



CBMS861

Laboratory Quality Systems

S2 Evening 2019

Dept of Molecular Sciences

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General Information

Unit convenor and teaching staff

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Credit points

4

Prerequisites

Admission to MLabQAMgt or GradDipLabQAMgt or GradCertLabQAMgt or MRadiopharmSc or MSc or MBiotech or MBioBus or MScInnovation

Corequisites

Co-badged status

CBMS761

Unit description

This unit covers topics and concepts central to the successful implementation of quality within analytical testing laboratories. Topics include coverage of various quality management system standards such as ISO 17025, ISO 15189, ISO 9000 and GLP, the reasons for implementing such standards and their requirements with respect to laboratory practices, as well as the accreditation process through agencies such as the National Association of Testing Authorities.

Important Academic Dates

Information about important academic dates including deadlines for withdrawing from units are available at <https://www.mq.edu.au/study/calendar-of-dates>

Learning Outcomes

On successful completion of this unit, you will be able to:

Analyse the requirements of international standards ISO/IEC 17025, ISO 15189, ISO 9000 and the OECD Principles of Good Laboratory Practice.

Prepare and maintain quality documentation.

Develop a quality management system

Critically analyse/evaluate an existing quality management system for the purpose of

quality improvement.

Communicate the elements of a good quality management system to management and staff in their own facility.

Understand, at an advanced level, technical management concepts including test methods, method selection, verification of methods, validation of methods, uncertainty of measurement, calibration and traceability.

Enhance customer service and the experience of interested parties through the use of quality improvement techniques and processes.

Assessment Tasks

Name	Weighting	Hurdle	Due
<u>Assignment 1</u>	10%	No	6 pm, Tuesday 13 August
<u>Assignment 2</u>	10%	No	6 pm, Tuesday 20 August
<u>Assignment 3</u>	10%	No	6 pm, Sunday 22 September
<u>Mid Session Test</u>	10%	No	11:59 pm Sunday 22 September
<u>Assignment 4</u>	20%	No	6 pm, Tuesday 15 October
<u>Assignment 5</u>	40%	No	6 pm, Friday 22 November

Assignment 1

Due: **6 pm, Tuesday 13 August**

Weighting: **10%**

Quality principles, policy and objectives

On successful completion you will be able to:

- Analyse the requirements of international standards ISO/IEC 17025, ISO 15189, ISO 9000 and the OECD Principles of Good Laboratory Practice.
- Prepare and maintain quality documentation.
- Develop a quality management system
- Communicate the elements of a good quality management system to management and staff in their own facility.

Assignment 2

Due: **6 pm, Tuesday 20 August**

Weighting: **10%**

This assessment task will consist of a series of hypothetical problem questions on the topics of impartiality, risk management and structural requirements for a laboratory organisation.

On successful completion you will be able to:

- Analyse the requirements of international standards ISO/IEC 17025, ISO 15189, ISO 9000 and the OECD Principles of Good Laboratory Practice.
- Prepare and maintain quality documentation.
- Develop a quality management system
- Enhance customer service and the experience of interested parties through the use of quality improvement techniques and processes.

Assignment 3

Due: **6 pm, Sunday 22 September**

Weighting: **10%**

Laboratory Processes

On successful completion you will be able to:

- Analyse the requirements of international standards ISO/IEC 17025, ISO 15189, ISO 9000 and the OECD Principles of Good Laboratory Practice.
- Prepare and maintain quality documentation.
- Develop a quality management system
- Understand, at an advanced level, technical management concepts including test methods, method selection, verification of methods, validation of methods, uncertainty of measurement, calibration and traceability.
- Enhance customer service and the experience of interested parties through the use of quality improvement techniques and processes.

Mid Session Test

Due: **11:59 pm Sunday 22 September**

Weighting: **10%**

The exam will consist of 15 multiple choice questions. Each question of the exam consists of a laboratory scenario, based on real life situations. For each scenario/question you will be required

to identify the relevant clause(s) or sub-clause(s) in ISO/IEC 17025 which you believe most specifically address the scenario.

The exam will be completed on-line on the iLearn site and will be released on Monday 9 September and access will close at 11:59 pm on Sunday 15 September. You may only make one attempt at the exam.

