

IGF authorized translation of a german-language Report A 8279/17

Report **on the inhalation exposure to formaldehyde during the** **preparation of body donations at the Ruhr Universität Bochum,** **Universitätsstraße 150, 44801 Bochum, Germany**

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1 Preliminary remarks

The Institut für Gefahrstoff-Forschung of the BGRCI carried out measurements for the assessment of inhalation exposure to formaldehyde at the anatomy of the Ruhr Universität Bochum.

The measurements were carried out on the basis of investigations in relation to § 19 SGB¹ VII "Authorisations of BG inspectors (Befugnisse von Aufsichtspersonen)" to determine the presence and concentration of hazardous substances and preparations and taking into account the obligations under the Ordinance on Hazardous Substances - (GefStoffV) § 7 para. 1 sentence 3 "Determination of information and risk assessment (Informationsermittlung und Gefährdungsbeurteilung)".

Thus, the quality criteria of a measurement according to SGB VII are met - but the anatomy is not a member company of the BGRCI.

After the Ordinance on Hazardous Substances came into force on 26.11.2010, the protection level concept was replaced.

The employer is obliged, to analyse and evaluate dangers to employees at the workplace (risk assessment - Gefährdungsbeurteilung), and to implement necessary measures as part of the minimisation imperative (Minimierungsgebot). The measurements documented in this report represent an important contribution to the risk assessment (Gefährdungsbeurteilung).

The investigation and evaluation of the measurements were done in accordance to the Technical Rule for Hazardous Substances (Technische Regel für Gefahrstoffe - TRGS) 402 "Identification and Assessment of the Risks from Activities involving Hazardous Substances: Inhalation Exposure (Ermitteln und Beurteilen der Gefährdungen bei Tätigkeiten mit Gefahrstoffen: Inhalative Exposition)".

1.1 Objective of the investigations

- The aim of this supplementary 3rd investigation was to determine the inhalation exposure to formaldehyde during the preparation of body donations after intensive structural changes (preparation tables with extraction and ventilation measures)
- The 1st measurement was done in order to be able to assess the improvement of the exposure situation. The measured values were significantly lower than the limit value for formaldehyde during the preparation of body donations (Bochum solution and formaldehyde reduced)

¹ SGB short for Sozialgesetzbuch (German Social Code)

- The 2nd measurement was carried out under conditions that approximate realistic course conditions. The experimental set-up included a preparation table occupied by 10 people, on which 5-6 experts prepared a body donation (Bochum solution). The measured values were significantly lower than the limit value for formaldehyde during the preparation of body donations (Bochum solution).
- The following 3rd measurement was carried out as an even further approximation to realistic course conditions with up to 10 persons per table and at least 3 experts preparing permanently. The preparation was performed on three body donations at the same time.

2 Investigation bases

2.1 Laws and Technical Rules for Hazardous Substances

- **GefStoffV (2016)** (Hazardous Substances Ordinance) Ordinance on Hazardous Substances
- **TRGS 400** "Risk assessment for activities involving hazardous substances" January 2010 edition last amended and supplemented GMBI S843-846 v. 21.10.2016
- **TRGS 402** "Identification and assessment of the risks from activities involving hazardous substances: inhalation exposure", January 2010 edition amended and supplemented: 02.04.2014
- **TRGS 900** "Occupational exposure limit values", edition: January 2006, last amended and supplemented: GMBI 2016 S 886-889 [No. 45] (v. 04.11.2016)
- **TRGS 905** "List of substances that are carcinogenic, mutagenic or toxic for reproduction", March 2016 edition GMBI S 378-390 [No. 19] v. 03.05.2016
- **TRGS 906** "List of carcinogenic activities or processes according to § 3 Abs. 2 Nr. 3 GefStoffV" 2005 Edition last amended and supplemented March 2007
- **TRGS 910** "Risk-related concept of measures for activities involving carcinogenic hazardous substances", February 2014 edition Last amended and supplemented GMBI 2016 p. 606-609 v. 29.7.2016 [No. 31] Corrected GMBI 2016 S 791 v. 7.10.2016 [No. 40]
- **Regulation (EC) No 1907/2006** of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Annex I No 1.01.
- **AGS Formaldehyde (2015)** - Justification for formaldehyde in TRGS 900.
- **MGU (2016) Project** "Formaldehyde Measurements in Anatomies" - Instructions for Action

