



**UNIVERSITI KUALA LUMPUR  
MALAYSIAN INSTITUTE OF INDUSTRIAL TECHNOLOGY**

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**FINAL EXAMINATION  
JANUARY 2016 SEMESTER**

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**COURSE CODE : JQB 20403**  
**COURSE TITLE : QUALITY SYSTEM AND STANDARDS**  
**PROGRAMME LEVEL : BACHELOR**  
**DATE : 30 MAY 2016**  
**TIME : 2.30 PM – 5.30 PM**  
**DURATION : 3 HOURS**

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**INSTRUCTIONS TO CANDIDATES**

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1. Please read the instructions given in the question paper **CAREFULLY**.
  2. This question paper is printed on both sides of the paper.
  3. This question paper consists of **ONE (1)** section only.
  4. Answer **FOUR (4)** questions only.
  5. Please write your answers on the answer booklet provided.
  6. Please answer all questions in English only.
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**THERE ARE 10 PAGES OF QUESTIONS EXCLUDING THIS PAGE.**

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**INSTRUCTION : Answer FOUR (4) questions only**  
**Please use the answer booklet provided.**

**Question 1**

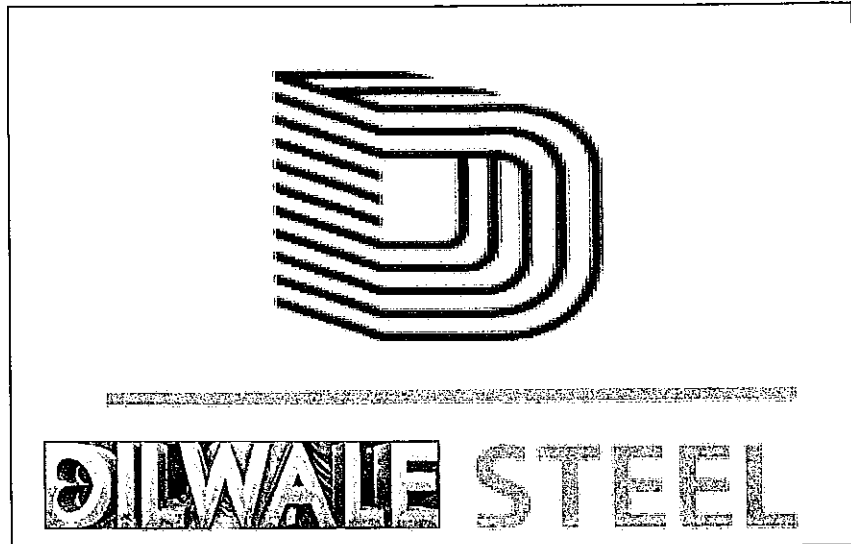


Figure 1 : Dilwale Steel Sdn Bhd Logo

Dilwale Steel Sdn Bhd (DSSB) located strategically at Petaling Jaya and Bukit Raja, Klang in the state of Selangor. The Bukit Raja factory produces steel bars and steel billets which are the feed stock for the rolling mill in Petaling Jaya. Both the manufacturing plants are equipped with modern equipment and are fully computerised to produce precision quality products from both the mills. The processes involves in production of these product are very sensitive to the environment condition such as temperature and humidity level.

The principal activities of DSSB are in the manufacturing and marketing of high tensile steel bars, mild steel bars and prime steel billets. DSSB has a wide network of customers domestically as well as internationally. The finished products manufactured by DSSB conform to MS 146:2000.

DSSB is now in the mist of implementing QMS in their organization to ensure their organization will always **Standardize, Consistent and Effective** in their operation for the benefits of their customer.

- a. As explained above, DSSB products are consists of steel component that are sensitive to the working environment. Accordance to ISO9001:2008 Clause 6.4, organization shall determine and manage the work environment needed to achieve conformity to product requirements. As an expert in QMS, demonstrates to DSSB on how to comply with the requirements stipulated in Clause 6.4 of ISO9001:2008.

