

Prince of Songkla University
The Faculty of Engineering

Midterm Examination Semester 2

Academic Year 2008

Date : Dec 26 , 2008

Time : 9:00-12:00

Subject : 225-468 Quality Engineering

Room : R300

Name : Student code :

เลขที่ตามใบเซ็นชื่อ คือ

Part	1	2	3	4	5	Total
Full score	30	10	15	10	15	80
Score						

คำสั่ง

1. นำเอกสารเข้าห้องสอบได้ทุกชนิด
2. นำ Dictionary และ เครื่องคิดเลข เข้าห้องสอบได้
3. ใช้ดินสอได้ แต่ต้องเขียนให้อ่านได้ชัดเจน
4. ให้ทำในกระดาษคำตอบเท่านั้น ตอบนอกกระดาษ คำตอบไม่มีคะแนน
5. เขียน ชื่อ ในกระดาษคำตอบทุกหน้าก่อนเริ่มทำ เพื่อป้องกันความสับสน ในกรณี
กระดาษคำตอบหลุดจากฉบับ

ทุจริตในการสอบ โทษขั้นต่ำปรับตกในรายวิชานั้น และพักการเรียน 1 ภาคศึกษา

Dr. Klangduen Pochana



Student code :

Part 1 Select best answer. Each question has 1 point. Total score for this part is 30 points.

Answer Sheet for Part 1 :

From above questions, choose most correct answer (X) in each question.

ใช้สัญลักษณ์กากบาท (X) เท่านั้นและขีดให้เต็มช่อง

Q #	Answer					Q #	Answer				
1	A	B	C	D	E	16	A	B	C	D	E
2	A	B	C	D	E	17	A	B	C	D	E
3	A	B	C	D	E	18	A	B	C	D	E
4	A	B	C	D	E	19	A	B	C	D	E
5	A	B	C	D	E	20	A	B	C	D	E
6	A	B	C	D	E	21	A	B	C	D	E
7	A	B	C	D	E	22	A	B	C	D	E
8	A	B	C	D	E	23	A	B	C	D	E
9	A	B	C	D	E	24	A	B	C	D	E
10	A	B	C	D	E	25	A	B	C	D	E
11	A	B	C	D	E	26	A	B	C	D	E
12	A	B	C	D	E	27	A	B	C	D	E
13	A	B	C	D	E	28	A	B	C	D	E
14	A	B	C	D	E	29	A	B	C	D	E
15	A	B	C	D	E	30	A	B	C	D	E

1. The justification of any exclusions in the QMS must be defined in
 - a) Procedure
 - b) Work Instruction
 - c) Quality Plan
 - d) Quality Manual
 - e) Record
2. Who is directly responsible for ensuring that the quality objectives are established?
 - a) DC
 - b) QMR
 - c) Top management
 - d) Middle management
 - e) Supervisor
3. DTAC, one of the biggest mobile companies in Thailand, has no purchasing process. In which clause, the exclusion should be made?
 - a) Clause 7.2
 - b) Clause 7.5
 - c) Clause 7.6
 - d) Clause 7.4
 - e) Clause 7.3
4. The process that is not operated by the organization is called.....
 - a) Outreach process
 - b) Outsource process
 - c) Output process
 - d) Outcome process
 - e) None of the above answers
5. What is the responsibility of QMR stated in ISO 9001:2000?
 - a) Establishing quality policy
 - b) Appoint IQA
 - c) Ensuring the quality policy is communicated within the organization
 - d) Establishing quality objective
 - e) Reporting performance of QMS to top management
6. What is **NOT** included in product requirement required by ISO9001?
 - a) Regulatory requirement
 - b) Customer requirement
 - c) Subcontractor requirement
 - d) Organization requirement
 - e) Law requirement
7. What is the document showing the processes needed for QMS and also the sequence and interaction of these processes?
 - a) Job description
 - b) Organization chart
 - c) Quality plan
 - d) Procedure
 - e) Business flow
8. Why does the extent of QMS documentation differ from one organization to another?
 - a) Due to the external origin
 - b) Due to the change of structure
 - c) Due to the competence of personnel
 - d) Due to the approval of documents
 - e) Due to the requirement of product



Student code :.....