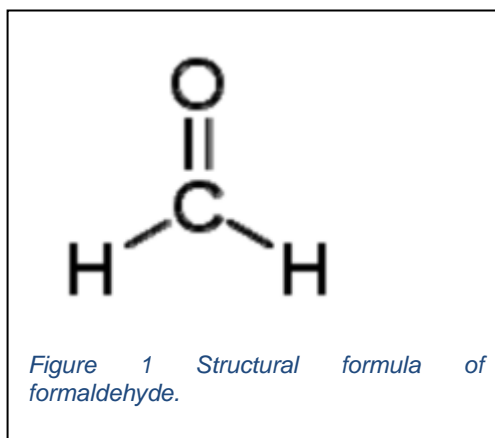
3 Formaldehyde

Systemic name: methanal. Synonyms: methyl aldehyde, methalaldehyde, methylene oxide, formol, formalin (aqueous solution).

CAS number: 50-00-02

Because of its physical properties, formaldehyde is highly volatile and soluble in water.

- Water solubility: 550 g/l at 20°C
- Melting point: -117°C (-92°C (gas); -16°C (25% aqueous solution))
- Boiling points: -19.1°C at 1013 hPa (gas), 99°C at 1013hPA (aqueous solution)
- Molar mass: 30.031g/mol



Formaldehyde is used in many ways in:

- Furniture production (in glue, plywood/chipboard)
- Interior finishing (OSB-boards, resin for glass and mineral fibres, in foams for insulation, adhesives, paints, lacquers, floor coverings)
- Fumigation, disinfectants in hospitals
- Fixation in anatomy and pathology etc.

Formaldehyde is formed during the oxidation of hydrocarbons (anthropogenic and biogenic). Among other things, formaldehyde is produced as an emission during combustion processes, e.g. as exhaust gas from motor vehicles and in tobacco smoke. Formaldehyde is detectable in the outside air in concentrations of 0.001 to 0.01 ppm [Grosjean 1993].

The adverse effects of formaldehyde are primarily ascribed to the protein reactive effect under formation of DNA-protein cross-links.

3.1 Formaldehyde at the Institut für Anatomie

Fixation of body donations:

Fixed body donations are used for the anatomical practical course of the medical students. The fixation of the donated bodies is performed in the anatomy using freshly prepared fixing solutions. The fixation is done by infusion. Depending on body weight and height, 12 to 15 litres of fixing solution are used per body. The fixing solutions formalin/phenol_old (Bochum solution), formalin/ethanol reduced and formalin/ethanol (Essen solution) prepared as follows:

Formalin/phenol old (Bochum solution):

- 800 ml formalin
- 600 ml phenol
- Fill up to 10 litres with water (8600 ml H₂O)

Formalin/phenol reduced:

- 600 ml formalin
- 450 ml phenol
- Fill up to 10 litres with water (8950 ml H₂O)

During the practical course, the bodies are stored in cooling chambers covered with Incidin® Ecolab® trickled cloth. Incidin® is described by the manufacturer Ecolab® as an aldehyde-free product for surface disinfection. If necessary, the bodies are re-fixed during the practical course.

Formaldehyde exposure at the anatomy during practical courses

- There is an inhalation exposure of formaldehyde for students and lectures during the practical course.
- There is an inhalation exposure of formaldehyde for sectional and preparation assistants during the preparation of the fixing solution and the fixation of the body donations and the transfer for preservation.

4 Limit values and reference values

With the entry into force of the new Ordinance on Hazardous Substances (GefStoffV) on 01 January 2005, there is a new limit value concept in Germany. The new Ordinance on Hazardous Substances only uses health-based limit values and no longer technical reference concentrations (TRK). The limit values are divided into occupational exposure limit values (AGW) and biological limit values (BGW). These limit values are legally binding.

Before the new Ordinance on Hazardous Substances came into force in 2005, the legally applicable limit values in Germany were MAK values (maximum workplace concentration, Maximale Arbeitsplatzkonzentration) and BAT values (biological agent tolerance value, Biologischer Arbeitsstoff-Toleranzwert). The terms MAK value and BAT value are still used in Germany by the Standing Senate Commission on Hazardous Substances of the German

Research Foundation (DFG). MAK values are published by the Senate Commission on Hazardous Substances of the German Research Foundation (MAK Commission). They serve the Committee for Hazardous Substances (AGS) as a basis for consultations on the establishment of occupational exposure limit values (OELs).

4.1 Occupational exposure limit values (AGW)

According to the Ordinance on Hazardous Substances (§2), the occupational exposure limit value (AGW) is the limit value for the time-weighted concentration of a substance in the air at the workplace in relation to a given reference period. It indicates up to which concentration of a substance acute or chronic effects on health in general are not to be expected. These are legally binding limit values.

