EU Directive 2013/35/EC – What needs to be done? The way forward

(Some problems with practical application of the Directive 2013/35/EC and ways for resolving them)

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Introduction

There are a lot of problems with the practical use of the Directive 2013/35/EC. Some of them have been solved for the RF frequency region after the ICNIRP 2020 publication on radiofrequency (RF) fields but many others interfere with the real practice in the working environment.

Some of the main questions are the followings:

1. What to do with the long-term exposures – if there are enough evidence to discuss them in future?
2. Exposure assessment in the near field zone – which parameters are adequate to be used, if calculations are possible to apply?
3. Is it appropriate to apply Exposure Limit Values/Action Levels for concrete working places/sources/occupations or to use the approach given in the EU Directive – general ELVs/Als for all of them?
4. How to manage the ELVs/Als for technologies where overexposure is expected, also for multifrequency exposure, for workplaces in the near field zone?
5. Which averaging time to use – 6 min or 30 min? What averaging time should be used for long-term exposures on the workplaces?
6. If the competence of the specialists performing measurements and exposure assessment is enough; is there a need of additional training?

Discussion

Long-term exposure, long-term effects, non-thermal effects

Concerning the long-term exposure, in Directive 2013/35/EC the Exposure Limit Values and Action Levels are for short-term exposure, based on literature review and scientific knowledge on thermal and non-thermal effects. In the introduction of the Directive, very clear is announced the following:

> *"This Directive does not address suggested long-term effects of exposure to electromagnetic fields, since there is currently no well-established scientific evidence of a causal relationship. However, if such well-established scientific evidence emerges, the Commission should consider the most appropriate means for addressing such effects, and should, through its report on the practical implementation of this Directive, keep the European Parliament and Council informed in this regard. In doing so, the Commission should, in addition to the appropriate information that it receives from Member States, take into account the latest available research and new scientific knowledge arising from the data in this area."*

At this time, the ICNIRP 2020 issue for RF exposure implemented *"high level of protection for all people against substantiated adverse health effects from exposures to both short- and long-term, continuous and discontinuous radiofrequency EMFs."*

Unfortunately, there is no any definition (or explanation) what ICNIRP imagines concerning the implementation cited above.

Most of the real health problems of working with EMF sources are connected not with short-term, and with long-term exposures, last for months and years at levels close to the limits or above them. Many questions arise concerning such type of exposure: how to define long-term exposure, what gives such exposure to the worker (long-term or other effects), how to evaluate the risk arising by such effect.

An additional important question is: When we will accept the long-term exposure as more important for the workers' health and how to distinguish the two types of exposures (and effects) – long- and short-term ones?

There are huge number of publications, most of them in famous peer review journals that discuss low level of exposure (below the ELVs), also long-term effects on biological tissues. This fact should oove the international organizations that review the scientific literature and develop exposure limits on the basis of new evidence to check these new evidences.

Concerning the exposure limits, the discussion should go further: What kind of biological indexes we should use for evaluation of long-term effects in future standards? There are different possibilities: to use additional safety factor for long-term exposure to define the limits (not 1:10) or to use the new publications (thousands for the less than 5 years) for international independent review, showing evidence for long-term effects, also for other non-thermal effects except electrostimulation.

At this time, there is not enough evidence for discussing cancer as a result of EMF exposure. Nevertheless, many new peer reviewed publications show different results that are a topic for consideration and for discussion. In few countries, the 0.4 μT (50 Hz) is a limit for some additional measures taken as a precautionary measure for the general public. It is a time may be to arise the question: If cancer should be discussed in preparing long-term exposure evaluation?

Finally, it is important to look the new scientific literature in details, and to find if there are enough evidence to accept for biological criteria in human exposure standards other non-thermal effects, not only electrostimulation.

Exposure assessment in the near-field zone

There is still misunderstanding in regard to the exposure assessment in near-field zone. The Practical Guides as a part of the EU Directive 2013/35/EC give very clear definitions how to manage the measurement results, what kind of equipment to be used, which parameters to test, etc.

