No	Donor Center Audit Checklist	Reference to WMDA Standards		Instructions for Auditor	Relevant Documents to Review	Reviewer comments
1. General Organization & Typing						
1.1.	**DC organizational chart and external partners (e.g. Collection Centers, Lab, Registries) Organizational chart of the entity in which the DC is included.**	2.08	The registry must retain a staff large enough to assume the volume and variety of services required to perform international searches within a time frame in accordance with WMDA metrics for unrelated donor search while maintaining the confidentiality of patient and donor.	● Review organizational chart of the donor center and, if applicable, the organizational chart of the entity with which the donor center is affiliated. ● Assess whether applicable functional areas are represented. If available, ask for organizational charts of partner organizations. If not, request information on external partners (how many, locations, center type, etc.).		
1.2.	**Copy of the latest valid certificate (EFI, ASHI/ other national organization) of the tissue typing laboratory accredited to perform HLA typing**	3.18 3.20.1	Registries must have established approaches to monitor and ensure the accuracy and completeness of the data listed in the donor database, including a system to ensure the quality of HLA typing results. The registry must use HLA testing laboratories that are capable of carrying out DNA–based intermediate and high resolution HLA-typing and are appropriately accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), European Federation for Immunogenetics (EFI), or other accrediting organisations providing histocompatibility services appropriate for hematopoietic stem cell transplantation.	● Ensure the EFI and/or ASHI certificate is current and valid for the testing performed.		

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1.3.	**CV of the Medical Director of the Donor Center**	2.04	The director or key registry personnel or consultants must have expertise in human histocompatibility and hematopoietic stem transplantation as documented by the relevant education and experience. At least one of these individuals must be a physician. These individuals must possess a basic understanding of diseases treatable by hematopoietic stem transplantation, comprehend alternative therapies and donor search problems associated with these diseases, understand HLA specificities (serologic and DNA-based) and haplotypes, and possess a knowledge of transplant centre, donor centre, collection centre, cord blood bank (if applicable), and registry protocols in their own country and abroad.	● Review the CV for medical license and relevant experience with cellular therapy donors.		
1.4.	**Significant changes which occurred in the functioning of the DC and associated recruitment procedures/policies within the last 4 years**	1.05	Changes to the status of a registry that may affect WMDA certification, qualification or accreditation must be brought to the attention of the WMDA in a timely fashion.	● Assess if the center has a defined process (SOP) for notifying WMDA of changes in donor center processes, including donor recruitment.		

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2. Recruitment						
2.1.	**Procedure for the donor management at time of registration. SOPs, policies and recruitment material.**	2.10.1	The registry must maintain documented policies and procedures for all processes performed in the registry. This must include manual of operations, standard operating procedures, and forms.	● Assess if the center has a defined process for recruitment of donors, and the management of consents and samples at the time of recruitment.		
2.2.	**Review several completed consent forms of donors recruited in the last 4 years.**	3.03 3.09	The willingness to become a donor must be the individual choice of each donor, that is, donations must be voluntary. Donors must be willing to donate on behalf of any patient being treated in any part of the world. Donors must not be paid for their donation but may be reimbursed for expenses incurred during the donation process, for example, time lost from work or travel to the collection center. Valid informed consent must be obtained initially at the time of recruitment.	● Assess that the donor center conveys required information at the time of recruitment that ensures informed and committed consent.		
2.3.	**Information material provided to the donor**	3.04 3.05 3.06	Donors must be informed regarding their potential role in the donation of hematopoietic stem cells, the risks involved in the donation, and the tests that the donor may undergo. Donors must be informed about the use of any medical intervention (e.g., administration of GCSF) and its known risks and/or side effects. A donor must be free to withdraw at any time.	● Assess that the donor center has printed or web based material that convey the required information at the time of recruitment. ● The level of detail of information provided at recruitment will be different from the level of information provided at later stages.		

