

T Level Technical Qualification in Healthcare Science

Core knowledge and understanding

Paper A

Elements 1-10

Mark scheme

v2.0: Specimen assessment materials
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This Mark Scheme has been written by the Assessment Writer and refined, alongside the relevant questions, by a panel of subject experts through the external assessment writing process and at standardisation meetings.

The purpose of this Mark Scheme is to give you:

- examples and criteria of the types of response expected from a student
- information on how individual marks are to be awarded
- the allocated assessment objective(s) and total mark for each question.

Marking guidelines

General guidelines

You must apply the following marking guidelines to all marking undertaken throughout the marking period. This is to ensure fairness to all students, who must receive the same treatment. You must mark the first student in the same way as you mark the last.

- The Mark Scheme must be referred to throughout the marking period and applied consistently. Do not change your approach to marking once you have been standardised.
- Reward students positively giving credit for what they have shown, rather than what they might have omitted.
- Utilise the whole mark range and always award full marks when the response merits them.
- Be prepared to award zero marks if the student's response has no creditworthy material.
- Do not credit irrelevant material that does not answer the question, no matter how impressive the response might be.
- The marks awarded for each response should be clearly and legibly recorded in the grid on the front of the question paper.
- If you are in any doubt about the application of the mark scheme, you must consult with your Team Leader or the Chief Examiner.

Guidelines for using extended response marking grids

Extended response marking grids have been designed to award a student's response holistically and should follow a best-fit approach. The grids are broken down into levels, with each level having an associated descriptor indicating the performance at that level. You should determine the level before determining the mark.

When determining a level, you should use a bottom up approach. If the response meets all the descriptors in the lowest level, you should move to the next one, and so on, until the response matches the level descriptor. Remember to look at the overall quality of the response and reward students positively, rather than focussing on small omissions. If the response covers aspects at different levels, you should use a best-fit approach at this stage and use the available marks within the level to credit the response appropriately.

When determining a mark, your decision should be based on the quality of the response in relation to the descriptors. You must also consider the relative weightings of the assessment

objectives, so as not to over/under credit a response. Standardisation materials, marked by the Chief Examiner, will help you with determining a mark. You will be able to use exemplar student responses to compare to live responses, to decide if it is the same, better, or worse.

You are reminded that the indicative content provided under the marking grid is there as a guide, and therefore you must credit any other suitable responses a student may produce. It is not a requirement either, that students must cover all of the indicative content to be awarded full marks.

Assessment objectives

This assessment requires students to:

- AO1: Demonstrate knowledge and understanding of contexts, concepts, theories and principles in healthcare science.
- AO2: Apply knowledge and understanding of contexts, concepts, theories and principles in healthcare science to different situations and contexts.
- AO3: Analyse and evaluate information and issues related to contexts, concepts, theories and principles in healthcare science to make informed judgements, draw conclusions and address individual needs.

The weightings of each assessment objective can be found in the Qualification Specification.

Quality of written communication (QWC)

Mark	Descriptor
3	The answer is clearly expressed and well-structured . The rules of grammar are used with effective control of meaning overall. A wide range of appropriate technical terms are used effectively.
2	The answer is generally clearly expressed and sufficiently structured . The rules of grammar are used with general control of meaning overall. A good range of appropriate technical terms are used effectively.
1	The answer lacks some clarity and is generally poorly structured . The rules of grammar are used with some control of meaning and any errors do not significantly hinder the overall meaning. A limited range of appropriate technical terms are used effectively.
0	There is no answer written or none of the material presented is creditworthy. OR The answer does not reach the threshold performance level. The answer is fragmented and unstructured , with inappropriate use of technical terms . The errors in grammar severely hinder the overall meaning.

Section A: The roles and responsibilities within healthcare science

This section is worth 34 marks, plus 3 marks for QWC and use of specialist terminology.

1(a) State the **main** method of funding for:

- private health care organisations
- public healthcare organisations.

[2 marks]

AO1 = 2 marks

AP = A2.1.1.1

Award **one** mark each method correctly stated.

- The private healthcare organisations are funded by payments/premiums from individuals. (1) AO1
- Public healthcare organisations are funded by taxes and National Insurance. (1) AO1

1(b) Give **one** reason why waiting times for routine operations in private hospitals are usually shorter than in NHS hospitals.

[1 mark]

AO2 = 1 marks

AP = A2.1.1.1, A2.1.2.1

Award **one** mark for a valid reason. Private hospitals are (often) less restricted by budget/have more funding, than NHS hospitals. (1) AO2 Fewer people can afford the fees charge by private hospitals so there will be less people seeking procedures/operations. (1) AO2 (inc private healthcare insurance). Private hospitals may have more staff/equipment than NHS hospitals. (1) AO2

Accept any other suitable response.

2(a) A Manager tells a technician in a hospital laboratory to perform a task which requires the skills of a fully trained Clinical Scientist.

The technician tells their manager that they do not feel comfortable undertaking the task as they have not had the required training.

The manager states that they must complete the task, but the technician refuses.

The technician raises a grievance procedure against the manager.

In this scenario, explain why the Technician is justified in raising a grievance procedure against the Manager.

[2 marks]

AO2 = 2 marks

AP = A1.1.6.1, A1.1.6.2

Award **one** mark for each valid explanation of why, they should follow the grievance procedure, up to a **maximum** of **two** marks.

- As the Technician does **not** have the required training, the Manager is **not** following the appropriate (Health and Safety) legislation. (1) AO2
- As the Technician does **not** have the required training, it is unlikely that this task will be covered by the employee's contract/job description/expected responsibilities. (1) AO2
- As the Technician does **not** have the required training and is being forced to carry out this task, they are **not** being treated fairly. (1) AO2

Accept any other suitable response.

2(b) Evaluate the potential impact for the Technician and the organisation if this grievance was upheld.
Your response should demonstrate reasoned judgements and/or conclusions.

[3 marks]

AO3 = 3 marks

AP = A1.1.6.1, A1.1.6.2

Award **one** mark for **each** valid point, up to a **maximum** of **three** marks:

- If the grievance is upheld, this could lead to I costs to the hospital/employer (compensation/legal costs) (1) AO3
- The grievance procedure could take up time which could affect the efficiency of the laboratory (and its ability to carry out its role). (1) AO3
- If the grievance procedure is upheld, this could lead to disciplinary action being taken against the manager, damaging their employment record/employability. (1) AO3
- If the grievance procedure is upheld, this could reverse any disciplinary action which was taken against the technician, preventing damage to the Technician's employment record/employability. (1) AO3

- If the grievance is upheld, this could prevent the same actions being taken again by the manager and the potential damage of this repeated action. (1) AO3
- The potential for negative media coverage could damage the hospital's reputation, this in turn could lead to intervention by regulators. (1) AO3
- If the hospital was a private hospital, damage to reputation caused by the dispute could lead to loss of patients and therefore profit. (1) AO3
- Failure to resolve disputes consistently/fairly could undermine staff confidence in/loyalty to the hospital/employer, leading to recruitment problems, which could result in lower efficiency. (1) AO3

Accept any other suitable response.

3(a) An elderly patient with progressive and severe mental impairment has a chronically ulcerated foot, causing considerable pain. The ulcers are not treatable and are spreading.

Their consultant is considering amputation of the foot.

