

E4. MONITORING AND CONTROL OF THE QUALITY MANAGEMENT SYSTEM IN BLOOD ESTABLISHMENTS: INSPECTION, SELF INSPECTION

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Introduction: Directive 2002/98/EC setting up standards of quality and safety for all specific activities of a BE foresees compliance control actions organized under the authority of the competent authority, through inspections and other appropriate measures, depending on the situation.

Monitoring and control of the quality management system in BE are key elements to ensure its functionality and improvement. Directive 2005/62/EC establishes that mandatory self-inspections must be organized by the BEs. Order 946/2005 establishes that it is mandatory for public institutions to organize an internal managerial control system. To ensure smooth and functional implementation of all these requirements corroborated and achieve as outcome a real improvement of medical activity is a challenge for the management team.

Objectives: Presentation of inspection and self-inspection scope and purpose and their benefits in terms of monitoring and improvement of the implemented quality system. Topics to be developed: types of inspection, how to prepare for inspection, attitudes during inspection, inspection reports; elaboration of self inspection plan, organization and valuing of its results, integration in the overall internal control measures plan.

Methods: National regulations-Law 282/2005, Order 1225/2006, 607/2013, 1132/2007, 1228/2006 - establish general requirements for inspection and self inspection. On this basis, a general national procedure will be developed (for inspection) and specific local procedure for each BE may be developed. There are various international guidelines and recommendations on these control activities. Taking into account the organizational and criteria diversity for both inspection and self-inspection among MS, the EC initiated a project to develop a guide for inspection and self inspection: EUBIS. Romanian Ministry of Health translated the guide into Romanian. This may be used as a documentation source for organizing inspection and self-inspection under a common national model; in case of self –inspection, it should be adapted to specific conditions of each institution, based on a risk assessment approach.

Results: Based on EUBIS guide and additional information on the practical aspects, the responsible persons in BEs may prepare self- inspection plans and organize such activities as a tool to assess the QMS effectiveness and efficiency.

Conclusions: Inspection and Self- inspection programs developed based on objective risk analysis and root-cause analysis (if applicable) can provide the competent authority and BEs management documented evidence of the level of quality and safety transfusion activities either nationwide, or institutional.