(5 marks)

Question 1b and 1c are based on Figure 2 below.

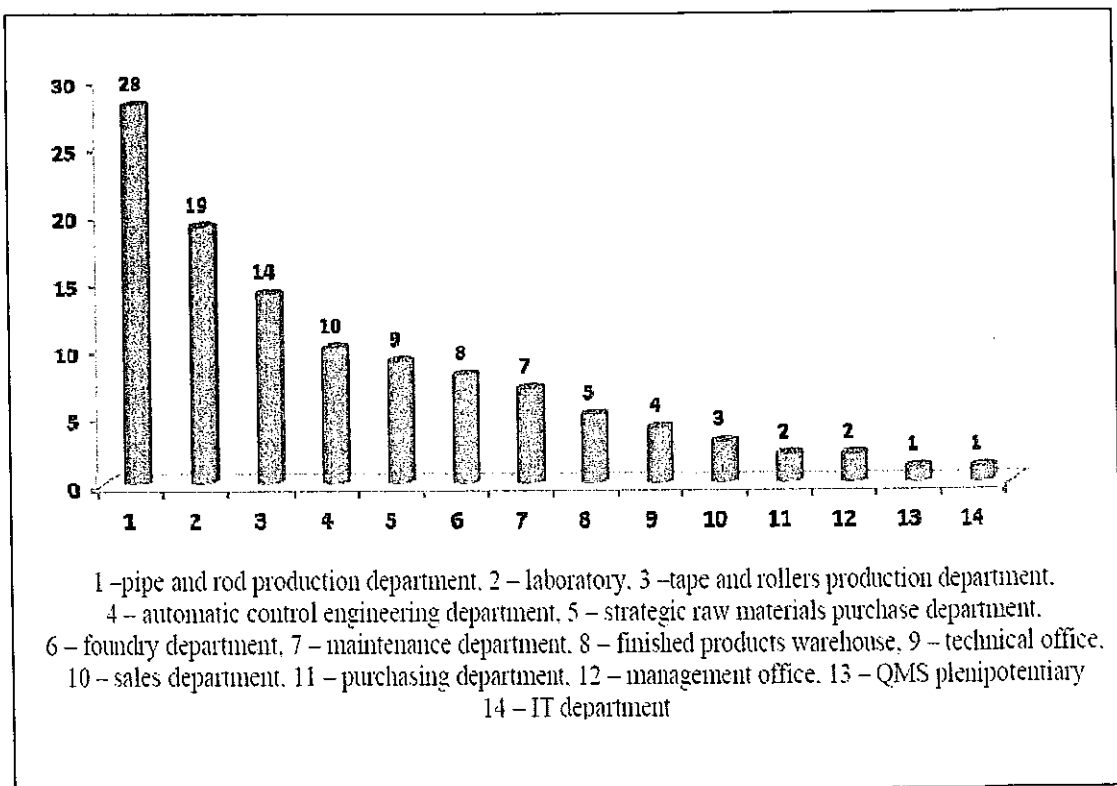


Figure 2 : Number of corrective actions in Dilwale Sdn Bhd

- b.. Figure 2 shows the corrective actions (their number) that were conducted in DSSB for year 2013 in particular units of the company. It shows that the number of DSSB's corrective action is varies based on department. To further enhance the effectiveness of the corrective action activities, assist DSSB to understand :

- i. The corrective and preventive actions function in quality management systems.

(2 marks)

ii. The role of employee towards effective corrective and preventive actions deployment.

(2 marks)

c. Identify **FOUR (4)** possible sources of information on nonconformities for Delwale Sdn Bhd

(4 marks]

d. By using the aids of an appropriate diagram, describe the Quality Management Cycles for DSSB. Explain possible inputs, processes and outputs of any **TWO (2)** departments listed in Figure 2 above. Explain how the Quality Management Cycles will influence the input, process and output of the department selected.

