

# T Level Technical Qualification in Healthcare Science

**Core knowledge and understanding**

**Paper A**

Elements 1–10

Mark scheme

v1.1: Specimen assessment materials  
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603/0783/X

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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 is to be awarded
- the allocated assessment objectives (AOs) 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 exactly 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.
- When allocating marks across AOs within an individual response, these should logically link and should not be from disparate points of indicative content provided in the mark scheme.
- 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 mark grids have been designed to assess students' work holistically. They consist of bands-based descriptors and indicative content.

Bands-based descriptors: each band is made up of several descriptors for across the AO range – AO1 to AO3, which when combined provide the quality of response that a student needs to demonstrate. Each band-based descriptor is worth varying marks.

The grids are broken down into bands, with each band having an associated descriptor indicating the performance at that band. You should determine the band before determining the mark.

Indicative content reflects content-related points that a student may make but is not an exhaustive list; nor is it a model answer. Students may make all, some or none of the points

included in the indicative content as its purpose is as a guide for the relevance and expectation of the responses. Students must be credited for any other appropriate response.

### **Application of extended response marking grids**

When determining a band, you should use a bottom-up approach. If the response meets all the descriptors in the lowest band, 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 focusing on small omissions. If the response covers aspects at different bands, you should use a best-fit approach at this stage and use the available marks within the band 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 other suitable responses a student may produce. It is not a requirement either that students must cover all the indicative content to be awarded full marks.

### **Assessment objectives (AOs)**

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 AO can be found in the qualification specification.

## Section A: the roles and responsibilities within healthcare science

This section is worth 34 marks, plus 3 marks for quality of written communication (QWC) and use of specialist terminology.

**1 (a) State why it is important to have a hospital safeguarding policy.**

[1 mark]

AO1 = 1 mark

AP = A1.1.2, A1.1.2.1

Award **one** mark for each statement, up to a maximum of **one** mark.

- A hospital safeguarding policy is important because it provides the basis for maximising the protection from harm of individuals.

Accept any other suitable response.

**1 (b) Identify one group of people a hospital safeguarding policy would apply to.**

[1 mark]

AO1 = 1 mark

AP = A1.1.2, A1.1.2.1

Award **one** mark for each group identified, up to a maximum of **one** mark:

- those working within the organisation – for example, employees
- those that are visiting the organisation – for example, patients, carers, and visitors.

Accept any other suitable response.

**2 (a) Marco has enrolled on an apprenticeship in a rehabilitation engineering department.**

**Explain what tier Marco will enter the profession.**

[1 mark]

AO2 = 1 mark

AP = A1.5, A1.5.1, A1.5.2, A1.5.3

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

- Marco will enter at the technical level, which is the lowest level, as he has little / no experience and his qualifications are at level 2 / 3 (1).

Accept any other suitable response.

<b>2 (b)</b>	<b>Explain both the qualifications and experience Marco must obtain to progress to a different tier.</b>	<b>[2 marks]</b>
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AO2 = 2 marks

AP = A1.5, A1.5.1, A1.5.2, A1.5.3

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

- higher technical – Marco can gain further qualifications at level 4 / 5 (eg Diploma of Higher Education / Higher National Diploma (HND) etc) as this would be an essential qualification required for applying to roles at this tier (1). Marco can also gain industry experience whilst working by developing his developing his industry skills and understanding. This will enable him to work at higher technical level (1)
- professional – Marco can continue his education to gain professional qualifications such as a degree apprenticeship, as a degree-level qualification would be required for applying to roles at this tier (1). Marco will also in time become more experienced within his profession and gain a proven record of competence to take a role in his department at professional level (1).

Accept any other suitable response.

<b>3 (a)</b>	<b>An employee is leaving their current role as an orthotic technician. Their manager is reviewing the job description to help with the recruitment process.</b>	
	<b>Describe three requirements that should be in the job description for this role.</b>	<b>[3 marks]</b>

AO2 = 3 marks

AP = A2.5.1, A2.5.1.1, A2.5.1.2, A2.5.1.3, A2.5.1.4, A2.6.5.1

Award **one** mark for each requirement described, up to a maximum of **three** marks:

- scope of role – to manufacture a range of orthoses / surgical appliances (1)
- purpose of role – ensure patients are provided with correctly fitting orthosis (1) and they are produced in a timely manner (1)
- responsibilities and reporting lines – working with other technicians to fabricate orthosis and to communicate with orthotists to ensure orthosis is fit for use (1), reporting to senior technician, workshop manager and orthotists (1)
- accountabilities – ensure orthosis are made to specification and comply with all health and safety regulations within the manufacturing process (1), ensure good workshop practice (1).

Accept any other suitable responses.

**3 (b) Discuss the importance of including detailed information in the job description.**

[3 marks]

AO3 = 3 marks

AP = A2.5.1, A2.5.1.1, A2.5.1.2, A2.5.1.3, A2.5.1.4

Award **one** mark for each discussion point, up to a maximum of **three** marks.

- It is necessary for the job description to be comprehensive as it may form the basis for the final contract of employment (1).
- The job description needs to be detailed, with no omissions, as changes to the role may be challenged once the job is offered (1).
- It is necessary to check that no elements of the scope of the role are ultra vires (above or outside of the employee's level of competence) as this could result in legal implications regarding HPC registration if it infringes upon other HPC regulated roles (1).
- It is necessary to ensure that no employment, health and safety, and equalities legislation are breached in the job description as this could cause legal challenges and affect the health, safety and wellbeing of the employee (1).
- It is necessary to ensure that the job description includes responsibilities and reporting lines, so that the employee is aware of collateral processes beyond the scope and purpose of the role (1).
- The job description must be relevant to the role otherwise you may get applicants from unsuitable candidates (1).

Accept any other suitable responses.

**4 (a) Define a person specification.**

[1 mark]

AO1 = 1 mark

AP = A2.5.2

Award **one** mark for each definition, up to a maximum of **one** mark:

- a person specification is a profile of your ideal new employee (1).

Accept any other suitable responses.

**4 (b) Your classmate asks for your advice on a job application they want to complete. They meet all the desirable criteria in the person specification, and they want to know if you think they should apply.**

**Explain two pieces of advice you should give your classmate.**

[4 marks]

AO2 = 4 marks

AP = A2.5.2.1, A2.5.2.1.1, A2.5.2.1.2, A2.5.2.1.3, A2.5.2.2, A2.5.2.2, A2.5.2.3, A2.5.2.3.1, A2.5.2.3.2

Award **two** marks for each explanation, up to a total of **four** marks.

- The criteria included as desirable are to enhance the applicant's ability in the job / role (1); these are covered as extras to essential criteria, to enhance the application (1).
- The criteria included as essential are necessary for the applicant to adequately do the role / job (1); if they do not meet these, they are unlikely to be successful (1).

