

<b>Technical Rules for Hazardous Substances</b>	<b>Biomonitoring</b>	<b>TRGS 710</b>
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The Technical Rules for Hazardous Substances (TRGS) convey the status of the safety, occupational-medicine, hygiene and industrial-science demands on hazardous substances with regard to placing them on the market and handling them.

They are established by the

### **Committee on Hazardous Substances (AGS)**

and adapted by the Committee to the current status of development.

The Technical Rules are announced by the Federal Ministry of Labour and Social Affairs in the Federal Labour Gazette (BArbBl).

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This Technical Rule lays down when, and under what conditions, biomonitoring of workers that handle hazardous substances is to be performed and how the results are to be assessed.

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## **1 Scope**

(1) This Technical Rule contains rules for the determination of the concentration of hazardous substances, their metabolites or other indicators in biological material taken from workers and an assessment of them in terms of occupational medicine.

(2) Biomonitoring is one of the tasks to be performed by the company physician in accordance with § 3 of the Work Safety Act (ASiG). Biomonitoring may form part of the medical surveillance required according to § 28 of the Hazardous Substances Ordinance (GefStoffV). In addition, with the consent of the worker concerned, it can be included in the assessment of the risk in the workplace. The company physician decides on the need for biomonitoring. The results of biomonitoring may lead to examination of the conditions obtaining in the workplace (see point 6).

## **2 Definitions**

### **2.1 Biomonitoring**

Biomonitoring is the examination of biological material taken from workers for the determination of hazardous substances, their metabolites or their biochemical or biological effect parameters. The aim here is to record the exposure and the health risk to workers, compare the values obtained as a result of the analyses with corresponding values (see point 2.5) and propose suitable measures for reducing the exposure and the health risk.

### **2.2 Biological material**

Biological material is understood to mean, inter alia, blood and/or urine in which the test parameter that is to be determined is analysed.

### **2.3 Test parameter**

The test parameter is the particular chemical substance or the biological indicator whose content or magnitude is determined in the biological material. A test parameter suitable for biomonitoring must indicate reliably, sensitively and, as specifically as possible, the exposure and/or strain caused by the hazardous substance. The choice of a suitable test parameter requires specialist knowledge in the field of occupational medicine.

### **2.4 Analytical procedures**

- (1) A complete analytical procedure includes the
- pre-analytical phase,
  - the analytical phase, including quality assurance (cf. point 5) as well as the
  - post-analytical phase with an assessment of the results in terms of occupational medicine.

(2) Elaborated and tested analytical procedures are included, inter alia, in the loose-leaf collection „Analyses in biological material“ produced by the Senate Commission for the Examination of Harmful Working Substances of the German Research Council (available from WILEY/VCH Verlag GmbH, D-69451 Weinheim).

## **2.5 Values for the assessment**

(1) The biological tolerance values (BAT) provided in Technical Rule 903 are considered in the assessment of the analysis results.

(2) If such values are not available, by comparing the analysis result with the recommendations provided in the specialist literature, such as the exposure equivalents for carcinogenic substances (EKA) in the MAK and BAT value lists produced by the German Research Council or reference values for the population at large, it can be examined whether, and at what level, occupational exposure to hazardous substances occurs.

## **3 General information**

**3.1** Since medical science is being applied, biomonitoring is subject to the statutory rules governing the medical profession. Accordingly, full information on the performance of biomonitoring, its purpose as well as the use of the analysis results must be provided in advance to the workers undergoing biomonitoring. The provision of biological material (cf. point 2.2) is to be assessed as an expression of consent to the investigation. A special declaration of consent by the workers is not required.

### **3.2 Aim**

Biomonitoring aims to measure the inner exposure due to hazardous substances or the resultant strain in exposed workers and to assess the relevance to health of such occurrences. Biomonitoring is especially indicated if one or more of the conditions according to point 3.4, section 2 are met.

