

KATHMANDU UNIVERSITY
End Semester Examination
March/April, 2017

Marks Scored:

Level : B.Tech.
Year : IV

Course : BIOT 403
Semester: I

Exam Roll No. :

Time : 30 mins.

F. M. : 20

Registration No. :

Date : MAR 30 2017

SECTION "A"

[20 Q. × 0.75=15 marks]

1. ISO 22000 standard required
 - a. Team Leader
 - b. Administrator
 - c. Engineer
 - d. Food Safety Specialist (as the Team Member)
2. Verification activities are involved in
 - a. ISO 9000
 - b. ISO 9001
 - c. ISO 22000
 - d. ISO 14001
3. Which one of the following is related to laboratory?
 - a. ISO 22000
 - b. ISO 14000
 - c. ISO 9004
 - d. ISO 17025
4. Which of the following ISO standard is used for certification of food safety?
 - a. ISO 9001
 - b. ISO 22000
 - c. ISO 14001
 - d. ISO 9004
5. Which ISO standard is used for performance improvement of the enterprise?
 - a. ISO 9001
 - b. ISO 9004
 - c. ISO 17025
 - d. ISO 9002
6. Which one of the international body is involved in the definition of HACCP?
 - a. International Association of Sanitarians
 - b. Codex Alimentarius
 - c. International Association of Food Safety
 - d. Food and Drug Administration
7. Which organization is responsible for deciding Deming Award?
 - a. ISO
 - b. UNIDO
 - c. JUSE
 - d. UNCTAD
8. The portion of defectives (fraction rejected) is given by
 - a. p chart
 - b. np chart
 - c. c chart
 - d. u chart
9. The letters SOPs stand for
 - a. Standard operating practices
 - b. Standard operating procedures
 - c. Standard operational practices
 - d. Sanitation operational principles

10. Why is milk pasteurized?
- a. Because it is virtually a sterile product
 - b. Because it is a nutritious food
 - c. To destroy microorganisms that can cause souring
 - d. Because most milking handling creates opportunities for contamination
11. Total quality is defined as 'conformance to requirements' by
- a. Joseph Juran
 - b. Edward Deming
 - c. Philip Crosby
 - d. Kaoru Ishikawa
12. In TQM Transition Model, planning process is related to
- a. Quality Metrics
 - b. Benchmarking
 - c. Creativity
 - d. PDCA
13. Which of the following is not associated with the hazard analysis portion of the HACCP program?
- a. A review of the menu to identify potential hazards
 - b. A risk assessment of both the likelihood that hazards will occur and their severity if they do occur
 - c. A series of questions use to facilitate the identification of potential problems in each step in the flow of food
 - d. The identification of critical control points whereby hazards can be prevented, eliminated, or reduced to acceptable level
14. The ultimate success of a HACCP program depends on
- a. Eliminating potentially hazardous food items from your menu
 - b. Providing proper training and equipment for employees who are implementing HACCP system
 - c. Having HACCP flow charts developed for all food sold by the establishment
 - d. Food establishment managers having sole authority for implementing the HACCP
15. Which of the following is an example of a critical control point?
- a. Poultry and eggs are purchased from approved sources
 - b. Chickens and noodles are heated on the stove until the centre of the product reaches 165F (74 C) for 15 secs.
 - c. Only pasteurized milk is used by the establishment
 - d. The cutting board is washed and sanitized between chopping carrots and cucumbers for preparing salad
16. Which of the following bacteria produce toxin that is most likely to cause death if consumed?
- a. *Campylobacter jejuni*
 - b. *Clostridium botulinum*
 - c. *Shiga-toxin producing Escherichia coli*
 - d. *Listeria monocytogens*

