METIIA Paper 6 Module 3P10 2014

1. (a) A Green company my be defined narrowly as minimising its environmental impact, though other factors such as Corporate Social Responsibility are often also included. Looking at environmental aspects one might expect to see awareness and efforts to improve in the areas of energy and resource consumption, the waste management hierarchy (reduce, re-use, recycle). Going round the factory, you might see information boards with energy consumption, defect rates, suggestions boards for process and environmental improvements, evidence of involvement of shop-floor workers in such matters. On the company website you might see environmental commitment statements – though beware of greenwash!
Less helpfully, on the 'Environment' boards in companies you often see emphasis on local activities such as schools visits and other involvement in the local community. Whilst this is all worthy and promotes good CSR and public relations, it may not have any direct environmental effects. If, however, part of this includes matters such as biodiversity on the factory site, this is relevant.

(b) ISO14001 is an internationally recognized standard that defines the criteria for a management system for developing and controlling those aspects of a firm's operations that can have an effect on the environment.
It requires an Environmental Policy to be in existence within the organisation, fully supported by senior management, and outlining the policies of the company, not only to the staff but to the public. The policy needs to clarify compliance with Environmental Legislation that may affect the organization and stress a commitment to continuous improvement.
The Environmental Policy provides the initial foundation and direction for the Management System. The statement must be publicised in non-technical language so that it can be understood by the majority of readers. It should relate to the sites within the organisation encompassed by the Management System, provide an overview of the company's activities on the site, a description of those activities, and a clear picture of the company's operations.
Benefits:

- Provides objective evidence of company commitment to protecting the environment, which can be helpful when dealing with the media.
- May also provide a competitive marketing advantage, and can help with international trade.
- Allows a proactive approach to risk management.

Public reporting of green credentials: This is a very vague description, so it is debatable whether as written it would have any real impact on environmental performance. Reporting against a specified set of criteria might be helpful. The stipulation of third-party verification should stipulate something about the credentials of this third party.

Carbon footprint: Measurement is the first stage in understanding and control, so this could be important, so long as there is a clear and rigorous definition of what is required. There will be variation in decisions about what the carbon footprint should encompass (the system boundary), but a minimum should be

factory operations plus 'office' operations (including space heating and lighting). To what extent accounting extends up and down the supply chain will be very variable.

More than 80% of suppliers assessed for environmental impact: May not have any effect on the sustainability of the company as such, but can have profound effects on sustainability more generally. Big companies are able to put pressure on suppliers by only dealing with people who reach defined minimum standards, thereby improving sustainable practices globally. From the 'accountability' perspective, this is a strong ethical card to play, and may also result in improved product safety standards because of the improved scrutiny. So properly presented, it can be used as positive marketing.
The requirement for only 80% of suppliers to be assessed is potentially damaging to the integrity of the criterion since companies could choose which suppliers to select.

Environmental training for new employees: Improvement in environmental understanding and awareness means that any measures imposed by the company are more likely to be followed. So this is important. Employees should also be encouraged to take ownership of environmental matters and to make suggestions for improvements on the shop floor.
But environmental training for existing employees is important too, since the buy-in of experienced and senior employees will increase the credibility of initiatives.

Energy consumption: Important. Impacts positively on the financial performance of the company, and has direct implications on emissions.

Waste reduction: Important. Similarly, impacts positively on finances.

Missing: Water usage, hazardous substances, emissions. Perhaps 'green' energy might be included.

(c) The first step should be to measure current performance, so that the starting-point is defined. Then assess the 'biggest hits' – perhaps by looking at McKinsey abatement charts to see where real savings can be made.
Cultural change is vital to embedding improvements in company operations.
The points below are common to many manufacturing operations; the pointer to the automotive industry provided useful examples from Toyota in particular.
Energy: Look at energy consumption of all operations. Manufacturing operations: turn off equipment when not being used. More profound chance requires changing manufacturing processes and equipment to something less energy intensive. Other factory operations: Turn off lighting when not needed. Office operations: lighting, heating, equipment (e.g. photocopiers) switched off when not needed.
Space heating of factories and offices is a major component: improve roof and wall insulation. Longer term: Might look at double glazing.

