



LEGAL OPINION

ON THE EFFECTS OF THE
REVISED TEXT OF THE TECHNICAL
RULES FOR BIOLOGICAL AGENTS (TRBA 250)
ON
DOCTORS' PRACTICES

by order of

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A. THE OBJECT OF THE LEGAL OPINION AND A STATEMENT OF THE PROBLEMS

This legal opinion deals with the Technical Rules for Biological Agents – Biological Agents in Health Services and in Welfare Care (“TRBA 250”). A particular part of TRBA 250, namely its section 4.2.4, deals with the protection of employees from injuries when carrying out activities with pointed or sharp medical instruments. This section was revised in May 2006. The revision has been in effect since August 1, 2006. The new section 4.2.4 contains special standards and protective clauses to protect employees from injuries resulting from activities with pointed or sharp medical instruments. The text of the revised Section 4.2.4 is printed in the **Appendix** of this Legal Opinion.

In the following, it will be investigated how the revised Section 4.2.4 of the TRBA 250 affects the registered doctor in private practice as employer. In particular it will be investigated as to which duties for the registered doctor in private practice result from TRBA 250 in the interests of the prevention of injuries and which consequences may threaten him in the event of a contravention of TRBA 250. In concrete terms, this Legal Opinion deals with the following legal questions:

- I. Does the revised text of Section 4.2.4 of the TRBA 250 have effects on the doctor as employer in the private practice? If so, which obligations are described for the registered doctor in private practice with respect to the creation of more work safety? To what extent and in which situations are safe instruments to be used in the private medical practice? How is the situation to be evaluated specifically for the taking of blood samples?
- II. How is the exceptional ruling in Section 4.2.4 Number 3 to be legally interpreted for a private practice and what role does the company doctor play in this?
- III. Which consequences does the private practitioner have to fear from the non-observance of the TRBA 250?

- IV. How are the following solutions to the problems, which present themselves in the practice of companies, to be assessed?
- a. The partial change to safe instruments;
 - b. The complete change to safe instruments.

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For the integration and the understanding of the Legal Opinion, knowledge of the legal connections between the operative norms is necessary. Thus, in the following section these connections will first be briefly summarized (see B.) before the legal questions which have been brought up are answered (see C.).

B. BACKGROUND: THE TRBA 250 AS PART OF THE OCCUPATIONAL HEALTH AND SAFETY LAW

The TRBA 250 is to be allotted to the overriding area of the Occupational Health and Safety Law. Therefore, the so-called German Occupational Health and Safety Act (“ArbSchG”)¹ is the legal source for the TRBA.

The legislator firstly specifies certain definite basic obligations to which all employers must comply. Accordingly, § 3, Para. 1 ArbSchG determines:

“The employer is obligated to meet the required measures of occupational health and safety taking into consideration the circumstances, which influence the safety and the health of employees at work. He must examine the measures for their effectiveness and if necessary adapt them to changing conditions. In doing so, he has to strive for an improvement in the safety and health protection of the employees.”

In the fulfilment of the – binding, but as such not concrete – basic obligations, the employer has, in accordance with § 4 ArbSchG, to comply with certain general principles. In particular he has, in accordance with § 4 No. [sic] ArbSchG, to take into account the rules corresponding to the state of the technology, work medicine and hygiene and other safeguarded work science information.

To the concretising of these principles – also binding, but as such not specified in any detail – § 18 Para. 1 ArbSchG empowers the Federal Government to issue statutory orders (with the agreement of the Federal Council). In these statutory orders, rulings on work safety should be made separately, which should take into account, in detail, the specific demands of the work area concerned (in the present case, e.g. healthcare). In statutory orders of this kind, it can also be determined according to § 18, Para. 2, No. 5 ArbSchG that committees be formed, to whom the task of advising the Federal Government or the Federal Ministry responsible for the application of

¹ Act on the implementation of measures of occupational health and safety for improving the safety and health protection of the employees at work, Federal Law Gazette I 1996, 1246.

the statutory orders issued, to investigate rules relating to the state of the technology, work medicine and hygiene and other safeguarded work science information and rules as to how the demands made in the regulations can be fulfilled.

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The Federal Ministry for Employment and Social Services can officially announce these rules and information.

The Federal Government has used the authority to issue statutory orders from § 18 ArbSchG for this area of interest by issuing the so-called Decree on Biological Materials² (“BioStoffV”). The BioStoffV is, like the ArbSchG, immediately binding. It applies to activities with biological agents³ and imposes upon employers special obligations (e.g.: implementation of assessment of danger; hygiene and protective measures; instruction, announcement and recording obligations and occupational health check-ups).

In accordance with § 17 BioStoffV, the Federal Government has established the Committee for Biological Agents (“ABAS”) for questions regarding biological agents. In accordance with § 17 Para. 3 BioStoffV, the ABAS is obligated to investigate the rules and information in accordance with § 4 ArbSchG. These are the Technical Rules for Biological Agents (TRBA).

The TRBA represent the concretising of the rules abstractly named in §§ 4 and 18 ArbSchG, which conform with and explain the rules regarding the state of the technology, work medicine and hygiene, and set forth how they can be fulfilled in the statutory orders for the specifications for work safety.

§ 10 BioStoffV charges the employers in concretising the general consideration principle of § 4, No. 3 ArbSchG, when taking the protective measures, to take into account the rules and information determined by the committee for biological agents and announced by the Federal Ministry for Employment and Social Services, i.e. the TRBA. They do not have to be taken into

² The complete description of the ordinance is: “Ordinance on Safety and Health Protection in Activities with Biological Agents”.

³ Biological agents are microorganisms, including those modified by genetic engineering, cell cultures and human pathogenic endoparasites that can cause infections, allergenic responses or toxic impacts in humans (§ 2, Para. 1 BioStoffV).

account when equivalent protective measures are taken; this is to be demonstrated in individual cases at the request of the relevant authorities.

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To summarize: The TRBA do not directly have the character of a law. They are, however, to be taken into account in the context of work safety, as they reflect the respectively valid state of science and technology (and thus the valid work medicine safety standard), and the employer has to bring his protective measures into line with this level of information in accordance with § 4 ArbSchG in connection with § 10 BioStoffV. Accordingly, it is stated in the introduction of the TRBA 250:

“The Technical Rules for Biological Agents (TRBA) reflect the state of safety technology, work medicine, hygiene and work science demands in activities with biological agents.”

