

MET2  
MANUFACTURING ENGINEERING TRIPOS PART IIA

---

Friday 2 May 2014     9 to 10.30

---

**PAPER 6**

**Module 3P10: CONTEMPORARY ISSUES IN MANUFACTURING**

*Answer **all** questions.*

*Answers to sections **A**, **B** and **C** must appear in three separate booklets.*

*All questions carry the same number of marks.*

*The **approximate** percentage of marks allocated to each part of a question is indicated in the right margin.*

*Write your candidate number not your name on the cover sheet.*

**STATIONERY REQUIREMENTS**

8 page answer booklet x 3

Rough work pad

Graph paper (linear)

**SPECIAL REQUIREMENTS TO BE SUPPLIED FOR THIS EXAM**

CUED approved calculator allowed

Engineering Data Book

**You may not start to read the questions printed on the subsequent pages of this question paper until instructed to do so.**

## SECTION A

1 A national newspaper is holding a competition to determine the Best Green UK Company. To enter the competition, the criteria which companies must meet are the following:

- An environmental management system that meets the ISO 14001 international standard.
- Public reporting of green credentials, subject to third-party verification.
- Companies must have calculated their carbon footprint.
- More than 80% of the suppliers to the company must have been assessed for environmental impact.
- New employees given environmental training on induction.
- 3% reduction in energy consumption compared to previous year.
- 10% decrease in waste to landfill compared to previous year.

(a) How would you define a *green* company? What attributes would you expect it to have, and what evidence might you see on a visit to the company? How might such a definition be varied to have validity for different sectors and companies of different sizes? [20%]

(b) Critically evaluate each of the criteria listed above, explaining what they encompass, how they may relate to the environmental performance of a company and suggesting improvements to these criteria. Discuss any major factors which have been omitted. [40%]

(c) As the environmental manager of an automotive company you have been tasked with achieving the last two criteria on the list above. What actions would you take? What further measures would you put in place if you were required to continue to make these improvements at the same rate over the next five years? [40%]

SECTION B

- 2 (a) (i) Describe in detail what is meant by a *medical device*. Where appropriate, include examples and a note on device categories. [10%]
- (ii) What roles do international standards play in medical device manufacturing? In particular, describe the role of ISO 13485. [10%]
- (iii) Write brief notes to describe any two concepts introduced with the implementation of the European Medical Device Directive (93/42/EEC). [15%]
- (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%]
- (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)	Number of spores
10	$7.94 \times 10^5$
20	$6.31 \times 10^4$
30	$5.01 \times 10^3$

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%]

- (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%]

SECTION C

3 (a) Describe the themes that were investigated during the MET industrial visits programme. [20%]

(b) Compare and contrast the maintenance services offered by Marshall Aerospace and the “power by the hour” service offered by Rolls Royce. [40%]

(c) Discuss the key challenges currently faced by the steel industry in the UK. Describe the practices adopted by Tata Steel to address these challenges. [40%]

**END OF PAPER**