

## Quality Management in Dialysis – a Must for You and Your Patients!

The service provision in the health sector requires quality and transparency. It is foreseeable that the reimbursement for treatments will be linked to the fulfilment of defined quality criteria – as it has already been implemented in Germany and other countries. Tenders often demand a QM certificate.

As a responsible operator of a dialysis center, more and more is required from you and your service: As health services continue to evolve, it must be conveyed to the critical patients that they are receiving the best possible care. We can help you to meet this challenge. We audit and certify your quality management system.

### What is “Good Dialysis Practice”?

“Good Dialysis Practice” is a certification mark which is exclusively issued by TÜV SÜD Product Service.

- It stands for approved quality and safety of dialysis units.
- It is used Europe-wide by dialysis units to demonstrate quality and safety to patients and other interested parties.

The design of the mark is based on the TÜV SÜD Group corporate certification seal design, the blue octagon. This octagon showing the TÜV SÜD logo is very well known and accepted by consumers as a mark of quality and safety. It is used in many industrial and service areas.

“Good Dialysis Practice” will be awarded after a successful system and safety audit of a dialysis unit according to

- EN ISO 9001:2000 “Quality Management Systems – Requirements”
- Draft of DIN VDE 0753 part 4 “Guideline for the safe use of medical products in dialysis treatment”. This document defines requirements for the safe and proper use of dialysis systems for the treatment and care of dialysis patients. This guideline can be obtained from the DIN Institute ([www.normung.din.de](http://www.normung.din.de)).

### Among other things, these guideline requires:

- Instruction of the users with regard to the safe handling of the medical devices
- Monitoring, operation and maintenance of e. g. dialysis machines, water-treatment units
- Compatibility of medical devices (disposables and machines)
- Requirements with regard to electric safety
- Hygiene guidelines for the treatment and operation of machines
- Implementation of legal precepts
- Periodical examination of patient and treatment system during treatment

### **Quality and Safety combined with Optimal Economic Efficiency**

Almost all medical products your patients are treated with have been tested by us for safety. The manufacturers of these products have been audited, ensuring the consistent quality of dialysis machines, water treatment systems, blood tube systems, dialyzers and dialysis concentrates.

You can rely on these products and concentrate on your patients. Through "Good Dialysis Practice", you ensure both: high quality of treatment and care of your patients and economic efficiency. Consistently safe use of medical devices and associated equipment is guaranteed. Any medical responsibility with respect to freedom of therapy remains unaffected in this connection.

You can attain your quality and safety goals by improving the efficiency of your organization while contributing to cost reduction at the same time.

### **Certification gains in importance**

Within the scope of risk evaluation, certification of dialysis practices increasingly gains importance. More and more health insurances require it when asked to pay reimbursement.

Furthermore a certification will help you to increase the patients' confidence placed in you.

Last but not least, you will stand out against competitors and thereby gain a competitive advantage – especially if our TÜV SÜD „Good Dialysis Practice“ seal of certification which is well-known all over Europe is presented openly.

And another advantage for you: Our competence and experiences both with regard to quality management (ISO 9001) and to product safety offers you everything "from one source".

### **Process Oriented Approach**

The interdisciplinary process oriented approach of the EN ISO 9001:2000, which also defers to services, is applied by TÜV SÜD Product Service for the certification of dialysis clinics.

The ISO standard does not specify how to conduct, but it defines a minimum of general requirements in order to establish a quality system. You define the processes such as patient care, procurement of medical products, technical service, training of employees and implementation of hygiene measures.

A user-friendly management system based on the description of the processes involved will be set up. The first step to this may be to establish a quality circle describing and organizing your employees' daily work.

### Why TÜV SÜD Product Service as certification body?

- A logical connection: safety and quality with the competence and experience of Europe's biggest Notified Body and world market leader in the dialysis equipment testing business.
- Most experienced certification organization for dialysis units (first certification in Germany in June 1998).
- International experience: certified dialysis clinics throughout Europe and Asia.
- Minimum audit time for a dialysis unit is one day.
- The good and well-known name of TÜV SÜD Product Service and the Octagon certification mark of TÜV SÜD.
- Audits performed by experienced, specially trained and authorized auditors.
- Most of the CE marked medical devices used in dialysis are marked with the TÜV SÜD Product Service identification number "CE 0123". This means that we were involved in the conformity assessment procedure.
- Close links to manufacturers and service providers because of our role as Notified Body and certification body, e. g. for technical services.
- We are informed about the actual safety problems of medical devices.
- We play an active part in the standardization body of DKE which is concerned with the safety with regard to development, production and use of medical devices in dialysis.
- We work very closely together with EDTNA.