Waste reduction: Look at waste reduction in all operations, 'office' as well as factory. Within a factory, look at reducing waste in production operations (material, energy etc), improving process efficiencies. Reduce defect rates by using good manufacturing practice and aiming for six sigma. Lean operations can reduce wastage from over-production. Move waste up the hierarchy, aiming for re-use. Long-term strategies might involve paradigm shifts such as Industrial Symbiosis and dematerialisation.

Examiner's comments: Part (a): Most answers showed good understanding and knowledge of the area, but many lost marks by failing to answer all aspects of the question.
Part (b): Generally well done. Credit was given for thoughtful analysis.
Part (c): Answers were rather patchy, and often focused very narrowly on a couple of aspects. There was often lack of detail.

2(a)(i) Describe in detail what is meant by a medical device. Where appropriate, include examples and a note on device categories. [10%]

1. State in a clear way that a medical device refers to a range of physical forms i.e. a machine, apparatus, material, appliance etc. Showing this understanding through examples is also acceptable. **(1 %)** *(The additional notes below marking scheme list usual way these are referenced).*

2. It should be noted that a device refers to a range of different actions such as diagnosis, prevention, monitoring, treatment. **(1 % for noting 2 actions, 2 % for noting more than 2 actions)**

3. It is important to note the principal action is not as a drug or pharmaceutical agent. **(1 %)**

4. As part of the categorisation, a medical device can also refer to in-vitro diagnostics, active medical devices, active implantable medical devices, custom-made devices, accessories intended to be used with the device and software with a medical purpose. If listing 4 or more of these OR if listing only 2 or 3 of these but include good definitions **(2 %)** Sample definitions are given below this marking scheme. Partial marks possible.

5. As part of the categorisation, note that devices are classified (note the classification) and have a graduated system of control based on vulnerability of the human body and device risks **(2 %)**

6. Providing specific examples of medical devices and their categorisation **(2 %)**

Additional notes:

Medical device is any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose

of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

For reference, the Global Harmonization Task Force has proposed the following harmonized definition for medical devices.

"Medical device" means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- investigation, replacement, modification, or support of the anatomy or of a
- physiological process
- supporting or sustaining life
- control of conception
- disinfection of medical devices
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

In-vitro diagnostics: *'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations. Directive 98/79/EC .*

Custom made device: *'custom-made device' means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. The abovementioned prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so. Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom-made devices.*

Active medical device: *'active medical device' means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.*

Active implantable medical device: 'active implantable medical device' means any active medical device which is intended to be totally or partially introduced,

surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

2(a)(ii) What roles do international standards play in medical device manufacturing? In particular, describe the role of ISO 13485. [10%]

A note that conveys the role of standards as documented agreements giving very specific instructions covering a very broad spectrum of activities in manufacturing, with an example of at least two such activities. **[5 %]**

A note about ISO13485 standard, referring to the design and manufacture of medical devices and implementation of a QMS. **[3 %]**

Further elaboration on ISO13485 or other international standards such as dealing with sterilisation or biocompatibility (both in lecture notes) or the fact that ISO13485 can be used to show conformity to regulations. **[2 %]**

Additional notes:

A sample definition of a standard:
Standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that materials, products, process and services are fit for their purpose. Standards approved by recognised bodies (e.g. ANSI, CEN, ISO, BSI).

ISO13485 concerns the requirements for the design and manufacture of medical devices and the implementation of a Quality Management System (appropriate organizational structure, procedures, processes). This covers methods, facilities, controls used by the manufacturer in the design, manufacture, packaging, labelling, storage, installation, servicing and post-market handling of medical devices. Compliance with medical device directives can be demonstrated by conforming to the appropriate standards.

