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# Quality management and safety in dialysis

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

As 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 (ISO 9001) and safety (IEC/TR 62653) 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. The TÜV SÜD octagon is very well known and accepted by consumers as a mark of quality and safety. It is used in many industry and service areas.

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

- EN ISO 9001:2015 “Quality management systems – requirements”
- IEC/TR 62653 Edition 1.0 2012-06 “Guideline for safe operation of medical equipment used for hemodialysis treatment”

### Among other things, the new international Technical Rule IEC/TR 62653 requires:

- Prevention of patient endangerments, which are not recognized by dialysis machines
- Periodical examination of patient and treatment system during treatment
- 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



## The TÜV SÜD certification mark stands for quality, safety and environmental friendliness worldwide

Advantages for your organization:

- Fulfillment of current legal requirements
- Risk reduction as part of the risk management for your unit
- Increased efficiency, transparency in the procedures, prevention of errors and double work
- Improvement of employee motivation
- Increasing patients' trust in your services
- Our esteemed independence
- Increased legal certainty
- An evaluation according to ISO 14001 is available as option

## Quality and safety combined with optimal economic efficiency

Almost all medical devices used for treatment of your patients have been tested for conformity with the Essential Requirements of Directive 93/42/EEC (MDD). The manufacturers of these devices have to undergo respective audits, ensuring the consistent quality of dialysis machines, water-treatment systems, blood-tube systems, dialyzers, and dialysis concentrates.

With "Good Dialysis Practice" you ensure both: high quality of treatment and care of your patients as well as economic efficiency. Consistent safe use of medical devices and associated equipment according to the state of the art is also guaranteed.

Routine treatment involves some residual risks not covered by dialysis equipment or other medical devices. The operating manuals of these products contain comprehensive warnings pointing out the operator's responsibilities with respect to safety. In addition, numerous measures must be performed to ensure the safety of the treatment.

Application of IEC/TR 62653 in connection with ISO 9001 shows how residual risks and errors in day-to-day routine can be systematically minimized in the interests of patient and operator safety.

## 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 confidence patients place in you. Especially if our TÜV SÜD "Good Dialysis Practice" certification mark, which is well known worldwide, is presented openly.

And another advantage: Our competence and experience both with regard to quality management (ISO 9001) and to product safety offers you everything from a single source. Any medical responsibility with respect to freedom of therapy remains unaffected.

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

## 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.
- The trusted name of TÜV SÜD Product Service and the well-known certification mark of TÜV SÜD.
- Audits performed by auditors who speak your language with long-time experience in dialysis.
- 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 IEC/DKE which is concerned with the safety with regard to development, production and use of medical devices in dialysis.
- We work together with EDTNA.

## Process-oriented approach

The interdisciplinary process-oriented approach of the EN ISO 9001:2015, which also refers to services, is applied by TÜV SÜD Product Service for the certification of dialysis clinics.

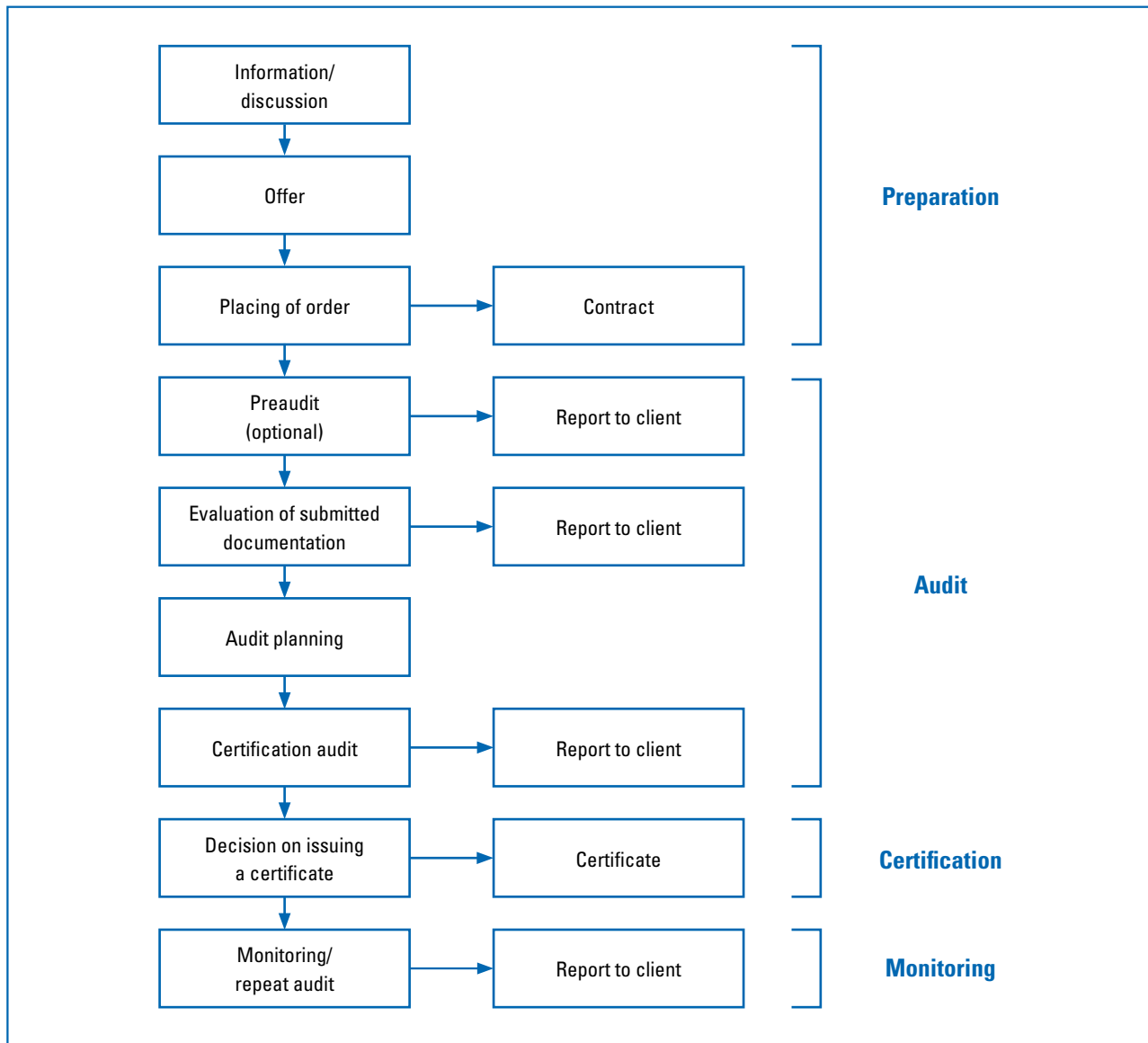
The ISO standard does not specify how to conduct a process, but it defines a minimum of general requirements in order to establish a quality system. You define the processes such as patient care, procurement of medical devices, technical service, training of employees, and implementation of hygiene measures.

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.

## 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 the specific requirements of each dialysis unit.



**Your contact partner at TÜV SÜD Product Service can provide further information.**

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