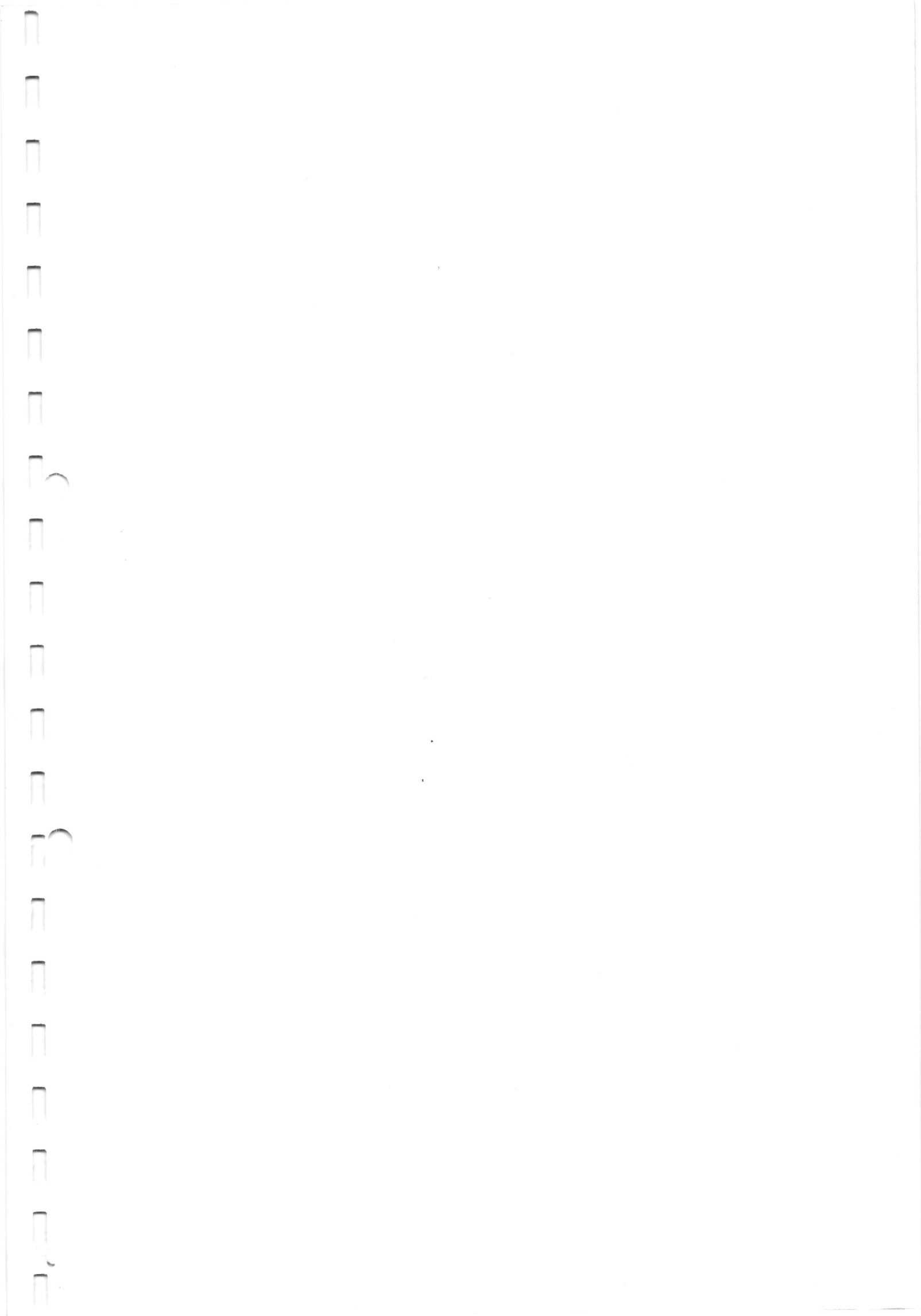
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17. The best way to encourage employees to wash their hands when needed is to
 - a. Provide separate restrooms for employees and the customers
 - b. Provide properly equipped hand washing stations convenient to work areas
 - c. Provide hand sanitizers instead of hand washing lavatories in food-preparation area
 - d. Put up a sign in the employee locker room reminding them the importance of hand washing
18. The most effective way to control growth of bacteria in a food establishment is by controlling
 - a. Time and temperature
 - b. pH and oxygen conditions
 - c. Temperature and water activity
 - d. Time and food availability
19. What factor has the greatest influence on where people choose to eat or shop for food?
 - a. Cost of the food
 - b. Nutrition of food
 - c. Quality of Service
 - d. Cleanliness of food and facilities
20. Who has developed 'Company-wide Quality control'?
 - a. Juran
 - b. Shewart
 - c. Ishikawa
 - d. Feigenbaum