Define the terms 'beneficence' and 'nonmaleficence'.

Explain how they can be applied here.

[4 marks]

AO1 = 2

AO2 = 2

AP = A.1.3.3, A.1.3.4

Award **one** mark for each correct definition up to a **maximum** of **two** marks.

Award **one** mark for an explanation of how each is applied here, up to a maximum of **two** marks.

- Beneficence is (defined as) doing good/promoting the best course of action in the circumstances. (1) AO1
- Without amputation the ulcers will spread and cause more damage and pain, amputation is the best course of action. (1) AO2
- Nonmaleficence is (defined as) avoiding the causes of harm. (1) AO1
- The ulcers are causing harm, amputation removes/avoids the cause of harm. (1) AO2
- Amputation of the foot can be regarded as harm and therefore it could be argued that nonmaleficence is **not** being applied here. (1) AO2

Accept any other suitable response.

3(b) Identify the appropriate type of power of attorney that may be needed in this situation. [1 mark]

AO2 = 1

AP = A5.25.4

- Award **one** (1) mark **maximum** for identifying the appropriate type of power of attorney. The type of power of attorney would be financial and medical in these circumstances. (1) AO2

4 A Healthcare Science Assistant spends one day per week working in five different departments.

Give **four** examples of how this Continuing Professional Development (CPD) could benefit them in their career. [4 marks]

AO2 = 4 marks

AP = A1.1.4.4

Award **one** mark for each of the following explanations, up to a **maximum** of **four** marks.

- This CPD will enable them to gain an insight into different roles within healthcare science (this will help them plan their career path). (1) AO2
- This CPD will enable them to develop additional skills (which are only used in these other departments), which can lead to higher qualifications/greater responsibility. (1) AO2
- This CPD will enable them to keep up to date with new technologies (which they encounter in these other departments). (1) AO2
- This CPD will enable them to improve their patient care (as they develop new skills). (1)
- This CPD will enable them to observe good practice (on which they can model their own practice). (1) AO2
- This CPD will enable them to gain confidence as they will constantly be meeting and working with new colleagues. (1) AO2
- This CPD will enable them to develop improved communication skills as they are having to communicate with new colleagues each week. (1) AO2

Accept any other suitable response.

5(a) Part of a job advert states that applicants must have at least ten years' experience in the healthcare sector.

Define the term 'direct discrimination' under the Equality Act 2010.

Explain why this advert could be discriminatory. [2 marks]

AO1 = 1 mark

AO2 = 1 mark

AP = A5.11.1.1, A5.11.1.2

Award **one** mark **maximum** for the correct definition of direct discrimination and **one**-mark **maximum** for the correct explanation.

Direct discrimination is where someone is treated differently to another person due to a protected characteristic. (1) AO1. Age is a protected characteristic; (by requiring at least 10 years' experience) this advert discriminates against people below a certain age (below 26 years of age). (1) AO2

Accept any other suitable response.

- 5(b)** The Chief Executive of a Health Care company states that the company complies with the Equality Act 2010 as it provides:
- ramps
 - wider doorways
 - wheelchair accessible lift to all floors
 - light and plug sockets at 1 metre above the floor.

Evaluate the extent to which these measures mean the company complies with the disability discrimination aspect of the Equality Act 2010, and evaluate areas where they might need to do more.

[6 marks]

AO3 = 6 marks

AP = A5.11.1, A5.11.1.2, A5.11.2.2

Award **one** mark for each **valid** evaluative point, up to a **maximum** of **six** marks.

- Provision of ramps would be a reasonable adjustment for wheelchair users and/or people with impaired mobility, therefore in line with the Equality Act 2010. (1) AO3
- Widened doorways, would be a reasonable adjustment for wheelchair users, therefore in line with the Equality Act 2010. (1) AO3
- Provision of a wheelchair accessible lift to all floors would be a reasonable adjustment for wheelchair users and/or people with impaired mobility, therefore in line with the Equality Act 2010. (1) AO3
- Placement of all light switches and wall sockets at 1 metre above the floor would be a reasonable adjustment for wheelchair users, therefore in line with the Equality Act 2010. (1) AO3
- However other reasonable adjustments would also need to be made (eg provision of disabled toilets), this is **not** in line with the Equality Act 2010. (1) AO3
- The provisions made are all focussed on wheelchair users and those with impaired mobility and ignore other forms of disability, (eg partially sighted, hearing impaired), this is **not** in line with the Equality Act 2010. (1) AO3
- No mention is made of policies/procedures which ensure that there is no discrimination against people with disabilities during the recruitment process, this is **not** in line with the Equality Act 2010. (1) AO3
- If this is the extent of the company's provision, they would **not** comply with the disability aspect of the Equality Act 2010. (1) AO3

Accept any other suitable response.

6. An elderly woman who lives alone, is admitted onto a hospital ward after being brought to the hospital in an ambulance. She is clearly unwell, in an agitated state, and her condition appears to be worsening.

The ambulance staff:

- brief the ward staff on the reasons for the 999 call and the observations and initial treatment prior to arriving at A&E
- inform the ward staff that English appears to be her second language and that her vocabulary appears to be limited
- inform the ward staff that she has two hearing aids but is refusing to wear them
- inform the ward staff that she appears to be confused.

The ward staff commence treatment based on the information they have received from the ambulance staff, from their own observations and on her medical records.

It is important to gain informed consent before commencing treatment with a patient.

Discuss the issue of gaining informed consent by the ward staff in this scenario.

Your response should include references to gaining informed consent and make reasoned judgements/conclusions.

[9 marks, plus 3 marks for QWC]

AO1 = 3

AO2 = 3

AO3 = 3

AP = A1.3.1, A5.12.1.1, A7.3.2

Band	Mark	Descriptor
3	7–9	<p>AO3: Evaluation of the ward staff's actions and how gaining informed consent apply in this context is comprehensive, effective and relevant, showing detailed understanding and logical and coherent chains of reasoning throughout. Informed conclusions that are fully supported with rational and balanced reasoned judgements are evident.</p> <p>AO2: Applied all relevant knowledge of the importance of gaining informed consent to the context, including an understanding of its limitations in this context, and shows a detailed functional understanding of the decisions involved.</p> <p>AO1: A wide range of relevant knowledge of how to gain informed consent and the additional steps which need to be taken in this context.</p> <p>The answer demonstrates comprehensive breadth and/or depth of understanding.</p>
2	4–6	<p>AO3: Evaluation of the ward staff's actions and how gaining informed consent apply in this context is in most parts effective and mostly relevant, showing mostly logical and coherent chains of reasoning. Conclusions supported by reasoned judgements that consider most of the relevant arguments are evident.</p> <p>AO2: Applied mostly relevant knowledge of the importance of gaining informed consent to the context, including an understanding of its limitations in this context, showing some functional understanding of the decisions involved.</p> <p>AO1: Knowledge and understanding of how to gain informed consent and the additional steps which need to be taken in this context, is in most parts clear and mostly accurate, although on occasion may lose focus.</p> <p>The answer demonstrates reasonable breadth and/or depth of understanding, with occasional inaccuracies and/or omissions.</p>
1	1–3	<p>AO3: Evaluation of the ward staff's actions and how gaining informed consent apply in this context is in some parts effective and of some relevance, with some understanding and reasoning taking the form of generic statements with some development. Brief conclusions supported by reasoned judgements that consider only basic arguments and show little relevance to the question aims are evident.</p> <p>AO2: Applied limited knowledge of the importance of gaining informed consent to the context including an understanding of its limitations in this context and may show a lack of functional understanding of the diagnostic tools.</p> <p>AO1: Knowledge and understanding of how to gain informed consent and the additional steps which need to be taken in this context shows</p>

		some but limited accuracy , focus and relevance.
		The answer is basic and shows limited breadth and/or depth of understanding, with inaccuracies and omissions.
	0	No credit worthy material

