Preface to the 2nd Edition

The content of the first edition of the guidelines[1] represents a standard ("Best-practice guidelines") which was worked out by experts of a national multi-professional working group dealing with the subject "Applied Hygiene in Dialysis". Important reason for the publication of the first edition was a deficit of binding statements from manufacturers and distributors dealing with the questions of hygiene during the use of medical devices and a lack of practically orientated descriptions of measures for operators, managers and users in the existing guidelines, regulations and laws.

Due to the developments in Europe, a changed engineering process and alterations in current and future legislation, it makes sense to look at hygienic processes in the second edition under the view points of an already process-orientated quality management system. The goals are to be predetermined according to the requirements, and measures to respect the limit values shall be described. They can be requested by examining bodies and have to be corrected using adequate measures in case of infringements as well as deviations.

The cross-reference to quality management as the basis of hygiene management and the scientific claims of the group requires that the requests mentioned are supported by valid literature citations. As a result, the working group carried out extensive literature research during the revision of this edition.

More than ever before, quality of treatment has to orientate itself towards economic requirements and standards. In the meantime the legislator has placed higher priority on prevention. As a result, investments for the prevention of additional complications and

[1] Leitlinie für die Praxis der angewandten Hygiene in Behandlungseinheiten für Dialyse, Hrsg. Arbeitskreis für angewandte Hygiene in der Dialyse, Pabst Science Publishers, 1998

costs under the aspect of security and efficiency can have a noticeable effect on the current running costs of treatment, care and technical provisions.

The present work is the result of the participation of highly committed experts. The result of this national and multi-professional working group is based on detailed knowledge, long term experience, diversity and the ability to reach consensus. I would like to thank all the members of the working group and the task groups for their excellent collaboration as well as the companies involved for their advice and their financial and technical support.

Alois Gorke
Co-ordinator of the working group

Additional preface to the translated 2nd Edition 2008 in English

A multidisciplinary workgroup in Germany has published two editions of "Guideline for Practical Hygiene in Dialysis Units" in 1998 and 2005.

The workgroup was founded in 1993 and, over the years, has included approx. 35 organisations and 50 co-workers. Both user organisations, doctors, nurses, hygienists, microbiologists, laboratories, producers of dialysis equipment, producers of water systems for dialysis, virologists, producers of disinfectants and nephrologists have participated.

The "Guideline" is covering all aspects of hygiene in dialysis. Since dialysis as such is an universal procedure, the issues of hygiene will be similar regardless of geographical area.

The workgroup wish to spread the knowledge, experience and information in the "guideline", which has been put together.

There are few documents in the field of hygiene which are covering all aspects.

Some references to laws and regulations are directed to German conditions, but these may of course be replaced by applicable local regulations and/or recommendations.

The workgroup is hoping that the English edition of the "Guideline" will prove to be an easily comprehensible and efficient reference for hygiene issues in the daily work in dialysis units.

Dr. Rolf Nystrand

1 Introduction

Treatment units for renal replacement therapy, e.g. various methods of dialysis, are among the areas with possible risk of infection.[2] The immunodeficiency of the dialysis patient, the risk of transmission of infectious diseases (e.g. hepatitis B viruses (HBV), hepatitis C viruses (HCV), human immunodeficiency virus (HIV) and multi-resistant pathogens (MRP)), the high technical demand of the treatment as well as the requirement for a regular repetition of the treatment, all these factors require that a distinct consciousness and behaviour concerning hygiene is respected by all those concerned within the facility.

The working group, called "Arbeitskreis (AK) für angewandte Hygiene in Dialyseeinheiten" ("Working Group for Applied Hygiene in Dialysis Units" in Germany) started work in May 1993. It arose from the obvious need of reproducibility of the disinfection procedures of the various dialysis machines and supply systems. At that time, guidelines and legal instructions as well as the information of the manufacturers of devices and procedures left important unanswered questions about their use in current practise.

The working group collects and discusses the experience and knowledge of hygiene in current practice of dialysis considering international publications, e.g.

