

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 <b>on behalf</b> of an organization/company, please name this here: organization/company		
<input type="checkbox"/> I hereby agree that, for the purpose of transparency, <b>my identity (last and first names, affiliation and organization where relevant) will be displayed</b> 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	95-96	General	<p>It is not clear whether medical procedures (lines 29-31) involving a pregnant woman and/or her fetus are excluded from the statement "Note that a fetus is here defined as a member of the general public, <u>regardless of exposure scenario</u>, and is subject to the general public restrictions." (Lines 95-96).</p> <p>Suggest excluding medical procedures involving pregnant women and/or their fetus from the statement "..... a fetus is here defined as a member of the general public, regardless of exposure scenario ...."</p> <p>Pregnant women give informed consent prior undergoing MRI procedures. Such procedures may be indicated either to examine the mother or the fetus or both. Clearly the health status of the mother has implications for the health of the fetus. It is common practice that parents/guardians provide informed consent prior to neonates and minors (who can be described as individuals of differing health statuses, who may have no knowledge of or control over their exposure to EMF) undergoing MRI procedures. If fetal exposure is subject to general public basic restrictions, then MRI procedures involving pregnant women would be limited to maternal head scanning. Numerical simulations of 3T MRI exposure of a pregnant woman body model carried out in our department (as yet unpublished) show that fetal whole body SAR would exceed 0.08 W/kg for scanning of other maternal anatomical sites. Such restriction would deprive the mother and her fetus of clinically important diagnostic information.</p> <p>Defining the fetus as a member of the general public with respect to medical procedures is inconsistent with other ICNIRP documents. For example, there is no mention of the fetus in ICNIRP GUIDELINES ON LIMITS OF EXPOSURE TO STATIC MAGNETIC FIELDS (2009). Since the general public basic restriction is 400 mT, defining the fetus in this way would exclude pregnant women from MRI procedures. The ICNIRP STATEMENT AMENDMENT TO THE ICNIRP STATEMENT ON MEDICAL MAGNETIC RESONANCE (MR) PROCEDURES: PROTECTION OF PATIENTS (2009) implies MRI exposure of the fetus, stating: "For the normal operating mode there should be an upper limit for whole-body exposure of 4 T, in view of uncertainties regarding the effects of higher fields, including effects on fetuses and infants".</p>
2	Guidelines	353-356	General	<p>Classifying the fetus as a type 2 tissue when considering local temperature increase is more relaxed than other guidance and standards.</p> <p>Suggest considering fetus as a special case with temperature increase limited in line with previous guidance and standards. The fetus is normally 0.3-0.5 deg C above maternal core temperature and heat loss from the embryo and fetus across the placental barrier may be less efficient than heat dissipation in other well vascularised tissues. A local temperature increase of 2 deg C is likely to exceed the guidance given in ICNIRP STATEMENT ON MEDICAL MAGNETIC RESONANCE (MR) PROCEDURES: PROTECTION OF PATIENTS (2004) namely "It seems reasonable to assume that adverse developmental effects will be avoided with a margin of safety if the body temperature of pregnant women does not rise by more than 0.5°C and the temperature of the fetus is less than 38°C." The IEC-60601-2-33 (2015) standard also adopts this more cautious approach which is especially important during the first trimester of pregnancy.</p>

<b>3</b>	Document ?	Line number	Type of comment	Insert your comment. Insert your proposed change. Explain the context of your comment.
<b>4</b>	Document ?	Line number	Type of comment	Insert your comment. Insert your proposed change. Explain the context of your comment.
<b>5</b>	Document ?	Line number	Type of comment	Insert your comment. Insert your proposed change. Explain the context of your comment.
<b>6</b>	Document ?	Line number	Type of comment	Insert your comment. Insert your proposed change. Explain the context of your comment.
Continue numbering	Document ?	Line number	Type of comment	Insert your comment. Insert your proposed change. Explain the context of your comment.

Add further rows if needed. For this copy the above row.

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