For the hazardous substances examined in this report, the AGW values from TRGS 900 are used. For carcinogenic substances that are defined as category 1A or 1B according to CLP Regulation, the AGS has defined acceptance and tolerance concentration values that can be found in the TRGS 910.

4.2 Technical reference concentrations (TRK)

Since the Ordinance on Hazardous Substances came into force on 01 January 2005 all TRK-values and technically based limit values have been declared void. For substances that previously had a limit value but now have a limit value in the TRGS 900, all former limit values were abolished. For the time being, the air limit values valid until 2004 can be used to assess exposure to substances without AGW.

4.3 Maximum Workplace Concentration (MAK)

The MAK value (maximum workplace concentration) is the maximum permissible concentration of a working substance as gas, vapour or suspended matter in the air at the workplace which, according to current knowledge, "does not generally impair the health of employees and does not cause them undue nuisance", even in the case of repeated and long-term exposure. If no binding occupational exposure limit value exists for a hazardous substance, TRGS 400 and 402 allow a different assessment standard to be used for the assessment, e.g. the MAK value from the MAK and BAT value list of the German Research Foundation (ML-DFG) or an international limit value (LIG).

4.4 International Limit Values (LIG)

As LIG value for a hazardous substance usually the lowest value listed in the GESTIS list "International limit values for chemical agents" is used, unless there are technical reasons (e.g. metrological limits of determination) for selecting a different value. The LIG is subordinate to the

ML-DFG. The indicated value for the LIG is to be understood as a recommendation. Since derivation criteria, level of protection and legal relevance of limit values are not uniform for the individual national expert committees and authorities, the explanations of the original limit value lists should be used as the primary source.

4.5 Derived No-Effect Level (DNEL)

Annex I 1.0.1 of the REACH Regulation defines the objective of determining the hazardous effects upon human health. Accordingly, besides classification and labelling of a substance, levels of exposure to it are to be derived "above which humans should not be exposed. This level of exposure is known as the Derived No-Effect Level (DNEL).

No DNEL can be derive for carcinogenic substances for which a toxicological-adverse-effect threshold cannot be specified. A value called DMEL (derived minimal effect level) could be used in this cases. So far, there is no specification of the degree of the cancer risk that is associated with a DMEL.

4.6 Activities involving carcinogenic hazardous substances – TRGS 910

For activities involving carcinogenic substances (category 1A or 1B according to the CLP Regulation) exposure-risk-relationships (ERB) have been derived for a number of substances [TRGS 910]. The ERB of a carcinogenic substance refers to the relation between the substance concentration (inhalation) and the statistical probability of developing cancer during the entire lifetime. The acceptable risk and the derived acceptable concentration expresses the statistical probability of developing cancer at a level of 4:10000. The tolerable risk and the derived tolerable concentration corresponds to the statistical probability of developing cancer at a level of 4:1000. Any occasion when this value is exceeded is associated with a high, intolerable risk.

To enable an assessment of the hazards posed by carcinogenic hazardous substances a concept of measures (TRGS 910) for activities involving carcinogenic hazardous substances was developed by the Committee on Hazardous Substances (AGS). The concept is directly applicable in practice only for those carcinogenic substances for which an exposure-risk relationship (ERB) has been derived.

4.7 Classification of carcinogenic hazardous substances using EU substance directives

For classification and labelling purposes, carcinogenic substances are divided into three categories according to the Dangerous Substances Directive RL 67/548/EWG (Annex VI, Chapter 4.2.1):

Category 1 (=K1): Substances are known to be carcinogenic to humans. The causal link between human exposure to the substance and the development of cancer has been sufficiently demonstrated.

Category 2 (=K2): Substances that are to be regarded as carcinogenic to humans. There is sufficient evidence to support the assumption that human exposure to the substance may cause cancer. This assumption is generally based on the following: appropriate long-term animal testing, other relevant information.

Category 3 (=K3): Substances which cause concern for humans, due to possible carcinogenic effects. But the available information is not sufficient enough for a satisfactory assessment. Some evidence has been obtained from appropriate animal testing, but this is not sufficient to classify a substance in category 2.

Classification according to CLP Regulation:

With the CLP Regulation, the names of the categories changed. The former category K1 corresponds to the category 1A CLP Regulation, the former category K2 corresponds to the category 1B CLP Regulation, the former category K3 corresponds to the category 2 CLP Regulation.

