



Implementation of 2013/35/EU in Germany - Risk Assessment based on Exposure Limit Values

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Abstract

The European Directive 2013/35/EU was implemented into German legislation by the EMF Ordinance in 2016. To improve the comprehensibility and usability of the EMF Ordinance, Technical Rules are currently being developed to assist employers, particularly in small and medium sized enterprises, to implement state of the art of occupational safety and health measures. By applying the information and measures contained in the Technical Rules, compliance with the EMF Ordinance is ensured

Action Levels or Exposure Limit Values are used to assess risks associated with exposure to electromagnetic fields at workplaces. When comparing risk assessments based on Exposure Limit Values against those based in Action Levels, it is rather challenging to assess measured or calculated exposure values against Exposure Limit Values. Besides detailed information on risk assessment of electromagnetic fields at workplaces, Technical Rules provide employers with thorough instructions on how to apply Exposure Limit Values when assessing risks arising from electromagnetic fields providing a simple and guided approach to fulfil the requirements of the EMF Ordinance. When reflecting this from an international perspective, in the facet of applying Exposure Limit Values for EMF risk assessment, EN 50499 will be well complemented by the open access Technical Rules for the German EMF Ordinance.

1 Introduction

1.1 Implementation of 2013/35/EU into German OSH legislation

The European Directive 2013/35/EU [1], which lays down the minimum health and safety requirements regarding the exposure of workers to the risks arising from electric, magnetic and electromagnetic fields (EMF) came into force in 2013. Similar to all other European member states, the Directive on Electromagnetic Fields [1] had to be implemented into German occupational safety and health legislation. It was open to the member states whether to implement the Directive 2013/35/EU into national legislation directly or to amend to existing regulations as in

Germany. For a detailed comparison of international policies on EMF please refer to [2].

The EMF Ordinance [3] came into force in November 2016 and is a binding regulation in Germany for any risks arising from the exposure to electromagnetic fields at workplaces. To support particularly small and medium sized enterprises (SMEs) with an elaborated but applicable safety approach, Technical Rules will improve the comprehensibility and usability of the German EMF Ordinance [3]. With Technical Rules Germany's occupational safety and health legislation supports employers in fulfilling their obligations arising from the German EMF Ordinance (and the Directive 2013/35/EU respectively). Applying Technical Rules entails presumption of conformity with the related German OSH Ordinance; comparable with harmonized standards in product safety.

1.2 Structure and content of Technical Rules on EMF

The German Federal Ministry of Labour and Social Affairs has assigned the Advisory Committee on Operational Safety to develop Technical Rules for the German EMF Ordinance. Representatives of employers' associations, labour unions, the German Social Accident Insurance, and governmental occupational safety and health authorities along with scientists are appointed members to this Advisory Committee. At the end of the development process, all appointed members reach consensus on the matter. Such process guarantees a well-defined balance between effectiveness and efficiency of safety measures. It differs significantly from the development process of international standards, which could be prone to be driven by other interests than for instance occupational safety and health. Application of Technical Rules along with presumption of conformity to the German EMF Ordinance marks a substantial difference compared to the European non-binding guide for implementing 2013/35/EU [4]. Based on the EMF Ordinance, three Technical Rules (TREM) are being currently developed by working groups of the Advisory Committee on Operational Safety covering the frequency range beginning with static electric and magnetic fields leading up to time-varying EMF at a frequency of 300 GHz:

1. TREMF LF, for static and low frequency EMF, $0 \leq f \leq 10$ MHz covering non-thermal effects;
2. TREMF RF, for high frequency EMF, $100 \text{ kHz} \leq f \leq 300$ GHz covering thermal effects;
3. TREMF MRA, for magnetic resonance applications (imaging and spectroscopy), implementing Article 10 Number 1 Letter (a) of the Directive 2013/35/EU.

3 Risk assessment for workplaces exposed to EMF

Risks related to EMF exposure at workplaces are assessed for workers without any particular risks, as well as for workers at particular risk. Workers at particular risk essentially include workers wearing active implants (e.g. pacemakers or defibrillators) or passive implants (e.g. stents, metallic prostheses) as well.

Accounting for the different demands of groups of workers wearing active and passive implants, risk assessment may be performed either based on individual properties (3.1), like an implant's settings or may focus on a detailed approach (3.2) accounting for the majority of workers.

3.1 Risk assessment for workers at particular risk on an individual basis

Risk assessments for workers wearing implants can be done under consideration of individual factors. These can be, for example, the so-called induction area, which depends on the positioning and length of the electrode leads, the sensing configuration (unipolar or bipolar) or the personal sensitivity settings of the implant. In order to consider these factors correctly, it requires a deeper professional understanding of the functioning of the implants as well as the influence of electromagnetic fields on these devices and the human tissue. TREMF provide a step by step instruction, in order to guide EMF-specialist safety and health professionals required to undertake such assessments.

3.2 Detailed risk assessment

When assessing risks for workers without any particular risks, groups of visitors, or temporary staff, German employers can be supported by either:

- EMF-specialist safety and health professionals (in Article 4 Number 4 of the Directive 2013/35/EU referred to as competent services or persons) or
- regular safety and health professionals (meaning non-specialists to EMF risk assessments).