AO1:

- Informed consent involves ensuring the patient is given and understands the full details of the treatment being recommended including consequences.
- Explaining procedures to the patient and checking understanding.
- Ensuring the patient can hear the explanation, if necessary, use hearing loops.
- Use non-verbal methods of explanation of procedures (body language).
- Use of appropriate reading materials.
- Use of reading materials in an appropriate form (eg language etc).
- Provision of an interpreter.
- Avoidance of the use of specialist terminology/jargon.
- Take account of the patient's capacity to understand the information you are providing.
- Take account of the patient's emotional state.
- Attempt to contact the next of kin or someone who can act as an advocate.

AO2:

- A patient cannot give informed consent if they do **not** understand the information they are being given.
- If the patient cannot hear the information they are being given, they will **not** be able to process and understand it (regardless of their mental capacity).
- If the patient cannot understand the information being given, because of language differences, then they will **not** be able to process and understand it.
- Providing an interpreter will help the patient to understand the situation they are in and may help to calm them down (and be more receptive).
- Providing an interpreter will help the patient to process the information and understand it better.
- Avoiding specialist terminology/jargon will help the patient to understand the information they are being given.
- Use of appropriate non-verbal communication, may help to calm the patient so that they have more chance of understanding the information they are being given.
- Contacting next of kin or providing an advocate, may help calm the patient and make them more able to understand the information they are being given.
- A next of kin/advocate may be able to give informed consent, should the patient **not** be able to.

AO3:

- As the ward staff have **not** attempted to gain informed consent, the treatment they provide may go against the wishes of the patient, this could lead to legal action against the ward staff.
- The condition of the patient appeared to be worsening, if they had spent time attempting to gain informed consent, this could have led to the death of the patient. This could lead to legal action from other family members.

- The ward staff acted on information they had received from the ambulance staff, their own observations and from the patients' medical records, so they had a significant amount of information on which to base the treatment.
- Due to the communication issues apparent in the patient, and the fact that her condition was worsening, it may **not** have been possible to gain informed consent in the time they had available.
- Although informed consent is a key principle of ethical practice, it can be overridden by the need to keep the patient alive.
- If the patient had a DNR order (do **not** resuscitate), this should be in their medical records, therefore the ward staff were justified in proceeding to give treatment.
- Even if a DNR order (do **not** resuscitate) is present, the ward staff would be justified in providing treatment to prevent the patient from suffering (eg pain relief).

Quality of written communication (QWC) = 3 marks

Mark	Descriptor
3	<p>The answer is clearly expressed and well-structured.</p> <p>The rules of grammar are used with effective control of meaning overall.</p> <p>A wide range of appropriate technical terms are used effectively.</p>
2	<p>The answer is generally clearly expressed and sufficiently structured.</p> <p>The rules of grammar are used with general control of meaning overall.</p> <p>A good range of appropriate technical terms are used effectively.</p>
1	<p>The answer lacks some clarity and is generally poorly structured.</p> <p>The rules of grammar are used with some control of meaning and any errors do not significantly hinder the overall meaning.</p> <p>A limited range of appropriate technical terms are used effectively.</p>
0	<p>There is no answer written or none of the material presented is creditworthy.</p> <p>OR</p> <p>The answer does not reach the threshold performance level. The answer is fragmented and unstructured, with inappropriate use of technical terms. The errors in grammar severely hinder the overall meaning.</p>

Section B: Personal and patient safety

This section is worth 34 marks, plus 3 marks for QWC and use of specialist terminology.

7(a) State **one** purpose of the Health and Safety at Work etc Act 1974.

[1 mark]

AO1 = 1 mark

AP = A3.1.1.1

Award **one** mark for any valid purpose to a maximum of **one** mark.

- Defines employers' responsibilities to protect the health, safety (and welfare) at work of employees and members of the public. (1)
- Defines employees' duties to protect themselves and each other. (1)

Accept any other suitable response.

7(b) Outline two of the requirements an employee is expected to follow within the Health and Safety at Work etc Act 1974.

[2 marks]

AO1 = 2 marks

AP = A3.1.1.1

Award **one** mark for any valid requirement, to a **maximum** of two marks.

- To take reasonable care for the health and safety of themselves. (1) AO1
- To take reasonable care of other persons who may be affected by their actions. (1) AO1
- To co-operate with their employer to ensure compliance with the act. (1) AO1
- Use safety provisions correctly. (1) AO1
- Must **not** misuse or recklessly interfere with any equipment which is provided in the interest of health and safety. (1) AO1
- Report any hazards, injuries or ill health to a supervisor. (1) AO1

Accept any other suitable response.

8(a) A patient in a radiography department trips and falls over a loose wire located in a busy walkway.

They are examined by a doctor and no injury is found.

Explain why this should be reported using Reporting of Injuries, Diseases and Dangerous Occurrences Regulation/RIDDOR 2013.

[2 marks]

AO2 = 2 marks

AP = A3.1.5.1

Award **one** mark for each valid explanation, up to a maximum of **two** marks.

- The patient had an accident without being injured – this would be regarded as a near miss (1) AO2
- RIDDOR requires the reporting of near miss incidents (1) AO2

Accept any other suitable response.

8(b) A review of the incident suggested the following possible strategies to prevent the incident happening again.

- Displaying warning signs regarding the hazard.
- Using a different route for the patients.
- Taping over the wire in its present position.
- Channelling the wires under the floor.

Assess the benefits and limitations of these strategies.

[4 marks]

AO3 = 4 marks

AP = A3.1.5.1, A3.2.1, A3.2.2, A3.2.3, A3.2.4

Award up to **one** mark for an appropriate evaluation of each strategy, up to a **maximum** of **four** marks in total.

- Displaying a warning sign is quick and cheap to apply, however it requires patients to be able to read and understand the sign (which they may **not** be able to do). (1) AO3
- OR**
- Displaying a warning sign indicates the organisation is aware of the hazard, should a patient/staff member trip and injure themselves, this could be used in evidence in a court case. (1) AO3
 - Using a different route may be simple and cheap to apply but may **not** be possible and/or may cause congestion/problems in other areas. (1) AO3
 - Taping the wire would be quick and simple to apply, however it would **not** completely remove the hazard/could easily come loose again. (1) AO3
 - Channelling the wires under the floor, would remove the hazard permanently, however it would be the most expensive option. (1) AO3

OR

- Channelling the wires under the floor, would remove hazard permanently, however it would cause (significant) disruption during the process. (1) AO3
- Although channelling the wires through the floor may initially be the most expensive, it is the safest and most permanent option and therefore may prove to be the cheapest option over time.

Accept any plausible/logical justification.

9 An Optical Technician's job role involves spending three hours each morning inputting prescription details into a computer system.

