Laboratory Safety
A Quality Systems Approach

Safety Training Program Workshop
hosted by the IUPAC Committee on Chemistry & Industry
BEXCO, Busan, Korea
10th August 2015

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Audette Consulting

Dr. Gerald F. Audette
Professor, Dept. of Chemistry, York University
$\text{CH}_3\text{Hg}$

exposure / toxicity

Graduate Studies
University of Saskatchewan
Summer 1969
# Life Long Laboratory Safety Journey

<table>
<thead>
<tr>
<th>Location and Period</th>
<th>Laboratory Safety Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemistry Dept., University of Saskatchewan (1967 - 1973)</td>
<td>Minimal written</td>
</tr>
<tr>
<td>RCMP Forensic Lab, Edmonton, AB (1973 - 1979)</td>
<td>Minimal written</td>
</tr>
<tr>
<td>Provincial Analysts Lab, Alberta Government (1979 - 1985)</td>
<td>Beginning to write</td>
</tr>
<tr>
<td><strong>Senior Lab Assessor - ISO/IEC laboratory accreditation standards (1984 - present)</strong></td>
<td></td>
</tr>
<tr>
<td>University of Alberta Hospitals (1985 - 2001)</td>
<td>Minimal written, developing QS approach</td>
</tr>
<tr>
<td>- Trace Elements/Environmental Toxicology lab</td>
<td></td>
</tr>
<tr>
<td>- Clinical Associate Professor, U. of A. Faculty of Medicine</td>
<td></td>
</tr>
<tr>
<td>Audette Consulting (2001 - present)</td>
<td>Developed full documented QS approach</td>
</tr>
<tr>
<td>- ISO/IEC lab standards (17025, 15189, 17043, G34/17034)</td>
<td></td>
</tr>
<tr>
<td>Audette Laboratory - structural biochemistry research</td>
<td>Implemented full QS approach (July 2007)</td>
</tr>
<tr>
<td>Dept. Chemistry, York University (July 2007 - present)</td>
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</table>
Lab Safety - still a university lab issue

“Death in the Lab”  Discover Magazine, June 2015

• UCLA laboratory safety standards on trial
• “family pushed for accountability from researcher in charge & for better safety standards in academic labs”
• “UCLA spent $4.5M on professor’s defence”
• http://discovermagazine.com/2015/june/20-death-in-the-lab
Laboratory accreditation involves assessment by a National Accreditation Body based on the ISO/IEC 17025:2005 Standard. This requires the laboratory having formal establishment and maintenance of:

1. **Quality Management System** modelled on and compliant with the ISO 9001 (2000) QMS requirements
   - that includes the evaluation of:
     - developed quality management system (QMS) & document control
     - specified management personnel including lab manager, quality manager and technical manager
     - Quality Manual and detailed Standard Operating Procedures (SOP) & test methods - full document control
     - purchasing services & supplies - including Reference Materials, Certified RMs, chemicals, instrumentation
     - control of records - management and technical

2. **Technical Requirements** with specific criteria and procedures to demonstrate technical competence
   - that includes the evaluation of:
     - technical training and competency of staff
     - accommodation and testing environmental conditions
     - traceability of measurements and calibrations to national/international standards
       - RMs & CRMs for traceable calibrations, defined quality of chemicals & reagents
     - suitability, calibration and maintenance of test equipment
“General requirements for competence of testing and calibration laboratories”

Scope

- management system “refers to the quality, administrative and technical systems that govern the operations of a laboratory”
- specifies general requirements for competence to carry out tests and/or calibrations
- used by accredited laboratories in developing their quality, administrative and technical systems

▶ compliance with regulatory and safety requirements is not covered

- Fundamentally, laboratory safety viewed as a company/departmental, municipal, state/provincial or national Occupational Health & Safety (OHS) regulations
  - ISO/IEC 17025 does NOT consider this a quality systems issue

- Hence vast majority of labs (> 99%) do not include lab safety in their QMS
- Lab safety normally covered by separate safety committee
ISO/IEC 17025 Quality Hierarchy

Modified from Tsiakals, J. The Quality Hierarchy
Quality Management System Document Hierarchy

Quality Manual

Policies
“What to do”

Processes
“How it happens”