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2.4.	**Assess rules for donor eligibility, age and gender**	3.22.1.	An initial health screening should be performed at the time of recruitment.	● Assess that the Donor Center medically screens donors at the time of registration, and has a procedure in place that provides a donor with the results of their screening if requested.		
2.5.	**Description of the interfaces with the registry (to maintain confidentiality of donor data, including, Transporting, transmitting, storing and protecting data integrity).**	3.07 5.15 5.23 5.25	To ensure confidentiality, the identity of donors must be protected. The registry must have policies and procedures in place to ensure donor confidentiality.When transferring data between organisations, there must be a validated protocol for the transfer of data. Both the transferring organisationand the receiving organisation must have policies to verify data.Prior to collecting, processing or sharing personal information, all unnecessary identifiers must be removed from the data set. Where it has not been possible to remove all personal identifiers, the data should be encrypted before it is copied to removable or portable media, or transmitted using unsecured channels.Records must be maintained for an appropriate period of time, at least as dictated by national laws or standards. Key documents related to donor traceability must be maintained at a minimum for thirty (30) years following donation. Data storage may be on paper or in electronic form.	● Assess that the donor center has an established procedure on the management of the storage, and transportation and/or transmission of anotymized donor data and HLA typing results.		

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2.6.	**Training matrix and training records for donor recruiters**	3.02	Recruitment of donors must be performed by professionals trained for recruitment, under the direction of individuals who are experienced in recruitment of donors and in management activities including education, consenting, counselling, confidentiality, and medical screening. These individuals must be appropriately qualified and provided with timely and relevant training. The training and experience of these individuals must be documented.	● Assess that the Donor Center has a training matrix outlining all relevant training for the Recruiter role, and has training records for each recruiter, and of the completion of each module within the training matrix. ● If volunteers are used in donor recruitment, assess how they are trained to fullfil their role.		
3. Verification Extended Typing						
3.1.	**Procedure for donor management at time of extended typing or blood sample collection for Verification typing. Get detailed checklist/relevant SOPs.**	3.10 3.10.1	Donors must be counselled when selected for further tests and when selected as a donor for a specific patient. Counselling for donors selected for specific patients must include anonymity of the donor and patient, requirement for further blood samples before donation, requirement for infectious disease and other testing, risk of donation, possible duration of loss of time from normal activities and duration thereof, location of the collection, the potential for collection of autologous blood, donor's right to withdraw and consequences for the patient, details of insurance coverage, possible subsequent donations of hematopoietic stem cells or blood products, alternative collection methods and whether blood is reserved for research purposes.	● Check the typical process of donor management: from first contact (letter/call), via health assessment and blood draw organization (correct type of tubes and blood volume) as well as information given after verification typing. Could also be done on an example during on site visits.		

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3.2.	Request for blood sample collection for verification/extended typing transmitted by the registry in _____(specify year) . Verify how request is received, current version of request in use, etc. See also 2.5.	5.19 6.01	The access to personal donor and patient data as well as the transmission of these data between organisations must be coordinated in a way that accidental or unauthorised access, destruction or modification is prevented Critical communications among registries and other organisations must be in legible writing or transmitted via an electronic system..	● Ensure that the data transferred between registry and Donor Center is set up in a secure way (to prevent mistakes --> communication in writing or electronically). The communication must be safe in terms of data protection ● Evaluate if process can handle unsuccessful request transmissions. ● Check donor unavailability are handled and communicated. ● Check if urgent requests handled differently. ● Evaluate if checks are in place to make sure information is transmitted correctly and in a timely manner.		
3.3.	Medical questionnaire completed at time of verification/extended typing. Verify current version is in use, current requirements included in the questionnaire, etc.	3.22.2 3.22.2.1	A health screening including infectious disease testing must be performed at time of verification typing. Information on the number of pregnancies (including all pregnancies, whether or not a child was born) and history of other prior sensitizing events such as transfusion must be obtained from donors at time of verification typing.	● Check the health information gathered, when and how. Also ask if there are additional national regulations. (As often there are also for blood donors).		
3.4.	Accompanying documents for shipment of blood samples		Samples need to be labelled according to national specifications for traceability purposes. Additional information can be provided in accompanying documents.	● Check if there are forms accompanying the shipment of the blood samples. ● Check if samples labelled appropriately, and if a standardised format is used.		