In May 2006, Section 4.2.4 of the TRBA 250 was revised. This revision is effective August 1, 2006.⁴

A number of other TRBAs exist along with TRBA 250, each with its own focus⁵. The TRBA 001 is emphasized (Allgemeines und Aufbau des Technischen Regelwerks zur Biostoffverordnung – Anwendung von Technische Regeln für Biologische Arbeitsstoffe [General and Assembly of the Technical Rules for Biological Agents – Application of Technical Rules for Biological Agents] – TRBA: “TRBA 001”). These comprise general regulations for the regulations listed before the parentheses, which are valid for all TRBAs.

⁴ The revision of these regulations was implemented verbatim in their policy by the Social Insurance Company for Occupational Accidents as underwriter of the legal accident insurance (BGR 250: BG Rules: Biological Agents in Health and Welfare Care). These rules do not represent a (legally binding) accident prevention regulation. They are referred to, however, in the legally binding accident prevention regulation “BGR A1 Accident prevention principles of prevention” (§ 4, Para. 2 BGR A1: “The employer must procure for his area of work or, for their activity, relevant content of the valid accident prevention regulations and BG Rules as well as the pertinent state regulations and policy in an understandable way.”). In this way, the changes of TRBA 250 have legal effects.

⁵ See the overview under: <http://www.baua.de/de/Themen-von-A-Z/Biologische-Arbeitsstoffe/TRBA/TRBA.html>.

C. ANSWERS TO THE LEGAL QUESTIONS

I. Does the revision of the TRBA 250 in Section 4.2.4 have any effects on the doctor as employer in the private practice?

The question on the effects on the doctor as employer in the private practice touches in essence the questions as to whether doctors or whether doctors' practices fall in the area of application of the TRBA 250 (see under 1.) and as to what degree of obligation befits the TRBA 250 (see under 2.). On the basis of answering these general questions, time aspects (see under 3.) and special effects will be represented on the basis of further questions of legal opinion on I. (see under 4.)

1. The scope of application of the TRBA 250

The question whether the TRBA 250 are valid for doctors' practices and registered doctors in private practice is to be answered in the affirmative. In Section 1.1 of the TRBA 250, its area of application is defined as follows:

“This TRBA applies to activities with biological agents in work areas of health and welfare care in which
- humans are medically examined, treated or cared for,
- animals are medically examined, treated or cared for.”

Then on this point in Section 1.4 of the TRBA 250, it is stated:

“The activities named in Sections 1.1 and 1.2 can, e.g., take place in the following institutions:
- hospitals and veterinary clinics,
- doctors' and dental practices, veterinary surgeons' practices, [...]”

Thus doctors' practices are expressly included in the area of application of TRBA 250.

As the whole section 4.2 of TRBA 250 is headed: “Protective Measures in Activities of Protection Level 2”, it could be argued that such Protection Level 2 activities are not carried out

in every doctor's practice, with the result that Section 4.2.4 would not be pertinent. This reflection does not go far enough, however.

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The TRBA itself contains a definition of "Protection Level 2", namely in Section 3.2.3.

Protection Level 2 states:

"Activities in which regular contact with large quantities of bodily fluids, discharges or tissues can come about so that danger of infection by pathogens of the risk group 2 or 3** can exist are as a rule assigned to Protection Level 2."

On this, in Section 1.4, the following are provided as examples for activities of Protection Level 2: among other things biopsies, injections, the taking of blood samples, insertions into vessels, the care of wounds, etc. Just these activities (and a number of other examples not named explicitly here) are typically found in a doctor's practice.

As a result therefore, registered doctors in private practice and doctors' practices fall within the area of application of the TRBA 250.

2. The binding character of the laws of the TRBA 250

The TRBA 250 – as other technical rules in work safety – do not *as such* represent an imperative law effective upon doctors. § 10, Para. 1 BioStoffV directs, in accord with § 4, No. 3 ArbSchG with regard to its application, "only" that it is "to be taken into account" in work protection. If the employer would prefer not to take TRBA 250 into account, he must, according to § 10, Para. 1 BioStoffV, take equivalent protective measures. He must provide evidence of these measures and above all their equivalence to the authority responsible in each individual case.

However, this "law of taking into account" is, with respect to the TRBA 250, binding for the employer and thus effects at least a de facto obligation. The employer has, in the normal case, to comply with the TRBA 250, and where he departs from it bears the responsibility to provide by argument and explanation his compliance with the rules of the BioStoffV and the ArbSchG. This de facto binding effect is further strengthened by further regulations. Firstly § 10, Para. 9 of the legally binding BioStoffV:

“If the safety technology of a work procedure is developed, if this has maintained and increased work safety considerably by this means, then the work procedure is to be adapted to this further development within a reasonable period of time.” (Underscoring added).

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This regulation prescribes, in an even more unmistakable way than in § 10, Para. 1 BioStoffV, that the employer has to observe de facto the TRBA 250, which depicts the state of the safety technology and the translation of work safety for dealing with biological agents and, where necessary, to adapt to them.

The basic system is confirmed by Number 1, Para. 3, Sentence 4 of the TRBA 001. According to this assumed rule, the employer can, when applying a TRBA, assume that the provisions of the Biological Agent Regulations are adhered to on these points. That means that in a claim for damages, the employer, in complying with the pertinent TRBA, will benefit from an exculpation effect. This exculpation effect may also be credited to the employer in terms of laws concerning liability (see under IV. for further details). Conversely, in a claim for damages, the employer would be under considerable pressure to provide evidence if he had not observed the TRBA.

Overall the TRBAs can be compared in their legal nature with other technical sets of rules, eg. the TA Noise. Precedents have regularly qualified⁶ this set of rules in the area of administration law as so-called anticipated expert opinions. The comparability of the TRBA with these sets of rules results from the orientation of their content (concretising of the current state of technology and science) as well as the form of its legal procedure (publishing of the TRBAs by a federal ministry, establishing a committee at the ministry, rulings on the manning of the committee and the calling of its members by the ministry).

The adjudication in the civil law concerning liability also applies technical sets of rules in the determining of the degree of care required of the doctor, also when a test is necessary in each

⁶ BVerwGE 55, p. 250, 254, Judgement of 2/17/1978 – 1 C 102/76; Stelkens/Bonk/Sachs, Kommentar zum VwVfG, § 26, Margin Index 32 ff. with further evidences.

individual case⁷. Therefore, as technical rules, the TRBA 250 can supplement the required degree of care when dealing with biological agents in healthcare.

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As a result – in spite of containing only technical rules rather than directly binding standards – as an anticipated expert opinion, TRBA 250 transpires as a regulation with a binding effect.