(8 marks)

e. Explain any **FOUR (4)** of 8 Management Principles for QMS to DSSB's top management.

(4 marks)

**Question 2**

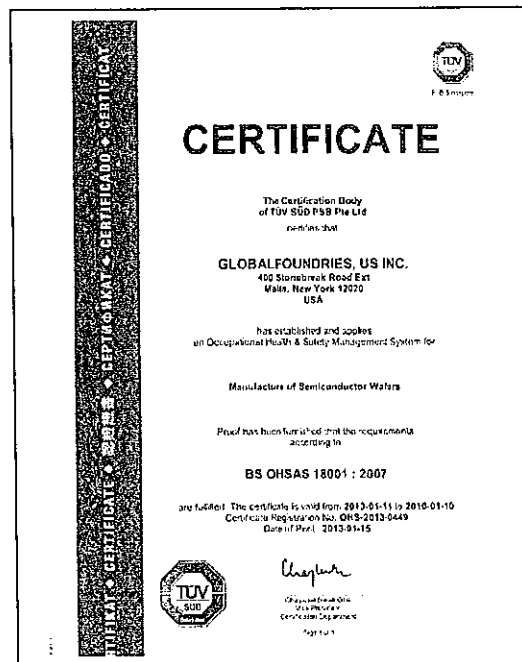


Figure 3 : Example of OHSAS 18001:2007 certificate of compliance

a. Figure 3 show the example of certificate of compliance on OHSAS 18001:2007 obtained by Global Foundries US Inc (GFI). As an expert on safety and health management systems, summarizes the key features of OHSAS 18001:2007 standard requirements that have been fulfilled by GFI.

(5 marks)

b. If GFI to operate in Malaysia and fulfil the safety and health regulation, it should comply to OSHA Act 1994 accordingly. Assist GFI's management by explain TWO (2) main functions of the safety and health committee as describe by OSHA act 1994 in Section 31. Discuss what action shall be undertaken by the safety and health committee if there is any accident happen in the workplace.

(5 marks)

c. In developing and designing Occupational Safety & Health management systems, GFI need to undergo an "Evaluation" stage. Explain clearly the activity need to be performed by GFI in the "Evaluation" stage.

(5 marks)

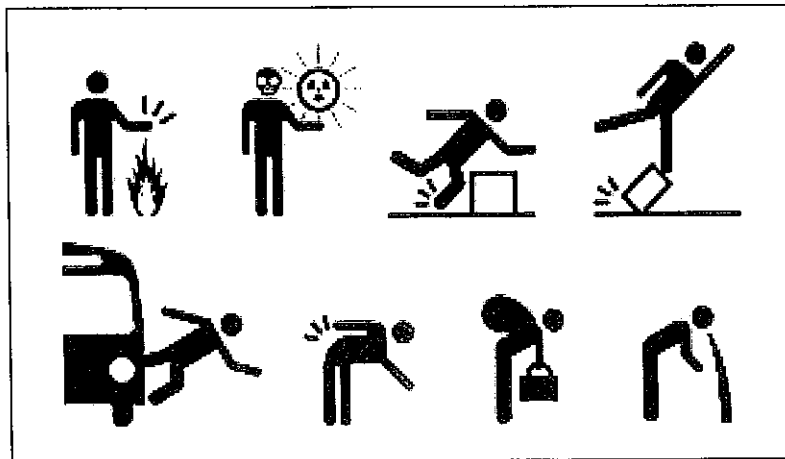


Figure 4 : Potential risk at workplace

d. Figure 4 shows the potential risk at workplace. In safety and health context, risk can be defined as the probability or threat of quantifiable damage, injury, liability, loss, or any other negative occurrence that is caused by external or internal vulnerabilities, and that may be avoided through preemptive action. As an expert in safety and

health management systems, list and explain any **FIVE (5)** types of risk organization may face on their operation. Give suitable example in your explanations.