Nevertheless, the discussion for applying the power density parameter (S, W/m^2) for evaluation the field levels in the near-field zone continues. Physics (electrodynamics) tells very clear that in near-field zone "power density" does not exist…and it is not possible to be used for any kind of measurement or evaluation. It can be used only as equivalent parameter calculated for plane wave in free space at the same frequency as if we were in far-field zone, and not as real parameter for assessment. Both – electric and magnetic field

strengths should be used there. The choice of parameter depends on the type of emitting element – dipole, capacitor or coil. It is possible, also, to use the electric and magnetic field energy (J_E/m^3 and J_H/m^3) in the volume close to the source of radiation.

This raises the question where is "the boundary" between the near- and far-field zones? In the both documents (ICNIRP 2020 and EU Directive 2013/35/EC), it is accepted to be 6 GHz. There, the wavelength is 5 cm, and it is so small that the EMF energy is absorbed in the human skin, not in entire organs. That is the reason above 6 GHz the power density on the workplace around the worker to be accepted as parameter defining ELV for this frequency range. But the human exposure standard developed by IEEE (IEEE C.95) proposes this boundary to be at 10 GHz (3 cm wavelength), not at 6 GHz. Which of them are more convenient to use in our future standards?

In addition, there is very big differences and also, difficulties to measure electric and magnetic fields in the near-field zone. Metal surfaces strongly distort the waves when we measure electric field strength, and less the magnetic field depending of the type of metal.

Nevertheless, we should measure both parameters because of lack of any simple dependency between them and because of the fact that calculations for any exposure evaluations in near-filed zone are impossible.

Specific exposure limits

Here the question is: If we need general requirements for all kind of working places or we should think for applying of a special approach concerning specific occupations, technologies or working places?

There are many occupations with high EMF levels of exposure, some of them with derogation in the Directive, as work duties connected with MRI equipment. There are, also other working places where high levels of EMF exposure are possible to be found, some of them listed in the *Table 3.2. Requirements for specific EMF assessments in respect of common work activities*, *Non-binding Guide to good practice for implementing Directive 2013/35/EU, Electromagnetic Fields, Volume 1: Practical Guide*. Some of them are the followings: workplaces around plastic sealers and heaters, in electric distribution units (power plants), in some kind of electrical transport technologies, working with radars and other power sources of communication, etc. There are many other sources of EMF that emit high levels of EMF in medicine, military.

Meanwhile, there are many work places where exposure to complex multifrequency fields are available, and risk assessment is not possible to be made on the base of the general requirements described in the Directive.

In our opinion, there is a need to develop specific standards with limits and methods for exposure and risk assessment of specific or concrete sources, technologies, occupations and working places. On way is this Directive with general requirements to have subdocuments describing different concrete uses of sources, technologies and specific working places, complex sources and those with specific time varying characteristics.

This will give the possibility multifrequency exposure to be evaluated, as well. An example of such occupation is the physiotherapy, where all kind of non-ionizing radiation – ELF, static fields, RF, ultrasound, optical and laser radiation could be found.

Working places with MRI equipment also is one example for exposure to EM fields of several frequency bands simultaneously – static magnetic field, low frequency, RF; all exposures are in the near field zone. Magnetic flux density measured at places of the personnel stay is not sufficient for exposure assessment. It is necessary to assess the induced currents in the body, which also depend on the way of movement in the shielded premise.

Welding is other occupation in this field - short-term exposure with high EMF values during welding, simultaneous exposure from cables. Exposure in also the near field zone.

Such approach (to have specific legislation for different specific occupations of sources) gives a possibility to apply different methods for exposure and risk assessment, also different exposure limits (Als) for specific exposures.

Overexposure, "worst case", complex EMF exposures, intermittent exposure

Here the discussion is very similar (or comes from) the Question 3. Here we discuss the possibility to have separate approach/exposure limits (and Als) for different specific occupations, technologies and sources where the general approach is not applicable.

The exposure limit values or ALs are adequate and applicable in cases where the exposure is continuous during the working day and there are no significant changes in the levels of the EMFs emitted by the source. A problem also arises in exposure assessment based on ALs in the case of local or inhomogeneous exposure within the workplace. Spatial averaging in this case largely underestimates the exposure. The maximal values are not considered in the assessment and it is based on lower average values. This is somewhat contrary to the concept of "worst case" in terms of hygiene. Even more it concerns areas / tissues in the human body with different thresholds for harmful effects.

It is not clear how the human body reacts to intermittent exposure - high levels of EMF in minutes / seconds, termination of the emission and repetition of cycles.

