DIAGNOSTIC ACCREDITATION PROGRAM

Accreditation Standards

Laboratory Medicine

Accreditation Standards Revision Record

Effective February 1, 2019

GLOSSARY

Standard or Criterion Number	2015 Version 1.3	Version 1.4 Revision
special cause testing		**New** Is performed in response to an alert from a monitoring procedure or a triggering event such as: failure of a frequent or periodic monitor; proficiency testing/external quality assessment failure; shift in a statistical monitoring parameter; quality control result; reagent or calibrator lot change.

ORGANIZATION

Standard or Criterion Number	2015 Version 1.3	Version 1.4 Revision
ORG1.1.7	The laboratory uses a risk management framework to proactively and reactively identify and manage significant risks to quality and safety. *Guidance: The risk management framework includes the scope, objectives and criteria for assessing risk, the identification of risk management responsibilities and functions, training, plans to address significant risks and the communication of risk plans to stakeholders.*	**Revised** The laboratory uses a risk management framework to identify and manage significant risks to quality and safety. *Guidance: The risk management framework includes the scope, objectives and criteria for assessing risk, the identification of risk management responsibilities and functions, training, plans to address significant risks and the communication of risk plans to stakeholders.*

Standard or Criterion Number		2015 Version 1.3	Version 1.4 Revision
ORG2.1.18	**M**	• equipment and supplies	**Revised** Reference # edit ISO 15189 4.1.2.5
ORG2.1.19		• technical operations	**Revised** Reference # edit ISO 15189 4.1.2.5
ORG2.2.10	**M**	Laboratory directors relate and function effectively with accrediting and regulatory agencies, administrative officials, the health-care community and the patient population served, and providers of formal agreements, when required. *Guidance: Laboratory directors ensure access for the DAP to the laboratory for the assessment of records, manuals and equipment, including the availability of personnel for interviews, and to any other data and information that may be required for the assessment of the operation and the quality of work produced by the laboratory.*	**Revised** Laboratory directors relate and function effectively with accrediting and regulatory agencies, administrative officials, the health-care community and the patient population served, and providers of formal agreements, when required. *Guidance: Laboratory directors ensure access for the DAP to the laboratory for assessment purposes without obstruction or hindrance. This includes access to records, manuals and equipment, personnel for interviews, and to any other data and information that may be required for the assessment of the operation and the quality of work produced by the laboratory.*
ORG3.1.16	**M**	The medical director or other authorized personnel reviews the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received (e.g. discontinuing outdated examinations) at a defined interval.	**Revised** Reference # edit ISO 15189 4.1.2.3
ORG3.2.2	**M**	Medical directors visit remotely supervised sites when medical leadership responsibility commences, and once per year thereafter. *Guidance: The annual visit may be undertaken by another pathologist, or a technical delegate deemed qualified by the medical director.*	**Revised** Medical directors visit remotely supervised sites when medical leadership responsibility commences, and at a defined interval thereafter. *Guidance: The visit may be undertaken by another pathologist, or a technical delegate deemed qualified by the medical director. The complexity of services provided by the site may warrant more frequent visits.*
ORG3.2.3	**M**	The medical director assesses the complexity of services provided and undertakes more frequent visits, if warranted.	**Deleted** Moved to ORG3.2.2 Guidance

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ORG3.2.4	**M**	A log is kept to record the visit of the medical director or delegate to the laboratory, recommendations for improvement or required follow-up are recorded in the log, and the log is signed by the person conducting the visit.	**Revised** A record of the medical director or delegate's visit to the laboratory is kept, either manually or electronically, which documents any recommendations for improvement or required follow-up. Status of completion of action items is also documented. If the visit is conducted by a delegate, evidence of medical director review is required.
ORG4.3.2	**M**	Job descriptions are reviewed at a defined frequency to ensure they reflect current practice and changing performance requirements, duties or qualifications.	**Revised** Mandatory
ORG4.5.1	**M**	Continuing education is encouraged, supported and made available for management and technical personnel.	**Revised** Continuing education is encouraged, supported and made available for laboratory personnel.
ORG4.6.8		• identifying, reporting and disclosing information regarding nonconformities	**Revised** • identification, reporting, disclosure of information, prevention and containment of nonconformities
ORG4.6.9	**M**	• the prevention and containment of the effects of nonconformities—this training is documented	**Deleted** Captured under safety – adverse incidents
ORG4.6.12	**M**	• roles and responsibilities of the individual and key personnel	**Deleted** Captured under 4.3.3
ORG4.6.13		• patient rights	**Revised** • patient rights (e.g. privacy, dignity, respect, personal safety and security, the right to refuse laboratory services) and consent
ORG4.6.14		• the mission, vision, and values of the organization	**Deleted** See ORG1.1.6
ORG4.8.1	**M**	There is a documented process to assess the competence of all personnel to perform assigned tasks after training.	**Deleted** See ORG4.84, ORG4.85
ORG4.8.2	**M**	Reassessment occurs annually and when the need to reassess is identified.	**Revised** Reassessment occurs at defined intervals and when the need to reassess is identified.

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ORG4.8.7	**M**	The education, experience and qualifications of individuals performing competency assessment are defined	**Revised** The education, experience and qualifications of individuals performing competency assessment are defined.
ORG4.8.8	**M**	Competency assessment uses a combination of approaches under the same conditions as the general working environment (e.g. direct observation, monitoring, recording and reporting of results, review of work records).	**Revised** Competency assessment uses defined materials and a combination of approaches under the same conditions as the general working environment (e.g. direct observation, monitoring, recording and reporting of results, review of work records).

