

Prince of Songkla University
The Faculty of Engineering

Midterm Examination Semester 2
Date : Dec 25 , 2009
Subject : 225-468 Quality Engineering

Academic Year 2009
Time : 9:00-12:00
Room : R200

Name : Student code :

Part	1	2	3	4	Total
Full score	45	15	35	35	130
Score					

คำสั่ง

- นำเอกสารประกอบการสอนที่อาจารย์แจกให้ในห้องเรียน (ISO/CD 9001) เข้าห้องสอบได้เท่านั้น (เขียนข้อความในเอกสารได้ ห้ามตัดแปะกระดาษเพิ่มเติมในเอกสาร)
- นำ Dictionary และ เครื่องคิดเลข เข้าห้องสอบได้ (ห้ามบันทึกข้อมูลที่เกี่ยวข้องกับวิชานี้)
- ห้ามใช้ดินสอ และห้ามยืมเอกสารหรือสิ่งของใดๆในห้องสอบ
- ให้ทำในกระดาษคำตอบเท่านั้น ตอบนอกกระดาษ คำตอบไม่มีคะแนน
- เขียน ชื่อ หรือรหัส ในกระดาษคำตอบทุกหน้าก่อนเริ่มทำ เพื่อป้องกันความสับสน ในกรณีกระดาษคำตอบหลุดจากฉบับ
- ข้อสอบมี 15 หน้า นับจำนวนหน้าให้ครบก่อนเริ่มทำ

ทูลงการสอบ โทษขันตำปรบตคในรายวิชานัน และพัทการเรียน 1 ภาคศึกษา

Dr. Klangduen Pochana



Name Or Code.....

Part 1 Select best answer. Each question has 1 point. Total score for this part is 45 points.

Answer Sheet for Part 1 : ใช้สัญลักษณ์กากบาท (X) เท่านั้นและขีดให้เต็มช่อง

Q #	Answer					Q #	Answer				
1	A	B	C	D	E	24	A	B	C	D	E
2	A	B	C	D	E	25	A	B	C	D	E
3	A	B	C	D	E	26	A	B	C	D	E
4	A	B	C	D	E	27	A	B	C	D	E
5	A	B	C	D	E	28	A	B	C	D	E
6	A	B	C	D	E	29	A	B	C	D	E
7	A	B	C	D	E	30	A	B	C	D	E
8	A	B	C	D	E	31	A	B	C	D	E
9	A	B	C	D	E	32	A	B	C	D	E
10	A	B	C	D	E	33	A	B	C	D	E
11	A	B	C	D	E	34	A	B	C	D	E
12	A	B	C	D	E	35	A	B	C	D	E
13	A	B	C	D	E	36	A	B	C	D	E
14	A	B	C	D	E	37	A	B	C	D	E
15	A	B	C	D	E	38	A	B	C	D	E
16	A	B	C	D	E	39	A	B	C	D	E
17	A	B	C	D	E	40	A	B	C	D	E
18	A	B	C	D	E	41	A	B	C	D	E
19	A	B	C	D	E	42	A	B	C	D	E
20	A	B	C	D	E	43	A	B	C	D	E
21	A	B	C	D	E	44	A	B	C	D	E
22	A	B	C	D	E	45	A	B	C	D	E
23	A	B	C	D	E						



1. In case that the requirement of ISO9001 standard cannot be applied due to the nature of an organization and its product, this requirement can be considered for.....
 - a) Explanation
 - b) Conformation
 - c) Certification
 - d) Exclusion
 - e) Information

2. Who is directly responsible for ensuring that the quality management system is established?
 - a) DC
 - b) QMR
 - c) Top management
 - d) Middle management
 - e) Supervisor

3. What is **NOT** included in product requirement required by ISO9001?
 - a) Regulatory requirement
 - b) Customer requirement
 - c) Organization requirement
 - d) Supplier requirement
 - e) Law requirement

4. TOYOTA, one of the biggest automobile companies in Thailand, has no design 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

5. 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

6. What is the responsibility of QMR stated in ISO 9001?
 - a) Establishing quality plan, and inform to all functions and levels of the organization
 - b) Appoint policy
 - c) Ensuring the promotion of awareness of customer requirements throughout the organization
 - d) Ensuring the quality policy is communicated within the organization
 - e) Establishing quality policy

7. What is the document showing the processes for the organization's activities and also including outsource processes that needed for QMS?
 - a) Organization chart
 - b) Business flow
 - c) Quality plan
 - d) Job description
 - e) Procedure

