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Self-inspection and classification of non-compliances

Y. Qiu,[1] T. Vuk,[2] L. Bust,[3] P. Strengers[4] & C. Seidl[5]

[1]*Beijing Red Cross Blood Center, Beijing, China*
[2]*Croatian Institute of Transfusion Medicine, Zagreb, Croatia*
[3]*African Society for Blood Transfusion (AfSBT), Cape Town, South African*
[4]*International Plasma Fractionation Association (IPFA), Amsterdam, The Netherlands*
[5]*German Red Cross Blood Donor Services (RCBDS) – EuBIS Academy, Frankfurt am Main, Germany*

Background and Objectives Self-inspection is a key part of the blood establishment quality management system and the base of different types of assessments. Self-inspection shall identify if there are problems, deficiencies or non-compliances against the quality policy, standard operating procedures (SOPs), guidelines, standards and regulations.

Methods The secret to a successful and efficient self-inspection is to adopt different standards and requirements, develop a sufficient inspection plan and assess the result and corrective and preventive action. Self-inspections shall verify compliance with the quality principles and policy of the blood establishment. Usually identify the contents of standards/legislation, quality manual, SOPs as self-inspection criteria. Self-inspection planning should include the objectives and scope of the inspection, the inspection team including the staff audited, the self-inspection audit trail. After completion of the self-inspection, the inspection report should include an action plan for non-compliances, measurements for improvement.

Results According to the severity, noncompliances should by classified into categories. Commonly used are as follows: critical, major, minor non-compliance and observation. Following risk assessment and the implementation of new preventive measurements, a new inspection may be needed and scheduled.

Conclusion In conclusion, self-inspection is part of a learning process, they should recognize the efforts given by the staff, will help to correct noncompliances effectively, and evaluate the facility's quality and operational systems to determine whether the service they provide is appropriate and in control.

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Introduction

Blood establishments undergo different types of assessments which may include the following: accreditation, ISO certification, licensing/authorization inspections, regulatory inspections by governmental authorities (competent authorities), event-related inspection, routine inspection, product-/process-related inspection and nonroutine/unannounced inspection. Self-inspection, also called internal audit or self-assessment, is a key part of the blood establishment quality management system [1].

Self-inspection serves as an ideal and valuable tool for evaluating the facility's quality and operational systems. It determines whether the service they provide is appropriate and in control. This should include risk assessment, quality indicators for processes and products, the implementation of necessary corrective/preventive actions or measurements to assist in continuous quality

Correspondence: C. Seidl, Vice Medical Director, Institute of Transfusion Medicine and Immunohematology, DRK Blutspendedienst Baden Württemberg Hessen (RCBDS), Sandhofstrasse 1, 60528 Frankfurt am Main, Germany
E-mail: c.seidl@blutspende.de

improvement and to ensure the safety and quality of blood and blood components.

The type of self-inspection includes

- Formal self-inspection carried out on a regular basis by the quality management department.
- Internal quality assessment including trend analysis of quality indicators to confirm compliance.
- Specific self-inspections in case of new processes/techniques, extended facilities.
- Ad hoc self-inspection to guide immediate corrective action in cases of errors or complaints and recall procedures.

Internal audit should be organized by the QA manager and conducted in all departments within a BE. The QA manager should be independent to give an objective assessment. The purpose of self-inspection is to verify on a regular basis whether or not it is in compliance with the internal quality policy and principles, the relevant regulatory requirements, regulations, guidelines and principles of good manufacturing practice (GMP). In general, the self-inspection will include a system-related inspection and a process-/product-related inspection part [2]. The system-related inspection will include job descriptions, qualification and training of staff, the document system including the quality manual and the change control of standard operating procedures (SOP). The process-/product-related inspection is onsite including interview of staff at operation, checking on equipment maintenance, calibration, validation of diagnostic tests and results of controls used. This shall include results of quality indicators, deviations and corrective action.

In general, the complexity of a blood establishment will require to organize the inspection precisely along an self-inspection audit trail. The audit trail will include the scope of the inspection, the relevant department and the staff in operation as well as the department director [3]. The audit trail should also take into account of previous findings and non-compliances. It is also important to perform a risk assessment and to discuss and document findings including the non-compliances or deficiencies of the self-inspection. These measures must, as a minimum, be applied to all departments involved in the collection, testing, processing, storage and distribution of blood, from donor selection systems to dispatch of the finished component [4].