QUALITY MANAGEMENT SYSTEMS

Standard or Criterion Number		2015 Version 1.3	Version 1.4 Revision
QMS1.1.2	**M**	The quality policy includes a commitment to good professional practice, examinations that are fit for intended use and continual improvement of the quality of laboratory services.	**Revised** Reference # edit ISO 15189 4.1.2.3b
QMS1.1.3	**M**	The quality policy provides a framework for establishing and reviewing quality objectives.	**Revised** Reference # edit ISO 15189 4.1.2.3c
QMS1.1.4	**M**	The quality policy is communicated and understood within the laboratory.	**Revised** Reference # edit ISO 15189 4.1.2.3d
QMS1.1.5	**M**	The quality policy is reviewed for continuing suitability and revised as required.	**Revised** Reference # edit ISO 15189 4.1.2.3e

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QMS3.1.3	**M**		**New** Arrangements with out-of-province referral laboratories and consultants are reviewed and evaluated within a defined time frame. A record of the review is retained. *Guidance: This standard does not apply to laboratories within BC as it is the DAP responsibility to award accreditation only to those laboratories that meet the standards.*
QMS4.2.2	**M**	Clinicians, patients, or other parties are informed of the process to register complaints and feedback.	**Revised** Mandatory
QMS5.2.4	**M**	When reviews by external organizations indicate the laboratory has potential nonconformities, the laboratory takes preventive action to ensure continuing compliance with the requirements of ISO 15189.	**Deleted** Duplicate of 5.1.9

SAFETY

Standard or Criterion Number		2015 Version 1.3	Version 1.4 Revision
SAF1.1.4	**M**	The safety program includes reviewing health and safety activities and incident trends.	**Revised** The safety program includes reviewing health and safety activities and incident trends as well as identifying and implementing courses of action to resolve concerns. Merged with SAF1.1.5
SAF1.1.5	**M**	The safety program includes identifying and implementing courses of action to resolve health and safety concerns.	**Deleted** Merged with SAF1.1.4
SAF1.2.8	**M**	Personnel review the safety procedures when there are changes relevant to their scope of practice at a defined frequency.	**Revised** Personnel review the safety procedures at a defined frequency and when there are changes relevant to their scope of practice.
SAF2.1.2	**M**	Safety inspections assess firefighting equipment and alarms. Alarm systems are tested at a defined frequency.	**Revised** Reference number edits only. ISO 15190 7.3.2, 19.3, 19.7

Standard or Criterion Number		2015 Version 1.3	Version 1.4 Revision
SAF3.2.8	**M**	Gloves are worn during routine collection of blood samples, and when there is the potential for exposure to blood or body fluids.	**Revised** Gloves are worn during routine collection of blood samples and are changed between patients. Merged with 3.2.9
SAF3.2.9	**M**	Gloves are changed between patients.	**Deleted** Merged with SAF3.2.8
SAF3.2.10	**M**	Gloves are removed prior to handling non-contaminated items.	**Revised** Gloves are worn when there is the potential for exposure to blood or body fluids and removed prior to handling non-contaminated items.
SAF3.3.3	**M**	Additional precautions (e.g. expedited procedures, separate waiting area, protective masks) are implemented when patients have a known or suspected communicable disease.	**Deleted** Duplicate of SAF3.3.2
SAF3.3.4	**M**	Appropriate respirators are available when required (e.g. spill control).	**Revised** Appropriate respiratory protection (e.g. masks, respirators) is available when required (e.g. spill control).
SAF3.4.1	**M**	The laboratory ensures that personnel and visitors (e.g. vendors, service personnel) wash their hands prior to leaving the laboratory.	**Revised** Personnel and visitors (e.g. vendors, service personnel) wash their hands prior to leaving the laboratory.
SAF3.4.2	**M**	The laboratory ensures that personnel wash their hands prior to and after contact with each patient.	**Revised** Personnel wash their hands prior to and after contact with each patient and after removing gloves.
SAF3.4.3	**M**	The laboratory ensures that personnel wash their hands after contact or potential contact with blood, body fluids, or other contaminated material.	**Revised** Personnel wash their hands after contact or potential contact with blood, body fluids or other contaminated material.
SAF3.4.4	**M**	The laboratory ensures that personnel wash their hands immediately.	**Deleted** Duplicate of SAF3.4.1

Standard or Criterion Number		2015 Version 1.3	Version 1.4 Revision
SAF3.5.1	**M**	First aid services and resources available onsite are in compliance with British Columbia Occupational Health and Safety Regulations. *Guidance: Detailed tables specifying the first aid requirements are found in the Occupational Health and Safety Regulation at the end of Part 3 (Schedule 3.A, Minimum Levels of First Aid). It must be noted that medical facilities are NOT exempt from these requirements. Medical facilities may have personnel take the appropriate occupational first aid course but some leeway is provided to allow for existing qualification to be considered equivalent.*	**Revised** Consolidated supplies for first aid are in a defined location in the laboratory. First aid services are available on site. *Guidance: An emergency department typically has resources equivalent to a first aid room and a first aid kit. First aid attendants are still required to address non-ambulatory injuries.*
SAF3.5.2	**M**	First aid attendants have access to material safety data sheet (MSDS) information for controlled substances used within the facility.	**Revised** First aid attendants have access to safety data sheet (SDS) information for controlled substances used within the facility.
SAF3.7.7	**M**	Laboratory surfaces (e.g. bench tops, chairs) are chemical resistant, impermeable, durable and readily cleanable.	**Revised** Mandatory
SAF3.8.1	**M**	Primary exit routes are designated and secondary exits (where applicable) are provided.	**Revised** Primary exit route is designated and secondary exits (where applicable) are provided. Emergency exits are well marked and provide unimpeded exit. Merged with 3.82 Reference numbers edit: ISO 15190 19.1, 19.2
SAF3.8.2	**M**	Emergency exits are well marked and provide unimpeded exit.	**Deleted** Duplicate Merged with 3.8.1
SAF3.8.4	**M**	All laboratory personnel participate in an emergency evacuation drill (e.g. fire drill) at least once per year. *Guidance: Emergency evacuation drills include each area, each shift and all personnel of the laboratory*.	**Revised** All laboratory personnel participate in an emergency evacuation drill (e.g. fire drill) at least once per year and a record of the drills must be kept. *Guidance: Emergency evacuation drills include each area, each shift and all personnel of the laboratory.*