8. Why does the extent of QMS documentation differ from one organization to another?
 - a) Due to the complication of the organization's processes



- b) Due to the change of customer processes
 - c) Due to the competent of supplier
 - d) Due to the size of product providing to customer
 - e) Due to the requirement of product interactions
9. What ISO standard (in the newest version of ISO9000 series) explains principle and vocabulary for QMS?
- a) ISO 9001:2005
 - b) ISO 9000:2000
 - c) ISO 9001:2000
 - d) ISO 9000:2005
 - e) ISO 9001:2008
10. Which procedure is required by ISO9001?
- a) Corrective Action procedure
 - b) Design and Development Procedure
 - c) Purchasing Procedure
 - d) Maintenance Procedure
 - e) Reactive Action Procedure
11. Which clause is directly related to 225-341 Maintenance Engineering subject?
- a) 6.4
 - b) 6.3
 - c) 7.5
 - d) 8.3
 - e) 8.4
12. The quality policy shall be...
- a) Understood by subcontractor
 - b) Realistic and disclosed to public
 - c) Consistent with the supplier responsibility
 - d) Established by top management of the organization
 - e) Appointed by QMR
13. Which function of the organization is not included in ISO 9000 QMS requirements?
- a) Sale and marketing
 - b) Incoming inspection
 - c) Maintenance spare part control
 - d) Financial
 - e) Human resource development
14. What ISO standard is out of date?
- a) ISO 9000:2005
 - b) ISO 9001:2000
 - c) ISO 9001:2008
 - d) All answer are correct
 - e) None of the above answers
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 9001:2008?
- a) PSU Computer Center
 - b) Thai Commercial Bank
 - c) Big-C supermarket



- d) Hatyai hospital
e) None of the above answers
17. What type of record is **NOT** required by ISO 9001:2008?
- a) Internal audit record
b) Maintenance record
c) Training record
d) Management review report
e) Result of prevention action
18. Who is responsible for distribution of document to the point of use?
- a) CAR
b) MD
c) NC
d) DC
e) IQA
19. Which answer is **correct**?
- a) Clause no. 5 can be excluded if the organization has less than 50 employees.
b) The product requirement does not include regulatory requirement.
c) The quality manual should be established by the supplier.
d) The obsolete version of ISO should be sent back to the International Organization for Standardization.
e) Quality plan is required according to clause no 7.1.
20. Which answer is **correct**?
- a) QMR should be appointed by customer.
b) "Supplier" in ISO9001:1994 means "Organization" in ISO9001:2008
c) The organization does not need to conform to the clause no. 8 if not applicable.
d) Product of the organization that is exported to USA must be registered to ISO.
e) The product of certified organization can be automatically exported to any countries worldwide.
21. Which answer is **correct**?
- a) The process approach is applied solely to production process.
b) SIPOC is referred to the value added process of supplier requirement.
c) The ISO9001 standard must be used within the organization purpose only, it cannot be used for external certification.
d) Supplier plays a significant role in defining requirements as an input to the organization.
e) The ISO9001 and ISO9004 have been developed as a consistent pair of QMS standards.
22. The external party that assesses the organization's ability to meet customer, statutory and regulatory requirements according to ISO standard. It is called.....
- a) Non Government Organization
b) Certification Bodies
c) Accreditation Bodies
d) Subcontractor
e) International Organization for standardization

23. The design and implementation of an organization's quality management system according to the ISO standard is influenced by.....
- Particular objectives
 - Products provided
 - Process employed
 - Size and structure of the organization
 - All above answers are correct.
24. What type of document shows the evidence of QMS performance?
- Quality Procedure
 - Quality Record
 - Quality Plan
 - Quality policy
 - Quality Work Instruction
25. What type of external audit is a routine assessment that required by ISO in order to monitor the ISO9001 conformation of the organization?
- Surveillance audit
 - Certification audit
 - Pre-audit
 - Re-assessment audit
 - Customer audit
26. The application of a system processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the
- Supplier audit action
 - Process approach
 - Re-validation action
 - Certification process
 - System compatibility
27. What department is mainly responsible for Clause no 7.5.4 "Customer property"?
- Production
 - QMR
 - QC
 - Raw material receiving
 - Maintenance
28. Which procedure is not required by this ISO standard?
- Internal audit procedure
 - Corrective action procedure
 - Preventive action procedure
 - Management control procedure
 - Document control procedure
29. Which clause is included in "Act" stage of PDCA loop in ISO9001?
- 8.2.2
 - 7.5.2
 - 6.3
 - 8.5.2
 - 5.3
30. Which clause relates to "Material" in 4M1E?
- 6.3
 - 7.4
 - 6.2
 - 7.5
 - 7.6
31. What type of document shows the scope of the QMS, including detail or



