Roll No.										

ANNA UNIVERSITY (UNIVERSITY DEPARTMENTS)
B.E. (Full time) – END SEMESTER EXAMINATIONS, MAY 2025
Biomedical Engineering
Semester - IV
BM23U01 Medical Standards and Regulations
(Regulation 2023)

Duration:3 Hrs **Marks: 100**

Answer ALL questions

CO1	Understand the role of medical ethics and Healthcare standard Organizations.
CO2	Analyze and articulate the various categories of healthcare data standards in medical data interoperability
CO3	Demonstrate the standard processes involved in the design, development and manufacture healthcare devices and e-waste disposal following Functional and Environmental safety norms.
CO4	Comprehend the standards for basic safety, essential performance, validation, risk assessment, testing and calibration for medical devices.
CO5	Understand and articulate the accreditation standards and approval processes involved in the medical device manufacturing facility
CO6	Implement hospital safety, equipment safety, Biomedical waste, its management and disposal as per standards

Part-A (10X2=20)

Q.No.	Questions	Marks	CO	BL
1.	What is IEC, FDA, BIS and CDSCO?	2	1	1
2.	List the four categories of healthcare data standards.	2	2	1
3.	What is the role of UMLS and MeSH in Medicine?	2	2	2
4.	Where do we need HIPPA standard?	2	2	2
5.	How are fire safety protocols handled in an hospital?	2	6	2
6.	How do you ensure radiation safety in a hospital?	2	6	2
7.	What is IEC 61508 standard?	2	3	1
8.	Distinguish between IEC 62304 and IEC 82304.	2	5	2
9.	Name the types of manuals needed for NABL accreditation processes.	2	5	1
10.	Define the terms calibration and uncertainty.	2	5	1

Part-B (5X13=65)

Q.No.			Questions	Marks	CO	BL
11.	a		Why do we need BIS and CDSCO? What are their objectives and primary functions? and justify their role in the context of Indian Medical Device market.	13	1	4
			OR			
	b		Define Medical Ethics and what are its scopes? With suitable illustrations, apply the principles of medical ethics to real world situations and evaluate their role and significance.	13	1	4
12.	a		What is SNOMED CT? What are its purposes and scopes? With suitable illustrations bring out the key features of SNOMED CT with the help of hierarchies, relationships, description logic inferences in solving interoperability issues.	13	2	2
			OR			

	b		What are LOINC standards? What is its structure, anatomy and axes? With suitable illustrations demonstrate its utility in any clinical investigation laboratory.	13	2	2
13.	a		Elaborate the salient features of NABH accreditation process in the light of quality parameters. With an illustration analyse how NABH Digital standards transform conventional NABH to meet the Digital Health standards.	13	6	3
			OR			
	b		How are Biomedical wastes classified? What are their sources? Analyse the processes and guidelines for segregation and disposal as per standards advocated.	13	6	3
14.	a		How are ISO 9001, ISO 13485 and ICMED 13485 Plus related? Analyse the role of each of them in the context of Indian manufacturing industry.	13	5	3
			OR			
	b		What is ISO 14971, ICE 62366 and IEC 62304? Why do we need them? and analyse their roles in the medical device design, development and manufacturing.	13	5	3
15.	a		Define the terms Basic Safety and Essential Performance. What are the various categories of Basic Safety Engineering? With a neat schematic diagram analyse the relationships among IEC 60601, its related and other standards.	13	4	3
			OR			
	b		Define the various metrology terms used in measurements. Analyse the role of ISO / IEC 17025:2017 standards in the context of Testing and Calibration of Medical Devices Laboratory.	13	4	3

Part-C (1X15=15)

Q.No.			Questions	Marks	CO	BL
16.			What standards are required to meet and sustain the environmental safety and e waste management in the context of establishing a medical device industry? Evaluate their roles and relevance.	15	3	5