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3.5.	Process for updating donor HLA from VT		Discrepancies need to be clarified. Handling of higher resolution data received from the TC.	● Check how incoming data from VT is handled		
3.6.	Infectious disease markers and blood group results sent with other blood samples to the transplant center. Information can be presented on site visit.	3.24 3.24.1 3.25 3.26	Infectious disease testing, as defined in 3.22.2, of donorsselected for specific patients must include testing for diseases thought to be important to consider in hematopoietic stem cell transplantation. Testing must monitor infection with human immunodeficiency virus (HIV), Human T-cell Lymphotropic virus I and II, Hepatitis B virus, Hepatitis C virus, Cytomegalovirus (CMV), Treponema pallidum (syphilis) and other infectious agents as defined by local regulation.Selected donors should be tested for local diseases that are important to consider in hematopoietic stem cell transplantation. Donors who have recently travelled outside their country should be evaluated for infectious diseases prevalent in the areas of travel.Infectious disease markers must be measured within thirty (30) days of the hematopoietic stem cell/cellular product collection and the results must be provided to the transplant centre before commencement of patient conditioning.The donor must be counselled in case of positive transmissibledisease test results.	● Check relevant infectious disease markers are tested. ● Check for special local diseases. ● Ensure that there is a process in place to inform the donor about positive test results.● Review also the process of informing the TC.		

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4. Work Up						
4.1.	**SOP for donor management at time of work up**	3.22.3	Policies for testing the donor selected for workup must be established and must include medical history, physical examination, and laboratory tests in order to determine the donor's fitness to donate.	● Ensure SOPs define process to inform and counsel the donor, to schedule and perform PE, to organize the workup together with CC.		
4.2.	**Result of extended/verification typing**	6.04.1	Verification typing of the adult donor at a minimum of HLA-A, -B, -C, -DRB1 DNA based typing at high resolution must be performed must be performed prior to a hematopoietic stem cell donation for a specific patient.	● Ensure the DC received the results of the test and HLA loci typed and the level of resolution comply with registry SOP before processing the work up request		
4.3.	**Request for donor workup-related documents and bone marrow /PBSC prescription**	6.06	The donor centre/cord blood bank must be informed of the proposed date(s) of transplant at the time a specific donor/cord blood unit is requested for transplantation for a specific patient. If a donor will be the source of HSC, the donor must also be informed. The transplant centre must specify the latest date by which the donor centre must approve the eligibility of a donor for donation of HSC for a specific patient (i.e., provide donor clearance).	● Confirm how donor is notified of proposed workup schedule. Check applicable forms e.g. workup form, donor clearance, workup checklist. ● Check how request is received (fax, e mail etc), version of request form (if it is the current version in use) signatures, time of processing, anonymity of donor. Work-up request forms of the registry are expected to include the following: dates of patient's conditioning, graft infusion date, proposed collection dates, and donor clearance date. ● The donor center must have clear donor identification (ID), prescription forms, patient status and degree of urgency. ● Donor center must have a communication system in place to inform the transplant centre in case the donor can't be reached in a reasonable number of days after workup request or when complications occur. Was the TC notified if there was a problem with the medical assessment or failure of assessment?		

No	Donor Center Audit Checklist	Reference to WMDA Standards		Instructions for Auditor	Relevant Documents to Review	Reviewer comments
4.4.	**Verification of the prescription**			● Check how Verification form is sent to the TC/Registry (fax, e-mail etc); the version of form (if it is the current version in use), signatures time of processing, anonymity of donor.		
4.5.	**Formal final consent forms signed by the donor (for HPC Marrow, HPC Apharesis, MNC)**	3.14	Consent documents signed by donors must be available for review by individuals designated by the registry or national authorities to evaluate the registry.	● Is there signed donor consent? If not on site, how does the DC know consent has been obtained? ● Check the correct version of consent has been used, the current requirements are included in the consent, signatures, etc . ● Confrim SLA relating to offsite storage of consent forms is current, if applicable.		
4.6.	**Medical questionnaire/PE completed at time of pre-donation for donor suitability to donate.**	3.23	The donor's medical history taken at the time of medical examination for donation must include questions to identify risk of disease transmissible through transplantation.	● Ensure the Medical and physical examination of the donor is completed and recorded. Questions concerning infectious diseases, genetic defects (e.g., autoimmune diseases) and disseminated malignancies have to be asked. ● Confirm results of donor evaluation are conveyed to the TC prior to donation.		