MAK Classification of carcinogenic effect:

1. Substances that cause cancer in humans and can be assumed to make a contribution to cancer risk. Epidemiological studies provide adequate evidence of a correlation between the exposure of humans and the occurrence of cancer. Limited epidemiological data can be substantiated by information of the mode of action in humans.
2. Substances that are considered to be carcinogenic for humans because sufficient data from long-term animal studies or limited evidence from animal testing substantiated by evidence from epidemiological studies indicate that they can make a contribution to cancer risk. On the other hand data from animal studies can be supported by evidence that the substance causes cancer by a mode of action that is relevant to man and by results of in vitro tests and short-term animal studies.
3. Substances that cause concern that they could be carcinogenic for humans but cannot be assessed conclusively because of lack of data. In vitro tests or animal studies have yielded evidence of carcinogenicity that is not sufficient for classification of the substance in one of the other categories. The classification in category 3 is provisional.
 - 3A Substances which cause cancer in animals or humans or which are to be considered as carcinogenic to humans. The conditions for classification as category 4 or 5 would be fulfilled. However, for the substances there is not sufficient information available to derive a MAK- or BAT-value.
 - 3B There is evidence from in vitro or animal testing of a carcinogenic effect but it is not sufficient to classify it in another category. Further investigations are

necessary to reach a final decision. If the substance or its metabolites have no genotoxic effects, a MAK- or BAT-value may be established.

4. Substances which cause cancer in animals or humans or which are considered to cause cancer in humans and for which a MAK-value can be derived. The focus is on a non-genotoxic mechanism of action and genotoxic effects play no or only a minor role if the MAK- and BAT-values are observed. Under these conditions, no contribution to the cancer risk for humans can be expected. The classification is supported in particular by findings on the mechanism of action, which indicate, for example, that an increase in cell proliferation, inhibition of apoptosis or disruption of differentiation are in the foreground. Classification and MAK- and BAT-values take into account the multiple mechanisms that can contribute to carcinogenesis and their characteristic dose-time response relationships.
5. Substances which cause cancer in animals or humans or which are considered to cause cancer in humans and for which a MAK-value can be derived. The focus is on a genotoxic mechanism of action, for which, however, only a very small contribution to the cancer risk for humans can be expected if the MAK- and BAT-values are adhered to. The classification as well as MAK- and BAT-values are supported by information on the mechanism of action, dose dependence and toxicokinetic data.

4.8 Short-term exposure values and exceedance factors

TRGS 900

Short-term values supplement the occupational exposure limit values, by limiting fluctuations in concentration around the time-weighted average upwardly as well as their duration and frequency. The maximum level of short-term exceedance of the occupational exposure limit value must be based on the very different properties of the individual substances. A blanket definition of the short-term value parameters is therefore not possible. The short-term exposure value concentration is the product of occupational exposure limit value and exceedance factor. The time-weighted average must always be observed.

The maximum exceedance factor is 8. If the occupational exposure limit value is exceeded 4 times in one shift over 15 minutes 8 times, no further exposure may occur in one shift, otherwise the product of the shift length and the occupational exposure limit value will be exceeded. For the intervals between the periods with a concentration above the occupational exposure limit value (short-term value phase), a period of one hour should be aimed for. A total of four short-term value phases within a shift are permissible.

When determining exposure peaks, substances are divided into the following two categories according to their toxicological effects:

Category I:

Substances whose local effects determine the limit value or airway sensitising substances.

- a) An exceedance factor of 1 is defined as the base value, which can be adapted to the specific substance (up to a maximum of 8). The short-term value phase must not exceed 15 minutes. Operational monitoring shall be performed by averaging over 15 minutes, e.g. by sampling for 15 minutes.
- b) In justified cases a momentary value may also be established which shall be complied with in addition to twice the occupational exposure limit value concentration, as an average value over 15 minutes and which may not be exceeded at any time during the same period by more than four times the occupational exposure limit value concentration.

Category II:

Substances with a resorptive effect: An exceedance factor of 2 is defined as base value (15-minute mean value), which can be adapted to the specific substance (up to a maximum of 8). Operational monitoring shall be performed by averaging over 15 minutes, e.g. by sampling for 15 minutes. For substances of the short-term value category II, longer exceedance durations are also permissible as long as the product of exceedance factor (ÜF) and exceedance duration is adhered to (example: with an ÜF of 8, an ÜF of 4 over 30 min or an ÜF of 2 over 60 min is also possible).

4.9 Limit values for formaldehyde

DFG Senate Commission– MAK-Value

The Senate Commission of the German Research Foundation already decided in 2000 on a maximum workplace concentration for formaldehyde of 0.37 mg/m³ or 0.3 ml/m³ (0.3 ppm).