### **3.3 Purpose of biomonitoring**

- (1) Biomonitoring permits conclusions to be drawn about
- the quantities of hazardous substances taken in by the worker by inhalation (inhalatively), via the skin (dermally) or by ingestion (orally),
  - specific biochemical and biological effects of an instance of exposure to a hazardous substance,
  - individual differences in the metabolization of hazardous substances,
  - the effectiveness of technical and personal protective measures,
  - the hygiene practised by an individual when handling hazardous substances.

(2) The results of biomonitoring are suitable for providing information of importance to the assessment of risk and the monitoring of workplaces. The results must be rendered anonymous. See point 6 for the approach to be applied here.

### 3.4 Reasons for biomonitoring

(1) Biomonitoring is always necessary when

- medical surveillance according to § 28 of the Hazardous Substances Ordinance is to be performed and
- a biological tolerance value (BAT) is provided in Technical Rule 903.

This may also apply to the initial investigation in order to record possible previous exposure.

(2) In addition, biomonitoring is always sensible in the case of activities

- a) involving direct dermal contact with hazardous substances that are absorbed well or predominantly via the skin (e.g. substances described by „H“ in Technical Rule 900)
- b) in which the oral route of uptake of hazardous substances may be of importance,
- c) in which there is exposure to hazardous substances with long biological half-lives (e.g. R 33),
- d) with exposure to
  - carcinogenic or mutagenic substances,
  - substances harmful to reproduction if these cannot be assessed by measurement of the workplace atmosphere,
- e) in which, for reasons of air-measurement technology (in the case of repair work, fault-fixing services, open-air work, cases of widely varying concentrations in the workplace atmosphere, frequently changing substances in batch operation), the hazardous substances are difficult to record or
- f) in which the inner exposure to a hazardous substance may be modified by physical work.

The application of biomonitoring in these cases presupposes the availability of a suitable value for the assessment of the analysis results (cf. point 2.5).

(3) In the cases cited under section 2 it is not, as a rule, possible to assess the risk on the basis of measurements of the workplace atmosphere alone (cf. Technical Rule 402). In accordance with section 2, the worker must be made aware of the voluntary nature of these tests.

(4) Biomonitoring is also sensible after accidental exposures, in particular if measurements of the workplace atmosphere are not available.

(5) Biomonitoring must also be performed if desired by the worker (cf. § 11 of the Health and Safety at Work Act (ArbSchG) unless, due to the assessment of the working conditions and the protective measures that have been taken, damage to health is not expected.

## **4 Performance of biomonitoring**

### **4.1 Measurement strategy and plan**

(1) The generally recognized rules of occupational medicine (see, inter alia, the „German Statutory Accident Insurance Institution’s principles for medical surveillance“) must be observed when determining the concentration of hazardous substances, their metabolites or other biological indicators in biological material as well as in the case of occupational-medicine assessment based on values in accordance with point 2.5.

(2) The test intervals for the particular test parameter are determined in dependence on the activity and the substance-specific criteria that apply to the hazardous substance. The results of the risk assessment as well as previous biomonitoring measurement results must be considered here. A measurement plan of relevance to the test parameters that are to be determined is drawn up and documented. This plan may also include measurements taken during the period between the intervals for medical surveillance investigations as laid down in Annex IV of the Hazardous Substances Ordinance. In these cases, additional medical investigations are only to be performed on a scale commensurate with the particular problem area.

### **4.2 Selection of the biological material, the test parameters and the analytical method**

The biological material must be readily accessible, i.e. obtainable under routine conditions and in a manner acceptable to the worker, and available in sufficient quantity. These criteria mainly apply to the urine and the blood. The company physician selects the biological materials, test parameters and analytical methods that are the most suitable for assessment of the health risk expected as a result of the hazardous substance. He can take advice here from the laboratory he has commissioned to perform the analyses. The requirements of Technical Rule 903 must be observed.

