1. **Principle**

The Transfusion Medicine Laboratory (TML) is required to monitor the outcome of its processes. The identification and correction of non-compliance (NC) is a means to achieve this.

1. **Scope and Related Policies**
	1. Standardized non-compliance forms will be used.
	2. The intent of these forms is to improve processes and not to initiate discipline.
	3. These files are part of the overall Quality Management System (QMS).
2. **Specimens– N/A**
3. **Materials**

**Supplies:** TML NC report form (ADM.005F) and/or

 Site specific Non-Conformance report

1. **Quality Control**
	1. An annual review (or sooner if indicated) should be made of all reports and a trend analysis performed and reported to the Transfusion Committee or equivalent.
	2. The TM Medical Director /Designate should review the analysis reports.
	3. Action taken as an outcome of the analysis reports (e.g. process change, employee training) should be documented and retained in the QMS files.
2. **Procedure**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. Non- Compliance Identified
 | 1. In-house TML non-compliance reportswill be completed when an error is detected in the TML and corrected prior to information or product release. The following categories will be followed:

|  |  |
| --- | --- |
| NC Category | Example |
| Clerical Error | Unit typing incorrectly entered  |
| Blood Product Wastage | Incorrect product thawed |
| Delay In Issue | Verbal order not passed on in timely way |
| Test Not Performed | Results not verified and completed  |
| Labelling Error | Sample label affixed to incorrect tube |
| Autologous Related | Missed name discrepancy when receiving product |
| Technical Testing Error | Addition of incorrect antisera to a test |
| Incorrect Report Charted | Incorrect result charted but noted in TML and amended. |

 |
| 1. Any incidents affecting patient care will be brought to the attention of the Manager and Medical Director immediately.
 |
| 1. Reporting Non-Compliance
 | 1. Hospital non-compliance reports will be issued for the following:
* Patient is affected in any way (incorrect product, incompatible product, unit infused to wrong patient, avoidable delay in issuing products)
* Blood products wasted (incorrect handling, storage)
* Sample unacceptable for testing– new sample required (no label, incorrectly identified)
 |
| 1. Corrective action taken will be documented and a copy will be kept on file in the designated area.
 |
| 1. Corrective actions will be documented and filed with the QMS documentation.
 |
| 1. Hospital NC reports will be signed off by the Manager of the TML or designate and reviewed monthly and brought to quarterly operations meetings for overall review by the Manager and Medical Director
 |
| 1. Review of Non-Compliance Reports
 | * + 1. Error reports will be reviewed monthly. Any repeated errors (same error or same Technologist) will be investigated to determine if procedural changes and / or retraining are required.
 |
| * + 1. Non-compliance reports will be reviewed regularly by the TM Medical Director and Hospital Transfusion Committee
 |

1. **Reporting**

At a minimum there will be annual review and preparation of trend analysis reports for the Medical Director and Transfusion Committee to review to monitor for improvement of activities.

1. **Procedural Notes – N/A**
2. **References**
	1. IQMH Program Requirements and Guidance Information, v6.0 Dec 2013; Section II – Quality Management System.
3. **Revision History**

|  |  |
| --- | --- |
| **Revision Date** | **Summary of Revision** |
| August 10, 2015 | * Revised name of manual
* Added “site specific Non-conformance report” to section 4.0
* Revised wording to include “to the Transfusion Committee or equivalent” to section 5.1
* Replaced “Medical Chief/Designate” with “TM Medical Director/Designate” in section 5.2
* Revised and renumbered section 6.0
* Revised wording of section 7.0
* Updated list of references to include most recent editions
 |