WHO

The WHO reassessed formaldehyde in 2010 and recommended a concentration of 0.1 mg/m³ (0.08 ppm) for both short-term and long-term exposure.

TRK

With the entry into force of the Hazardous Substances Ordinance in the version of the 23.12.2004, air limit values for carcinogenic and mutagenic substances were declared invalid. Thus, the previously valid limit value for formaldehyde of 0.63 mg/m³ or 0.5 ml/m³ (0.5 ppm) from TRGS 900 was abolished.

AGW

For carcinogenic substances, it is normally not possible to specify a threshold below which there is no longer any tumour risk. By classifying formaldehyde as category 4 in 2000, the MAK

Commission made it clear that formaldehyde is a carcinogenic substance for which no significant contribution to the cancer risk is to be expected if the MAK-value is complied with. Furthermore, the determination of a MAK-value indicates that the health of the employees is not impaired if this concentration is undercut and that they are not unduly harassed - i.e. no irritative effects are to be expected, for example. The AGS only imposes an AGW if acute or chronic harmful effects on health are not to be expected below this concentration.

The AGS has set an AGW for formaldehyde in the TRGS 900 in March 2015. The AGS provides the scientific justification for the AGW in its statement on formaldehyde of February 2015. The derivation of an AGW is regarded as appropriate due to the mechanism of action and a very good data situation [AGS 2015]. "Overall, all endpoints show a clear non-linearity and a concentration without measurable adverse effect. Based on this data a threshold can be assumed according to a "weight of evidence" procedure and thus an AGW can be derived" [AGS 2015].

Limit value type	mg/m ³ (= ppm)	Source
AGW	0,37 mg/m ³ / 0,3 ppm	TRGS 900
exceedance factor	2 (I)	TRGS 900
skin sensitisation	SH	TRGS 900
pregnancy group	Y	TRGS 900

Pregnancy group Y: According to the Commission's assessment, there is no need to fear a risk of teratogenic effects in pregnancy group C if the MAK value and the BAT value are complied with.

4.10 Classification as carcinogenic hazardous substance

In 1995 formaldehyde was classified by the IARC as 2A (probably carcinogenic to humans). In 1996, the 22nd Council Directive of the European Union (67/548/EEC) was used to classify the product in category 3.

In 2000, the MAK Commission classified formaldehyde in category 4 of carcinogenic substances. In 2014, an IARC working group reclassified formaldehyde from group 2A to group 1 (human carcinogen).

Also in 2014, formaldehyde was reclassified by the Commission Regulation (EU) No 605/2014 and the CLP Regulation (EG1272/2008, June 2014) and is now listed in the carcinogenic **category 2 (Category 1B** of the CLP Regulation - sufficient evidence for CMR properties in animal testing - suspected carcinogenic effect in humans).

EU

The EU classifies substances as carcinogenic according to the hazard categories of the CLP Regulation (EG1272/2008, "classification, labelling and packaging of substances and mixtures"). In Regulation 1272/2008 of 16.12.2008 formaldehyde was classified as carcinogenic.

An update of the CLP Regulation was published in Official Journal L167, p. 36 - 49 of the European Union of 6.6.2014 (EU 605/2014; 6th ATP - Adaptation to Technical Progress). The EU classifies formaldehyde in category 1B as carcinogenic in animal testing. The classification into mutagen 2, i.e. suspected germ cell mutagenicity, is also new. The reclassification was to take effect on 1.01.2015, but, following an amending regulation to the 6th ATP, will not enter into force until 01.01.2016.

In 1977, the then Federal Health Office published a (emission) guideline value of 0.1 ppm (0.12 mg/m³) for formaldehyde. It is still valid today and, among other things, forms the basis for restrictions on the use of construction products in accordance with the Chemicals Prohibition Ordinance.

4.11 Legal validity of the GefStoffV for the handling of formaldehyde in the anatomy

The activities occurring in the anatomy involve a targeted handling of the "work equipment" body donation. Therefore the corresponding regulations of the Hazardous Substances Ordinance apply and the legally binding AGW.

5 Sampling systems and methods of analysis

5.1 Sampling system for formaldehyd

Personal dust samplers with battery-operated pumps (GSA) are used for stationary and personal sampling. A Waters Sep-Pak Xposure is used as the sample carrier according to the "Messsystem Gefährdungsermittlung" of the accident insurer (UV-Träger) (MGU).



Figure 2 XPoSure™ cartridge.