Procedures
“How to do it”

Standard Operating Procedures
Audette Laboratory Quality Management System

Document Hierarchy

- Quality Manual
- Administration Manual
- Laboratory Safety Manual
- SOPs and Test Methods
- Records

Designated roles & responsibilities
- Principle Investigator
- Quality Manager
- Technical Manager
- Safety Officer

- Biochemistry Research
- QMS implemented
  - July 2007

fundamentally included in QMS to ensure good laboratory safety practices
Typical Document Identification & Control No.’s

**QUALITY MANUAL**

**SCOPE:**
This Quality Manual is designed to meet the ongoing Quality Management System processes and procedures of the Audette Laboratory.

**POLICY:**
The Audette Laboratory management is committed to good professional practice, to the quality of its research and development services, to the education of its university undergraduate and graduate students as well as post doctoral fellows and to quality service to its customers.

The Audette Laboratory shall employ good management system practices in general compliance with the principle requirements of national and international laboratory accreditation standards to ensure that quality research results are generated.

**OBJECTIVES:**
The Audette Laboratory Quality Manual encompasses the following:
- compliance of management system practices of a Quality Management System
- processes and procedures for the quality, administrative and technical systems that govern the ongoing operations of the laboratory
- employing this manual as an educational tool for university undergraduate and graduate students as well as post doctoral fellows
- general compliance with the principle requirements of the international standard ISO/IEC 17025

**DOCUMENT REVISION HISTORY**

<table>
<thead>
<tr>
<th>Date (DD/MM/YYYY)</th>
<th>SOP Rev.#</th>
<th>Summary of Revision</th>
<th>Revised by</th>
<th>Reviewed by</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/07/2007</td>
<td>1.0</td>
<td>Initial implementation of QMS document</td>
<td>RJA</td>
<td>GFA</td>
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<tr>
<td>12/08/2011</td>
<td>2.0</td>
<td>Replaced “date signed” with “date issued”, replaced all “will” by “shall”, added Document Revision History section, revised to word 2007 format (docx)</td>
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<td>GFA</td>
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<td>03/09/2013</td>
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<tr>
<td>16/09/2014</td>
<td>4.0</td>
<td>Updated Policy &amp; Objectives sections</td>
<td>GFA</td>
<td>RJA</td>
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<tr>
<td>13/03/2015</td>
<td>3.1</td>
<td>customized “styles” gallery to display most often used template styles</td>
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**Document Control No.:** AL-QMS-G-000.DOC  **QM Rev. No.:** 4.1

**Computer File Name:** QM 00 Title page r1 1.docx **QM Rev. Date:** 13 March 2015

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Scope & Objectives

2. INTRODUCTION

[ISO/IEC 17025 4.5]

SCOPE

This Quality Manual describes the quality, administrative and technical systems, procedures and processes for achieving quality for research and development results and for operating the Audette Laboratory management system in general compliance with the principle requirements of the international ISO/IEC 17025:2005 laboratory accreditation standard.

The Audette Laboratory’s Quality Manual has been designed to:
- describe how process improvement is administered in the Audette Laboratory;
- identify how the Audette Laboratory management system is implemented and maintained;
- outline the management system structure;
- be employed as an educational tool for university undergraduate and graduate students as well as post doctoral fellows and
- describe management responsibility with respect to quality philosophy, policy and procedures.

POLICY

The Audette Laboratory seeks to achieve the highest possible degree of efficiency, effectiveness and fiscal responsibility, and to continuously improve the quality of its research and development programs (projects) including the education of university undergraduate and graduate students as well as post-doctoral fellows.

The Audette Laboratory shall employ good management system practices in general compliance with the principle requirements of national and international laboratory accreditation standards to ensure that quality research results are generated.

OBJECTIVES

The Audette Laboratory’s management system encompasses the following:
- a management system encompassing the quality, administrative and technical systems that govern the daily operations of the laboratory;
- employing this manual as an educational tool for university undergraduate and graduate students as well as post doctoral fellows
- general compliance with the principle requirements of the international standard ISO/IEC 17025 “General Requirements for the Competence of Testing and Calibration Laboratories”
- the Principle Investigator (PI) being responsible for the administration of the overall management system;
Quality System Manuals TOCs - specific Lab Safety documentation

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</tbody>
</table>

2. Student (graduate and undergraduate) and post-doctoral fellow work descriptions are written to reflect the duties of the position and the qualifications and experience required.

