

MOSAES Submission Form Guide

Question	Notes
1) MOSAES seek to record site and reporter details. These will be held privately and not included in any public reports. Your data may be used by a member of the IPEM MRI SIG to clarify any responses. If an approved person is seeking further information on your entry, your data may also be shared with them by the IPEM MRI SIG. I consent to the use of my personal details for these Purposes. <i>Single selection:</i> - Yes - No	If you want your contact details removed from the database, please contact the MOSAES group lead.
2) Contact Details <i>Free text</i>	Please provide contact details so, if required we can clarify anything about your submission. Your details will not be added to the database if you select “no” to question 1.
3) Submission type <i>Single selection:</i> - <i>Individual patient event</i> - <i>Multiple patient events</i>	Whether the particulars of a case pertain to a one-off event, or a series of events <i>under the same risk assessment</i> e.g. repeated off-label surveillance scans for one patient, routine off-label use for patients with a particular model of device under a local policy.
4) Number of scans performed <i>Free text</i>	If ‘Multiple patient events’ selected in question 3.
Implant Details	
5) Implant category Main implant of concern - you can add details of other implants later <i>Single selection:</i> - <i>CIED</i> - <i>DBS</i> - <i>SNS</i> - <i>SCS</i> - <i>VNS</i> - <i>Auditory implant</i> - <i>External fixation</i> - <i>Other (Free Text)</i>	If no implant could be considered the primary implant of concern, choose the most commonplace of those present. This is to widen the relevance of the submitted case to those requesting information later.

6) Implant manufacturer (if unknown please describe what is known about the implant) <i>Free text</i>	For the implant described in question 5.																																													
7) Implant model (details of each component) <i>Free text</i>	For the implant described in question 5.																																													
8) Details of any other relevant implants <i>Free text</i>																																														
Scan Details																																														
9) MR safety labelling <i>Single selection:</i> - <i>MR Conditional</i> - <i>MR Unsafe</i> - <i>MR Unlabelled</i>	For cases with multiple devices, select the worst-case option, e.g. an MR Conditional CIED and an MR Unlabelled abandoned lead would be categorised as MR Unlabelled. This is to widen the relevance of the submitted case to those requesting information later.																																													
10) Aware of implant prior to scanning? <i>Single selection:</i> - <i>Yes</i> - <i>No</i>	This gives an indication of the degree to which off-label scenarios are encountered without prior knowledge in the MR community.																																													
11) Patient specific risk assessment performed? <i>Single selection:</i> - <i>Written patient specific risk assessment</i> - <i>Scanned under GISP (general implant safety procedure)</i> - <i>Other (Free Text)</i>	If the case was scanned as a slight deviation from an existing GISP or other off-label scanning policy, select this here and note deviations in question 18.																																													
12) Requested scan (body area) <i>Free text</i>	Please include an indication of isocentre location relative to the implant(s') location(s).																																													
13) Control measures put in place e.g. SAR, TR coil used, patient positioning, scanning time, field strength, CP transmit <i>Free text</i>	Please include any relevant on-label conditions if these were followed (e.g. patient positioned supine).																																													
14) Estimation of risk with control measures in place <i>Single selection:</i> - <i>Low</i> - <i>Medium</i> - <i>High</i> - <i>Very high</i>	This uses the Likelihood-Consequence risk matrix as: <table border="1"> <tr> <td></td> <td></td> <th colspan="5">Likelihood</th> </tr> <tr> <td></td> <td></td> <th>Rare</th> <th>Unlikely</th> <th>Possible</th> <th>Likely</th> <th>Almost Certain</th> </tr> <tr> <td rowspan="5">Consequence</td> <th>Catastrophic</th> <td>Medium</td> <td>High</td> <td>High</td> <td>Very High</td> <td>Very High</td> </tr> <tr> <th>Major</th> <td>Medium</td> <td>Medium</td> <td>High</td> <td>High</td> <td>Very High</td> </tr> <tr> <th>Moderate</th> <td>Low</td> <td>Medium</td> <td>Medium</td> <td>High</td> <td>High</td> </tr> <tr> <th>Minor</th> <td>Low</td> <td>Medium</td> <td>Medium</td> <td>Medium</td> <td>High</td> </tr> <tr> <th>Negligible</th> <td>Low</td> <td>Low</td> <td>Low</td> <td>Medium</td> <td>Medium</td> </tr> </table>			Likelihood							Rare	Unlikely	Possible	Likely	Almost Certain	Consequence	Catastrophic	Medium	High	High	Very High	Very High	Major	Medium	Medium	High	High	Very High	Moderate	Low	Medium	Medium	High	High	Minor	Low	Medium	Medium	Medium	High	Negligible	Low	Low	Low	Medium	Medium
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	Minor	Low	Medium	Medium	Medium	High																																								
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15) Patient awareness & ability to communicate <i>Multiple selection:</i> - <i>Patient fully aware and able to communicate</i> - <i>Scan under GA</i> - <i>Sedated</i> - <i>Unable to communicate</i> - <i>Other (Free Text)</i>	Multiple selection enables description of e.g. a nonverbal patient under sedation, a person without capacity under GA.
16) Did an adverse event occur? <i>Single selection:</i> - <i>Yes</i> - <i>No</i>	
17) Details of adverse event <i>Free text</i>	Please include details of the event and any resolution at the time or after the fact. Any institutional learning or changes resulting from the event would be useful to include if possible. Including the UKHSA incident reporting taxonomy code is useful where possible. Please ensure adverse events are also reported using the appropriate local (e.g. DATIX) and national (e.g. MHRA Yellow Card) systems.
18) Please add anything else you may think would be relevant to this event including any references or resources you used to help you reach your assessment of the risk to the patient. <i>Free text</i>	For references, if possible please note what was useful about the references included, e.g. relevant section of a book, paper, or website. For institutional resources, if possible please describe how these were useful to the case(s) described, e.g. off-label risk assessment guidance, RF burn prevention and handling SOP.