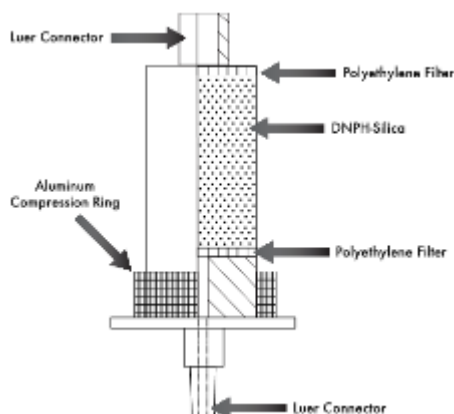


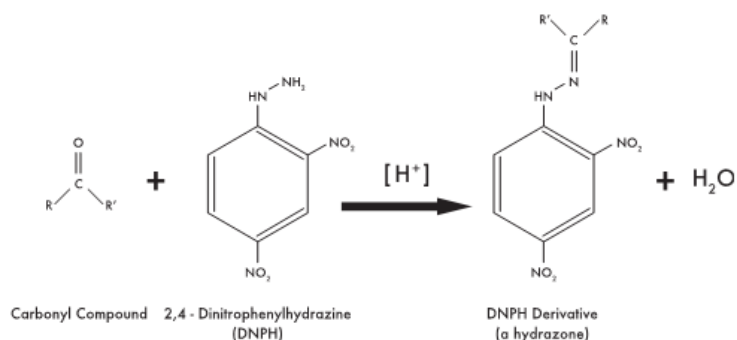
Figure 3 XPoSure™ cartridge. schematically as cross section

XPoSure™ has an efficiency higher 95% at flow rates up to one litre per minute [Waters].

5.2 Method of analysis for formaldehyde

The analysis for formaldehyde follows DIN ISO 16000-3:2013-01 Part "Indoor air. Part 3: Determination of formaldehyde and other carbonyl compounds in indoor air and test chamber air - Active sampling method" and the corresponding DFG Method "Aldehyde Method 2 HPLC / IFA 6045 Aldehyde".

The method for the analysis of aldehydes is based on the reaction with 2,4 dinitrophenylhydrazine (DNPH) and the subsequent analysis of the formed hydrazone derivatives by HPLC.



High performance liquid chromatography (HPLC) is performed according to the IFA method 6045. The hydrazones are detected by absorption of ultraviolet light. The detection of e.g. formaldehyde takes place at 365 nm.

6 Measuring situation and measuring strategy

The sampling time depends on the duration of the activity. In order to obtain representative results for the conditions in an anatomical practical course, the aim is to prepare the bodies for approximately 2 hours. The personal/person-carried and stationary measurements are performed simultaneously. Short-term values are determined stationary and person-carried over a representative period or the duration of the activity, whereby the individual sampling period is 15 minutes.

6.1 Measurements in the anatomy

The measurements were carried out in the Saal West, which is already equipped with improved ventilation technology. Personal measurements and stationary measurements were carried out.

6.2 Operation and measurement location

The Institute für Anatomie has two preparation rooms (Ost and West):

Length: approx. 40 meters

Height: approx. 4 meters

Width: approx. 15 meters

The measurements were carried out in the Saal West.

6.3 Climatic conditions

Temperature (°C):	Inside	Outside
Start of measurement	18	14
End of measurement	18	14
Air pressure (hPa):		
Start of measurement	1008	1009
End of measurement	1007	1008
Relative humidity (%)		
Start of measurement	35	37
End of measurement	36	37

6.4 Technical specifications at the measurement location

Measurement location room closed (open connections to adjacent rooms)

Ventilation technology (room)

Free ventilation available no

Room-ventilation system available yes and in operation



Figure 4 Preparation room West

6.5 Room-ventilation system (RTL) of the preparation rooms

The newly installed RTL unit supplies cooled fresh air directly via the preparation table. The dissection/preparation tables (Medis Medical Technology) and work tables are equipped with side suction. According to the existing measurement protocols, approx. 800 m³/h are fed to each table and 900 to 1000 m³/h are discharged. The supply and exhaust air was in operation at 8 tables with body donations during the entire period.

6.6 Measuring stations

The measurements are made to assess whether the AGW is complied with.

- Measurements are carried out on 3 body donations (Bochum solution (formalin / phenol)). A total of 8 body donations were placed on the preparation tables.
- Table 6 occupied by 8 persons and 3 permanently preparing persons.
- Table 10 occupied by 10 persons and 4 permanently preparing persons.
- Table 7 occupied by 7 persons and 3 permanently preparing persons.