On successful completion you will be able to:

- Analyse the requirements of international standards ISO/IEC 17025, ISO 15189, ISO 9000 and the OECD Principles of Good Laboratory Practice.
- Critically analyse/evaluate an existing quality management system for the purpose of quality improvement.

Assignment 4

Due: **6 pm, Tuesday 15 October**

Weighting: **20%**

Management System problem questions

On successful completion you will be able to:

- Analyse the requirements of international standards ISO/IEC 17025, ISO 15189, ISO 9000 and the OECD Principles of Good Laboratory Practice.
- Prepare and maintain quality documentation.
- Develop a quality management system
- Enhance customer service and the experience of interested parties through the use of quality improvement techniques and processes.

Assignment 5

Due: **6 pm, Friday 22 November**

Weighting: **40%**

For assignment 5 you have the option of selecting 2 plus 1 compulsory assessment task from a total of 5 possible assessment tasks. Topics covered include:

Quality Control Charts, Laboratory Records, OECD Principles of Good Laboratory Practice, Preparing for Accreditation, Laboratory Assessment - A Case Study.

On successful completion you will be able to:

- Analyse the requirements of international standards ISO/IEC 17025, ISO 15189, ISO 9000 and the OECD Principles of Good Laboratory Practice.

- Prepare and maintain quality documentation.
- Develop a quality management system
- Critically analyse/evaluate an existing quality management system for the purpose of quality improvement.
- Understand, at an advanced level, technical management concepts including test methods, method selection, verification of methods, validation of methods, uncertainty of measurement, calibration and traceability.
- Enhance customer service and the experience of interested parties through the use of quality improvement techniques and processes.

Delivery and Resources

Co-badged status

This unit is taught concurrently with CBMS761.

Classes

- **Timetable:** Please check <https://timetables.mq.edu.au/2019/> for the official timetable of the unit. Lectures will be held in [9 Wallys Walk - 102 Theatre](#).
- **Lectures:** There is a one (1) hour lecture per week. The material presented in the lectures is important and you should not assume that all examinable material is available in the prescribed text or the lecture notes. Conversely, do not assume that all examinable material is to be found in the lecture notes.
- **Tutorial:** A weekly two (2) hour POGIL style tutorial/workshop session will immediately follow the lectures.
- **Laboratory Work:** There is no laboratory work in this unit.

Attendance

Attendance of all lectures and tutorials is **strongly** recommended.

Technology Used

Use will be made of literature search tools, such as the library's catalogue and MultiSearch resources, Word (**all assignments will need to be word-processed**) and Excel. Items of interest and links to other on-line material will be placed on the unit website i.e iLearn.

All assessment tasks are to be submitted in Turnitin on iLearn.

General use computers are provided by the University, but it would be extremely advantageous to have your own computer and internet access.

Required and Recommended texts and/or materials

Prescribed text:

AS ISO/IEC 17025:2018 General requirements for the competence of testing and calibration laboratories (ISBN: 978-1-76072-043-8)

Available via the library's 'MultiSearch', search for 'SAI Global on-line premium, standards association of Australia' then click on the blue link 'SAI Global on-line premium'. **Note 1:** The license for the downloaded PDF requires you to print out the standard within 3 days or else the PDF will become unusable. **Note 2:** The university has only one license to Standards Australia. Thus, if someone else is using it, you will not be able to access the documents until they log off.

This text will be used on a regular basis. You must bring your copy to every lecture/tutorial.

Primary References:

All (except OECD GLP) are available via the library's 'MultiSearch', search for 'SAI Global on-line premium, standards association of Australia' then click on the blue link 'SAI Global on-line premium'. **Note 1:** The license for the downloaded PDF requires you to print out the standard within 3 days or else the PDF will become unusable. **Note 2:** The university has only one license to Standards Australia. Thus, if someone else is using it, you will not be able to access the documents until they log off.

The reference list is also available in [Leganto](#); look for the 'Unit readings - Leganto' purple block in right-hand side of the iLearn unit page.