**The TÜV SÜD certification is considered worldwide to be a sign of quality, safety and environmental friendliness.**

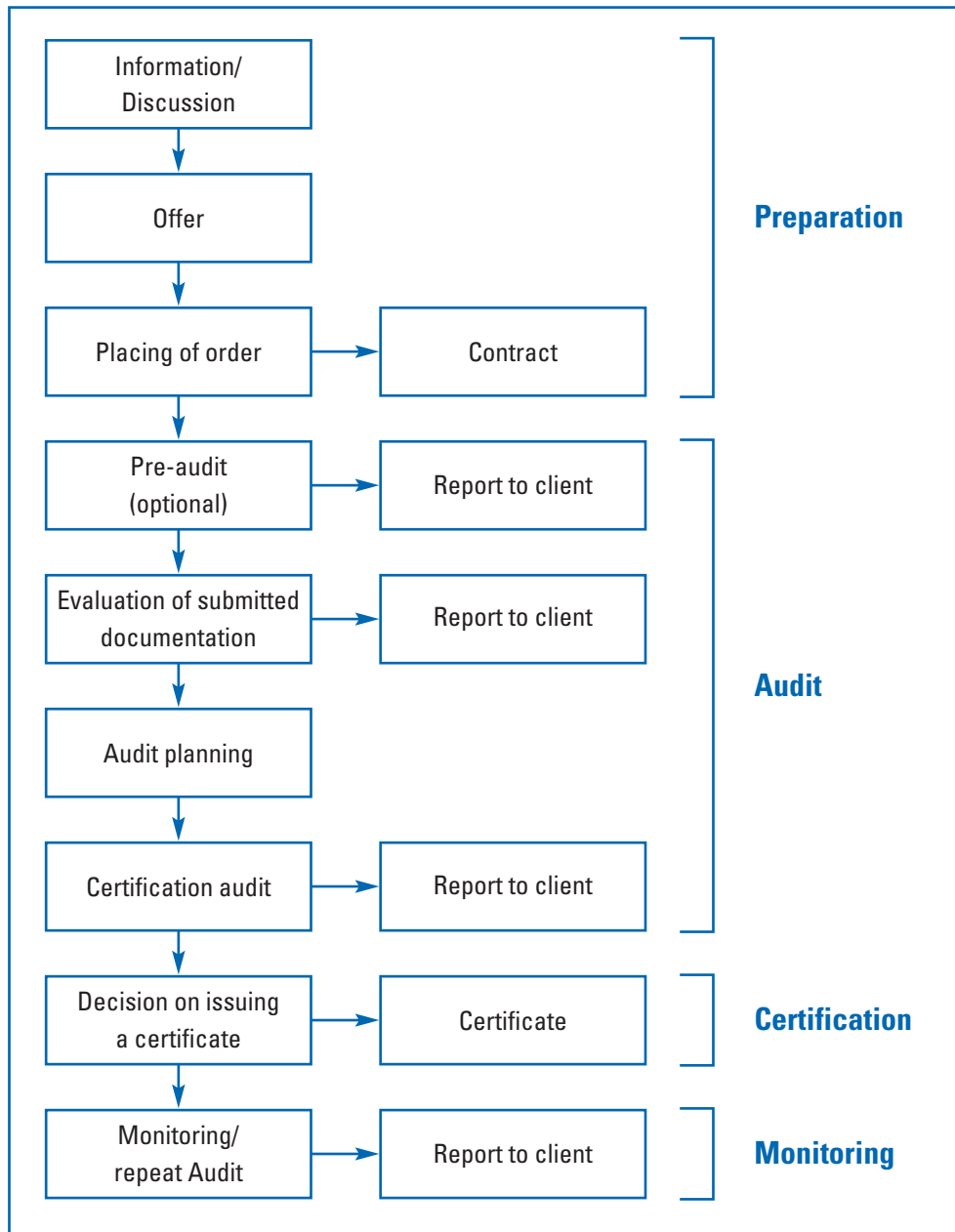


### Advantages for your organization

- Fulfilment of current and planned legal requirements
- Differentiation from competitors
- Increased efficiency, transparency in the procedures, prevention of errors and double work
- Improvement of employee motivation
- Increasing trust in your services
- Safeguarding your quality standards
- Our estimated independence

### Certification Process

Expert assessment and certification process follow a sequence which has been successfully used for QM systems. It is flexible and can be easily adapted to specific requirements of each dialysis unit.



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