– Infektionsschutzgesetz (Infection Protection Act),
– Guidelines for hospital hygiene and prevention of infections of the Robert Koch Institute[3] (RKI),
– Dialysis standard of the German Working Group for Clinical Nephrology[4] (DAGKN),

[2] RKI-Empfehlung: Anforderungen der Hygiene bei Reinigung und Desinfektion von Flächen. Bundesgesundheitsbl – Gesundheitsforsch – Gesundheitsschutz, 2004 (47): 51-61 (www.rki.de)

[3] RKI: www.rki.de

[4] DAGKN: www.nephrologie.de

– Application rules for haemodialysis of the German Commission for Electrical, Electronic & Information Technologies (DKE)[5]

and other European and International standards with the goal to jointly compile practice-oriented and hygiene-conscious guidelines for the work of dialysis staff.

The latest version is always valid when using legal texts and referring to internet addresses. All the internet addresses cited were checked at the time of going to press. Deviations from the text of this guideline and supplements are possible.

1.1 Goals, Structure and Working Method of the Working Group

The working group set itself the general goal of quality assurance and improvement in the field of hygiene in dialysis. At the same time partial goals are to be considered:

- Deepening the knowledge of the users, the companies involved and other professional groups on hygiene in dialysis
- Re-examining the relevance of existing guidelines to the present circumstances and translating them into practice
- Compiling the basics for the education of users
- Putting together recommendations and requirements for the manufacturers of technical installations and dialysis machines as well as consumables
- Developing standards for collecting, examining and evaluating microbiological samples
- Informing the associations and decision-making organs on the expert opinion and adding these to the guidelines
- Adjusting/revising the existing guidelines

[5] DKE: www.dke.de

The participants come from companies, providers of dialysis treatment, nephrological therapy, nursing and care associations, public authorities and other organisations.

Within this circle there are:

- Physicians specialised in nephrology
- Nephrology nurses
- Dialysis technicians
- Hygienists and microbiologists
- Engineers for occupational health and safety, construction, environment and hygiene among others
- Manufacturers and distributors of medical devices (dialysis machines, water treatment plants and dialysis consumables) and disinfectants.

The working group met about 4 times per year till the end of the revision for a new edition of the guideline.

The revision of individual chapters, the discussion and exchange during meetings and in electronic form with up-to-date return took place in sub-committees and results were sent back to the co-ordinator/moderator of the working group who took care that the texts were distributed to all the working group members for comments and discussion during the working group meetings.

Chapters which have already been approved cannot be changed without the approval of a majority of the working group. Propositions for changes will be sent to the co-ordinator of the working group who after consulting the working group can arrange for further action.

The working group named an editorial board which was responsible for the completion of the new edition. Printing and if necessary reprints were and will be ordered by the co-ordinator. The working group members will be informed before the printing order is given.

1.2 Purpose

The guideline serves all professional groups mentioned above who are directly or indirectly involved in the supply, care, nursing, and therapy of dialysis patients as well as the assessment of hygienic treatment standards.

Advantages for the User
The guideline provides a bridge between external documents (e.g. laws, guidelines, and regulations) and internal documents (e.g. hygiene plan). Processes which are embedded in quality management become clear. The guideline shall represent a reference book which links hygiene with quality management and gives answers to practical questions.

Advantages for the responsible organisation
Streamlining and optimising the process, prevention of mistakes and their resulting costs as well as the improvement of treatment safety are striven for. The areas of responsibility become clearer. Documented processes ease the tractability as well as the assessment and education of new employees. Analyses of weak points ensure increased treatment safety. The documented evidence of achieved treatment and quality results will become even more important in the future.

1.3 Usage and Assessment

1.3.1 Language of the Guideline

In this guideline, the modal auxiliary verb
– "must" (also "is/are to" or "has/have to") means that the observance of a requirement or the passing of an examination is an unconditional commandment (urgent recommendation which is scientifically proven: evidence-based) to observe these rules.
– "shall" means that the observance of a requirement or the passing of an examination is being recommended (recommenda-

tion according to expert opinion), however the compliance to these regulations is not an unconditional rule.
– "can/may/might" means that the observance of a requirement or the passing of an examination represents a possibility or an attempt at a solution.

In this form, the guideline linguistically follows other directives or norms closely.

Remark:
The Robert Koch Institute adds one more category IV in their Guidelines. These are based on laws and decrees[6].