2(a)(iii) Write brief notes to describe any two concepts introduced with the implementation of the European Medical Device Directive (93/42/EEC). [15%]

A list and brief description of 6 concepts that will most likely be chosen from as they were noted in lectures/handouts.

- Defined the risk assessment requirements for medical devices (estimating the potential of a device becoming a hazard.
- Introduced 'classification': a ‘risk based’ system based on the vulnerability of the human body taking account of the potential risks associated with the devices.
- Introduced a means of dealing with drug-device combinations.

- Used performance as a criteria of acceptability (as opposed to effectiveness). (The action of a device with reference to its intended use when correctly applied).
- Defined the requirements for clinical data during the approval process for a medical device.
- Introduced the requirement for adverse event reporting and device monitoring in use.

  There are many other concepts that may be cited depending on their level of background reading and are equally acceptable.

For each concept identified with adequate explanation [6 %] (partial marks possible)
An additional 3 % available for clear explanations of concepts.

2(a)(iv) Describe briefly two challenges to harmonisation between the USA and EU of the procedures used to assess whether a medical device conforms to regulations. What would be the benefits to medical device manufacturers if such harmonisation were achieved? [15%]

[5 % for each "challenge" that is well communicated, 5 % for clearly identifying a range of benefits to the manufacturer]

- Six challenges are described below that have been discussed, any 2 of which are acceptable. Others need to be considered and may be expected in this question depending on their level of background reading.
- Suggested benefits are described that are most likely to be noted but this question needs to consider any answer for its validity.
- If examples / cases are provided instead of a very clear description, this should also be considered for full marks.

1. Performance/Effectiveness

- U.S. require the manufacturer to show effectiveness: The extent to which a specific intervention, procedure, regimen of service, when deployed in the field, does what it is intended to do for a defined population. (i.e. a benefit to the user).
- E.U. require the manufacturer to show performance: The action of a device with reference to its intended use when correctly applied. Performance does not refer to the outcome. Outcome may be influenced by other factors. (i.e. works as intended but not necessarily showing benefit to user)

2. Classification

- Classification categories and rules / methods for classification differ between the U.S. and the E.U.
- E.U. have four categories, U.S. have three.
- E.U. has a set of defined rules for classification, U.S. use a system of precedent.

3. Centralised vs. distributed approach to systems

- E.U. have Notified Bodies approve medical devices. A Notified Body can be authorised by the Competent Authority for this role (each Member State has one Competent Authority). The Notified Body is a private enterprise
- U.S. have a centralised system run by the FDA.

4. Manufacturing standards

The U.S. and E. U. do not share an international standard defining the manufacturing of medical devices.

5. Approval Process

The U.S. have a system whereby demonstration of substantial equivalence of to an approved device allows a fast route to approval.

6. Clinical data requirements

Definitions of both when clinical trials are required and the level of benefit they need to show differ between U.S. and E.U.

Examples of benefits to manufacturer (a wide selection expected)

Importantly harmonisation will allow a route to market for medical devices in either region, irrespective of the location of the manufacturer. This will reduce the cost and time to bring a new device to a wider market.

Reduce complexity of sourcing items from global third parties.

2(b)(i) The bioburden for an assembled device is found to be 10^7 spores. It is subjected to sterilisation for 10, 20 and 30 seconds and the numbers of spores remaining after each step are shown in the table below.

