Institute for Quality Management in Healthcare

Centre for Accreditation

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

IQMH Requirement	TM Specific Requirement	Comments/Explanation
I.B.10 There shall be a process in place to evaluate staff skills to perform assigned managerial and/or technical tasks according to established criteria following training. Reassessment shall take place at regular intervals. Retraining shall occur when necessary. Records shall be maintained. Employers who terminate an employee belonging to a regulatory body for professional misconduct shall report the individual to the appropriate body following the rules of any applicable regulated acts.	**TM111** The health care facility and blood transfusion service shall ensure that there is ongoing training for clinical staff involved in the administration of blood components. A formal program to access skills in the administration of blood components shall be developed and maintained in conjunction with all healthcare professionals and staff involved in the administration of blood components. NOTE: assessors will expect to see evidence of a formal program within all departments involved in the administration of blood components.	Applies to dispensary/administration staff who administer blood components.
I.B.11 The laboratory shall provide training for technical and managerial personnel prior to the performance of duties without direct supervision. Records shall be maintained.	N/A	Applies to dispensary/administration staff who manage the transfusion program.
I.B.12 The laboratory shall have a policy for continuing education for personnel who participate in managerial and technical processes. The effectiveness of the policy shall be periodically reviewed.	N/A	Applies to the dispensary/administration policies.
I.C.12 Laboratory management shall be responsible for or participate in emergency and disaster planning.	**TM188** The emergency and disaster plans shall address the safety, quality, efficacy and level of supply of blood components/products during an emergency or disaster and shall include a process for the management of blood shortages. To ensure proper storage in emergency situations, written procedures that contain directions on how to maintain blood components within permissible temperature ranges during a power failure or other disruption of refrigeration shall be readily available. *In Canada, shortage plans should be based on the National Plan for the Management of Shortages of Labile Blood Components and provincial plans.*	Dispensary sites require a plan and procedures for alternate storage of blood components and products. Administration sites should ensure their emergency plan includes provision for the movement or transportation of any blood components or products recently received.

Institute for Quality Management in Healthcare

Centre for Accreditation

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

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II.D.1 Laboratory management shall ensure that the laboratory participates in quality improvement activities. Some of these activities shall include relevant areas and outcomes of patient care.	**TM182** There shall be a transfusion medicine committee with documented terms of reference. It shall meet at least quarterly and document its activities.	Provide evidence of QI activities (e.g. TAT, specimen rejection rates, audits). Are the transfusion committee minutes and communication shared with the disp/admin sites?
II.F.12 All records shall be stored so that they are readily retrievable, secure and can be accessed by only authorized personnel.	**TM183** Procedures for copying transfusion records for storage shall include documentation of records copied, an audit process to ensure that copies are legible, accurate, and complete, retention of original records until all verifications are complete, accessibility of all copied records, a contractual agreement for copying records off-site detailing the requirements for validation, transport, storage, and where necessary, destruction of the original documents.	Requirements for record storage, retrieval and copying.
II.H.1 Where a laboratory enters into an agreement to provide medical laboratory services, it shall ensure that: a) requirements including the methods to be used are adequately defined, documented and understood b) the laboratory has the capability and resources to meet the requirement c)appropriate methods selected are able to meet the requirements of the agreement and clinical needs d) reference is made to any work referred by the laboratory to another laboratory or consultant There shall be a documented procedure for this activity. Records of review shall be maintained.	**TM193** Where the laboratory enters into an agreement to provide transfusion services or blood components/products for another laboratory, both facilities shall meet applicable standards and regulations. The laboratory shall have policies and procedures for blood products it supplies to another facility including a) definition of its responsibilities and the receiving facility's responsibilities with respect to the product b) provisions of instructions for storage and preparation c) reporting and follow up for errors and other adverse events d) return and disposition of unused product e) traceability f) processes for notification of product recall/lookback *For example, in Ontario, this applies when a licensed laboratory enters into an agreement with a dispensary/ administration facility that is not accredited under the IQMH program.*	The licensed transfusion service must have an agreement with dispensary and administration sites when blood components and/or products are provided. All types of facilities must meet the corresponding IQMH requirements. The Memorandum of Understanding template found in ORBCoN's toolkit can be used as a model for the agreement.
III.12 Laboratory storage space and conditions, whether within the facility or off site, shall be adequate to ensure the integrity of samples, supplies, records and results.	**TM006** The laboratory shall ensure that refrigerators for blood components/product storage shall be equipped with an air-circulating fan or ensure that refrigerators have the capability to maintain a suitable temperature throughout the cabinet.	These requirements apply to both on and off site storage. The environment shall be suitable to prevent damage, deterioration, loss and unauthorized storage.