1.3.2 State of Technology

The state of technology is referred to in Directive 93/42 EEC Medical Device Directive (MDD)[7]. "The state of technology is the stage of development of progressive processes, installations and operational modes which according to the prevailing opinion of leading specialists assures the attainment of the legally fixed goals. The codification of the state of technology also conforms to the regulations in other legal sectors (e.g. for machines which need Surveillance and X-ray installations) as well as the purpose of the present law in the interest of preventive health care. Thus it is also in accord with Council Directive 93/42/EEC. Likewise reference ismade there in Annex I to the state of the technology as it is generally recognised in EU countries."[8]

Remark:
The introduction of medical devices is regulated in Article 2 of the Medical Device Directive (MDD) [93/42/EEC] placing on the market and putting into service for all EU member states. This EC-Directive was put into national law by the

[6] Vorwort und Einleitung zur der Richtlinie für Krankenhaushygiene und Infektionsprävention. Bundesgesundheitsbl – Gesundheitsforsch – Gesundheitsschutz, 2004 (47): 409-411 (www.rki.de)

[7] Council Directive 93/42/EEC of 14th June 1993 on medical devices.

[8] Stellungnahme des Bundesrates zu § 17 Abs. 1 Nr. 6 des Entwurfes des Medizinproduktegesetzes. Bundestag-Drucksache 12/6991, 8. März 1994 (www.parlamentsspiegel.de)

Medical Devices Act (MPG). In § 14 (MPG) installation, operation, use and maintenance of medical devices is referred to § 37 paragraph 5 which authorises the Federal Ministry of Health to determine the installation, operation, use and maintenance of medical devices. This authorisation was realised through the Medical Device Operator Ordinance (MPBetreibV). The introduction is regulated in § 5 section 1 clause 2 and annex 1.

1.3.3 Approved Disinfectants and Procedures

If disinfectants and procedures are named, they refer to disinfectants and procedures which have been tested according to the present state of science and have been found effective; at least the limited spectrum of virucidal activity must have been proven. Sources for disinfectants are the lists of professional organisations, e.g. DGHM[9], RKI with the list for epidemic cases.[10]

Editorial note:
According to a joint statement of the Robert Koch Institute (RKI), the German Society for Hygiene and Microbiology (DGHM), the German Association against Virus Diseases (DVV) and the German Society of Hygiene and Microbiology, there is a distinction between a virucidal and a limited virucidal activity. The term "limited virucidal" describes the activity against enveloped viruses e.g. HBV, HCV, HIV, while "virucidal" has an additional activity against non-enveloped viruses e.g. polio viruses, HAV, Norwalk-like viruses[11].

[9] List certified according to the Directive for the examination of chemical disinfectants and accepted by the German Society for Hygiene and Microbiology (DGHM) to be effective disinfection procedures and procedures for the hygienic washing of hands. (www.dghm.de)

[10] List of the examined and accepted disinfectants and procedures by the Robert Koch Institute. Federal Health Gazette – Health Research – Health Protection, 2003 (46): 72-95. (www.rki.de)

[11] Examination and declaration of the effectiveness of disinfectants against viruses, statement of the Working Group Virucides of the Robert Koch Institute as well as the Committee of Experts "Virus Disinfection" of the German Association against Virus Diseases (DVV) and the Disinfectant Commission of the German Society for Hygiene and Microbiology (DGHM). Federal Health Gazette – Health Research – Health Protection, 2004 (47): 62-66 (www.rki.de)

1.4 Quality and Hygiene

1.4.1 Quality and Hygiene Management

Quality management has its origins in the manufacturing industry. It was there that ideas dealing with quality management were systematically developed and out of this a doctrine was developed which brought an enormous increase in quality for many companies.
The secret of its success lies in the fact that attention is not only directed to the quality of a product or the outcome of a service (outcome quality), but the quality desired is already systematically "planned in" and monitored during the development of a product or service. Furthermore, the general conditions and processes have to be attuned to the desired quality.
These findings can be directly applied to the hygiene management. Defined hygienic conditions can only be achieved when the required structural preconditions are fulfilled and all activities,

