MET IIA Paper 6 2020-21 Cribs

1 (a) Energy usage provides a basis for estimating the carbon footprint.

Carbon footprint is relatively straightforward to estimate and can be used to provide a partial indication of environmental impact, so this approach is practical and should yield useful information without excessive effort. However, the omission of other environmental factors (e.g. water usage, use of hazardous substances, production of toxic waste) may be significant for some manufacturing operations (e.g. particularly in the electronics industry). In this case, chemicals used in the painting process may carry particular environmental impacts.

Defining the 'system boundaries' of the analysis is an essential initial step, and means making compromises between the magnitude of the task and the accuracy of the results. In this case, the boundaries are reasonably clearly defined and the limitations of the study can be stated with some accuracy. Justification can be made for confining the study in this way. However, the excluded factors may form a big part of the total environmental impact of the operation of the company, and it is not clear to what extent the company should be regarded as taking responsibility for them.

Goods in or out would be a big factor in the environmental footprint of assessment of the operation of the factory since the 'embodied energies' of materials are high. Some sort of material flow analysis would look at the difference between the amount of material entering the factory and leaving it: net quantities should be zero, but material leaving the factory will be converted into either products or waste so would be measured differently.

A big question is: to what extent should the firm take responsibility for the environmental impact of its products? Current thinking is that it is responsible for the articles themselves (e.g. materials). Some would include also any operational aspects (e.g. power consumption for electrically powered toys; what about batteries?). And an environmentally aware firm might consider what happens to its products at end-of-life: is there any possibility of recycling? There is increasing pressure for some sort of take-back at end-of-life, particularly for electrical goods.

Some consideration might be given also to the nature and origin of input materials or goods: environmentally aware sourcing.

A big omission is waste streams: the factory is responsible for its waste, and this should therefore be included. Analysis will not be straightforward: material types, whether there is contamination, and the end destination of the material (recycle, energy-from-waste, landfill) will all affect the carbon footprint.

Transport, of goods upstream or downstream, and of people, may be a big factor.

An eco-audit could be conducted for the products. This is limited to energy usage (or carbon footprint, which is related) for all stages in the product lifecycle, but excludes other environmental factors (e.g. 'pollutants' various, water).

Much more information on other environmental factors is provided by a full LCA, but this is much more difficult and not likely to be something the company could do itself.

(b) Carbon footprint.

Regardless of the energy-saving measures below, there is scope for reducing the carbon footprint of energy sources: 'green electricity' from renewable resources including solar; biomass boilers. This may be cost-neutral to the company, depending on how they do it.

The cost and effectiveness impact of other carbon reduction measures can be assessed using McKinsey Abatement Curves.

Looking at the identified factors in decreasing order of importance:

- Space and water heating, for the factory and office areas, is often the dominant factor, depending on the size and nature of the factory. Space heating can be improved by better insulation (ceilings, windows). Saves on heating bills so financially beneficial (with a finite pay-back period).

- Operation of manufacturing machinery and equipment (this may in some cases be more important than space/water). For the manufacturing operations, the injection moulding (involving heating polymer) is likely to be the most energy-intensive process, followed by machine tools. Little scope for reducing energy usage for manufacturing processes, but machines should be switched off when not in use.
- Improving quality control will reduce the number of off-specification goods, so reducing overall energy demand.
- Other office equipment (computers, photocopiers etc). The main way of reducing energy usage is to switch off when not in use.
- Lighting. Not such a big impact now that nearly all lighting is low-energy LED, but any other light sources should be changed. Saves on electricity bills so financially beneficial with finite payback period.

Basic answer: Show familiarity with main concepts and demonstrate understanding of factors that influence carbon footprint.

Good answer: Well-informed and mainly factually correct analysis of a good range of the areas covered.

Excellent answer: Thorough understanding of all the concepts and their inter-relationships, and evidence of insight into their relative importance. Appropriate well-reasoned proposals for additional factors at the end of each question part.

2 (a) (i) A basic answer will highlight that there must be sufficient mechanical properties to ensure that the suture holds for the length of time required for the tissue to heal. A basic answer will also highlight that polymers can be designed to degrade at a predictable rate and so a programmable release is feasible.