Accept any other suitable responses.

**4 (c) Assess the potential impacts of a person specification not having the required information.**

[5 marks]

AO3 = 5 marks

AP = A2.5.2, A2.5.2.1, A2.5.2.1.1, A2.5.1.2, A2.5.2.2, A2.5.2.3, A2.5.2.4

Award **one** mark for each assessment point, up to a maximum of **five** marks.

- If the person specification is not relevant, it can fall foul of equalities and employment legislation (1).
- Omissions / exclusions can make the role untenable once the person has been employed (1), such as if an employee is not sufficiently qualified, this could lead to the company being fined, reduced profits or reputational damage (1).
- It could possibly put potential employees and customers at risk if the employee does not have the correct level of training or skills required to safely complete the role (1).
- The reputational damage caused by this could open the company up to criticism and further scrutiny from the public and possible regulatory bodies (1).

Accept any other suitable response.

**5 (a) Healthcare organisations work across three main sectors. One is the public sector, identify the other two sectors.**

[2 marks]

AO1 = 2 marks

AP = A2.1.2, A2.1.2.3, A2.1.3, A2.1.3.1, A2.1.3.2, A2.1.3.3

Award **one** mark for each sector identified, up to a maximum of **two** marks:

- private sector
- charity / voluntary sector.

Accept any other suitable responses.

**5 (b) Compare the funding sources available to the public sector with another type of healthcare organisation's funding sources.**

[2 marks]

AO2 = 2 marks

AP = A2.1.2, A2.1.2.3, A2.1.3, A2.1.3.1, A2.1.3.2, A2.1.3.3

Award **two** marks for each comparison, up to a maximum of **two** marks.

- Public sector (NHS) is funded by the state through National Insurance contributions and general taxation, whereas voluntary / charity sector is funded through donations, (1) and / or by fundraising activities or grants (1).
- Public sector (NHS) is funded by the state through National Insurance contributions and general taxation, whereas private sector is funded through individuals or companies and/or through premiums (1).

Accept any other suitable response.

**6 Sarah is an 88-year-old woman who has dementia.**

- Sarah is physically active, can walk unaided and has good coordination and manipulation.
- Sarah can do basic domestic tasks but needs supervision, as she places objects in inappropriate locations.
- Sarah can dress herself, although she may choose inappropriate clothing for weather conditions.
- Sarah has poor short-term memory and can usually only communicate her thoughts and needs with prompting.
- Sarah needs to be reminded of her hygiene routine and preparations for bedtime.
- Sarah can use the toilet unaided.



**Evaluate the impact of including Sarah’s preferred activities and essential tasks in her patient-centred care plan.**

**Your answer should include reasoned judgements and conclusions.**

[9 marks, plus 3 marks for QWC]

AO1 = 3 marks

AO2 = 3 marks

AO3 = 3 marks

AP = A5.25, A5.25.1, A5.25.2, A5.25.2.1, A5.10.1, A510.7, A5.10.8, A5.3, A5.3.1.

Band	Mark	Descriptor
3	7–9	<p><b>AO3:</b> evaluation of the relevance of the features in the question being included in a care plan, using a patient / carer-centred approach, and incorporating Sarah’s preferred activities and essential tasks is <b>comprehensive, effective, and relevant</b>, showing <b>detailed understanding</b> and <b>logical and coherent</b> chains of reasoning throughout. Informed conclusions are fully supported with <b>rational, balanced</b>, and reasoned judgements, with most of the relevant arguments evident.</p> <p><b>AO2:</b> applied <b>all</b> relevant knowledge and information for a care plan for Sarah, showing a <b>detailed, functional understanding</b> of the need for a patient / carer-centred approach and the implications of incorporating Sarah’s preferred activities and essential tasks.</p> <p><b>AO1:</b> a <b>wide</b> range of relevant knowledge in implementing a patient / carer-centred approach to a care plan that incorporates Sarah’s preferred activities and essential tasks, which is <b>accurate and detailed</b>.</p> <p>The answer demonstrates comprehensive breadth and / or depth of understanding.</p>
2	4–6	<p><b>AO3:</b> evaluation of the relevance of the features in the question being included in a care plan, using a patient / carer-centred approach, and incorporating Sarah’s preferred activities and essential tasks is in <b>most parts effective</b> and <b>mostly relevant</b>, showing <b>mostly logical</b> and <b>coherent</b> chains of reasoning. Conclusions supported by reasoned judgements that consider <b>most</b> of the relevant arguments are evident.</p> <p><b>AO2:</b> applied <b>mostly</b> relevant knowledge and information for a care plan for Sarah, showing <b>some functional understanding</b> of the need for a patient / carer-centred approach and the implications of incorporating Sarah’s preferred activities and essential tasks.</p> <p><b>AO1:</b> knowledge in implementing a patient / carer-centred approach to a care plan that incorporates Sarah’s preferred</p>

		<p>activities and essential tasks, is in most parts <b>clear</b> and <b>mostly accurate</b>, 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><b>AO3:</b> evaluation of the relevance of the features in the question being included in a care plan, using a patient/carer-centred approach, and incorporating Sarah’s preferred activities and essential tasks is in <b>some parts effective</b> and of <b>some relevance</b>, with some understanding and reasoning taking the form of <b>generic</b> statements with <b>some</b> development. <b>Brief</b> conclusions, supported by reasoned judgements that consider only <b>basic arguments</b> and show <b>little</b> relevance to the question aims, are evident.</p> <p><b>AO2:</b> applied limited knowledge and information for a care plan for Sarah. The answer also may show a <b>lack of functional understanding</b> of the need for a patient / carer-centred approach and the implications of incorporating Sarah’s preferred activities and essential tasks.</p> <p><b>AO1:</b> knowledge in implementing a patient / carer-centred approach to a care plan that incorporates Sarah’s preferred activities and essential tasks, shows some but <b>limited accuracy</b>, 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:** demonstrates the impacts of a well-designed care plan for Sarah, using a patient / carer-centred approach, incorporating Sarah’s preferred activities and residual ability to do some essential tasks.

Describes how Sarah’s abilities and preferences outlined in the question can be placed into a well-designed care plan, which may include the following information.

- A suitable care plan will take into account Sarah’s wishes and abilities.
- A care plan must be able to be adapted if one-off activities occur such as trips out or visits by friends.
- It is important to ensure day-to-day tasks that Sarah is capable of are integrated into the plan.
- Informed consent should be obtained where possible and should also be obtained regarding the compilation of the care plan.
- If the patient cannot give consent, then decisions should be made in the ‘best interests of the patient’.
- It is important to ensure that the care plan takes into account the level of Sarah’s mental and physical health.