3. Chronological aspects of the adaptation to the revised text of the TRBA 250

Generally speaking, the requirements of TRBA 250 must be implemented without undue delay⁸. The responsibility for the implementation of TRBA 250 in the operation is upon the pertinent employer, i.e., usually the physician as the owner of the medical practice and thus the employer⁹.

4. Effects on the individual registered doctors in private practice

Since TRBA 250 has *de facto* a binding effect for physicians with a private practice and can require immediate adjustments within the sphere of occupational safety, this material subsequently examines which obligations of physicians with a private practice regarding the ensurance of occupational safety are described, to what extent and in which situations safe instruments must be used in the private practice of a physician, and how to assess the current situation especially in the area of blood sampling.

⁷ BGHZ 54, p. 335; OLG Hamm, OLGZ 1990, p. 119; Palandt, Code of Civil Procedure, § 276, Margin Index 18.

⁸ The following resolution adopted by the ABAS on November 28, 2006 is relevant to the deadline for the implementation of the TRBA 250 content: According to TRBA 001, the amended TRBA 250 is to be implemented as of August 2006. As regards the procurement of safer work tools, the implementation must be realized immediately. ABAS recommends to the pertinent regulatory authorities and agencies to reasonably tolerate the use until full depletion of pointed and sharp medical instruments until August 1, 2007. This does not apply to the treatment of and care for those patients who are conclusively infected with pathogens of the risk group 3 (including risk group 3**) or higher. In this case, the requirements must be implemented immediately. The procurement of these instruments must include proper instructions for the use of the safe work tools.

⁹ If – instead of an individual physician - the so-called medical supply center (MVZ) is the employer, then the employer's duties apply to the operator of the MVZ accordingly.

a. Obligations of registered doctors in private practice resulting from Section 4.2.4 of the TRBA 250

At the beginning of Section 4.2.4, the TRBA 250 generally stipulate that in order to protect employees from injuries suffered during activities with pointed or sharp medical instruments, in accordance with Numbers 1 to 7 of Section 4.2.4 of TRBA 250, these instruments must be replaced - as much as technically possible - with suitable safe work tools that create no or little risk of stabbing or cutting injuries.

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In view of new available tools, the exchange of the existing instruments with safe work tools should be considered to be possible.

The structure of Numbers 1 – 7 of Section 4.2.4 of TRBA 250 is as follows:

- Numbers 1 and 2 of Section 4.2.4 regulate to what extent and in which situations safe work tools must be implemented in a physician's private practice (more on this under b.);
- Number 3 regulates certain exceptions to Number 2 (more on this under II.);
- Numbers 4 to 6 provide for further activities of the physician with regard to the training of the staff and checking on the adherence to the occupational safety rules.
- Number 7 contains – in the form of a list of criteria – a specification of the required properties and safety mechanisms that safe work tools must have.

b. Extent and situations of the implementation of safe work tools

Numbers 1 and 2 of Section 4.2.4 of TRBA 250 stipulate to what extent and in which situations the physician's private practice must implement safe work tools. Number 1 stipulates:

- “Safe work tools must be implemented for the following activities and in the following areas with a higher infection or accident risk:
- Treatment of and care for those patients who are conclusively infected with pathogens of the risk group 3 (including risk group 3**) or higher;
 - Treatment of patients dangerous to third parties;
 - Activities in the rescue service and in emergency admission;
 - Activities in prison hospitals.”

Number 2 stipulates:

In general, in addition to the cases under Number 1, safe work tools must be implemented in activities where body fluids are transferred in infection-relevant quantities. These activities especially include:

- Blood sampling;
- Other punctures for the purpose of collecting body fluids.

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From the viewpoint of structure, please note that Number 1 contains a binding rule (“must be implemented”), whereas Number 2 only indicates a basic rule (“in general”...). Thus, Number 3 regulates – departing from Number 2, not Number 1 – that the existing work tools may continue to be used if the risk assessment prepared with the participation of the company physician identifies work processes, which minimize the injury risk and/or determine a low infection risk (More on this under II.). In more detail, Numbers 1 and 2 mean:

aa. On Number 1 of Section 4.2.4

It is the first two groups of cases under Number 1 that are relevant to the situation of a physician’s practice. The physician must use a safe work tool

- when he is treating and caring for patients who are conclusively infected with pathogens of the risk group 3 (including risk group 3**) or higher¹⁰. Pathogens that fall under the risk group 3 are indicated in Appendix III to Guideline 2000/54/EG. Among others, this group includes hepatitis B and hepatitis C viruses and HIV. However, the risk groups 3** and higher go beyond these viruses. They also contain a number of bacteria, parasites and fungi. Thus, this group of cases does not apply only to HIV-focus practices and liver consultations by internal medicine specialists, but rather to all medical practices.
- when treating and caring for patients that pose a risk to third parties.

Thus, Number 1 of Section 4.2.4 of TRBA 250 clarifies that in the case of the above-mentioned patient groups and risk situations, the sheer use of safe work tools meets the requirements of the current status of the occupational safety. If no safe work tool is used with these patients, unless an equivalent measure has been taken, the employer has not implemented the current status of the relevant technical and professional information.

With regard to the extent of the use of a safe work tool, when the wording is strictly examined, it must be concluded that TRBA 250 does not unambiguously determine whether these first two groups of cases under Number 1 also include the collection of blood.

¹⁰ The two stars (**) are assigned to such biological materials that are classified under Group 3, which, however, pose a limited infection risk for the employee, because an infection through the air normally cannot occur.

The regulation stipulates that this has to occur during the “treatment of and caring for” the relevant risk patients, or especially during the “treatment” of patients dangerous to third parties. The diagnostics are not indicated here so that one could argue that Number 1 does not include the collection of blood. This argumentation could be supported with a view to Number 2, which stipulates the general use of safe work tools for the collection of blood “in addition to Number 1”. Should this concept be correct, the physician would not be forced by Number 1 but rather only encouraged by Number 2 to use safe work tools during the collection of blood.

However, this argumentation does not hold. Collection of blood is very much a part of the medical treatment even if it is only done for diagnostic purposes. This is implied from the definition of the term “medical treatment” in the social law (§ 28 of the *Sozialgesetzbuch* [Social Security Act]):

“Medical treatment includes an activity of a physician that is sufficient and purposeful for the prevention, early diagnosis and treatment of illnesses by the rules of the medical art. Medical treatment also includes auxiliary services of other persons which the physician orders and is responsible for.”

Thus, medical treatment is a unified process. It cannot be artificially split into separate sections of diagnostics, therapy and subsequent care. Rather, these sections represent non-independent phases of the same medical treatment. The physician liability law cases decided by the Supreme Court classify an error in the phase of diagnostics of a patient as a treatment error.