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4.7.	**Certificate signed by the physician confirming the donor clearance for bone marrow donation/PBSC collection**	3.22.3 3.22.3.1 3.22.3.2	Policies for testing the donor selected for workup must beestablished and must include medical history, physical examination,and laboratory tests in order to determine the donor's fitness to donate.This examination must be performed or supervised by a physician who is not the primary treating physician overseeing the care of the patient.Female donors of childbearing potential must have a pregnancy test and be counselled to avoid pregnancy during the workup stage before use of mobilising agents, collection or initiation of the recipient's preparative regimen, whichever occurs first.	● Check the right version has been used, the current requirements are included in the clearance, signatures, etc, date of transmission to TC is recorded.● Confirm the physician evaluting the donor does not care for the patient. ● Is there evidence of counselling female donors of childbearing age to avoid pregnancy during the workup process?		
4.8.	**Certificate signed by the physician confirming the suitability for PBSC donation of the donor receiving growth factors**	3.22.3 3.22.3.1 3.22.3.2	Policies for testing the donor selected for workup must be established and must include medical history, physical examination, and laboratory tests in order to determine the donor's fitness to donate. This examination must be performed or supervised by a physician who is not the primary treating physician overseeing the care of the patient. Female donors of childbearing potential must have a pregnancy test and be counselled to avoid pregnancy during the workup stage before use of mobilising agents, collection or initiation of the recipient's preparative regimen, whichever occurs first.	● Check the right version has been used, the current requirements are included in the clearance, signatures, etc, date of transmission to TC is recorded. ● Confirm the physician evaluting the donor does not care for the patient. ● Is there evidence of counselling female donors of childbearing age to avoid pregnancy during the workup process?		

No	Donor Center Audit Checklist	Reference to WMDA Standards		Instructions for Auditor	Relevant Documents to Review	Reviewer comments
4.9.	**Pre-donation planning, including the date at which the patient's conditioning starts, and the date at which the donor's final clearance will be sent**	6.06.1	Prior to transplantation, the registry must have a process for communicating the donor's preference to the appropriate transplant centre in a timely fashion to indicate the type of cells and to communicate any other donor-specific issues that may impact the transplantation. Nevertheless, the donor must be free to change their mind at a later date.	● Check how the DC (CC) has communicated availability to meet the preferred collection date including the expected donor work-up schedule, the counseling and medical assessment dates and when donor final clearance will be available. ● Evaluate if the appropriate people are notified in a timely fashion of the cancellation, in the case of a cancellation.		
4.10.	**Information transmitted by the DC to organize the product transportation**	8.0	Collection, processing and transport of haematopoietic progenitor cells	● Ensure the DC clearly communicates expected hour for end of collection, pick up address for the product and collection center contact information. ● Is there evidence of timely and reliable transport of cells to the transplant centre?		
4.11.	**Donor's final clearance**	6.06	The donor centre/cord blood bank must be informed of the proposed date(s) of transplant at the time a specific donor/cord blood unit is requested for transplantation for a specific patient. If a volunteer donor will be the source of HSC, the donor must also be informed. The transplant centre must specify the latest date by which the donor centre must approve the eligibility of a donor for donation of HSC for a specific patient (i.e., provide donor clearance).	● Ensure the correct version is in use, current requirements included in the consent, signatures.		

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4.12.	**Results of the entire biological suitability check up performed before donation**	3.25	Infectious disease markers must be measured within thirty (30) days of the hematopoietic stem cell/cellular product collection and the results must be provided to the transplant centre before commencement of patient conditioning.	● Check dates, signatures of Infectious disease markers, haematological check up, pregnancy tests, PE results. ● Ensure IDMs obtaned wihtin 30 days of collection and results provided to TC before patient conditioning.		
4.13.	**Document specifying the insurance coverage for the donor**	10.09 10.10 10.11	The registry must assume responsibility and establish procedures for all donor medical expenses including the pre-collection physical examination, the collection procedure and all post-collection medical expenses that are directly related to the donation. No donor should assume financial liability for any portion of the follow up testing and/or HPC procurement process. The registry is responsible for all reasonable expenses incurred by the donor. The registry, or its designee, should offer disability and death benefits to donors. The registry should maintain liability insurance.	● Check how the donor is informed regarding extra expenses and insurance. Ensure material is given to the donor with information about insurance.		