The computer screen is small, and its brightness is turned up as it is in direct sunlight.

The Technician complains of eyestrain and headaches.

Identify the regulation applicable to these circumstances and explain **two** ways an employer could meet its requirements.

[4 marks]

AO1 = 1 mark

AO2 = 3 marks

AP = A3.1.12.1

Award **one** mark **maximum** for identifying the correct legislation. The year does **not** need to be included for the mark to be awarded:

Legislation:

- The Health and Safety (Display Screen Equipment) Regulations 1992 (Amended 2002). (1) AO1.

Award **one** mark for each valid explanation of how an employer could meet its requirements, up to a **maximum** of **three** marks:

- Provide eye examinations and spectacles specific to staff who are 'users' of computer equipment to correct any display screen prescription needs. (1) AO2
- Break up the time the technician spends inputting data, into several shorter periods spread throughout the day. (1) AO2
- Move the computer to an area away from direct sunlight, and/or provide blinds/curtains/shading at the window. This will enable the screen to be seen more easily, (leading to less eyestrain). (1) AO2
- Provide a larger screen so that the details can be enlarged, leading to less eye strain. (1) AO2

Accept any other suitable response.

10 A member of staff gets a minor cut whilst using a blunt instrument in the workplace.

They cannot locate a first aider and the first aid kit does **not** contain any suitable dressings.

Identify which regulation applies to this scenario and explain why in this scenario the employer is in breach of this regulation.

[3 marks]

AO1 = 1 mark

AO2 = 2 marks

AP = A4.1.1.1, A4.4.1.1, A4.4.2.1, A4.5.1, A4.5.3

Award **one** mark for correctly naming the Health and Safety (First-Aid) Regulations 1981 (1) (AO1). The year does **not** need to be included for the mark to be awarded.

Award a maximum of **one** mark for a valid requirement and **one** mark for each explanation of why the employer was in breach, up to a maximum of **two** marks.

- The employer may have failed to provide an appropriate number of first aiders across the organisation. (1) AO2
- There was no access to a first aider, (therefore the employer is in breach of these regulations). (1) AO2
- Although a first aid kit was available, it was **not** appropriately stocked (therefore the employer is in breach of these regulations). (1) AO2

Accept any other suitable response.

11 Whilst unpacking a delivery of over the counter medication you notice that the dosage information on the outside of the pack on the new stock is different to that on the existing stock.

Identify which regulatory body should be alerted and explain why.

[2 marks]

AO1 = 1 mark

AO2 = 1 marks

AP = A4.2.1, A4.2.2, A2.2.1.1

Award **one** mark for identifying the relevant regulatory body and **one** mark for explanation of why they should be alerted, up to a **maximum** of **two** marks.

Regulation

- The Medicines and Healthcare products Regulatory Agency (MHRA) should be alerted (1) AO1.

Explanation

- The MHRA should be alerted:
 - as it is responsible for ensuring compliance with any statutory obligations relating to medicines (1) AO2
 - if the dosage is incorrect, this could cause harm to service users (1) AO2
 - it is important that the reason for the change is investigated to prevent it happening again. (1) AO2

Accept any other suitable response.

12(a) A Domestic Assistant cleans a number of day clinics each evening. As they are cleaning a wound clinic, they notice a small amount of fluid on the floor.

The clinic treats patients with chronic wounds which are often infected.

Explain why cleaning up the fluid poses a risk to the Domestic Assistant.

[2 marks]

AO2 = 2

AP = A6.1.1.1, A6.1.1.2, A6.1.1.4, A6.1.3.1

Award **one** mark for each valid explanation up to a maximum of **two** marks.

- The clinic treats wounds which are often infected, therefore the fluid may have come from a wound/treatment of a wound and contain pathogenic/harmful microbes. (1) AO2
- The clinic treats wounds which are often infected, the fluid may be some form of medication/disinfectant/antiseptic which may pose a risk. (1) AO2

12(b) The Domestic Assistant cleans up the fluid in the following way:

- they wear disposable gloves
- they wear a non-surgical mask
- they use an absorbent wipe to clean up the fluid
- they then clean the area with an antiseptic wipe
- they place both wipes into waste for incineration bin.

Evaluate the cleaning method they used in this scenario.

Your response should include reasoned judgements/conclusions.

[4 marks]

AO3 = 4

AP = A6.1.1.1, A6.1.1.2, A6.1.1.4, A6.1.3.1, A6.2.2.2

Award **one** mark for each valid reasoned judgement up to a maximum of **four** marks.

- They may have carried out a limited assessment of the risk, as they did take some precautions to keep themselves safe (wore disposable gloves and non-surgical mask). (1) AO3
- However, the use of disposable gloves and a mask may be standard procedure/procedure all staff use all the time. This could indicate no assessment of the risk. (1) AO3
- They did **not** wear eye protection, cleaning the fluid could have led to contamination of their eyes, this put them at risk. (1) AO3
- They did **not** wear any form of (disposable) protective apron to prevent their clothing being contaminated. (1) AO3
- They did **not** know what the fluid was and did **not** attempt to find out, this could put them at risk. (1) AO3
- As they used an antiseptic wipe, this would reduce the levels of any pathogens/harmful microbes that may have been in the fluid (but would **not** completely eliminate them), reducing risk. (1) AO3
- As they placed the (used) wipes into the waste for incineration bin, this should prevent transfer of any pathogens/harmful microbes to others, reducing risk. (1) AO3
- As the Domestic Assistant is working in a number of clinics, they could transfer pathogens/harmful microbes to other clinics on their clothes, putting others at risk. (1) AO3

Accept any other suitable response.

12(c) Explain why the wipes used to clean up the spill must be disposed of by incineration.

[2 marks]

AO2 = 2

AP = A6.3.1.3.1

Award **one** mark for each valid explanation, up to a maximum of **two** marks.

- Incineration is a form of sterilisation and it will eliminate all pathogenic/harmful microbes. (1) AO2
- Any other form of disposal (eg landfill, recycling) would put others at risk from contamination with pathogenic/harmful microbes. (1) AO2

Accept any other suitable response.

13 The following items are examples of multiple-use products:

- scalpels
- blood pressure cuffs
- stethoscopes
- ear thermometers.

The **three** main methods of decontamination are:

- cleaning
- disinfection
- sterilisation.

To prevent MRSA infection, a Hospital Manager makes the decision that all multiple-use products should be sterilised.

Evaluate this decision in relation to these products.

Your response should include a demonstration of your understanding of the **three** main methods of decontamination and reasoned judgements/conclusions.