- AS ISO/IEC 17025:2018 General requirements for the competence of testing and calibration laboratories
- ISO 15189:2013 Medical laboratories – Particular requirements for quality and competence
- AS/NZS ISO 9000:2016 Quality management systems – Fundamentals and vocabulary
- AS/NZS ISO 9001:2016 Quality management systems – Requirements
- AS/NZS ISO 9004:2018 Quality management - Quality of an organization - Guidance to achieve sustained success
- ISO/TR 10013:2001 Guidelines for quality management system documentation
- AS/NZS ISO 10001:2012 Quality Management - Customer Satisfaction - Guidelines for codes of conduct for organizations
- ISO 10002:2018 Quality management – Customer satisfaction – Guidelines for handling complaints in organizations
- ISO 10003:2018 Quality management – Customer satisfaction – Guidelines for dispute resolution external to organizations
- TS ISO 10004:2011 Quality management – Customer satisfaction – Guidelines for

monitoring & measuring

- AS ISO 31000:2018 Risk management - Guidelines
- AS/NZS ISO 19011:2014 Guidelines for auditing management systems
- OECD, 1998 OECD Principles of Good Laboratory Practice (available from https://www.oecd-ilibrary.org/environment/oecd-principles-on-good-laboratory-practice_9789264078536-en)

Recommended references:

All are available in University Library, Call numbers provided at the end of each reference. The reference list is also available in [Leganto](#); look for the 'Unit readings - Leganto' purple block in right-hand side of the iLearn unit page.

- Buchanan, R.W, 1996, The Enemy Within: Actions that self-destruct companies, customer service and jobs, McGraw Hill, USA (HF5415.5.B83)
- Crosby, P., 1989, Let's Talk Quality, McGraw Hill, USA (HD62.15 .C755/1989)
- Crosby, P., 1979, Quality is free. The Art of Making Quality Certain, McGraw Hill, USA (HD62.15.C76)
- Hibbert, D. Brynn, 2007, Quality Assurance for the Analytical Chemistry Laboratory, Oxford (electronic version available via Library)
- Bergman, B, & Klefsjo, B., 1994, Quality: from customer needs to customer satisfaction, McGraw Hill, Sweden University Press (HF5415.5.B45713/1994)
- Parkany M. 1995, Quality assurance and TQM for analytical laboratories (QD51.Q34)
- Ryan T.P., 2011 (3rd ed), Statistical Methods for Quality Improvement, John Wiley & Sons (electronic version available via Library)
- Townsend P., 2000, Quality is Everybody's Business, St Lucie Printing, USA (HD62.15 .T692 2000)
- Reichenbacher, M., & Einax, J.W.,2011, Challenges in Analytical Quality Assurance, Springer (QD75.4.Q34 R45 2011)

Useful websites:

National Association of Testing Authorities (NATA)	https://www.nata.com.au/
Asia Pacific Accreditation Cooperation (APAC)	https://www.apac-accreditation.org/
Eurachem	https://www.eurachem.org/

Unit web page

The web page for this unit can be found at: <https://www.mq.edu.au/iLearn/>

You are expected to access the web pages frequently, where you may find announcements, links to interesting internet facilities and sites of interest to the course, view your marks in relation to unit averages, and lots of other interesting stuff.

Unit Schedule

Week 1	Quality management principles
Week 2	Acting ethically and laboratory structures
Week 3	Resource requirements: People
Week 4	Resource requirements: Facilities and equipment
Week 5	Process requirements: Client interactions and testing
Week 6	Process requirements: Method development, validation and QC
Week 7	Reporting results, Customer complaints
	Mid-semester break
Week 8	When things go wrong: nonconformances, corrective action and problem solving
Week 9	Controlling information and data
Week 10	Internal audits and management reviews
Week 11	OECD GLP
Week 12	Technical infrastructure and conformity assessment
Week 13	Q&A session including preparation of final assignment

Note: Schedule is subject to change. Please check the unit web page on <https://www.mq.edu.au/iLearn/> regularly for any updates made.