In order to assess risks emerging from EMF sources with very low EMF emissions, for example regular office workplaces or workplaces accessible by the general public, TREMF offers tables with pre-assessed exposure

situations/equipment based on [4, 5, and 6]. Such EMF sources require no further assessment nor safety measures. Both shall be recorded within the risk assessment documentation to satisfy the demands led out by the German EMF Ordinance [3].

For workplaces where EMF exposure is expected to exceed Action Levels, risk assessment at a specialist level is required. If the employer does not have specialist EMF-expertise, EMF-specialist safety and health professionals have to be consulted to support the risk assessment.

When carrying out the risk assessment, the following has to be taken into account

- particular requirements set out by IEC- or CENELEC-standards on EMF measurement or numerical simulation of EMF exposure levels,
- comparing exposure levels with permissible Action Levels or Exposure Limit Values, and
- deducting appropriate provisions aimed at avoiding or reducing risks.

All results of the risk assessment are required to be reported transparently and comprehensibly. To report the outcome in such a way supports future reassessments and comparison with potentially modified exposure levels.

It is important to point out, that risk assessment may either be based on Action Levels or on Exposure Limit Values. Whereas physical quantities to be compared to Action Levels are relatively easy to be determined, those to be compared with Exposure Limit Values are not. According to Article 2 of the Directive 2013/35/EU Exposure Limit Values were established on the basis of biophysical and biological considerations, meaning internal electric field strength for non-thermal effects and specific absorption rate for thermal effects.

As it proves challenging to assess those physical quantities at workplaces, the employer requires support to make use of the choice between risk assessment based on Action Levels or Exposure Limit Values as given by the Directive 2013/35/EU [1].

3.3 Risk assessment based on Exposure Limit Values

What is the reason for employers to carry out risk assessments based on Exposure Limit Values, when it is comparatively difficult to determine those?

Just a quick reminder: According to Article 2 Letter (g) of the Directive Action Levels are “*established for the purpose of simplifying the process of demonstrating the compliance with relevant ELVs or, where appropriate, to take relevant protection or prevention measures specified in this Directive*”. To put it simpler: If EMF exposure exceeds Action Levels, actions to mitigate risks need to be taken. What those actions are to be comprised of, depends on the nature of the exceeded Action Level (Directive 2013/35/EU, Article 2 Letter (g) (i)-(ii)):

- for electric fields [...] Action Levels relate to the specific protection or prevention measures and

- for magnetic fields, Action Levels relate to the sensory effects ELVs and to the health effects ELVs.

Given the scenario, EMF exposure exceeds relevant Action Levels. In Article 5 Number 2 2013/35/EU employers are given the freedom of choice to either

- implement safety measures in accordance to Article 5 Number 2 Letters (a)-(i) or
- demonstrate that the relevant Exposure Level Values are not exceeded and that safety risks can be excluded.

To decide upon the right choice, employers may balance costs and benefits of either alternative. To support an employer's decision making, both TREMF LF and RF provide a detailed explanation of pros and cons regarding the influence of different calculation/simulation methods on uncertainty budgets. As the diversity of methods range from simple homogenous human models (e.g. disc model) to as far as sophisticated anatomical models, one can imagine that the uncertainty budget of less detailed methods must be higher.

It is important to emphasize that, any EMF risk *“Assessment shall take into account uncertainties concerning the measurements or calculations, such as numerical errors, source modelling, phantom geometry and the electrical properties of tissues and materials”* (Article 4 Number 3 of the Directive 2013/35/EU). In other words, a less detailed method with a reasonable high uncertainty budget is very likely to entail only small exposure indices. For exposure indices please refer to Appendix D in [5]. An adequate choice of method does not account for mistakes regarding modelling and abstracting the real world exposure scenario, e.g. position of the worker to the EMF source, conductor geometry etc.

As most employers are likely to assign the demonstration to “competent services or persons”, TREMF LF and RF provide an almost exhaustive list of criteria to be accounted for and checked in this case. Additionally, selected application scenarios, such as resistance welding or Anti-Theft Devices, are introduced to employers.

To look back at the Technical Rules for the German EMF Ordinance from an international perspective, this paper showed, risk assessment as of EN 50499 will be well complemented. Once the TREMF are announced by the German Federal Ministry for Labor and Social Affairs, they will be made publicly available via www.baua.de/emf (please switch to English language).

4 References

1 “Directive on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)”; entered into force on 29.06.2013.

2 R. Stam “Comparison of international policies on electromagnetic fields (power frequency and radiofrequency fields)”, 20 pages, Bilthoven: RIVM.

3 German Ordinance on the Protection of Workers against the Risks arising from Electromagnetic Fields (EMF Ordinance), entered into force on 15.11.2016.

4 Non-binding guide to good practice for implementing Directive 2013/35/EU Electromagnetic Fields; Volume 1, 2, and Guide for SMEs.

5 EN 50499:2019 “Procedure for the assessment of the exposure of workers to electromagnetic fields”

6 DGUV-I 203-043 „Beeinflussung von Implantaten durch elektromagnetische Felder”, Berlin, 2012.