9. What ISO standard explains principle and vocabulary for QMS?
- a) ISO 9000:2000
 - b) ISO 9001:2000
 - c) ISO 9002:2000
 - d) ISO 9003:2000
 - e) ISO 9004:2000
10. What ISO standard is invalid?
- a) ISO 9004:2000
 - b) ISO 9000:2000
 - c) ISO 9001:2000
 - d) ISO 9003:2000
 - e) None of the above answers
11. Which procedure is required by ISO9001:2000?
- a) Design and Development Procedure
 - b) Purchasing Procedure
 - c) Maintenance Procedure
 - d) Internal audit procedure
 - e) Reactive Action Procedure
12. Which clause is related to machine maintenance activities?
- a) 6.4
 - b) 6.3
 - c) 7.5
 - d) 8.3
 - e) 8.4
13. The quality policy shall be...
- a) Understood by customer
 - b) Realistic and disclosed to public
 - c) Established by top management of the organization
 - d) Consistent with the organizational structure
 - e) Appointed by QMR
14. Which function in the organization is not relevant to QMS?
- a) Financial
 - b) Sales
 - c) Warehouse
 - d) Marketing
 - e) Engineering
15. The document that is used for controlling revision of all documents in the organization is called.....
- a) Quality Plan
 - b) Master list
 - c) Document control
 - d) Record control
 - e) Business flow
16. What type of organization is not applicable to ISO 9001:2000?
- a) 7-11 shop
 - b) Lotus supermarket
 - c) PSU hospital
 - d) Faculty of Engineering
 - e) None of the above answers



Student code :.....

17. What type of record is **NOT** required by ISO 9001:2000?
- a) Internal audit record
 - b) Maintenance record
 - c) Training record
 - d) Management review report
 - e) Result of prevention action
18. IQA is related to ISO9001:2000 in clause number
- a) 8.2.2
 - b) 8.3
 - c) 8.2.4
 - d) 8.5.1
 - e) 8.5.2
19. Who is responsible for distribution of document to the point of use?
- a) CAR
 - b) MD
 - c) DC
 - d) NC
 - e) IQA
20. Which answer is correct?
- a) Quality procedure is the first level of quality document.
 - b) The document should be approved for adequacy before issuing.
 - c) The external origin document should not be controlled.
 - d) The obsolete documents should not be retained in the organization.
 - e) The scope of QMS must be defined in record control.
21. Which action demonstrates good control of document?
- a) Document is approved after issuing.
 - b) Document is distributed to customer.
 - c) Revision of document is identified.
 - d) Unintended use of document is obsolete.
 - e) All answers are correct.
22. Which type of document describes how a specific work is done by an operator?
- a) Quality manual
 - b) Procedure
 - c) Work instruction
 - d) Document from external source of origin
 - e) Record
23. What type of document shows the commitment of top management to comply with requirements and continually improve?
- a) Quality Procedure
 - b) Quality Record
 - c) Quality Plan
 - d) Quality Work Instruction
 - e) Quality policy
24. What type of audit is required to annually evaluate the conformity of organization's system to ISO9001:2000?
- a) Certification audit
 - b) Pre-audit
 - c) Re-assessment audit
 - d) Surveillance audit
 - e) Customer audit



Student code :

25. What type of action shall the organization take to remove the cause of nonconformities in order to prevent recurrence?
- a) Management review
 - b) Supplier audit action
 - c) Preventive action
 - d) Corrective action
 - e) Re-validation action
26. What clause is related to inventory control?
- a) 8.2.4
 - b) 6.2.2
 - c) 5.6.2
 - d) 7.5.2
 - e) 7.5.5
27. Which procedure is not required by this ISO standard?
- a) Internal audit procedure
 - b) Corrective action procedure
 - c) Preventive action procedure
 - d) Management control procedure
 - e) Document control procedure
28. What type of control is **not** required by ISO9001?
- a) Control of complexity of process
 - b) Control of obsolete document
 - c) Control of record disposition
 - d) Control of version of document
 - e) Control of change of document
29. Who is responsible for surveillance audit?
- a) QMR
 - b) CB
 - c) AB
 - d) NC
 - e) DC
30. The term "supplier" in ISO9001:1994 means in ISO9001:2000.
- a) The subcontractor
 - b) The customer
 - c) The auditor
 - d) The manager
 - e) The organization