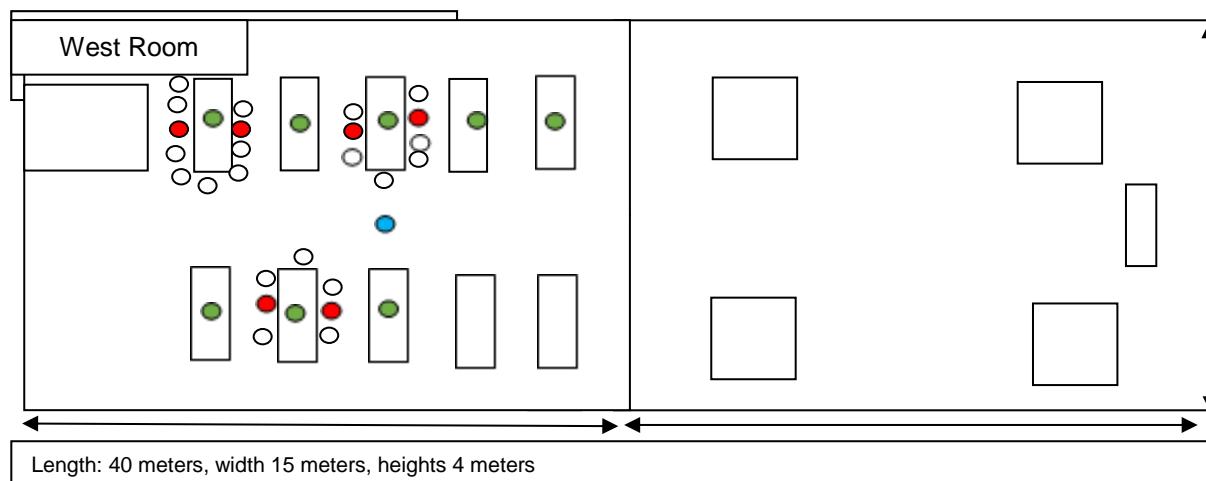


Figure 5 Sketch of the measuring location

7 Investigation results

In accordance with TRGS 402, the measured values determined must be related to the work shift length and stated as measurement results (ME). Exposure is measured under normal operating conditions over a maximum measurement period of approx. 2 hours. Therefore, the measured values can be regarded as time-weighted average values and thus as measurement results without conversion. The measurement result can be used to determine the so-called **substance index (I)**, which is the quotient of the measurement result and the limit value ($I = ME/GW \cdot F$). F is the quotient of the shift length and exposure duration. If the shift length and the exposure duration are identical, the factor = 1.

The binding occupational exposure limit values of TRGS 900 are used to evaluate the substance indices and evaluation indices.

Short-term values can be monitored by averaging over 15 minutes, e.g. by sampling for 15 minutes.

If no binding occupational exposure limit value exists for a hazardous substance, TRGS 400 and TRGS 402 allow a different assessment standard to be used for the assessment, e.g. the MAK- and BAT-value list of the German Research Association or another international limit value (LIG). For carcinogenic substances, the acceptance and tolerance concentrations according to TRGS 910 must be used.

As a rule, the lowest value from the GESTIS list "International limit values for chemical agents" is used as the LIG for a hazardous substance. Only if there are technical reasons (e.g. metrological determination limits), another can be considered.

The LIG is subordinate to the ML-DFG. The indicated value for the LIG is to be understood as a recommendation. Since derivation criteria, level of protection and legal relevance of limit values are not uniform for the individual national expert committees and authorities, the explanations of the original limit value lists should be used as the primary source.

Substance index:

An exposure duration of 8 hours was assumed in the sense of a worst case scenario. The factor is therefore 1.

7.1 Measurement at table 7 – Body donation Bochum solution (Formalin/Phenol)

Work area	Preparation room west	Preparation room west	Preparation room west	Preparation room west			
Measurement	Person-carried Dr. Napirei	Person-carried Dr. Maricic	Stationary top of the table	Stationary short-term			
Sample carrier	Waters Sep-Pak Xposure	Waters Sep-Pak Xposure	Waters Sep-Pak Xposure	Waters Sep-Pak Xposure			
Sample carrier no.	17001176	1700988	1700985	1700972	1700973	1700974	1700975
Pump capacity (l/min)	0,66	0,66	0,66	0,66			
Measuring time (min)	125	124	118	15	15	15	15
AGW (mg/m ³)	0,37	0,37	0,37	0,37			
Measurement results (mg/m ³)	0,16	0,03	0,04	0,06	0,05	0,04	0,04
Substance index	0,43	0,08	0,1	0,16	0,13	0,1	0,1
Remarks	perparation	perparation	perparation	perparation			



