Implementation of 2013/35/EU in Germany: Risk Assessment Based on Exposure Limit Values

Peter Jeschke, Carsten Alteköster, Ingo Bömmels, Kai Jagielski, Corinna Becker, and Mathias Hoffmann

Abstract — 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 occupational safety and health measures. By applying the information and measures contained in the technical rules, compliance with the EMF Ordinance is ensured (i.e., presumption of conformity). Action levels or exposure limit values are used to assess risks associated with exposure to electromagnetic fields (EMF) in workplaces. When comparing risk assessments based on action levels against those based on exposure limit values, the latter approach is rather challenging. Besides detailed information on risk assessment of EMF in workplaces, technical rules provide employers with thorough instructions on how to apply exposure limit values when assessing risks arising from EMF, providing a simple and guided approach to fulfill 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 and EN 50413 will be well complemented by the open-access technical rules for the German EMF Ordinance.

1. Implementation of 2013/35/EU Into German OSH Legislation

European Directive 2013/35/EU [1], which lays down the minimum health and safety requirements regarding the exposure of workers to 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 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, refer to [2].

The EMF Ordinance [3] came into force in November 2016 and is a binding labor regulation in Germany for any risks arising from the exposure to EMF in workplaces. To support particularly small and medium-sized enterprises with an elaborate 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 Directive 2013/35/EU, respectively. Applying technical rules entails the presumption of conformity with the related German OSH Ordinance, comparable with harmonized standards in product safety.

2. Structure and Content of Technical Rules on EMF

The German Federal Ministry of Labor and Social Affairs has assigned the Advisory Committee on Operational Safety to develop technical rules for the German EMF Ordinance. Representatives of employers' associations, labor unions, German Social Accident Insurance, and governmental occupational safety and health authorities along with scientists are appointed members to the Advisory Committee. At the end of the development process, all appointed members reach consensus on the matter. Such a 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 interests other than occupational safety and health. Application of the technical rules along with the presumption of conformity to the German EMF Ordinance marks a substantial difference compared to the European nonbinding guide for implementing 2013/35/EU [4].

Based on the EMF Ordinance, three technical rules (TREMF) 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:

Manuscript received 22 December 2021.

Peter Jeschke is with the German Federal Institute for Occupational Safety and Health, Friedrich-Henkel-Weg 1-25, 44149 Dortmund, Germany; email: physical.agents@baua.bund.de

Carsten Altekoester is with the Institute for Occupational Safety and Health of the German Social Accident Insurance, Alte Heerstraße 111, 53757 St. Augustin, Germany; email: carsten.altekoester@dguv.de

Ingo Boemmels is with the Institute for Occupational Safety and Health of the German Social Accident Insurance, Alte Heerstraße 111, 53757 St. Augustin, Germany; email: ingo.boemmels@dguv.de

Kai Jagielski is with the VDE Association for Electrical, Electronic and Information Technologies, Merianstraße 28, 63069 Offenbach am Main, Germany; email: kai.jagielski@vde.com

Corinna Becker is with the Berufsgenossenschaft Handel und Warenlogistik (BGHW), M 5, 7 68161 Mannheim, Germany; email: c.becker@bghw.de

Mathias Hoffmann is with the Lower Saxon State Department for Waterway, Coastal and Nature Conservation, An der Scharlake 39, 31135 Hildesheim, Germany: email: mathias.hoffmann@nlwkn.niedersachsen.de

1. TREMF LF—for static and low-frequency EMF, $0 \leq f \leq 10$ MHz, covering nonthermal effects
2. TREMF RF—for high-frequency EMF, 100 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 Directive 2013/35/EU [1].

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 medical implants (e.g., pacemakers or defibrillators) or passive medical implants (e.g., stents or metallic prostheses) as well.

Accounting for the different demands of groups of workers wearing active or passive implants, risk assessment either may be performed based on individual properties (3.1), such as 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 medical 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, the risk assessment requires a deeper professional understanding of the functioning of the implants as well as the influence of EMF on these devices and the human tissue. TREMF provides step-by-step instructions to guide EMF-specialist safety and health professionals required in undertaking 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 Directive 2013/35/EU [1] referred to as competent services or persons) or
- regular safety and health professionals (meaning nonspecialists to EMF risk assessments).