- It is important to prioritise Sarah's preferred and chosen activities within the care plan.
- It is important to ensure that the care plan can be reviewed as Sarah's clinical condition deteriorates in the future.
- It is important to ensure that tasks can be changed as Sarah's preferences may change.
- It is important to split the day up into specific sections – morning, afternoon, evening and night-time – to best suit Sarah's abilities and preferences.

**AO2:** application of how Sarah's abilities and preferences are outlined in the question can be placed into a well-designed care plan, which may include the following information.

- A suitable care plan may consider Sarah's wishes and desires, which may have an effect on Sarah's motivation and happiness.
- A suitable care plan will ensure the day-to-day tasks that Sarah is capable of are integrated into the plan, so as to maintain Sarah's residual capabilities for longer.
- It is important for the care plan to be flexible and to make allowances for one-off activities, such as family visits or outings, which will improve Sarah's happiness and wellbeing.
- Ideally, consent should be obtained, and this may be difficult with a patient who has dementia; also, consent may be partial, inconsistent and temporary.
- If the patient cannot give consent, there is a legal duty to ensure that decisions should be made in the 'best interests of the patient'.
- It is important to ensure that the care plan takes into account possible fluctuating and regressive levels of mental and physical health, and there are possible health implications if such are not considered.
- It is important that the care plan includes those preferred activities that Sarah is still able to do.
- It is important to ensure that the care plan is flexible enough to evolve as Sarah's clinical condition deteriorates in the future.
- It is important to ensure that tasks in the care plan can be changed as Sarah's preferences may change, to prevent causing undue stress and unhappiness.
- It is beneficial to split up the day into specific sections: morning, afternoon, evening and night-time.
- A disorganised plan may well impact on the physical and mental wellbeing of Sarah.

**AO3:** evaluation of the impacts a well-designed care plan for Sarah using a patient / carer-centred approach, incorporating Sarah's preferred activities and essential tasks.

Potential impacts of a well-designed patient / carer-orientated care plan may include the following.

- The implications of an unsuitable care plan are that Sarah will not have an optimally fulfilled life as her abilities, interests and residual abilities are not considered. This could lead to physiological issues, depression, undue stress, that could also affect her physical health.
- The benefits of ensuring day-to-day tasks that are within Sarah's abilities are integrated into the plan are a positive psychological impact gained by engaging in meaningful tasks.
- It is important to ensure the care plan is flexible and allows for one-off activities, enabling Sarah to participate – for example, family visits, outings, internal events – providing Sarah with a more fulfilled care experience with long-term physical and psychological advantages.

- It is important to ensure that consent may also be needed, if it can be given. If Sarah can give consent and is not given this opportunity, then this could escalate and result in legal action. Sarah may also only be able to give consent depending on the complexity of the issue concerned; it is important to try and gain consent where possible.
- Where consent cannot be given, there is a legal responsibility that decisions made should be in the best interests of the patient, otherwise legal action could ensue.
- It is important to ensure that the care plan takes into account fluctuations and deterioration of the levels of mental and physical health, which may cause psychological implications such as depression, withdrawal or stress, and that may also affect physical health if they are not considered.
- It is important to ensure that the care plan includes Sarah's preferred activities; her mental and physical health may be impacted if these are not taken into account.
- It is important to ensure that the care plan can evolve as Sarah's clinical condition deteriorates in the future, taking into account changing desires, needs and abilities.
- It is important to be aware that tasks can be changed as Sarah's preferences may change. If this is not considered, it may have a detrimental psychological and physical effect on Sarah's health, both in the short-term and long-term.
- It is beneficial to split the day up into specific sections – morning, afternoon, evening and night-time – so that Sarah may be able to recognise some degree of structure and consistency, and so that she is more able to realise that specific tasks – washing, breakfast, going to bed – should be done within specific timeframes of the day. These do need to be done in context; for example, Sarah may wish to take a short sleep in the afternoon or vary the time in the evening when she wishes to go to bed. The care plan should be flexible, so as to allow such.

Accept any other suitable response.

### Quality of written communication (QWC) = 3 marks

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

	<p>The answer does <b>not</b> reach the threshold performance level. The answer is <b>fragmented and unstructured</b>, with <b>inappropriate use of technical terms</b>. The errors in grammar severely hinder the overall meaning.</p>
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SAMPLE

## Section B: personal and patient safety

This section is worth 34 marks, plus 3 marks for quality of written communication (QWC) and use of specialist terminology.

**7 (a) State three purposes of a risk assessment in the context of the Regulatory Reform (Fire Safety) Order 2005.**

[3 marks]

AO1 = 3 marks

AP = A3.1.10, A3.1.10.1

Award **one** mark for each purpose stated, up to a maximum of **three** marks:

- to consider who may be at risk of fire
- to reduce death or injury caused by fire
- to reduce damage caused by fire
- to ensure appropriate evacuation procedures are in place.

Accept any other suitable responses.

**7 (b) George is a wheelchair user who has just started work at a new company. As part of his induction, a fire safety risk assessment must be undertaken.**

**Describe three requirements of a suitable fire risk assessment that would support George.**

[3 marks]

AO2 = 3 marks

AP = A3.1.10, A3.1.10.1

Award **one** mark for each requirement described, up to a maximum of **three** marks:

- ensure that George and other disabled staff have means of evacuating in the risk assessment (1)
- ensure there are procedures in place for periodic maintenance of fire-fighting facilities (1)
- ensure that training is given to George and all other staff during induction and also periodically on fire awareness in the workplace (1)
- ensure that there is appropriate training for staff doing specific roles, for example, fire warden, staff responsible for areas of increased fire risk such as workshops and chemical storage, health and safety reps (1).

Accept any other suitable responses.

**8 Discuss the reasons for the Medicines and Healthcare products Regulatory Agency (MHRA) regulating medical products used only within a hospital.**

[5 marks]

AO3 = 5 marks

AP = A4.2, A4.2.2.1, A4.2.2.1.2, A4.2.2.1.3, A4.2.2.1.4, A4.2.2.1.6, A4.2.2.1.7

Award **one** mark for each discussion point, up to a maximum of **five** marks.

- MHRA approval of a medical product's safety, efficacy and quality ensures that the product performs as it should, and is consistent in its composition, measurements, effect within pre-determined agreed and safe limits, so that it is safe for patients to use or to be used on patients (1).
- The MHRA regulates a product's manufacture, so as to ensure that all manufacturing processes are safe, thereby protecting the employees involved in manufacture (1).
- MHRA regulations ensure that materials are sourced from approved sources and tracking systems are in place, so that if there is a problem, products with faulty materials can be found and withdrawn, reducing the extent of the safety problem (1).
- The MHRA regulates a product's distribution and supply, to ensure that it may not be misused or is not dangerous, when not used for specific purposes / specific cases, thereby protecting patients from possible harm (1).
- The MHRA regulates the product's labelling so that it adheres to appropriate standards and is linked to the product's application, so as to minimise inadvertent misuse and patient harm (1).
- The scope of the damage for in-house products is likely to be less than for those used in the wider community as it is easier for recall and the number made is likely to be less (1).