Figure 6 Table 7- stationary and personal measurements during a preparation of a body donation (Bochum solution)

7.2 Measurement at table 6 – Body donation Bochum solution (formalin/phenol)

Work area	Preparation room west	Preparation room west	Preparation room west	Preparation room west			
Measurement	Person-carried Dr. Corvace	Person-carried Dr. Moroson	Stationary top of the table	Stationary short-term			
Sample carrier	Waters Sep-Pak Xposure	Waters Sep-Pak Xposure	Waters Sep-Pak Xposure	Waters Sep-Pak Xposure			
Sample carrier no.	17001179	17001180	1700986	1700976	1700977	1700978	1700979
Pump capacity (l/min)	0,66	0,66	0,66	0,66			
Measuring time (min)	120	122	120	15	15	15	15
AGW (mg/m ³)	0,37	0,37	0,37	0,37			
Measurement results (mg/m ³)	0,07	0,2	0,07	0,17	0,12	0,1	0,11
Substance index	0,18	0,54	0,18	0,45	0,32	0,27	0,29
Remarks	perparation	perparation	perparation	perparation			



Figure 7 Stationary and personal measurements during a preparation of a body donation (Bochum solution)

7.3 Measurement at table 10 – body donation- Bochum solution (formalin/phenol)

Work area	Preparation room west	Preparation room west	Preparation room west	Preparation room west

Measurement	Person-carried	Person-carried	Stationary	Stationary			
	Prof. Brand-Saberi	Dr. Pu	Kopfende	short-term			
Sample carrier	Waters Sep-Pak Xposure	Waters Sep-Pak Xposure	Waters Sep-Pak Xposure	Waters Sep-Pak Xposure			
Sample carrier no.	17001178	17001177	1700987	1700980	1700981	1700982	1700983
Pump capacity (l/min)	0,66	0,66	0,66	0,66			
Measuring time (min)	122	123	120	15	15	15	15
AGW (mg/m ³)	0,37	0,37	0,37	0,37			
Measurement results (mg/m ³)	0,03	0,07	0,04	0,09	0,1	0,29	0,07
Substance index	0,08	0,18	0,1	0,24	0,27	0,78	0,17
Remarks	perparation	perparation	perparation	perparation			



Figure 8 Table 10- personal measurement during a preparation of a body donation (Bochum solution)

7.4 Measurement – stationary in the middle of the room

Work area	Preparation room west
Measurement	Middle of the room, stationary
Sample carrier	Waters Sep-Pak Xposure
Sample carrier no.	1700984
Pump capacity (l/min)	0,66
Measuring time (min)	121

AGW (mg/m ³)	0,37
Measurement results (mg/m ³)	0,04
Substance index	0,1
Remarks	-



Figure 9 Stationary measurement in the middle of the room.

8 Assessment of inhalation exposure and finding

8.1 Results

The Institut für Gefahrstoff-Forschung carried out formaldehyde measurements on behalf of the Department Planen und Bauen Hochschulvermögen Bochum - Bau und Liegenschaftsbetrieb NRW in the modernised preparation room of the anatomy of the Ruhr Universität Bochum.

- The formaldehyde concentrations of the personal measurements during the preparation of fixed body donations are all below the AGW of 0.37 mg/m³.
- The short-term measurements also showed concentrations below the AGW for formaldehyde.
- The measurement in the middle of the room showed that the AGW for formaldehyde was clearly undercut.

8.2 Finding

For the preparation on a fixed body donation under the test conditions (ventilation conditions see test protocol) the finding for formaldehyde (Bochum solution) is:

	Protective measures sufficient	

8.3 Supplementary investigations

- From our point of view, the three simulations carried out are well comparable with the real conditions in the preparation course for medical students. According to the available results, compliance with the AGW for formaldehyde can be deduced under the newly created conditions. The extent to which additional investigations are required is the responsibility of the operator in consultation with the responsible accident insurer.

8.4 Minimisation imperative

In accordance with the Hazardous Substances Ordinance § 7 Basic obligations (Grundpflichten), there is always a minimization imperative for hazardous substances. "The employer must exclude risks to the health and safety of employees when working with hazardous substances. If this is not possible, he must reduce them to a minimum".

The IGF is at your disposal for further consultations and possible follow-up investigations.

Measurement and reporting:

**Institut für Gefahrstoff-Forschung (IGF) der
Berufsgenossenschaft
Rohstoffe und chemische Industrie (BG RCI)**

9 Literature

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