

Dear Contributor,

Thank you for participating in the public consultation of the ICNIRP draft guidelines.

Please note that it is important that ICNIRP understands exactly the points that you are making. To facilitate our task and avoid misunderstandings, please:

- be concise
- be precise
- provide supporting evidence (reference to publication, etc.) if available and helpful.

How to complete the comments table:

Please use 1 row per comment. If required, please add extra rows to the table.

This response document asks you to provide your 'comment', your 'proposed change', and the 'context' to this comment and proposed change. What is meant by these is the following:

Comment : A brief statement describing the issue that you have identified (and that you would like ICNIRP to take into account in the final version of the guidelines).

Proposed Change: A brief statement describing how you would like the document changed to account for this issue.

Context: A brief statement identifying relevant documents in support of your comment and proposed change.

Please, provide your details below as per the online form and the provision of the privacy policy

Last name, first name: LAST NAME, First name	Email address: Your email address.	Affiliation (if relevant): Your affiliation
If you are providing these comments officially on behalf of an organization/company, please name this here: organization/company		
<input type="checkbox"/> I hereby agree that, for the purpose of transparency, my identity (last and first names, affiliation and organization where relevant) will be displayed on the ICNIRP website after the consultation phase along with my comments. <input checked="" type="checkbox"/> I want my comments to be displayed anonymously.		

	Document (Guidelines, App A, App B)	Line Number #	Type of comment (General/ Technical/ Editorial)	Comment. Proposed change. Context.
1	Guidelines	43-70	General	<p>The principles of limiting RF exposure used by ICNIRP are clearly stipulated, and repeated here because it relates to some of my comments below: (1) scientifically substantiated to be harmful to human health, (2) reported effects need to be independently replicated. The lowest exposure known to cause the health effect is the “adverse health effect threshold”, and are stated to be strongly conservative. Additionally, an “operational threshold” is introduced where ‘more-general knowledge’ provides a basis for additional concern, without reported harm. Reduction factors are introduced to address biological and environmental variability. The conservativeness of the approach is appreciated and considered valuable. It is also appreciated that both rate of energy deposition, as well as cumulative deposition is considered as risk-determining parameters – primarily related to global and localized heating effects.</p> <p>No change</p> <p>This is the basis for my request to consider the thresholds as also applicable for medical applications, and ensure consistency for that purpose</p>
2	Guidelines	25-34	Technical	<p>Exposures for medical purposes, including volunteers under IRB, are not covered by ICNIRP. This is understood, but relies on product standards, and medical expertise, to establish a benefit-risk assessment (RBA). It would be valuable to reinforce this understanding.</p> <p>Also, I want to bring to ICNIRPs attention that the scientific basis for “adverse health effect thresholds” and “operational thresholds” is identical for occupational and for medical exposures. As such, it would be valuable for the ICNIRP Guidelines to provide a well-established set of Basic Restrictions in the covered frequency range, to which medical and engineering professionals can refer when performing their risk assessment.</p> <p>Clarify that the thresholds and Basic Restrictions are based on assessment of biological hazards, and apply equally to medical use of RF. The reference levels and exposure limits will be different, and need to be covered in other standards</p> <p>Ensure consistency among occupational and medical applications of the basic restrictions</p>
3	Guidelines	463/4	Technical	<p>ICNIRP now clearly stipulates that both global and local restrictions must be met simultaneously. This is indeed a reasonable requirement based on both experimental and simulation evidence in support of establishing operational thresholds. Nevertheless, it would be useful to further strengthen this requirement by some literature references, from different groups (Adair, Hirata, others?). It is noted that this data provides very little coverage of vulnerable individuals, in terms of the need to consider core temperature increase to raise the baseline for local temperature values.</p> <p>Add references to Adair and Hirata papers</p>