Thus, collection of blood is also an activity in which the use of safe work tools is mandatory in accordance with Number 1.

bb. On Number 2 of Section 4.2.4

In Number 2, the general use of safe work tools is tied to the fact of whether, during the pertinent activity, the transfer of infection-relevant quantities of body fluids is possible. What kind of a quantity is understood under that term is not further specified. This is also not quite possible due to the different “infection-relevant quantities” depending on the particular pathogen.

Instead, the regulation provides for a flexible differentiation that reflects the particularities of individual cases.

In addition to the collection of blood and other punctures required for the collection of body fluids, Number 2 indicates examples, which allow a legal delimitation and a better classification of the mandatory risk threshold. The listing is not exhaustive (“especially ...”).

According to the risk classification made possible by the examples, it appears quite professionally appropriate to also sub-total under Number 2 as further activities the puncture of veins and arteries for the purpose of administering drugs or contrast media. Just like with the collection of blood and other punctures for the collection of body fluids, these activities involve hollow needles being directly exposed to the blood stream. Therefore, they also represent an infection risk in case of needle stab injury, although this is statistically not comparable with (i.e., much lower than) the collection of blood.

II. How should the exceptional ruling in Number 3 in Section 4.2.4 be legally interpreted for a registered doctors’ private practice and what kind of a role does a company doctor or an occupational physician play in this process?

The exceptional ruling in Number 3 of Section 4.2.4 of TRBA 250 reads

“Departing from Number 2, existing work tools can continue to be used if a risk assessment prepared with the participation of the company physician identifies work processes, which minimize the injury risk and/or determine a low infection risk.

For example, the risk of injury is minimized by

- defined work processes, which are not circumvented even in emergency cases,
- schooling and annual training seminars of employees and
- a well-proven disposal system for used instruments (see Section 4.1.2.8).

There exists a minute risk of infection when the infection status of the patient for HIV, HBV and HCV is negative. The result of this part of the risk assessment must be specially documented.

As an exception from the “general” duty (according to Number 2) to use safe work tools in activities during which body fluids in infection-relevant quantities can be transferred, Number 3 allows a continued use of the existing work tools if the following requirements are met:

- a risk assessment must be prepared with the participation of the company doctor (more on this under 1.);
- a risk assessment identifies work processes which minimize the injury risk and/or determine a low infection risk (more on this under 2.);

1. Risk assessment

A risk assessment at the workplace represents the core duty of the occupational safety system. This importance of such an assessment is also stressed in the regulation BioStoffV and in TRBA 250. This assessment is of a decisive importance for the whole concept of occupational safety. Consequently, it represents the decisive step when the physician wants to use the exception regulation under Number 3.

ArbSchG, BioStoffV and TRBA 250 contain concrete criteria for the practical implementation of the risk assessment. Furthermore, the Professional Association for Medical Services and Welfare (BGW) issued a publication “Risk Assessment in Human Medicine” in November 2006.

a. Formal requirements for a risk assessment – participation of the company doctor and sufficient documentation

The first formal requirement for the risk assessment is that the employer must involve a company doctor if he wants to continue to use the existing work tools.

A combined review of the ArbSchG, BioStoffV and TRBA 250 suggests that the duties stipulated in these regulations also apply to a physician with a private practice as an employer. § 8 of the BioStoffV requires that the employer

“when performing the risk assessment, must employ a professional advisor if he himself does not have the necessary professional knowledge. Professional persons are especially a company doctor and a specialist for occupational safety.”

Pursuant to § 4 of the Occupational Health and Safety Act, only such persons can be appointed to the company doctor's position who are entitled to practice as physicians and who have sufficient knowledge in the field of occupational medicine to perform the tasks assigned to them. The requirement of the "field of occupational medicine" is met if the physician may use the designation "Facharzt für Arbeitsmedizin" [Specialist for Occupational Medicine] or the addition "Betriebsmedizin" [Occupational Medicine]¹¹. According to this doctrine, a professional advisor would not be required only if the owner of the medical practice has himself qualifications that correspond to those of a company doctor or a specialist for occupational medicine. This is usually not the case.

The same also applies to Number 3 of Section 4.2.4 of TRBA 250, which is a specification of the general requirement for a professional advisor from § 8 of the BioStoffV. Here too, generally speaking, there is no space to circumvent the use of a person qualified to be a company doctor. An exception would be conceivable if the medical practice owner himself has these special qualifications¹².

Moreover, in the formal aspect, the employer has also substantial documentation duties when performing the risk assessment. On the one hand, the documentation must contain information underlying the assessment. The assessment itself must be documented with the associated considerations made, especially those for protection and the risk situation. Above all, the protection measures taken as the exception from the use of safe work tools must be documented. The documentation requirement also applies to the appropriateness and purposefulness of the protection measures selected instead of safe work tools. This applies both to the regulatory audits and any subsequent events of injury. All facts and assessments that are to justify the application of the exceptional ruling in Number 3 of Section 4.2.4 must be documented.

¹¹ As regards the "necessary knowledge", this would be met by the professional knowledge of a company doctor. *Cf.* also the accident prevention regulation "Betriebsärzte BGV A 7 (VBG 123)" [Company doctors BGV A7 (Regulations of Professional Associations)].

¹² Every employer is obliged to procure the opinion of a company doctor also pursuant to the provisions of the Occupational Health and Safety Act. Company doctors have the task to support the employer in the area of occupational safety. There was a temporary "protection period" for small business – under which physicians with private practice were also classified. However, this period no longer applies.

b. Content requirements of the risk assessment

As for the content of the risk assessment, the physician must adhere to the provisions of §§ 5 and subsequent of the BioStoffV. According to this regulation, the physician must procure sufficient information when performing a risk assessment. This includes the following information:

- All information related to such activity and accessible to the physician regarding the identity, classification and infection potential of the existing biological materials and any sensitization and toxic effects caused by them;
- Activity-related information about operation processes and work procedures;
- Type and duration of such activities and the associated possible transmission paths and information about the exposition of employees;
- Experience from comparable activities, load and exposition situations, and known activity-related illnesses and counter measures taken.

As for the content, the risk assessment must also determine the relevant patient or risk groups. Then, the activities occurring in the particular practice must be assigned to relevant protection level. Depending on these results, the physician must select and define any possible (alternative) protection and safety measures.

The results of the risk assessment must be regularly reviewed and, if need be, the protective measures adjusted.

