

# BME4103: BIO-SAFETY AND RISK ASSESSMENT

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## Effective Term

Semester A 2024/25

## Part I Course Overview

### Course Title

Bio-safety and Risk Assessment

### Subject Code

BME - Biomedical Engineering

### Course Number

4103

### Academic Unit

Biomedical Engineering (BME)

### College/School

College of Engineering (EG)

### Course Duration

One Semester

### Credit Units

3

### Level

B1, B2, B3, B4 - Bachelor's Degree

### Medium of Instruction

English

### Medium of Assessment

English

### Prerequisites

Nil

### Precursors

Nil

### Equivalent Courses

Nil

### Exclusive Courses

Nil

## Part II Course Details

### Abstract

Introduction to biosafety and medical device regulations. Overview of the biosafety work practices, equipment, and facilities for the safe and secure handling of dangerous pathogens in a laboratory setting. Related topics can be discussed,

such as rules and regulations for biolaboratory, medical devices and medical technology. Risk Assessment and Management are discussed to involve identifying, analyzing, and responding to risk factors, risk assessment focuses on detecting biohazards and analyzing all potential risks in biological laboratory, medical devices and medical technology.

### Course Intended Learning Outcomes (CILOs)

CILOs		Weighting (if DEC-A1 DEC-A2 DEC-A3 app.)			
1	Describe the basic concepts of biosafety and lab safety work practice		x		
2	Analyze relevant knowledge and technologies (including lab equipment and facility design) for safe biological laboratory to handle bio-related hazards			x	
3	Analyze relevant knowledge in rules and regulations for biosafety and medical device regulations			x	
4	Integrate the principles of biosafety, and medical device safety to analyze some practical problems			x	x
5	Demonstrate reflective practice in an engineering context using Risk Assessment and Management			x	x

#### A1: Attitude

Develop an attitude of discovery/innovation/creativity, as demonstrated by students possessing a strong sense of curiosity, asking questions actively, challenging assumptions or engaging in inquiry together with teachers.

#### A2: Ability

Develop the ability/skill needed to discover/innovate/create, as demonstrated by students possessing critical thinking skills to assess ideas, acquiring research skills, synthesizing knowledge across disciplines or applying academic knowledge to real-life problems.

#### A3: Accomplishments

Demonstrate accomplishment of discovery/innovation/creativity through producing /constructing creative works/new artefacts, effective solutions to real-life problems or new processes.

### Learning and Teaching Activities (LTAs)

LTAs	Brief Description	CILO No.	Hours/week (if applicable)	
1	Lecture	Explain key concepts about various biosafety levels and hazardous conditions, laboratory safety and control.	1, 2, 3, 4, 5	3 hrs/week for 12 weeks
2	Tutorial	To discuss some biosafety problems and questions as well as identify a group-based project.	3, 4, 5	3 hrs/week for 1 week

3	Group-based Project	Students will have the opportunity to participate in the learning tasks of the mini-project activities. For the mini-project, a brief outline of the work topic(s), effective team work and expected presentation and report-writing will be provided emphasizing opportunities for discovery and innovation inherent in this student activity.	3, 4, 5	
4	Laboratory Work	Group activities which involve various laboratory sessions related to Biosafety.	1, 2, 3, 4	3 hrs/week for 1 week

**Assessment Tasks / Activities (ATs)**

ATs	CILO No.	Weighting (%)	Remarks (e.g. Parameter for GenAI use)
1	Mid-term Test	1, 2	10
2	Mini-project	2, 3, 4	20
3	Assignment	1, 2	10
4	Lab Report	3, 4	10

**Continuous Assessment (%)**

50

**Examination (%)**

50

**Examination Duration (Hours)**

1.5

**Additional Information for ATs**

For a student to pass the course, at least 30% of the maximum mark for both coursework and examination should be obtained.

**Assessment Rubrics (AR)****Assessment Task**

Mid-term Test

**Criterion**

Ability to Explain the basic concepts of biosafety and work practice.

**Excellent (A+, A, A-)**

High

**Good (B+, B, B-)**

Significant

**Fair (C+, C, C-)**

Moderate

**Marginal (D)**

Basic

**Failure (F)**

Not even reaching marginal levels

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**Assessment Task**

Mini-project

**Criterion**

Capacity for Self-directed Learning to understand the principles, methodology and applications of bio-safety and control.

**Excellent (A+, A, A-)**

High

**Good (B+, B, B-)**

Significant

**Fair (C+, C, C-)**

Moderate

**Marginal (D)**

Basic

**Failure (F)**

Not even reaching marginal levels

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**Assessment Task**

Assignment

**Criterion**

Ability to Explain the basic concepts of biosafety and medical device regulations.

**Excellent (A+, A, A-)**

High

**Good (B+, B, B-)**

Significant

**Fair (C+, C, C-)**

Moderate

**Marginal (D)**

Basic

**Failure (F)**

Not even reaching marginal levels

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### **Assessment Task**

Lab Report

#### **Criterion**

Ability to Explain the methodology and procedures of various experimental works for biosafety and medical device regulations.

#### **Excellent (A+, A, A-)**

High

#### **Good (B+, B, B-)**

Significant

#### **Fair (C+, C, C-)**

Moderate

#### **Marginal (D)**

Basic

#### **Failure (F)**

Not even reaching marginal levels

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### **Assessment Task**

Examination

#### **Criterion**

Ability to Explain in Detail various issues and technical aspects of biosafety and medical device regulations.

#### **Excellent (A+, A, A-)**

High

#### **Good (B+, B, B-)**

Significant

#### **Fair (C+, C, C-)**

Moderate

#### **Marginal (D)**

Basic

#### **Failure (F)**

Not even reaching marginal levels

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## **Part III Other Information**

### **Keyword Syllabus**

- Biosafety: biological safety level, risk group
- Biohazard
- Rules and Regulations for biosafety and medical devices
- Risk Assessment and Management

**Reading List****Compulsory Readings**

Title	
1	Fleming, Diane O. and Hunt, Debra A., Biological Safety: Principles and Practices, Amer Society for Microbiology, 4th Edition, 2006.
2	Burnette, Ryan, Biosecurity: Understanding, Assessing, and Preventing the Threat, Wiley, 2013.
3	Seeram Ramakrishna, Lingling Tian, Charlene Wang, Susan Liao, Wee Eong Teo, Medical Devices: Regulations, Standards and Practices, 2005

**Additional Readings**

Title	
1	Nil