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SAF4.2.11	**M**		**New** Small, task-specific centrifuges (e.g. Sero-Fuge) have intact gaskets for lids that protect personnel from exposure to aerosols within the rotor chamber.
SAF5.1.5	**M**	Current MSDS are available for all controlled substances.	**Revised** Current SDS are available for all controlled substances.
SAF5.1.6	**M**	All controlled substances are labeled in accordance with WHMIS information. *Guidance: This applies to both the original supplier issued container and any secondary containers that have a workplace label.*	**Revised** All controlled substances are labeled and stored in accordance with WHMIS information. *Guidance: Labelling applies to both the original supplier issued container and any secondary containers that have a workplace label.* Merged with 5.1.7
SAF5.1.7	**M**	Controlled substances are stored in accordance with MSDS information and any applicable requirements.	**Deleted** Merged with 5.1.6
SAF5.1.11	**M**	There are procedures for the safe disposal of chemical products used in the laboratory according to MSDS information and current guidelines for waste management.	**Revised** There are procedures for the safe disposal of chemical products used in the laboratory according to SDS information and current guidelines for waste management.
SAF5.2.5	**M**	Metal storage containers are grounded to avoid static charge.	**Revised** Metal storage containers are grounded to avoid static charge. *Guidance: Safety cabinets may be grounded in addition to metal storage containers, but not instead of.*
SAF5.2.6	**M**	Piped-in gas has a readily accessible emergency shut-off valve and pipework in accordance with any regulations.	**Revised** Piped-in gas has a readily accessible emergency shut-off valve.
SAF5.4.3	**M**	MSDS information on specific spill clean-up procedures and PPE required is available.	**Revised** SDS information on specific spill clean-up procedures and PPE required is available.
SAF7.1.1	**M**	Electrical equipment complies with electrical safety regulations (e.g. Canadian Standards Association).	**Revised** Electrical equipment complies with electrical safety regulations (e.g. Canadian Standards Association (CSA)).

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SAF10.2-10.3	A risk analysis has been performed to determine if any laboratory activities require application of a universal protocol.	**Delete the whole section: (10.2.1-10.3.8)** As per DAP Committee recommendation approved on September 20, 2017
SAF10.4.1	Personnel have been provided with training on and are aware of the rights of patients. *Guidance: Patient rights include privacy, dignity and respect, personal safety and security, consent and the right to refuse laboratory services.*	**Delete** Duplicate of ORG4.6.13

EQUIPMENT AND SUPPLIES

Standard or Criterion Number		2015 Version 1.3	Version 1.4 Revision
ERS3.2.2	**M**	Where there are multiple components of a reagent kit, the laboratory uses only components of those kits within the same lot number, unless otherwise specified by the manufacturer.	**Revised** Where there are multiple components of a reagent kit, the laboratory uses only components of those kits within the same lot number, unless otherwise specified by the manufacturer. *Guidance: Allowable exceptions for mixing kit components from different lots are defined and documented.* Merged ERS3.2.2 and ERS3.2.3
ERS3.2.3	**M**	Allowable exceptions for mixing kit components from different lots are defined and documented.	**Deleted** Merged ERS3.2.2 and ERS3.2.3

QUALITY ASSURANCE

Standard or Criterion Number		2015 Version 1.3	Version 1.4 Revision
QUA1.1.6	**M**		**New** Controls are used for all qualitative and quantitative examinations. Moved from QUA1.2.5 to 1.1.6 Delete QUA1.2.5

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QUA1.2.2	**M**	Concentrations of control materials are chosen at or near clinical decision values, where possible.	**Revised** Now mandatory
QUA1.2.5	**M**	Controls are used for all qualitative and quantitative examinations.	**Deleted** Moved to 1.1.6
QUA1.2.9	**M**	QC procedures are documented and include the frequency, type of material used, number of levels of controls and acceptable ranges or tolerance limits.	**Revised** QC procedures are documented and include the frequency, type of material used, number of levels of controls and acceptable ranges or tolerance limits. *Guidance: This applies to both commercial and non-commercial QC.*
QUA1.3.7	**M**		**New** The authority to withdraw equipment or discontinue an examination in the event of QC failure is defined.
QUA1.4.1	**M**	If moving averages are used, more than 100 samples are run daily (long-term average) or the number of samples run daily has been established.	**Revised** If moving averages are used, the number of samples run daily has been defined.
QUA2.1		Laboratories participate in mandated proficiency testing (PT) programs or establish alternate assessment.	**Revised** Laboratories participate in proficiency testing (PT) or establish alternate assessment, to monitor all measurands in their scope of service.
QUA2.1.1	**M**	The laboratory participates in all DAP-mandated PT appropriate to the laboratory's scope of testing. Guidance: When there is more than one automated analyzer used to detect or quantitate an individual measurand at one site, only one PT subscription per measurand is required.	**Revised** The laboratory participates in formal PT programs for all DAP-reportable measurands relative to the laboratory scope of service. *Guidance: When there is more than one automated analyzer used to detect or quantitate an individual measurand at one site, only one PT subscription per measurand is required.*
QUA2.1.2	**M**	For quantitative and qualitative examinations where PT is not mandated by the DAP, the laboratory participates in a formal PT program or conducts an alternative assessment to confirm the accuracy of results.	**Revised** The laboratory participates in formal PT programs or establishes alternate assessment for all examinations not included in the DAP-reportable measurand list.