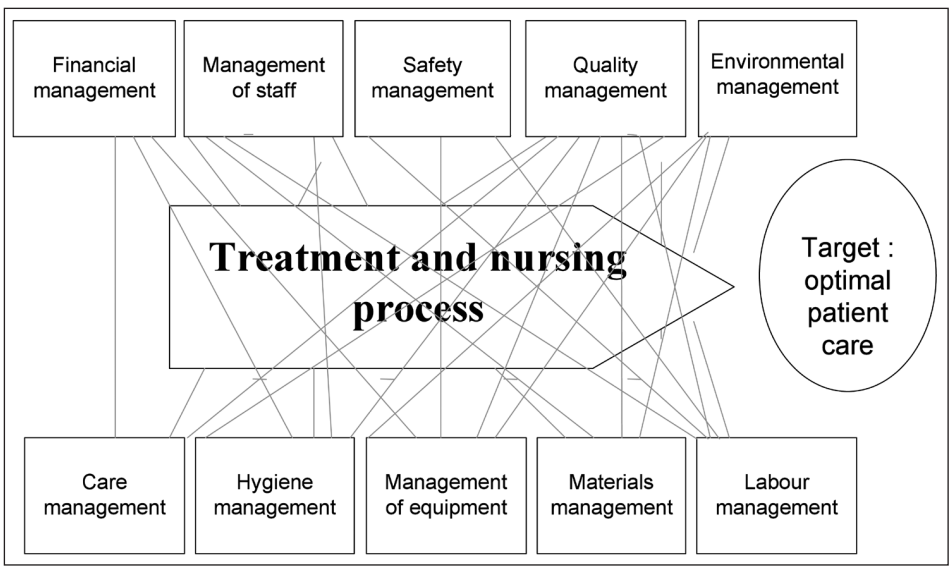


Fig. 1: Interconnectedness of different processes of a dialysis unit

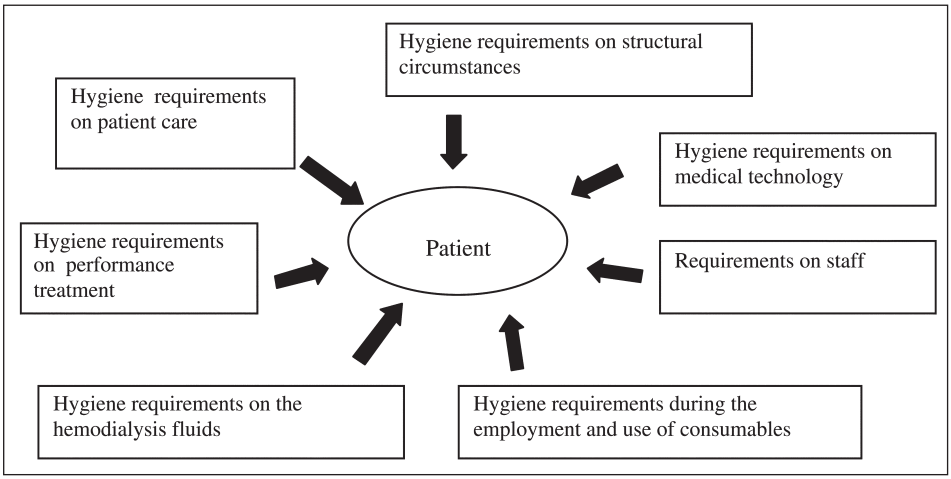


Fig. 2: Hygiene requirements and patient orientation

operations and processes are co-ordinated according to the results to be achieved. Among these are also processes which are not directly linked to hygiene or have apparently nothing to do with it. Therefore hygiene management shall always be seen as part of the whole management system, because many measures are mutually dependent and influence each other.

1.4.2 The Patient at the Centre of Attention

All processes and activities have to be in line with the expectations and requirements of the patient. It is thus logical that hygiene management also has to be focussed on the patient.

1.4.3 Continuous Quality Improvement of Hygiene in Dialysis

The basic principle of every functional management process is the continuous monitoring, further development and improvement of

applied activities, procedures or actions. The system will then be adapted not only to constantly changing external conditions like new technologies or legal directives but also to internal changes.

Therefore hygiene management shall be set up according to the same principles. Regular monitoring for suitability and efficacy is indispensable.

This has been tried and tested in practice using the Deming or PDCA cycle; "plan, do, check, act"[12]. It obliges the user to regularly check the system for weak points and possible improvements.

