Appendix # 3

Standards and Regulations

Numerous reference publications exist to provide regulatory or voluntary structure to Transfusion Medicine processes. The pre-eminent standards and regulations used for the development of Saskatchewan Transfusion Resource Manual include:

- Western Canada Diagnostic Accreditation Alliance (WCDAA) Standards for Diagnostic Laboratory Accreditation: Transfusion Medicine
- CAN/CSA-Z902:20 Standard for Blood and Blood Components
- Health Canada's Blood Regulations
- The Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) for Serious Adverse Drug Reactions (ADRs)

Western Canada Diagnostic Accreditation Alliance (WCDAA) Standards for Diagnostic Laboratory Accreditation: Transfusion Medicine

The Laboratory Quality Assurance Program (LQAP) requires laboratories to meet the requirements of the WCDAA Standards for Diagnostic Laboratory Accreditation. The WCDAA standards are evidence based and reference accepted best practices, Provincial and Canadian legislation, relevant International Organization for Standardization (ISO) standards, and other recognized provincial, national and international standards (e.g. AABB, College of American Pathologists, CLSI, CSTM, Canadian Standards Association). Each accreditation standard has an accompanying reference citation(s). A detailed reference list is provided at the end of the document.

CAN/CSA-Z902:20 Blood and Blood Components

The standard CAN/CSA-Z902:20 Blood and Blood Components provides requirements for facilities that collect, process, store, and use human blood and blood components for transfusion. It addresses issues of safety and efficacy for patients, and safety for facility personnel and others who are exposed to or potentially affected by blood and blood components. The requirements set out in this Standard are the minimum criteria for acceptable performance and may be exceeded in practice.

Blood Regulations (SOR/2013-178)

The Health Canada Blood Regulations came into force October 23, 2014. The Blood Regulations are only applicable to blood components; blood products are not in the scope of the Blood Regulations. The Blood Regulations regulate the processing, labeling, storage, distribution, and importation of blood and its components intended for transfusion. The Blood Regulations apply to all establishments that handle blood; the level of oversight corresponds to the level of risk of the activity being performed by each establishment.

The Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)

The Protecting Canadians from Unsafe Drugs Act, also known as Vanessa's Law came into effect on December 16, 2019. Vanessa's law introduces amendments to the *Food and Drugs Act* that give Health Canada more power to protect Canadians from unsafe products. In addition to mandatory reporting of serious adverse drug reactions (ADRs) and medical device incidents (MDIs), Vanessa's Law empowers Health Canada to order recalls, impose tougher penalties for unsafe products, and compel drug companies to review labels or do further testing on products.