A stronger answer will explain in more details what will contribute to good mechanical properties, such as a long chain length and high levels of cross-linking. The cross-linking chemistry or backbone chemistry is chosen to be suitable for reaction by hydrolysis, to allow a controlled breakdown. The polymer will then be chosen to ensure access of water to the polymeric chains by ensuring the appropriate side chains to ensure crystallinity, where needed. The geometry is fixed for this product, but the porosity may be tuneable to ensure water access at the correct level.

The tuning of polymer chemistry to get the correct release rate allows a longer term release at a safe level, rather than a rapid release at a high level. Also, different polymer choices or designs could be provided to vary the release rate or suture dissolution according to the patient's needs. A strong answer may also include a comment about targeting either bulk erosion or surface erosion through polymer choice and the needs of the product.

(ii) A basic answer will highlight that sterilisation is a process that removes all living/viable micro-organisms from a medical device, including bacteria and viruses. A stronger answer will describe that this is a process that relies on identifying the probability that a specific number of micro-organisms were capable of surviving the sterilisation process, because it is not feasible to know that a device is 100% free. An advanced answer will note something about the mechanism, such as noting that sterilisation is a process that targets proteins or amino acids to either break them apart or denature them to destroy their function.

(iii) A range of different techniques were covered in the lectures. A basic answer will note the name of a suitable technique and the key active component (e.g. reaction of ethylene oxide with proteins in viable micro-organisms, denaturing of the proteins due to heat from steam sterilisation, ionising nucleic acids in gamma radiation, etc). A good answer would highlight at least one reason in detail why this may be a suitable technique. A stronger answer may include a few more details

about key parameters that need to be controlled and some of the main benefits or challenges to using this approach. Once the method has been described, a basic answer may include that challenge devices could be included to check sterilisation (with a stronger answer describing these in more detail). A basic answer may also include that international standards would be consulted to ensure the correct documentation and tests were carried out to ensure compliance. A strong answer would also note a range of tests that should be carried out to check the function of the device has not changed, including the mechanical testing of the polymer, the testing of the degradation rate, release rate and drug activity.

(iv) In this question, the candidate does not need to carry out any calculations or draw a graph. However, if they wish to draw a graph as part of the explanation, that is acceptable in place of a detailed description. The candidate should describe a graph of the number of microorganisms against time. The description should highlight that they would plot the log (to base 10) of the number of micro-organisms against time and assume the trend is linear. They can then extend the line up to identify the bioburden, and extend it down until it intersects with the sterility assurance level (likely 10^{-6}). A basic answer will show an understanding of the technique, while a stronger answer will show an understanding of bioburden, SAL and additional processes, such as including a safety factor.

(v) This question is not focused on the production technology, but more what happens when you change manufacturing. The key cost to consider for a device with a high classification is the additional cost to go through regulations again. A basic answer would highlight this, whereas a good answer would note cleaning, biocompatibility, sterilisation, clinical evaluation studies (possibly trials), would also all need to be repeated and all add additional costs. An advanced answer would highlight that this would likely have to be repeated for FDA and the European submissions and may give an example of the additional litigation costs if this is not done, with an example.

3 (a) (i) A brief answer will highlight (in words or as a diagram) that there are a series of stages from idea generation through to commercialisation, where information is collected for a range of functional areas, scored and a decision is made at each stage whether to continue (go), discontinue (kill), or suspend (hold) a project. There may also be a decision to work longer at a current stage (recycle).

A strong answer will include more details about the different 5 stage and highlight at lease 3 of the standard decision criteria with a brief explanation of each. These may include the strategic fit, the competitive advantage, the technical feasibility, and financial reward but other suitable criteria are acceptable.

An advanced answer will note that at each gate there is a mix of must-meet criteria (with an example) and scoring of the standard criteria (with an example), and note some of the good practices when operating a phase-gate process, such as defining each gate clearly, ensuring a decision is reached at a gate meeting, active monitoring of the process, among other potential points.