To assess risks emerging from EMF sources with very low EMF emissions, such as regular office workplaces or workplaces accessible by the general public, TREMF offers tables with preassessed exposure situations/equipment based on [4–6]. Such EMF sources require no further assessment or safety measures. Both shall be recorded within the risk assessment documentation to satisfy the demands set 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 planning, execution, and interpretation of the results of 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
- Deducting appropriate provisions aimed at avoiding or reducing risks

All results of the risk assessment are required to be reported transparently and comprehensively, Reporting the outcome in such a way supports future reassessments and comparisons with potentially modified exposure levels or across machinery.

It is important to point out that risk assessment may be based on either action levels or exposure limit values. Whereas physical quantities to be compared to action levels are relatively easily determined, those to be compared with exposure limit values are not. According to Article 2 of Directive 2013/35/EU [1], exposure limit values were established on the basis of biophysical and biological considerations, meaning internal electric field strength for nonthermal effects and specific absorption rate for thermal effects.

As it proves challenging to assess those physical quantities in 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 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?

A quick reminder: According to Article 2, Letter (g), of Directive 2013/35/EU, 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." More simply 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 [1], Article 2, Letter (g) (i)–(ii)):

- For electric fields, action levels relate to the specific protection or prevention measures.
- 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, of Directive 2013/35/EU [1], 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 on the right choice, employers may balances costs and benefits of either alternative. To support an employer's decision making, both TREMF LF and RF provide a detailed explanation of the pros and cons regarding the influence of different calculation/simulation methods on uncertainty budgets. As the diversity of methods range from simple homogeneous human models (e.g. disc model) to sophisticated anatomical models, one can imagine that the uncertainty budget of less detailed methods must be higher.

3.4 Uncertainty Estimations

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 Directive 2013/35/EU). In other words, a less detailed method with a reasonable high uncertainty budget is very likely to permit only small exposure indices. For exposure indices, refer to Appendix D in [5].

It is an important difference to be noted: calculation uncertainty does not account for modelling mistakes when modelling and abstracting the real world exposure scenario, e.g. position of the worker to the EMF source, conductor geometry etc.

4. Quality Assessment

As most employers are likely to assign the risk assessment based on ELVs to "competent services or persons," TREMF LF and RF provide a nearly exhaustive list of criteria to be accounted for quality. Additionally, selected application scenarios, such as resistance welding or antitheft devices, are introduced to employers.

5. Conclusion

To look back at the technical rules of the German EMF Ordinance from an international perspective, this article showed that risk assessment as of EN 50499 [5] and EN 50413 [7] will be well complemented not only for risk assessments based on ELVs. Once the TREMF is announced by the German Federal Ministry for Labor and Social Affairs, they will be made publicly available at https://www.baua.de/emf (use the English translation).

6. References

1. European Commission, "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 June 2013.
2. R. Stam, *Comparison of International Policies on Electromagnetic Fields (Power Frequency and Radiofrequency Fields)*, 20 pages, Bilthoven, Netherlands, RIVM, 2018.
3. "German Ordinance on the Protection of Workers Against the Risks Arising From Electromagnetic Fields (EMF Ordinance)," entered into force on 15 November 2016.
4. European Commission, Directorate-General for Employment, Social Affairs and Inclusion, Non-binding guide to good practice for implementing Directive 2013/35/EU Electromagnetic Fields. Volume 2, Case studies, Publications Office, 2016, https://data.europa.eu/doi/10.2767/098908
5. EN 50499, "Procedure for the Assessment of the Exposure of Workers to Electromagnetic Fields," 2019.
6. DGUV-I 203-043 "Beeinflussung von Implantaten durch elektromagnetische Felder," 2012.
7. EN 50413 "Basic Standard on Measurement and Calculation Procedures for Human Exposure to Electric, Magnetic and Electromagnetic Fields (0 Hz–300 GHz)," 2019.