Prince of Songkla University

The Faculty of Engineering

Final Examination Semester 2 **Academic Year 2006**

Date : February 19, 2007. **Time : 9:00-12:00**

Subject : 225-468 Quality Engineering **Room : A401**

Name : .....

Student code : .....

Part	1	2	3	4	Total
Full score	**20**	**15**	**15**	**40**	**90**
Score					

<u>คำสั่ง</u>

1. นำเอกสารเข้าห้องสอบได้ ห้ามยืมเอกสารและสิ่งของใดๆ
2. นำ Dictionary และ เครื่องคิดเลข เข้าห้องสอบได้
3. ใช้ดินสอได้ แต่ต้องเขียนให้อ่านได้ชัดเจน
4. ให้ทำในกระดาษคำตอบเท่านั้น ตอบนอกกระดาษ คำตอบไม่มีคะแนน
5. เขียน ชื่อ <u>หรือ</u> รหัส ในกระดาษคำตอบทุกหน้าก่อนเริ่มทำ เพื่อป้องกันความสับสน ในกรณีกระดาษคำตอบหลุดจากฉบับ

ทุจริตในการสอบ โทษขั้นต่ำปรับตกในรายวิชานั้น และพักการเรียน 1 ภาคศึกษา

Dr. Klangduen Pochana

Name :.....

Part 1 : Select best answer from each following question and fill in the answer in the answer sheet given in page #5. Each question has 1 point. Total score for this part is 20 points.

1. What type of document shows the scope of the QMS, including details of and justification for any exclusions?

a) Procedure
b) Work Instruction
c) Quality Plan
d) Quality Manual
e) Record

2. Who is responsible for reporting to top management on the performance of QMS?

a) Middle manager
b) QMR
c) MD
d) Lower manager
e) Supervisor

3. What type of organization is not applicable to ISO 9001:2000?

a) Hospital
b) Bank
c) School
d) Fund Broker
e) No correct answer

4. What type of record is not required by ISO 9001:2000?

a) Financial record
b) Training record
c) Management review report
d) Result of prevention action
e) No correct answer

5. What type of audit is required to certify ISO9001:2000?

a) First party audit
b) Second party audit
c) Third party audit
d) Internal quality audit
e) No correct answer

6. What does the organization firstly do when product requirements are changed?

a) Preventive action
b) Relevant document are amended
c) Improvement of the quality of product
d) Set up new quality objective or target
e) Personnel affecting quality of product must be trained

7. 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)

Name :.....

8. What ISO standard explains guidance for improvement of the QMS?

a) ISO 9000:2000

b) ISO 9001:2000

c) ISO 9002:2000

d) ISO 9003:2000

e) ISO 9004:2000

9. What should be effectively communicated to customer?

a) customer complaints

b) contract amendments

c) customer feedback

d) product information

e) All above answers are correct

10. What should be included in design input?

a) reference product acceptance criteria

b) any problems and propose necessary actions

c) appropriate information for production

d) applicable statutory and regulatory requirements

e) results of verification

11. Who is responsible for distribution of document to the point of use?

a) CAR

b) MD

c) DC

d) NC

e) IQA

12. Who is responsible for stating quality policy?

a) CAR

b) MD

c) DC

d) NC

e) IQA

13. Which answer is correct?

a) Quality plan is the first level of quality document.

b) Product traceability is not necessary for food industry.

c) Identification of product has to be performed only after testing process is made.

d) Quality plan is established according to clause no. 7.1.

e) In clause no. 7.2, organization has to establish business plan.

14. Which answer is correct?

a) PA is mostly done after the occurrence of actual NC.

b) IQA is a second party audit.

c) Customer satisfaction is normally evaluated by production department.

d) After IQA, QMR has to correct all CARs within 1 week.

e) CA includes the prevention of recurrence of found NC.

Name :.....

15. What should be done when NC is found during IQA?
    a) QMR has direct responsibility to correct that NC.
    b) Lead auditor corrects that NC immediately.
    c) Person responsible for that area is responsible for correcting that NC
    d) NC has to be proved by top management before issuing to auditee.
    e) Urgently correct document relating to NC.

16. Which action demonstrates good control of document?
    a) Document is approved before issuing.
    b) Document is distributed to point of use.
    c) Change of document is identified.
    d) Document is legible.
    e) All answers are correct.