2. Selection of suitable alternative protection measures according to Number 3

The application of the exceptional ruling under Number 3 further presumes that the physician defines suitable and purposeful alternative measures if he intends to use the existing instruments. Number 3 indicates the above-mentioned two procedures:

- In the first variant, the physician must define work processes that minimize the risk of injury. When doing so, he should select such work processes that are not circumvented even in an emergency situation. Schooling and annual training seminars for employees, as well as a well-proven disposal system for used instruments also belong to the possible measures.

However, when comparing these permissible measures as an exception with the use of safe work tools – even if legally defensible – there arise certain doubts whether these organizational measures ensure the owed level of protection in a comparably reliable fashion, i.e., whether they, for example, prevent a needle stab injury as well as safe tools¹³. In any case, the employer must also answer this question of equality of the protection level.

- As further alternative protection measures, Number 3 indicates the determination of a minute risk of infection. A minute risk of infection exists if the infection status of the patient regarding HIV, HBV and HCV is negative¹⁴. However, in real life scenarios we encounter the problem where the negative infection status of the patient is not known to start with. The determination of the minute infection risk of a patient requires that he first be collected a blood sample. Thus, the substance of this exception would compel the physician, before applying it, to test all patients of the particular practice for HBV, HBC and HIV. In addition, this would have to be repeated before each new treatment. For this background, the appropriateness and practicability of this exception appears legally dubious. This also applies under the aspect of the equal level of safety (criterion of the suitability and equivalence).

3. Overall assessment

Overall, in view of the strict formal and content-related requirements for a careful risk assessment and the selected alternative protective measures, the possible exceptions from the general duty to use safe work tools pursuant to Number 3 of Section 4.2.4 of TRBA 250 appear rather difficult to justify even though not completely excluded. Furthermore, apart from the legal aspect, we would also have to take into consideration the cost of performing a risk assessment that involves the company doctor, of the documentation requirements, and of the alternative organizational, staff and technical protective measures.

¹³ These concerns are based, among other things, on the fact that these injuries usually occur not due to any deficiency in the training but rather due to a “situational failure” of an employee.

¹⁴ The result of this part of the risk assessment must be separately documented.

Therefore, from both legal and non-legal aspects, it appears justified that it be made known in the professional community that in the future, probably also in the activities indicated under Number 2, especially as regards the collection of blood, as a rule only safe work tools should be used¹⁵.

III. Which consequences does the registered doctor in private practice have to fear if he does not respect the TRBA 250?

Non-adherence to the requirements of TRBA 250 can result in consequences under criminal law, civil law, social law, occupational law and social-insurance law. It is decisive in all these legal fields whether the physician acted culpably. For reasons of a uniform approach within the entire legal system, the principles of culpability must be applied in an equal fashion. Therefore, in further text we explain these principles (more on this under 1.). Subsequently, individual consequences are discussed in more detail (more on this under 2.-5.).

1. Culpability of the doctor, required care and TRBA 250

In the present case, for the consequences of an act it is relevant whether the physician acted in a culpable way. Culpability means the possibility to hold someone liable. The levels of culpability can be sub-divided into negligence (more on this under a.) and premeditation (more on this under b.):

a. Negligence

He who disregards normal care in normal operations acts with negligence¹⁶. In this connection, important criteria are predictability and possibility to avoid damage/injury. Which measure of care should be considered depends on the specification of the particular technical or professional area.

¹⁵ This was the statement of ABAS and the State Medical Board of Registration of Nordrhein (Dr. Hefer) on the occasion of announcing the new version of Section 4.2.4 of TRBA 250 in: *Rheinische Ärzteblatt* 9/2006, page 72. See also Wittmann, *Praktische Arbeitsmedizin* [Practical Occupational Medicine] 2006; 4: 18 (19): The same opinion can be found in a recommendation of the Professional Association for Medical Services and Welfare (BGW) on the technical protective measures for pointed and sharp instruments; see the publication “*Gefährdungsbeurteilung in der Humanmedizin*” [Risk Assessment in Human Medicine], (November 2006), page 25.

¹⁶ Legal definition in § 276, Paragraph 2 of the German Civil Code.

The established case law recognizes that in order to determine the measure of required care, legal norms and regulations can be used, even though in each individual case a concrete examination is required¹⁷. Thus, TRBA 250 as a set of technical rules is suitable to ensure “due diligence” when handling biological materials in the healthcare sector. In the process of examining any negligence, a breach of Section 4.2.4 of TRBA 250 can have the effect of an indication against the physician.

In addition, when determining the measure of required care owed and the assessment of a physician’s breach of a duty, the following factors must be considered.

- Professional acceptance of a certain protective measure / procedure in the professional community.
- Practical dissemination of a certain protective measure / procedure.
- Development of protective measures / procedures and experience with them in foreign countries (comparable to Germany).

The more professional acceptance and practical dissemination a protective measure has obtained, the more any breach of it will be seen as contrary to required care. Therefore, in this case the following factors also speak in favor of using safe work tools:

- According to the new version of TRBA 250, various professionally proven and independent entities support the use of safe work tools as defined by TRBA 250¹⁸. It is especially the observations of ABAS and the State Medical Board of Registration of Nordrhein that allow discovery of a supporting tendency¹⁹.
- Experts experienced in occupational safety also speak out in support of using safe work tools²⁰.
- According to data obtained in the USA, the use of safe work tools can allow a reduction in needle injuries by up to 90%.

¹⁷ Cf. accident prevention regulations BGH, NJW 1957, page 499, VersR 1962, page 358; for technical rules see BGHZ 1954, page 335; OLG Hamm, OLGZ 1990, page 119; Palandt, BGB [Civil Code], § 276, marginal number 18; for DIN standards, see BGHZ 103, page 341; BGHZ 139, page 17.

¹⁸ For ABAS and the State Medical Board of Registration of Nordrhein, see Rheinische Ärzteblatt 9/2006, page 72. See also BGW, “Gefährdungsbeurteilung in der Humanmedizin” [Risk Assessment in Human Medicine], (November 2006), page 25.

¹⁹ Hefer, for ABAS and the State Medical Board of Registration of Nordrhein see Rheinische Ärzteblatt 9/2006, page 72: Use of safe instruments “*may become the rule in the future.*”

²⁰ Cf. Wittmann, Praktische Arbeitsmedizin [Practical Occupational Medicine] 2006, 4, pages 18 and subsequent.

In case of a real injury, the court will also take into consideration this new information and statements when examining whether a physician acted negligently²¹.

b. Premeditation

The employer can be blamed for premeditation if he foresaw the result of his acting, i.e., the injury of the injured person as possible, and acquiesced in the case it really occurred. For this it is sufficient that he sees such result as possible and not too abstract and comes to terms with it. It is not required that he wanted such a result or it was desirable to him.