(5 marks)

- e. Examine the environmental aspect process in EMS so that the establishment of procedures for identifying an environmental aspect in GIF can be performed accordingly.

(5 marks)

### Question 3

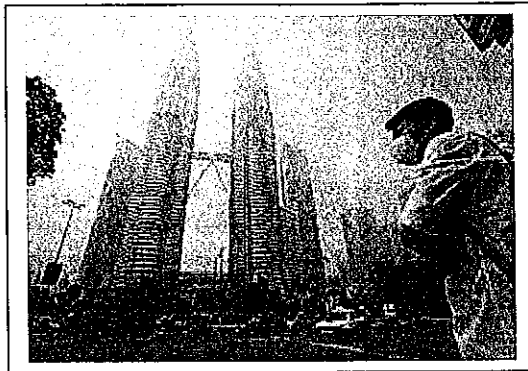


Figure 5 : Haze in Malaysia 2015

***Southeast Asia's haze: Find out what is behind the choking smoke covering Indonesia, Malaysia and Singapore***

Southeast Asia has been enveloped in choking haze from agricultural fires in Indonesia over the past fortnight, prompting flight cancellations, closing schools and raising fears this weekend's glitzy Formula One night race in Singapore could be affected. **The region has suffered for years from annual bouts of smog caused by slash-and-burn practices in Indonesia's Sumatra and Kalimantan islands, but governments in the region have failed to address the problem.**

The fires have been exacerbated this year by the effects of the El Nino weather phenomenon as a prolonged dry season in Indonesia has parched the top soil, fuelling the flames. Tens of thousands have fallen ill in parts of Indonesia as the haze thickened over the past fortnight, and the smog has led to unhealthy air quality and reduced visibility in neighbouring Singapore and Malaysia. This year's haze had already caused hundreds of millions of dollars in losses to the Indonesian economy, with further losses now expected.

Source : Online ABC News dated 19 Oct 2015 : <http://www.abc.net.au/news/2015-09-17/southeast-asia-haze>

By referring to this incident;

- a. Identify and explain in details any TWO (2) reasons on why organization in this planet should consider registering for ISO14001.

(5 marks)

- b. The haze problem has given a significant effect to many Indonesian's companies involve in plantation to maintain their internal control systems. Currently, they might confuse whether to emphasize on the QMS or EMS as to strengthen their internal control to avoid the same problems from occur. Help those companies by clearly distinguish the differences between Quality Management System and Environment Management System. Explain how both management systems can be integrated.

(5 marks)

- c. If companies involved in plantation industry is considering registering their organization as ISO14001:2004 registered company, what will be the appropriate and suitable steps for them to be certified. Show your answer in the forms of Gantt Chart format that consist of all registration steps and planning for ISO14001:2004. You are free to decide the duration of your planning as long as it will provide most benefits to the companies.

(10 marks)

- d. Provide example and introduce one of **certification** body and one **accreditation** body available in Malaysia. In your opinion, between certification and accreditation, which will be most suitable for the plantation company in Indonesia, justify.

(5 marks)

Question 4

Figure 6 : GST Refund Form for Royal Malaysian Customs (RMC)

GST which is also known as VAT or the value added tax in many countries is a multi-stage consumption tax on goods and services. GST is levied on the supply of goods and services at each stage of the supply chain from the supplier up to the retail stage of the distribution. Even though GST is imposed at each level of the supply chain, the tax element does not become part of the cost of the product **because** GST paid on the business inputs is claimable. The Royal Malaysian Customs received and process thousands of GST refund application every day from various parties. Therefore Royal Malaysian Customs shall properly control and maintain all application received and document submitted to them.

- a. Explain in details, what will be the implication if the documentation received by RMC is not being properly control and maintain.