Examiners, please note that the student should be able to select the relevant aspects of the legislation and not discuss other non-relevant aspects governing an in-house medical product and justify the inclusion of such aspects into the regulations.

Accept any other suitable responses.

**9 Safia was anxious about receiving another blood transfusion as she had adversely reacted to a previous transfusion.**

**Explain how two functions within the Serious Hazards of Transfusion (SHOT) haemovigilance scheme's remit could provide information that might benefit Safia.**

[4 marks]

AO2 = 4 marks

AP = A4.7, A4.7.1, A4.7.1.1, A4.7.1.2, A4.7.2

Award up to **two** marks for each function explained, up to a maximum of **four** marks.

- Anonymised data on Safia's adverse effects can be pooled with other patients' anonymised data to produce publications including peer-reviewed articles, book chapters and annual reports (1). These are designed to improve safety in the blood transfusion process and could benefit Safia if she ever required future transfusions (1).
- SHOT produce their annual recommendations to improve safety; Safia's anonymised data will be used to inform this report (1). Safia and her doctors can access this information and allow her to make an informed decision around the risk of adverse effects (1).

Accept any other suitable responses.

**10 Discuss the reasons for ensuring effective antibiotic stewardship in reducing antibiotic resistance.**

[4 marks]

AO3 = 4 marks

AP 6.6, A6.6.1, A6.6.2, A6.6.2.1, A6.6.2.2, A6.6.3, A6.6.3.1

Award **one** mark for each discussion point, up to a maximum of **four** marks.

- effective antibiotic stewardship controls microbial resistance to more ably treat diseases caused by pathogenic bacteria that are multi-resistant (1)
- effective antibiotic stewardship prevents antibiotic overuse, this is done by minimising antibiotics in circulation (1)
- there is restriction of the choice of antibiotics for non-resistant pathogens, so that antibiotics reserved for multi-resistant strains are not used in the mainstream and continue to be effective (1)
- poor antibiotic stewardship may result in prolonging illness due to being infected with resistant pathogens resulting from the incorrect historic use of antibiotics (1)
- poor antibiotic stewardship may encourage outbreaks of resistant strains, this increases the burden on healthcare providers and / or could cause an increased mortality rate (1)
- antibiotics only work on bacteria and not on viral infections, any use on non-bacterial infections could cause potential resistance development (1).

Accept any other suitable response.



**11 (a) State two sterilisation techniques that may be used in a laboratory.**

[2 marks]

AO1 = 2 marks

AP = A6.4.1, A4.6.2, A6.4.3

Award **one** mark for each technique stated, up to a maximum of **two** marks:

- autoclaving (wet or dry method) (1)
- chemical sterilisation (1)
- radiation sterilisation (1).

Accept any other suitable responses.

**11 (b) You work in a pathogen laboratory, where they sterilise their own equipment.**

**Explain two sterilisation techniques that may be used and give examples of how each could be used in the laboratory.**

[4 marks]

AO2 = 4 marks

AP = A6.4.1, A4.6.2, A6.4.3

Award a **maximum** of **two** marks per explanation and example, up to a maximum of **four** marks total:

- autoclave – uses high-pressured steam, creating temperatures that will easily kill pathogens, including spores (1); can only be used to sterilise heat-resistant equipment such as petri dishes and instruments used to test samples (1)
- chemical sterilisation – uses a solvent diluted with water to kill pathogens and may kill spores, if exposed for sufficient time (1); used for quick sterilisation of work surfaces and equipment / materials that are not heat resistant, such as scales and containers (1).

Accept any other suitable responses.

**12 You work in a workshop repairing medical devices that creates a wide variety of waste products, some of which may be contaminated with body fluids.**

**Discuss how you would ensure compliance with the Environmental Protection Act 1990, with respect to the disposal of all waste and the control of pollution within your waste management plan.**

**Your response should include relevant policies and demonstrate reasoned judgements and conclusions.**

[9 marks, plus 3 marks for QWC]

AO1 = 3 marks

AO2 = 3 marks

AO3 = 3 marks

AP = A3.1.6, A3.1.6.1, A3.1.7, A3.1.7.1, A3.1.8, A3.1.8.1, A3.1.9, A3.1.9.1

Band	Marks	Descriptor
3	7–9	<p><b>AO3:</b> discussion of the Environmental Protection Act 1990, incorporating the underpinning policies, is <b>comprehensive, effective, and relevant</b>, showing <b>detailed understanding</b> and <b>logical and coherent</b> chains of reasoning throughout. Informed conclusions that are fully supported with <b>rational and balanced</b> reasoned judgements are evident.</p> <p><b>AO2:</b> applied <b>all</b> relevant knowledge of the Environmental Protection Act 1990, incorporating the underpinning policies, showing a <b>detailed, functional understanding</b> of how this policy enables compliance with this act.</p> <p><b>AO1:</b> a <b>wide</b> range of relevant knowledge in implementing the Environmental Protection Act 1990 through the underpinning policy, which is <b>accurate and detailed</b>.</p> <p>The answer demonstrates comprehensive breadth and / or depth of understanding.</p>
2	4–6	<p><b>AO3:</b> discussion of the Environmental Protection Act 1990, incorporating the underpinning policies, is in <b>most parts effective</b> and <b>mostly relevant</b>, showing <b>mostly logical</b> and <b>coherent</b> chains of reasoning. Conclusions supported by reasoned judgements that consider <b>most</b> of the relevant arguments are evident.</p> <p><b>AO2:</b> applied <b>mostly relevant knowledge</b> of the Environmental Protection Act 1990, incorporating the underpinning policy, showing <b>some functional understanding</b> of how this policy enables compliance with this act.</p> <p><b>AO1:</b> knowledge and understanding of the importance of the Environmental Protection Act 1990, incorporating the underpinning policy, is in most parts <b>clear</b> and <b>mostly accurate</b>, 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><b>AO3:</b> discussion of the Environmental Protection Act 1990, incorporating the underpinning policies, is in <b>some parts effective</b> and of <b>some relevance</b>, with some understanding and reasoning, taking the form of <b>generic</b> statements with <b>some</b> development. <b>Brief</b> conclusions supported by reasoned judgements that consider only <b>basic arguments</b> and show <b>little</b> relevance to the question aims are evident.</p>

		<p><b>AO2:</b> applied <b>limited knowledge</b> of the Environmental Protection Act 1990 and its underpinning policy. The answer also may show a <b>lack of functional understanding</b> of the purpose of this act and underpinning policy.</p> <p><b>AO1: knowledge and understanding</b> of the Environmental Protection Act 1990 and its underpinning policy shows some but <b>limited accuracy</b>, 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:** demonstrates the specific regulations put in force to ensure that the workshop and its workers comply with the Environmental Protection Act 1990.

