MOLS7253

Laboratory Quality Systems

Session 2, Special circumstance 2020

Department of Molecular Sciences

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Disclaimer

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Notice

As part of Phase 3 of our return to campus plan, most units will now run tutorials, seminars and ot her small group learning activities on campus for the second half-year, while keeping an online ver sion available for those students unable to return or those who choose to continue their studies onli ne.

To check the availability of face-to-face and onlin e activities for your unit, please go to timetable vi ewer. To check detailed information on unit asses sments visit your unit's iLearn space or consult yo ur unit convenor.

General Information

Unit convenor and teaching staff
Anita Stone
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Credit points
10

Prerequisites
Admission to MRes

Corequisites

Co-badged status
MOLS8253

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 (NATA).

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:

ULO1: Analyse the requirements of international standards ISO 17025, ISO 15189, ISO 9000 and the OECD Principles of Good Laboratory Practice.

ULO2: Prepare and maintain quality documentation

ULO3: Critically analyse/evaluate an existing quality management system for the purpose of quality improvement.

ULO4: Develop a quality management system

ULO5: Demonstrate an understanding, at an advanced level, of the technical management concepts including test methods, method selection, verification of methods, validation of methods, uncertainty of measurement, calibration and traceability.

ULO6: Enhance customer service and the experience of interested parties through the use of quality improvement techniques and processes.

General Assessment Information

Assignment Submission

In general, this is a paperless unit so no assignments or quizzes will be physically handed in. You will be required to submit all assignments through iLearn via a Turnitin link. Turnitin is an online program that detects plagiarised pieces of work. It compares not only work between students in the current year but also across previous years, across institutions, with all published materials, and the internet. Do not under any circumstances lend your work to another student. If that student plagiarises your work you too will be liable. The penalties imposed by the University for plagiarism are serious and may include expulsion from the University. ANY evidence of plagiarism WILL be dealt with according to University policy. A full outline of the Universities policy on plagiarism is found at http://www.mq.edu.au/pol icy/docs/academic_honesty/policy.html. It is your responsibility to ensure all documents submitted or uploaded in ilearn are the correct file(s) and readable by the person marking your assignment. If files cannot be read, then late penalties will apply until re-submission of the work occurs.

Extensions and penalties

10% will be deducted for each day (up to and including any time in the 24 hr period) if an assignment is late. This includes each day of a weekend. If you are unable to submit the assignment by the due date then an extension must be sought **BEFORE** the due date unless this is absolutely impossible. Notification after the event of an "anticipatable" absence will not be looked upon favourably. To support your extension, you must submit a "Special Consideration Request" request via www.ask.mq.edu.au. See https://students.mq.edu.au/study/my-study-program/special-consideration for instructions on how to do this. Please note that evidence must be given to support your request for an extension. Applications must also be made within five working days of the assessment task due date. Decisions to approve/not approve a special consideration request are made by the university (and NOT the unit convenor).

Marks released on iLearn

It is your responsibility to check that marks released on iLearn are accurate. Note, marks released on iLearn do not have late penalties applied. Late penalties are applied AFTER marking of the submitted work. See extensions and penalties section of this document.

Attendance at tutorials

There are 13 tutorials in total, one delivered online each week. The POGIL style tutorials put into action material covered in the lectures. Attendance of all tutorials is strongly recommended.

Further details of tutorial content and meeting links will be made available through the iLearn

site.

Assessment Tasks

Name	Weighting	Hurdle	Due
Assignment 1: Quality principles, objectives, actions and impartiality	10%	No	20/08/20
Midsemester Test	5%	No	10/09/20
Assignment 2: Management systems	30%	No	15/10/20
Assignment 3	15%	No	29/10/20
Assignment 4: Critical analysis and application of international standards	40%	No	20/11/20

Assignment 1: Quality principles, objectives, actions and impartiality

Assessment Type [1]: Report
Indicative Time on Task [2]: 10 hours
Due: **20/08/20**
Weighting: **10%**

There will be three written tasks relating to: quality principles, objectives, action plans and the importance and nature of impartiality.

On successful completion you will be able to:

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

Midsemester Test

Assessment Type [1]: Quiz/Test
Indicative Time on Task [2]: 5 hours
Due: **10/09/20**
Weighting: **5%**

The quiz will consist of 15 multiple choice questions. Each question of the quiz 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 quiz will be completed on-line on the iLearn site.