3. Current versions of work descriptions are held on each laboratory member’s personnel file and in the Principle Investigator’s (Dr. G. Audette) office, and are available on request.

The “Human Resources” document (AL-QMS-A-008.DOC) in the Administration Manual has more specific details.

QUALIFICATIONS & COMPETENCE

EDUCATION & CV

Each laboratory staff member shall meet the minimum education requirements for their position.

Each laboratory staff member is responsible for maintaining updated Curriculum Vitae on their personnel file located in the Principle Investigator’s office. The CV shall be reviewed and updated at least yearly, where possible.

The CV shall include publication record, relevant experience including performing method development and evaluation, conference participation etc.

CERTIFICATION

Where professional certification is required for the conduct of the employee’s duties, York University and the Department of Chemistry shall, insofar as resources permit, allocate time and funds in support of the achievement and maintenance of this requirement.

TRAINING & DEVELOPMENT

ORIENTATION

Each new laboratory staff member shall complete an orientation process including:

- introduction to the Audette Laboratory staff and their duties
- familiarization with floor plan, safety and security procedures
- review and understand laboratory quality documents
- reviewing and understanding any relevant York University documents
- sign-off of the appropriate Acknowledgement form when complete

All laboratory staff shall, once they have read the appropriate QMS document(s), or revisions to these QMS documents, using the copy of the appropriate “XX...Acknowledgement form” complete the specific Acknowledgement form following the instructions within that form and email that “signed” form to the Principle Investigator for his records.


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METHODS AND SPECIFIC TECHNIQUES

Before any laboratory staff member conducts any analysis using an established specific technique or method, the appropriate Specific Techniques (AL-XXX-F08S,TV-XXX) and Test Method (AL-QMST-XXX) documents shall be read and understood. The following familiarization steps are required:

- perform the technique or method under the supervision of an authorized staff member
- results meet performance criteria specified by the specific technique or method
- authorization to use the specific technique or method independently

All laboratory staff shall, once they have read the appropriate specific technique or method QMS document(s), or revisions to these QMS documents using the copy of the “Acknowledgement of Reading Specific Techniques” (AL-QMS-F-025.DOC) or “Acknowledgement of Reading Test Methods” (AL-QMS-F-007.DOC) forms complete that specific Acknowledgement form following the instructions within that form and email that “signed” form to the Principle Investigator for his records.

YORK UNIVERSITY DOIS TRAINING

All laboratory personnel shall have the following training as required by the York University Department of Occupational Health & Safety (DOIS):

- WHMEM II
- Biosafety
- Compressed Gases
- Solvents

In addition if laboratory personnel are to use the Audette Laboratory X-ray equipment they shall also have the following required training:

- York University DOIS X-ray training
- Audette Laboratory X-ray training

These training requirements shall be documented in the “YorkU DOIS Training Record” form (AL-QMS-F-023.DOC) and shall be updated as required by YorkU DOIS and the Audette Laboratory.

All laboratory staff, once they have read the YorkU DOIS documents, using the copy of the “XX...YorkU DOIS Training Acknowledgement form” complete the specific Acknowledgement form following the instructions within that form and email that “signed” form to the Principle Investigator for his records.

Refer to the “Document Control Process” document (AL-QMS-S-003.DOC) for more specifics.

TRAINING AND COMPETENCY RECORDS

Unlike an accredited testing laboratory, in the context of the research and development done in the Audette Laboratory, “training and development” is interpreted in a very broad sense. This means, for example, the lab staff have acknowledged reading all the required QMS documents, ongoing discussions with the Principle Investigator concerning their specific project, demonstrated proficiency in specific testing techniques, participating in weekly staff meetings, a project report (technical or otherwise) at weekly staff meetings, a class or departmental seminar presentation, a yearly report on research work by graduate students, a research thesis, lectures, scientific presentation at local, provincial, national and international conferences.
ISO/IEC 17025:2005

