CBMS761

Laboratory Quality Systems

S2 Evening 2014

Chemistry and Biomolecular Sciences

Contents

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General Information

Unit convenor and teaching staff
Unit Convenor
Christopher McRae
christopher.mcrae@mq.edu.au
Contact via christopher.mcrae@mq.edu.au
F7B 328
Students are encouraged to arrange a meeting via email.

Credit points
4

Prerequisites
Admission to MRes

Corequisites

Co-badged status
CBMS861

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:

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.

Develop a quality management system

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

improvement.

Communicate the elements of a good 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 through the use of quality improvement techniques and processes.

Assessment Tasks

Name	Weighting	Due
Assignment 1	8%	Week 5
Assignment 2	10%	Week 8
Assignment 3	12%	Week 9
Mid Semester Test	10%	Week 7
Assignments 4-6	60%	Weeks 11-15

Assignment 1

Due: **Week 5**
Weighting: **8%**

Quality policy, objectives and action plans

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.
- Communicate the elements of a good management system to management and staff in their own facility.
- Enhance customer service through the use of quality improvement techniques and processes.

Assignment 2

Due: **Week 8**
Weighting: **10%**

Sampling and Sample Management

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.

Assignment 3

Due: **Week 9**
Weighting: **12%**

Laboratory Test Methods

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.

Mid Semester Test

Due: **Week 7**
Weighting: **10%**

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

Assignments 4-6

Due: **Weeks 11-15**
Weighting: **60%**

For assignments 4-6 (20% ea) you have the option of selecting 2 plus 1 compulsory assessment task from a total of 5 possible assessment tasks. Topics cover in assignments 4-6 (20% ea) 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 17025, ISO 15189, ISO 9000 and the OECD Principles of Good Laboratory Practice.

- Develop a quality management system
- Critically analyse/evaluate an existing 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.

Delivery and Resources

Classes

- **Timetable:** Please check http://www.timetables.mq.edu.au/for the official timetable of the unit. Lectures will be held in Building F7B, Room 322. If you will be coming late to the lecture/tutorial, please let Dr McRae know as the doors to the building auto-lock at 7 pm!
- **Lectures:** There is one, 1.5 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-hour POGIL style tutorial/workshop session will immediately follow the lectures.
- **Laboratory Work:** There is no laboratory work in this unit.

Attendance

Attendance at lectures and tutorials is compulsory, and non-attendance **may** be taken as grounds for applying a failing grade. A poor attendance record will certainly result in **reduction of the aggregate mark**. Students unable to attend due to illness or misadventure and who are unable to catch up in a reserve session must provide formal documentary evidence to the University as soon as possible after the absence. For one such justified absence students will receive the average mark from the sessions that they did attend. For any unjustified absences students will receive a zero mark and may be subject to compulsory withdrawal from the unit.

If an absence is **anticipated** (perhaps for a mandatory religious event, or University sporting event etc), the student must inform teaching staff *in advance* that this will be the case and make alternative arrangements. It is the responsibility of the student to undertake this. Notification *after* the event of an anticipatable absence will not be looked upon favourably.

Technology Used

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.

General use computers are provided by the University, but it would be extremely advantageous to have your own computer and internet access. Notebook computers will be provided during lecturer/tutorials when required.

Required and Recommended texts and/or materials
Prescribed text:

AS ISO/IEC 17025-2005: 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] : on-line premium".

Use will be made of this text on a regular basis. You **must** bring your copy to **every** lecture/tutorial.