Such sources for example are dielectric sealers where high background EMF levels are registered when there is more than one device in the premise, high values of electric field strength within seconds and then repeating the cycle, as well as high local exposure.

Averaging time

It is very clear the approach discussed by ICNIRP 2020 for 30 min averaging time. At the same time, 6 min is the averaging time in The Directive.

However, the use of 30 min creates new problems – how the EMF parameters to be measured and how to be evaluated? If somebody needs to measure due to the whole time of 30 minutes at every workplace? There is not any explanation on it.

Here arises the question the use of averaging time when somebody evaluates long-term exposure.

Additional problem is that the averaging will not assume the actual exposure from intermittent emission of the source. It doesn't give the real exposure on the worker.

Competence of the specialists performing measurement and exposure assessment

EU Directive discusses the need of specialists with a knowledge in the field of measurements and exposure assessment. In our opinion, this topic is very important because most of the engineers don't have enough knowledge in physics, especially electrodynamics, and also, physicists without specialized courses in such measurements have big problems to understand the real results received by measurements.

The competence of the personnel performing assessment and measurement is of utmost importance for the reliability of the results.

Correct determination of the measuring points, where to place the probe of the measuring device, determination of the distance from the EMF source, measurement in the near or far zone – influencing factors, EMF parameters to be measured/evaluated, exposure depending on the work posture. The duration of the measurement depending on the duty cycle of the source is an important factor for applying appropriate approach for measurement.

Data needed for correct exposure assessment: Source characteristics (type, frequency, power, operating mode, etc.), distance to the source, tasks performed by the worker during the measurement.

Correct selection of technical equipment - appropriate frequency range, dynamic range, sampling rate, isotropy/anisotropy, calibration, the real measured parameter, time constant, etc.

The equipment that everyone can buy from the companies is not for direct use in such measurements, and the specialists that are going to perform measurements are not ready to use it.

Some practical measurement principles are discussed in the Non-binding guide to good practice for implementing Directive 2013/35/EU (Vol. I and Vol. II). It may be useful, if there are some more specific requirements, on how to assess exposure, depending on the specificity of the EMF source, source operation (duty cycle, etc.), and the source characteristics. There is always uncertainty in the exposure assessment depending on EMF characteristics, the measurement method, and the measurement equipment used, etc., which makes it difficult to develop standardized measurement protocols that are valid in all cases of exposure. To assess the occupational EMF exposure, it is necessary to systematize the criteria for performing measurements, summarizing the methods for measuring EMF, which field parameters should be assessed, to set requirements concerning measuring equipment, and the competence of the personnel performing exposure assessment. A practical guide combining all these issues will serve occupational health services, sanitary engineers and other professionals to apply protocols specifically designed to assess EMF exposures in a specific work environment.

The strategy of performing measurements is important task - determining the measurement sites, the duration of the measurement, knowledge of the technological process, use of appropriate devices for measuring EMF, collection of additional data concerning the appropriate evaluation of EMF exposure.

Finally, the uncertainty of measurement of EMF on the workplace can be more than 100% in cases where the competence of the specialists performing measurements is not high enough. In our point of view, there is a need of special requirements for the basic knowledge and training and education for such specialists.

Conclusion

The Directive 2013/35/EU is the main European document ensuring the minimum health and safety requirements regarding the exposure of workers from electromagnetic fields. It is in force over 8 years. The distance of time and the practice we had with the implementation of this document gave us the opportunity to raise some issues that need to be improved.

An important issue is a review of the new scientific literature to be made in order to find if there are enough evidence to accept biological criteria in human exposure standards other non-thermal effects, not only electrostimulation.

There is a need to develop and set of specific exposure limits for concrete sources, technologies, occupations and working places, also a specific methods of exposure and risk assessment.

Additional problem that should be discussed is the averaging time/method. There should be requirements how to assume the actual exposure from intermittent emission of the source.

Competence of the specialists performing measurement and exposure assessment is of utmost importance for the reliability of the results.

Finally, the Directive 2013/35/EU is very complex for direct practical use by the employers, and this is one of the reasons this document to enter so hard in exposure and risk assessment of EMFs at the working places. Nevertheless, it is a great achievement for the European Commission, for the workers in member states to have a possibility to evaluate the risk arising by EMF exposures in different occupations. The obligation of the science is to improve this document to achieve dignified protection for all workers exposed to electromagnetic fields by implementation of all new evidences in the field of risk assessment.