- reference to the documented procedures established for the QMS?
- a) Procedure
 - b) Work Instruction
 - c) Quality Plan
 - d) Quality Manual
 - e) Record
32. Who is directly responsible for ensuring that processes required for QMS are maintained?
- a) DC
 - b) QMR
 - c) Top management
 - d) Middle management
 - e) Supervisor
33. What is the document stating the direction of top management on the organization's quality management?
- a) Quality of Product Requirement
 - b) Quality Management System
 - c) Quality Organization chart
 - d) Quality Policy
 - e) Quality Plan
34. What is **NOT** responsibility of top management stated in ISO 9001?
- a) Establishing quality policy
 - b) Appoint QMR
 - c) Ensuring the quality policy is communicated within the organization
 - d) Establishing quality objective
 - e) Conducting management reviews
35. What is **NOT** included in product requirement required by ISO9001?
- a) The requirement of supplier that supplies raw material to the organization
 - b) Industrial specification specified by the institute that the organization subscribes
 - c) Detail of specification requested by the customer
 - d) The additional requirement stated by organization
 - e) Thai Industrial Standard related to product
36. In which clause, the exclusion can be made?
- a) Clause 4 (Quality management system)
 - b) Clause 5 (Management responsibility)
 - c) Clause 6 (Resource management)
 - d) Clause 7 (Product realization)
 - e) Clause 8 (Measurement, analysis, and improvement)
37. Which procedure is required by ISO9001:2000?
- a) Design and Development Procedure
 - b) Purchasing Procedure
 - c) Marketing Procedure
 - d) Customer Satisfaction Procedure
 - e) Corrective Action Procedure
38. Which clause is not included in "Plan" stage of PDCA loop in ISO9000?
- a) 5.2
 - b) 5.3

- c) 5.4
 - d) 5.5
 - e) 5.6
39. What is the document used to identify the processes needed for the quality management system and the sequences and interaction of these processes?
- a) Business flow
 - b) Business plan
 - c) Quality plan
 - d) Documented procedure
 - e) Quality Manual
40. The quality policy shall be...
- a) Understood by supplier
 - b) Reliable and Public
 - c) Consistent with the organizational purpose
 - d) Appointed by a member of organization
 - e) Established at all functions
41. Which function in the organization is not included in the scope of QMS?
- a) Accounting
 - b) Sales
 - c) Store
 - d) Maintenance
 - e) Marketing
42. Which clause is related to incoming inspection?
- a) 7.4.1
 - b) 7.4.2
 - c) 7.4.3
 - d) 8.3
 - e) 8.2.3
43. What type of record is required by ISO 9001:2008?
- a) Financial record
 - b) Purchasing record
 - c) Quality policy record
 - d) Management responsibility report
 - e) Result of generative action
44. Which clause of ISO9001 states that work instruction shall be available in a process?
- a) 7.4.1
 - b) 7.5.1
 - c) 7.6
 - d) 8.1
 - e) 8.5.2
45. What is the difference between “form” and “record”?
- a) “Form” is used for production but “record” is used for management
 - b) “Form” has specific pattern, but “record” has no pattern
 - c) “Form” shows current status of document, but “record” shows current revision of document
 - d) “Form” is included in the QMS documentation system, but “record” is included in the QMS performance system
 - e) “Form” is controlled by clause 4.2.3, but “record” is controlled by clause 4.2.2

Name Or Code.....

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			The document in ISO9001:2008 should be controlled according to clause 8.5.2.
2			ISO9001:2008 has not changed in term of standard structure however, in this version it refers to principle and vocabulary in ISO9000:2005.
3			QMR is one of the certification bodies that are embedded in the organization to support QMS system.
4			Business flow is the document that the organization has to establish to demonstrate the conformity with the legal requirement.
5			The organization can use the ISO9004 as guidance for establishing quality management system in the organization.
6			In an organization, the transformation of inputs into outputs can be considered as a process.
7			The quality management system according to ISO9001:2008 intends to imply uniformity in the structure of QMS and uniformity of documentation system.
8			The element of clause 8 of ISO9001 that does not affect the organization ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements, shall be excluded.
9			The adoption of a quality management system in an organization should be strategic decision of an organization, so that it can be differ from one organization to another organization.
10			The statutory and regulatory requirements that are applicable to the product of the organization should be considered and included in the organization's product requirements.
11			The organization shall not choose to outsource any processes that affect product conformity requirements.
12			The detail of and justification for any exclusions should be included in quality manual.
13			The organization shall establish quality manual of each product to demonstrate the ability of the organization.
14			The acknowledgement body (AB) is an external party that has an authorization to accredit a certification body to perform ISO certification.
15			The requirement of ISO9001:2008 states that the certification body shall visit the certified organization to access its continual conformity to ISO requirements every three years.