- The purpose of the act is to regulate the management of waste so as to reduce pollution.
- This act is reinforced through subsidiary regulations, using the examples below.
- The Special Waste Regulations 1996 Act ensures the following:
  - the transport of waste is controlled
  - there is a reduction and / or elimination of pollution caused by waste
  - this act can enforce the requirement for an assessment of the impact on the environment of products likely to have significant effects on the environment
  - the Hazardous Waste (England and Wales) Regulations 2005 ensure that measures are taken to control the storage, transport, and disposal of hazardous waste (waste stream).
- The Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU:
  - ensures that measures are taken to reduce the amount of electronic and electrical equipment incinerated or sent to landfill sites
  - places onus on all businesses to correctly store and transport electrical waste.

**AO2:** application of specific regulations put in force to ensure that the workshop and its workers comply with the Environmental Protection Act 1990.

- The purpose of this act is to enforce improved control of pollution to air, water and land by regulating the management of waste and the control of emissions.
- This act is reinforced through subsidiary regulations, using the examples below.
- The Special Waste Regulations 1996 ensures that measures are taken as below:
  - this act can be used to regulate and control the transport, import and export of waste (including recyclable materials)
  - this act can be used to prevent, reduce, and eliminate pollution caused by waste
  - this act can enforce the requirement for an assessment of the impact on the environment of products likely to have significant effects on the environment, as well as evaluate the scale of the potential impact on the environment
  - The Hazardous Waste (England and Wales) Regulations 2005 ensure that measures are taken to control the storage, transport, and disposal of hazardous waste (waste

stream), to ensure that it is appropriately managed, and any risks are minimised, thus minimising the risks of pollution.

- The Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU ensures that the measures below are taken:
  - this act ensures that measures are taken to reduce the amount of electronic and electrical equipment incinerated or sent to landfill sites
  - this act places the onus on all businesses to correctly store and transport electrical waste, enabling the recycling of recyclable products and ensuring pollutants are not released into the environment.

**AO3:** discussion of the impacts of specific regulations put in force to ensure that the workshop and its workers comply with the Environmental Protection Act 1990.

- This is an overarching act that enforces the improved control of pollution to air, water and land by regulating the management of waste and the control of emissions, thus reducing environmental pollution and protecting the environment, preventing short- and long-term environmental harm.
- This act is reinforced through subsidiary regulations, which when combined work together to minimise pollution.
- These subsidiary regulations create this overarching legislative framework to enable enforcement of the act, with the implications of non-compliance being the release of toxic or environmentally unfriendly substances into the environment, as well as significant fines, bad publicity.
- The objective of the Special Waste Regulations 1996 is to ensure that measures are taken, examples of which are from the following:
  - regulation and control of the transport, import and export of waste (including recyclable materials), so as to minimise deliberate or accidental exposure of substances to the environment
  - prevent, reduce, and eliminate of pollution caused by waste
  - enforce the requirement for an assessment of the impact on the environment of projects likely to have significant effects on the environment, so as to ensure that the environmental impact on procedures, production is minimised.
- The Hazardous Waste (England and Wales) Regulations 2005 Act ensures that measures are taken:
  - to control the storage, transport, and disposal of hazardous waste (waste stream)
  - to ensure it is appropriately managed and any risks of exposure to the environment are minimised, reducing the impact of short- and long-term harm to the environment.
- The importance of the Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU is to ensure that measures are taken to reduce the amount of electronic and electrical equipment incinerated or sent to landfill sites. This act places the onus on all businesses to correctly store and transport electrical waste. In doing so, this enables the recycling of valuable recyclable products, as well as preventing hazardous electronic waste (refrigerants, fluorescent tubes, lead acid batteries) from entering the environment, causing short- and long-term environmental harm.

Accept any other suitable response.

**Quality of written communication (QWC) = 3 marks**

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

**13** You are working in the laboratory, and you notice some confidential patient records have fallen behind a radiator. As a result, you:

- **secure the information**
- **record and report the incident**
- **ensure you follow the specific organisational policies and procedures.**

**Explain the reasons for taking these three steps.**

[3 marks]

AO2 = 3 marks

AP = A7.11, A7.11.1, A7.11.2

Award one mark for each reason explained, up to a maximum of **three** marks (note: marks are awarded for those points not in bold):

- **secure the information** if possible, or ensure the document is guarded if it cannot be removed (the document may not be easily removed from behind the radiator) (1)
- **record and report the incident** so you have evidence to make your workplace aware of the problem and takes any necessary further steps (1)
- **ensure that you follow specific organisational policies and procedures** to ensure the data breach can be dealt with in the most effective way by the organisation (1).

Accept any other suitable response.

**14** Give two examples of image-based records.

[2 marks]

AO1 = 2 marks

AP = A8.1.1, A8.1.1.1, A8.1.1.2, A8.1.1.3, A8.1.2

Award **one** mark for each example, up to a maximum of **two** marks:

- X-rays (1)
- computed tomography (1)
- retinal images (for example, photographs) (1).

Accept any other suitable responses.

<b>15</b>	<p><b>You are designing a clinical trial to compare two sets of equipment being used in a spinal injury unit. A colleague suggests asking for advice from a data scientist.</b></p> <p><b>Justify the spinal unit's additional expenditure on a data scientist when planning a trial.</b></p> <p style="text-align: right;">[4 marks]</p>
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AO3 = 4 marks

AP = A8.5, A8.5.1, A8.5.2, A8.5.3, A8.5.4, A8.5.5

Award **one** mark for each justification, up to a maximum of **four** marks.

- The data scientist should be able to optimise methods of data acquisition in the trial by bringing together relevant information, technology and healthcare science data (such as recorded biomechanical and physiological data) (1).
- The data scientist will be able to propose optimally effective and efficient clinical trial methodologies as well as explaining the advantages / disadvantages of each proposed methodology, so that you can make an informed decision as to which is best for in the clinical trial in the spinal injury unit (1).
- The data scientist may save time and resources by ensuring there is no unnecessary data collection or reduce the repeating of procedures caused by inaccurate experiment design (1).
- The data scientist can advise as to an effective survey methodology for gathering of feedback / biometric / physiological data, leading to a more effective analysis of the results and ensuring greater accuracy in the discussions/conclusions (1).
- The data scientist can give advice on the most effective statistical techniques that can be used in analysing and processing the data, ensuring greater accuracy in the discussion / conclusions (1).
- The data scientist can provide guidance and assistance on the interpretation and analysis of the data (1).
- The data scientist can give guidance in the use of databases or provide a custom database for research / audit purposes, thus ensuring the chosen database is optimised to the research audit question (1).
- The data scientist can ensure the clinical trial is of the highest possible standard for submission into more prestigious journals (1).