(5 marks)



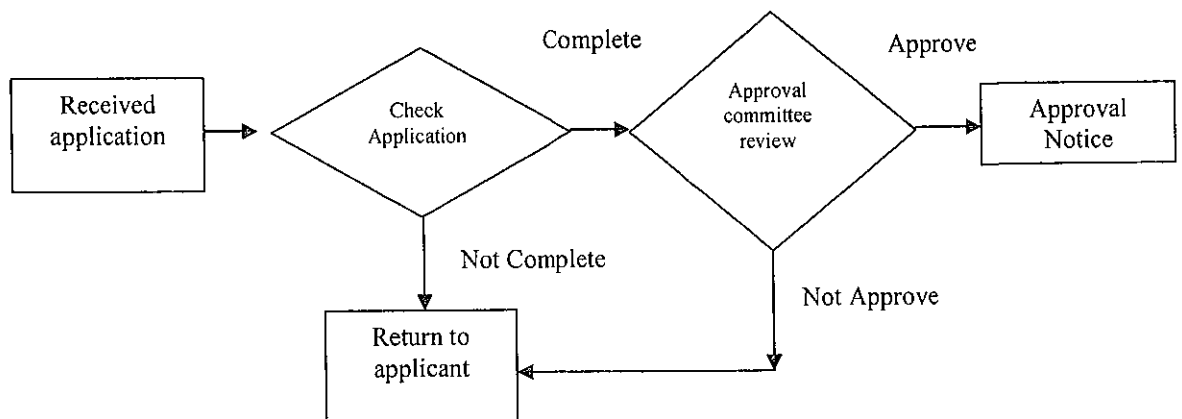
b. RMC need to establish and maintain the documentation as required by the ISO9001:2008 standard. By using the aids of an appropriate diagram, explain in details the documentation levels and functions of each levels. Explain; in which level of the document structure is suit for the application form send by the applicant.

(9 marks)

c. To claim the refund for GST, all parties need to strictly follow the procedure prepared by RMC so that the application can be process easily. Therefore, RMC need to established good procedure to be used by its customer. Elaborate the criteria of good procedure.

(5 marks)

d. Below diagram is the flow of RMC GST refund application processes. Based on the flow below, design and develop appropriate standard operating procedure for RMC GST refund process. You may use any format of standard operating procedure.



(6 marks)

## Question 5

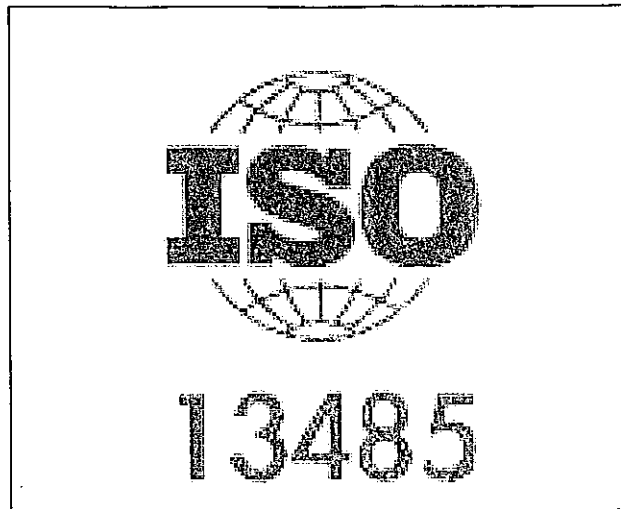


Figure 7 : ISO 13485 Medical Devices: Quality Management System: Requirements For Regulatory Purposes

ISO 13485 is an International Organization for Standardization (ISO) standard, published in 2003, that represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices. This standard supersedes earlier documents such as EN 46001 and EN 46002 (both 1997), the ISO 13485 published in 1996 and ISO 13488 (also 1996).