Learning and Teaching Activities

Lectures

Lectures covering the week's main topic area

Workshops

POGIL style workshops to put into action material covered in the lectures

Policies and Procedures

Macquarie University policies and procedures are accessible from [Policy Central \(https://staff.mq.edu.au/work/strategy-planning-and-governance/university-policies-and-procedures/policy-central\)](https://staff.mq.edu.au/work/strategy-planning-and-governance/university-policies-and-procedures/policy-central). Students should be aware of the following policies in particular with regard to Learning and Teaching:

- [Academic Appeals Policy](#)

- [Academic Integrity Policy](#)
- [Academic Progression Policy](#)
- [Assessment Policy](#)
- [Fitness to Practice Procedure](#)
- [Grade Appeal Policy](#)
- [Complaint Management Procedure for Students and Members of the Public](#)
- [Special Consideration Policy](#) (**Note:** *The Special Consideration Policy is effective from 4 December 2017 and replaces the Disruption to Studies Policy.*)

Undergraduate students seeking more policy resources can visit the [Student Policy Gateway](https://students.mq.edu.au/support/study/student-policy-gateway) (<https://students.mq.edu.au/support/study/student-policy-gateway>). It is your one-stop-shop for the key policies you need to know about throughout your undergraduate student journey.

If you would like to see all the policies relevant to Learning and Teaching visit [Policy Central](http://staff.mq.edu.au/work/strategy-planning-and-governance/university-policies-and-procedures/policy-central) (<http://staff.mq.edu.au/work/strategy-planning-and-governance/university-policies-and-procedures/policy-central>).

Student Code of Conduct

Macquarie University students have a responsibility to be familiar with the Student Code of Conduct: <https://students.mq.edu.au/study/getting-started/student-conduct>

Results

Results published on platform other than [eStudent](#), (eg. iLearn, Coursera etc.) or released directly by your Unit Convenor, are not confirmed as they are subject to final approval by the University. Once approved, final results will be sent to your student email address and will be made available in [eStudent](#). For more information visit ask.mq.edu.au or if you are a Global MBA student contact globalmba.support@mq.edu.au

Student Support

Macquarie University provides a range of support services for students. For details, visit <http://students.mq.edu.au/support/>

Learning Skills

Learning Skills (mq.edu.au/learningskills) provides academic writing resources and study strategies to improve your marks and take control of your study.

- [Workshops](#)
- [StudyWise](#)
- [Academic Integrity Module for Students](#)
- [Ask a Learning Adviser](#)

Student Services and Support

Students with a disability are encouraged to contact the [Disability Service](#) who can provide

appropriate help with any issues that arise during their studies.

Student Enquiries

For all student enquiries, visit Student Connect at ask.mq.edu.au

If you are a Global MBA student contact globalmba.support@mq.edu.au

IT Help

For help with University computer systems and technology, visit http://www.mq.edu.au/about_us/offices_and_units/information_technology/help/.

When using the University's IT, you must adhere to the [Acceptable Use of IT Resources Policy](#). The policy applies to all who connect to the MQ network including students.

Graduate Capabilities

PG - Capable of Professional and Personal Judgment and Initiative

Our postgraduates will demonstrate a high standard of discernment and common sense in their professional and personal judgment. They will have the ability to make informed choices and decisions that reflect both the nature of their professional work and their personal perspectives.

This graduate capability is supported by:

Learning outcomes

- Develop a quality management system
- Critically analyse/evaluate an existing quality management system for the purpose of quality improvement.
- Communicate the elements of a good quality management system to management and staff in their own facility.
- Understand, at an advanced level, technical management concepts including test methods, method selection, verification of methods, validation of methods, uncertainty of measurement, calibration and traceability.

Assessment tasks

- Assignment 2
- Assignment 4
- Assignment 5

Learning and teaching activities

- POGIL style workshops to put into action material covered in the lectures

PG - Discipline Knowledge and Skills

Our postgraduates will be able to demonstrate a significantly enhanced depth and breadth of knowledge, scholarly understanding, and specific subject content knowledge in their chosen fields.