5.3 Accommodation and Environmental Conditions

- The laboratory shall ensure:
  - technical requirements for the facilities are documented
  - conditions do not compromise the quality of test results
  - monitors, controls and records environmental conditions
  - tests and/or calibrations are terminated when results are jeopardised
  - effective separation between areas of incompatible activity
  - access to office and laboratory areas is controlled
  - good housekeeping measures are maintained including any special procedures required

  **compliance with regulatory and safety requirements is not covered**
Quality Manual Examples

**21 LABORATORY EQUIPMENT**

**SECTION: QMS**

**SOP ID: QM-M21-LAB EQUIPMENT**

**AUTHORIZED OPERATORS**

Laboratory staff (Audette Laboratory or otherwise) shall undergo familiarization training, either conducted by the manufacturer’s training service or a qualified laboratory staff member, before being authorized to conduct independent operation of the following categories of instruments:

- Analytical balances
- Top loading balances
- pH meters
- Pipettors
- Centrifuges
- Incubators
- PCR Thermocyclers
- Microscopes (stereo)
- Shakers
- Shaking Water Baths
- Spectrophotometers
- Fast protein liquid chromatograph [FPLC]
- X-Ray crystallography
- and other equipment as identified.

**INSTRUCTIONS ON USE**

Instrument operating manuals are maintained at the instrument workstation, for ready reference.

Operating instruction SOPs are prepared where operating instructions over and above those provided in the instrument operating manual are required. SOPs for major instruments shall include at least the following information:

- Start-up & shut-down procedures
- Calibration & quality control
- Operating instructions (critical control points)
- Record keeping instructions
- List of authorized operators
- Maintenance plan

These documents shall be designated “QMS-O” document control number management system documents.

**AHERENCE TO AUDETTE LABORATORY’S POLICIES & PROCEDURES**

Members of the Life Sciences Building community are welcome to use the equipment or instrumentation available in the Audette Laboratory.

However, to maintain compliance with the international ISO/IEC 17025 standard, should they wish to use the Audette Laboratory equipment or instrumentation, it shall be required that all Principle Investigators, on behalf of their research groups, sign the “Acknowledgement for usage of Audette Laboratory equipment” form (AL-QMS-F-027.DOC) to indicate that all staff of their research group shall be familiar with and adhere to all the policies and procedures for the usage and operation of the equipment.

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**22 MEASUREMENT TRACEABILITY**

**SECTION: QMS**

**SOP ID: QM-M22-TRACEABILITY**

**PREPARATION OF STANDARDS AND REAGENTS**

**AUDIT TRAIL**


All laboratory staff shall properly record the preparation of standards and reagents in a traceable manner in their personal laboratory notebook. Specific instruments (e.g., Balances) employed to prepare these shall have their “Usage Record” form completed and signed.

The protocols for the receipt and inventory of all supplies including chemicals, reagents, buffers, enzymes, reagent kits, reference materials, certified reference materials etc. in a traceable manner are documented in the “Purchasing” document (AL-QMS-A-000.DOC) and the “Inventory” document (AL-QMS-A-009.DOC) of the same manual.

**SAFETY**

Procedures for handling, transport and storage of hazardous materials may also apply to certain reference materials. Due care shall be taken to ensure the risk to health and safety of staff is minimized.

**LABELS FOR STANDARDS & REAGENTS**

To ensure traceability all standards and reagents, each standard, chemical, reagent, solvent or reagent kit etc container in the laboratory shall be clearly and legibly labelled with the following information, some of which may be on the supplier’s label:

- Name (product identifier)
- Supplier identifier
- Concentration/solvent [where appropriate]
- Receipt date
- Expiry date [where appropriate]
- Identity of receiver (i.e. the lab staffs initials)
- Storage conditions
- Reference to SDS
- Hazard symbol(s)

1. A logbook where the preparation of standards and reagents are recorded is clearly labelled and kept near the equipment.

2. Entries shall be dated and signed by the person preparing the standard or reagent.

Administration Manual Examples

Accommodation & Environmental Conditions

SCOPE
The safety measures and procedures described in this section of the Administration Manual are provided as a guide toward the achievement of a safe and productive work environment. They should be practiced to keep laboratory injuries to a minimum.