				<p>For example</p> <p>Adair et al, Bioelectromagnetics 2003; 6:S148-161 doi:10.1002/bem.10133, and Ann N Y Acad Sci. 1992 Mar;649:188-200, and Magn Reson Imaging. 1989 Jan-Feb;7(1):25-37</p> <p>Hirata et al. Phys Med Biol. 2013 Feb;58(4):903-21 doi:10.1088/0031-9155/58/4/903</p>
4	Guidelines	175-183	Technical	<p>Thermal effects are discussed in terms of temperature increase, where 2 types of tissue are recognized. This dichotomy is largely based on CEM43 assessments and hyperthermia. It is surprising to me that this body of evidence is not reviewed explicitly in the proposed Guideline and its Annexes. I strongly advice to repair this omission (refer to recent publications from Van Rhoon's group, introducing the "functional psSAR10g concept"; where it is noted that their conclusions require careful review when applying them to the wider population).</p> <p>Add references to the CEM43 literature in support of the established time-duration (local) thesholds. Excellent reviews are available, and used to derive conservative limits for Ultrasound equipment.</p> <p>Yarmolenko et al. Int J Hyperthermia. 2011, 27(4): 320-343, doi: 10.3109/02656736.2011.534527</p> <p>Van Rhoon et al. Int J Hyperthermia. 2018 Jan;;1-7 doi:10.1080/02656736.2018.1424945 and Eur Radiol. 2013 Aug;23(8):2215-27 doi:10.1007/s00330-013-2825-y</p>
5	Guidelines	321ff	Technical	<p>I also want to express some confusion why temperature rise is now considered, whereas the ICNIRP/WHO report after the Istanbul workshop (Sienkiewicz, Health Physics 2016) suggests that absolute temperature (and time) are the parameters on which restrictions should be based.</p> <p>The difficulty to establish a reasonable anticipated baseline temperature is understood, but establishing thresholds will require such consideration – it is now only very implicit in ICNIRP's involved reasoning to derive SAR values.</p> <p>Reconsider the approach in the Guidelines and Appendix B, to include clarity that the temperatur-time relation is generally well described by CEM43, and that SAR as well as duration of exposure needs to be controlled in order to prevent exceeding the reference levels</p> <p>Explain the context of your comment.</p>
6	Guidelines	143-145	Technical	<p>The statement concerning SA is understood, but too limiting. Extensive simulation evidence for the 60-300 MHz exposures in MRI systems (a.o. Murbach from ITIS) shows that this not only applies for 'brief exposures where there is not sufficient time for heat diffusion to occur'.</p> <p>Core temperature elevation should be considered in terms of SA (Adair & Berglund in their MRI paper, 1989; and other related scientific reports). It is recognized that thermoregulation will be able to store a lot of absorbed energy in the peripheral parts of the body, under normal circumstances. Irrespectively, very little is known concerning variability in response for whole body deposited energies exceeding 10-12 J/g, esp. for slightly compromised individuals.</p> <p>Insert your proposed change.</p>