On successful completion you will be able to:

- Analyse the requirements of international standards ISO 17025, ISO 15189, ISO 9000 and the OECD Principles of Good Laboratory Practice.
- Enhance customer service and the experience of interested parties through the use of quality improvement techniques and processes.

Assignment 2: Management systems

Assessment Type [1]: Report
Indicative Time on Task [2]: 30 hours
Due: **15/10/20**
Weighting: **30%**

This assignment has three tasks relating to: control charts, customer complaints, calibration and metrological traceability of equipment.

On successful completion you will be able to:

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

Assessment Type [1]: Professional writing
Indicative Time on Task [2]: 15 hours
Due: **29/10/20**
Weighting: **15%**

This assignment involves selecting one scenario from a list and writing a laboratory procedure to ensure proper performance of the selected method in accordance with the international standard provided.

On successful completion you will be able to:

- Analyse the requirements of international standards ISO 17025, ISO 15189, ISO 9000 and the OECD Principles of Good Laboratory Practice.
- Prepare and maintain quality documentation
- Critically analyse/evaluate an existing quality management system for the purpose of quality improvement.
- Develop a quality management system
- Demonstrate an understanding, at an advanced level, of the 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.

Assignment 4: Critical analysis and application of international standards

Assessment Type [1]: Report
Indicative Time on Task [2]: 40 hours
Due: **20/11/20**
Weighting: **40%**

This assignment involves a compulsory task that is a critical analysis of select quality principles developed by a leading quality thinker and a choice of two tasks from a list of tasks relating to implementing a quality system in the workplace.

On successful completion you will be able to:

- Analyse the requirements of international standards ISO 17025, ISO 15189, ISO 9000 and the OECD Principles of Good Laboratory Practice.
- Prepare and maintain quality documentation
- Critically analyse/evaluate an existing quality management system for the purpose of quality improvement.
- Develop a quality management system
- Demonstrate an understanding, at an advanced level, of the 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.

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[1] If you need help with your assignment, please contact:

- the academic teaching staff in your unit for guidance in understanding or completing this type of assessment
- the Writing Centre for academic skills support.

[2] Indicative time-on-task is an estimate of the time required for completion of the assessment task and is subject to individual variation

Delivery and Resources

MOLS7253 is taught concurrently with MOLS8253.

MOLS7253 is a 10-credit-point, one semester unit, comprising:

- Lecture: one 1-hour online based lecture per week.
- Tutorial: one 2-hour online based tutorial at the scheduled session per week. Your own laptop/device will be required for the sessions (meeting links will be made available through the ilearn site).
- Self-Study: there is an expectation that you will also engage in study of the material outside of the formal contact.

In order to complete (and do well) in this unit you must:

- Review all lecture materials.
- Participate in all tutorial sessions.
- Submit all assignments by the specified dates (unless special consideration is approved).

- Attempt the mid-session quiz (60 minutes), held during a standard lecture time.

MOLS7253 Unit Web Site

The web page for MOLS7253 can be found at ilearn.mq.edu.au. The MOLS7253 iLearn web site is your primary source of data and information for this unit and will be used as a repository of lectures and workshop materials, and as a means of communication. Login to iLearn and follow the prompts to MOLS7253. You will be asked for a username and password. Your User Name is your Macquarie Student ID Number, which is an 8-digit number found on your Campus Card. The password is your myMQ Student Portal password. If you have any problems with iLearn log a ticket with OneHelp at onehelp.mq.edu.au. More information about OneHelp can be found at http://informatics.mq.edu.au/help/.

Announcements on ilearn are also emailed to your student email account. It is your responsibility to ensure your settings in iLearn are active to receive all announcements.

Recommended Texts

Prescribed text:

AS ISO/IEC 17025-2018: General requirements for the competence of testing and calibration laboratories (ISBN: 0-7337-7018-5).

Available via the library's "Journal Finder", search for "Standards Australia [electronic resource] SAI Global:on-line premium".

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

Primary texts:

All are available via the library's "Journal Finder", search for "Standards Australia [electronicresource] : SAI Global on-line premium".

Note: The license for the downloaded PDF requires you to print out the standard within 3 days or else the PDF will become unusable. Note also that 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.

- 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 (hardcopy only available from the Library)

- AS/NZS ISO 10001:2012 Quality management – Customer satisfaction – Guidelines for codes of conduct for organizations
- AS/NZS ISO 10002:2014 Guidelines for complaint management in organizations
- TS ISO 10004:2011 Quality management – Customer satisfaction – Guidelines for monitoring and measuring
- AS ISO 31000:2018 Risk management – Guidelines
- AS/NZS ISO 19011:2019 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)

Secondary texts:

All are available in University Library, Call numbers provided at the end of each reference.

