UNIVERSITI TEKNOLOGI MARA

BMS533: BIORISK MANAGEMENT

Course Name (English)	BIORISK MANAGEMENT APPROVED
Course Code	BMS533
MQF Credit	2
Course Description	The course covers the principles, practices, equipment and facilities for safe and secure handling of microbes especially pathogens and living modified microorganisms in a laboratory setting. Various components of laboratory biosafety and biosecurity and the concept of risks, hazards and methods for conducting biosafety and biosecurity risk assessment will be discussed. Issues on biosafety and biosecurity will also be highlighted.
Transferable Skills	Risk assessment for biological hazards Risk mitigation for biological hazards
Teaching Methodologies	Lectures, Blended Learning, Lab Work, Demonstrations, Practical Classes
CLO	CLO1 Describe the concepts of biosafety, biosecurity, biorisk management and relate to applicable regulations, standards and guidelines CLO2 Discuss risk assessment and risk mitigation measures for the handling, containment and deactivation of biological agents based on risk analysis CLO3 Demonstrate skills for measuring and continuous improvement of biorisk management in the laboratory
Pre-Requisite Courses	No course recommendations

Topics
1. Introduction to biorisk management 1.1) Principle of biosafety and biosecurity 1.2) Historical aspects
2. Regulations and guidelines 2.1) WHO and BMBL guidelines 2.2) The Bioweapon and Toxin Act 2.3) The Biosafety Act 2007 and the Cartagena Protocol 2.4) The CWA 12953 document 2.5) Other relevant regulations, guidelines and standards
3. Hazard identification and characterization 3.1) Biological hazards 3.2) Agent-based hazards 3.3) Procedure -based hazards 3.4) Factors that increase hazards 3.5) Hazard characterization
4. Risk Assessment 4.1) Hazard and Risk 4.2) Likelihood and Consequence 4.3) Risk matrices 4.4) Biosafety risk assessment
5. Risk mitigation - Administrative controls 5.1) Definition 5.2) Policy, regulations and guidelines 5.3) Administrative committees 5.4) Medical surveillance 5.5) Education and Training 5.6) Standard Operating Protocols

6. Risk mitigation - Engineering controls 6.1) Biosafety classification for biological hazards 6.2) Biosafety levels 6.3) Laboratory layouts 6.4) Biological Safety Cabinets
7. Risk mitigation - Personnel Protective Equipments 7.1) Types 7.2) Respiratory protection 7.3) Donning and Doffing
8. Decontamination, Waste management and Transport 8.1) Disinfectant and decontamination 8.2) Validation of decontamination effectiveness 8.3) Waste segregation and management 8.4) Packaging biological hazardous materials 8.5) Transport of biohazard materials
9. Measuring Performance 9.1) Documentation and archive 9.2) Monitoring, Inspection and Audits 9.3) Performance Indicators
10. Biosecurity 10.1) Biosecurity threats 10.2) Biosecurity risk assessment 10.3) Conrols and measures for biosecurity 10.4) Dual-use-of-concern and Select Agents 10.5) Data security

Assessment Breakdown	%
Continuous Assessment	60.00%
Final Assessment	40.00%

Details of Continuous Assessment

Assessment Type	Assessment Description	% of Total Mark	CLO
Case Study	Case study on performance	20%	CLO3
Lab Exercise	Laboratory reports for risk mitigation	20%	CLO2
Test	Test 1	20%	CLO1

Reading List

Recommended Text

- **World Health Organization 2004, *Laboratory Biosafety Manual*, 3rd Ed. Ed., World Health Organization [ISBN: 9241546506]**
- **CDC/NIH 2009, *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed. Ed., U.S. Department of Health and Human Services**

Reference Book Resources

- **Dawn P. Wooley,Karen B. Byers 2017, *Biological Safety*, 5th ed. Ed., ASM Press [ISBN: 9781555816209]**
- **WHO 2006, *2. Biorisk Management- Laboratory Biosecurity Guidance*, World Health Organization**
- **Reynolds M. Salerno,Jennifer Gaudioso 2015, *Laboratory Biorisk Management*, CRC Press [ISBN: 9781498749749]**
- **Manfred Weidmann,Nigel Silmann,Patrick Butaye,Mandy Elschner 2013, *Working in Biosafety Level 3 and 4 Laboratories*, John Wiley & Sons [ISBN: 9783527675333]**

Article/Paper List

This Course does not have any article/paper resources

Other References

- **PDF OECD *Biosafety and the Environmental Uses of Micro-Organisms* http://dx.doi.org/10.1787/9789264213562- en**
- **PDF European Union centre for Standardisation 2008, *The CEN Workshop Agreement 16393 : 2012 document : Laboratory biorisk management - Guidelines for the implementation of CWA 15793:2008* , Cen De Normalization https://www.cdc.gov.tw/downloadfile.aspx ?fid=49B44973866FEC44**