Accept any other suitable response.

<b>16</b>	<p><b>Employees working in a hospital department often need to check patient information on computers in the public reception area, where patients are able to see the screen from the waiting area.</b></p> <p><b>Describe three ways in which an employee could ensure patient information remains confidential when using the computer screens in the public reception area.</b></p> <p style="text-align: right;">[3 marks]</p>
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AO2 = 3 marks  
 AP = A7.9.1.4, A7.9.2.1

Award **one** mark for each way described, up to a maximum of **three** marks:

- logging out of a system when leaving the screen ensures that no patients or any other employees can access or view your files from that screen (1)
- ensure that you do not leave information about your login and password out where people in the public reception area could access it (1)
- be aware of your surroundings when they use the screen, preventing opportunistic observation of your screen from patients in the waiting area (1)
- use privacy screens to minimise the possibility of opportunistic observation of your screen by patients in the waiting area (1).

Accept any other suitable response.

**17 Your healthcare science department intends to change to an IT-based data system, using an outside agency to evaluate their intention. Your manager is worried about the potential risks and consequences of changing to this system.**

**Discuss the advantages, risks and consequences of using IT systems to record, store and retrieve information and data.**

**Your response should include reasoned judgements and appropriate conclusions.**

[9 marks, plus 3 marks for QWC]

AO1 = 3 marks  
 AO2 = 3 marks  
 AO3 = 3 marks  
 AP = A7.9, A7.9.2, A7.9.2.1, A7.9.2.2, A7.9.2.3

Band	Marks	Descriptor
3	7–9	<p><b>AO3:</b> discussion of the potential risks of using IT systems to record and store information and data, as well as the implications of such risks, is <b>comprehensive, effective, and relevant</b>, showing <b>detailed understanding</b> and <b>logical and coherent</b> chains of reasoning throughout. Informed conclusions that are fully supported with <b>rational and balanced</b> reasoned judgements are evident.</p> <p><b>AO2:</b> applies <b>all</b> relevant information regarding the potential risks of using IT systems to record and store information and data, as well as the implications of such risks, showing a <b>detailed, functional understanding</b>.</p>



		<p><b>AO1:</b> a <b>wide</b> range of relevant knowledge is displayed in the potential risks of using IT systems to record and store information and data, as well as the implications of such risks, which is <b>accurate and detailed</b>.</p> <p>The answer demonstrates comprehensive breadth and / or depth of understanding.</p>
2	4–6	<p><b>AO3:</b> discussion of the potential risks of using IT systems to record and store information and data, as well as the implications of such risks, is in <b>most parts effective</b> and <b>mostly relevant</b>, showing <b>mostly logical</b> and <b>coherent</b> chains of reasoning. Conclusions supported by reasoned judgements that consider <b>most</b> of the relevant arguments are evident.</p> <p><b>AO2:</b> applies <b>mostly relevant knowledge</b> of the potential risks of using IT systems to record and store information and data, as well as the implications of such risks, showing <b>some functional understanding</b> of the potential risks of using IT systems to record and store information and data, as well as the implications of such risks.</p> <p><b>AO1: knowledge and understanding</b> of the potential risks of using IT systems to record and store information and data, as well as the implications of such risks, is in most parts <b>clear</b> and <b>mostly accurate</b>, 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><b>AO3:</b> discussion of the potential risks of using IT systems to record and store information and data, as well as the implications of such risks, is in <b>some parts effective</b> and of <b>some relevance</b>, with some understanding and reasoning, taking the form of <b>generic</b> statements with <b>some</b> development. <b>Brief</b> conclusions supported by reasoned judgements that consider only <b>basic arguments</b> and show <b>little</b> relevance to the question aims are evident.</p> <p><b>AO2:</b> applies <b>limited knowledge</b> of the potential risks of using IT systems to record and store information and data, as well as the implications of such risks. The answer also may show a <b>lack of functional understanding</b> of using IT systems to record and store information and data, as well as the implications of such risks.</p> <p><b>AO1: knowledge and understanding</b> of the potential risks of using IT systems to record and store information and data, as well as the implications of such risks, shows some but <b>limited accuracy</b>, 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:** demonstrates the potential risks of using IT systems to record, retrieve and store information and data, including analysis of the consequences of such risks, if they occur.

Potential advantages:

- ease of access
- ease of sharing and transferring data
- speed of data analysis
- security (for example, password-protected)
- standardisation of data
- enables continuous and / or real-time monitoring of data
- cost and space saving
- enables integrated working and supports safeguarding practices

Potential risks:

- there are serious implications of security breaches
- there are serious implications if data is corrupted
- there are also implications of a lack of access due to system failure, which vary depending on the duration of the system failure.

**AO2:** application of using IT systems to record, retrieve and store information and data, including analysis of the consequences of such risks, if they occur.

Potential risks:

- the implications of security breaches are that patient details (or other confidential information) are exposed to a wider audience
- there are time and cost implications caused by corruption of data and its retrieval, or if the data is lost
- there are implications with regards to lost time, increased effort and financial costs caused by a lack of access due to system failure.

Potential consequences of such risks:

- reputational damage may ensue due to loss of confidential information of patients, sensitive financial information and research / audit information
- there are serious legal implications with regard to loss of such data – Data Protection Act 2018, exposure to fraud
- there are implications in restoring the damage caused by security breaches, data corruption or lack of access due to system failure. Time delays may result in possible delays in patient treatment or digitally recorded treatment procedures for patients, or data may become irretrievably lost
- there will be increased costs in restoring the damage caused by security breaches, data corruption or lack of access due to system failure.

#### Potential advantages:

- the ease of access ensures that the information is available at the point required and will be up to date in-line with any new information
- the ease of sharing and transferring data means that any updates will be available to all who need access and can be easily shared between relevant individuals and organisations if required
- standardisation of data is ensured by all processes and entries being input on set forms with clear methods for inputting data to ensure comparability and consistency
- it can save in costs and space as all relevant files will now no longer require storage facility on site in a secure room and space can be used for other purposes. It will save on cost as the use of printers / ink, paper and files will become unnecessary.

**AO3:** discussion of using IT systems to record, retrieve and store information and data, including analysis of the consequences of such risks, if they occur.

#### Potential risks:

- the implications of security breaches, be they accidental or malicious, are that patient details are exposed to a wider audience, as well as other confidential information (for example, financial, administrative, research information)
- there are time and cost implications caused by corruption of data and its retrieval, or if the data is lost. Research outputs may be seriously delayed, and patient treatment procedures may also be delayed
- there are implications with regard to significant amounts of lost time, increased effort and financial costs caused by a lack of access due to system failure, especially if there are no backup procedures for temporary storage on ongoing data processing. Some data lost may be pertinent to patient treatment processes, causing delays.

