads "Adverse event means any untoward medical occurrence associated with the donation or administration of a cellular therapy product."	Changed to "Adverse Event (AE)" to align with FDA terminology.
Glossary – Circular of Information (COI)	Revised definition. Now reads: "The *Circular of Information for the Use of Cellular Therapy Products* (hereafter referred to as the *Circular*) is an extension of container labels, as the space on those labels is limited. The focus of this *Circular* is restricted to unlicensed cellular therapy products that are minimally manipulated. The *Circular* is intended to provide general information to those who administer cellular therapy products and serves as an extension and enhancement of the label found on the cellular therapy product."	Revised to match COI
Glossary – Confirmatory Testing Stage	New glossary term. "The designation of the stage in the search process during which a potential adult donor is being evaluated as a donor for a specific patient, commonly called CT."	New term.
Glossary – HPC, Cord Blood [HPC(CB)]	Removed "Cord Blood Unit" from term. Revised definition. Now reads: "Hematopoietic cells collected from umbilical cord blood and placenta after delivery that has been typed and stored for potential future transplant."	Revised to reflect ISBT 128 terminology.
Glossary – Protocol Deviation	Removed term and definition.	Consolidated under definition of deviation.
Glossary – Deviation From Standards	Removed term and definition.	Consolidated under definition of deviation
Glossary – Disposition	"The status assigned to a cellular therapy product based on evaluation of specific characteristics."	Edited for clarity.
Glossary – Donor Medical Suitability		Edited for clarity

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Glossary – Eligibility		Edited for clarity
Glossary – Examining Practitioner	"A licensed physician, physician's assistant, or nurse practitioner, consistent with applicable law."	New term.
Glossary – Indefinite Record Retention	"Records identified as having an "indefinite" or similar retention requirement shall be retained for an indefinite period. For purposes of this definition, "indefinite" means retention shall be permanent and ongoing, unless and until a different retention period is specified for the documents at issue."	New term.
Glossary – Manipulation	Removed term and definition.	Word not in the Standards.
Glossary – Mid-Level Practitioner	Removed term and definition	Now covered under "Examining Practitioner"
Glossary – National Coordinating Center	Removed term and definition	Obsolete.
Glossary – TC, Whole Blood	Removed term and definition	Product not facilitated by NMDP.
Appendix I	Removed	See 10.5000
Appendix II	Removed	See 10.5000
Appendix III	Removed	See 10.5000