[9 marks, plus 3 marks for QWC]

AO1 = 3 marks

AO2 = 3 marks

AO3 = 3 marks

AP = A6.2.2.1, A6.2.2.2, A6.2.2.3, A6.3.1.1.1, A6.3.1.2.1, A6.3.1.3.1

Band	Mark	Descriptor
3	7–9	<p>AO3: Evaluation of the Hospital Managers proposed actions in this context is comprehensive, effective and relevant, showing detailed understanding and logical and coherent chains of reasoning throughout. Informed conclusions that are fully supported with rational and balanced reasoned judgements are evident.</p> <p>AO2: Applied all relevant knowledge of the mechanisms of decontamination to the products in the given context and shows a detailed functional understanding of the potential outcomes of the decision.</p> <p>AO1: A wide range of relevant knowledge and understanding of the mechanisms of decontamination and the nature of the products is demonstrated which is accurate and detailed.</p> <p>The answer demonstrates comprehensive breadth and/or depth of understanding.</p>
2	4–6	<p>AO3: Evaluation of the Hospital Managers proposed actions in this context is in most parts effective and mostly relevant, showing mostly logical and coherent chains of reasoning. Conclusions supported by reasoned judgements that consider most of the relevant arguments are evident.</p> <p>AO2: Applied mostly relevant knowledge of the mechanisms of decontamination to the products in the context, showing some functional understanding of the potential outcomes of the decision.</p> <p>AO1: Knowledge and understanding of the mechanisms of decontamination and the nature of the products is demonstrated and is in most parts clear and mostly accurate, although on occasion may lose focus.</p> <p>The answer demonstrates reasonable breadth and/or depth of understanding, with occasional inaccuracies and/or omissions.</p>
1	1–3	<p>AO3: Evaluation of how the Hospital Managers proposed actions apply in this context is in some parts effective and of some relevance, with some understanding and reasoning taking the form of generic statements with some development. Brief conclusions supported by reasoned judgements that consider only basic arguments and show little relevance to the question aims are evident.</p> <p>AO2: Applied limited knowledge of the mechanisms of decontamination to the products in the context and may show a lack of functional understanding of the potential outcomes of the decision.</p> <p>AO1: Knowledge and understanding of the mechanisms of</p>

		decontamination and the nature of the products is demonstrated and shows some but limited accuracy, focus and relevance. The answer is basic and shows limited breadth and/or depth of understanding, with inaccuracies and omissions.
	0	No creditworthy material

Indicative content

AO1: Knowledge and understanding of the three main methods of decontamination may include.

- Cleaning is the physical removal of visible organic/inorganic material.
- Cleaning reduces the level of microbes/microorganisms but doesn't necessarily kill them.
- Cleaning minimises the risk of transfer of microbes/microorganisms but does **not** completely prevent the risk.
- Disinfection is the reduction of non-visible microbes/microorganisms, using a specific chemical/specific physical mechanism such as heat.
- Disinfection achieves this reduction by destroying cell walls/interfering with cell metabolism.
- Sterilisation is the complete elimination of all microbes/microorganisms.
- MRSA is a bacterium resistant to most antibiotics.
- MRSA is **not** resistant to disinfection processes.
- Sterilisation is carried out using high temperatures, chemicals or (ionising) radiation.
- Scalpels are invasive/used to cut into the body, used inside the body.
- Scalpels are usually made of steel/metal.
- Blood pressure cuffs are a mixture of plastic/rubber and other materials.
- Ear thermometers are made from plastic and other materials.

AO2: Application of the three levels of decontamination in this context may include.

- As sterilisation is the complete elimination of all microbes/microorganisms, it would completely decontaminate all of the products listed.
- As sterilisation is the complete elimination of all microbes/microorganisms, it would prevent MRSA being transferred via these products.
- Disinfection will reduce the amount of MRSA (if present) on the surface(s) of these products, and thus reduce the chances of transfer.
- Cleaning may **not** reduce MRSA levels at all, and therefore have little/no impact/effect on reducing/preventing transfer.
- As blood pressure cuffs, ear thermometers and stethoscopes are made from a mixture of plastics/rubber and other materials, they may be damaged by the sterilisation process.

AO3: Evaluation (comparison and judgement) of statement in relation to the three products.

- Although sterilisation would completely eliminate MRSA (from these objects), it may damage the blood pressure cuffs, stethoscope and ear thermometer (preventing them from being used again). Sterilisation is **not** a suitable process.
- As scalpels are made from metal, they will **not** be damaged by the sterilisation process and will be completely free of MRSA, so will **not** transfer it. Sterilisation is a suitable process.
- As scalpels are invasive/used to cut into the body, they come into contact with body fluids,

and could easily transfer MRSA, therefore it is essential/vital/necessary that they are sterilised.

- Although sterilisation does eliminate MRSA on these products, it is **not** the only way MRSA is transferred, therefore it would need to be used with other strategies.
- As blood pressure cuffs and stethoscopes are only used on the body surface, they are much less likely to come into contact with body fluids therefore cleaning and/or disinfection may be sufficient.
- As ear thermometers do come into contact with ear wax, they will need chemical disinfection to reduce the chance of MRSA being on the surface.

OR

- Most ear thermometers are used with a single use plastic cover, this prevents the thermometer contacting ear wax, and reduces the chances of MRSA transfer.
- As sterilisation is time consuming and involves specialist equipment, it should only be used when this is necessary (ie with the scalpels).
- The quickest and most cost-effective mechanism required to minimise the risk of MRSA transfer without damaging the equipment should always be selected.
- Recognise the difference in effectiveness of decontamination and why there are these differences.
- Give examples of the types of processes required for the different methods and the strengths and limitations of these.
- Recognise the importance of reliability, heat temperatures and operator safety and how these affect choices.

Accept any other suitable response.

Mark	Descriptor
3	<p>The answer is clearly expressed and well-structured.</p> <p>The rules of grammar are used with effective control of meaning overall.</p> <p>A wide range of appropriate technical terms are used effectively.</p>
2	<p>The answer is generally clearly expressed and sufficiently structured.</p> <p>The rules of grammar are used with general control of meaning overall.</p> <p>A good range of appropriate technical terms are used effectively.</p>
1	<p>The answer lacks some clarity and is generally poorly structured.</p> <p>The rules of grammar are used with some control of meaning and any errors do not significantly hinder the overall meaning.</p> <p>A limited range of appropriate technical terms are used effectively.</p>
0	<p>There is no answer written or none of the material presented is creditworthy.</p> <p>OR</p> <p>The answer does not reach the threshold performance level. The answer is fragmented and unstructured, with inappropriate use of technical terms. The errors in grammar severely hinder the overall meaning.</p>

Section C: Data handling and confidentiality

This section is worth 21 marks, plus 3 marks for QWC and use of specialist terminology.

14 A hospital administration department is responsible for handling patients' personal data and is looking to improve ways of working.

Explain **four** advantages of maintaining secure data management within the department.

[4 marks]

AO2 = 4 marks

AP = A5.16.3, A7.6.3.1

Award **one** mark for any of the following explanations of an advantage of good data management in a hospital administration department, up to a **maximum** of **four** marks.

- The likelihood of a data breach occurring is lower, which means the hospital is less likely to suffer damage to its reputation. (1) AO2
- If the hospital manages personal data securely there will be a reduced risk of legal action and possible fines (resulting in smooth running of organisation). (1) AO2
- The hospital will comply with GDPR and will be less likely to risk legal action. (1) AO2
- Good data management supports departmental efficiency because clear procedures will be in place. (1) AO2

Accept any other suitable response.

15(a) A twelve year old girl is brought into A&E with a suspected fracture of her arm. The examining Doctor notices:

- she has bruises resembling finger marks on her upper arms
- she has numerous healed parallel scratches on her lower arms
- she is quiet and withdrawn
- her medical records show she has been brought into A&E several times before.

Give **two** reasons why the Doctor would be justified in sharing these details with other agencies.