Continue numbering	Document ?	Line number	Type of comment	<p>Explain the context of your comment. Insert your comment.</p> <p>Clarify that SA is also relevant for whole body and whole brain SAR</p> <p>Explain the context of your comment.</p>
7	Guidelines	367-370	Technical	<p>Another point related to this observation is the total absence of the concept of whole-head SAR, which has been generally accepted to be limited to 3.2 W/kg. It is unclear why ICNIRP does not derive basic restrictions in the head, related to brain exposures, for whole-head SAR, for local SAR (eye) and for 10g SAR, including SA values. Indications of allowed psSAR10g values for different parts of the brain would also be relevant to establish. The stated 20 W/kg in the Head seems incorrect for the eye, based on several simulation studies (line 367-370), and a 3.2 W/kg whole head SAR limit would not allow local SAR to exceed approx. 10 W/kg.</p> <p>It is understood that in principle both limits should be met, but the whSAR limit of 3.2 W/kg is not considered as 'operational threshold' in ICNIRP's proposed guidelines. This should be corrected.</p> <p>Limit to whole-head SAR must be added, in addition to whole-body SAR</p> <p>For example:</p> <p>Van Lier et al, J Magn Reson Imaging. 2012 35:795-803 doi:10.1002/jmri.22878</p> <p>Massire et al J Magn Reson Imaging. 2012 35:1312-21 doi:10.1002/jmri.23542</p> <p>Kodera et al BioMed Eng OnLine (2018) 17:1 doi:10.1186/s12938-017-0432-x</p>
8	Guidelines	277-279	Technical	<p>The choice for the operational health threshold of 1 °C for core temperature is acknowledged, and correlates quite well to 4W/kg for reasonable exposure durations of 30-60 min, for fit individuals. Substantial evidence for patients is lacking, however, and reduced exposures should be advised, similar to the Normal Mode concept for MRI systems. Some data exists that core temperature increases > 1 °C occur in 'virtually normal people' within 15 minutes.</p> <p>The statement on 277-279 may be conflicting with ICNIRP's rigorous policy statements in Section 3.</p> <p>Review available evidence and correct 277-279 if needed</p> <p>Unpublished results, and some data by Adair.</p>
9	Guidelines	408-410, 510	Technical	<p>The formula introduced on lines 408-410 allows for surprisingly high local SAR values for short and medium exposure times. According to Appendix A, line 446, this formula is based on unpublished results. This seems to violate ICNIRP's own stipulated policy in section 3 of the guidelines. Please reconsider. The discontinuity at 400 MHz is also notable, and seems not justifiable from biological or physical considerations.</p> <p>It is noted that the associated 500 J/kg (line 510) is very high, and exceeds typical MRI exposures per pulse by approx. one order of magnitude. I am not aware of any scientific data that supports safety of such high exposure per pulse.</p>

				<p>Provide solid, and peer-reviewed evidence; ensure that the frequency dependence is analyzed in sufficient detail to avoid an arbitrary discontinuity at 400 MHz</p> <p>Explain the context of your comment.</p>
10	Guidelines	441-445	General	<p>Line 441-445 concerning the foetus and the pregnant woman have implications to medical decisions. Though potentially justifiable from a cautionary principle, it appears that medical professionals do not understand the implications, and it is unlikely successful in a consulting setting without clear indications what the actual risks are. Can ICNIRP provide further clarity, also in relation to e.g. the ACR guidance document for the use of MRI in the context of pregnancy?</p> <p>Provide clarification of the socio-ethical implications of this statement, and practical consequences thereof</p> <p>See JOURNAL OF MAGNETIC RESONANCE IMAGING 37:501–530 (2013)</p>
11	Guidelines	448, 459-463	Technical	<p>The concept of “averaged over the entire body mass and a 30-minute interval” can easily lead to confusion. The Basic Restriction relates to a core temperature not to exceed 1 °C; this will definitely occur when the total SA continues to accumulate for longer than 30 minutes. So, I infer that 30 minutes is the longest exposure time allowed at 4 W/kg, and not a ‘rolling averaging time’. Please clarify.</p> <p>Similarly, the statement on line 459-463 is not completely correct; short term 1 min exposures exceeding 4 W/kg, within the averaging time of 6 or 30 min, can lead to transient core temperature elevations exceeding 1 °C, see Nadobny 2007, for example.</p> <p>Clarify what the context of 1 °C is, and what a true operation threshold is considered to be</p> <p>Nadobny et al IEEE Trans Biomed Eng 2007 54(10): 1837-1849</p>
12	Guidelines	482	Technical	<p>The reference to ‘scientific uncertainty’ to apply a reduction factor of 2 for the 20 W/kg local SAR should be substantiated a bit better. This rationale would also be relevant to writers of equipment standards, if scientifically solid</p> <p>Clarify where evidence for the need and adequacy of this factor 2 can be found in scientific literature</p> <p>Explain the context of your comment.</p>