

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

<b>Specialty:</b>	<b>Clinical Pharmaceutical Science</b>
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### CBD Scenario

<b>CBD Scenario Title</b>	Unusual biodistribution of a radiopharmaceutical									
<b>CBD Scenario Aim</b>	To assess whether the trainee can deal effectively with complaints, problems with products, testing of products and assessment of clinical impact.									
<b>CBD Focus</b> (please provide the codes of the module(s) this scenario addresses)	Professional Practice (core module SCC110)				Radiopharmacy 1 and 2 (SPE203 and SPE223)					
<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>	
<b>CBD Scenario description</b>	You've received a complaint from your Nuclear Medicine Department to say they have seen thyroid uptake on an MAA lung scan. Describe all the actions you would take.									
<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>Pass indicators: One or more of the following should be discussed</p> <ol style="list-style-type: none"> <li>1. Follow complaints procedure</li> <li>2. Communication with clinical team to get details</li> <li>3. Carry out investigation – include Radiochemical Purity (RCP) testing, Out Of Specification (OOS) investigation if necessary.</li> <li>4. Validation of RCP test method</li> <li>5. Clinical impact on patient – discussion with clinician</li> <li>6. Are other batches / patient doses affected?</li> <li>7. Product recall if appropriate</li> <li>8. Reporting – Medicine and Healthcare products Regulatory Agency (MHRA), British Nuclear Medicine Society (BNMS), internal governance</li> <li>9. (Corrective and Preventive Actions) CAPA</li> <li>10. Final reply to customer</li> </ol> <p>Fail indicators: No mention of complaint procedure, no consideration of clinical impact, no investigation</p>									

## IACC 2023 CBD Scenario Descriptor

<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>	<p>No specific instructions</p>
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### 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	
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	X
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	X
12. Consideration of patient/professionalism	
13. Overall ability to perform	