### **4.3 Sampling time in relation to the rhythm of the shift**

The time of sampling is to be determined on the basis of the relevant data on the particular test parameter provided in Technical Rule 903 or corresponding publications. In the absence of such information, sampling is to be undertaken at a time when the inner exposure of the person to be tested is in a state of equilibrium with the external exposure. The establishment of a state of equilibrium is not to be expected in cases where activities are only performed for short periods of time (repair work, fault-fixing services etc.). In such cases, sampling shall be performed at the end of the relevant activity.

### **4.4 Storage and transportation of the biological material**

Storage and transportation of the biological material must take place in such a way that factors affecting the result of analysis in vitro are reduced to a minimum. Where necessary, the company physician shall obtain advice from the analytical laboratory.

## **5 Assuring the quality of the analysis results**

### **5.1 Quality assurance**

(1) Analyses in biological material in the area of occupational medicine/toxicology (biomonitoring) must correspond to the state of technology and meet the quality criteria that apply to analytical chemistry in the field of occupational medicine and toxicology. Sampling, analyses and assessment represent the application of medical science and are thereby subject to medical quality assurance according to § 5 of the (specimen) professional rules for physicians – (specimen) amendment of the professional rules 1997 (Journal for German Physicians 1997; 94: C, issue 37, 1772-1780). With regard to the implementation of quality assurance, attention is additionally drawn to „Quality assurance of quantitative determinations in the laboratory“ according to the Federal Medical Board’s guideline that applies at the time.

(2) With regard to the preparation of samples (pre-analytical phase) and analysis, the general demands on the competence of test laboratories apply. If, within the framework of biomonitoring, the company physician makes use of external analytical services he must satisfy himself that the laboratory commissioned by him has the relevant expertise and apparatus and applies quality-assurance methods according to the current state of technology. However, the physician can assume that the results obtained by an external laboratory are correct if this laboratory is recognized jointly by the non-profit German Society for Occupational and Environmental Medicine (DGAUM) and the regional accreditation centre for measurement and testing centres for the enforcement of hazardous substances legislation (AKMP). Proof of a valid certificate of successful participation in a relevant DGAUM ring study must be available for the individual test parameter.

## **5.2 Cooperation between the company physician and the laboratory**

With regard to sampling, storage and transportation, the company physician shall observe the measures stipulated by the commissioned laboratory.

## **6 Assessment and conclusions**

### **6.1 Assessment of the analysis results by the laboratory**

The assessment of, and plausibility check on, the biomonitoring analysis results must be undertaken by the head of the laboratory responsible for this. This person relies here on the quality assurance performed within and outside the laboratory. In this regard, attention must also be paid to the detection limit of the analytical method.

### **6.2 Assessment by the company physician**

The company physician assesses the analysis results by means of comparison with the values cited in point 2.5. In this assessment, attention must be paid to the working conditions, the characteristics of the substance (toxicokinetics of the hazardous substance) and particular special features as possible influencing factors. Since a single measurement of a test parameter is not always sufficient for assessment purposes, repeated measurements may be necessary in order to protect the test result against error.

### **6.3 Transmission of the analysis results and a physician's duty to ensure confidentiality**

Since they represent person-related data, the biomonitoring analysis results are subject to the rules on professional confidentiality that apply to physicians (§ 203 section 1 of the Penal Code). Without the consent of the person concerned, analysis results may only be transmitted to third parties in a form that has been rendered anonymous. The anonymity of the workers must also not be prejudiced by particular attendant circumstances (e.g. individual workplace) relating to the medical surveillance or the measurements.

### **6.4 Conclusions from the assessment of biomonitoring**

(1) The company physician discusses the result of his assessment of the biomonitoring with the affected worker.

(2) The results of biomonitoring performed within the framework of medical surveillance examinations according to § 28 of the Hazardous Substances Ordinance are to be considered in the medical certificates according to § 31 of the Hazardous Substances Ordinance.

(3) In observance of the rules on anonymity contained in point 6.3, the results of biomonitoring are included in the risk assessment. If necessary, protection measures according to § 19 of the Hazardous Substances Ordinance must be taken.