- 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 (QD75.4 Q34 H53 2007)
- Bergman, B, & Klefsjo, B., 1994, Quality: from customer needs to customer satisfaction, McGraw Hill, Sweden University Press (HF5415.5.B45713/1994)
- McConnell J., 1986 (2nd edition), The Seven Tools of Total Quality Management, Delaware Books, Australia (TS156.M37/1986)
- Parkany M. 1995, Quality assurance and TQM for analytical laboratories (QD51.Q34)
- Ryan T.P., 2000 (2nd ed), Statistical Methods for Quality Improvement, John Wiley & Sons (TS156 .R9/1989)
- Townsend P., 2000, Quality is Everybody's Business, St Lucie Printing, USA
- Reichenbächer, M., & Einax, J.W.,Challenges in Analytical Quality Assurance, Springer (available online at library)

Useful websites:

- National Association of Testing Authorities (NATA) - https://www.nata.com.au/
- Asia Pacific Accreditation Cooperation (APAC) - https://www.apac-accreditation.org/about/
- International Laboratory Accreditation Cooperation (ILAC) - https://ilac.org/

- OECD iLibrary - https://www.oecd-ilibrary.org/
- Eurachem - https://www.eurachem.org/

Lectures

It is strongly advised that you attend ALL lectures. Students who do not attend all lectures often find it difficult to pass the Unit. 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.

Tutorials

Tutorials give you an opportunity to work with your peers to put your knowledge learnt from the lectures into practice. The aim of the tutorials is to help you develop an understanding of the concepts central to the successful implementation of quality within analytical testing laboratories. You will review the concepts presented in the lecture and how they are practically applied in testing laboratories. Additional revision material may be provided to you via ilearn to help you prepare for the tutorials or provide further information post-tutorials.

Each tutorial will begin with a short introduction and expected outcomes. You will then work through an online based workshop individually or in small groups and perform short activities.

Technology Used

We expect all students to own a laptop and have internet access. **If you do not have your own laptop**, then please advise teaching staff on this unit **PRIOR** to the tutorial sessions.

You are expected to have access to the ilearn site and be able to download PDF files on your laptop. Acrobat Reader can be used to view lecture material and can be downloaded from the Adobe at get.adobe.com/reader/.

Use will be made of literature search tools, such as the library's catalogue and Journal Finder 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.

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

Communication

All communication will be given via the iLearn site. Alerts for new announcements will also be sent to your student email account (unless you turn this feature off which is NOT recommended). It is your responsibility to check the ilearn site and your email account on a frequent basis. It is not uncommon for mail from iLearn to be initially recognised as spam. All unit-related correspondence must be conducted using your official university account. E-mails sent to teaching staff from your private email accounts will be IGNORED.

Additional learning resources/ Self Directed Learning & Study

You are expected to spend some time in reading a relevant text and other sources of information relating to laboratory quality management systems to review lecture material, and to self-assess your degree of understanding. An approximate estimate of the time commitment for a 10 credit point postgraduate unit of study such as MOLS7253 is 150 hours over 15 weeks (including the

break) ~10 hours per week.

Unit Schedule

Lecture notes and materials used in lectures will be available for download via ilearn.

Note: This schedule may be subject to change. Any updates will be communicated via ilearn.

Week	Date	Lecture Topic
1	30-Jul	Quality management principles
2	6-Aug	Acting ethically and laboratory structures
3	13-Aug	Resource requirements: People management
4	20-Aug	Resource requirements: facilities and equipment
5	27-Aug	Resource requirements: client interactions and testing
6	3-Sep	Process requirements: method development and quality control
7	10-Sep	Test reports and customer complaints
	14-27 Sep	**Mid-semester break**
8	1-Oct	System improvements
9	8-Oct	Controlling documentation and information
10	15-Oct	Internal audits and management review
11	22-Oct	OECD Good Laboratory Practice (GLP)
12	29-Oct	Technical infrastructure and conformity assessment
13	5-Nov	Q&A session for including preparation of final assignment

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). 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.)*

Students seeking more policy resources can visit the 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 (https://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 help you improve your marks and take control of your study.

- Getting help with your assignment
- Workshops
- StudyWise
- Academic Integrity Module

The Library provides online and face to face support to help you find and use relevant information resources.

- Subject and Research Guides
- Ask a Librarian

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.

Changes from Previous Offering

Assessment has been aligned with MOLS8253.