

## IACC 2023 Case-based discussion (CBD) scenario

<b>Specialty:</b>	<b>Critical Care Science</b>
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### CBD Scenario

<b>CBD Scenario Title</b>	Safety Action Bulletin Response										
<b>CBD Scenario Aim</b>	To assess the trainee's knowledge of how to respond to a medical device alert.										
<b>CBD Focus</b> (please provide the codes of the module(s) this scenario addresses)											
<b>GSP Domains covered</b> (enter X to indicate all that apply)	<b>GSP 1</b>	x	<b>GSP 2</b>	x	<b>GSP 3</b>	x	<b>GSP 4</b>		<b>GSP 5</b>	x	
<b>CBD Scenario description</b>	<p>You have received a Safety Action Bulletin/Field safety Notice regarding a medical device in use in your area of work.</p> <ol style="list-style-type: none"> <li>Please describe the steps you would take to risk assess the issue reported.</li> <li>Explain the actions that you would take and advice you would give for immediate management of safety considerations.</li> </ol>										
<b>CBD Scenario model answer/ assessor guidance</b>  Detailed guidance that will be available for the assessors. Include guidance on what kinds of behaviours, actions, comments should secure a pass. What should the assessor expect to see? Assessors will be asked to plan questions in advance including links to trainee's IACC submission.	<p><b>1. Steps to assess risk</b></p> <ul style="list-style-type: none"> <li>- Follow local procedure for onward reporting / communication of SAB</li> <li>- contact local MHRA rep</li> <li>- Follow SOPs for assessing risk to patient, staff and / or service delivery</li> <li>- accurate documentation for serial number / location of affected equipment</li> <li>- Assess impact for repair / removal or replacement on patient / staff / service delivery</li> </ul> <p><b>2. actions taken / advice for immediate action / safety</b></p> <ul style="list-style-type: none"> <li>- ensure accurate documentation of processes below</li> </ul>										

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	<p>- develop a contingency plan for both short- and long-term plans including</p> <p>- once all risks assessed and appropriate procedures followed to determine action plan and contingency plans follow next steps:</p> <p>- Consider user training / competence implications for replacement of equipment / new equipment</p> <p>- wider work with ensuring calibration / PAT testing etc as required</p> <p>- Assist with process to implement action plan: repair / remove / replace as per safety guidelines</p> <p><b>Failure indicators</b></p> <ul style="list-style-type: none"> <li>• Fails to communicate Safety Notice to appropriate channels.</li> <li>• Does not Risk assess clinical/service implications.</li> <li>• Does not advise on short and long-term plans.</li> <li>• Undertakes inappropriate actions.</li> <li>• Does not document or follow up.</li> </ul>
<p><b>Trainee instructions</b></p> <p>Please include any specific information to be provided to the trainee as part of the CBD scenario</p>	

### Criteria being assessed by this CBD scenario

Aspect	Please indicate if this criterion is being assessed
1. Understands the clinical context of the scenario, including priority setting and testing strategies	Y
2. Understands scientific principles of scenario	
3. Can discuss the relevant procedures involved in the scenario and associated health and safety issues	Y
4. Understands and applies the appropriate test validation, IQC, EQA, relevant professional/clinical guidelines	Y
5. Understands and applies associated IT/bioinformatics and other appropriate resources	

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6. Is able to interpret and report patient results and provide appropriate clinical advice	
7. Can discuss the significance of patient results within the clinical context of the referral	
8. Understands the ethical, legal and social implications of the scenario	Y
9. Is aware of the importance of audit and can use this tool effectively	
10. Output meets accepted laboratory/professional standards	
11. Demonstrates awareness of the limits of responsibility and when to seek advice	
12. Consideration of patient/professionalism	
13. Overall ability to perform	Y