This will assist the continuous improvement of the quality and safety of blood and blood components manufactures by the blood establishment. The self-inspection is also important to prepare the facility and staff for external inspections. These are regulatory inspections by governmental institutions, competent authorities based on the licence and authorization of the blood establishment. In addition, other inspections or assessments of the BE could be necessary due to accreditation schemes (such as of the AfSBT or the ISO 9000) or inspections related to third-party contracts with pharmaceutical companies of the blood establishment. In this respect, the self-inspection is also a mock audit and is the basis of different types of external assessments and audits.

Common practice for self-inspections including inspection criterions with cross-references to international standards such as GMP, good manufacturing practice (GPG) (Directive 2016/2014), PICS, and the European blood legislation has been developed recently by EuBIS [2, 5, 6].

Self-inspectors and staff being audited

The self-inspection should be conducted by designated and appropriately qualified persons. These competent inspectors are experienced individuals with excellent skills related to careful interviews and audit communication. They should have an investigative mind and knowledge of investigative techniques, an empirically driven approach using consistency and objectivity without compromising logic, and inherently honest [3].

In blood establishments and/or organization, respected technical experts and senior staff members who have

- practical experience in operational areas,
- are familiar with processes and
- knowledge of standards, guidelines, regulatory requirements, legislation,
- and have ability to communicate effectively,

can be trained as inspector to review procedures and identify problems.

Self-inspectors not only have to be competent and experienced, but also must be independent, free from bias and influences that could affect their objectivity and compliance. Training of self-inspectors should include specialized and ongoing training programmes in order to keep the inspectors up to date with new technologies and regulations and standard requirements [3]. Using unqualified inspectors increases the uncertainty of blood establishment self-inspection results and can lead to severe deficits in quality.

The blood establishment should organize an official self-inspection team which consist of a team leader and additional member who are formally trained and qualified.

The lead self-inspectors should be with experience as team member and authorized or appointed by blood establishment. The lead self-inspector serves as the contact person to co-ordinate the internal inspection and communicates with the team members.

The additional self-inspection team members should be assigned due to their special knowledge on particular processes (e.g. virology, clean room facilities). They are better

from local staff who have practical experience in operational area of the blood establishment and are familiar with the document system/SOPs.

In addition, the self-inspection team can include an assessment trainee inspector. This trainee inspector can observe experienced members as they perform all aspects of the assessment, assist inspectors to complete the evaluation and observe the preparation of the summary report.

If the self-inspector is officially part of the process or system being audited, this could also lead to skewed results. The lead inspector and team members should be part of the quality management system of the blood establishment and shall have clearly defined job description.

All inspectors should understand the process steps of conducting a self-inspection/audit, understand the process orientation, systems-based architecture and the many nuances of the regulations and standards. The quality management system of the blood establishment should develop an annual self-inspection plan. Taking into account of the structure and complexity of the blood establishment, the self-inspection plan can be set-up as a matrix, with different departments inspected at different dates. It should also take into account of processes that involve different departments and should include those into the inspection scope. The self-inspection plan contains time and evaluates the situation objectively and with no conflict of interest [2, 7].

Because self-inspection help blood establishments to find what is still needed to do for improving the QMS, the whole facility should familiarize staff with the self-inspection process. The staff should know the quality policy and principles. Based on their job description, they should be qualified and trained. This includes the numbers, location and contents of SOPs. During self-inspection, they should keep these documents at fingertips being able to give examples to the inspectors, making a good impression.

In this respect, the self-inspection is not only the common QMS assessment work for the whole facility, but also a learning–training process for the staff. It makes the staff learning practices and techniques, network with peers for ideas, questions and collaboration, share knowledge and expertise with others, discover a variety of ways to meet requirements, access the professional education and training result.

Self-inspection schedule and procedure

The frequency to perform self-inspections may depend on blood establishment requirements and should be stated in the procedure of the QMS [3]. Usually, the frequency is preferably at least once a year. If there are compliance and process uncertainties, failures and questionable anomalies within the framework of the quality system, the frequency of performing self-inspections should be increasingly redefined to accommodate timely and effective corrective action(s) and improvement.