2. Criminal responsibility of the doctor

Should avoidable injury occur due to non-adherence to TRBA 250 and due to the absence of equivalent measures, the penal liability of the practice owner due to negligent bodily injury pursuant § 229 of the Criminal Code becomes possible. The punishment for negligent bodily injury includes imprisonment of up to three years or monetary penalty. The physician can even be prohibited to practice (§ 70 of the Criminal Code).

Should the physician have caused the injury by premeditation, the stricter penal liability for premeditated bodily harm may be considered. This may result in imprisonment of up to five years or monetary penalties as punishment. In case of severe injuries (for example, permanent disability, death), the court would impose substantially stricter punishment. In this case, however, the risk of the employer's penal liability for premeditated bodily injury is to be considered distant. It would have to be proved that such physician approvingly acquiesced in this premeditated injury. In this respect, the established case law is quite restrained. So, the established occupational safety law recognizes that the premeditation of injury is not proved (even) if the employer disregards accident prevention regulations.

²¹ Here, the differentiation between the criminal law and the civil law when assuming negligence should be mentioned. In civil law, it is sufficient that the physician objectively abstractly breaches the duty of required care that is required in his professional environment (for example, in the specialist group). Subjective aspects are legally immaterial. In criminal law, which asks about personal culpability, an objective disregard for required care must be complemented by a subjective breach of due care. The breach must be provable to the physician also by his individual capabilities.

The risk of penal liability for the owner of a private practice thus primarily consists of the liability for a bodily injury out of negligence if the owner omits the prescribed protective measures or takes measures that are not up to the prescribed standard. When determining the prescribed standard, TRBA 250 has to be taken into consideration.

3 Risks of penal liability and regulatory offences in case of breaches of the ArbSchG [German Occupational Health and Safety Act] and the BioStoffV [Decree on Biological Materials]

Risks of penal liability for the physician as employer exist also in case of disregarding the ArbSchG [German Occupational Health and Safety Act] and the BioStoffV [Decree on Biological Materials]. These are based on regulatory offences that are separately identified in § 18 of the BioStoffV. According to § 25 of the ArbSchG in conjunction with § 18, a regulatory offence arises if the employer

- does not perform the required risk assessment, does not perform it correctly or completely or not according to the requirements indicated in § 8, sentence 1, Numbers 2 or 3 (i.e., with the involvement of the company doctor),
- contrary to § 11 of BioStoffV, personal protective equipment is not disinfected, cleaned, repaired, replaced or destroyed or is done so incorrectly or not in time,
- contrary to § 11 of BioStoffV, the effectiveness of technical protective measures is not regularly checked,
- contrary to § 12 of BioStoffV, does not instruct employees, does not instruct them in the prescribed fashion or in time or does not set the time or subject of the instruction, does not set it in the prescribed manner or does not do so in time.

This listing of the regulatory offences in § 18 of BioStoffV is not final. However, the first description alone illustrates again the special importance of the risk assessment, the improper performance of which can be punished as a regulatory offence with a penalty. Penalties in the ArbSchG can reach up to Euro 25,000. In addition, the regulatory authorities are entitled to institute supervision over and injunctions against any such physician. Furthermore, § 22 of the ArbSchG accords special rights to the authorities (for example, the right of information, inspection of the facility, inspection of the business documentation and examination of procedures).

In addition, the physician becomes liable according to § 26 of the ArbSchG if he

- “repeatedly commits” the aforementioned regulatory offences, or
- endangers the life or the health of an employee by a premeditated regulatory offence.

This penal liability does not require that someone be really injured. The endangerment alone is sufficient. Thus, the threshold of the risk of penal liability is lower here than in the case of premeditated bodily injury in the general criminal law. These criminal acts are punishable by imprisonment of up to one year or monetary penalties. The sanctions also include the prohibition to practice medicine.

4 Legal consequences for doctors registered with social health insurance bodies

The list of regulatory consequences includes measures and sanctions imposed by the pertinent medical doctor panel of the association, if the physician holds his private practice as a contractually authorized physician. If the physician continues to breach his duties under the occupational health and safety law, causes endangerment of his colleagues or patients and thus creates the impression of a lack of reliability, it is obvious that the regulatory authorities (healthcare insurance authority) take measures against such physician who is possibly not fit to operate a private medical practice.

5 Civil law liability of the doctor

In the case of the civil law liability of the physician, we must distinguish between his patients and his employees as the potential injured parties and claimants.

a. Liability with respect to patients

The physician’s liability comes into consideration in case of an injury of patients. A patient can be harmed by unsafe instruments if they are put into an inappropriate place or are stored there. A similar principle applies to their inappropriate disposal. Special principles of the physician liability law apply to these injuries.

In the event of injuries caused to patients due to a breach of organizational duties, under which the indicated reasons are to be classified, the established case law is very strict to physicians. Special specific rules of evidence have developed in the physician liability law. It is exactly for the field of organization safety that the established case law applies

to the so-called “fully controllable risks”²². In this group of cases, the culpable error in treatment committed by the physician is assumed if it is determined that the injury originates in a field whose dangers the physician can fully control. This is the case with pointed and sharp medical instruments, including their disposal. In these cases, within the physician liability process, the patient’s burden of evidence is reduced up to a full reversal of the burden of evidence imposed upon the physician, which usually causes the physician to lose the lawsuit. To this extent, there exists a relevant civil law liability risk in case of a patient’s injury due to non-adherence to the measures imposed by TRBA 250²³.

b. Liability with respect to employees

Due to the peculiarities of the social security law (law of the mandatory accident insurance), the physician’s risk of liability towards his employees is limited. This is based on a special liability exclusion of bodily harm in consequence of occupational accidents and occupational illnesses (pursuant to §§ 104, 105 of SGB [Social Security Code] VII) instituted in favor of the employer.

The purpose of the liability exclusion is to release the employer from liability for personal injury due to negligence. The injured employees are entitled to receive benefits from the mandatory accident insurance. Therefore, in general, an employer is liable towards his employees pursuant to § 104 of the Social Security Code VII only in the event of the pertinent physician’s premeditated act. Premeditated injuries are not included in the exclusion of liability. This also includes immaterial damage (compensation for pain and suffering) and property loss due to injury or killing.