[2 marks]

AO2 = 2

AP = A8.3.1, A8.3.2, A8.7.3, A8.7.4

Award **one** mark for each valid explanation up to a **maximum** of **two** marks.

- There is evidence of self-harm due to the parallel scratches on her arms. (1) AO2
- There is evidence of physical abuse/safeguarding concerns, due to the bruising and medical history. (1) AO2
- The Doctor has a duty of care to protect the child. (1) AO2

Accept any other suitable response.

15(b) In the scenario described above, give **one** advantage and **one** risk of using IT systems to record, retrieve and store information and data.

[2 marks]

AO2 = 2

AP = A7.9.1.1, A7.9.1.2, A7.9.1.4, A7.9.2.1, A7.9.2.2, A7.9.2.3

Award **one** mark **maximum** for a valid explanation of an advantage, and **one** mark **maximum** for a valid explanation of a risk.

Advantage

- The Doctor was able to quickly examine her medical history which they used in their decision to share the information. (1) AO2
- The Doctor could rapidly share information about the girl with other agencies. (1) AO2
- The information can be stored securely as it is password protected. (1) AO2

Disadvantage

- There is a risk of breach of security (malicious or accidental). (1) AO2
- If there is an IT system failure, the information would not be (immediately) available. (1) AO2
- There is a risk of corruption of the data, meaning it could be lost. (1) AO2

Accept any other suitable response.

16 A data breach has occurred where patient information has been wrongly shared from an online database.

The organisation that runs the database states that this must have been maliciously shared by a staff member as all IT based systems are password protected.

Evaluate this statement and provide reasoned justifications for whether this could be either true or false.

[4 marks]

AO2 = 2 marks

AO3 = 2 marks

AP = A7.9.1.4, A7.9.2.1

Award **one** mark for each explanation of the possible breach, up to a **maximum** of **two** marks and **one** mark for each reasoned judgement, up to a **maximum** of **two** marks.

- The breach could have been due to user error, showing lack of understanding of systems or regulations (1) (AO2). A malicious act is deliberate/has intent, if the breach was due to user error, then the act was not deliberate/there was no intent, therefore it was not a malicious act and the statement is false. (1) AO3
- The breach could be due to a cyber-security attack (1) (AO2). A malicious act is deliberate/has intent, if the breach was caused by a cyber-attack, this is a malicious act from outside the organisation, **not** from a member of staff, therefore the statement is false. (1) AO3
- Password protected systems, if used correctly, will prevent unauthorised access to data (1) (AO2). As data has been wrongly shared, this may be due to an individual with password access, deliberately/with intent, accessing and sharing the data, this would be a malicious act and the statement is true. (1) AO3

Accept any other suitable response.

17 The senior management of a private hospital trust were debating the role of social media in the future of the trust.

The Chief Executive states that, “the trust will gain more from the positive effects of social media than they will lose from the negative effects.”

Evaluate the Chief Executive’s statement.

Your response should demonstrate:

- consideration of social media influences
- reasoned judgments and/or conclusions about the statement.

[9 marks plus 3 marks for QWC]

AO1 = 3 marks

AO2 = 3 marks

AO3 = 3 marks

AP = A7.8.1, A7.9.2.1, A7.9.2.2

Band	Mark	Descriptor
3	7–9	<p>AO3: Analysis of the Chief Executive’s statement in relation to the positive and negative effects of social media for the trust is comprehensive, effective, and relevant, showing detailed understanding and logical and coherent chains of reasoning throughout. Informed conclusions that are fully supported with rational and balanced reasoned judgements are evident.</p> <p>AO2: Applied all relevant knowledge of the positive effects of social media to establish the negative effects to the given context and shows a detailed functional understanding.</p>

		<p>AO1: A wide range of relevant knowledge and understanding of the positive effects of social media, which is accurate and detailed. A wide range of appropriate technical terms are used.</p> <p>The answer demonstrates comprehensive breadth and/or depth of understanding.</p>
2	4–6	<p>AO3: Analysis of the Chief Executive’s statement in relation to the positive and negative effects of social media for the trust is in most parts effective and mostly relevant, showing mostly logical and coherent chains of reasoning. Given conclusions are supported by reasoned judgements that consider most of the relevant arguments.</p> <p>AO2: Applied mostly relevant knowledge of the positive effects of social media to establish the negative effects, showing some functional understanding.</p> <p>AO1: Knowledge and understanding of the positive effects of social media is in most parts clear and mostly accurate, although on occasion may lose focus.</p> <p>The answer demonstrates reasonable breadth and/or depth of understanding, with occasional inaccuracies and/or omissions.</p>
1	1–3	<p>AO3: Analysis of the Chief Executive’s statement in relation to the positive and negative effects of social media for the trust is in some parts effective and of some relevance, with some understanding and reasoning taking the form of generic statements with some development. Given brief conclusions supported by judgements that consider only basic arguments and show little relevance to the question aims.</p> <p>AO2: Applied limited knowledge of the positive effects of social media to establish the negative effects to the context and may show a lack of functional understanding.</p> <p>AO1: Knowledge and understanding of the positive effects of social media show some but limited accuracy, focus and relevance.</p> <p>The answer is basic and shows limited breadth and/or depth of understanding, with inaccuracies and omissions.</p>
	0	No creditworthy material

Indicative content

AO1 and AO2 will be implicit through the level of evaluation and reasoned judgements/and or conclusions that the learner provides.

(AO1) Positive effects:

- Contacting huge numbers of people, quickly.

- Contacting people who are difficult to reach through more traditional methods (eg newspapers and TV advertising).
- Information/awareness campaigns can be disseminated/made available.
- Information/awareness campaigns can be targeted to particular groups of people who have a certain profile.
- Fake news/misinformation can be corrected/countered/challenged.
- Communication can be very rapid in a crisis situation.
- Data can be gathered about a huge range of factors important to the hospital trust.
- It can be used as an effective recruitment tool.
- It can be used for marketing/advertising.

(AO2) Negative effects:

- Inaccurate and/or non evidence based information and/or deliberate misinformation and/or fake news can be spread quickly and widely.
- Professional boundaries and/or relationships with clients and/or service users can be eroded.
- Sensitive and/or personal information can be posted, potentially damaging the hospital trust.
- Customers are free to talk about the problems/issues they face when dealing with the hospital trust on social media.
- An overreliance on social media can leave the hospital trust vulnerable to future changes that might be made to how the sites work and/or operate.

(AO3) Evaluation of effects:

- People who increasingly look to social media as a way of investigating private medical care and care products are difficult to reach through traditional mechanisms.
- As analysis of social media habits can lead to the identification of groups who may be potential consumers of a particular product, survey-based market research may **not** be necessary.
- Due to the speed and wide reach of social media, information can be transmitted rapidly to large numbers enabling a rapid response to a particular situation
- Due to the speed and wide reach of social media negative/fake information can be transmitted rapidly to large numbers which can cause lasting damage (even if the hospital trust succeeds in making the social media company take the post down).

(AO3) Reasoned judgements/conclusions about the overall positive effects.

- If a hospital trust does **not** have a social media presence it will be increasingly difficult to remain competitive and innovative.
- Advertising through social media will become more important for private hospital trusts to reach their potential consumers as more people are accessing advertising through social media (and this may grow over time).
- Although there can be negative effects, hospital trusts can employ strategies to minimise the impact of this, mitigating the negative effects on the hospital trust and retaining any positive impact.
- Although there can be negative effects from the use of social media, these are outweighed by the larger number of positive effects.