(a) (ii) A basic answer would briefly highlight the challenges when scaling-up an innovation and note why this management tool helps. A strong answer would describe in more detail the challenges of scaling-up and describe in detail they key characteristics of the phase-gate approach that would benefit a firm.

There are a wide range of points that can be made. Some anticipated points include:

It is challenging to manage the multiple dimensions of scale-up (e.g. value-chain, business, process, technology development). Multiple dimensions need to be monitored and assessed simultaneously as they are interdependent, and the phase-gate approach is one tool that can be used to help with this management. The process monitors a range of criteria (either the standard criteria used by most

firms or selected criteria decided upon by the firm) in a very structured approach that enables assessment and decisions to be made.

The process ensures input from across all key functions at every stage, with stakeholders involved who have knowledge of each dimension of scale-up. It ensures best practice by requiring attendance from all gatekeepers at every meeting and structures the handing over of the gatekeeper responsibilities at very specific times as a project moves towards commercialisation.

This approach de-risks scale-up as it provides decision points prior to a more expensive stage of development, allowing the project to fail early and minimise losses.

The technique acts as a funnel, allowing the initial assessment of many approaches or ideas, before reducing in stages to the key approach that will be commercialised. The structured assessment across all functions during this process ensures the best chance of picking a successful approach.

This is a management tool that is not only useful at a high-level (or management level) but is important at an operation level, and so can be important for day-to-day task management that is tied into the strategic goals of the firm.

(a) (iii) Additional management tools from the lectures include the Technology Stage Gate process, the use of Technology Readiness Levels, and the use of Manufacturing Readiness Levels. Additional management tools from the candidate's broader experience will be considered and accepted where suitable.

A basic answer will name an additional management tool and note briefly describe how this tool can be employed for high-risk emerging technology innovations. A strong answer will provide a good level of detail about the tool and highlight specifically why it is considered to help in such cases. An advanced answer will provide an excellent level of detail when describing the tool and multiple reasons why it may be helpful.

As an example, the Technology Stage Gate approach is particularly helpful when the research is expected to lead to unpredictable discoveries and barriers, which means the standard stage-gate approach is not sufficiently flexible to manage the project. This also provides a much more detailed technology review section of the project, because it is the higher risk part of the project. With this in mind, the additional part of the stage gate process has a variable number of gates. It is seen as an add-on, preceding the traditional stage gate process. There will be multiple areas of literature and patent research to design the overall stage plan for the given project. This drives experimental work on multiple leading options, both in terms of the technology but also importantly in terms of the production process. With each stage the number of leading options is reduced with larger scale experiments taking place. Once a lead option is identified and a scale-up process testing approach has commenced, the standard stage gate approach for product development can commence.

(b) (i) The key points to note are that generic technologies are also platform technologies that can be applied to many different applications across different industries. These can seed the development of new applications in the private sector.

The infra-technologies are underpinning translational tools, such as measurement and test methods or analysis techniques, without which advanced technology applications cannot be developed to be made at a large scale. It may also be noted that development of proprietary technologies in the private sector typically relies on tapping into public sector innovation in both of these areas.

A basic answer will provide a reason that applies to one of the two technology types. A strong

answer will give a clear reason or multiple reasons that apply to both technology types. An advanced answer will include examples of each technology to clarify the answer and may also link this investment combination as a way to help firms avoid the Valley of Death.

(b) (ii) The key messages that are important to convey are:

Frameworks help with the clarification and communication of the different dimensions of scale-up. It is important that the answer conveys that there are always multiple dimensions that need to be considered.

A framework is usually developed where a specific sector has the need to manage a set of dimensions that are particular to them. Examples discussed in the lectures include the Carbon Trust, the FDA and the Materials Genome Initiative.

It may also be noted that such frameworks can help as part of a management tool, providing information about key activities and risks over the typical lifetime of a project, or may help by linking the progress to particular measures in risk, such as TRLs, MRLs, or equivalent.

A basic answer will highlight the benefit of noting the different dimensions appropriate to a sector. A strong answer will give examples of why this may differ across sectors or link it to overall project management.