Therefore, the physician is only exposed to a risk of liability in the event of a premeditated causing of injury/damage. However, as has already been observed, premeditation can be assumed in these fields only on a restricted basis. The premeditated injury will not be established by the physician’s mere disregard of TRBA, but rather only

²² BGH NJW 1975, 2245; NJW 1978, 584; NJW 1978, 1683; NJW 1982, 699; NJW 1984, 1403; NJW 1991, 1540, 1541; *cf.* on this and in general on physicians’ liability Koyuncu, Das Haftungs-dreieck Pharmaunternehmen – physician – patient [Liability triangle Pharmaceutical company – Physician – Patient] (2004), page 220.

²³ As rules for occupational safety, TRBA 250 primarily focuses on the protection of employees. However, as sentence 1 of Number 7 of Section 4.2.4 of TRBA 250 illustrates, the patients’ protection is also the goal of TRBA 250 in some places.

in the case of an approving acquiescence of the result of the injury.²⁴ In the Federal Labor Court's opinion, the premeditated disregard for the accident prevention regulations does not result in preclusion of the liability exclusion²⁵. This is why for personal damage the general civil-law liability (liability for tort) also fails. Therefore, there only exists a limited risk of liability of the employer towards his employees.

6. Liability of the doctor with respect to social security insurers

However, in case of injured employees, the physician is exposed to the danger of risks of liability towards the carriers of the social security. Pursuant to § 110, Paragraph 1 of the Social Security Code VII, the social security carrier can seek recourse with the physician if the physician has caused the accident (for example, a needle stab injury and subsequent infection) due to gross negligence or premeditation. Unlike in the relationship with his employees, the employer is liable for gross negligence towards the social security insurer.

Questionable is when the physician acts with gross negligence, especially whether this can be assumed in the event of a breach of TRBA 250. Gross negligence is an aggravation of a simple negligence. It is established in the event of an especially severe breach of required care²⁶. We also find an illustrative wording that negligence is light if one were to say: "That can happen." On the contrary, it is gross if one has to say: That must not happen." Gross negligence is also established in the case of breach of generally recognized rules of technique.

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²⁴ To preclude the liability exclusion according to § 104, Paragraph 1 of the Social Security Code VII, it is not sufficient that a specific act that was causal for the accident was performed by the employer knowingly or with approval, if the accident itself was not wanted or approved, *cf.* LAG LAG Hamm, judgment of 5/26/2004 – reference number: 18 Sa 71/04.

²⁵ Federal Labor Court, judgment of 10/10/2002 – reference number: 8 AZR 103/02; see also Regional Labor Court in Cologne, judgment of 1/30/2003 – reference number: 5 Sa 966/02: Employer's liability for personal damage cause by occupational accidents pursuant to § 104, Paragraph 1 of the Social Security Code VII presumes that the employer at least acquiesced the personal damage as such; a premeditated breach of accident prevention regulations alone does not suffice.

²⁶ See the legal definition of gross negligence in § 45, Paragraph 2, page 3, Number 3 of the Social Security Code X. The established case law describes gross negligence using various wording: breach of elementary duties to care, especially severe disregard for required care or obvious, easily implementable measures; disregard for quite obvious considerations and such procedures that anybody would have thought of in the particular case; *cf.* BGHZ [Decisions of the Federal Court in Civil Law Matters], page 16, BGHZ 89, page 161; BGHZ, NJW 1992, page 3236; BGH, NJW-RR 1994, page 1471.

The question whether this can be assumed in case of a breach of TRBA 250 must be individually assessed. The more recognized a TRBA stipulation, the more professional acceptance and practical dissemination it obtains, the more obvious it becomes to assess its disregard as grossly negligent. Here, too, we must take into consideration the fact that various entities and experts advocate the use of safe work tools (*cf.* the evidence under IV. 1.a.).

Finally, also important for the recourse of the physician is § 110, Paragraph 1, Sentence 3 of the Social Security Code VIII, according to which the culpability “must only relate to the act or omission to act that caused the insured event”. This is why it is sufficient that the physician culpably performs the damaging act or the damaging omission to act (for example, breach of protection duty in the form of an omitted protective measure). In this case, the culpability – unlike towards the injured person – need not to relate to the occurred injury.

In general, the possible recourse of the social security insurer creates, for the physician as the employer, a relevant risk of liability if he grossly negligently disregards the prescribed protection standard when handling biological materials and takes insufficient protective measures or omits effective measures.

IV. Evaluation of the problem solutions offered in practice

1. Partial transition to safe instruments

In the event of a partial transition, a kind of a kit with a certain number of safe instruments is provided (blood collection needles, safety butterflies, safety catheters, etc.). These should always be used with a set of instructions for the staff in such situations described by TRBA 250, Section 4.2.4.

The legal measure for the safety of the work tools used in the event of a partial transition is Number 7 of Section 4.3.4. There, we find detailed criteria and safety mechanisms that must be permanently adhered to. This expert legal opinion presumes that this compliance with Number 7 should be permanently guaranteed and checked.

A partial transition can represent a flexible solution for such practices that momentarily do not switch its set of instruments to safe work tools, but

temporarily has patients with pathogens of the risk class 3** and higher. Number 1 of Section 4.2.4 applies to these patients, i.e., those for whom safe work tools must be implemented. Therefore, within the process of conversion, the provided safe work tools could (and would have to) be used in the treatment of these patients.

In the event of a partial transition, the staff must be regularly trained. This applies all the more because they must work with two different systems and primarily use the unsafe instruments. Errors may result from a lack of practical exercise. New employees must undergo a new instruction course. The physician must also check the safety of the instruments and examine his employees. These measures should be documented.

In summary, a partial transition appears to be appropriate and advisable for physicians' practices that have not completely implemented a switch to safe work tools after a thorough risk assessment. In this way they can – in conjunction with special training for their staff – especially comply with the requirements of Number 1 of Section 4.2.4 if the patients indicated there are to be treated.

2 Complete transition to safe instruments

Here too, it should be pointed out that the safe work tools must be legally compatible with the criteria and safety mechanisms indicated under Number 7 of Section 4.2.4.

From the legal point of view, a complete transition of the physician's practice to safe instruments is seen as the safest way to go. This holds both from the safety law and liability and penal liability law aspects. In this way, the physician literally complies with Numbers 1 and 2 of Section 4.2.4 of TRBA. Furthermore, this eliminates the obligation to justify any exceptional protective measures according to Number 3 in addition to a related risk assessment. It is quite clear that this approach also eliminates costs (among others, costs of a company physician, documentation, schooling, protective measures).

Moreover, a complete transition eliminates the duty of individual consideration whether the treatment of each individual patient requires the use of safe instruments due to some individual characteristics (this is the case in the event of a partial transition). Furthermore, in case of a complete transition, the employees need not distinguish various types of instruments. This reduces another source of errors for "situation-related failures".