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QUA2.1.3	**M**	Any PT program or alternative assessment chosen by the laboratory provides clinically relevant challenges that mimic (to the extent possible) patient samples and has the effect of checking the entire examination process.	**Revised** Any PT program or alternative assessment chosen by the laboratory provides clinically relevant challenges that mimic (to the extent possible) patient samples and has the effect of checking the entire examination process, including the pre-examination and post-examination where possible.
QUA2.1.5	**M**		**New** The proficiency testing programs and alternate assessments meet the frequency requirements as defined in the DAP Laboratory Medicine PT Manual.
QUA2.2.4	**M**	There is no communication with other participants about PT samples until after the final date for data submission.	**Revised** There is no communication with other participants about PT samples until after the final date for data submission. PT samples are not referred out for examination or confirmation.
QUA2.3.3	**M**	The laboratory monitors the PT results and implements corrective actions when predetermined performance criteria are not fulfilled.	**Revised** The laboratory monitors PT results and implements corrective actions for unacceptable results. *Guidance: This includes identification of nonconformity, implementation, and monitoring of corrective action and its effectiveness. This is documented and retained.*
QUA2.3.4	**M**	When predetermined performance criteria are not fulfilled, personnel participate in the identification, implementation, recording and monitoring of corrective action and its effectiveness.	**Deleted** Merged into 2.3.3
QUA2.3.5	**M**	Unacceptable PT results are investigated. This investigation is documented and retained.	**Deleted** Merged into 2.3.3
QUA2.3.7	**M**	A record of corrective action is filed with the DAP within the required reporting time frame, when required. This record is retained by the laboratory.	**Revised** A record of corrective action for DAP-reportable tests is filed. *Guidance: DAP reportable criteria can be found in the DAP Laboratory Medicine PT Manual.*

Standard or Criterion Number		2015 Version 1.3	Version 1.4 Revision
QUA3.1.7	**M**		**New** The laboratory has defined situations where special cause comparability verification is performed in addition to routinely scheduled comparability verification. *Guidance: Special cause testing is performed in response to an alert from a monitoring procedure or a triggering event such as: failure of a frequent or periodic monitor; proficiency testing/external quality assessment failure: shift in a statistical monitoring parameter; quality control result; reagent or calibrator lot change.*

HEMATOLOGY

Standard or Criterion Number		2015 Version 1.3	Version 1.4 Revision
HEM1.3.7	**M**	There are procedures for reporting significant numbers of unlyzed RBC, giant platelets, or platelet clumps that may lead to spuriously high white blood cell (WBC) counts.	**Revised** There are procedures for rechecking the WBC count by another method, when significant numbers of unlyzed RBC, giant platelets or platelet clumps are detected.
HEM1.3.10	**M**	A platelet estimate is provided when other cells or cell fragments are detected or suspected.	**Revised** There is a system (such as microscopic correlation with the blood film) to prevent reporting erroneous platelet counts. *Guidance: Erroneous platelet counts may be due to platelet clumps, giant platelets, platelet satellitism, or other, such as red cell fragments or other causes such as cryoglobulin.*
HEM2.1.1	**M**	There are guidelines for the preparation of peripheral blood films.	**Revised** Reference number edit only. CAP HEM.34300
HEM2.1.9	**M**		**New** Slides are stored for a defined period. All body fluid smears must be retained for at least one week for possible review.

Standard or Criterion Number		2015 Version 1.3	Version 1.4 Revision
HEM3.1.8	**M**	Samples for coagulation examination are not stored in a frost-free freezer.	**Revised** Samples for coagulation examination are not stored in a frost-free freezer. *Guidance: Storage of coagulation samples in a frost-free freezer is acceptable provided the freezer is monitored by a continuous temperature monitoring device or a maximum/minimum thermometer that demonstrates the acceptable temperature range has not been exceeded.*
HEM3.2.1	**M**	The International Sensitivity Index (ISI) and geometric mean used to determine the INR are validated and documented.	**Revised** Reference number edit only. CLSI H54-A 4.3
HEM3.5.1	**M**	For coagulation endpoint-based factor examinations three or more points are plotted for the standard curve.	**Revised** Reference number edit only. CLSI H48, 2nd ed.
HEM3.5.2	**M**	The standard curves are verified with at least two reference points for each factor examination for every eight hours of examination. CLSI H48-A11	**Revised** Reference number edit only. CLSI H48, 2nd ed.
HEM3.5.3	**M**	Three or more dilutions are plotted for each factor examination. CLSI H48-A11	**Revised** Reference number edit only. CLSI H48, 2nd ed.
HEM4.1.3	**M**	Blood films for malarial parasites are prepared within two hours of collection or the delay in preparation time is noted on the report.	**Revised** Blood films for malarial parasites are prepared within one hour of collection or the delay in preparation time is noted on the report.
HEM5.1.4	**M**	Cytochemical stains are checked for intended reactivity on each day of use. *Guidance: QC slides are stained along with the sample.*	**Revised** Cytochemical stains are checked for intended reactivity on each day of use. *Guidance: QC slides are stained along with the sample for cytochemical stains including iron, etc.*

