



University of Nicosia, Cyprus

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| Course Code | Course Title | ECTS Credits |
| BISC-510 | Laboratory Quality Assurance Management | 6 |
| Department | Semester | Prerequisites |
| Life and Health Sciences | Fall | None |
| Type of Course | Field | Language of Instruction |
| Required | Biomedical Sciences | English |
| Level of Course | Year of Study | Lecturer |
| 2 nd Cycle | 1 st | Alkis Papis |
| Mode of Delivery | Work Placement | Co-requisites |
| Face to Face | N/A | None |

Objectives of the Course:

The aim of this course is to discuss clinical laboratory issues related to administration and management and to quality control and quality assurance to enable students to understand and apply methods and tools within quality management and laboratory safety for accreditation purposes and compliance with regulatory agencies.

The main objectives of the course are:

- Explain the role of managing and supervising in a clinical laboratory and the related skills that have to be acquired and practiced in such a setting.
- Demonstrate how safety regulations have to be integrated into clinical laboratory management and practices.
- Demonstrate how to develop protocols for quality assurance purposes, accreditation and maintaining accreditation.
- Demonstrate how to evaluate the quality of testing methods, setting up standards and validate test performance specifications
- Provide guidelines for procedures for calibration and method and equipment performance test specifications verification
- Demonstrate the role of laboratory systems in laboratory data management

Learning Outcomes:

After completion of the course, students will be expected to be able to:

- Discuss the application of total quality management concept in service providing settings.
- Apply methods and techniques for the organization and management of a clinical laboratory.
- Apply risk assessment to support patient care.
- Apply methods for quality assurance including monitoring and evaluating the quality of testing procedures, standardizing operating procedures and establishing reference intervals.
- Apply validation of test performance specifications and compliance
- Explain calibrations and quality control for equipment and reagents.
- Explain the role of supervisor and the role of clinical laboratory scientist in initial accreditation and in maintaining accreditation of a clinical laboratory
- Discuss the importance of information for sustainable quality work
- Describe the role of laboratory systems in laboratory data management.
- Integrate safety regulation into clinical laboratory management and practices.
- Describe the ethical principles of providing clinical laboratory services

Course Contents:

1. Organization and Management: Definition, concepts and function of total quality management. Quality principles
2. Risk management: Establish laboratory's processes (pre-examination, examination and post-examination processes) and apply the principles of risk management to the cycle of laboratory medical care
3. Administration; Laboratory design and organization, Personnel management and code of contact, leadership and communication
4. Management of laboratory resources (Time, space, equipment, supplies)
5. Management of laboratory data and budget.
6. Safety in the Laboratory: source of hazards, safety and infection preventing measures. Waste management.
7. Quality Assurance: Definition and purposes of QA. Internal quality control. Westgard rules
8. External quality control (interlaboratory comparison programmes). Control of referral laboratories.
9. Methods and tools for QA and improvements. Evaluation and audits
10. Validity and appropriateness of pre-examination, examination and post-examination processes (sample collection, transport and sample handling, recording and reporting)
11. Validation and verification of analytical procedure (test methods)
12. Evaluation of results. Reporting and releasing of results. Report contents.
13. Traceability of measurements and calibrations to relevant standards. Suitability, calibration and maintenance of test equipment
14. Laboratory information management
15. Research and development; Intellectual property rights; application of appropriate ethics

PRACTICAL EXERCISES:

1. Within a virtual laboratory setting apply the concepts of Laboratory organizational, needs and of Total Quality Management (TQM).
2. Given a personnel problem situation, apply personnel competence assessment and performance to established criteria.
3. Given specific problems, to apply and evaluate external quality control and control on referral laboratories.
4. Given specific problems, to apply internal quality control of analytical procedures (test methods).
5. Given specific problems to apply an audit to an area of a laboratory.
6. Given specific situations, prepare a laboratory budget, including direct and indirect costs, instrument evaluation and cost analysis.
7. Apply verification of analytical procedures (test methods).
8. Write a laboratory procedure and work instruction according to ISO 15189 guidelines.

Learning Activities and Teaching Methods:

Lectures; problem based learning, poster and/or oral presentations of forms and documents required for Laboratory Management and for QA/Laboratory Accreditation. The lecturer will be introducing each topic through lectures and problem based learning sections with individual tasks related to Quality Assurance and Quality Control in Laboratory setting.

Assessment Methods:

Assignments, Tests and Mid-term Exam/Paper; Final Exam

Required Textbooks/Reading:

| Authors | Title | Publisher | Edition | ISBN |
|---------|--|-----------|---------|---|
| ISO | ISO 15189:2012 -- Medical laboratories - Requirements for quality and competence | ISO | 2012 | CYS Cyprus Organisation for Standardisation www.cys.org.cy email: cystandards@cys.org.cy tel: 22 411 411 |

Recommended Textbooks/Reading:

| Authors | Title | Publisher | Edition | ISBN |
|--------------------|--|--------------------|------------------------------|---|
| ISO | ISO 15190:2003 : Medical laboratories -- Requirements for safety | ISO | 2003 | CYS Cyprus Organisation for Standardisation www.cys.org.cy email: cystandards@cys.org.cy tel: 22 411 411 |
| ISO | ISO TS 22367:2010 Medical laboratories -Reduction of errors through risk management and continual improvement” - -- Recommended | ISO | 2010 | CYS Cyprus Organisation for Standardisation www.cys.org.cy email: cystandards@cys.org.cy tel: 22 411 411 |
| Kenneth N. Parson | LABORATORY QUALITY/MANAGEMENT : A Workbook with an Eye on Accreditation Paperback | XLIBRIS | December 29, 2012 | ISBN-10: 1479753947 ISBN-13: 978-1479753949 |
| Donald C. Singer | A Laboratory Quality Handbook of Best Practices & Relevant Regulations Paperback – April 1, 2001 | ASQ Quality Press | (April 2001) | ISBN-10: 087389491X ISBN-13: 978-0873894913 |
| Jane Hudson | Principles of Clinical Laboratory Management: A Study Guide and Workbook [Paperback] | Prentice Hall; | 1 edition (October 25, 2003) | ISBN-10: 0130495387 ISBN-13: 978-0130495389 |
| Lionel A. Varnadoe | Medical Laboratory Management and Supervision, 2nd Edition Hardcover | Lionel A Varnadoe; | 2nd edition (2008) | ISBN-10: 1605855472 ISBN-13: 978-1605855479 |