#### Potential consequences of such risks:

- reputational damage may ensue due to loss of confidential information of patients, sensitive financial information and research / audit information. This information could also be useful for competitors or for criminal uses
- there are serious legal implications – non-compliance with the Data Protection Act 2018, fraud, fines, legal action taken by patients, increased costs in reducing the impact of the data breach, fraudulent use of money obtained from data breaches
- the impact of increased time implications includes restoring the damage caused by security breaches; data corruption – restoration of data quality; the loss of data – implications and its detrimental effects on patient care; and possible danger to patients if their care relies on the data. Lack of access to data during the period of system failure could result in failed appointments, delays in diagnosis
- there may be increased costs in restoring the damage caused by security breaches, data corruption or lack of access due to system failure. These will all cause increased internal costs and possibly external costs, due to legal cases / out-of-court settlements / appeals.

#### Potential advantages:

- ease of access will ensure all who need to access the files are able to efficiently and regardless of location / timings, this will benefit as will ensure an efficiency and speed. This could see a decrease in length of time that it takes to complete any data / admin and therefore allow for more time to undertake other responsibilities
- the ease of sharing and transferring data will mean that all those who need access to the files are able to access it where needed, with the notes being up to date and easy to access. This will allow for more efficiency in co-operation and ease of care across teams and departments, benefitting both service users and also healthcare employees by allowing for higher efficiency.

Accept any other suitable response.

**Quality of written communication (QWC) = 3 marks**

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

## Section D: regulatory and professional frameworks

This section is worth 21 marks, plus 3 marks for quality of written communication (QWC) and use of specialist terminology.

**18 Identify two possible impacts of inefficient working practices caused by not regularly cleaning and preparing work areas for use.**

[2 marks]

AO1 = 2 marks

AP = A9.6.3.2

Award **one** mark for each possible impact identified, up to a maximum of **two** marks:

- leads to increased costs (1)
- increased timescales (1).

Accept any other suitable response.

**19 You become aware that a medical refrigerator in your lab is not meeting the required temperature range for the samples it contains.**

**Discuss the steps that should be taken and the impact if such steps are not actioned.**

[6 marks]

AO3 = 6 marks

AP = A9.8, A9.8.1, A9.8.2, A9.8.3, A9.8.4

Award one mark for each discussion point, up to a maximum of **six** marks for the discussion:

- taking the refrigerator out of use, so that it cannot be used and thereby ensuring that no future samples can be stored within the refrigerator (1), and so to ensure that all samples in the refrigerator have been transferred to another unit and stored correctly (1)
- labelling the refrigerator as being out of use, so that others will also not use it (1), so as to ensure that future samples will not be stored within the refrigerator by anyone else working within the lab (1); non-compliance could have legal implications for the company (1)
- reporting concerns about the refrigerator not working to the relevant person in your lab (in line with the lab's policies and procedures) who should be able to take the most effective course of action (1); non-compliance would mean internal processes and possible regulatory requirements are breached and could result in legal actions (1)
- recording concerns according to the lab's procedures, so that the organisation is aware of the broken refrigerator and can take the most effective course of action (1); non-compliance with a suitable procedure can result in health and safety issues and product safety issues extending beyond the lab (1).

Accept any other suitable response.

**20 The Medicines and Healthcare products Regulatory Agency (MHRA) are to conduct an inspection of your medicine manufacturing facility.**

**Give four requirements of good manufacturing practice (GMP) that must be complied with in order to pass this inspection.**

[4 marks]

AO2 = 4 marks

AP = A10.3.1, A10.3.2, A10.3.3

Award **one** mark for **each** requirement, up to a maximum of **four** marks.

- Procedures are in place in the facility that ensures that the medicines are of consistent high quality (1).
- Following GMP ensures compliance with manufacturing standards, ensuring consistency of materials used and consistency of production (1).
- Procedures are in place to ensure weights, measures, temperatures, composition of a product etc are strictly controlled, ensuring consistency of production (1).
- Equipment used for weighing, measuring etc is frequently calibrated and evidence of this is available (1).
- Premises must be clean and procedures to prevent cross-contamination and accidents should be in place (1).
- All equipment should be placed or stored appropriately with appropriate stock management (1).
- All staff should have appropriate training in their respective roles to ensure they understand their responsibilities (1).

Accept any other suitable responses.

**21 You work in a laboratory testing patients' blood samples. You have noticed a colleague who does not always perform their role in line with the requirements of Good Scientific Practice (GSP).**

**Discuss the potential impact of not adhering to the requirements within GSP for the handling of hazardous materials and substances within the lab.**

**Your response should include reasoned judgements and conclusions.**

[9 marks, plus 3 marks for QWC]

AO1 = 3 marks

AO2 = 3 marks

AO3 = 3 marks

AP = A10.1, A10.1.2.1, A10.1.2.2

Band	Marks	Descriptor
3	7–9	<p><b>AO3:</b> discussion of the need for compliance with the technical and quality guidelines, stated in the domain of Scientific Practice within the requirement for GSP, as well as the implications of non-compliance, is <b>comprehensive, effective, and relevant</b>, showing <b>detailed understanding</b> and <b>logical and coherent</b> chains of reasoning throughout. Informed conclusions that are fully supported with <b>rational and balanced</b> reasoned judgements are evident.</p> <p><b>AO2:</b> applies <b>all</b> relevant information regarding the need for compliance with the technical and quality guidelines, stated in the domain of Scientific Practice within the requirement for GSP, as well as the implications of non-compliance, showing a <b>detailed, functional understanding</b>.</p> <p><b>AO1:</b> a <b>wide</b> range of relevant knowledge is displayed in the need for compliance with the technical and quality guidelines, stated in the domain of Scientific Practice within the requirement for GSP, as well as the implications of non-compliance, which is <b>accurate and detailed</b>.</p> <p>The answer demonstrates comprehensive breadth and / or depth of understanding.</p>
2	4–6	<p><b>AO3:</b> discussion of the need for compliance with the technical and quality guidelines, stated in the domain of Scientific Practice within the requirement for GSP, as well as the implications of non-compliance, is in <b>most parts effective</b> and <b>mostly relevant</b>, showing <b>mostly logical</b> and <b>coherent</b> chains of reasoning. Conclusions supported by reasoned judgements that consider <b>most</b> of the relevant arguments are evident.</p> <p><b>AO2:</b> applies <b>mostly relevant knowledge</b> of the need for compliance with the technical and quality guidelines, stated in the domain of Scientific Practice within the requirement for GSP, as well as the implications of non-compliance, showing <b>some functional understanding</b>.</p> <p><b>AO1: knowledge and understanding</b> of the need for compliance with the technical and quality guidelines, stated in the domain of Scientific Practice within the requirement for GSP, as well as the implications of non-compliance, is in most parts <b>clear</b> and <b>mostly accurate</b>, 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><b>AO3:</b> discussion of the need for compliance with the technical and quality guidelines, stated in the domain of Scientific Practice within the requirement for GSP, as well as the implications of non-compliance, is in <b>some parts effective</b> and of <b>some relevance</b>, with some understanding and reasoning, taking the form of <b>generic</b> statements</p>