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HEM6.1.9	**M**		**New** There is evidence for each fluid phase separation technique (e.g. HPLC procedure, capillary zone electrophoresis) that the limit of detection (sensitivity), the analytical measurement range (AMR) and carryover for quantitative methods have been determined.
HEM8.3.5	**M**	The performance of reagents and staining procedures is verified by the use of positive or normal controls where available (e.g. CD 103).	**Revised** The performance of reagents and staining procedures is verified by the use of positive controls. If antigen-positive cells are not available through commercial controls or patient materials then there is an alternative procedure in place to meet the positive control requirements.
HEM8.6			**New** There are procedures for rare event flow cytometric assays. Examples of rare events are Paroxysmal nocturnal hemoglobinuria (PNH) and B-ALL minimum residual disease (MRD).
HEM8.6.1	**M**		**New** The lower limit of enumeration for rare event flow cytometric assays has been validated.
HEM8.6.2	**M**		**New** The lower limit of enumeration for rare event flow cytometric assays is included in the diagnostic report.

TRANSFUSION MEDICINE

Standard or Criterion Number		2015 Version 1.3	Version 1.4 Revision
TRM1.5.1	**M**	An established facility or regional committee meets to discuss transfusion-related issues at least quarterly. *Guidance: Although a transfusion committee is preferred, the used of an established group such as the medical advisory committee is acceptable. Transfusion Committee meetings may be conducted by teleconference or other venue.*	**Revised** An established facility, regional or provincial committee meets to discuss transfusion-related issues at least quarterly. *Guidance: Although a transfusion committee is preferred, also acceptable is to have a structure of committees in place that can meet the required activities of a transfusion committee. Examples are the facility or regional medical advisory committee, or the BC Transfusion Medicine Advisory Group. Transfusion committee meetings may be conducted by teleconference or other means.*
TRM1.5.7	**M**	The transfusion committee ensures that audits of transfusion practices are performed every two years at a minimum.	**Revised** The transfusion committee ensures that audits of transfusion practices are performed at defined intervals, reviewed and corrective action taken as required.
TRM2.3.2	**M**	Any nonconformity that has or may have adversely affected patient care is reported to the Canadian Blood Services or Health Canada, as appropriate.	**Revised** Any nonconformity that has or may have adversely affected the quality and safety of the blood component and/or patient care is reported to Health Canada, as appropriate.
TRM3.2.6	**M**	All recipients of blood components and products are notified in writing.	**Revised** All recipients of blood components and products are notified by an established policy and process.
TRM5.2.5		Blood component and product storage equipment is monitored with an additional separate independent thermometer in a fluid equal in heat transfer characteristics to the smallest volume of blood product or component in storage.	**Revised** Blood component and product storage equipment is monitored with a NIST-calibrated thermometer in a fluid equal in heat transfer characteristic of the smallest volume of blood component in storage.
TRM5.2.7	**M**	Equipment used for blood component and product storage has an audible alarm with a backup power supply for the alarm. Any battery powered alarm backup is checked monthly.	**Revised** Equipment used for blood component and product storage has an audible alarm with a backup power supply for the alarm. Any battery powered alarm backup is checked at a defined interval.

Standard or Criterion Number		2015 Version 1.3	Version 1.4 Revision
TRM5.2.13	**M**		**New** Blood storage access areas are restricted to designated personnel only.
TRM5.2.14			**New** All blood storage equipment located in patient care areas incorporate electronic/computerized (smart) technology to track blood component and products access and prevent access by unauthorized personnel.
TRM5.4.2	**M**	The temperature, speed and processing time for centrifugation is checked with each use and documented daily.	**Revised** The temperature(s), speed and processing time(s) for blood component centrifugation is checked and documented each day of use and for type of component. *Guidance: The transfusion service has defined the appropriate temperature, speed and processing time for each component.*
TRM7.1.1	**M**	An emergency supply of group O Rh negative red blood cells is available at all times for emergency release. *Guidance: A system that allows immediate allocation may be a suitable substitute for a dedicated emergency supply.*	**Revised** An emergency supply of group O red blood cells is available at all times for emergency release. A policy is established which details the acceptable and unacceptable indications for utilization of group O negative red blood cells.
TRM7.3.7	**M**	Thawed cryoprecipitate is stored at 20°C to 24°C with an expiry of four hours after thawing.	**Revised** Thawed cryoprecipitate is stored at 20°C to 24°C with an expiry of twenty four hours if maintained in a closed system. Thawed cryoprecipitate once opened is stored for four hours at 20°C to 24°C.