This graduate capability is supported by:

Learning outcomes

- Analyse the requirements of international standards ISO/IEC 17025, ISO 15189, ISO 9000 and the OECD Principles of Good Laboratory Practice.
- Prepare and maintain quality documentation.
- Develop a quality management system
- Critically analyse/evaluate an existing quality management system for the purpose of quality improvement.
- Communicate the elements of a good quality management system to management and staff in their own facility.
- Understand, at an advanced level, technical management concepts including test methods, method selection, verification of methods, validation of methods, uncertainty of measurement, calibration and traceability.
- Enhance customer service and the experience of interested parties through the use of quality improvement techniques and processes.

Assessment tasks

- Assignment 1
- Assignment 2
- Assignment 3
- Mid Session Test
- Assignment 4
- Assignment 5

Learning and teaching activities

- Lectures covering the week's main topic area
- POGIL style workshops to put into action material covered in the lectures

PG - Critical, Analytical and Integrative Thinking

Our postgraduates will be capable of utilising and reflecting on prior knowledge and experience, of applying higher level critical thinking skills, and of integrating and synthesising learning and knowledge from a range of sources and environments. A characteristic of this form of thinking is the generation of new, professionally oriented knowledge through personal or group-based

critique of practice and theory.

This graduate capability is supported by:

Learning outcomes

- Analyse the requirements of international standards ISO/IEC 17025, ISO 15189, ISO 9000 and the OECD Principles of Good Laboratory Practice.
- Prepare and maintain quality documentation.
- Develop a quality management system
- Critically analyse/evaluate an existing quality management system for the purpose of quality improvement.
- Understand, at an advanced level, technical management concepts including test methods, method selection, verification of methods, validation of methods, uncertainty of measurement, calibration and traceability.
- Enhance customer service and the experience of interested parties through the use of quality improvement techniques and processes.

Assessment tasks

- Assignment 2
- Assignment 3
- Assignment 4
- Assignment 5

Learning and teaching activities

- POGIL style workshops to put into action material covered in the lectures

PG - Research and Problem Solving Capability

Our postgraduates will be capable of systematic enquiry; able to use research skills to create new knowledge that can be applied to real world issues, or contribute to a field of study or practice to enhance society. They will be capable of creative questioning, problem finding and problem solving.

This graduate capability is supported by:

Learning outcomes

- Prepare and maintain quality documentation.
- Develop a quality management system
- Critically analyse/evaluate an existing quality management system for the purpose of quality improvement.
- Understand, at an advanced level, technical management concepts including test

methods, method selection, verification of methods, validation of methods, uncertainty of measurement, calibration and traceability.

- Enhance customer service and the experience of interested parties through the use of quality improvement techniques and processes.

Assessment tasks

- Assignment 2
- Assignment 3
- Assignment 4
- Assignment 5

Learning and teaching activities

- POGIL style workshops to put into action material covered in the lectures

PG - Effective Communication

Our postgraduates will be able to communicate effectively and convey their views to different social, cultural, and professional audiences. They will be able to use a variety of technologically supported media to communicate with empathy using a range of written, spoken or visual formats.

This graduate capability is supported by:

Learning outcomes

- Prepare and maintain quality documentation.
- Communicate the elements of a good quality management system to management and staff in their own facility.

Assessment tasks

- Assignment 1
- Assignment 3
- Mid Session Test
- Assignment 4
- Assignment 5

Learning and teaching activities

- POGIL style workshops to put into action material covered in the lectures

PG - Engaged and Responsible, Active and Ethical Citizens

Our postgraduates will be ethically aware and capable of confident transformative action in relation to their professional responsibilities and the wider community. They will have a sense of connectedness with others and country and have a sense of mutual obligation. They will be able

to appreciate the impact of their professional roles for social justice and inclusion related to national and global issues

This graduate capability is supported by:

Learning outcome

- Enhance customer service and the experience of interested parties through the use of quality improvement techniques and processes.

Assessment task

- Assignment 1

Learning and teaching activity

- POGIL style workshops to put into action material covered in the lectures

Changes from Previous Offering

Information in the lecture and associated materials have been updated to reflect changes in laboratory quality systems standards and regulations. The structure of the unit has been substantially revised to reflect the change in structure and content of the main laboratory standard, AS ISO/IEC 17025.

The assessment structure and dates have been modified to allow for early assessment prior to the census date and to more evenly spread assessment tasks throughout the unit.