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

IQMH Requirement	TM Specific Requirement	Comments/Explanation
III.12, continued	**TM007** The laboratory shall ensure that freezers for storage of plasma components/products are maintained at -18 degrees Celsius or colder, and that red cells are maintained at a temperature appropriate to the cryoprotectant for red cells **TM008** Equipment for storage of platelets shall maintain a temperature of 20-24 degrees Celsius and ensure constant gentle agitation of the component as per the supplier's recommendations	Administrative sites will not store blood components/products but will store specimens.
III.12.1 Sufficient and appropriate refrigerators and freezers shall be available for the storage of plasma/serum samples and reagents.	**TM112** Blood components/products shall be stored separately from all other substances including blood specimens, tissues for transplantation and reagents. This may involve the use of clearly identified segregated areas within the same storage equipment. Note: if using one refrigerator for blood components/product and specimens (segregated), the laboratory must ensure that a temperature of 2-6 degrees Celsius is maintained as per manufacturer's instructions to ensure the integrity of both blood products and samples. **TM113** Blood components/products that do not meet the necessary criteria for release shall be stored in a secure, quarantined location. There shall be a process for release from quarantine including a person assigned responsibility for the release from quarantine.	Requirements for storage of components/products in the same storage unit as specimens. Quarantine requirements for components/products.
IV.2 The inventory control system shall include the inspection, acceptance/rejection and storage of consumable materials, and records of action taken following rejection shall be maintained.	**TM016** Blood components/products shall be visually inspected upon receipt in the laboratory for leakage, discolouration, abnormalities such as clots or hemolysis, and that the blood component/product is properly labelled. Shipping boxes shall be inspected prior to opening for evidence of abnormal appearance or evidence of tampering. This shall be documented.	Inspection requirements for components/ products and shipping containers.

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

IQMH Requirement	TM Specific Requirement	Comments/Explanation
IV.2 Continued	**TM070** A procedure shall be established for the return of blood components/products into useable inventory. The laboratory shall ensure that: a) all closures are intact b) for red cells, there is at least one remining sealed segment of integral donor tubing attached to the blood bag or available to the transfusing site. Previously removed segments may be used after confirming that the tubing identification numbers on both the removed segment(s) and the blood bag are identical c) temperatures have not exceeded acceptable limits as defined by the laboratory or in the absence of a temperature monitoring system, that the blood component has not been outside of a controlled environment for more that 60 minutes (measured per occurrence not cumulatively. Mechanisms may include: a) the use of temperature indicator stickers on all red cells, b) a complete physical check of temperature on returned units using calibrated equipment c) the implementation of strict guidelines for the control of component/product temperature outside the laboratory coupled with periodic audits of compliance d) the use of validated transport containers that are capable of maintaining the appropriate temperature, coupled with periodic audits.	Acceptance criteria for components/products returned that were not transfused.
IV.9 Each piece of equipment, including computer network devices shall be labelled with a unique ID.	N/A	All laboratory/transfusion related equipment requires a unique identification.
IV.9.1 Each piece of equipment shall be labelled or otherwise coded to indicate status of calibration or a log shall be kept. These records shall be maintained at a minimum for the lifespan of the equipment.	N/A	Calibration requirements for all transfusion related equipment such as: storage devices, infusion pumps and warmers.