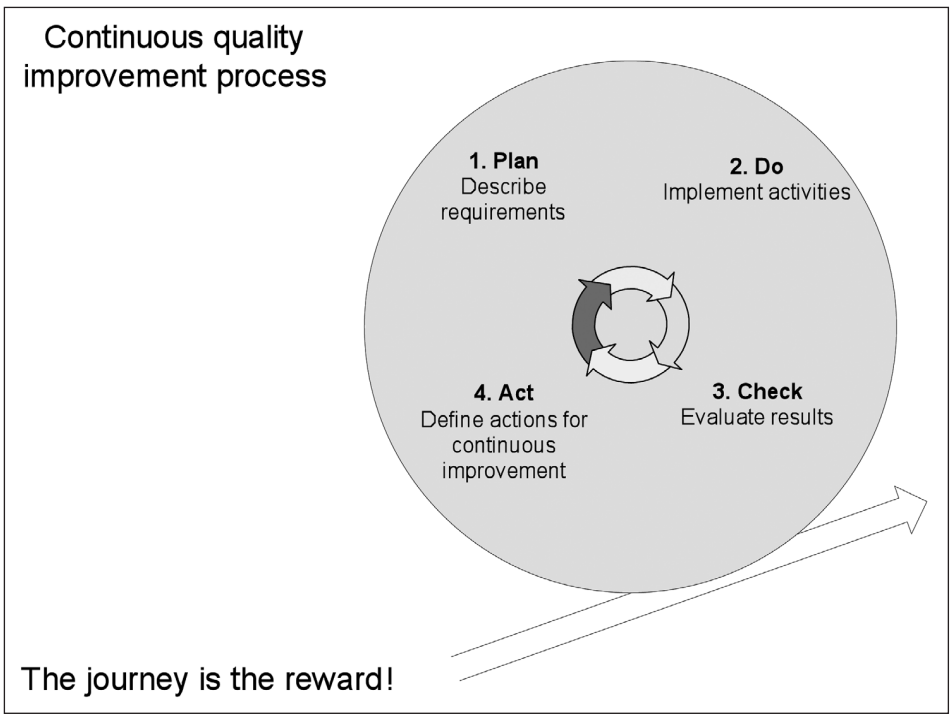


Fig. 3: The continuous improvement process

[12] www.qm-infocenter.de

The guideline supports the use of a continuous quality improvement process according to the PDCA principle:

- Description of the requirements
- Implementation activities
- Possibilities of evaluation of results
- Possible actions to be undertaken when nonconformity was observed.

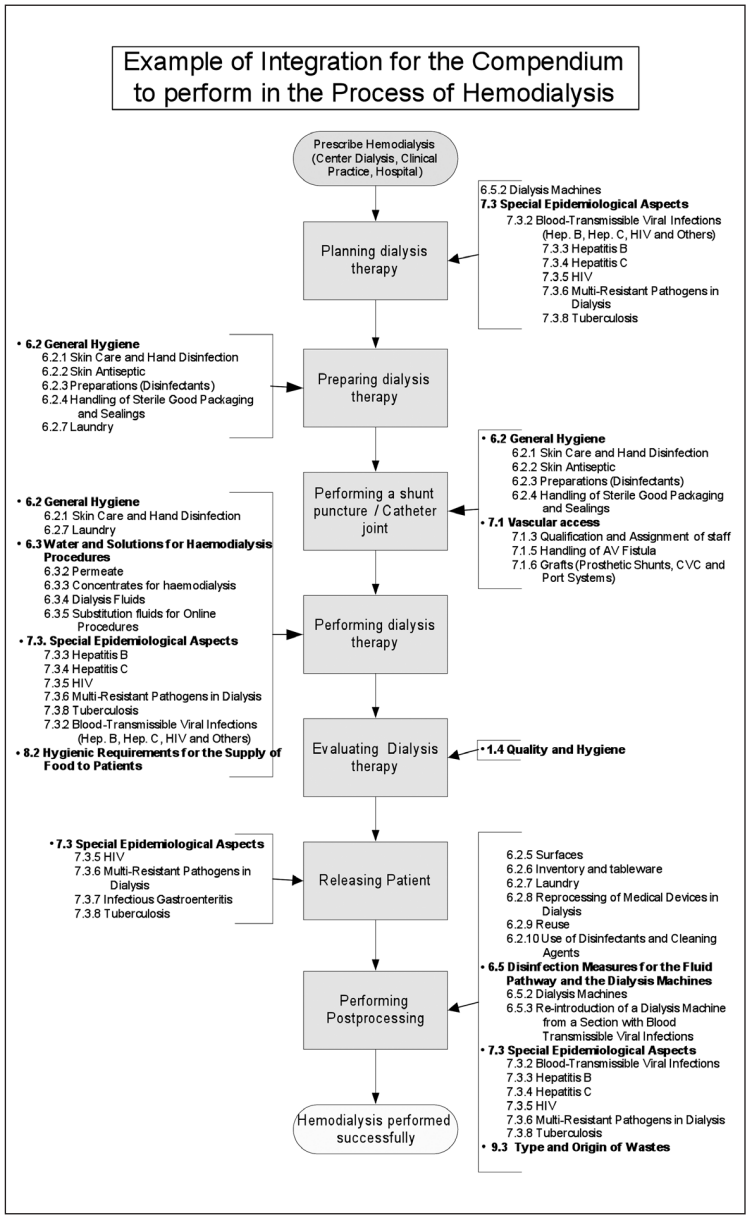
1.4.4 Integration of the Guideline in a QM System

Hygiene measures are part of very different processes. If a hygiene management system is to be implemented in a dialysis unit, then the general processes have to be described first and secondly the necessary hygiene requirements are to be integrated in the procedures.