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5. Follow-Up						
5.1.	**Example of Follow-up forms after donation (short- and long-term)**	9.019.02	The registry must have policies and procedures for the first year following donation for the follow-up and care of donors immediately following the donation.The registry must have policies and procedures for the long-term follow-up and care of donors for conditions related to the HPC donation, including a mechanism for donors to contact the registry to report related medical concerns for a minimum of ten (10) years after donation.	● Ensure that the registry is following up on the donor for up to 10 years, starting with the first follow-up immediately after the HPC donation. Check for questionnaires, forms, lab results and the documentation of attempts to proceed with the follow-up (in cases where donors don't show up for follow-up appointments, or don't fill the questionnaire).		
5.2.	**SOP for donor follow-up during the first year after donation**	9.01	The registry must have policies and procedures for the first year following donation for the follow-up and care of donors immediately following the donation.	● Check the policies and procedures in place and check for metity with WMDA and registry requirements		
5.3.	**SOP for long term donor follow-up**	9.02	The registry must have policies and procedures for the long-term follow-up and care of donors for conditions related to the HPC donation, including a mechanism for donors to contact the registry to report related medical concerns for a minimum of ten (10) years after donation.	● Check the policies and procedures in place and check for conformity with WMDA and registry requirements		

No	Donor Center Audit Checklist	Reference to WMDA Standards		Instructions for Auditor	Relevant Documents to Review	Reviewer comments
6. SAR/SAE						
6.1.	**Example of documentation and investigation of SAR/SAE and initiation of necessary remedial and/or corrective action**	8.09 8.10.2 9.03	Serious Adverse Events affecting a cellular product intended for a specific patient must be identified, documented, investigated and remedial and/or corrective action taken. The Serious Adverse Events must be submitted to the WMDA S(P)EAR Committee. Serious Adverse Events and Reactions affecting donors undergoing collection of HSC and/or cellular product, occurring both in the long term and/or the short term as a consequence of the donation must be identified, documented, investigated and remedial and/or corrective action taken. The Serious Adverse Events and Reactions must be submitted to the WMDA S(P)EAR Committee. Similar actions must be taken for adverse reactions occurring due to registry operations and impacting the health and safety of donors or patients.	● Ensure that procedures and policies for identification and investigation of reported/observed SARs/SAEs are in place. ● What are the procedures for remedial and/or corrective actions? ● Check how they are put into action (e.g. SOPs, documents/systems for reporting and following up on incidents). ● If available, review documented incidents and how they have been investigated and resolved. This includes medical incidents, as well as those resulting from problems which occurred at the registry or affiliated center.		

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6.2.	**Example of communication of SAR/SAE (if any) to the registry, as well as the TC and other organizations as applicable**	8.10 8.10.1 9.03 9.04	Serious Adverse Reactions impacting the cellular product and hence potentially the patient's health must be identified, documented, investigated and remedial and/or corrective action taken. The Serious Adverse Reactions must be submitted to the WMDA S(P)EAR Committee. Reports of Serious Adverse Reactions affecting the donated cellular product must be communicated to the registry/organisations involved in the transplant if the event might affect the transplantation or subsequent donation. Other individuals or groups should be notified as appropriate. Serious Adverse Events and Reactions affecting donors undergoing collection of HSC and/or cellular product, occurring both in the long term and/or the short term as a consequence of the donation must be identified, documented, investigated and remedial and/or corrective action taken. The Serious Adverse Events and Reactions must be submitted to the WMDA S(P)EAR Committee. The registry must comply with local regulations including requirements to report such adverse reactions to a regulatory agency.	● The center must have a policy for reporting SAE/SAR to the registry in accordance with the WMDA document 20141105-SEAR-S(P)EAR SOP, examples of S(P)EAR cases listed in 20141209-SEAR-INFO S(P)EAR and any applicable guidelines and legislation. ● Review the policy and forms/systems used to report incidents to the registry. If available, review reports submitted to the registry and management of further enquiries from the registry or WMDA, if appropriate. A policy or procedure should address the communication of information, if the patient could be affected. Review communication of such a case if available.		