A complete transition would probably also reduce costs associated with schooling and control.

Finally, in the event of a complete transition, all employees and patients are treated equally (safely). Since the physician thus literally implements the provisions of Numbers 1 and 2 of Section 4.2.4 of TRBA 250, the assumption indicated under Number 1, Paragraph 3 of TRBA 001 applies in his favor so that he can presume that he is acting in compliance with the BioStoffV.

C. SUMMARY

This legal expert opinion deals with the Technical Rules for Biological Agents – Biological Agents in Health Services and in Welfare Care (TRBA 250). Section 4.2.4 of TRBA 250, which deals with the protection of employees from injuries suffered during activities using pointed and sharp medical instruments, was amended in May 2006. The new version came into force on August 1, 2006. The new version has the following results:

1. In spite of containing only technical rules rather than directly binding standards, TRBA 250 transpires as a regulation with a de facto binding effect. With regard to the handling of biological materials, they specify the current state of the technique, occupational medicine and hygiene, as well as other acquired work and scientific knowledge. Therefore, they can be used before a court as the so-called “anticipated expert opinion”, and can be further used to determine any breach of an obligation in case of a liability, and the extent of due diligence when dealing with biological materials.
2. The scope of application of TRBA 250 also extends to a physician with a private practice in the position of an employer. It applies to all medical practices. The new version of TRBA specifies the requirement that, in the interest of occupational safety in activities involving pointed and sharp medical instruments, these instruments must be replaced with suitable safe work tools that create no or only a minute risk of a stabbing or cutting injury. Thus, all medical practices should now use safe work tools in connection with the collection of blood and care for patients who are infected with pathogens of the risk group 3** or higher. The same applies to the treatment of patients who endanger third parties. Moreover, safe instruments must now be implemented and used in activities in the rescue service and in emergency admission, as well as in prison hospitals.
3. In addition, safe work tools must be implemented in all other activities where body fluids are transferred in infection-relevant quantities (for example, collection of blood, punctures for the purpose of collecting body fluids). Number 3 of Section 4.2.4 of TRBA 250 allows exceptions from this principle under certain circumstances. The requirements for an exception are high.

- The physician must prepare a risk assessment involving a company doctor: in doing so, the physician must meet special formal and content-related requirements and respect the duty to document the whole process. The involvement of a company doctor is only then unnecessary if the physician himself brings the corresponding qualifications.
- The physician must take suitable and purposeful protective measures. This is associated with big practical problems.

In view of these formal and content-related requirements, possible exceptions from the general duty to use safe work tools can be difficult to justify. Therefore, the professional community is of the opinion that in the future, the use of safe work tools in the collection of blood and punctures for the collection of body fluids should be the rule.

4. If employees or patients of a medical practice are injured due to non-adherence to TRBA 250, the owner of the practice is exposed, above all, to criminal-law, liability-law and occupational safety-law consequences. Since the rules stipulated in TRBA 250 can be used as a concretized extent of due diligence when handling biological materials, its disregard in a situation of missing equivalent measures represents a serious breach of required care, which may result in penal liability for bodily injury or in the obligation to pay the injured parties damages in relation to the injured parties and the social security carriers. Bodily injury due to negligence can result in imprisonment of up to three years or a monetary penalty. In addition, in the event of a breach of the Occupational Health and Safety Act and the Decree on Biological Materials, the physician is exposed to the risk of special penal liability and/or a penalty. Last but not least, the physician can be exposed to punishment by the panel of doctors.
5. This legal expert opinion assessed, as practice-relevant problem solutions, a partial transition and a complete transition by the medical practice to safe instruments. The partial transition can represent a flexible solution of the tension between the legal and the economic considerations. A risk assessment must precede the use of such partial transition.

In addition, such partial transition requires consideration of requirements for the practice organization, staff training and supervision. The partial transition is advisable if the medical practice does not intend to implement a complete transition. With the risk patients mentioned in TRBA 250, the use of safe work tools is mandatory. From the legal point of view, the most protective and thus safest way for the physician is a complete switch to safe work tools.

Frankfurt am Main, January 22, 2007

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APPENDIX

Section 4.2.4. of TRBA 250 in the version applicable as of August 1, 2006:

In order to protect employees from injuries caused by pointed and sharp medical instruments, these instruments must be replaced with such suitable safe work tools - to the extent technically possible and in accordance with Numbers 1 to 7 - which do not pose any or very small risk of a jabbing or cutting injury.

1. Safe work tools must be implemented for the following activities and in the following areas with a higher infection or accident risk:

- Treatment of and care for those patients who are conclusively infected with pathogens of the risk group 3 (including risk group 3**) or higher;
- Treatment of patients dangerous to third parties;
- Activities in the rescue service and in emergency admission;
- Activities in prison hospitals.

2. In general, in addition to Number 1, safe instruments must be used in activities in which body fluids can be transferred in infection-relevant quantities. These activities especially include

- Collection of blood;
- Other punctures for the collection of body fluids.

3. Departing from Number 2, existing work tools can continue to be used if a risk assessment is prepared with the participation of the company physician who identifies work processes, which minimize the injury risk and/or determine a low infection risk. For example, the risk of injury is minimized by

- defined work processes, which are not circumvented even in emergency cases,
- schooling and annual training seminars of employees and
- a well-proven disposal system for used instruments (see Section 4.1.2.8).

There exists a minute risk of infection when the infection status of the patient HIV, HBV, and HCV is negative. The result of this part of the risk assessment must be specially documented.

4. The safe work tools must be selected in relation to their application, as well as with the consideration of their ease of handling and acceptance by the employees. Work processes must be adjusted with regard to the use of safe systems.

5. It must be ensured that the employees are in a position to correctly use safe work tools. This necessarily requires to inform them of safe work tools and to communicate the handling of safe work tools.

6. The effectiveness of the measures taken must be re-examined.

7. Safe work tools preventing stabbing and cutting injuries must not endanger patients. Moreover, they must have the following properties:

- The safety mechanism is a part of the system and is compatible with other accessories
- They must be able to be activated with one hand
- The activation must be possible immediately after use
- The safety mechanism rules out new use
- The safety product does not require any change of the application technique
- The safety mechanism must be characterized by a clear signal (to be felt or heard)

Equivalent to the use of safe work tools are also procedures in which the safe retractable insertion of the needle into a protective shell can be done with one hand, for example, local anesthetics in dental medicine or during the injection of drugs (Pen).

* * *