Part 2 : Answer all questions. Please determine whether these following sentences are correct (✓) or incorrect (✗). One point (1 point) will be given for the right answer. Minus half point (-0.5 point) will be given for the wrong answer. (Total 15 points)

Q #	✓	✗	Questions
1			QMR is a member of management of the organization and he is responsible for ensuring that QMS is established.
2			Records of the results of training shall be maintained according to clause no. 4.2.3.
3			Business flow is the document that is used to describe flow of the production process of the organization.
4			ISO9001:2000 has been aligned with ISO14001:1996 in order to enhance the compatibility of the two standards for the benefit of the organization.
5			To prevent of accidental use of outdated documents, the document should be kept in department that originates those documents.
6			IQA is an audit that is done by supplier.
7			ISO9001:2000 must be officially approved by the Minister of Industry before being used in Thailand.
8			In ISO9000 series version 1994, the ISO9002 and ISO9003 are excluded.
9			The function of marketing relates to clause no. 7.2
10			“Product” in ISO9001:2000 standard means tangible product only.

Name :code.....

Part 3 : Find suitable words (or terms) to fit or relate with the explanation of each question. Each question has 1 point. Total score for this part is 15 points. (ห้ามตอบด้วยย่อ)

Q#	Explanations	Words or terms
1	The keyword of QA.	
2	Overall commitment and direction of an organization as formally expressed by top management.	
3	Evil of quality.	
4	Non- fulfillment of a requirement.	
5	Action to eliminate the cause of a potential nonconformity.	
6	The organization that monitors the performance of certification body.	
7	The international standard that describes requirements of quality management systems.	
8	The name of ISO9001:2000 in term of Thai industrial standard.	
9	Recurring process of enhancing the QMS in order to achieve improvements in overall performance consistent with the organization's quality policy.	
10	The standard that is used for local product certification.	
11	The term in ISO9001:2000 that is used to call the person or organization that provide raw material, part or personnel to the organization.	
12	Yearly visit of CB.	
13	The document provides evidence of conformity to requirements and of the effective operation of QMS.	
14	The document describes the qualification of personnel needed for a particular job.	
15	The action that has to be done after non-conformity of the system is found.	



**Part 4. Answer questions in table “B” by using the words in table “A “ only.
Some words can be used more than once. Some words may not be used. (1
 point each, total 10 points)**

Table “A”

Quality program	Financial record	Business plan
design and development stages	reference acceptance criteria	validate for production provision
Management review	characteristics and trends of processes and products	Prevention action audit
Distribution of document	Customer audit	Ethics
AB audit	ISO9004:2000	Business flow
QMR	EQM	Annex
Corrective action	Preventive maintenance	Objective and target
Document controller	Organization chart	ISO 9002:2000
Training record	Certification audit	Statutory and regulatory requirements
Research and development	Work Instruction record	Quality manual
Quality plan	Internal complaint	Environmental quality audit
re-approve	Marketing	IQA

Table “B”

No	Question	Answer
1	The document states structure of management function in the organization.	
2	Where should we find the informative document which shows correspondence between ISO9001:2000 and ISO14001:1996.	
3	Where documents are changed, what shall the organization do prior to issue?	
4	This record is not required by this ISO standard.	
5	The second party audit.	
6	The letter “E” in PQCDSMEE .	
7	Inapplicable standard.	
8	The function that is responsible for design and development.	
9	Te function responsible for reviewing of requirements related to product.	
10	His or her function is to control records disposition.	

Name :code.....

Part 5 Answer all questions. Total score for this part is 15 points. (Answer must be in Thai)

1. What is the difference between “document” and “record”? (2 points)

2. Identify ISO9001:2000 clauses relating to these following topics in IE and MfE curriculum (5 points). Select only **one clause (most suitable one)** in each question.

No.	Subject	Clause no. in ISO9001:2000
1	Work study	
2	Quality control	
3	Industrial safety	
4	Inventory control	
5	Engineering Statistics	



Name :code.....

3. From your assignment (“Quality Guru”), describe information about your “Guru”. (4 points)

4. Your recommendation and suggestion on the activities in LMS to improve teaching and learning activities for this course. (4 points)

Good luck

Dr. Klangduen Pochana