SECTION "B"

[10 Q. × 0.5=5 marks]

1. The principle of equivalence between two trading partners is based on-----
2. The preventive approach of spore-forming bacteria (*Bacillus cereus*) is done by-----
3. The relationship between change in brix and acid production during lactic fermentation is shown by-----
4. The distribution of variation in output of penicillin production is preferably indicated by-----
5. The efficiency of beer manufacturing plant is determined by-----
6. The essential feature of ISO 9001:2008 is based on -----
7. In risk management, the Risk Balancing Policies is based on-----
8. The unit of 1000 ppt of pesticides in raw vegetables is indicated by the unit-----
9. International recognition of laboratory report can be achieved by-----
10. The labeling requirements in the packaged medicinal plants products fall under-----



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SECTION "C"

(Long answer questions)

[3 Q.×7=21 marks]

Attempt *ANY THREE* questions:

1. Explain the outlining principles of ISO 9001 Standard that can be applied for certification of biotech products.
2. How can you implement SPS Agreement in exploring export potentiality of Nak Cheese from Nepal to EU market?

3. Case study 1

A recently established Biotech Company started manufacturing products like enzymes (Amylolytic and Glucose Isomerase) which are quite unique and different from other manufactured products in Nepal. The Himalayan Biotech Company was established in 2013, and the industry is in operation since last three years. In the first year, the company optimized various processing conditions in terms of Solid State and Submerged Fermentation. The company could produce only 500 Kg of enzymes to introduce this product in the Nepalese market such as in Pharmaceutical Companies, Food Industries, and traditional brewing sector. The company had to face a lot of issues relating to introduce this product in the domestic market. The traditional Murcha starters were used as a source of enzyme for indigenous breweries. They could neither sell all their products in the local market nor introduce this product in the export market. The enterprise was initiated by young, energetic, and enthusiastic biotech graduates who wanted to get established themselves in the country by creating some innovative approach in biotech area. The company established R & D Centre for developing improved products including diversified various products. Quite surprisingly, R & D Centre could isolate thermophilic Bacillus and yeasts for the company. These strains could increase the yield by 66% than what was being used for the production of enzymes. The enterprise up scaled the manufacturing plant to produce at least 5000 tons of enzymes annually. Now, the enterprise has a lot of uphill tasks to get established in the domestic as well as in international market.

Discuss:

- a. Assess the issues including pros and cons of the products of Himalayan Biotech Company in the existing market situation.
- b. How can this improved enzyme be made popular in domestic as well as in international market?
- c. What marketing strategies you need to explore for promoting this product including sustainability of the product by QFD tool?

4. Case study 2

Mr. Bikash is a manager of Innovative Biotech Company. This company manufactures Vitamin B12 for export. The company was established ten years ago. The total number of employees is 25 from managers to the workers. The industry had provided in-house training to all the employees and therefore they are quite knowledgeable about their work responsibility. The industry had earned good name and fame in the market. The rejection rate was quite negligible. The Union of the employees had been demanding for the wage increase, otherwise they had threatened to go on for indefinite strike. There are four unions and the employees are more or less equally divided. The company manager is a very busy person and manages four other companies located in different countries. He visits this company once in two months and stays there for about 2 days. Surprisingly, the customers have put a few restrictions; they wanted to procure the products only from quality companies. Mr. Bikash has been given the responsibility of sustaining the market share.

Discuss:

1. How do you assess SWOT analysis for resolving the issues of the company?
2. Do you perceive the relevance of cultural changes?
3. How would you suggest strategic planning modality that you recommend?

SECTION "D"

(Short answer questions)

[6 Q.×5=30 marks]

5. What are the key issues in TQM model?
6. How to set up ISO 17025 system in the biotechnology laboratory?
7. What are the essential features of Fish Bone Diagram?
8. Why is Proficiency Testing required in enhancing capacity of laboratory output?
9. What are the seven habits of effective people?
10. How is control chart implemented in process control of manufacturing biotech industry?

SECTION "E"

11. Distinguish between. (Any TWO) [2 Q.×2=4]
 - a. Hazard characterization and Risk characterization
 - b. System Audit and Process Audit
 - c. Horizontal and Vertical Standard