POLICY
York University, Department of Chemistry and the Audette Laboratory shall be committed to providing a safe and healthy working environment for all its employees and students, regardless of tenure of status, promoting OSH as an integral part of its corporate culture, and integrating OSH into its management and business decision-making processes.

The Audette Laboratory safety policy shall extend to all laboratory personnel and all visitors to the laboratory, inclusive of the Audette Laboratory staff.

OBJECTIVES
The Audette Laboratory shall encompass the following:
- general compliance of good laboratory safety practices that produces fully traceable quality research services which satisfy the needs of the research programs served
- general compliance with the principle requirement of the international standard ISO/IEC 17025 “General Requirements for the Competence of Testing and Calibration Laboratories”

RESPONSIBILITIES
It is the responsibility of the Principle Investigator (Dr. G. Audette) in conjunction with the Faculty of Science & Engineering Safety Officer to implement all procedures in the laboratory and oversee the Safety Program.

The Principle Investigator and the Safety Officer are responsible for:
- Maintaining complete and accurate records of all accidents, incidents, spills, safety infractions and staff training programs.
- Identifying all situations within the laboratory that could pose a safety or health hazard.
- Ensuring that MSDS sheets for all chemicals used in the lab are readily accessible, up-to-date and that all staff is aware of their location.
- Performing yearly safety checks in the laboratory and the office.

Employees and students are responsible for communicating, to the Laboratory Principle or the Faculty Safety Officer, their concerns or suggestions about health or safety issues in the laboratory.

LABORATORY SAFETY REQUIREMENTS

GENERAL
1 Suitable facilities for quick drenching or flushing of the eyes (eyewash stations) and body (emergency showers) shall be provided within the work area for immediate use in the event of an emergency. Refer to the Floor Plans for locations.
Laboratory Safety Manual Examples

2. ROUTINE LABORATORY SAFETY PRACTICES

SECTION: QMS

SOP ID: QM-LSM02-RLSP

PROCESS

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<tr>
<th>Personal Safety</th>
<th>DO</th>
<th>DO NOT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workers shall</td>
<td>Wash hands after exposure to chemicals, biological fluids.</td>
<td>Eat.</td>
</tr>
<tr>
<td></td>
<td>After removal of gloves.</td>
<td>Drink.</td>
</tr>
<tr>
<td></td>
<td>Before leaving a work area and after each specimen collection.</td>
<td>Chew gum.</td>
</tr>
<tr>
<td>Use gloves whenever there is the risk of contamination from specimens or chemical, or to cover cuts/abrasions on hands.</td>
<td>Apply cosmetics.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Handle contact lenses in lab areas.</td>
<td>Smoke.</td>
</tr>
<tr>
<td>Replace gloves immediately when torn or contaminated.</td>
<td>Do not wash or disinfect gloves.</td>
<td></td>
</tr>
<tr>
<td>Grossly soiled lab coats shall be changed immediately. Discard used lab coats in the appropriate area.</td>
<td>Do not pipette by mouth.</td>
<td></td>
</tr>
<tr>
<td>Eye and face protections, including safety glasses, goggles, and shields shall be worn whenever there is a risk of chemical or biological fluids being splashed into the eyes or face.</td>
<td>Do not wear contaminated lab coats outside the laboratory.</td>
<td></td>
</tr>
<tr>
<td>Work areas should be kept clean and free of unnecessary equipment or materials.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab work surfaces shall be disinfected daily.</td>
<td>Do not use &quot;oxidized&quot; chlorine disinfectants.</td>
<td></td>
</tr>
<tr>
<td>During centrifugation, all tubes shall be stoppered or covered and appropriate safety buckets used.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After use, needles, disposable syringes and other sharps shall be placed in a staricycle sharps container (RED).</td>
<td>Do not recap needles or remove from disposable syringes.</td>
<td></td>
</tr>
<tr>
<td>Any sharps contaminated with biomedical/biological waste shall be placed into a YELLOW sharps container labelled with a biohazard symbol.</td>
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### 4. CHEMICAL HYGIENE