- a. Standards such as ISO13485 has been revised and amended for several times. Base on your understanding on "Standard", explain on why such revision or amendment is required.  
(5 marks)
- b. If you are one of the members of the ISO/TC 176 Quality management and quality assurance, do you suggest to the committee to combine the ISO13485 standard with ISO 9001:2008 standards? Justify and explain clearly your opinion.  
(5 marks)
- c. Outline the differences between Organization Oriented Standard and Product Oriented Standard in ISO14001  
(5 marks)

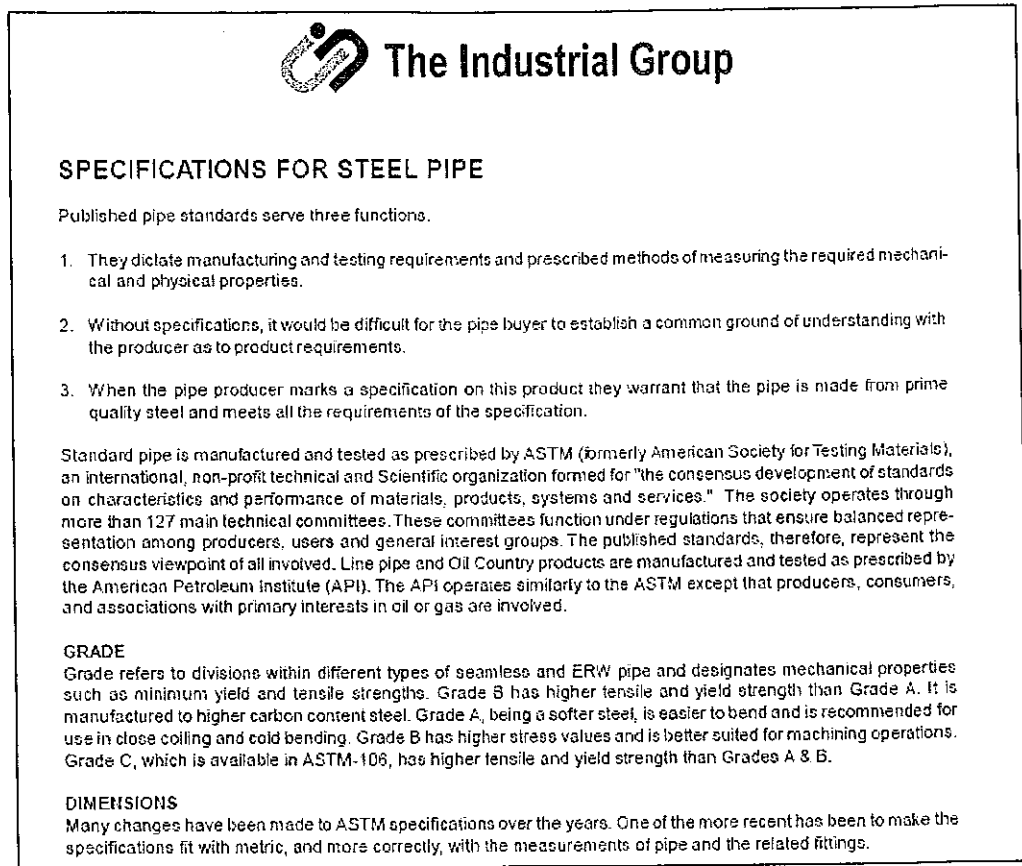


Figure 8 : Example of internal specification used to manufacture steel pipes

d. In certain cases, internal specification is being established to be use internally by the organization. Figure 8 show an example of internal specification used to manufacture steel pipes. This internal standard is referring to external standard such as API and ASTM as part of important requirements and guidance. Explain the significant reasons of internal specification being established although the specific requirement can be referred from related standard published by the international body such as API, ASTM, BSI (British Standard Institutes), WHO, American National Standards Institute (ANSI) etc.

(5 marks)

e. Describes the action should be taken by the organization if the reference standard used in their internal specification is being revised by the originator.

(5 marks)

**END OF EXAMINATION PAPER**