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TRM9.6.2	**M**	When using a computer crossmatch, the recipient's ABO group is determined twice. *Guidance: This includes ABO grouping on the current sample and verification by a second independent test of the same sample, previous ABO grouping stored in the computer system, or examination of a second correctly identified and labeled sample.*	**Revised** The recipient's ABO group is determined twice when crossmatching red cells for transfusion. This applies to both the serological or computer crossmatch method. The facility has a policy as to what constitutes a valid second ABO determination. *Guidance: The first determination is the ABO grouping on the current sample and the second determination is a verification by: comparing to a previous ABO grouping on record; or examination of a second current sample (a separate collection); or a second independent test of the same current sample only where positive patient identification technology is used at the time of the sample collection.*
TRM9.6.9	**M**	The ABO group of donor red cells is confirmed using a segment of the blood component if a serological crossmatch is not performed.	**Revised** The ABO group of donor red cells is confirmed for all red cell units.
TRM10.1.4	**M**	Recipients are transfused with plasma that is ABO compatible with their own red cells.	**Revised** Recipients are transfused with plasma that is ABO compatible with their own red cells. *Guidance: There is a policy for ABO group substitution in an emergency release.*
TRM10.2.1	**M**	There are procedures that define when irradiated cellular blood components are provided. *Guidance: Current BC Transfusion Medicine Advisory Group (TMAG) guidelines are available.*	**Revised** There are procedures that define when irradiated cellular blood components are provided. *Guidance: NAC Recommendations for Use of Irradiated Blood Components in Canada are available.*

Standard or Criterion Number		2015 Version 1.3	Version 1.4 Revision
TRM10.2.3	**M**	There are documented processes to ensure that patients receive cytomegalovirus (CMV) safe or CMV negative blood components when required.	**Revised** There are documented processes to ensure that patients receive cytomegalovirus (CMV) safe or CMV negative blood components when required. *Guidance: CMV safe (leukoreduced) and CMV IgG seronegative products are considered equivalent except for Intrauterine transfusion. CMV seronegative components are for use in Intrauterine transfusion only.*
TRM10.3.3	**M**	When a portion of a blood component is removed from the original container, the component label is changed to indicate the new volume.	**Deleted** Duplicate of 10.4.3
TRM10.4.4	**M**	The new or additional label applied to modified blood components and products indicates the storage temperature.	**Revised** Now mandatory
TRM10.4.10	**M**	Handwritten additions or changes are applied only to the label and not to the bag itself.	**Revised** Now mandatory
TRM10.4.11	**M**	Only permanent moisture proof ink that will not leach through the label is used.	**Revised** Only permanent moisture-proof ink that will not leach through the label is used. *Guidance: Confirm with the label manufacturer that inks are safe for use on blood bags.*
TRM10.4.12	**M**	Procedures ensure that all additions and changes are done using a consistent format that is understandable to the personnel who will be handling the blood component or product.	**Revised** Now mandatory
TRM10.4.13	**M**	Procedures outline the steps to be taken if a label or bag is marked accidentally.	**Revised** Procedures outline the steps to be taken if a label or bag is marked.

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TRM10.4.14	**M**	The blood component and product label applied by the blood supplier is not obscured, changed or removed.	**Revised** The blood component and product label applied by the blood supplier is not obscured, changed or removed except when the components are modified. The label is revised to properly identify the contents. *Guidance: Confirm with the label manufacturer that adhesives are approved for use on blood bags.*
TRM10.6.6	**M**	Irradiated red cells have an expiry of 28 days from the time of irradiation or retain the original expiry date if this is less than 28 days.	**Revised** Red cells may be irradiated up to 28 days after collection. Irradiated cells must be transfused as soon as possible, but no later than 14 days after irradiation, and in any case, no later than 28 days after collection.
TRM10.6.7	**M**	There is a policy that defines the expiry date for irradiated red cells designated for prenatal and neonatal recipients.	**Revised** There is a policy that defines the expiry date for irradiated red cells.
TRM10.6.9	**M**	A permanent label is applied to irradiated blood components indicating that the blood component has been irradiated, the facility performing the irradiation and if applicable, the new expiry date.	**Revised** Now mandatory
TRM11.1.7	**M**	An examination is performed to determine the amount of fetomaternal hemorrhage in an eligible candidate. The examination includes procedures to determine the appropriate dose of RhIg.	**Revised** Now mandatory
TRM11.1.8	**M**	There are procedures for RhIg administration to Rh negative patients receiving components containing D positive red cells.	**Revised** There are policies and procedures for RhIg administration to Rh negative patients receiving components containing D positive red cells.
TRM11.2.1	**M**	An appropriate venous or capillary sample from the mother or neonates is used for pre-transfusion examinations. *Guidance: Cord blood is not acceptable for neonatal transfusion examination.*	**Revised** An appropriate venous or capillary sample from the neonate is used for pre-transfusion examinations. *Guidance: Cord blood is not acceptable for neonatal transfusion examination.*

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TRM11.2.3	**M**	Screening for clinically significant red cell antibodies uses a neonatal sample when available.	**Revised** Screening for clinically significant red cell antibodies uses a neonatal sample. If neonatal sample is insufficient, maternal plasma/serum may be used.
TRM11.2.5	**M**	If a neonate's initial antibody screen demonstrates clinically significant unexpected red cell antibodies, units selected for transfusion either do not contain the corresponding antigen, or are compatible by antiglobulin crossmatch until the antibody is no longer demonstrable.	**Revised** A serological crossmatch is performed with a donor red cell unit that lacks the corresponding antigen when the initial pre-transfusion antibody screen demonstrates clinically significant antibodies (including passive anti-D due to RhIg). *Guidance: Antibody investigation and donor unit crossmatch do not need to be repeated if the same antigen negative donor unit is used for subsequent transfusions during any single hospital admission. Once the maternal antibody is no longer demonstrable, continued use of antigen negative red cells and serological crossmatching are no longer required until the neonate is four months of age.*
TRM11.3		There are procedures for the selection of blood components and products for neonates.	**Revised** There are procedures for the selection of blood components and products for neonatal and intrauterine transfusions.
TRM11.3.1	**M**	CMV-seronegative red cells are provided for intrauterine transfusions and neonates with a birth weight less than 1200 g.	**Revised** CMV-seronegative red cells are provided for intrauterine transfusions.
TRM11.3.2	**M**	CMV-safe red cells are provided for neonates with a birth weight greater than 1200g.	**Deleted**
TRM11.3.3	**M**	Cellular blood components from a blood relative are irradiated for neonatal transfusion.	**Revised** All cellular blood components from a blood relative (directed donation) are irradiated for neonatal or exchange transfusion.