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

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IV.12 There shall be records of each item of equipment that include: a) the condition of equipment when received (new, used, reconditioned) b) the manufacturer's name c) serial numbers and/or other unique identifiers d) the date when equipment is received and put into service e) equipment location, where appropriate. These shall be readily available at minimum for the life span of the equipment	N/A	Equipment record requirements for IV.9.1
IV.12.5 Manufacturer's instructions shall be retained.	N/A	Manufacturer's equipment instructions must be available.
IV.12.10 There shall be records of malfunction and trouble-shooting.	N/A	All episodes of malfunction and trouble-shooting are documented and maintained.
IV.12.11 There shall be records of service reports, repairs or modification of equipment.	N/A	Service reports should include the name of the contractor and any specification deviations.
IV.13 The electrical supply to equipment and computers shall be protected from fluctuations and interruptions in electrical current where required.	**TM190** To ensure proper storage in emergency situations, written procedures that contain directions on how to maintain blood components within permissible temperature ranges during a power failure or other disruption of refrigeration shall be readily available.	Electrical supply protection evidence includes grounding, voltmeters and UPSs. For transfusion purposes, there must be written procedures pertaining to emergency storage of components/products.
IV.14 Up-to-date instructions on the use and maintenance of equipment shall be readily available. Maintenance of laboratory equipment shall ensure proper performance and assure accurate and reliable test performance. There shall be records of maintenance.	**TM108** The laboratory shall ensure that the following equipment follows appropriate standards: plasma thawers, blood warmers, irradiators, sealers, temperature controlled centrifuges, equipment for platelet storage, rapid infusion devices, water baths and other heating devices. T**M138** All equipment used to warm blood components shall include a temperature sensing device and an audible alarm system. Blood warmers shall be verified and shall meet applicable national safety standards.	These items would pertain to blood warmers only (if the facility has them), as dispensary/administration facilities would not have any of the other devices described.
IV.15 Temperature dependent equipment shall be equipped with thermometers and the temperature shall be read and documented at the beginning of each testing day, or more frequently as required.	**TM001** The temperature of refrigerators, freezers, incubators, and open areas for the storage of blood components/products shall either: a) be continuously monitored using a validated continuous monitoring system	Retain temperature charts and the corresponding corrective action reports, if component/products are stored on site.

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

IQMH Requirement	TM Specific Requirement	Comments/Explanation
IV.15 Continued	**TM001** continued or b) be manually checked and recorded every 4 hours if an automated system is not available. **TM002** Refrigerators and freezers, when in use for storage of blood components and blood products, shall have an audible temperature alarm with a back-up power supply. The alarm and back-up power supply for the alarm shall be checked at least monthly, and the check shall be documented. The alarm warning shall signal in a location that is continuously monitored or staffed so immediate corrective action can be taken.	Alarm requirements.
V.A.1.1 There shall be collection instructions for blood specimens and all other types of specimens.	N/A	Specimen collection manual available for staff including transportation requirements.
V.A.1.10 There shall be detailed instructions for the positive identification of the patient from whom a specimen is collected and for handling patients with communication challenges.	N/A	Applies to both dispensary and administration sites.
V.A.1.11 There shall be instructions for recording the identity of the person collecting the specimen.	**TM013** The identity (name, initials or computer code) of the phlebotomist drawing a pre-transfusion specimen, and the date and time of collection shall be recorded. The information must be retrievable for one year.	Ensure the phlebotomist record is traceable for at least 1 year.
V.A.3 The identity of the patient shall be confirmed prior to collection. Patient identity shall be verified using at minimum, two identifiers.	N/A	Applies to both dispensary and administration sites.
V.B.1 Specimens and blood components/products shall be transported safely both within the facility and externally. There shall be documented instructions.	**TM019** Blood components/products shall be visually inspected before shipment and this shall be documented. **TM021** There shall be policies, processes and procedures document for the transportation of blood components/ products outside the facility and within the facility, including automated tube systems. These shall specify who may receive and transport blood components/products, and acceptable transit times.	Shipping instructions. Containers must be validated. Receiving sites must know the requirements for shipping, inspection and labelling.