17. What should be included in product requirement?
    a) Regulation relating to product
    b) Customer satisfaction
    c) Preventive action
    d) Quality of IQA
    e) Quality improvement

18. What is AVL?
    a) Acceptance of quality level of vendor after purchasing process has been made.
    b) List of suppliers that have been approved for purchasing.
    c) Level of suppliers that organization approved.
    d) Value of acceptance level of quality.
    e) Vendor level that organization wants to contract.

19. Which type of document describes how a specific work is done?
    a) Quality manual
    b) Procedure
    c) Work instruction
    d) Document from external source of origin
    e) Record

20. What should be done if customer property is damage and unable to use for intended purpose?
    a) Fix it immediately
    b) Inform customer
    c) Buy a new one
    d) Use something similar
    e) Report to IQA to inspect it before doing anything

Name :.....

Answer Sheet for Part 1 :

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

Q #	A	B	C	D	E	Q #	A	B	C	D	E
1						16					
2						17					
3						18					
4						19					
5						20					
6											
7											
8											
9											
10											
11											
12											
13											
14											
15											

Name :.....

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 has to establish ISO system by himself.
2			The integrity of the QMS is maintained when changes to QMS are planned and implemented.
3			A process approach emphasizes the important of continual improvement of processes based on objective measurement.
4			ISO9001:2000 is the second edition.
5			ISO9001:2000 has been aligned with ISO14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.
6			To prevent of unintended use of obsolete documents, the retention time of document has to be identified.
7			Validation of processes must be performed where the resulting output cannot be verified by subsequent monitoring or measurement.
8			Records of the results of calibration and verification shall be maintained according to clause no. 4.2.3.
9			The function of warehouse relates to clause no. 7.5.5
10			The responsibilities and authorities for design and development shall be determined during design and development review.
11			ISO9001:2000 must be officially approved by the Minister of Industry before being used in Thailand.
12			In ISO9000 series version 2000, the ISO9002, ISO9003 and ISO9004 are excluded.
13			In ISO9001:2000 standard, the term "product" applies exclusively to tangible product.
14			The documentation in this ISO9001:2000 standard can be in any form or type of medium.
15			Traceability must be done in each step of product realization process.

Name :.....

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.

Q#	Explanations	Words or terms
1	It has to be done to ensure that the equipments used for monitoring and measurement are accurate.	
2	Overall intentions and direction of an organization as formally expressed by top management.	
3	Non- fulfillment of a requirement.	
4	Action that conduct at planned intervals to determine whether the QMS conforms to the ISO9001:2000 and is effectively implemented and maintained.	
5	Action to eliminate the cause of a potential nonconformity.	
6	Recurring process of enhancing the QMS in order to achieve improvements in overall performance consistent with the organization's quality policy.	
7	Action to demonstrate the ability of the processes to achieve planned results, where deficiencies become apparent only after the product is in use.	
8	How the Personnel are concerned of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.	
9	One of the measurements of the performance of the QMS that the organization shall monitor to receive customer perception.	
10	The international standard that describes fundamentals and vocabulary of quality management systems.	
11	The term in ISO9001:1994 that was 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 states the justification of exclusion made in the QMS.	
14	The document describes the responsibilities relating to personnel's jobs.	
15	The document states the detail of non-conformity found during the internal audit.	

Name :.....

Part 4 : Answer all questions. Total score for this part is 40 points.

1. What should be done when an NC product was found? (2 points)

2. What is the difference between design validation and design verification? (2 points)

3. What is the quality record required in purchasing? (2 points)

4. What are the steps of the subcontractor evaluation process? (2 points)

5. What is the difference between "identification" and "traceability"? (2 points)

Name :.....

6. From your plant visits in both factories (Siam Sempermed and CP), **select only one factory** which is your most favorite. Explain and discuss the quality management system of that factory. (5 points)

7. From your homework (establishment of QMS for Chili factory), explain your work that you have submitted via VCR on your own account. What is your work in detail? What are the academic difficulties when you did this work and how did you overcome them? (5 points)

Name :.....

8. Supposed that our IE department wants to establish quality management system that conforms to ISO9001:2000. Answer these following questions with **enough explanations**. (20 points)

8.1 What is the "product"? (3 points)

8.2 What is "design and development inputs"? (3 points)

8.3 What is "customer property"? (3 points)

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Name :.....

8.5 What is "NC product"? (3 points)

8.4 Give example of monitoring and measurement devices that are needed to control according to clause no 7.6 (4 points)

8.6 Give example of "preventive action" (4 points)

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