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<th>Instructions</th>
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<tr>
<td>Storage</td>
<td>General</td>
<td>All chemicals should be stored in their original container with the manufacturer’s label intact. All chemicals shall be labelled using WHMIS guidelines. If the manufacturer’s label is missing or the chemical has been transferred to another container, a WHMIS Workplace label shall be applied to the container that identifies the chemical and its’ main chemical constituents. All chemicals shall be stored in a container that is inert to the contents and sealed so it shall not spill during transport or handling. When in doubt as to how a chemical should be stored, refer to the MSDS sheet for the product.</td>
</tr>
<tr>
<td>Flammable &amp; Combustible</td>
<td></td>
<td>Store in proper flammable storage cabinets, which are labeled appropriately. The total quantity of flammable or combustible liquids stored in an approved cabinet shall not exceed 500L. Maintain as small a supply as needed for the efficient, uninterrupted operation of your laboratory. Not more than 50L of flammable liquids and not more than 300L of flammable &amp; combustible liquids shall be permitted in any open working laboratory areas. This includes open shelves, benches and flame hoods. Containers used for the storage of flammable or combustible liquids shall not exceed 5L in capacity except if they are approved safety storage cans up to 25L capacity. If flammable or combustible liquids shall be refrigerated, store them only in explosion proof refrigerators.</td>
</tr>
<tr>
<td>Corrosive Material</td>
<td></td>
<td>Containers of acids and highly caustic material shall be stored in the proper storage cabinets, near the floor, to minimize the danger of bottles falling from shelves. Rubber or plastic safety containers shall be used to transport bottles over 500mL in size. Use only the smallest size containers compatible with the current need.</td>
</tr>
</tbody>
</table>

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### 5. CHEMICAL SPILL PROCESS

**SCOPE**

This section of the Laboratory Safety Manual outlines the process for handling a chemical spill in the laboratory.

**PROCESS**

- **EMERGENCY SPILL AND/or ODOR PROCEDURE**
  - LEAVE AREA. Shut down activities. Take essential belongings. SHUT DOWN ANY GAS FLOWS. LEAVE THE BUILDING.
  - CLOSE DOOR.
  - HIGH RISK? Immediate health hazard to yourself/colleagues? Chance of fire or explosion?
  - YES NO or DON'T KNOW
  - CALL 53333 OR 416-734-5333 FROM CAMPUS PHONE OR CALL 416-734-5333 FROM CAMPUS PHONE or mobile phone.
  - WAIT FOR INFORMATION FROM AUTHORITIES (Dept. of OCC, Health and Safety) AND/OR OBTAIN SPILLS KIT TO CLEAN UP SPILL (Take precautions as needed).
External Audits / Validation

Administration & Laboratory Safety Manuals have been audited and validated by:

- York University Dept. of Occupational Health & Safety as well as the YorkU Joint Health & Safety Committee
  - yearly from 2007 - 2015
  - minor suggested revisions 2008
  - full detailed review 2009 - again only minor revisions
  - fully endorsed, never seen this level of detail
  - accepted this QMS laboratory safety approach is used as a teaching tool
  - [http://www.yorku.ca/dohs](http://www.yorku.ca/dohs)

- Public Health Agency of Canada, Canadian Government
  - Nov. 2014
  - 1 minor comment - diluted bleach solution life span

- suggested revisions fully implemented
Audette Laboratory students’ comments

“Lab safety is at the heart of keeping a well-running shared working space. Our lab safety manual ensures we work in a safe environment and makes sure that instruments remain clean ...., but this also leads to overall better science.”

- Cristina L. (graduate student)

“The implementation of the laboratory safety manual in our laboratory brings some truly spectacular features that come to aid during my day-to-day laboratory work.....”

- Fettah E. (graduate student)

“The QMS is useful because it has allowed us to maintain and practice good lab safety techniques and proper lab records, in order to keep track of any changes that may occur over time, and for traceability purposes. Quality assurance is reinforced with these lab safety practices and ensures we are constantly aware of safety standards. Something most undergraduate students don’t get exposed to.”

- Fatima A-P. (undergraduate student)
Laboratory Safety
A Quality Systems Approach

Questions?  Discussion

Safety Training Program Workshop
hosted by the IUPAC Committee on Chemistry & Industry

BEXCO, Busan, Korea
10th August 2015

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Audette Consulting

Dr. Gerald F. Audette
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