The secret to a successful and efficient self-inspection is based on the adopted standards/legislation, inspection plan, results assessment, corrective and preventive action and risk assessment. Usually according to the procedure in the QMS manual, the inspector team identifies the self-inspection scope and creates an audit trail. Along the self-inspection audit trail, the inspectors check whether the operations are compliant with adopted standards and verify the compliance with National legislation/SOPs.

The principle for self-inspection should cover all aspects of the 'vein'-to-vein' process from donor selection, processing, testing, storage and distribution taking into account quality control points. The self-inspection should be designed to detect shortcomings in the implementation of GMP and must recommend corrective action if shortcomings are observed and set a timetable for corrective action to be completed. This should include risk assessment and requires to include the number and severity of non-compliances from previous inspection/assessment.

Blood establishments must realize that conducting effective and timely self-inspections, with advanced planning and well-thought-out schedules based on risk assessment, is critical to QMS. Self-inspection planning should include the objectives and scope of the inspection, the date and the time of the inspection, the inspection team member, their respective roles and responsibilities, the detail inspection procedure and the timetable of the self-inspection agenda.

The self-inspection procedure usually includes an opening meeting, compliance application review, on-site tour, ask questions to the on-duty staff with a list of prepared questions or interviews, using checklist or audit trails and the documentation of observations or non-compliances. A stagnant and unchanging audit schedule could mean that your QMS is perfect or that you are looking at the same things over and over again without a true return on investment. It is necessary to perform the audit prospectively, concurrently or retrospectively [4, 8].

There are a variety of tools to help carry out self-inspection, including manual recording processes, incident reporting mechanisms, gap analysis (gap between current performance and standard) and information systems.

Classification of non-compliances

Self-inspection can help the blood establishment to identify areas of gaps, deviations and non-compliances. The

identification and control of non-compliances and continual improvement are the aims of self-inspection. Based on risk assessment and the evidence, non-compliances are classified. A very common classification uses four categories [3]: (i) Critical non-compliance: any non-compliance in a process or a written procedure which directly affects the safety of the donor or patient. (ii) Major non-compliance: a serious non-compliance in a process or a written procedure but does not in its own affect the safety of the donor or patient. (iii) Minor non-compliance: a non-compliance in a system or process or there is insufficient information to classify it as a major or critical. (iv) Observation or recommendation: an inadequacy in a system or process that is not a failure to comply with standard.

The following three points should be addressed for description of the non-compliances:

- Write the details of each non-compliance in concise and understandable words.
- Give clear reference to the audit criterion or regulatory requirements so that the auditee can make reference to same while constructing corrective action plans;
- Perform a risk assessment and classify the non-compliance (e.g. critical, major, minor, observation)

In addition, justification of non-compliances can include references, pictures, copies that can help to plan the corrective actions. The auditee will have to understand the non-compliance or observation so that corrective action is approached in a 'straight-up' manner. [3]

When we face and handle non-compliances, the following facts should be considered

- Nobody is perfect
- Do not try to hide anything wrong
- Accept graciously if we are in the wrong
- Understand exact detail of NCs
- Sign and aim to fix problem
- Focus on addressing/improving system
- Address fully and avoid victimization
- NCs start high and will reduce over time with handling the NCs.

Self-inspection report and correction/ prevention measurements

After the inspection completion, the responsible person (RP), quality manager or supervisor, members of the inspection team and relevant staff members (e.g. Department director) should discuss on any relevant observation, findings, non-compliances and decide necessary immediate measures. In particular in case of critical non-compliances, immediate actions have to be decided. Following the inspection (closing meeting), a detailed self-inspection report should be written, the action plan and measurements adopted and followed up to reach full effectiveness.

The self-inspection report should be clear, concise, accurate, factual, objective and complete, not subject to misinterpretation, be simple to read and to understand, clearly related to the applicable regulations, made a permanent record.