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

IQMH Requirement	TM Specific Requirement	Comments/Explanation
V.B.1 Continued	**TM021** continued They shall ensure that all blood components/products are stored and transported at optimal temperatures and conditions. They shall include instructions for power failures or other disruptions, maximum time for completion of transfusion, acceptable off-site processing storage. Packaging for transport outside the facility shall be of sturdy construction and have a tamper-proof seal. **TM118** The release voucher to another facility shall accompany each shipment of blood components/products and contain the following information: a) the name of the site receiving blood components/products b) the unique serial number of the voucher c) a description of the type of blood components/products being shipped, including notice if quarantined blood components/products have been included d) the donation numbers of the blood components e) the total number of items f) the date and time of shipping g) the signature(s) of the designated person(s) responsible for the packing **TM119** The issuing facility shall be responsible for notifying the receiving transfusion service when a blood component/product accompanies a patient **TM176** The package shipping label of blood components/products for external transport shall be labelled with the following information: a) that the contents are not for transfusion if an unusable blood component/product is being shipped for investigation or disposal b) the site of origin c) the destination d) a notice that it contains human blood components/product, and e) any cautions or descriptions required under provincial or federal transport regulations	

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

IQMH Requirement	TM Specific Requirement	Comments/Explanation
V.C.1.2 Specimens shall be accessioned. The date and time of specimen receipt as well as the identity of the receiver shall be recorded in an accession book, worksheet, computer or other comparable record. Instructions shall be provided in the form of a documented process and/or procedure(s).	N/A	The dispensary/administration sites must be able to track the specimen to determine if it is a current sample for transfusion purposes.
V.C.2.2 Specimens shall be uniquely labelled and accompanied by a requisition (electronic or paper) to which they are traceable. Accessioning shall ensure the unique identifier is retained on all aliquots, portions or slides.	N/A	A requisition must be provided with each specimen.
V.C.2.3 Each specimen shall be labelled at the time and point of collection with a firmly attached label containing: (a) the patient's full name (or unique code number in the case of anonymous testing) and b) one other unique identifier such as the admission/identification or accession number and c) the date of collection and d) the time of collection (for time-sensitive examinations only). For microsamples where the specimen tube is too small for the above information, an appropriate labelling system may be defined by the laboratory.	N/A	Labelling requirements for specimens.
V.C.2.4 Specimens lacking proper identification shall not be processed, except if the specimen would be difficult or impossible to recollect, or irretrievable.	N/A	Mislabelled specimens will not be accepted by the testing laboratory.

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

IQMH Requirement	TM Specific Requirement	Comments/Explanation
V.C.2.5 If a specimen lacking proper identification is accepted because it would be difficult or impossible to recollect, or irretrievable, it shall be identified by the requesting health care provider or person responsible for specimen collection. The signature of the requesting health care provider/responsible person shall be recorded on, or traceable to the requisition.	N/A	Facility needs to be aware of IQMH explanation: *For transfusion medicine testing, any specimen lacking proper identification shall not be accepted and redraw of sample is required.*
V.C.2.6 If compromised, irretrievable specimens are accepted for processing, the final report shall indicate the problem, and if applicable, that caution is required in interpreting the result(s).	N/A	Awareness that the irretrievable specimen requirements do not apply to transfusion as the specimen will NOT be accepted.
V.C.2.8 A record of all rejected specimens shall be maintained.	N/A	Ability to trace rejected specimens required.
V.C.4 Specimens shall be stored for a specified time at conditions that ensure stability of specimen properties to enable repetition of the examination after reporting of the result or for additional examinations.		Defined conditions and length of storage for specimens.
V.D.1.1 Requisitions shall include: a) sufficient information to identify the patient (first and last name, date of birth, gender and patient health card number and/or unique patient identification number) b) the patient location (e.g., hospital room number or specimen collection centre) c) the authorized requester's name or other unique identifier, together with the destination for the report (d) the type of specimen and the anatomic site of origin, where appropriate e) clinical or additional information, when the nature of the laboratory examination requires it.	**TM179** Requisitions for blood components/products shall specify the item being requested and the quantity/volume/dosage as appropriate.	Transfusion requisition requirements.