Primary References:

All are available via the library's "Journal Finder", search for "Standards Australia [electronic resource] : 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 17025:2005 General requirements for the competence of testing and calibration laboratories
- ISO 15189:2013 Medical laboratories – Particular requirements for quality and competence
- AS/NZS ISO 9000:2000 Quality management systems – Fundamentals and vocabulary
- AS/NZS ISO 9001:2000 Quality management systems – Requirements
- AS/NZS ISO 9004:2000 Quality management systems – Guidelines for performance improvements.
- ISO/IEC Guide 2:2004 Standardization and related activities – General vocabulary
- AS ISO 10013:2003 Guidelines for quality management system documentation
- ISO 10002:2004 Quality management – Customer satisfaction – Guidelines for complaints handling in organizations
- ISO 10003:2007 Quality management – Customer satisfaction – Guidelines for dispute resolution external to organizations
- ISO/CD TS 10004: 2008(?) Quality management – Customer satisfaction – Guidelines for monitoring & measuring
- OECD, 1998 OECD Principles of Good Laboratory Practice (available from http://www.sourceoecd.org/environment/9264012826)

Recommended references:

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

Useful websites:

Asia Pacific Laboratory Accreditation Cooperation (APLAC)	http://www.aplac.org
Eurachem	http://www.eurachem.org/
National Association of Testing Authorities (NATA)	http://www.nata.asn.au/

Unit web page

The web page for this unit can be found at: **http://ilearn.mq.edu.au**

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

| 1 | Concepts of Quality Management |
| 2 | Documentation Part 1 |

3	Documentation Part 2
4	People Management Part 1
5	People Management Part 2
6	Technical Management Part 1
7	Technical Management Part 2
8	Technical Management Part 3
9	Quality Control
10	Laboratory Records and Reports
11	Good Laboratory Practice (GLP)
12	System Improvement
13	Conformity Assessment and Technical Infrastructure

Learning and Teaching Activities

Lectures

Lectures covering the week's main topic area

Workshops

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

Policies and Procedures

Macquarie University policies and procedures are accessible from Policy Central. Students should be aware of the following policies in particular with regard to Learning and Teaching:

Academic Honesty Policy http://mq.edu.au/policy/docs/academic_honesty/policy.html

Assessment Policy http://mq.edu.au/policy/docs/assessment/policy.html

Grading Policy http://mq.edu.au/policy/docs/grading/policy.html

Grade Appeal Policy http://mq.edu.au/policy/docs/gradeappeal/policy.html

Grievance Management Policy http://mq.edu.au/policy/docs/grievance_management/policy.html

Disruption to Studies Policy http://www.mq.edu.au/policy/docs/disruption_studies/policy.html *The Disruption to Studies Policy is effective from March 3 2014 and replaces the Special Consideration Policy.*

In addition, a number of other policies can be found in the Learning and Teaching Category of

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/support/student_conduct/

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

IT Help

For help with University computer systems and technology, visit http://informatics.mq.edu.au/help/.

When using the University's IT, you must adhere to the Acceptable Use Policy. The policy applies to all who connect to the MQ network including students.

Graduate Capabilities

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 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 management system for the purpose of quality improvement.
- Communicate the elements of a good 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 through the use of quality improvement techniques and processes.

Assessment tasks

- Assignment 1
- Assignment 2
- Assignment 3
- Mid Semester Test
- Assignments 4-6

Learning and teaching activities

- Lectures covering the week's main topic area
- POGIL style workshops to put into action material cover 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 17025, ISO 15189, ISO 9000 and the OECD Principles of Good Laboratory Practice.
- Critically analyse/evaluate an existing 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.

Assessment task

- Assignments 4-6

Learning and teaching activity

- POGIL style workshops to put into action material cover 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 outcome

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

Assessment task

- Assignments 4-6

Learning and teaching activity

- POGIL style workshops to put into action material cover 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 outcome

- Prepare and maintain quality documentation.

Assessment tasks

- Assignment 1
- Assignment 2
- Assignment 3
- Mid Semester Test

- Assignments 4-6

Learning and teaching activities

- POGIL style workshops to put into action material cover 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 through the use of quality improvement techniques and processes.

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
- Communicate the elements of a good 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 task

- Assignments 4-6

Learning and teaching activity

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

Changes from Previous Offering

This is the first offering of this unit.