1. **Principle**

To establish the elements of a quality system to write, revise, review, distribute, maintain and retain controlled documents of the Ontario Transfusion Technical Resource Manual (OTTRM).

1. **Scope and Related Policies**
2. Applies to all OTTRM procedures and is intended for use by facilities with a hospital Transfusion Medicine Laboratory (TML).
3. Document control will be used to ensure appropriate archiving and documentation of revisions.
4. ORBCoN performs document control activities.
5. Documents for OTTRM include procedures contained in:

* Section PA Pre-Analysis
* Section RT Routine Testing
* Section GM Gel Methods
* Section SPM Solid Phase Methods
* Section NRT Non-Routine Testing
* Section SP Special Procedures
* Section RP Reagent Preparation
* Section CSP Component Selection and Preparation
* Section IM Inventory Management
* Section QCA Quality Control/ Assurance
* Section ADM Administration

1. The document control system provides for back up of all electronically stored documents and a method for filing and archiving all documents.
2. **Specimens – N/A**
3. **Materials**

**Supplies:** OTTRM Change Control form (ADM.001F)

1. **Quality Control** 
   1. ORBCoN controls procedure revisions, additions and removal of procedures, and updates to the master index.
   2. OTTRM users use procedure manuals that are maintained in controlled locations at each user hospital. Master document templates are stored at the Ontario Regional Blood Coordinating Network (ORBCoN) in Ottawa.
   3. ORBCoN maintains the revision record and electronic file for each procedure.
   4. Each document change and rationale supporting the change should be documented on ADM.001F. Changes are reviewed and approved by ORBCoN and any designated stakeholders requested to review prior to implementation.
   5. All approved and current hospital specific procedures should be available to the laboratory personnel in the hospital TML department. Document(s) that have been subsequently revised must be immediately removed from point of use and replaced with the revised document.
   6. A listing of all procedure templates, current revisions and effective dates is maintained by ORBCoN and is located on the [www.transfusionontario.org](http://www.transfusionontario.org) website.
   7. All records of change and each official revision of a procedure template is maintained in a Master electronic file.
   8. A back up file is maintained of all documents.
   9. All procedure templates, change request forms and outside correspondence relating to the procedures are retained and archived.
2. **Procedure**

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| 1. Requesting revision to a current procedure template or submit a subject for development of a new procedure | 1. Complete ADM.001F1 – OTTRM Change Control form and submit it via fax or email to the ORBCoN office (Ottawa). |
| 1. ORBCoN will send an acknowledgment of receipt to the originator once it has been received. |
| 1. Review and revise request | 1. ORBCoN will request stakeholder consultation to review current or new procedures, and create working groups where necessary |
| 1. ORBCoN will create or revise a procedure or send an explanation if the procedure will not be revised or developed to the original requester |
| 1. ORBCoN will obtain final approval of new procedure or revisions to existing procedure and save the changes in a master file |
| 1. Posting New or Revised Procedures | 1. Send final version of new or revised procedure to translation once approved. |
| 1. Post English and French versions on [www.transfusionontario.org](http://www.transfusionontario.org) and indicate “New or Revised.” |

1. **Reporting – N/A**
2. **Procedural Notes – N/A**
3. **References**
   1. Nevalainen DE, Callery MF. Quality systems in the blood banks and laboratory environment. Bethesda, MD: American Association of Blood Banks, 1994: module III.
   2. Delaney S. Beyond SOP’s: developing an effective document control system program. Bethesda, MD: American Association of Blood Banks. 1997.
4. **Revision History**

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| **Revision Date** | **Summary of Revision** |
| August 10, 2015 | * Revised name of manual * Revised section 2.0 * Replaced “Swim Working Team (SWT)” with “ORBCoN” in sections 5.0 and 6.0 |