The structure of the official inspection report should contain:

- The inspection scope and objectives of the audit.
- Details of the audit plan.
- Identification of the audit criteria against which the audit was conducted.
- Results (findings, non-compliances, observations, including the details of documents and records that were reviewed).
- Evaluation of systematic aspects of the QMS. This should include the document change control system, risk and trend analysis, product quality review, management review.
- Proposals recommended for corrective actions to reduce, eliminate and prevent product nonconformities and process defectives and timeline for corrective action.
- Responses made to these proposals and a follow-up time frame (if applicable).
- The dates of submission for any corrective actions as necessary.

The corrective action plan should be created addressing all nonconformities and deficiencies, including a time line for corrective action and a responsible person, and review status of action plan regularly. There should be an effective follow-up programme in the report to control the implementation of corrective action. This process should be supervised by the QMS. The following aspects should be taken into consideration during the follow-up period of the self-inspection:

- Corrective actions last far too long without explanation.
- The root cause analysis is incomplete and not disseminated.
- The self-inspection report is issued lately or with inconsistencies.
- The management is not apprised of the findings from the audit [7].

The management should evaluate the self-inspection report and support the measurements to be implemented following the report. Non-compliances that have been corrected during the inspection should be included in the inspection report with a statement that it has been corrected. In control measures have to be defined in case of serious adverse events or reaction (SAE/SARs) involving

donors and/or transfused patients [9, 10]. Risk assessment has to be balanced between the need for highest quality and safety of blood components versus a potential limitation in blood supply. The QMS should organize inspections, control measures, corrective and preventive actions as a dynamic, active and continuous process, aiming to guarantee best quality and safety. In general, the time limits for major non-compliances are within 14 days, other significant non-compliances are within 30 days [3, 7] Once the correction is delayed, risk assessment should be performed timely. Following the implementation of preventive measurements, a new inspection may be needed and scheduled. The management review must evaluate both the self-inspection and corrective actions and following up of results.

Conclusion

In conclusion, self-inspection can help the BE to evaluate the effectiveness and the suitability of the quality system, analyse overall performance, correct non-compliances as quickly as possible, use self-assessment as part of a learning process, identify areas for future improvement, follow-up on any recommendations, start working towards next self-assessment, recognize efforts of staff, realize the continuous improvement and strive to improve the quality and safety of collecting, processing, testing, distributing and administering blood and blood products in the blood establishment.

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Conflict of interests

The authors declare no conflict of interests.

References

1 Seidl C, Seifried E: Chapter 11. Quality management and inspection in blood transfusion medicine. in Follea G (ed): *Blood, Tissue and Cells from Human Origin*, Chapter 11. Amsterdam, European Blood Alliance (EBA), 2013:201–221. ISBN 9789082031003.

2 The European Blood Inspection Project (EuBIS) has been co-funded under the Public Health Programme of the European Commission, EuBIS homepage www.eubis-europe.eu.

3 The EuBIS inspection manual and guide are available as e-book through the EuBIS homepage (http://www.eubis-europe.eu/eubis_manual_details.php) or can be ordered as PDF (http://www.eubis-europe.eu/blood_manual_ordering.php), Edition 1·0·1, 2016

4 Wagstaf W: GMP in Blood Collection and Processing. *Vox Sang* 1998; **74**(Suppl. 2):513–521

5 European Good Manufacturing Practice (GMP) standard. Eudralex – The rules Governing Medicinal Products in the European Union. European Medicines Agency (EMEA). Available at http://ec.europe.eu/enterprise/pharmaceuticals/eudralex/ index.htm.

6 Pharmaceutical Inspection Convention/Pharmaceutical Inspection Co-operation Scheme (PIC/PICS) PIC/S GMP Guide for blood establishments, PE-005-3, 25. September 2007 under https://www.picscheme.org/

7 John Gagliardi: The Internal Quality Audit Process: risk Indicators and Uncertainties. *Biomed Instrum Technol* 2008; **42**:55–57

8 Girish P., Dennis F.: Audit in transfusion practice. *Journal of Evaluation in Clinical Practice* 1998; **4**:141–146

9 European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (EDQM): *Guide to the Preparation, Use and Quality Assurance of Blood Components*, 19th edn. Strasbourg, France, European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (EDQM), 2017.

10 European Blood and Tissue Directives are available in English or translations covering the European languages under the European Commission Portal, www.europa.eu or directly to the section of Public Health, Area of blood tissue and organs at http://ec.europa.eu/health/blood_tissues_organs/policy/index_en.htm