The reader can choose the relevant actions from the guideline. At the same time, indications are given how to evaluate the results of the actions taken. Additional suggestions for documentation can be used.

The checklists included in the guideline support the implementation of the required measures into practice.

This Guideline does not follow a particular model for quality management e.g. DIN EN ISO 9001:2000 so that it can be integrated in various QM systems.


Example of Integration for the Compendium to perform in the Process of Hemodialysis
Prescribe Hemodialysis (Center Dialysis, Clinical Practice, Hospital)
Planning dialysis therapy
6.5.2 Dialysis Machines
7.3 Special Epidemiological Aspects
7.3.2 Blood-Transmissible Viral Infections (Hep. B, Hep. C, HIV and Others)
7.3.3 Hepatitis B
7.3.4 Hepatitis C
7.3.5 HIV
7.3.6 Multi-Resistant Pathogens in Dialysis
7.3.8 Tuberculosis
Preparing dialysis therapy
6.2 General Hygiene
6.2.1 Skin Care and Hand Disinfection
6.2.2 Skin Antiseptic
6.2.3 Preparations (Disinfectants)
6.2.4 Handling of Sterile Good Packaging and Sealings
6.2.7 Laundry
Performing a shunt puncture / Catheter joint
6.2 General Hygiene
6.2.1 Skin Care and Hand Disinfection
6.2.2 Skin Antiseptic
6.2.3 Preparations (Disinfectants)
6.2.4 Handling of Sterile Good Packaging and Sealings
7.1 Vascular access
7.1.3 Qualification and Assignment of staff
7.1.5 Handling of AV Fistula
7.1.6 Grafts (Prosthetic Shunts, CVC and Port Systems)
Performing dialysis therapy
6.2 General Hygiene
6.2.1 Skin Care and Hand Disinfection
6.2.7 Laundry
6.3 Water and Solutions for Haemodialysis Procedures
6.3.2 Permeate
6.3.3 Concentrates for haemodialysis
6.3.4 Dialysis Fluids
6.3.5 Substitution fluids for Online Procedures
7.3. Special Epidemiological Aspects
7.3.3 Hepatitis B
7.3.4 Hepatitis C
7.3.5 HIV
7.3.6 Multi-Resistant Pathogens in Dialysis
7.3.8 Tuberculosis
7.3.2 Blood-Transmissible Viral Infections (Hep. B, Hep. C, HIV and Others)
8.2 Hygienic Requirements for the Supply of Food to Patients
Evaluating Dialysis therapy
1.4 Quality and Hygiene
Releasing Patient
7.3 Special Epidemiological Aspects
7.3.5 HIV
7.3.6 Multi-Resistant Pathogens in Dialysis
7.3.7 Infectious Gastroenteritis
7.3.8 Tuberculosis
Performing Postprocessing
6.2.5 Surfaces
6.2.6 Inventory and tableware
6.2.7 Laundry
6.2.8 Reprocessing of Medical Devices in Dialysis
6.2.9 Reuse
6.2.10 Use of Disinfectants and Cleaning Agents
6.5 Disinfection Measures for the Fluid Pathway and the Dialysis Machines
6.5.2 Dialysis Machines
6.5.3 Re-introduction of a Dialysis Machine from a Section with Blood Transmissible Viral Infections
7.3 Special Epidemiological Aspects
7.3.2 Blood-Transmissible Viral Infections
7.3.3 Hepatitis B
7.3.4 Hepatitis C
7.3.5 HIV
7.3.6 Multi-Resistant Pathogens in Dialysis
7.3.8 Tuberculosis
9.3 Type and Origin of Wastes
Hemodialysis performed successfully

2 Legal Basis

2.1 Definition of Responsibilities

The responsible organisation bears the overall responsibility for the dialysis units operated. An appropriate organisational framework must be provided, which ensures a functioning work process, considering all relevant legal regulations for the organisation