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TRM11.3.4	**M**	The storage period for irradiated red cells prior to exchange transfusion or transfusion to a neonate is defined.	**Revised** The storage period for irradiated red cells prior to exchange transfusion or transfusion to a neonate is less than 24 hours. *Guidance: In the event of red cells stored for greater than 24 hours from irradiation allocated for a neonate, the red cells must undergo centrifugation and supernatant plasma removal prior to transfusion*.
TRM11.3.12	**M**	Cellular blood components for intrauterine transfusion are irradiated.	**Revised** All cellular blood components for intrauterine transfusion are irradiated, as fresh as possible and transfused within 24 hours of irradiation.
TRM11.3.13	**M**		**New** Irradiated cellular blood components are provided for neonates who have received an intrauterine transfusion, in which case irradiated components should be administered until six months after the expected delivery date.
TRM11.3.14	**M**		**New** All cellular blood components for exchange transfusion are irradiated, as fresh as possible and transfused within 24 hours of irradiation.
TRM11.3.15	**M**		**New** All cellular blood components for neonatal small volume (top up) transfusions are irradiated for very low birthweight neonates, up to four months of age. *Guidance: There must be a facility policy that defines very low birth weight.*
TRM12.1.3	**M**	When there is insufficient time to complete ABO and Rh grouping or a sample cannot be obtained, group O red cells are issued. Group O Rh negative red cells are issued for women of childbearing potential and children.	**Revised** When there is insufficient time to complete ABO and Rh grouping or a sample cannot be obtained, group O red cells are issued. Group O Rh negative red cells are issued for women of childbearing potential.

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TRM12.1.5		Group AB plasma, if required, is issued when there is insufficient time to complete ABO and Rh grouping or a sample cannot be obtained.	**Revised** Group AB plasma, if required, is issued when there is insufficient time to complete ABO and Rh grouping or a sample cannot be obtained. *Guidance: A facility policy is in place for the substitution of AB plasma with A plasma.*
TRM12.4.5	**M**	When an abnormality is detected the unit is not issued and quarantined until appropriate disposition is determined. The blood supplier is notified regarding the final disposition. This notification is documented.	**Revised** When an abnormality is detected the unit is not issued and is quarantined until appropriate disposition is determined. The blood supplier or the originating facility is notified regarding the final disposition. This notification is documented.
TRM12.5.5	**M**	For issued blood components the record documents the blood component identification number and a verification of compatibility for red cells.	**Revised** Now mandatory
TRM12.5.6	**M**	For blood products issued the record documents the blood product name, lot number, volume, potency, manufacturer and the dosage or vials issued.	**Revised** Now mandatory
TRM12.6.3	**M**	When blood components are returned to inventory, a temperature-monitoring system indicates that the blood component has not reached an unacceptable temperature since being released, or in the absence of a temperature monitoring system, that the blood component has not been outside of a controlled environment for more than 30 minutes.	**Revised** When blood components are returned to inventory, a temperature-monitoring system indicates that the blood component has not reached an unacceptable temperature since being released, or in the absence of a temperature monitoring system, that the blood component has not been outside of a controlled environment for more than 60 minutes.
TRM13.1.6		The transfusion order specifies the use of a blood warmer or rapid infusion device with the exception of clinical areas where there is an established hospital policy and procedure.	**Deleted** Duplicate of 13.5
TRM13.3.6	**M**	Only a 0.9% sodium chloride solution is used to prime the administration set if priming is required. When intravenous immune globulin (IVIG) is not compatible with 0.9% sodium chloride, D5W is used.	**Revised** The blood component or a 0.9% sodium chloride solution is used to prime the administration set if priming is required. When intravenous immune globulin (IVIG) is not compatible with 0.9% sodium chloride, D5W is used.

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TRM13.5		There are procedures for the documentation and reporting of adverse reactions.	**Revised** There are procedures for the management, investigation, documentation and reporting of adverse reactions.
TRM13.5.1	**M**	There are procedures for the documentation, reporting, evaluation and follow-up of all suspected transfusion reactions.	**Revised** There are procedures for the management, investigation, documentation and reporting of all adverse transfusion reactions.
TRM13.5.2	**M**	In the event that a patient exhibits signs of a transfusion reaction, the transfusionist follows established hospital procedures for management of a transfusion reaction.	**Deleted** (13.6.2)
TRM13.5.3	**M**	The laboratory has defined when a suspected adverse transfusion reaction is to be reported to the transfusion service. At a minimum, serious adverse transfusion reactions are reported.	**Revised** The transfusion service has defined for clinical staff, when a suspected adverse transfusion reaction is to be reported to the transfusion service.
TRM13.5.4	**M**	The transfusion service investigates all reports of suspected adverse reactions. The investigation determines the probable cause and includes appropriate laboratory examinations.	**Revised** The transfusion service investigates all reports of suspected adverse transfusion reactions. The investigation determines the probable cause and includes appropriate laboratory examinations. The investigation is documented.
TRM13.5.5	**M**	The transfusion service submits reports of adverse reactions to authorities as required by regulations.	**Revised** The transfusion service investigation includes a check of all relevant documentation to exclude the presence of a clerical error in all relevant documents of the: • identification of the recipient • the recipient's pre transfusion blood sample • the labelled blood component or blood product
TRM13.5.6	**M**	Any adverse reaction that can be attributed to the quality of a blood component or product is reported to the blood supplier or to the blood product manufacturer.	**Revised** For suspected hemolytic transfusion reactions the investigation includes a visual hemolysis check and a direct antiglobulin test on the patient sample.

