## E9. MAINTAINING QUALITY DOCUMENTS IN BRASOV BLOOD TRANSFUSION CENTER.

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**Introduction**. Complying with the requirements of EU legislation, BTC Brasov, like each blood transfusion center in the country, had to realize and maintain a quality system based on the Guide on Good Practice of Directive 2003/94/EC and meet the requirements specified in Directive 2005/62/EC, transposed in our Law 282/2005.

The quality system is very important to ensure the quality and safety of blood components produced and supplied to hospitals and to ensure the safety and satisfaction of blood donors. To cover all activities that influence the quality of blood components produced by BTC Brasov, it was necessary to create rules, objectives and responsibilities clearly defined and to apply them through planning, quality control, quality assurance and continuous improvement.

**Working method**. This system has always tried to ensure that, if possible, the processes taking place in the BTC Brasov are specified in appropriate instructions, that they are carried out according to the principles of good practice and they respect current standards, domestic and international.

A representative of Quality Management has been appointed, in 2007 (RQM).

This, along with others in Brasov BTC drafted Standard Operating Procedures (SOP) that describe in detail the work of each department, General Procedures (GP) which establish rules of conduct and activities available for the whole institution, and all other internal documents of quality. All documents produced were recorded annually in the document control register.

The document control system involves also reviewing all documents, periodically, once a year, or by necessity when working procedures changes occur due either to change the law or to the acquisition of new equipment. Thus, in 2011, in the Laboratory of Biochemistry a change for all SOP has been required, due to purchase Vitros Biochemistry Analyzer and Hematology Analyzer MEK-6400.

In the Quality Control Laboratory, also due to purchase new equipment (Hematology Analyzer MEK-6400 and Bacteriology Analyzer BacT/ALERT 3D) all the control procedures were completely changed, both haematological and bacteriological control procedures.

The need to draft new operating procedures permanently appeared, due to trying to improve and diversify the blood testing methods, for example in the Laboratory of Immunohematology, where we introduced new techniques of donors extensive phenotyping.

RQM kept, in electronic format, all internal quality documents, quality control registers, year by year, records of reviews, year by year and all archiving documents.

Also archived in electronic format and on paper, all quality documents that are out of service, for a period of 15 years, according to the regulations.

**Conclusions**. All theese provide good traceability, according to the EU requirements. We tried that documentation is accessible to all (each containing a distribution list) and be drawn as clearly, while respecting data protection laws.
The BTC management always checks RQM activity, there is also a permanent information, consultation and cooperation, in both directions, as a mechanism for evaluation and continuous improvement. Where appropriate remedial measures are applied.