

The audit process is the tool to help management gain an understanding of the current situation and identify opportunities for making improvements. The definition of audit is: the inspection and examination of a process or quality system to ensure compliance with requirements.

CSTM Requirements

8.1- Each Transfusion Committee shall establish an internal audit program to ensure quality of all processes and procedures. Internal audits shall be performed at least annually by qualified personnel who are not directly responsible for the audited activities. Audit observations shall be documented. The Laboratory Manager shall regularly review its compliance with department policies and procedures and correct any deficiencies which are found to exist.

IQMH Requirements

II.D.7 Internal audits shall be conducted at planned intervals defined in the quality management system (suggest once per year) to verify that operations continue to comply with the quality management system, both managerial and technical.

II.D.7.1 The process and procedures for internal audits shall be defined and documented. Each of the main elements in the quality management system shall be included.

II.D.7.2 Auditors shall, wherever resources permit, be independent of the activity to be audited to ensure objectivity and impartiality.

II.D.7.3 Internal audit results shall be submitted to laboratory management for review.

II.D.7.4 When deficiencies and opportunities for improvement are noted from internal audit, the laboratory shall undertake appropriate corrective or preventative actions, which should be documented and carried out within an agreed time.

POLICY: **GENERAL INFORMATION**

A. Performance of self-assessments enables management and staff to ensure that all employees comply with policies and standard operating procedures and take proactive steps to correct any items that are identified as non-compliant.

B. Transfusion audits provide a review of policies and practices to ensure safe and appropriate transfusions and are based on measurable, predetermined performance criteria. Transfusion Medicine Services should investigate an adequate sampling of cases (eg. 10%) in order to accurately identify any trends. Internal audits will help assess the facility's performance and effectiveness in:

- Blood ordering practices for all blood and blood components.
- Minimizing wastage of blood components.

This document is provided by ORBCoN and is intended for reference purposes only.

- Distribution, handling, use and administration of blood components.
- Evaluating all confirmed transfusion reactions.
- Meeting patients' transfusion needs.

C. Self-assessments should be performed and related documentation retained in accordance with your facility's document retention policy.

POLICIES AND PROCEDURES TO BE AUDITED

- D. The Laboratory Manager or designate should annually select the policy or procedure on which self-audits are to be performed in the Transfusion Service.
- E. The Laboratory Manager or designate should identify specific areas that are required to perform annual self-audits and select the policies or procedures on which the audits are to be performed. The Laboratory Manager may select additional policies/procedures on which to perform self-audits.

SELF-AUDIT PLAN

- F. Each year, the Transfusion Committee delegate is required to conduct an annual self-assessment and should submit a plan for performing the assessment during the next calendar year. The plan should include a list of the policy directives to be audited, including those selected by the director or designate, and the schedule for completion of the self-assessment.

PERFORMING SELF-AUDITS

- G. Each Laboratory Manager or designate for Transfusion Medicine Service required to conduct self-audits, should be responsible for the overall completion of required audits including; reviewing, overseeing completion of audit reports and ensuring that all necessary corrective action is taken. This also includes assigning staff to perform the audit. Staff assigned should not be directly responsible for implementation of the policy directive being audited.
- H. Self-audits should address compliance with each factor listed on the Primary Audit Checklist for each policy or procedure, if one has not been developed, and the pertinent elements of the policy or procedure. The audit also should address compliance with the pertinent elements of the operating procedures involved in the policy or procedure. Detailed work papers (e.g., results of any tests performed or interview notes) shall be maintained which identify how the audit was performed and how the findings of the audit were reached.
- I. At the conclusion of the self-audit, a report should be submitted to the Laboratory Manager, or designate, with copies to the Medical Director and the Transfusion Committee delegate.

This document is provided by ORBCoN and is intended for reference purposes only.

The report should include the following:

1. Identification of the policy, operating procedures, and/or blood component audited;
2. A summary of how the audit was performed. This should include which documents were reviewed and what was observed;
3. A summary of the findings of the audit. This should include identifying the results of any sampling or other audit work performed and where there is and is not compliance;
4. Recommendations for corrective action to be taken for each finding of non-compliance and suggestions to improve operations;
5. A description of the corrective action taken or that will be taken for each finding of non-compliance, including expected compliance dates.

Audit Model

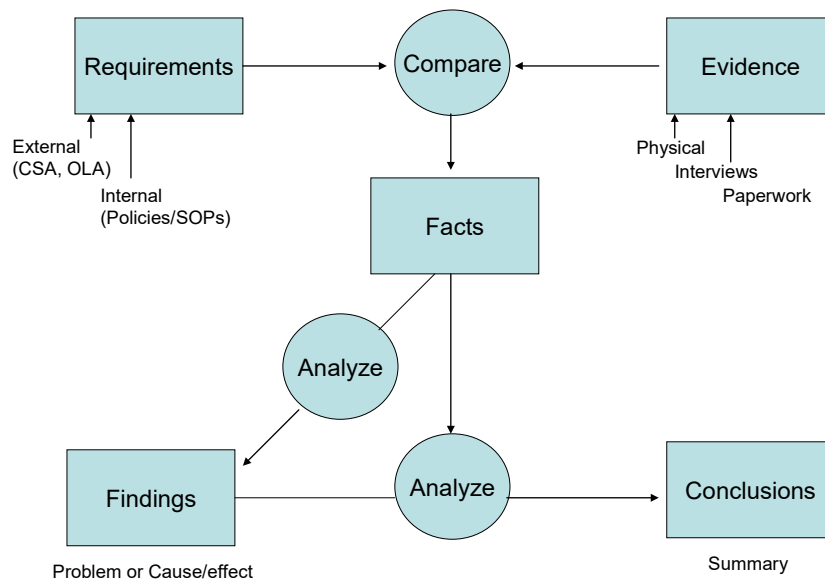


Figure 1 Audit model