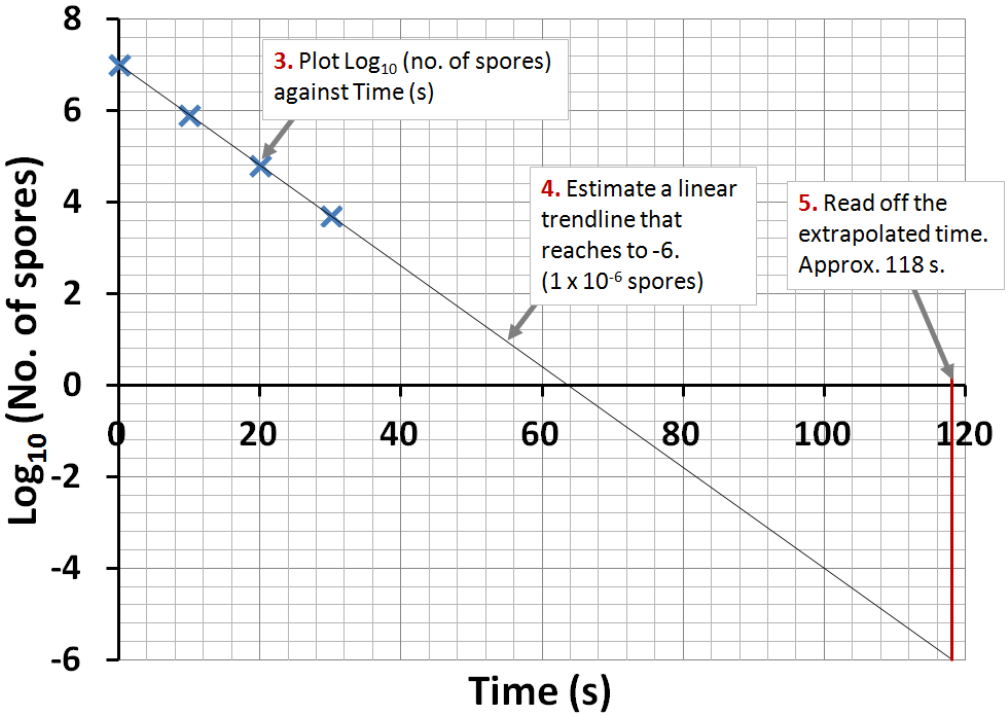
Time (s)	No. of spores
10	7.94×10^5
20	6.31×10^4
30	5.01×10^3

To receive approval, the manufacturing process must reach a Sterility Assurance Level (SAL) of 10^{-6}. Using these data, what would you recommend for the sterilisation process time? [35]

1. Bioburden is the level of contamination at time = 0 s

Time (s)	No. of spores	Log_{10} (No. of spores)
0	1.00E+07	7
10	7.94E+05	5.9
20	6.31E+04	4.8
30	5.01E+03	3.7

2. Change to log base 10.



- Include bioburden as point 1, showing an understanding that it is t=0, **[5 %],**
- Translating the number of spores into log scale **[5 %]**
- Showing an understanding that this is expected to be a linear relationship and plotting (or calculating) accordingly **[5 %]**
- Showing an understanding that this linear relationship needs to be extended to 10^{-6} **[5 %]**
- Reading off or calculating the associated time for that extrapolation **[5 %]**
- Good communication of how the final figure was achieved (either by the quality of the graph or the workings provided for a calculation) **[5 %]**
- Including a safety factor on top of their final estimate (e.g. 10% margin to bring it up to ≈ 130 s). **[5 %]**

2(b)(ii) Write brief notes on five considerations for a manufacturer trying to choose between ethylene oxide sterilisation and gamma radiation sterilisation for a medical device. [15%]

Most likely replies are below based on material in lectures. **3 %** for each point noted. Important to show considerations make reference to both processes in some way or are applicable to both processes, as in the examples below. Partial marks possible.

i. If the manufacturer needs to process in packaging, the ethylene oxide approach requires packaging that is sufficiently permeable. Gamma radiation can penetrate through most packaging.
ii. The material compatibility will need to be assessed. Ethylene oxide has good compatibility with most materials, whereas gamma radiation can lead to degradation of polymers in some cases and discolouration in other cases.
iii. Due to residues, ethylene oxide sterilised products are often quarantined for 7-14 days. Gamma radiated products are available immediately.
iv. Level of process control is important. This is quite straight forward with gamma radiation (using dosimeters to check the radiation level achieved) but ethylene oxide requires careful control of the temperature, total pressure, partial pressure of ethylene oxide and the relative humidity.
v. Significant maintenance health and safety considerations for ethylene oxide as it is toxic, a carcinogen to humans, flammable and potentially explosive. Once completed, the system needs to be flushed with air. While it is also important for personnel not to enter into the gamma radiation area, the source can be submerged in water and very quickly shielded.
vi. The initial capital outlay for a gamma radiation setup is very high compared with ethylene oxide but ongoing costs are relatively small.
vii. They may comment on the availability of third parties and finding out if the minimum batch size matches their manufactured output.
viii. There is a continual decay of the isotope, even when not in use whereas ethylene oxide can be turned off when not in use. Expected scheduling will be important.
ix. Important to find out what regulations may be coming about the control of these substances.
x. Important to check if they can set up the process to conform with the appropriate manufacturing standards for sterilisation.