- §§ 618 und 823 Bürgerliches Gesetzbuch – BGB (German Civil Code)
- § 62 Handelsgesetzbuch – HGB (Commercial Code)
- § 120 Gewerbeordnung – GewO (Industrial Code)
- §§ 9 and 130 Ordnungswidrigkeitengesetz – OwiG (Administrative Offences Act)
- §§ 13 and 14 Strafgesetzbuch – StGB (Penal Code)
- §§ 1, 8, 34, 35, 36, 42 and 43 Infektionsschutzgesetz – IfSG (Infections Protection Act)
- §§ 1, 2, and 4 Medizinproduktgesetz – MPG (Medical Devices Act)
- §§ 1-9 Medizinprodukt-Betreiberverordnung – MPBetreibV (Medical Device Operator Ordinance)
- §§ 3, 5-6 Arbeitsschutzgesetz – ArbSchG (Health & Safety at Work Law)
- §§ 2-14 Berufsgenossenschaftliche Vorschriften (BGV), Allgemeine Vorschriften – BGV A 1, Unfallverhütungsvorschrift, Grundsätze der Prävention (Regulations of the Employers' Liability Insurance Association)
- §§ 1-5, 7-16 Biostoffverordnung (Biological Agents Ordinance)
- Technische Regeln biologische Arbeitsstoffe ("Technical regulations for biological agents") (BGR 250/TRBA 250 „Biologische Arbeitsstoffe im Gesundheitswesen und in der Wohlfahrtspflege") ("Biological agents in the health care system and welfare work")
- TRBA 400 „Handlungsanleitung zur Gefährdungsbeurteilung bei Tätigkeiten mit biologischen Arbeitsstoffen" ("Operational instructions for risk assessment when handling biological agents")

– Richtlinien des Robert-Koch-Institutes (RKI-Richtlinien) (Directives of the Robert Koch Institute)
– Sterilgutversorgung DIN 58953-8 (Supply of sterile goods)

The responsible organisation must establish an appropriate organisational structure.

The following applies irrespective of any regulations of the duties and responsibility of the employer:
– Every individual is responsible for all her/his actions and what he/she decisively influences or can influence.
– The respective supervisors act on behalf of the employer and within their field of responsibility.

2.2 Responsible Organisation

The "responsible organisation" can be a legal entity, e.g. diocese, association, foundation, society as well as natural persons, e.g. group practise of physicians or a physician in private practise.

2.3 Equality of Occupational Health and Patient Safety

Responsibility in the sense of "responsible organisation" involves the implementation of the existing hygiene requirements for patients and staff safety.

All those concerned in provision of dialysis care are responsible for their safety and health at work and shall act according to the instructions and directives of the employer. Staff members also have to take care of the safety and health of patients and others involved. It is within this framework that the machines, tools, working materials, means of conveyance and other materials as

well as safety devices and personal protective equipment placed at their disposal are to be used according to the regulations[13].

2.4 Biological Agents Ordinance (BioStoffV)

2.4.1 The Biological Agents Ordinance and its Effects on the Operation of a Dialysis Centre

The BioStoffV concerning safety and health protection when working with biological agents was issued as an ordinance to the Health & Safety at Work Law and it is the implementation of a European Directive (90/679/EWG) into German law. It applies to all sectors in which employees handle biological agents.

In terms of this ordinance, biological agents are bacteria and similar organisms, viruses, parasites and fungi.

Blood and other body fluids are actually no biological agents. They are regarded as human material which can still be contaminated with biological agents. The exact definition of biological agents can be found in § 2 of the BioStoffV. They are listed in the joint classification (Annex III of Directive 2000/54 of the European Parliament and Council of 18th September 2000[14]) while taking into consideration their potential danger. Also specific circumstances are described in the technical regulations for biological agents (TRBA).

The Biological Agents Ordinance differentiates between specific and non-specific handling of biological agents.

Remark:
Only the non-specific handling of biological working materials is relevant in the public health service sector and thus for dialysis. It is for this reason that here too, only the above will be dealt with.

[13] vergl. § 15 Abs. 1 und 2 Arbeitsschutzgesetz – ArbSchG, http://bundesrecht.juris.de sowie Medizinproduktegesetz – MPG mit seinen Verordnungen.
[14] http://europa.eu.int/eur-lex