National School of Healthcare Science

NHS England

IACC 2023 Case-based discussion (CBD) scenario

Specialty:	Device Risk Management & Governance

CBD Scenario

CBD Scenario Title	Complex Medical Device – Operation & Equipment Management									
CBD Scenario Aim	To test the trainee's understanding of complex medical devices: underlying science, calibration, risks & management									
CBD Focus (please provide the codes of the module(s) this scenario addresses)	SPE326c2		SPE326c3							
GSP Domains covered (enter X to indicate all that apply)	**GSP 1**	X	**GSP 2**	X	**GSP 3**	X	**GSP 4**		**GSP 5**	
CBD Scenario description	Please could you choose a medical device you are familiar with in your practice. It should be a device that has at least one patient connection and either makes physiological measurements, delivers a therapeutic output, or delivers medication / fluids. We would like you to explain: 1. Its underlying scientific principles and how it is used. 2. Key elements of that device's lifetime management for both the user and service provider, to ensure it remains safe & fit for use									
CBD Scenario model answer/ assessor guidance 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	The trainee should give a clear, concise and accurate account of the underlying science. The trainee should cover the following areas (as appropriate): - 1. User Maintenance (daily checks) 2. Assurance (Essential performance & basic safety) & Calibration 3. Preventative maintenance 4. Quality control (checks/artefacts) 5. Risk mitigation									

to plan questions in advance including links to trainee's IACC submission.	6. Infection control (If prompts are needed then use the following questions) How do you make sure the device is giving the correct measurement/therapeutic effect? How do you ensure the patient is kept safe? A good trainee will cover at least 3 of the above unprompted. If not covered unprompted, the assessor should ensure the trainee understands the processes involved in obtaining a good result and keeping the patient safe. Prompt questions should be asked if necessary.
Trainee instructions Please include any specific information to be provided to the trainee as part of the CBD scenario	

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	X
2. Understands scientific principles of scenario	X
3. Can discuss the relevant procedures involved in the scenario and associated health and safety issues	X
4. Understands and applies the appropriate test validation, IQC, EQA, relevant professional/clinical guidelines	X
5. Understands and applies associated IT/bioinformatics and other appropriate resources	
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	
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	