Institute for Quality Management in Healthcare

Centre for Accreditation

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

IQMH Requirement	TM Specific Requirement	Comments/Explanation
VI.1 The laboratory shall use methods for examinations that are cited in current published peer-reviewed literature, are recommended by current international, national, or regional guidelines, or are specified in the instructions for use of in vitro medical devices. If in-house developed procedures are used, they shall be validated for their intended use and fully documented.	**TM042** When performing a crossmatch, the ABO group of the recipient must be tested on a current sample. There shall be a second check of the ABO group either by retesting of a second current sample, comparison with previous records or retesting of the same sample (only if positive patient ID technology is used at the time of specimen collection).....when this is not possible, the patient shall receive group O red blood cells. **TM055** In emergency situations where the ABO group and Rh of the recipient is unknown, the patient shall receive group O red blood cells. The use of Rh negative red blood cells is preferable for female children and women of child-bearing age. Emergency pre-transfusion testing shall be completed as soon as possible. **TM056** In emergency situations where pre-transfusion compatibility testing has not been performed the following shall apply: a) the component label and/or issue form shall indicate this b) the requesting physician or authorized personnel shall sign a declaration that the clinical situation warranted the release and c) if possible, the requesting physician shall obtain informed consent from the recipient. Compatibility tests shall be completed promptly. If red cell units issued as emergency are subsequently found to be incompatible, the attending physician shall be immediately informed and transfusion shall be stopped. Note: Facility directives may allow alternate authorization. Units tested by immediate spin crossmatch only must not be labelled as "crossmatched" in this situation. Assessors will look for a policy that the physician is notified of increased risk of uncrossmatched blood when the patient has an antibody.	Facilities may be asked to draw a second, independent sample for ABO confirmation OR the patient will receive only group O red cells until the ABO group can be confirmed. Requirements for those facilities that transfuse under emergency situations.

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

IQMH Requirement	TM Specific Requirement	Comments/Explanation
VI.1 Continued	**TM060** Policies, processes and procedures shall be established by the transfusion laboratory to ensure all candidates for Rh-immune globulin are identified. Obstetrical patients shall have their Rh group determined, and if Rh-negative and unsensitized to the D antigen, they receive the recommended required dose of Rh-immune globulin to cover the estimated bleed at: a) 28 weeks gestation b) within 72 hours of: abortion/ miscarriage, bleeding during pregnancy, obstetrical trauma or manipulation with the potential for causing increased risk of fetal maternal hemorrhage, following delivery of an Rh positive infant. Note 1: If the fetus or neonate is confirmed Rh negative, or the mother has clinically significant anti-D antibody not related to Rh immune globulin prophylaxis; RhIG is not needed Note 2: If 72 hours have passed after the event, the RhIG is clinically indicated to be given up to 28 days. **TM061** If an Rh negative woman delivers an Rh positive infant of fetus (including weak D positive), or if the fetus is of unknown Rh type, the maternal blood shall be tested for fetal-maternal hemorrhage and the volume of hemorrhage shall be quantitated to ensure that the standard dose of RhIG is appropriate and will provide effective prophylaxis. **TM064** Procedures shall ensure that there is unequivocal identification of both the recipient and the blood component/product at the time of issue and prior to transfusion	Guidance for use of Rh immune globulin and identification requirements of the recipient of components/products.

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

IQMH Requirement	TM Specific Requirement	Comments/Explanation
VI.1 Continued	**TM065** Blood and blood components/products shall be labelled with: a) the recipient's first and last name and identification number b) the donor unit identification number (pooled unit number if applicable) c) the donor and recipient ABO and Rh group if applicable d) the interpretation of compatibility tests if required e) the date and time of issue **TM066** The laboratory's records shall ensure that blood components/products can be traced from the collecting facility to final disposition. **TM068** There shall be a record of each blood component/product transfused that includes: a) the recipient's first and last name b) the recipient's identification number c) the recipient's ABO and Rh group d) donor ABO and Rh group e) the interpretation of compatibility tests f) donor unit identification number (pooled unit number if applicable) g) date and time of issue h) date and time of transfusion i) the identity of the individual who administered the blood component/product j) any adverse reactions to the component/product transfused. **TM069** All components/products shall be visually inspected for acceptable appearance immediately before issue or re-issue. This shall be documented. Blood components/ products shall not be released from inventory if visual leakage or abnormalities are noted. **TM074** The process for the transfusion of blood components/products shall ensure positive identification of the recipient, and the association of the blood component/product with the recipient verified in the physical presence of the recipient, including documentation of those performing this check.	Label and record requirements for the component/product. Visual inspection requirements. Requirements for the identification of the recipient and documentation of those performing this task.