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TRM13.5.7	**M**	All serious adverse reactions including fatalities related to blood transfusion are reported to the blood supplier or blood product manufacturer within 24 hours.	**Revised** There is a policy and procedure in place for the correct submission of reports of adverse reactions. Fatalities related to transfused blood components within 24 hours of death are reported to Health Canada and Canadian Blood Services.
TRM13.6		There are procedures for the management and investigation of suspected hemolytic transfusion reactions.	**Revised** There are procedures for the clinical management of adverse reactions.
TRM13.6.1	**M**	There are guidelines for clinical personnel to recognize and manage suspected hemolytic transfusion reactions.	**Revised** There are guidelines for clinical personnel to recognize and manage all suspected transfusion reactions.
TRM13.6.2	**M**	In cases of suspected hemolytic transfusion reactions, the transfusion is stopped and investigation begins immediately. The investigation is documented.	**Revised** In the event that a patient exhibits signs of a transfusion reaction, the transfusionist follows established hospital procedures for management of a transfusion reaction.
TRM13.6.3	**M**	The implicated blood component is returned to the transfusion service.	**Revised** The implicated blood product of a suspected transfusion reaction is returned to the transfusion service except for minor allergic reactions or as per facility policy.
TRM13.6.4	**M**	A post-transfusion blood sample is collected and sent to the transfusion service with any accompanying documentation.	**Revised** A post-transfusion blood sample is collected and sent to the transfusion service with any accompanying documentation or as indicated by the facility procedure.
TRM13.6.5	**M**	All relevant documentation is compared and verified to exclude clerical errors.	**Deleted** Duplicate of 13.6.6
TRM13.6.6	**M**	The identification of the recipient and the recipient's pre-transfusion blood results are verified.	**Deleted** Duplicate of 13.6.8

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TRM13.6.8	**M**		**New** The transfusion service investigation includes a check of all relevant documentation to exclude the presence of a clerical error in all relevant documents of the identification of the recipient, the recipient's pre transfusion blood sample, the labelled blood component or blood product.
TRM15.2.1	**M**	An outer label that meets transport regulations is applied to all shipping containers that identifies the shipping facility, the receiving facility and confirms the contents are blood components and products.	**Revised** An outer label is applied to all shipping containers that identifies the shipping facility, the receiving facility and confirms the contents are blood components and products.
TRM15.2.2	**M**	A packing slip with a unique serial number is included with each shipment that identifies the shipping facility and the receiving facility.	**Revised** A packing slip with identifying characteristics is included with each shipment that identifies the shipping facility and the receiving facility.
TRM16.1.1	**M**	Policies and procedures for hospital-based donations comply with CSTM standards, CSA-Z902-10 standards and Health Canada Blood Regulations, if performed.	**Revised** Policies and procedures for hospital-based donations comply with the most recent versions of the CSTM Standards, CSA-Z902 Standards and Health Canada Blood Regulations.
TRM16.1.2	**M**	Policies, processes and procedures for preoperative autologous donations comply with CSTM standards, CSA-Z902-10 standards and Health Canada Blood Regulations, if performed.	**Revised** Policies, processes and procedures for preoperative autologous donations comply with the most recent CSTM Standards, CSA-Z902 Standards and Health Canada Blood Regulations, if performed.
TRM16.1.3	**M**	Policies, processes and procedures for perioperative autologous donation programs comply with CSTM standards, CSA-Z902-10 standards and Health Canada Blood Regulations, if performed.	**Deleted** Moved to 16.2
TRM16.1.4	**M**	Policies, processes and procedures for directed and designated donation programs comply with CSTM standards, CSA-Z902-10 standards and Health Canada Blood Regulations, if performed.	**Revised** Policies, processes and procedures for directed and designated donation programs comply with the most recent CSTM Standards, CSA-Z902 Standards and Health Canada Blood Regulations, if performed.

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TRM16.1.5	**M**	Policies, processes and procedures for a home transfusion program comply with CSTM standards, CSA-Z902-10 standards and Health Canada Blood Regulations, if performed	**Revised** Policies, processes and procedures for a home transfusion program comply with the most recent CSTM Standards, CSA-Z902 Standards and Health Canada Blood Regulations, if performed.
TRM16.2			**New** There are policies and procedures for perioperative collections.
TRM16.2.1	**M**		**New** Policies, processes and procedures for perioperative autologous donation programs comply with the most recent CSTM Standards, CSA-Z902 Standards, if performed.
TRM16.2.2	**M**		**New** The perioperative collection program shall include a program of quality assurance and quality control that has been developed by all departments involved in the program. Quality indicators include those to measure the safety and quality of perioperative collections and results shall be documented, reviewed, and retained. The criteria for acceptable performance are defined by the facility.
TRM16.2.3	**M**		**New** The transfusion service should collaborate on the development of perioperative policies, processes and procedures, and the management of the perioperative collection program.