- Advertising can be targeted to groups who are likely to be potential consumers, this increases efficiency, thus raising profit.

(AO3) Reasoned judgements/conclusions about the overall negative effects.

- There are large groups of people who (do **not** have access to), and/or (choose **not** to access social media), so if a hospital trust relies only on social media for communication it will lose this section of its potential customer base which will negatively affect profit.
- As some people resent social media companies accessing their online activities, they will use search engines which do **not** allow profiling, depriving hospital trusts access to this section of its potential client base and negatively affecting profit.
- Some potential customers may **not** regard private medical care as a business and may lose confidence in the hospital trust due to its online presence.
- Damaging social media posts can be rapidly amplified, (if these posts are memorable or becomes popular) it can become difficult for the company to distance themselves and may damage their reputation, (thus negatively effecting profits).

Accept any other suitable response.

Quality of written communication (QWC) = 3 marks

Mark	Descriptor
3	The answer is clearly expressed and well-structured . The rules of grammar are used with effective control of meaning overall. A wide range of appropriate technical terms are used effectively.
2	The answer is generally clearly expressed and sufficiently structured . The rules of grammar are used with general control of meaning overall. A good range of appropriate technical terms are used effectively.
1	The answer lacks some clarity and is generally poorly structured . The rules of grammar are used with some control of meaning and any errors do not significantly hinder the overall meaning. A limited range of appropriate technical terms are used effectively.
0	There is no answer written or none of the material presented is creditworthy. OR The answer does not reach the threshold performance level. The answer is fragmented and unstructured , with inappropriate use of technical terms . The errors in grammar severely hinder the overall meaning.

Section D: Regulatory and professional frameworks

This section is worth 21 marks, plus 3 marks for QWC and use of specialist terminology.

- 18** A new hospital cytopathology laboratory is being developed. The laboratory will examine samples from patients with potentially infectious diseases.
- The Director of the laboratory states:
- ‘Standard Operating Procedures must be developed and followed for all procedures used in the laboratories activities.’
- Define the term ‘Standard Operating Procedure’ (SOP) and evaluate the importance of SOPs in this setting.
- Your response should demonstrate reasoned judgements and/or conclusions.

[4 marks]

AO1 = 1 mark

AO3 = 3 marks

AP = A3.3.3, A6.10.1.1.1, A6.10.2.1

Award **one** mark for the correct definition and up to **three** marks for each valid evaluative point of the importance.

Definition

- A standard operating procedure is a set of sequential steps/instructions (designed to standardise the approach to a process or action). (1 AO1)
- A way of making sure that processes are always carried out in the same way. (1) AO1

Implications

- As the centre is working with potentially infectious samples/samples from patients with infectious diseases, **not** following SOP's may lead to staff **not** following appropriate procedures, this could lead to infection of staff. i (1) AO3
- **Not** following SOP's may lead to staff **not** following appropriate procedures this could lead to incorrect results from tests, leading to risks to patient and further spread of infection. (1) AO3
- If not following SOP's leads to incorrect results, this could negatively affect understanding of a particular disease and how infection spreads, leading to further infection. (1) AO3
- If patients receive incorrect results and spread infection further, this could lead to negative media coverage and loss of confidence in the hospital. (1) AO3
- Any errors or issues arising from failure to follow SOPs, may need to be investigated by a regulatory body and could lead to legal action or fines for the setting or staff. (1) AO3

Accept any other suitable response.

19 Identify **two** reasons for effective stock management.

For each reason explain the impact of poor stock management in a healthcare science lab.

[4 marks]

AO1 = 2 marks

AO2 = 2 marks

AP = A9.9.1, A9.9.2, A9.9.3, A9.9.4, A9.9.5, A9.9.6

Award **one** AO1 mark for each reason, up to a **maximum** of **two** marks.

Award **one** AO2 mark for each impact upon a healthcare science lab, up to a **maximum** of **two** marks.

- Ensuring sufficient supply of required products and equipment, (1) AO1 if this was **not** the case lab tests could be delayed which could delay patient diagnosis or treatments. (1) AO2
- Ensuring materials and products are **not** passed their use by date, (AO1 1) if this was **not** monitored it could cause incorrect results on lab tests and lead to incorrect results for patients. (1) AO2
- Ensuring materials and products are stored correctly, (1) AO1 if this was **not** managed it could lead to the products being damaged and unable to be used. (1) AO2
- Management of costs for the lab as (1) AO1 this could lead to waste of money, which could be used to improve patient care. (1) AO2

20 You are measuring out small amounts of a catalyst. The electronic scales are undermeasuring and you cannot recalibrate them.

Describe and justify two procedures to follow in this scenario.

[4 marks]

AO2 = 2 marks

AO3 = 2 marks

AP = A9.7.1, A9.7.3, A9.8.1, A9.8.2, A9.8.3, A9.8.4

Award **one** mark for a description of each valid procedure of their action, up to a **maximum** of **two** marks, and **one** mark for each valid justification of a given procedure, up to a **maximum** of **two** marks.

- Label the scales with a (short) statement of the problem, (1) AO2 this is immediate action to prevent the scales being used again, thus preventing harm/further harm. (1) AO3
- Isolate the scales, (1) AO2 as this will prevent someone else using them who may **not** notice they are **not** working/your label, thus preventing harm/further harm. (1) AO3
- Use the procedures of the workplace to identify the person responsible for calibration/maintenance of machinery (1) AO2 as this will ensure that the problem is resolved quickly, enabling the scales to be recalibrates so that they can continue to be

- used, or replaced. (1) AO3
- Make notes on times, dates and actions taken. (1) AO2 This provides a record of action taken, which could be part of an evidence trail to safeguard yourself, if use of the (defective) scale had led to harm. (1) AO3
 - Report the event to the responsible person so that you are adhering to procedures according to health and safety legislation. (1) AO2 This will help avoid reputational damage/action involving Trade Union/Workers' Council Safety Representative/additional cost. (1) AO3

Accept any other suitable response.

21	<p>A pharmaceutical company produces a variety of drugs for the treatment of a variety of conditions.</p> <p>Discuss the importance of the company following Good Manufacturing Practice (GMP) in their production.</p> <p>Your response should include reasoned judgements/conclusions.</p> <p style="text-align: right;">[9 marks, plus 3 marks for QWC]</p>
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AO1 = 3 marks