		<p>with <b>some</b> development. <b>Brief</b> conclusions supported by reasoned judgements that consider only <b>basic arguments</b> and show <b>little</b> relevance to the question aims are evident.</p> <p><b>AO2:</b> applies <b>limited knowledge</b> of the need for compliance with the technical and quality guidelines, stated in the domain of Scientific Practice within the requirement for GSP, as well as the implications of non-compliance. The answer also may show a <b>lack of functional understanding</b></p> <p><b>AO1: knowledge and understanding</b> of the need for compliance with the technical and quality guidelines, stated in the domain of Scientific Practice within the requirement for GSP, shows some but <b>limited accuracy</b>, 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:** demonstrates the potential impact of not adhering to the requirements within GSP for the handling of hazardous materials and substances within the lab.

The requirements within GSP for the handling of hazardous materials and substances:

- identifying and managing sources of workplace risk (for example, specimens, clinical waste)
- application of health and safety practice to all areas of the workplace
- refer to and adhere to Control of Substances Hazardous to Health (COSHH) assessment (where applicable) and / or SOPs
- application of correct methods of disinfection, sterilisation and decontamination when dealing with waste and / or spillage
- maintain and apply quality standards across all clinical, scientific and technological activities:
  - quality control
  - quality assurance
  - protect patients from risk or harm at all times

**AO2:** application of the potential impact of not adhering to the requirements within GSP for the handling of hazardous materials and substances within the lab.

- Incorrect handling of samples could increase the likelihood of risks, for example incorrect disposal of clinical waste.
- Not applying health and safety practice to all areas of the workplace could result in inconsistent application and result in unsafe working practices and environments for your colleague and others working in the laboratory.
- If you do not refer or adhere to Control of Substances Hazardous to Health (COSHH) assessment (where applicable) and / or SOPs it could put you in breach of internal policies and wider regulations.



- Not applying the correct methods of disinfection, sterilisation and decontamination when dealing with waste and / or spillage could cause contamination of blood samples and hinder processes.
- By not complying, your colleague could possibly put patients at risk of harm through impacting the analysis of their blood samples.
- By not maintaining and applying quality standards across the laboratory, the quality control and assurance of the blood sample analysis will be negatively impacted.

**AO3:** discussion of the potential impact of not adhering to the requirements within GSP for the handling of hazardous materials and substances within the lab.

- Incorrect handling of samples could increase the likelihood of risks, for example incorrect disposal of clinical waste such the blood samples from the laboratory. This could result in increased cost and waste issues due to poor compliance and therefore impact upon the overall costs of the laboratory. It could also lead to contamination of waste, leading to a breach of waste regulations (for example, Hazardous (England and Wales) Waste Regulations 2005).
- Not applying health and safety practice to all areas of the workplace could result in inconsistent application and result in unsafe working practices and environment. This would result in disciplinary action via the employer or the professional body (HCPC) if your colleague is a member of such. The employee / employer may also incur costs / fines, if proven to be negligent.
- If you do not refer or adhere to Control of Substances Hazardous to Health (COSHH) assessment (where applicable) and / or SOPs it could put you in breach of internal policies and wider regulation. There are subsequent legal, reputational and economic implications of non-compliance. Legal action may extend to patient safety issues.
- Not applying the correct methods of disinfection, sterilisation and decontamination when dealing with waste and / or spillage could cause contamination of blood samples in the laboratory. This could lead to further breaches of GSP and the credibility of blood samples being tested and the results given.
- By not complying and possibly putting patients at risk of harm, the lab could therefore be in breach of regulations and face disciplinary or legal impacts. This could cause reputational damage and impact upon the ability of the lab to function and continue their work, whilst also negatively impacting upon patients if results cannot be provided in a timely and safe manner and in-line with GSP.

**Quality of written communication (QWC) = 3 marks**

Mark	Descriptor
3	<p>The answer is <b>clearly expressed</b> and <b>well-structured</b>.</p> <p>The rules of grammar are used with <b>effective control</b> of meaning overall.</p> <p>A <b>wide range</b> of appropriate technical terms is used effectively.</p>
2	<p>The answer is generally <b>clearly expressed</b> and <b>sufficiently structured</b>.</p> <p>The rules of grammar are used with <b>general control</b> of meaning overall.</p> <p>A <b>good range</b> of appropriate technical terms is used effectively.</p>

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

SAMPLE

## Assessment Objective Grid

### Section A

Question Number	AO1	AO2	AO3	Maths	QWC	Total
1 (a)	1					1
1 (b)	1					1
2 (a)		1				1
2 (b)		2				2
3 (a)		3				3
3 (b)			3			3
4 (a)	1					1
4 (b)		4				4
4 (c)			5			5
5 (a)	2					2
5 (b)		2				2
6	3	3	3		3	12
<b>Total</b>	8	15	11		3	37
<b>Totals required</b>	7-9 marks	13-15 marks	11-13 marks			
<b>Kil</b>	3					

### Section B

Question Number	AO1	AO2	AO3	Maths	QWC	Total
7 (a)	3					3
7 (b)		3				3
8			5			5
9		4				4
10			4			4
11 (a)	2					2
11 (b)		4				4
12	3	3	3		3	12
<b>Total</b>	8	14	12		3	37
<b>Totals required</b>	7-9 marks	11-14 marks	10-12 marks			
<b>Kil</b>	2					

### Section C

Question Number	AO1	AO2	AO3	Maths	QWC	Total
13		3				3
14	2					2
15			4			4
16		3				3
17	3	3	3		3	12
<b>Total</b>	5	9	7		3	24
<b>Totals required</b>	3–6 marks	9–13 marks	4–8 marks			
<b>Kil</b>	2					

### Section D

Question Number	AO1	AO2	AO3	Maths	QWC	Total
18	2					2
19			6			6
20		4				4
21	3	3	3		3	12
<b>Total</b>	5	7	9		3	24
<b>Totals required</b>	4–7 marks	7–10 marks	7–10 marks			
<b>Totals required paper</b>	<b>25–29</b>	<b>40–48</b>	<b>36–39</b>			
<b>Kil</b>						
<b>Whole Paper Totals</b>	26	45	39			
<b>Kil Paper Total</b>	6					

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Owner: Head of Assessment Design

## Change History Record

Version	Description of change	Approval	Date of Issue
v1.0	Additional specimen assessment materials		November 2022
v1.1	Sample added as a watermark	November 2023	20 November 2023