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

IQMH Requirement	TM Specific Requirement	Comments/Explanation
VI.1 Continued	**TM074** Continued If any discrepancy is found in the identifying information, the transfusion shall not be administered until the discrepancy is satisfactorily resolved. All identifying information attached to the blood bag shall remain attached at least until completion of the transfusion. **TM076** Red cells shall be transfused within 4 hour of removing the unit from controlled temperature. **TM077** Pretransfusion and post-transfusion vital signs shall be recorded and the recipient shall be observed for adverse reactions. **TM078** Blood bags and tubing shall be returned to the laboratory for investigation in cases of suspected or known hemolytic transfusion reaction, bacterial sepsis and other clinically significant adverse reactions which occur at the time of the transfusion. **TM080** The blood transfusion record, or a copy, shall be retained in the recipient's permanent medical record. **TM094** An error reporting system shall be established and shall ensure that all errors and accidents are reviewed and significant errors and accidents are investigated and documented. Documentation of corrective action taken and an evaluation of the effectiveness of corrective action shall be included in the error management system. **TM096** A list of signs and symptoms of suspected transfusion reactions shall be included in the nursing and transfusion medicine manuals. **TM097** All significant transfusion reactions shall be reported to the blood supplier and to the appropriate authorities as specified by provincial, territorial, or federal regulations including the results of investigations. The investigation shall determine the probable cause and shall include the appropriate laboratory tests. Reportable reactions include,	Red cell transfusion time limitations. Vital sign requirements. Transfusion record requirements. Guidance for transfusion reactions and error reporting.

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

IQMH Requirement	TM Specific Requirement	Comments/Explanation
VI.1 Continued	**TM097** Continued but are not limited to, hemolytic reactions (acute or delayed), anaphylactic shock, graft-vs-host, bacterial sepsis, TRALI, and other reactions with the potential for permanent disablement or loss of life. Investigation of the implicated blood and blood components for suspected bacterial contamination shall include preparation of a gram stain and cultures of the component contents, not segments. **TM098** The transfusion reaction investigation report shall be retained in both the patient's medical chart and in the transfusion laboratory. **TM100** Cases of suspected transfusion-transmitted disease shall be reported to the blood supplier and a lookback procedure shall be carried out. A record of implicated blood components/products shall be sent to the blood supplier. **TM120** Each blood sample for compatibility testing shall be collected within 96 h prior to the scheduled transfusion if the recipient: a) has been transfused with a blood component containing red cells within the previous three months b) has been pregnant within the previous three months c) the transfusion history is questionable or unavailable **TM170** Policies, processes and procedures shall be documented for the recall of any released blood components/products upon notification of any information that brings into question the safety or efficacy of the blood component/product. Procedures for recall shall: a) include the identity of the individual responsible for recall activities b) allow the initiation of the recall procedure at any time; c) describe the notification of recipients	Guidance for suitability of specimens for transfusion and expiry. Recall processes for components/products.