No	Donor Center Audit Checklist	Reference to WMDA Standards		Instructions for Auditor	Relevant Documents to Review	Reviewer comments
6.3.	**Example of documentation of an SAR and corresponding reports to WMDACovered by two points above**	8.10.1 9.03 9.04 9.05	Serious Adverse Events and Reactions affecting donors undergoingcollection of HSC and/or cellular product, occurring both in the long term and/or the short term as a consequence of the donation must be identified, documented, investigated and remedial and/or corrective action taken. The Serious Adverse Reactions must be submitted to the WMDA S(P)EAR Committee. Reports of Serious Adverse Reactions affecting the donated cellularproduct must be communicated to the registry/organisationsinvolved in the transplant if the event might affect the transplantationor subsequent donation. Other individuals or groups should benotified as appropriate.The registry must comply with local regulations including requirements to report such adverse reactions to a regulatory agency.Donor health issues post-donation potentially affecting the health of a patient having received a HPC donation from that donor must be reported to the transplant center.	● Check how SARs are being submitted (fax, e mail etc) to a WMDA sponsored international database and to the transplant center (if applicable) (SOPs).		

No	Donor Center Audit Checklist	Reference to WMDA Standards		Instructions for Auditor	Relevant Documents to Review	Reviewer comments
7. KPI						
7.1.	**% of blood samples for VT shipped within 14 days**	6.03 6.03.1	Registries must respond to search requests and to requests for additional information and donor/cord blood/maternal samples within a time period consistent with WMDA metrics and in a defined manner. Registries or their associated donor centres/cord blood banks must have the capability of shipping samples, if available, to the facility indicated by the transplant centres if required for further testing. The sample must be appropriate for the testing required.	● The proposed target value for this KPI is 89% (or more). ● If the availability is low, are cancellations not directly related to medical reasons or patient-related reasons reported separately and correlated to donor recruitment or donor retention measures?		
7.2.	**% of donor availability at VT stage**	6.04 6.04.1 6.04.2	Verification typing of: i) the adult donor at a minimum of HLA-A, -B, -C, -DRB1 DNA based typing at high resolution must be performed prior to a hematopoietic stem cell donation for a specific patient; ii) the cord blood unit at a minimum of HLA-A, -B, -DRB1 DNA based typing must be performed prior to shipment for a specific patient in a way that at least one typing result (previous or extended typing) for each locus is at high resolution.	● Review policies and documents related to determination of donor availability. ● Is a policy for monitoring of donor availability in place? ● Is this indicator regularly checked? ● If it is below the target value, what measures have been taken to improve donor availability and retention, if reasons for cancellation could potentially be influenced by the center?		

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7.3.	**% of donor availability at work-up stage? - also included in WMDA Recommendation on KPIs**	6.02.3	A donor/cord blood unit selected for a specific patient must be placed on a "reserved" status from the time of verification typing until the donation/cord blood unit shipment date is reached.	● Review policies and documents related to determination of donor availability at work-up. ● Is a policy for monitoring of donor availability in place? ● Is this indicator regularly checked? ● If it is below the target value, what measures have been taken to improve donor availability and retention for cancellation reasons which could potentially be influenced by the center?		
7.4.	**% of discrepant typing results (technical or clerical error) - also included in WMDA Recommendation on KPIs**	3.17 3.17.1 3.18 3.19	#	● A policy should be available if the DC notes or is notified of a discrepant result. ● Check the policy and related documents/databases for documentation and clarification of discrepancies. ● If the value is higher than the recommended metric (for errors originating at the DC), what measures have been implemented to improve the accuracy of donor HLA typing results?		

No	Donor Center Audit Checklist	Reference to WMDA Standards		Instructions for Auditor	Relevant Documents to Review	Reviewer comments
8. Additional National Topics						