Name : Or 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 35 points. (ห้ามตอบด้วยข้อ)

system	regrade	quality management system	NC product
requirement	product	top management	quality plan
surveillance	specification	management system	QMS
process	job description	prevention of defect	TISI
quality policy	customer audit	quality management	first party audit
AB	procedure	quality planning	quality objective
record	traceability	document controller	pre audit
QMR	quality control	business flow	share vision
CB	organization	TQM	quality manual
customer	preventive action	organizational structure	IQA
correction	corrective action	job specification	NAC
TQA	effectiveness	continual improvement	exclusion
outsource	efficiency	nonconformity	quality assurance

no	Answer	Description
1		need or expectation that is stated, generally implied or obligatory
2		Yearly visit of CB.
3		system to establish policy and objectives and to achieve those objectives
4		management system to direct and control an organization with regard to quality
5		overall intentions and direction of an organization related to quality as formally expressed by top management
6		something sought, or aimed for, related to quality
7		The document describes the qualification of personnel needed for a particular job.

Name : Or code.....

no	Answer	Description
8		person or group of people who direct and controls an organization at the highest level
9		coordinated activities to direct and control an organization with regard to quality
10		part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfill the quality objectives
11		part of quality management focused on fulfilling quality requirements
12		part of quality management focused on providing confidence that quality requirements will be fulfilled
13		recurring activity to increase the ability to fulfill requirements
14		extent to which planned activities are realized and planned results achieved
15		group of people and facilities with an arrangement of responsibilities, authorities and relationships
16		arrangement of responsibilities, authorities and relationships between people
17		organization or person that receives a product
18		set of interrelated or interacting activities which transforms inputs into outputs
19		result of a process
20		specified way to carry out an activity or a process
21		ability to trace the history, application or location of that which is under consideration
22		non-fulfillment of a requirement
23		action to eliminate the cause of a potential nonconformity or other undesirable potential situation
24		action to eliminate the cause of a detected nonconformity or other undesirable situation
25		action to eliminate a detected nonconformity
26		alteration of the grade of a nonconforming product in order to make it conform to requirements differing from the initial ones



Name : Or code.....

no	Answer	Description
27		His or her function is to control records disposition.
28		document stating requirements
29		document specifying the quality management system of an organization
30		document specifying which procedure and associated resources shall be applied by whom and when to a specific project , product , process or contract
31		document stating results achieved or providing evidence of activities performed
32		The organization that monitors the performance of certification body.
33		The products that are not conform to the product requirement.
34		The keyword of TQA.
35		The second party audit.



Name : Or code.....

Part 4 Answer all questions. Total score for this part is 35 points.

1. Identify ISO9001:2008 clauses relating to these following topics in IE or MfE curriculum (5 points). Select only **one clause (most suitable one)** in each question.

No.	Subject	Clause no. in ISO9001:2000
1	Maintenance Engineering	
2	Work study	
3	Safety and Environmental Engineering	
4	Inventory control	
5	Engineering Statistics	

2. How can you apply “P-D-C-A” to improve your study? (5 points)

3. From your assignment (Task1: Thai Industrial Standard), what is your submitted standard? Describe product requirement of the submitted product. (5 points)



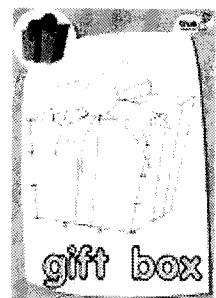
Name : Or code.....

4. Relate to the group assignment and workshop (Chili Company), please answer these following questions. (15 points)
- a) What is your position in your company?
 - b) What is your responsibility in this position?
 - c) According to ISO9001:2008 requirement, which clause is related to your duty?
 - d) What is the policy of your company?
 - e) What is the KPI related to your responsibility?
 - f) What is your product requirement and specification?



Name : Or code.....

5. Your recommendation and suggestion on the activities in LMS to improve teaching and learning activities for this course. (5 points)



Wishing you good times, good health and good cheer
for the New Year 2010,
Dr. Klangduen Pochana.

Handwritten signature of Dr. Klangduen Pochana.