AO2 = 3 marks

AO3 = 3 marks

AP = A10.3.5

Band	Mark	Descriptor
3	7–9	<p>AO3: Discussion of the importance of GMP and how its principles apply in this context is comprehensive, effective and relevant, showing detailed understanding and logical and coherent chains of reasoning throughout. Informed conclusions that are fully supported with rational and balanced, reasoned judgements are evident.</p> <p>AO2: Applied all relevant knowledge of the principles of GMP to the given context and shows a detailed, functional understanding of the diagnostic tools involved.</p> <p>AO1: A wide range of relevant knowledge and understanding of the principles of GMP which and is accurate and detailed.</p> <p>The answer demonstrates comprehensive breadth and/or depth of understanding.</p>
2	4–6	<p>AO3: Evaluation of the importance of GMP and how its principles apply in this context is in most parts effective and mostly relevant, showing mostly logical and coherent chains of reasoning. Conclusions supported by reasoned judgements that consider most of the relevant arguments are evident.</p> <p>AO2: Applied mostly relevant knowledge of the principles of GMP to the context, showing some functional understanding of how they can be applied in this scenario.</p> <p>AO1: Knowledge and understanding of the principles of is in most parts clear and mostly accurate, although on occasion may lose focus.</p> <p>The answer demonstrates reasonable breadth and/or depth of understanding, with occasional inaccuracies and/or omissions.</p>
1	1–3	<p>AO3: Evaluation of the importance of GMP and how its principles apply in this context is in some parts effective and of some relevance, with some understanding and reasoning taking the form of generic statements with some development. Brief conclusions supported by reasoned judgements that consider only basic arguments and show little relevance to the question aims are evident.</p> <p>AO2: Applied limited knowledge of the principles of GMP to the context and may show a lack of functional understanding of the diagnostic tools.</p> <p>AO1: Knowledge and understanding of the principles of GMP shows some, but limited accuracy, focus and relevance.</p> <p>The answer is basic and shows limited breadth and/or depth of understanding, with inaccuracies and omissions.</p>
	0	No creditworthy material.

AO1: Elements of GMP may include:

- A clean and hygienic manufacturing area.
- A controlled environment (to protect against cross-contamination).
- A clearly defined and controlled process of manufacturing.
- Good documentation practices (for example, process is clearly recorded).
- Thorough evaluation of any proposed process changes to production mechanisms.
- Comprehensive records must be maintained (manual or electronic).
- All personnel should have appropriate job training.
- All production and distribution records must be retained.
- The mechanisms of distribution must minimise risk to product quality.
- An effective recall system must be in place.
- A complaints procedure must be available and used.

AO2 Explanation of importance of GMP may include:

- A clean and hygienic environment will prevent/reduce the chance of contamination of the drugs, ensuring they are safe to use.
- A controlled environment will prevent cross contamination of different drugs, ensuring they are safe to use.
- A clearly defined and controlled process of manufacturing will ensure that the drugs have a consistent quality, ensuring they are safe to use.
- A clearly defined and controlled process of manufacturing will ensure that the drugs have a constant dosage/level of active ingredient, ensuring that patient dosage levels are controlled/safe.
- Good documentation will ensure that processes can be replicated ensuring uniformity of product.
- Thorough evaluation of any proposed process changes to production mechanisms, will ensure that these enhance efficiency of production.
- Thorough evaluation of any proposed process changes to production mechanisms, will ensure that these do **not** reduce the quality and safety of the drug, ensuring it remains safe to use.
- Maintenance of comprehensive records will ensure drugs are delivered within their sell by date and remain safe to use.
- Maintenance of comprehensive records will ensure that stock is used within its sell by date, ensuring drugs produced are safe and effective.
- All personnel having training appropriate to their role, will ensure that production mechanisms are understood and used consistently.
- Retention of all production records will enable products to be traced if required.
- Retention of all production records will and will aid in investigations if required.
- Ensuring the mechanisms of distribution are **not** a risk to the quality of the product, will ensure that the product is safe and effective when it reaches the customer.
- Having an effective recall system in place, will ensure that products can be quickly recalled should there be a problem.
- Having an effective complaints procedure will enable customers to raise complaints with the company, so investigations can take place.

AO3 Evaluation of importance of GMP may include:

- If the company follows GMP in their production, they will ensure that all their products are of consistent quality and dosage, this is vital as they will be given to patients, failure to follow GMP could lead to illness or even death of patients using the products.
- If the company fails to follow GMP and this results in the illness or death of a patient(s), this could lead to legal action by the patient and investigation by the HSE, both of which could lead to fines and other actions.
- If the company fails to follow GMP and this results in investigation from the HSE and/or legal action from patients, this will cause reputational damage to the company which could be significant.
- If the company follows GMP and there is a problem with a new drug (eg severe adverse reactions) it will be possible to quickly recall the drug, preventing further injury to patients.
- If the company follows GMP and there is a problem with a new drug, (eg severe adverse reactions) it will be possible to quickly recall the drug, reducing the chances of legal action/reputational damage.
- If the company follows GMP and a drug is found to have an unexpected positive effect, the record keeping will enable this to be investigated so that the positive effects of the drug can be replicated.

Quality of written communication (QWC) = 3 marks

Mark	Descriptor
3	<p>The answer is clearly expressed and well-structured.</p> <p>The rules of grammar are used with effective control of meaning overall.</p> <p>A wide range of appropriate technical terms are used effectively.</p>
2	<p>The answer is generally clearly expressed and sufficiently structured.</p> <p>The rules of grammar are used with general control of meaning overall.</p> <p>A good range of appropriate technical terms are used effectively.</p>
1	<p>The answer lacks some clarity and is generally poorly structured.</p> <p>The rules of grammar are used with some control of meaning and any errors do not significantly hinder the overall meaning.</p> <p>A limited range of appropriate technical terms are used effectively.</p>
0	<p>There is no answer written or none of the material presented is creditworthy.</p> <p>OR</p> <p>The answer does not reach the threshold performance level. The answer is fragmented and unstructured, with inappropriate use of technical terms. The errors in grammar severely hinder the overall meaning.</p>

Assessment Objective Grid

Section A

Question Number	AO1	AO2	AO3	Maths	QWC	Total
1a	2					2
1b		1				1
2a		2				2
2b			3			3
3a	2	2				4
3b		1				1
4		4				4
5a	1	1				2
5b			6			6
6	3	3	3		3	12
Total	8	14	12		3	37
Totals required	7–9 marks	13–15 marks	11–13 marks			
Kil	2					

Section B

Question Number	AO1	AO2	AO3	Maths	QWC	Total
7a	1					1
7b	2					2
8a		2				2
8b			4			4
9	1	2				3
10	1	2				3
11	1	1				2
12a		2				2
12b			4			4
12c		2				2
13	3	3	3		3	12
Total	9	14	11		3	37
Totals required	7–9 marks	11–14 marks	10–12 marks			
Kil	3					

Section C

Question Number	AO1	AO2	AO3	Maths	QWC	Total
14		4				4
15a		2				2
15b		2				2
16		2	2			4
17	3	3	3		3	12
Total	3	13	5		3	24
Totals required	3–6 marks	9–13 marks	4–8 marks			
Kil						

Section D

Question Number	AO1	AO2	AO3	Maths	QWC	Total
18	1		3			4
19	2	2				4
20		2	2			4
21	3	3	3		3	12
Total	6	7	8		3	24
Totals required	4–7 marks	7–10 marks	7–10 marks			
Totals required paper	25–29	40–48	36–39			
Kil	1					
Whole Paper Totals	26	48	36		12	122
KiL Paper Total	6					

Document information

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Change History Record

Version	Description of change	Approval	Date of Issue
v1.0	Published.		2020
v1.1	NCFE rebrand.		September 2021
v1.2	Content change	June 2022	June 2022
v1.3	Sample added as a watermark	November 2023	20 November 2023
v2.0	Annual review 2024 – change of marks in question 8(a) on page 14 and in assessment objective (AO) grid on page 35. Change of marks in question 7(b) in AO grid on page 35.	May 2024	30 April 2024