3. (a) The themes that were investigated during the MET industrial visits were:

- Industry-level context
- Company level context
- Materials, production processes and technology
- Industrial Engineering
- Operations Management
- Design Management
- Human Resources
- CSR, H&S, Environment & Sustainability

Good responses described each of the themes to a certain degree of detail.

(b) Rolls Royce is one of the globally leading manufacturers of aircraft engines. 'Power-by-the-Hour' is the business model used by Rolls Royce as part of their service offering to their customers. A complete engine and accessory replacement service is offered on a fixed-cost-per-flying-hour basis. This aligned the interests of the manufacturer and operator, who only paid for engines that performed well. The features of this service include engine health monitoring, which tracks on-wing performance using on-board sensors; lease engine access to replace an operator's engine during off-wing maintenance, thereby minimising downtime; and a global network of authorised maintenance centres to ensure that world-class support is readily available to customers whenever required. The service allows operators to remove risk related to unscheduled maintenance events and make maintenance costs planned and predictable.

In comparison, Marshall Aerospace is a MRO (Maintenance, Repair and Overhaul) organisation that provide bespoke maintenance services to (mostly) military (air force) customers. They have developed strong links with key manufacturers such as Lockheed Martin and provide third party maintenance services to the customers of other OEMs. For instance, they are the world's first fully OEM approved C-130B to H Service Centre, and is now currently the first and only C-130J Heavy Maintenance Centre. They design and carry out the full remit of maintenance and modification requirements on the C-130, including advanced requirements such as Fatigue Testing and NDT through to a full Avionics upgrade. The operational focus of the company is therefore to provide a quick turnaround service to their customers.

(c) The key uncertainties that are faced by the steel industry are:

- Volatility of ore price – the price of iron ore has trebled in the last 5 years
- Availability of raw material – iron is no longer mined in the UK in significant quantities since the miners strike in 1984/85, and have to be imported from other countries.
- Weakening of demand and price of steel from Europe
- Volatility and uncertainties in demand of steel, as the demand for steel is highly dependent on the countries' economic situation

- Decrease in European & Chinese demand caused profits to fall from £1.15 billion to £0.25 billion in Q2 2012.
- Limited capacity to vary production – efficiency depends on machines operating at full capacity
- Long lead time in supply chain (need to know production a week in advance)

The practices adopted by Tata steel to address these challenges are:

- Vertical integration of supply
- Joint ventures with other companies, e.g., JV with New Millenium Capital Corp in Canada where all the output is fed into Tata.
- There are long established partners, particularly the rail sector who have a constant demand for the product. In lower demand period, some inventory produced for rail.
- Make to order but fill spare capacity by producing inventoried stock for regular customers
- Focus on cost reduction:
    - Outsourcing of non-core operations eg. transport, mining activities
    - Raw materials sourced at lowest cost
    - Contract workers on worse compensation schemes than Tata standards - so money saved
    - Recycling by-products/waste e.g. gas, slag, cut-offs
    - 2/3 of site electricity from waste gas power station
    - Recently started extracting remaining iron ore from slag
- Focus on the Chinese and other emerging markets

Examiner's comments: Part (a) generally well answered. Some good answers for parts (b) and (c), but a handful of candidates seemed to have no knowledge at all of the companies in question. A tendency in both parts to make observations from the visits without relating them directly to the question.

CYB/RD