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

IQMH Requirement	TM Specific Requirement	Comments/Explanation
VI.1 Continued	**TM170** Continued d) ensure that recalled blood components/products are quarantined until final disposition is determined **TM172** The transfusion service shall acknowledge receipt of retrieval notification. **TM186** There shall be policies, processes and procedures for managing Rh-negative recipients who receive blood components containing Rh-positive red cells.	Management of Rh negative individuals who receive Rh positive components.
VI.3 All laboratory technical procedures, including manufacturer's instructions used as procedures and electronic instructions, shall be documented and available at the workstation for relevant staff. Technical procedures shall include the following, where appropriate. a) the principle and/or purpose of the examination b) applicable performance specifications (e.g. analytic accuracy, precision, uncertainty of measurement, reproducibility, analytic sensitivity, specificity, detection limit, reportable range,linearity) c) specimen type (including specimen container and additives) and patient preparation d) required equipment and reagents or examination system e) calibration procedures f) step-by-step directions g) quality control procedures h) interferences and cross-reactions i) instructions for calculating results, including, where relevant the measurement uncertainty j) reference intervals k) critical values l) laboratory interpretation of results m) safety precautions n) potential sources of variability o) references.	**TM054** Policies, processes and procedures for emergency transfusions shall be established that comply with established standards. **TM059** Policies, processes and procedures for the storage, selection and administration of blood components/products shall be established that comply with established standards. This shall include the storage conditions, indications and administration of the following blood components: a) red cells b) cryoprecipitate c) platelets d) plasma products e) plasma derivatives and related products f) granulocytes (if applicable) **TM062** Policies and procedures for blood components/products shall include, where applicable, a process to identify patients requiring irradiated blood or blood components/products, the indications for irradiated blood components and the permitted storage periods. There shall be an established process to ensure that all future cellular blood components/products for that recipient are irradiated, as long as clinically indicated. Irradiated blood components/products may be released for patients not requiring irradiated blood components/products.	Policy, process and procedure requirements for emergency transfusion, storage, selection, issuing and administration of components/products, irradiated and CMV-blood components.

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

IQMH Requirement	TM Specific Requirement	Comments/Explanation
VI.3 Continued	**TM063** Policies and procedures for blood components shall include, where applicable, a process to identify patients requiring anti-CMV (cytomegalovirus) negative products and the indications for the administration of anti-CMV negative blood components. **TM067** Policies and procedures for the issue of blood components/products for transfusion shall include the issuing of: a) red cells b) cryoprecipitate c) platelets d) plasma products e) plasma derivatives and related products f) granulocytes (if applicable). **TM081** Procedures for the administration of blood components/products shall include a mechanism for the informed consent for recipients. **TM082** Processes for the administration of blood components/products shall include notification of the transfusion for inpatients. **TM095** The laboratory shall have written policies, processes and procedures for the documentation, reporting, evaluation, and follow-up of transfusion complications that comply with established standards. **TM099** The laboratory shall document policies, processes and procedures for inventory retrieval, post-donation information, lookback and traceback based on communication from the blood supplier, public health agencies and other government agencies. **TM130** There shall be a mechanism in place to ensure that current information concerning the risks associated with transfusion is communicated to all personnel associated with patient care in the facility.	Policy, process and procedures for adverse transfusion events, informed consent, retrievals, staff communication about transfusion risks.

Transfusion Dispensary and Administration Sites – Relevant IQMH Accreditation (April 2017 v 7.1) Requirements

IQMH Requirement	TM Specific Requirement	Comments/Explanation
VI.3 Continued	**TM131** The hospital and transfusion service shall ensure there are operating procedures for the operation of infusion devices and associated equipment; all infusion devices and ancillary equipment in Canada shall be approved by Health Canada. **TM132** The hospital and transfusion service shall ensure that there are procedures in place for the administration of blood components/products including: a) rate of infusion prescribed by physician b) requirements for transfusion sets and filters and how often to change c) compatible solutions and allowable additives.	Requirements for infusion devices and administration sets for the administration of components/products.
VI.9 Current examination methods and performance specifications shall be available to users of laboratory services upon request. Significant changes in methods (producing results or interpretations that may be significantly different) must be explained to users of laboratory services in writing prior to the introduction of the change (e.g. via direct mailing, newsletter or as part of the test report itself).	**TM015** The laboratory shall ensure that manuals of other departments relating to transfusion medicine are consistent with the policies, processes and procedures of the transfusion laboratory.	Requirement to ensure laboratory procedures harmonize with other departments and notification of changes.
VI.10 Laboratory staff shall be available to provide the users of laboratory services with advice on choice of examinations and use of services where appropriate. Interpretation of the results of examinations shall be provided where appropriate.		Requirements for laboratory staff to be available for, and to provide, advice.